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REAUTHORIZATION OF THE ANIMAL DRUG USER FEE PROGRAMS

THURSDAY, MARCH 30, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:01 a.m., in Room 2123, Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Bucshon, Latta, Griffith, Bilirakis, Johnson, Carter, Dunn, Pence, Joyce, Harshbarger, Obernolte, Rodgers (ex officio), Eshoo, Sarbanes, Ruiz, Kuster, Craig, Schrier, and Pallone (ex officio).

Staff Present: Kate Arey, Content Manager and Digital Assistant; Jolie Brochin, Clerk, Health; Corey Ensslin, Senior Policy Advisor, Health; Grace Graham, Chief Counsel, Health; Jack Heretik, Press Secretary; Tara Hupman, Chief Counsel; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Clare Paoletta, Professional Staff Member, Health; Lydia Abma, Minority Policy Analyst; Hannah Anton, Minority Staff Assistant; Waverly Gordon, Minority Deputy Staff Director and

General Counsel; Tiffany Guarascio, Minority Staff Director; Perry Hamilton, Minority Member Services and Outreach Manager; Stephen Holland, Minority Senior Health Counsel; and Una Lee, Minority Chief Health Counsel.

Mr. Guthrie. The subcommittee will come to order and the chair recognizes himself for an opening statement.

Today, we take the first step to reauthorizing the Animal Drug User Fee Agreements through 2028. These must-past agreements play important roles in keeping our pets and farm animals healthy and happy. This process gives Congress the unique ability to help ensure brand name animal drugs and their generic equivalents are able to reach the market as quickly ans as safely as possible. Animal health is also important to human health.

For example, there is currently a severe bird flu outbreak going around the world. One way to prevent that virus from potentially mutating and becoming potentially infectious in humans is to prevent it or cure the disease in animals. Originally established in 2004, the first Animal Drug User Fee Agreement transformed the review process for these drugs.

Before the establishment of these agreements, it took roughly 7 to 10 years to get new animal drugs approved. This backlog made it more difficult for veterinarians to treat house pets for treatable and nonlife threatening conditions. Food was also delayed getting to the grocery store shelves because of delays in determining that antibiotics given to food producing animals did not jeopardize the safety of that food for human consumption.

The first ADUFA agreement eliminated the backlog of applications sitting with the FDA Center for Veterinary Medicine, and decreased the review times for new animal drug applications from over 600 days to 180 days. The ADUFA agreement we are considering

today will allow the agency to collect 174 million in fees from the industry from 2024 to 2028, and make critical program enhancements to streamline the review process for both regulators and industry.

These include more stringent reporting requirements for the FDA and review times, and outcomes of investigational new animal drug applications. The agreement also includes a third party review process of these applications to increase oversight and help identify ways this process can be more predictable for drug sponsors.

Today, we are also considering the Animal Generic User Fee Agreements, AGDUFA. Since Congress backs AGDUFA in 2009, these agreements have been instrumental in reducing long wait times for drug reviews and getting more lower cost generic drugs on the market. The AGDUFA agreement we are examining would permit the FDA to collect up to 130 million enduser fees through 2028 on review of the generic animal drugs. This also includes improved transparency requirements for FDA, who will help sponsors more effectively work with regulators to address outstanding issues with the file for which sponsors use to share information about an abbreviated new animal drug application.

It also includes a commitment from the FDA to take action on 90 percent of these requests within 100 days of submission. Overall, both of these agreements will significantly enhance our ability to keep household pets and farming animals healthy, while continuing to promote human health in the process. I would like to thank my subcommittee colleagues, Representatives Pence and Schrier, for their work in introducing the legislation before us today that reauthorizes these programs.

As subcommittee chair, I want to ensure we are taking care of business by getting this legislation to President's desk well before its September 30 deadline. Thank you,

and I yield back.

The chair now recognizes the Gentlelady from California, Ms. Eshoo, the ranking member, for an opening statement.

[The prepared statement of Mr. Guthrie follows:]

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Ms. Eshoo. Thank you, Mr. Chairman, and good morning colleagues.

Today, we consider the reauthorization of the Animal Drug User Fee programs. A source of pride of this subcommittee is our history of bipartisan work to advance user fee agreements that enable the U.S. to lead the world in innovation and drug development. I voted for the initial Animal Drug User Fee Act, known as ADUFA, in 2003 to authorize the FDA to collect fees for animal drug applications, as well as the Animal Generic Drug User Fee Act, known as AGDUFA, in 2008 to expand these authorities to generic animal drugs.

These programs are reauthorized every 5 years to ensure the center for veterinary medicine and continue to meet the needs of the animal drug industry as it evolves. Today, we are considering a new set of agreements negotiated by the FDA and stakeholders in the animal drug industry. These agreements will lead to increased transparency, additional pathways for animal drug approvals and reduced review times for pioneer and generic drug applications while maintaining high standards for safety and efficacy.

Everyone on this subcommittee has a vested interest in moving these reauthorizations because they are critical to animal and human health. Millions of American pet owners and veterinarians rely on the robust animal drug pipeline to keep their companions safe and healthy. Livestock and poultry producers also rely on animal health products to protect food producing animals from diseases that threaten the safety of our food supply.

FDA continues to make progress to mitigate the growth of antimicrobial resistance in food producing animals, including ending over-the-counter access to medically

important antibiotics, which are used in both human and animals, but more needs to be done. ADUFA V and AGDUFA IV are the latest evolutions to further strengthen the review process for animal drugs and ensure robust funding for the Center for Veterinary Medicine. We are also considering Congresswoman Nancy Mace's legislation, the Generic Animal Drug Advancement Act to allow a generic animal drug manufacturer to seek approval for fewer species than were on the original pioneer drugs labeling.

So thank you to, Director Forfa, for being with us today. I look forward to hearing from you, and our other expert witnesses about the negotiated animal user agreements, and I remain fully committed to moving ADUFA and AGDUFA -- how do we come up with all of this? The federal government wins the prize for all of this alphabet soup -- and a swift reauthorization as the chairman of our subcommittee just stated before the programs expire on September 30.

With that, I yield back, Mr. Chairman.

[The prepared statement of Ms. Eshoo follows:]

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Mr. Guthrie. Thank you. The Gentlelady yields back. So the Gentleman from New Jersey, you are recognized for five minutes for your opening statement.

Mr. Pallone. Thank you. Thank you, Chairman Guthrie.

The two animal user fee programs we are reviewing today support the timely review of both pioneer and generic drugs at the Food and Drug Administration, while supporting the agency's public health mission and gold standard for safety and efficacy. Today's hearing and these user fees highlight, of course, the importance of medicine for our four-legged friends at home. At the same time, we have to stress that animal drugs support a healthy agricultural economy and protect the nation's food supply.

User fees are -- I am sorry. We have to also remain vigilant in supporting animal health due to its known impact on human health as we have repeatedly seen through outbreaks like Ebola, Zika, coronavirus, Avian influenza, or bird flu. Infectious diseases can be transmitted between species, and scientists have also drawn a direct connection between our changing environment and the heightened risk of interspecies transmission of disease.

And similarly, the careful and responsible management of animal or antimicrobial use in animals is of critical importance in our fight against antimicrobial resistant pathogens that could infect humans. So animal drug user fees provide critical supplemental funding for the FDA and have helped ensure faster, more predictable review timelines for new drugs and generic competition.

But I do want to highlight that user fees are intended to be supplemental to FDA's appropriated budget allocations. Our reauthorization of user fees should not been seen by the majority or anybody as a justification to cut FDA's budget in the Republican quest

to dramatically slash funding across the government. So I am committed to seeing these programs authorized on time well ahead of the September deadline. Of course we will see what the Senate does to support the FDA's mission. I am sure everyone remembers when we did everything quickly, and then the Senate took like another year to get it done, so that is why I mentioned that.

But after successfully reauthorizing human drug user fee programs and enacting the Food and Drug Omnibus Reform Act in a bipartisan way last year, I am confident that we can come together and get this done. So I look forward to learning more today about the new user fee agreements, as well as additional policy proposal that can improve animal health. And welcome to our witnesses.

Thank you, Mr. Chairman. Yield back.

[The prepared statement of Mr. Pallone follows:]

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Mr. Guthrie. Thank you. T Gentleman yields back. And the chair recognizes the chair of the full committee, Chair McMorris Rodgers.

The Chair. Good morning. Whether or not you know it, almost everyone in the room relies on animal drugs approved by the FDA, whether you have a pet, drink milk, eat meat, the FDA plays a very important role in making sure the drugs we give animals work and are safe. This is especially important to make sure food is safe for humans to eat. The Center for Veterinary Medicine at FDA is responsible for regulating animal drugs and is funded in part by congressional appropriations and in part by user fees paid by industry.

If we don't reauthorize this legislation on time, FDA can no longer collect fees, and the drugs that farmers and pet owners rely on may not come to market. It is important that we get this done on time and work in a bipartisan way to keep any controversial policies from slowing this down.

We are off to good start. I am glad that industry and FDA submitted recommendations for this reauthorization ahead of the January 15 deadline, and today, we will be considering legislation that reauthorizes the Animal Drug User Fee Amendments and the Animal Generic Drug User Fee Amendments. The agreements before us reflect nearly 2 years of negotiations between FDA and industry. We appreciate the hard work from those involved in those discussions.

This will be the fifth ADUFA reauthorization, and fourth reauthorization of AGDUFA. And in the 20 years since these authorities were established, we have seen significant improvements to review times for new animal drug applications, and continue progress towards getting safe and cost effective products to the market faster. Over the

course of the negotiation process, we have heard industry and stakeholders on current challenges within the animal health market, including rising cost of pet care and limited options available for treatment.

We are also hearing how the significant growth in new drug application fees are limiting participation in the Animal Drug User Fee Programs. This ultimately leaves us with fewer and less affordable options to treat our country's animals. It is clear that we need more innovative and affordable medicines on the market, and I look forward to discussing FDA's plans to better utilize existing processes to expedite the review and approval of animal drugs.

The agreements contain several proposals that address supply chain issues, funding for pre-approval foreign inspection capabilities and commitments to exploring additional EU and U.S. good manufacturing agreements. FDA will also commit to a third party evaluation of CVM's utilization of review processes of animal drug applications.

Independent assessments such as these are critical as this committee conducts oversight over the agency's mission and fulfilling its regulatory and public health responsibilities. We look forward to reviewing the findings from this assessment. The proposed agreement for the Animal Generic User Fee Program should help get more lower cost animal drugs to farmers and pet owners. FDA is committed to providing increased engagement with generic drug sponsors through new meeting processes.

These meetings will provide additional opportunities for sponsors to engage with the agency's scientific staff to better understand what data is needed to support new animal drug applications. I am also looking forward to discussing CVM's plans to transition staff and resources back to in-person operations as we continue the corner on 3 years since the beginning of the pandemic, and as the COVID-19 public health

emergency is set to end May 11.

In addition to the user fee agreements, we are also considering legislation introduced by Representative Nancy Mace, the Generic Animal Drug Availability Act. This bill would improve pathways for generic animal drugs seeking approval for a single species and as combination products.

I look forward to today's discussion. I believe there is a bipartisan commitment to reauthorizing these agreements on time. Thank you. I yield back.

[The prepared statement of The Chair follows:]

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Mr. Guthrie. Thank you. The Chair yields back. The chair reminds Members that pursuant to the committee rules, all Members' opening statements will be made part of the record. Are there any Members seeking for an opening statement?

Mr. Pence, you are recognized for 3 minutes for an opening statement.

Mr. Pence. Thank you, Chairman Guthrie, and Ranking Member Eshoo, and Director Forfa for being here. I am proud to champion the fifth reauthorization of the Animal Drug User Fee Act with my colleague, Congresswoman Schrier. This important legislation is critical to ensuring safe and effective drugs for our nation's livestock industry and farm animals for the next 5 years. Farmers, ranchers, and rural communities across southern Indiana rely on veterinary medicines and therapeutics produced by animal drug manufactures.

Innovators in the Hoosier state, like Elanco Animal Health, are leading the charge to keep America's farm animals safe and healthy. The fees associated with this legislation is a collaborative investment between the FDA and America's animal health companies. In addition to providing the FDA with resource to expedite reviews and approvals, my legislation would ensure the agency is transparent and held accountable for performance goals.

