Kyle Kinner: Alright. Good afternoon, everyone. We're gonna give folks just a few seconds to join the virtual room, and then I'll initiate the program.

Well, good afternoon. I'm Kyle Kinner, an Alliance board member, and Senior Governance Relations Officer at the Pew Charitable Trust – a foundation which uses evidence-based, non-partisan analysis to solve today's challenges. In that role, I work on a variety of nutrition, food safety, and other FDA regulatory issues.

I'm joined today by our co-moderators – Dr. Peter Lurie of the Center for Science in the Public Interest, and Ms. Allison Phipps of Merck Animal Health. Peter Lurie is the President and Executive Director of CBI with overall responsibility for CBI's operations, including public advocacy, legislative, and regulatory affairs, scientific analysis, and communications activities. Previously, he was the Associate Commissioner for Public Health Strategy, and Analysis at the Food and Drug Administration, where among other things, he worked on amicrobial resistance.

Allison Phipps is the Associate Director for Public Policy, and Government Relations for North America at the Merck Animal Health, and she's based in Washington DC. Merck Animal Health is a global research driven company that develops, manufactures, and markets a broad range of veterinary medicines, and services. Allison has been with Merck Animal Health for four years, and has a background in Animal Science, and Research.

We'd also like to welcome Alliance members, the media, and Alliance guests to our webinar today with Dr. Steven Solomon, who is the Director of FDA's Center for Veterinary Medicine. First, a quick word about the Alliance for a Stronger FDA. We are a multistakeholder coalition that advocates for increased appropriated resources for the Food and Drug Administration. We have been an important force in the doubling of FDA's budget authority from $1.6 billion to $3.3 billion. Our other mission is to educate policymakers, the American people, and the media about the FDA's growing mission and responsibilities.

We are also the only advocacy organization focused on resources for both food safety and medical products, as well as other components of FDA's mission. Our members include consumer and patient groups, research advocates, health professional societies, trade groups, and industry. We have approximately 150