This legislation would preserve security of our nation's food supply by making certain the medications administered to food producing animals are safe for animal and human health. I look forward to working with my colleagues on the Energy and Commerce Committee to get this legislation across the finish line. Since 2004's fees paid to the Center for the Veterinary Medicine at FDA have increased exponentially across both programs while the workload and number of animal drug approvals have

declined.

Within the ADUFA program, supported full-time equivalents at CVM have also increased. However, approval timelines are still far behind our counterparts around the world, such as the European Medicine's Agency. This places the United States at a competitive disadvantage as foreign producers gain access to cutting edge medicines before producers here in the United States.

Director Forfa, I hope today that you will answer a few -- give us some thoughts on some of the issues involved here going forward, and I hope you will commit to executing the independent third party assessment of the program. And I hope that you will explain what the timeline for when CVM plans to begin this assessment and the process to keep industry stakeholders form. And then I hope you can share your thoughts in how the negotiated goals and authorized fees in my legislation could reverse this trend of approval delays at the FDA.

And with that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Pence follows:]

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Mr. Guthrie. The Gentleman yields back. Any opening statements from the Democrat side? No opening statements. Seeing none, I will introduce -- we will move into witness testimony. I will introduce our witness. Our first witness today is Tracey Forfa, Director for the Center for Veterinary Medicine at the U.S. Food and Drug Administration. You are recognized 5 minutes for your opening statement.

STATEMENT OF TRACEY FORFA, J.D., DIRECTOR, CENTER FOR VETERINARY MEDICINE (CVM), U.S. FOOD AND DRUG ADMINISTRATION

Ms. Forfa. Good morning, Chairman Guthrie. Thank you, Ranking Member Eshoo, and Members of the subcommittee. I am Tracey Forfa, the Director of the Center for Veterinary Medicine, or CVM, of the FDA. Thank you for this opportunity to discuss FDA's proposals for reauthorization of the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, ADUFA V and AGDUFA IV.

The enactment of ADUFA and AGDUFA enabled CVM to resolve a longstanding backlog of animal drug applications and created predictability in the review process. Both programs help FDA maintain a stable, scientific, and technical workforce, reduce review times, and improve communication with drug sponsors. Since then, FDA has approved over 360 new animal drugs and over 227 generic drugs.

These medicines in our larger American's health systems impact American's lives every day. They make a difference for the pets that live in over two thirds of American households and support food producing animals, a critical part of the American agricultural economy.

With this reauthorization, we have several proposals that we believe will advance CVM's highly successful animal health programs. I will highlight just a few. Building on the ADUFA IV performance goals, FDA and industry have agreed to report certain programmatic metrics and participate in an independent third party assessment of first cycle reviews. We will offer a new virtual option for presubmission meetings so industry can receive feedback from CVM on development plans without logistical delays or travel

costs, and will work with industry to host annual public education conferences.

We have agreed to form FDA industry work groups to explore potential program enhancements, including tools to improve review efficiency, the drug residue analytical method trial process, and the policies and procedures on Animal Drug Availability Act drug combinations.

We also offered financial recommendations, including implementing and operating reserve adjustment, modifying the workload adjustor, and establishing an annual financial plan. AGDUFA IV proposals include agreements on several program enhancements, formalizing the bioequivalence meeting process, creating a dosage form specific template letter, adding the request to open a generic investigational animal drug file as a sentinel submission, implementing U.S./U.K. and U.S./EU mutual recognition agreements, and potentially establishing MRAs with other countries.

Financial recommendations include modifying the workload adjustor, updating the fee structure, and adding a shortfall provision. The negotiations are positive and cooperative and the proposals put forward serve mutual goals of continuous process improvement, transparency, and the protection of public health.

I have been with the Center for 21 years and have seen many dedicated public servants come and go. I truly respect and admire the people I work with and their commitment to public health. I did not say animal health. Human health, animal health, environmental health, and other aspects of societal health do not exist in a vacuum. At CVM, we take a collaborative, multisectoral, and transdisciplinary approach called the One Health approach.

When we review drugs for food producing animals, for example, we consider the safety of people consuming meat, milk, or eggs from those animals. The safety of

people handling the drugs and the impact on the products on the environment. Our drug review teams house a wealth of experience, and I commend their dedication. The international public health community increasingly recognizes the value of One Health. CVM has led FDA and HHS to recognize this utility.

CVM is often deeply engaged in unexpected cross disciplinary issues. We have seen a recent explosion of products that cut across human, animal, and environmental health, advancement in technologies like gene editing and cell and tissue based therapies, and innovative chemical uses like the potential cattle food ingredients to cut emissions of greenhouse gases. Such innovations challenge us to assess whether the study data legally required for approval are scientifically necessary or appropriate to protect public health.

We maximize flexibility to get safe and effective products into the market with undue burden on sponsors. In addition, we have issued guidances on expanded conditional approval and alternative data sources. Our veterinary innovation program established in 2019 gives sponsors of animal cellular products and intentional genomic alterations more opportunities to consult. 52 product developers have enrolled in the program so far.

In closing, I appreciate your consideration of our recommendations and hope for a timely reauthorization. I also hope to work with you to examine our animal product safety system for opportunities and to breakdown barriers to innovations that will advance human and animal health.

Thank you for your time.

[The prepared statement of Ms. Forfa follows:]

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Mr. Guthrie. Thank you. I thank for your opening statement, and we will now move into Member questions. I will recognize myself 5 minutes for that purpose.

Ms. Forfa, the ADUFA one eliminated a significant backlog of 680 submissions and reduced review times from 700 days to 270 for these products. And the question is how will this agreement further reduce these backlogs and reduce review times, and likewise ADUFA work to address significant backlogs and long waits? So how will this agreement accelerate development of pioneer drugs? So what is going to be the improvement? You all have done a good job. So what is the improvement that we are looking for?

Ms. Forfa. I thank you very much for the question, and we thank you for your support.

So, as you said, the animal drug user fees provide predictability. We have all set goals, and we have met and succeeded all of those goals a hundred percent of the time. We have moved to a hundred percent electronic submissions, which has really sped up the process for both the sponsors providing us with the information and for us reviewing it.

We want to continue to increase our response times and increase the enhancements to both programs. We also want to ensure that our reviews are timely and flexible, as I said in my opening statements. And we are going to continue to work with the industry to build in as many flexibilities as we can to make sure that drugs to come to the market in the most expeditious manner possible.

Mr. Guthrie. All right. Thank you. I appreciate that. And how has FDA worked with drug sponsors to develop new antimicrobials in food producing animals that are also safe for humans?

Ms. Forfa. The antimicrobial resistance is a huge priority for CVM and FDA and the government overall. We are in the final year of a 5-year plan. We have made significant progress in implementing that plan, and we have provided a report in fiscal year 2022 that provided the data elements and identified gaps and places where we still need to work harder on antimicrobial resistance. We have also engaged the Reagan-Udall Foundation who has spoken to 30 stakeholders from various Ag associations, producers, researchers, and academics, and consumer advocacy groups on next steps in our next 5-year plan, which we will be putting out shortly. We really are looking forward to developing potential public/private partnerships, and we continue to want to work with the agriculture sector and other interested stakeholders to make sure our antimicrobial resistance policy addresses this very critical issue.

Mr. Guthrie. Thank you very much. That concludes my questions. So I will yield back the time. And I will recognize the Gentlelady from California, Ms. Eshoo, for 5 minutes for questions.

Ms. Eshoo. Thank you, Mr. Chairman. And thank you for your opening statement.

Does the FDA know where most animal drugs are manufactured? The United States? China? India?

Ms. Forfa. I don't have that information right off the top of my head, so we would be happy to get back to you on that.

Ms. Eshoo. All right. I think it would be interesting to know that. Are you facing similar delays and barriers to inspecting foreign manufacturers as the human drug side of FDA has?

Ms. Forfa. During the pandemic, we did face similar challenges. Some of the

companies are the same, and some of the companies are the same ones to be inspected. So we leverage our inspectional force wherever we can. We are working with our foreign counterparts on mutual recognition agreements and other tools to help speed up those inspections. But during the pandemic we faced similar challenges.

Ms. Eshoo. But what is the state now?

Ms. Forfa. It is gradually improving, and we are hoping that, you know, it will continue to improve at a faster pace.

Ms. Eshoo. I have been a critic of foreign inspections relative to FDA, and that is why I asked the question. I think that, you know, heightened inspections are really so very important. So if you have anything to add to that, you can get it to me in writing.

During the last ADUFA and AGDUFA reauthorization, this subcommittee spent a great deal of time on the important issue of antibiotic use in animals. Overuse of antibiotics in animals can contribute to the emergence of antimicrobial resistance that can then be transferred to humans through food producing animals, which your center regulates. In the U.S. alone, the CDC estimates there are more than 2.8 million antimicrobial resistant infections each year killing more than 35,000 Americans. Those are pretty stunning numbers.

Can you describe the actions that the FDA has taken regarding antibiotic use in animals since the last two reauthorizations, and has the CVM measured whether antibiotic stewardship in food producing animals have improved, and what steps do you plan to take in the future to encourage that stewardship?

Ms. Forfa. Thank you for that question. As I said earlier, antimicrobial resistance is a huge priority for CVM. It has been. There is a number of steps that we have taken. I will answer your second question first. We continue to monitor

antimicrobial resistance progress through a number of different ways. One is through our national antimicrobial resistance monitoring system, where we monitor the resistance factors.

We put out annual reports on whether we are making progress in the number of antimicrobial resistant bacteria reported. We continue to work with other government agencies, including USDA and CDC to implement that program. Also, we are working, as I said earlier, with the Reagan-Udall Foundation to ensure that our antimicrobial resistance strategy is strong and robust and is taking the right steps and measures.

We also have a reporting requirement where we report out the number of antimicrobials sold during the course of the year, and we monitor either the increase or the decrease in actual sales. So we have a number of tools at our disposal. I think that we recognize there have been additional requests for more data. And we certainly are looking at that, and hopefully we can figure out the best way to continue to assure the American public that we are indeed attacking this very, very serious problem.

Ms. Eshoo. So in the proposals that you are presenting to us in these reauthorizations, do you have new steps included to address these numbers, the 2.8 million antimicrobial resistant infections and the deaths of Americans as a result of it?

Ms. Forfa. So not in the proposal specifically, but this work is going on at the -- this work is continuing to be going on in the center. It is part of our priorities and our strategies for our key strategies for the year each year, and we devote a significant number of resources to that particular work.

Ms. Eshoo. Thank you. I yield back. Thank you.

Mr. Guthrie. Gentlelady yields back.

The chair recognizes the Chair, Chair McMorris Rodgers for 5 minutes of

questions.

The Chair. Good morning.

Ms. Forfa. Good morning.

The Chair. Director Forfa, I wanted to start -- I had mentioned in my opening remarks about the importance of getting everyone back to the office and returning -- the return to office plans as we approach the end of the COVID pandemic, the public health emergency ending on May 11. In January, Dr. Califf announced that the FDA Centers for Drug and Biologics would resume in person, face-to-face meetings beginning February 13 of this year.

So we have had over 3 years now of virtual work across federal agencies, and I have heard a lot of concerns especially from the regulated industry on how that has impacted fulfilling critical agency duties, granting sponsor meeting requests, conducting necessary facility inspections and ultimately getting new products to the market efficiently.

That being said, I just wanted to ask you: Can you share the status of your center's plans to resume in-person operations and transition towards granting face-to-face meetings?

Ms. Forfa. Sure. I would be happy to. Thank you. So we are working right now under what we call a business hybrid model -- and so -- driven by business needs. So if a sponsor requests an in-person meeting, we are happy to grant that. My very first in-person meeting with a large group was with The Animal Health Institute not that long ago. And so, we certainly are very, very open to having requests. I have had a number of requests for in-person meetings. And I am always happy to entertain those and come in to meet.

Many of my staffs actually want to come back to the office. They want to be together with their teams. They have felt disconnected. So they are coming back, and we are ensuring that the facilities are safe for their return. But we are -- again, any time that we get a request, we do it on a business-needs basis. And again, happy to -- we have had several of those meetings, both some with our foreign counterparts, with the regulated industry, individuals. So we with are certainly happy to do that.

The Chair. Great. Can you give me an estimate, like a percentage of how many you believe of the staff are back to in-person, being in the office every day?

Ms. Forfa. On an everyday basis, I can't really estimate that. It varies. But people are looking forward to coming back.

The Chair. Is there a reason that Dr. Califf did not include the Center for Veterinary Medicine as one of the centers to resume in-person meetings starting February 13 in his announcement earlier this year?

Ms. Forfa. I don't know. I haven't discussed that with him. But again, we are following the rest of the agency, what the agency is doing. We follow their guidance, and we follow the department's guidance. And so we don't do anything really different than the rest of the agency is doing.

The Chair. Thank you.

Ms. Forfa. Thank you.

The Chair. It remains a concern, and so I am -- you are in front of us today. I have had this conversation with Dr. Califf too. We need to get people back to work.

Dr. Forfa, this year's ADUFA agreement includes a million dollar investment, an independent third party assessment of efficiently CVM is utilizing existing review processes for new animal drug applications. What will be the scope and timeline of this

assessment, and how does CVM plan on implementing the findings of this independent evaluation?

Ms. Forfa. Since I don't have all the granular details on that, I would more than happy to get back to you with a more robust answer on that.

The Chair. Okay. Okay. Well, I look forward to hearing the outcome of that evaluation. Thank you for being here.

Ms. Forfa. Thank you.

Mr. Guthrie. The Gentlelady yields back. The chair now recognizes the Gentlelady from Washington State, Dr. Schrier. You are recognized for 5 minutes.

Ms. Schrier. Thank you, Mr. Chairman. The other lady from Washington State, thank Director Forfa, for coming to speak to the committee today about this important issue. I want to begin by setting the stage for the bill that my colleague Representative Pence and I have been working together to reauthorize ADUFA. And I want to thank, Representative Pence, also for working with me on this important issue.

It is incredibly important that this process and relationship works for both the government and for the industry so that we ensure that animal health and human health are protected, and we do it in an expedient fashion. I think it is just a matter of good governance to ensure that we put guardrails in place to protect animal health and safety, which translates to our health and safety. That starts with ADUFA, an Animal Drug User Fee Agreement.

Animal safety is incredibly important for my district. I think in every district, so many of us have found ourselves in situation with a sick pet at home and have turned to trusted veterinarians who depend on the availability of safe drugs that ADUFA ensures get to market.

In my district, we have farmers and ranchers and dairymen who need healthy livestock and poultry and dairy production. And having timely access to affordable effective medicines is a key part of their economy and our domestic food chain. I want to note that the FDA is in the process of reviewing the use of feed additives to reduce methane emissions from cattle, which would go a long way to eliminating greenhouse gas emissions from the agriculture sector. I want to thank you for that, ensuring that the FDA has appropriate staff and resources to review these applications and products will help, again, animals and food remain safe and help us cut emissions.

Director Forfa, can you just take a moment to expand on why having ADUFA pass in a timely manner is important for animal health?

Ms. Forfa. Thank you very much for the question. So if the agreements aren't passed in a timely manner, there may be delays in our ability to improve the important drugs for pets and food producing animals that you mentioned. These agreements ensure that there are enough staff to adequately review animal drug submissions and applications. It supports the infrastructure as well increase the transparency of our approval requirements through guidance documents and other documents that we put out to help industry.

Ms. Schrier. And speaking of important medications, I want to just touch on antimicrobial resistance, something that is top of mind for us. Something that I am concerned about as a pediatrician, and I think that is a place where veterinarians and physicians in addition to sometimes having nonverbal patients, where veterinarians and pediatricians know that judicious use of antibiotics is critical to reducing the emergence of antibiotic resistance bacteria.

At the same time, we say that the bacteria are smarter than we are and eventually

there will be resistance. That is why we need to incentivize the industry to do research in this area, which is not necessarily an area where there is economic incentive otherwise to do it. In September of 2018, the FDA Center for Veterinary Medicine issued a 5-year stewardship action plan intended to combat antibiotic resistance and preserve the future effectiveness of these medications.

I was wondering if you could describe some of the goals of that action plan, the progress FDA has made, and maybe some of the challenges that you have found along the way?

Ms. Forfa. Thank you for that. I will touch on that briefly. I think the -- there has been significant progress in reducing antimicrobial resistance. I think one thing that comes to the top of the mind is the transition from the over-the-counter antimicrobials to vet prescription only so that a veterinarian -- there has to be a veterinarian involved. This promotes judicious use of these antimicrobials and helps preserve them for both animal and human health.

So I think that was one of the significant accomplishments. That work is continuing. We are also continuing to work with a wide variety of stakeholders on next steps in our next 5-year plan.

Ms. Schrier. Just to touch on -- I am going to make a comment here about One Health and the intersection of human health and animal health some of my colleagues have referred to, and I just wanted to kind of put an exclamation point on how important it is FDA has the resources to do surveillance monitoring of animals to prevent next the pandemic.

Thank you, and I yield back.

Mr. Guthrie. Gentlelady yields back.

The chair recognizes from Mr. Latta for 5 minutes for questions.

Mr. Latta. Thank you, Mr. Chairman and thanks for holding this very important hearing today, and Director, thanks so much for being with us today.

Question, how is the agency prioritizing reviews of new animal drugs for treatment of severe and/or pry on diseases that may also pose serious risk to humans, such as chronic wasting disease?

Ms. Forfa. So when we -- when we get an application in house, we have a process set up to triage it, to look at -- we meet with sponsors early in the process even before their applications come in. And so we can look at products across and kind of triage them in a way so that we know which ones are amenable to our veterinary innovation program, and some of the other flexibilities that we built into the new animal drug process over the years. And so we do -- there are procedures in place so that if a critical drug comes in, we don't have all of the same authorities that our human colleagues do, but we have recently gotten emergency use authorization authorities that we can use, and it is based on public health -- declaration of a public health emergency. So there are things that we can do to help prioritize the review and approval of those type of products.

Mr. Latta. Well, you know, I am following up on that. What are the challenges, then, when you are conducting the necessary research on diseases like chronic wasting disease that would an effective treatment in an expedited manner?

Ms. Forfa. Well, we always face a number of challenges in the animal drug space. Very often, we don't -- we can't find a sponsor who is willing to, you know, bring a product forward. Sometimes there is limited research. Sometimes there is just not enough data out there to be able to, you know, do a robust review. So there a number

of factors that actually sort of limit the ability to move things quickly through the process. We try to do the best we can on a case by case basis with each particular product. And I think over the years, we have shown that we can actually get products on the market relatively quickly. But, you know, it certainly depends on what comes in the door.

Mr. Latta. When you say about getting all the necessary data, and then also, you know, having that information and make that and getting those products to market quickly, do you have any kind of idea generally what timelines are on some of these things? How long it takes to get maybe a product out there?

Ms. Forfa. It varies so widely that I would, you know, I would hate to you give an exact number. Much depends, again, on the data that we receive initially and how robust it is. And that often determines how quickly we can get a product reviewed and approved.

Mr. Latta. And you know, as we look into the future, are there many opportunities for a bipartisan collaboration in the ADUFA space?

Ms. Forfa. Absolutely. And lots of opportunities for us to continue to work with industry, to work with you all in this space, yes. Lots of good opportunities.

Mr. Latta. Thank you very much. Mr. Chairman. I am going to yield back the balance of my time.

Mr. Guthrie. Gentleman yields back.

The chair now recognizes Mr. Sarbanes for 5 minutes for questions.

Mr. Sarbanes. Thanks very much, Mr. Chairman. Thank you, Director Forfa, for being here. This is an important function that our committee plays. We take it seriously. I just wanted to talk a little bit more about this One Health initiative. And you know, that is an effort that acknowledges that we are all connected, the health of

people, animals, and environment are intertwined, interdependent. And not only can these zoonotic diseases pose a great threat to human health, but the drugs we give to animals to ward those off, a treated disease can also affect our food supply, individual health, our environment, and so forth.

And the initiative I know aims to promote total ecosystem health by building bridges between physicians and veterinarians, public health officials, and so forth, as well as environmental scientists. As part of our comprehensive efforts to restore the Chesapeake Bay, which I am very focused on as you can imagine, we have worked with farmers to reduce the impacts their have operations on the Bay's health. I am glad that promoting environmental health broadly through things like the One Health initiative is a guiding imperative at FDA as well.

So could you speak, again, on how reauthorizing the Animal Drug User Fee program providing FDA with a strong budget through the appropriations process, all of those things can support the One Health initiative, and what impacts in turn will have on the health of the environment and all the people, species that occupy it? Thank you.

Ms. Forfa. Thank you for that question. It is one of my favorite topics, so I am happy to talk about it. So CVM has taken a very strong lead at One Health at FDA. We are working across the agency. I co-chair the One Health steering committee across FDA that includes all of the component centers. I also sit on an intergovernmental group formed by CDC as part of the fiscal year 2023 consolidated appropriations the One Health coordination unit with Dr. Casey Barton Behravesh.

So we see, as you said, that it is a critical intersection of human health, animal health, and the environment. And we try to say and help our colleagues across the agency understand that everything we do pretty much at FDA every day is in the One

Health space. And so when we have an approval, we look at -- of animal drug, we look at what are -- both the environmental and the human health consequences of that particular approval.

And so that is just built into our approval process. We have a target animal safety, human user safety, and an environmental safety review when an animal drug is presented to us. It is the same on the food side. And so we see that One Health is just critical to the work that we do every single day in every single aspect of the center.

Mr. Sarbanes. Let me ask you a question slightly related, but I was listening to a piece the other day about, you know, this concern of viruses jumping from animal population into human population and whether the research that I guess up until now has been focused on sort of trying to look at all these millions of viruses in the animal population as opposed to focusing on the ones that are already made to jump into human population, where should the focus be particularly as we think about the potential for pandemics and other kinds of public health threats that come when you see that jump.

Do you have any perspective on that discussion or the research on how we monitor the relationship between viruses and animals and in humans?

Ms. Forfa. As we move forward, I think that we have to keep the three pieces deeply connected. I think we have to keep animal health, human health, and environmental health connected, and I think we have to look at all three at all times. I think that there is -- we are very concerned about zoonotic diseases and we are concerned about transmission. There is also all of the potential that humans can transmit viruses to their animals, to their pets, which we saw during COVID. And so I don't think there is any way that we can do our work on a daily basis without thinking about all three components.

Mr. Sarbanes. Great. Thank you. Yield back.

Mr. Guthrie. The Gentleman yields back. The chair now recognizes the Gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. Bilirakis. Thank you. I appreciate it, Mr. Chairman.

Ms. Forfa welcome. I want to briefly discuss the unique instance of an animal drug approved for use in veterinarian medicine by the FDA that has no human use, Xylazine. Right now, Xylazine is at the center of a rapid shift in the drug overdose epidemic with its use as an to fentanyl. This drug has mirrored the geographic patterns of fentanyl when it first infiltrated the drug market. Elicit fentanyl that is cut with Xylazine is a street drug referred to trank dope. I think you probably know that. And its use has been found in all 50 states unfortunately. It has never been approved for human consumption, and it is sedative to induce a state of unconsciousness. There is no doubt we need to be working together to address this, and we need to be out in front of this, to tell you the truth.

I am co-leading a bipartisan bill with several of my colleagues, some are on this committee, including Mr. Fulcher, that looks to address this issue. I welcome the opportunity to move this bill through committee as soon as possible.

Ms. Forfa, the FDA has also spoken out about this drug. We are well aware of its legitimate and safe use within the veterinary space and how important it is to veterinarians, cattlemen, and ranchers. The FDA has put out guidance in an attempt to elicit opioids coming into the country through the mail. Could you please elaborate on this?

Ms. Forfa. Thank you very much. And I am equally concerned as you are about this development. Early on in my tenure as the center director, I was faced with this

issue. And so we moved -- as an agency, we moved quickly to put in an import alert in place to make sure that all Xylazine coming through the borders would be screened to make sure it was going to a legitimate manufacturer. We have been working with the Drug Enforcement Administration on the tools that they have to be able to address the issue. We have also been working with our colleagues in the Center for Drug Evaluation and Research, which is the liaison to the Drug Enforcement Administration at FDA. We are using every tool we have in our toolbox to be able to try to address this. And so we are -- again, at this point I cannot speak to your legislation because I haven't had a chance to read it.

Mr. Bilirakis. Please review it and get back to me on that. Very important.

Ms. Forfa. I will. But we certainly -- again, I think you articulated it very well about striking the balance between the need for the veterinary community and the stopping of the elicit use of it because it is, I agree with you, the side effects are horrifying.

Mr. Bilirakis. This is what I hear. Now, the FDA has put in place similar guidance around fentanyl in the past, but it was not found that FDA encountered very little fentanyl. So -- it was found they found very little fentanyl in this instance, but rather the vast majority of packages seized contained uncontrolled drugs purchased by individuals personal use.

Does the FDA have a sense of how much elicit Xylazine is being shipped into the country, if you could give me an estimate on that, I would appreciate it. What steps are being taken to ensure a strategic target approach rather for these efforts so that elicit drugs rather than legal ones are being seized, if you can elaborate a little bit in the time I have left, I would appreciate it.

Ms. Forfa. Certainly. I don't have the statistics about how much we have actually stopped to our import alert. I would be happy to get back to you on that. We are using every single tool we have to be able to stop the elicit use of the product, and we are working -- there are a number of different components of the agency, including the office of regulatory affairs who we are working very closely with to be able to leverage their inspectional tools and their import alert tools to be able to stop things at the border.

Mr. Bilirakis. This is a very serious issue, as you know. You know what is happening in our communities. Our kids are dying.

Ms. Forfa. I agree.

Mr. Bilirakis. The combination of fentanyl and Xylazine, it is just awful. So we got to do everything we possibly can. I do have other questions, but I ran out of time. I will yield back, Mr. Chairman.

Mr. Guthrie. The Gentleman yields back.

The chair recognizes Dr. Ruiz for 5 minutes for questions.

Mr. Ruiz. Hi. Good morning. Thank you for being here.

Ms. Forfa. Thank you.

Mr. Ruiz. Ms. Forfa, as you discussed in your testimony, the work of the Center for Veterinary Medicine affects human health, animal health, and also can affect the health of our environment. And of course, the health of our environment is directly linked to the health of our communities. And as a doctor, I have seen firsthand how poor environmental conditions lead to poor health statuses and outcomes.

As my colleagues have all heard before, one of the greatest sources of greenhouse gas emissions comes from livestock. This committee has been focused on innovative new ways to address the climate crisis, and I would like to know more about how

innovative products for animals might help us combat climate change. So is there anything we can do in the animal food or drug space to address the emissions caused by livestock? And if so, how would FDA be able to regulate a claim on a food product, for example, that claimed to reduce emissions from that animal?

Ms. Forfa. Thank you for the question. We do see a big benefit in some of the new and innovative products that have been coming out to address climate change and greenhouse gas emissions. It -- we call it One Health in action, as you have. So we are working with stakeholders, including Congress, on a pathway. There is legislative language that we have been working with you all on. And as developers come to us, we work with them on a case by case basis to build in as many flexibilities as we can to get these products on the market as quickly as possible. There is one approved product out there. It was approved under the animal drug paradigm, but we recognize that a lot of these are animal food ingredients. And so we are looking for new authorities in that space to be able to bring them -- the products to market under the animal food ingredient paradigm.

Mr. Ruiz. Can you give me an example of a product and how it works? I am curious.

Ms. Forfa. So they work a number of different ways. They work mostly on the microbiome of the animal itself, and they change the microbiome to be able to reduce the emissions.

Mr. Ruiz. The amount of CO2 and methane and all that?

Ms. Forfa. Yes.

Mr. Ruiz. Great. So what tools would be helpful for FDA and innovators to inform consumers about this products?

Ms. Forfa. The thing that would be the most helpful for us is consistent with some of the legislative language that we have proposed, which allows us to review this in a slightly different paradigm than our animal drug. Because mostly these products need our animal drug definition because they affect the structure of function of the animal. And so this new legislation that we -- legislative language that we have put forward allows us to review it more in the animal food ingredient and give it a little bit of flexibility. We still look at safety very closely, but it allows us some new tools to be able to move these innovative products forward more quickly.

Mr. Ruiz. Look, as a forever family of a rescued husky, the best husky ever that has ever walked this earth, his name is Blues, white Siberian, and a father of a young daughter who wants to be a veterinarian, I want to say thank you for the work you do.

Ms. Forfa. Thank you.

Mr. Ruiz. I yield back my time.

Mr. Guthrie. Thank you.

RPTR KERR

EDTR ZAMORA

[9:59 a.m.]

Mr. Guthrie. Thank you. The gentleman yields back.

The chair now recognizes Mr. Carter for 5 minutes for questions.

Mr. Carter. Thank you, Mr. Chairman.

And thank you, Director, for being here. This is important, particularly to our world in pharmacy because we are obviously very involved in a number of different ways, including and certainly not the least of which is with compounding.

And I know that you all have been very involved in this, and I really do want to commend you for that. I want to commend you for the open line of communication. And I think it has been good between your agency and between some of the organizations that have represented pharmacists and veterinarians as your agency has finalized and now, I assume, will begin implementing 256, the compounding animal drugs from bulk substances.

You know, the agency, in 256, has taken it upon itself to create a Federal regulatory framework over animal drug compounding that somewhat resembles the statutory framework Congress gave the FDA to regulate human drugs, and I think that is a good thing as well.

And the drug compounding -- Congress gave the FDA to regulate human drug compounding by 503A, traditional State-registered regulated pharmacies, and by FDA register 503B, outsourcing facilities. And that was in the Food, Drug, and Cosmetic Act.

So, you know, I feel strong, very strongly that compounded drugs, including those from bulk substances, are an integral part of animal healthcare. And I know that this is

practiced quite often, and particularly in our rural areas, the compounding with a lot of the farmers and a lot of the ag community is extremely important, but -- because there are times when, you know, there is a shortage of something or when there is a lack of access to something.

And I just wanted to ask you, first of all, will you commit today that you will continue working with veterinarians and with pharmacists to provide further clarification and education to all the stakeholders, including the veterinarians, pharmacists, and the State boards of pharmacy? That is going to be important too. I have actually got some calls from the State board of pharmacies about this.

Ms. Forfa. Yes, sir, I certainly can commit to that.

Mr. Carter. Good, good.

Can you tell me where you are at in the implementation? I mean, can you just give me an update about how you intend to enforce the components of this?

Ms. Forfa. Certainly. So we are taking a very balanced approach as we move forward. And as you requested and we have done, we are working with all affected entities to try to provide as much clarity as we can. I think you mentioning of outsourcing facilities, we recognize that we have to provide additional clarification in that space as well.

In April -- we have announced that, in April, we are shifting some of our resources more to inspections, but those inspections are going to be -- it is a limited inspection. It is not going to be some sort of wholesale inspectional blitz. It is still going to be working -- we would be working with State licensing authorities. And it is not going to be -- it is not going to be a huge -- as I said, there is just going to be a limited number of those.

You know, our policy, we just -- we want to make -- we want to strike that balance that you spoke. We want to give veterinarians and their patients access. We want to make sure that the integrity of the approval process gets preserved, and we want to make sure that, you know, all drugs are safe and effective, whether compounded or approved.

Mr. Carter. Good. Let me ask you this. I know you mentioned earlier in your statement that you have approved over X number of drugs. But still, if you look at the approvals over the last few years, the number of animal drugs has really not kept up with what some other countries have approved.

Why has ADUFA not stimulated an increase in product approvals like on the human side it has?

Ms. Forfa. So it is multifactorial. You know, certainly we work very hard to approve the products that are brought to us. I do think that in the animal -- particularly in the pioneer animal drug industry, we have seen a consolidation of companies, and I think that, in some ways, has decreased the number of products that are on the market. I think it is an economically driven situation.

And so, you know, we are working very closely with the animal health industry and the animal generic industry to try to address, you know, shortages where there is not enough approved products.

Mr. Carter. Right. Well, I am out of time. But, again, I want to compliment you and thank you for the line of communication. I have been very impressed, and we really do appreciate it. It is extremely important. So thank you.

And I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

And the chair recognizes Mr. Pence from Indiana, for 5 minutes.

Mr. Pence. Thank you, again, Mr. Chairman.

And I am going to kind of go off my opening remarks, if that is okay, Director, reread something that I said at the beginning.

Since 2004, fees paid at the Center for Veterinary Medicine at FDA have increased exponentially across both programs, while the workload and number of animal drug approvals have declined. And that is 2004.

You know, when Chair Rodgers mentioned that not everybody is in working, while, in fact, your constituents are, I found that a little troubling.

Has that contributed to that, the delay in approvals over the last 3 years?

Ms. Forfa. No, sir. I believe that our workforce is continuing to work as well or maybe even slightly better than they did before, and we have met all of our ADUFA goals.

Mr. Pence. Sure. And I understand that that is something that you are adhering to. You made that a little bit clear. But I always think people working together, face-to-face, is always a little better than not.

So let me ask just a few questions, kind of a commitment going forward. Let's not look back. Let's look forward.

Will you commit to executing the independent third-party assessment of the program outlined in the goals agreement?

Ms. Forfa. Certainly, yes.

Mr. Pence. Okay. Thank you.

Is there a timeline for when CVM plans to begin this assessment and the process to keep industry stakeholders informed?

Ms. Forfa. I will have to get back. I don't have the details at my fingertips, so I

would be happy to get back to you on that.

Mr. Pence. Okay. I would appreciate that. Thank you.

Can you share your thoughts on how the negotiated goals and authorized fees in my legislation -- our legislation will reverse this trend of approval delays at the FDA?

Ms. Forfa. Certainly. And we are -- you know, thank you very much for your support of the program. We think it is a very critical program to be able to give us the tools necessary to approve animal drugs that are brought to us in a timely manner to ensure that they are safe and effective, that we can hire the staff, build the infrastructure, and do everything we need to do for the American public.

Mr. Pence. Okay. Thank you, Mr. Chair. I yield back the balance of my time.

Mr. Guthrie. The gentleman yields back.

The chair now recognizes the gentleman from Indiana, Dr. Bucshon, for 5 minutes for questions.

Mr. Bucshon. Thank you, Mr. Chairman.

I heard one of my colleagues raise the question about CVM's work on antimicrobial resistance. Was the topic raised by CVM or industry during the negotiations?

Ms. Forfa. I was not at the table during the negotiations, so I would have to get back to you.

Mr. Bucshon. Okay. So, I mean, I understand CVM published or will publish a strategic plan on this for the years 2019 to 2023. Is that publicly available yet?

Ms. Forfa. No, not yet.

Mr. Bucshon. No. And so do you have any idea when that would be available?

Ms. Forfa. It is under development, and we would be happy to keep you

informed as it moves forward.

Mr. Bucshon. Yeah. Okay. That would be great. Keep the committee and myself informed about how that is going along. I was a doctor before. This is an important issue.

So I wonder if it is necessary to go ahead with a new study. I guess people are mentioning a potentially new study while we are still wrapping our heads around this one?

Ms. Forfa. You know, I think our engagement with the Reagan-Udall Foundation and their engagement with over 30 stakeholders, I think will -- we are still waiting for that information to come in. And I think that will be dispositive about, you know, maybe where some of the gaps are and where we can fill in some of the -- you know, the gaps moving forward.

Mr. Bucshon. Okay. And maybe this had been asked. Sorry, I had so many things going at the same time here.

I understand that these user fee agreements include many important tactics related to performance evaluations and closing performance gaps. One stands out as very promising to me, the independent third-party assessment. This has been part of the PD -- you know, the PDUFAs for years.

Will you, Director Forfa, commit to the agency's full and timely participation in this assessment?

Ms. Forfa. I can commit to that, yes.

Mr. Bucshon. Great. It is also my understanding the CVM works with animal drug sponsors to change labels when necessary to reflect changes or new revelations about the safety of a product. But I am also understanding that during ADUFA

negotiations, CVM asked for additional post-market authorities, including requiring safety labeling changes.

Why would CVM need additional authorities if industry has a proven record of updating their labels upon new safety data?

Ms. Forfa. So thank you for that question. Currently, CVM does not have a broad range of authorities to be able to address adverse events raised during post-marketing.

So, for example, CVM approved 85 pioneer animal drugs products in a 10-year period between 2011 and 2021. We recommended safety-related labeling changes for 35 of the 85 products. That is 40 percent. And the average time for negotiation of a labeling change during this period was 2.4 years, with a range of 4 months to 10 years.

So we really hope that we could get additional authorities to speed up and reduce that time.

Mr. Bucshon. Okay. Great. Thank you.

Mr. Chairman, I yield back.

Mr. Guthrie. The gentleman yields back.

The chair now recognizes the gentlelady from Tennessee, Mrs. Harshbarger.

Mrs. Harshbarger. Thank you, Mr. Chairman.

Thank you, Ms. Forfa, for being here.

And compounding has been a big part of my life, especially vet compounding. So this is good to be able to talk to you today.

Now, we know that the animal health drug approval process is not the same as the human process. Instead, it is done on a rolling basis. So my question is: How many full-time equivalent hours does it take to review each of the technical sections?

Ms. Forfa. I can get back to you with more specificity, but I do think it varies from product to product.

Mrs. Harshbarger. Okay. Has the time spent reviewing each technical section changed over time?

Ms. Forfa. I certainly think that we have worked very hard to build in efficiencies and also provide additional clarity to sponsors who are coming to us, so that when they do come to us, it is -- the data that they bring to us is more robust and that the applications are -- there isn't so many back and forth between our reviewers and sponsors.

Mrs. Harshbarger. Okay. Are there areas where more staff or different expertise is needed when it comes to that?

Ms. Forfa. I think that we, you know, certainly are staffing up. We have a great cadre of experts who review animal drugs. Certainly, I think we could always use more staff, but we make due. Since we are still the smallest center at FDA, we have learned to make due. With the broadest portfolio, we have learned to make due with what we have to.

Mrs. Harshbarger. Well, you know, we see a lot of drug shortages. Things are on long-term back order. You see it on the human side. You especially see it on the animal side.

And talking about -- going a little further with Mr. Carter's comments about that GFI 256. You know, and I have talked to different veterinarians and compounders that, you know, compound for animal use and, you know, I guess there are some reservations about that nominating process for bulk, to use bulk chemicals, basically. It is missing specifics around the process to nominate those ingredients for review and possible

inclusion on a list of preps that could be used for office use.

And they go on to say -- also concerning, he said, in human health, the bulk ingredient list is an ingredient list; however, the construct of the FDA's list includes the specific dosage form, strength, species, and doesn't allow the type of flexibility generally required to meet the variety and needs around animal patients.

And, you know, I have done compounding for, you know, not animal -- food animals, but pets, you know, a lot of expensive animals. But there needs to be clarity there on that bulk ingredient list. Because you said earlier that you did not know where the drugs were coming from or their country of origin, where some of these bulk chemicals are coming from or final use product?

Ms. Forfa. So that was for xylazine specifically.

Mrs. Harshbarger. Okay.

Ms. Forfa. We are, you know, certainly concerned about the flow of illicit xylazine into the country, and that is what our import alert was very specific for, xylazine.

Mrs. Harshbarger. Okay. Well, you said something a minute ago too about you are putting funding into inspections. Is that going to be more funding for 503B? 503A? Can you elaborate on that?

Ms. Forfa. So if I wasn't clear, I apologize. Let me clarify. So we are shifting our resources. Previously, we had been doing a lot of education and outreach, and now we are really shifting resources into more traditional inspectional activities into the State-licensed compounding pharmacies.

Mrs. Harshbarger. So is that traditional, the 503A? Because they do a lot of patient-specific.

Ms. Forfa. Yes. What we really want to do is just provide that balance so

veterinarians can have access, the appropriate access while we make sure that, you know, the products that they are getting for individual patients are safe and effective.

Mrs. Harshbarger. What do you do with the veterinarians that compound in their practices?

Ms. Forfa. We don't regulate the practice of veterinary medicine.

Mrs. Harshbarger. Okay. But, yeah, I just would like a little more clarity on where the funding on those inspections are going. 503A traditional? 503B outsourcing? If you could do that --

Ms. Forfa. Yes. Certainly.

Mrs. Harshbarger. -- get me a breakdown, that would be -- and is it allocated.

And, with that, I know my time is up, but I appreciate you answering the questions.

And I yield back.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Mr. Griffith from Virginia for 5 minutes for questions.

Mr. Griffith. Thank you very much. And I apologize. I had to step out for a few minutes to take care of another matter.

But let me associate myself with remarks of Ms. Eshoo earlier in relationship to the active pharmaceutical ingredients. We need to, whether it be human medicines or animal medicines, we need to be producing those more in the United States. And if we cannot produce them more in the United States, we need to make sure that we have FDA inspectors overseas, robust, on the ground, looking at these facilities. Because in many cases, the active pharmaceutical ingredient is going to go sometimes into medicine for humans and sometimes into medicine for animals, and we need to make sure that we are

getting the best quality products that we can for our citizens.

All right. That being said, let me move on to another one that was raised also by Ms. Eshoo, and that was the antibiotic-resistant bacteria and microbes. I am hopeful that FDA on both sides -- but you are here, so I get to bring it up with you -- is working on making sure we have a proper and fast way to approve viruses used in phase therapy, which is, outside of antibiotics, is the best known way to deal with bacteria that are causing problems. But you have got to find the right mix, and you have got to move fast.

And so I would hope that you all would have some -- do you have anything on that you would like to say about how quickly you can move? Because whether it is a herd of cattle or a human being, we want to move quick to knock those things out.

Ms. Forfa. I appreciate that. And one of the things that I have seen in the 6 to 7 weeks that I have been sitting in the director's chair is there are many, many innovative products coming forward in the future to address many, many of the challenges that we face. You know, antimicrobial resistance, climate change, all of those things that we are facing. I recognize that we have to be very flexible with the authorities that we have to be able to get these products, to not be the delay that stops these products from coming to market.

Mr. Griffith. All right. Now, let me switch to telemedicine.

Ms. Forfa. Okay.

Mr. Griffith. I have a district that stretches from what is known as central Virginia, just barely outside of the city of Lynchburg, all the way to Ewing, Virginia, which is west of Detroit, Michigan. It is a huge district.

The 800,000, roughly, people that live in the Ninth District are in a territory, an

area that is larger than the State of New Jersey, and we don't have enough vets, and as a result of that, using telemedicine during COVID was extremely helpful. Most of the time, I would say at least 98 percent of the time my farmers know the vet. The problem is the vet might live on the other side of the mountain. They might live, you know, by car, an hour, 2 hours away.

We don't have enough vets is one problem, but you can't solve that. But FDA changed the rules on my farmers, and the rule went into effect in February, making it much harder for them to use telemedicine.

And, look, farmers are savvy. They want their animals to be healthy. I mean, I am not going to say there isn't a rogue person out there somewhere, but if you get a rogue farmer working with a rogue vet, we already have other bigger problems.

They can use a telephone, use that camera on the phone they have in their pocket. Now, they might have to go back to the house to get a signal or drive down the road to get a signal, but they can take a picture of something that is going on on one of their animals, send it to their vet. The vet can call the prescription in and they can go get it.

We are making it hard on farmers by not updating telemedicine. We know it works. We know it works for the farmers. We know it helps the large animal vets in particular.

And I say that and, you know, we talk about the shortage, but I have the distinction, I think, of being the only Congressman in the country who has two vet schools physically located in his district. I have the Virginia Tech school and then I mentioned Ewing earlier, and there is a vet school. It is licensed to Harshbarger's district. I think it might be even further west than Harshbarger, but it is licensed in Harrogate, Tennessee,

but it is physically in my district in Ewing, Virginia. And we are putting out some great vets, but a lot of times they are going elsewhere or they choose, for obvious reasons, to go into small animal veterinary.

But my farmers, whether they be sheep or cattle, and mostly cattle in my district -- we don't have a lot of chickens outside of Abingdon where we have a big egg facility -- but they need the telemedicine rules to be more flexible so that they can provide food for us and livelihoods for their families.

What say you?

And I am over my time, but if you would give me 30 seconds, Mr. Chairman.

Ms. Forfa. We are working really closely with the AVMA on this. We recognize there is a shortage of veterinarians. I think the key factor for us is the veterinary-client-patient relationship. Once a veterinary-client-patient relationship is established, I think, you know, we are continuing to work with AVMA on what makes the most sense.

Mr. Griffith. All right. So here is what I want you to do. Work with them. Get me language. Let's put a bill in. I mean, that makes it easy. I agree there should be a relationship, but once that relationship is established, let's stop making vets drive 2 hours and farmers have to wait for their animal to be seen, particularly if it is something that could be contagious and could affect the whole herd.

I yield back, Mr. Chairman.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes the gentleman from Pennsylvania, Dr. Joyce, for 5 minutes.

Mr. Joyce. Thank you for yielding, Mr. Chairman, and thank you for holding this hearing today.

It is very important that we complete our work on time reauthorizing the Animal Drug User Fee Act, to ensure that we are supporting advancements and safety in animal health.

In my district, state-of-the-art laboratories, like Lampire Biologic Laboratories, provide high-quality products and services to the life science industry.

Dr. Forfa, thank you for appearing with us today. What are some of the major improvements that this agreement makes from the current goals? And how will it create new efficiencies for the FDA CVM?

Ms. Forfa. So thank you for that. This new agreement really does help us continue to build on the successes that we have had, maybe fill in the gaps where we have identified gaps in previous agreements. We want to continue our 100 percent goals, meeting our objectives and goals. I think it allows us to do the third-party review that has been talked about. It allows us to build in new efficiencies where we see innovative products. So this is critically important to continuing to, as I said, build on the successes that we have had previously.

Mr. Joyce. Thank you. The ADUFA agreement increases user fee funding from $156 million to $174 million over the next 5-year cycle.

Dr. Forfa, how will CVM utilize these additional resources across the two user fee programs?

Ms. Forfa. We have seen actually -- I am going to start with our generic -- generics first.

We have seen an exponential increase in generic products coming to the market, and so I think the additional revenue will help support those. And when those particular products come to the market, it provides additional choices for animal owners. So in

that space, it will help really bolster that program.

In our pioneer space, we are hoping to be able to, as I said, build in efficiencies, but I am also hoping that it will help enhance the sponsors coming to work with us. We are seeing shortage -- I mean, we don't have as many products on the market as we would like to have. And we would like to continue to work with the industry to bring products to us to approve.

So we are committed to continuing to work with both industries on the vital work that we all do collectively.

Mr. Joyce. And the advancement of lower cost generics, safe and effective generics are important to me and to my district as well.

The ADUFA and AGDUFA agreements both contain provisions to enhance agency engagement with sponsors throughout the drug review process. Namely, AGDUFA V would establish a new meeting process to provide opportunities for the aforementioned generic drug makers to seek discussion of bioequivalent status submissions.

Could you speak to why this new meeting process was added to the agreements? And will these meetings occur in person or will they occur virtually?

Ms. Forfa. So, as I said earlier, if a sponsor requests an in-person meeting, we certainly honor -- we have certainly started honoring those requests. So sponsors -- and we have honored them, and so sponsors are more than -- are free to request coming in and meeting with us in person. We are happy to do that.

So the bioequivalence meeting helps to determine what requirements are going to be necessary to prove bioequivalence. We know that there is a generic proposal that will allow sponsors to get single species, as opposed to multiple species in the pioneer, and we are supportive of that. And so we just -- we want to build in flexibilities in the

generic space to, as you said, you know, provide greater access in the marketplace.

Mr. Joyce. And I encourage you to continue to offer those in-person meetings. As we put the pandemic in the rearview mirror, it is time to resume that person-to-person contact.

Thank you for being here today.

And thank you, Mr. Chairman. I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

And that concludes all members seeking questions for the first panel. We appreciate you for being here.

Ms. Forfa. Thank you.

Mr. Guthrie. We appreciate your answers, and I know you will respond -- I think there were some things that needed to respond back to. I know we will get that in a timely manner. So we appreciate your time. So thank you.

Ms. Forfa. Thank you.

Mr. Guthrie. And now we will move to the second panel and kind of quickly because we are kind of facing votes. We are trying to get as much of this hearing in as we can. So if the third panel will take their seats.

Thank you all very much. We appreciate having you here today. We appreciate all of you agreeing to testify.

I will introduce our witness. Our first witness will be Dr. Rachel Cumberbatch, director of Regulatory Affairs for Animal Drugs at the Animal Health Institute. We also have Stephanie Batliner, chair of the Generic Animal Drug Alliance. And we also have Lori Teller, president of the Animal Veterinary Medical Association.

And so the first witness today will be Dr. Cumberbatch. You are recognized for 5

minutes for your opening statement.

STATEMENTS OF RACHEL CUMBERBATCH, DVM, DIRECTOR, REGULATORY AFFAIRS, ANIMAL DRUGS, ANIMAL HEALTH INSTITUTE (AHI); STEPHANIE BATLINER, CHAIR, GENERIC ANIMAL DRUG ALLIANCE (GADA); AND LORI TELLER, DVM, PRESIDENT, AMERICAN VETERINARY MEDICAL ASSOCIATION (AVMA)

STATEMENT OF RACHEL CUMBERBATCH, DVM

Dr. Cumberbatch. Thank you, Mr. Chairman. Thank you, Ranking Member, and thank you members of the committee. Thank you for holding a hearing on this important piece of legislation and for the opportunity to speak with you today.

My name is Dr. Rachel Cumberbatch. I am a veterinarian, and I am here on behalf of the Animal Health Institute, a trade association that represents companies who make animal medicines.

I am here today to ask Congress to reauthorize the Animal Drug User Fee Act, or ADUFA. This program is important to ensure Americans have efficient and flexible regulatory system capable of evaluating innovative solutions to unmet medical needs and to meet the challenges of the future.

This legislation is important for the simple reason that keeping animals healthy provides economic and social benefits that touch everyone. In fact, some 70 percent of U.S. households have at least one pet, and every U.S. household benefits from a safe and available food supply.

Animal health products protect the health and welfare of companion animals. These animals improve the mental and physical well-being of their human caretakers,

work alongside many of our public servants, and assist with therapy for those in need.

The pandemic highlighted the importance of pets when stress and isolation contributed to the prevalence of mental health issues and the need for companionship.

Animal health products also protect food-producing animals from diseases that affect food availability and the safety of consumers. These important medicines give veterinarians, producers, and the tools necessary to care for the 9 billion food-producing animals annually.

Animal medicines also help farmers operate more sustainably and profitably. Healthy animals are simply more productive.

Since animals struggle with disease, they require more resources, and many of them will never produce as much as if they remained disease free. The ADUFA program is designed to provide supplemental funding to the FDA Center for Veterinary Medicine and to meet agreed-upon performance goals to accomplish the congressional mandate of expediting the review process of drug applications.

As we prepared for this reauthorization, we spent time examining the public data available on the program's performance over its nearly 20-year history. It became apparent that a gap has developed between program capacity and performance.

Over the life of the program, fees have increased 600 percent, and staff at CVM have also increased, yet the sentinel workload has declined by 12 percent, and the number of products approved has remained flat.

Perhaps most concerning, products are becoming available in the European Union before they are being approved in the United States, and that puts the U.S. animal health industry and U.S. pet owners and farmers at a disadvantage.

The compromise agreement before you today takes some immediate steps to

close that gap, and proposes further collaboration and data collection that will help lead to an improved ADUFA VI. Highlights of this agreement include appropriate funding, program enhancements, a focus on metrics, and financial sustainability. The agreement includes base funding of $33.5 million per year, as well as one-time allowances from carryover.

ADUFA fees fund about one-third of the new animal drug review budget, which we believe meets the congressional intent that these fees are supplemental.

Several technical improvements are also included, such as opportunities for earlier feedback for presubmission conferences, updating policies and procedures, and, importantly, an annual face-to-face meeting between the FDA and industry, and able to provide education.

We highly value face-to-face interaction. It is necessary when talking about these complex scientific issues and finding solutions to important regulatory decisions.

Additionally, some new metrics will be implemented immediately and more will be explored for the future. For example, we will work together to find a way to measure time in agency and time in industry. Under the current process of phased review, it is very difficult to measure that total time to approval. Yet that is the key metric that is going to be a perfect measure to the ADUFA success going forward.

Lastly, the agreement provides for a third-party assessment. This is a tool that has been successfully used in other fee programs to identify new efficiencies and develop new metrics. It is going to be a first for the ADUFA program.

Mr. Chairman, Ranking Member, we believe this ADUFA agreement sets the program on a more sustainable path. It will continue to provide the agency with resources necessary to maintain the program and will institute enhancements to improve

the animal drug approval process.

We support this investment because a modern and flexible regulatory program is necessary for innovative solutions to reach veterinarians, producers, and animal owners. Those are the people that need them to help keep their animals healthy and live longer and more productive lives.

We urge the committee to pass this agreement without amendments or modifications.

Thank you.

[The prepared statement of Dr. Cumberbatch follows:]

******** COMMITTEE INSERT ********

Mr. Guthrie. Thank you. I appreciate your testimony.

The chair now recognizes Ms. Batliner for 5 minutes for your opening statement.

STATEMENT OF STEPHANIE BATLINER

Ms. Batliner. Hello. And I appreciated your comment earlier about alphabet soup. So bear with me as we get through this.

Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee, on behalf of the Generic Animal Drug Alliance, GADA, thank you for the opportunity to testify today.

I am Stephanie Batliner, currently serving as chair of GADA. We support the reauthorization of the user fee program and, more specifically, support the Animal Generic Drug User Fee Act of 2023, or AGDUFA IV.

GADA is the only U.S.-based independent professional trade organization that represents the interests of generic animal drug sponsors and industry stakeholders.

Generic animal drugs provide significant benefits by providing cost-effective alternatives to their pioneer drug counterparts and by providing supply, security, and access to pharmaceutical treatments that would otherwise be unavailable. These treatments contribute to the safety of the Nation's food supply, the treatment of diseases in animals that can be transmitted to humans, and the ability of owners to provide care to their pet family members. However, the potential cost savings and supply advantages from the use of generic animal drugs cannot be fully achieved without broad availability.

For the AGDUFA IV program, the key GADA objectives were to establish a

functional user fee program that supports an efficient, predictable, and timely FDA review and approval process while employing a cost-effective and equitable payment structure.

While the proposed AGDUFA IV program does not include significant review program enhancements, such as reduced review timelines or increased metrics around efficiency of the program, we do support the proposed fee structure revisions. These changes will bring some relief to the application fee, which has increased to the point that it has become prohibitive for the development of smaller market but medically important generic drugs.

The proposed user fee program is not perfect, however. A fundamental concern for GADA is the disparity between how the generic and pioneer animal drug programs are funded. The ratio of appropriations to user fee funding between these two review programs is radically different.

On the generic animal drug side, industry user fees fund roughly two-thirds of the total CVM review program cost; whereas, on the pioneer side, as my colleague Rachel pointed out, the animal drug industry user fees fund roughly one-third of that review program cost.

GADA appreciates that CVM proposed additional moneys for generic animal drug review in the President's fiscal year 2023 budget; however, this does not significantly close the gap between the two programs.

CVM reports significant growth in generic animal drug workload, but there appears to be a disconnect, as the number of generic animal drug approvals are not increasing accordingly. In 2021, generic animal drug sponsors overall made nearly twice as many submissions to CVM than they did in 2017. However, the number of generic animal drug approvals per year has remained relatively stable.

The program's focus should remain on ensuring the program is cost-effective, efficient, predictable, and geared toward expediting the availability of FDA-approved generic animal drugs based on sound science. Additionally, the industry should be protected from unfair competition from illegal pharmacy compounding, and we do not support the user fee funding for surveillance or enforcement activities, but believe these funds should come from appropriations.

While generic animal drugs are in the spotlight, we also support and call for the passage of the Generic Animal Drug Advancement Act, H.R. 1683, introduced by Representative Nancy Mace. This legislation adjusts decades-old legislative language that have left generic animal drug sponsors at a significant disadvantage. The legislative fixes would allow generic animal drug approval for only the targeted species, as well as expand pathways for generic animal drug products to be approved as combination products.

We thank the committee for including H.R. 1683 in today's discussion.

It should be noted there is a significant overlap between ADUFA and AGDUFA programs. Many generic animal drug sponsors pay fees into both programs. As AGDUFA fees grow, the range of medically important generic drug targets decrease due to the lack of profitability.

In conclusion, GADA supports the proposed legislation for the timely reauthorization of AGDUFA IV. It remains critical for continued viability of the veterinary generic drug industry that the FDA CVM review process maintains predictability and improves efficiency.

Thank you for the opportunity.

[The prepared statement of Ms. Batliner follows:]

******** COMMITTEE INSERT ********

Mr. Guthrie. Thank you.

I just want to make the committee -- or subcommittee aware that votes are on the floor, but we are going to finish opening statements, and then we will recess and then come back for questions. So to let everybody know what the plan is.

So we are going to finish your opening statement, Dr. Teller, then we will recess, and that will give you guys some time to get something to eat. But make sure you coordinate with staff because we are not sure when we will finish. And we will come straight back when we finish, but I think there are several votes on the floor. So you should have time.

But, Dr. Teller, you are now recognized for 5 minutes.

STATEMENT OF LORI TELLER, DVM

Dr. Teller. Thank you.

And good morning, Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee.

I am Dr. Lori Teller, president of the American Veterinary Medical Association. And on behalf of the AVMA, I appreciate the opportunity to emphasize the importance of reauthorizing the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act for our more than 101,000 members.

The AVMA supports collection and effective utilization of user fees to enhance the U.S. Food and Drug Administration Center for Veterinary Medicine's review of pioneer and generic animal drugs. Access to new FDA-approved animal drugs has the potential to improve treatment outcomes, provide better alternatives to existing therapies, fill unmet medical needs in veterinary medicine, and ultimately improve patient care.

The needs of veterinarians are unique because we treat a multitude of species across an incredible range of sizes for a variety of diseases and conditions. Despite this vast range of needs, veterinarians have far fewer FDA-approved animal drugs available than our colleagues who treat human patients.

Also, for food-producing species, our veterinarians take care to ensure food derived from these animals is safe for human consumption.

Veterinarians need more new and innovative animal drugs demonstrated to be safe and effective for optimal patient care and the protection of public health. Effective utilization of user fees under ADUFA and AGDUFA is of keen interest to veterinarians, as

we are the primary prescribers and purchasers of FDA-approved animal drugs.

Ultimately, however, it is our clients who pay the cost of FDA-approved animal drugs. Drug costs directly impact our clients' ability to care for their animals. Animal owners, thereby, rely on animal drugs to not only be safe and effective but also reasonably priced.

We urge FDA CVM to ensure the review process is efficient in bringing new animal drugs to market to safeguard the public's access to affordable treatment for animals.

Under previous animal drug user fee agreements, FDA CVM committed to utilizing user fees to improve efficiency of the animal drug review and approval process. However, we believe additional work is needed to attain the program's goals.

The AVMA suggests, where appropriate, that FDA CVM consider adopting processes used by other similar regulatory agencies that may streamline and shorten the time needed to approve animal drugs for the U.S. market. Our understanding is U.S. approvals lag behind Europe and Canada by up to a year. The U.S. is the largest animal drug market in the world, and we should be the leader in bringing innovative products to market.

With respect to the AGDUFA program, veterinarians need access to more generic animal drugs that have been demonstrated to be bioequivalent to pioneer drugs, are properly manufactured, accurately labeled, are subject to post-market approval requirements, and are available at a reasonable cost. We need more generic drugs for new areas where there is currently no generic competition, as well as multiple generic approvals to provide stability in the market.

We recommend FDA CVM prioritize those applications for which a generic animal drug is not currently available. Having more new generic drug approvals when a pioneer

drug comes off patent or an exclusivity period expires would signal to manufacturers that their time and investment in generic drugs is worthwhile, leading to increased competition and, ultimately, reduced costs borne by our clients.

However, having multiple generic animal drug approvals for the same pioneer drug can also be beneficial. The supply chain volatility and vulnerability experienced over the past several years has demonstrated the need for multiple sources of important animal drugs. In such instances, access to another FDA-approved generic animal drug with demonstrated bioequivalence that is manufactured under FDA's good manufacturing practices is preferred to alternatives such as compounded drugs.

Ultimately, in order to provide the best care, we need a robust pipeline of innovative new animal drugs and a strong generic industry.

Thank you for the opportunity to provide testimony on these important programs. The AVMA appreciates the attention the subcommittee is giving to this issue to addressing unmet needs in veterinary medicine, and we look forward to working with the committee and the FDA CVM to increase the number of improved animal drugs for the benefit of animals under our care, their owners, and the public.

Thank you very much.

[The prepared statement of Dr. Teller follows:]

******** COMMITTEE INSERT ********

Mr. Guthrie. Thank you, Dr. Teller.

The committee will now recess for the purpose of votes on the floor. And our staff will get with you and make sure you guys go do what you need to do, but we will be available when we get back. We don't know exactly when that will end.

So the committee is now in recess.

[Recess.]

RPTR KERR

EDTR ZAMORA

[11:56 a.m.]

Mr. Griffith. [Presiding.] I call this meeting to order.

Chair Guthrie will be back in a couple of minutes, but we want to respect as much of the time as we can.

That being said, I will now recognize Mr. Bucshon for 5 minutes.

Mr. Bucshon. Thank you very much.

First of all, I want to let everybody know everybody has written statements that their staff and members take seriously. So I just want to -- but I want to let you know that.

Dr. Cumberbatch, as I discussed with Director Forfa, previously, FDA Center for Veterinary Medicine, CVM, has post-approval authority that protects human and animal health.

Could you speak from the drug sponsor perspective and tell us how CVM works with drug sponsors to change labels to reflect what is known or learned about the safety of a product?

Dr. Cumberbatch. Thank you very much for the question. Currently, there is a lot of engagement. What happens is that data comes from both FDA and the sponsors in the pharmacovigilance, and when there is a need for a conversation, they come together enable to debate the scientific data behind those decisions. That provides greater rigor to the process.

From AHI's perspective, this process is very important, because it allows for any label changes to make sure that what is going on the label is scientifically sound.

And I would also like to add, one of the differences between animal health and human health is, on this post-approval, they are not looking for causation. It is association. And our customers, the veterinarians, they want causation.

Mr. Bucshon. Okay, great. She testified they wanted a little more authority on the subject because of the turnaround time on label changes. But I wanted to get the perspective from the other -- the other perspective on that.

Has this approach been prove -- you mentioned it. It has been proven successful, though, right?

Dr. Cumberbatch. Yes, it has. It has been successful. And you can see publicly the label changes that are in place, and, importantly, label changes that are backed by data.

Mr. Bucshon. Yeah. All right. That is what I thought.

I just have a comment, no more questions, but I agree with Dr. Teller and your statement that the process in the U.S. should be the best in the world.

I was a surgeon before I was in Congress. So on the human side of the situation, and the frustration that all of us feel sometimes about this slow process through FDA and, honestly, all Federal agencies is real. And so, you know, I -- and the same thing is true with generics.

So I just wanted to say I think you have a lot of -- a lot of people on both sides of the aisle agree with you on that, and we are constantly looking at ways to streamline the process, make it better and more efficient because, you know, we do have the largest market for what you are talking about in the world and probably the largest human drug market in the world also, and we need to do better.

With that, Mr. Chairman, I yield back.

Mr. Griffith. I thank the gentleman.

And now recognize Ms. Eshoo, the ranking member of the subcommittee, for her 5 minutes of questioning.

Ms. Eshoo. Thank you, Mr. Chairman.

And thank you to the witnesses for being patient, but, you know, votes are votes. So thank you.

First an observation, and I think that -- obviously, I think it is an important one, to have three women testifying and that we have leaders of organizations, doctors. It is a real source of pride to me and I think to my colleagues as well because this hasn't always been the case. So I am proud of you.

I asked Director Forfa about where animal drugs are manufactured. I think this is a very important issue for our country.

And so, Dr. Cumberbatch and Ms. Batliner, can you tell us where animal drugs are manufactured?

Dr. Cumberbatch. Thank you for the question. And it really gets to the heart of, is our supply chain resilient? That is a space where we share your --

Ms. Eshoo. Or do we have a supply chain?

Dr. Cumberbatch. Because there are multiple components. You bring up a good question. There are multiple components, and we need a resilient supply chain.

In the pandemic, the animal health industry was quite resilient. We did not see a significant number of shortages, but enable to make sure that flexibility is there, this flexibility is key when you are talking about finding new areas to manufacture. That is one of the goals under ADUFA, because that manufacturing section needs to be in place, enable for the companies to manufacture where it is best. And right now, that

manufacturing, that supply chain is global.

Ms. Eshoo. And predominantly from any foreign country?

Dr. Cumberbatch. Ranking Member, I am not able to give the specifics right now because what we know is that it comes from many places.

Ms. Eshoo. Do you know what the percentage of foreign versus domestic are?

Dr. Cumberbatch. Ranking Member, I do not.

Ms. Eshoo. Okay. Ms. Batliner?

Ms. Batliner. I also don't have specifics in terms of percentages. I can speak a bit to the supply chain. And I think for the finished dosage form, the actual, you know, FDA-approved product that is given to the end user here, many of them are manufactured in the United States. Many of them are also manufactured elsewhere. But manufacturing for that finished dosage form in the United States is much more common than if we look at the active ingredient that goes into that finished dosage form.

And so I think if you really want to look at where we are not predominantly supplied by manufacturers within our own boundaries, then the active ingredients are majority from China, with India becoming a second source in that category.

Ms. Eshoo. Still, that is the case that remains, which I find deeply troubling.

Is there an effort that you see that would move animal drug manufacturing to the United States?

Ms. Batliner. Those types of discussions are not something that our member companies really talk about within the Generic Animal Drug Alliance.

For a company that I work for in my day job, we have two manufacturing sites in the United States. One in Canada that served the U.S. market, and we are not currently exploring bringing additional manufacturing to the United States.

Ms. Eshoo. And what company is that?

Ms. Batliner. Bimeda Incorporated.

Ms. Eshoo. Well, I think, Mr. Chairman, this continues to be not only a deep concern of mine, but I think on a bipartisan basis this is an area that we need to really thoroughly examine and address. I think it is a serious one.

Thank you to the witnesses.

I yield back.

Mr. Guthrie. [Presiding.] Thank you. The gentlelady yields back.

And the chair recognizes Mr. Griffith for 5 minutes for questions.

Mr. Griffith. Ms. Batliner, the company you work for in your day job manufacturers medicines. Do they get their active pharmaceutical ingredients from overseas and manufacture them here or do they get their active pharmaceutical ingredients in the U.S. or North America?

Ms. Batliner. Our primary source for active ingredients is China. We also have suppliers in India, Latvia, elsewhere. But predominantly, active ingredients are not coming from the United States.

Mr. Griffith. What can we do -- and you may not have an answer for me today, but what can we do to bring more of the production of the active pharmaceutical ingredients onto the shores of the United States or at least our allies in North America?

Ms. Batliner. I think that is an excellent question, and I would love to help you solve it.

Mr. Griffith. All right. And I look forward to, you know, as you all think of -- any of you all think of ideas.

I think that this is a bipartisan concern in this subcommittee at least, if not

elsewhere, and we should be trying to solve this issue. And that is not to say that it should all be brought back to the United States, but we need to have a good enough supply that, in a crisis, we can ramp up production at facilities that are located here that already know what they are doing.

All right. Thank you.

Dr. Teller, you knew I had to be coming to you.

Dr. Teller. I did.

Mr. Griffith. You heard my questions in the previous panel and know of my concerns with my large district and the fact that we need telemedicine.

What say you? What are your folks saying?

Dr. Teller. I say we have telemedicine, and we are happy to work with you more.

The scenario that you laid out for Ms. Forfa this morning is actually currently legal under both FDA and the State of Virginia laws.

Mr. Griffith. Then how come my farmers don't know that?

Dr. Teller. That is the problem.

Mr. Griffith. Because they think they have to have the vet show up even if they have got something they can show them on the phone.

Dr. Teller. So they need to have a veterinarian to establish their veterinarian-client-patient relationship, and once that is established, they can use telemedicine and send them a picture, show it to them. The veterinarian can make the appropriate treatment recommendations. If a prescription is needed, they can authorize the prescription for the medication.

So we are happy to work with you to improve the education of both the veterinarians in your district and the farmers.

Mr. Griffith. Yeah. No, I look forward to that because this is -- I mean, if I had just gotten it from one farmer, I might think, yeah, maybe this is not a districtwide problem. But across the board, I have gotten this question on at least three or four different occasions in different parts of the district, which is why I went after it.

Dr. Teller. Absolutely.

Mr. Griffith. Because I want our folks to be served because they are part of the food chain, and we want to make sure that we have an abundant supply and a healthy supply.

Dr. Teller. Absolutely. I eat steak. I had one last night, and I want that steak to be healthy and tasty and be safe.

Mr. Griffith. And hopefully it was, you know, raised right there in the foothills of the Appalachian Mountains, maybe even on top.

Dr. Teller. I will ask that next time, yes.

Mr. Griffith. Yeah. All right. I appreciate that.

Is there anything else that we should be doing in that regard to make telemedicine easier for the farmers to access?

Dr. Teller. So the AVMA has a tremendous coalition of several State organizations and ally groups, as well as industry partners in the pharmaceutical world, and we are working very hard to educate our stakeholders. And whatever you can do to help us amplify that message would be quite welcome.

Mr. Griffith. All right. And then let's talk phase therapy. I have got about 1 minute and 15 seconds. Is this something that -- and anybody can answer it, but is this something that you all are looking at? Is it something that you have even thought about?

Because I think it is an area -- because it hasn't been explored heavily, even for human being usage, it is an area of medicine that we need to be exploring because it may be the answer to bacterial infections that do not respond to antibiotics.

Anybody want to take it?

Dr. Teller. I will say, as the end user, we would love anything new and innovative that is safe, that helps alleviate the concerns around antimicrobial resistance. We are happy to use that as long as it is safe and efficacious. I will defer to the industry folks over here to make that happen.

Mr. Griffith. Yeah. Dr. Cumberbatch?

Dr. Cumberbatch. Thank you for the question. Specifically, we need more tools in this toolbox. And so certainly when products, innovative products come forward, there is both the FDA and the USDA enable to determine the best jurisdiction for those. But the important thing is let's bring innovation forward so that it can be approved and used appropriately by the veterinarians.

Mr. Griffith. And, Mr. Chairman, what we need are kids that -- you know, the kids that always love to get their hands dirty, because to find the viruses that attack the bacteria, you usually find those. So it is treatment plan.

I yield back.

Mr. Guthrie. The gentleman yields back.

The chair recognizes Dr. Schrier for 5 minutes for the purpose of questions.

RPTR SCHOETTLE

EDTR HUMKE

[12:10 p.m.]

Ms. Schrier. Thank, you Mr. Chairman.

First, let me thank the witnesses for being here today. It is nice to see you again, Dr. Teller. I also want to associate myself with Mr. Griffith's remarks about the importance of having a robust supply chain for pharmaceuticals, not putting our food's health at risk, about -- comments about innovation in pharmaceuticals and antibiotics and treatment of infections. So thank you.

I wanted to just start by saying that of course this reauthorization is critical for animal and human health. And I wanted to start with you, Dr. Cumberbatch. In your testimony, you discussed how ADUFA, its reauthorization, as has a robust focus on metrics, new metrics, including the metric of time. And I was wondering if you could just talk about these new metrics, including time, and how they will make a difference and get drugs to market?

Ms. Cumberbatch. Yes. Thank you. One of the challenges that we saw going into this negotiation is that while CVM was able to respond by the ADUFA goal, we were seeing more and more cycles. And remember in the phased approach, with more and more cycles means longer and longer time. And so we were measuring activities. The metric of measuring time is going to help us measure outcomes, but it is not easy. And so there is a commitment to work towards that. But it is when that commitment is finally implemented that we will really be able to see a return focused on the outcome.

Ms. Schrier. Thank for that clarification. I want to turn my attention, now, to Dr. Teller. Again, it is very nice to see you again.

You mentioned in your testimony that where appropriate, the FDA Center for Veterinary Medicine should consider adopting processes used by other similar regulatory agencies that may streamline and shorten the timeline needed to approve drugs for animals in the U.S. market. In fact, just yesterday, you mentioned that medications were getting approved much more rapidly in Europe and some frustration with our system.

Could you talk a little bit more about that and why it is so important to veterinarians.

Ms. Teller. It is really important. There are over 20,000 FDA approved medications for humans. There are approximately 1,600 available for veterinarians to use across a wide variety of species. And we need more drugs, and if there is way to streamline that process, learn from what is happening in Europe, Canada, Australia, those places, that would benefit our animals, our patients so much better.

Ms. Schrier. It seems like there is good opportunities for collaboration there.

Ms. Teller. Absolutely.

Ms. Schrier. In the realm of human medicine, we came upon some of these frustrations with the approval of rapid COVID tests that people could use at home that were approved much more rapidly in other countries before they were available on our drugstore shelves.

Dr. Teller, I have another question about antimicrobial resistance. Pediatrician, I have long worried about this. I have seen with my own eyes the evolution of drug resistance and the limitation on which antibiotics we can use to treat diseases. It is getting very scary. So we try to prevent it with very judicious use of antibiotics only where absolutely needed. And I was wondering if you could expand a bit on judicious

use of antimicrobials, why it is so important for veterinarians to consider treating your patients, and if you could talk about this with respect to ADUFA?

Ms. Teller. Absolutely. Judicious being the keyword there, and it is something the AVMA believes very strongly. And we have a committee dedicated just to antimicrobials. Experts from across the veterinary profession, and the spend a lot of time focused just on this. We provide guidelines to our members, the prescribers, also across the species and for certain disease conditions. And we work with our clients, whether these are companion animal veterinarians, are there other ways to prevent the problems that the antibiotics are using to treat. So preventive care, wellness care, other treatment modalities that are not antimicrobial. We invest a lot of time and money into doing that, and we are starting to see the results of that. And it is really important to the profession.

Ms. Schrier. Thank you. I have had discussions with some of the dairymen, for example, in my district about just that.

I also just wanted to touch on the other issue that Mr. Griffith had brought up about telemedicine and its importance because the issue of being able to purchase antibiotics without a prescription, with the involvement of a veterinarian contributes to antimicrobial resistance. So being able to use telemedicine especially as we are trying to expand broadband is a real win for resistance, for the animals, veterinarians, and for the farmers.

Thank you, and I yield back.

Mr. Guthrie. Thank you. The Gentlelady yields back.

The chair recognizes himself 5 minutes to ask questions. And I want to follow up what Dr. Schrier was talking about with one of my questions. I was looking at, Dr. Teller,

how has the FDA worked with drug sponsors to develop new antimicrobiologicals in food producing animals that are safe for human consumption and get to they have guidance judicious use of antimicrobial drugs. And the question is how has that guidance impacted the ability to get food from food producing animals into grocery stores?

Ms. Teller. I am going to have to --

Mr. Guthrie. How well have they been good to work to together and how that impacted --

Ms. Teller. Yeah. So the FDA, the AVMA, the manufacturers, we all work together on that. A lot of it does come down to education. Veterinarians are in the trenches working with our food animal producers, our allied associations such as the American Association of Bovine Practitioners, our swine Veterinarians, our poultry veterinarians, to make sure that we can advocate for them here with Congress, as well as with the regulatory agencies to help streamline that process so that we do have rapid, but safe turn around to approve these medications.

Mr. Guthrie. Okay. All right. And then the guidance, the judicious use of medically important antimicrobial drugs, that guidance?

Ms. Teller. Yes. So that guidance is very important to us. We work to educate our veterinarians on how to apply that guidance to what they are doing in the real world. There is obviously -- whenever there is change, there is angst particularly on the producer side. And we are working very hard with them and our food animal veterinarians to educate them on how they can best implement that guidance.

Mr. Guthrie. Okay. Thank you.

So for Dr. Cumberbatch and Ms. Batliner, though the questions is about the same except for one different word: How will the agreement accelerate Dr. Cumberbatch, the

development of pioneer drugs, and Ms. Batliner, how will agreements the bills before us today help accelerate for generic animal drugs? Dr. Cumberbatch, if you would like to go first?

Ms. Cumberbatch. Yes. Thank you. The agreement before you would maintain the stability of this program. It is going to help us get products to the market faster and make sure that they are backed by data. Now we need to measure the progress we are making not just the wheels that are spinning. The activity that is being done, that is very important. And I know that you guys have a focus on the supply chain and manufacturing. There is goals within this agreement to make sure that we are specifically improving the manufacturing section within the drug approval process. That is a big priority for us.

Mr. Guthrie. Thank you. Ms. Batliner.

Ms. Batliner. The proposed ADUFA IV program would continue to build upon the performance that we have seen across the previous programs in terms of the predictability and the time by which FDA gives us their response, whether that be positive or negative. With that said, we do have a good relationship with CVM, and we are committed to continuing that collaboration where they are being more clear, developing more guidance, and so forth, which then helps us to put forth a better package for them to approve, that subject generic animal drug.

It think it is important to note just how few pioneer animal drugs have a generic counterpart. So we would really like to see better penetration of generic animal drugs into the marketplace in general. So we look forward to continuing the progress that we have made with AGDUFA and really focus, though, on efficiency. For me to get a rejection letter faster doesn't really help anyone. So what we look to do as an industry

is to work with CVM to make sure we understand the requirements, but then also have them, you know, keep those requirements kind of in check and based on sound science.

Mr. Guthrie. Thank you.

Ms. Batliner. Requirements for the sake of more paper work, I think, maybe you know doesn't accomplish the goal so a focus on the science and what is really required to keep these products safe and effective.

Mr. Guthrie. Thank you. I appreciate that. That concludes my questions. So I will yield back, and I will recognize the lady from Tennessee, the Gentlelady from Tennessee, Mrs. Harshbarger.

Mrs. Harshbarger. Thank you, Mr. Chairman. Thank you to the witnesses for being here today. I want to start with you, Ms. Batliner, and it was something you said in your statement. You said, CVM should have the resources necessary to meet the stated goals of AGDUFA and to protect the generic animal industry from unfair competition from illegal pharmacy compounding.

Can you tell me what illegal pharmacy compounding means?

Ms. Batliner. Sure. Thank you for the question. And I do want to draw a clear bright line between legal and completely acceptable and necessary pharmacy compounding in veterinary health. It does serve a purpose. There are guardrails around how that compounding happens, and we have no challenge on that.

Mrs. Harshbarger. I am very aware of how that compounding happens. Are you talking about 503Bs versus 795 compliant 503As?

Ms. Batliner. So where our concerns lie is when compounding pharmacies are importing bulk drugs and formulating finished dosage forms for masses, not for one individual, you know, client/patient relationship, but rather formulating to bulk stock,

office stock.

Mrs. Harshbarger. Well, that is what the GFI addresses.

Ms. Batliner. Right. So once that becomes enforced, then we are hopeful that that definitely improves the situation.

Mrs. Harshbarger. Because we know we have to have a patient specific prescription for those animals and there is several guidelines on that. You know, there is 503A. You know, the traditional compounders, and they have to be 795 compliant or 797 if they do sterile, and of course, 503Bs it is a different setup but, they can certainly do that.

Dr. Teller, in your statement, you said more approvals of generic animal drugs help ensure consistent access to the drugs veterinarians use to treat our patients. Such instances access to another FDA approved generic animal drug was demonstrated by equivalence that it is manufactured under FDA's good manufacturing practices is preferred to alternatives such as compounded drugs.

I guess my question is, what do you do when you can't get any alternative? You have to turn to a compounder, or the animal goes without. I have seen this in many instances, even with human drug compounding.

Ms. Teller. We absolutely compound. We work with compounding pharmacies, and we have to do it every day. There is not ever going to be enough drugs approved to cover all the species, the sizes, and the doses that we need. So certainly being able compound from approved drugs is our first choice. We also know that there are times that we need to be able to do that from bulk drug substances. And we work with the FDA when they came out with guidance 256. I have to say we are not super in favor of the list. So we are cautious and working with them on that, and they have

publicly committed to being efficient in reviewing those drugs and moving them to approved list.

Mrs. Harshbarger. I know, it is like, you know what needs to be on the list. We are here to help them. I have offered my assistance many times.

Dr. Teller, I have another question. In your testimony, you mentioned the need for new and innovative medicines to fill those unmet needs for veterinarians. Can you walk us through some of the unmet needs your members have in their practices?

Ms. Teller. Sure. So a couple of examples on the food animal side, ocular squamous cell carcinoma, so cancer around the eye. That is tremendous. It impacts cattle.

Mrs. Harshbarger. Absolutely,

Ms. Teller. And on the small animal side, hemangiosarcoma, which is a blood-based tumor. There is no great treatment for that at this moment. Life expectancy in general is around 3 months. Maybe if you do chemo, 5, 6 months. And if we had a medication that could take care of that, it would be amazing.

Mrs. Harshbarger. Yeah. Can you explain how the animal drug user fee agreements have improved animal health, both for pets and for food producing animals?

Ms. Teller. We appreciate the fees being reasonable and going towards making the process safer and more efficient because it does get those medications to us faster so that we can treat our patients, whether it is on a farm or in somebody's house.

Mrs. Harshbarger. Okay. I just wanted to make sure you understood the importance of compounding, not just for animals in the veterinarian industry, but also on the human side too. That is just something I have done for 37 years. And you know, there is such value in that. I guess with that, my time is up, and I yield back, Mr.

Chairman.

Mr. Guthrie. I thank the Gentlelady for yielding back.

I believe that is all Members who have been presented to ask questions. We have concluded that part of this hearing. I ask unanimous consent to insert in the record the documents included on the staff hearing document list.

There is one. No objection?

Ms. Eshoo. No objection, Mr. Chairman.

Mr. Guthrie. Without objection, so ordered.

I remind the Members that they have 10 business days to submit questions for the record and ask witnesses to respond to questions promptly. Members should submit their questions by the close of business on April the 13. Thank you all for being here. I know it has been a long morning because we broke for votes for a while, but really appreciate your attention to this, the hard work that you do before you come to the hearing just to get the bills ready, and to prepare for the hearing. And it is much appreciated, and we thank you for being here.

And without objection, the subcommittee --

Ms. Eshoo. Mr. Chairman, it is not that I have an objection, but I just want to raise, I think, a very serious issue. This morning, a federal judge in Texas struck down major portions of the ACA's requirement that health insurers cover preventative services with no cost sharing for patients. This ruling applies nationwide, affecting everyone with private insurance. And that is -- I want to raise it. It is not only ACA. And what this affects, at least some of the preventative services, we know that we are way behind in cancer screenings in our country due to the pandemic. It effects drugs to prevent HIV infections, pregnancy care, colonoscopies, and there is no stay while it is appealed.

So I am asking you to take under consideration as chairman of our subcommittee that we have a hearing on this. It is not only ACA enrollees, but all privately insured people in our country.

Mr. Guthrie. Thanks. We just saw that this morning and haven't had time to review --

Ms. Eshoo. I understand.

Mr. Guthrie. We are concerned. We want people to get cancer screenings and screenings they need. We will commit to a hearing. I am not sure what our schedule will be. We are mindful of it, and we want to make sure that people have the proper screenings. We think prevention saves money in the long run, but not only does it save money, but saves life. That is the most important.

Ms. Eshoo. Thank you for taking it under consideration.

Mr. Guthrie. Thank you. Well, the subcommittee, without objection, is adjourned.

[Whereupon, at 12:26 p.m., the subcommittee was adjourned.]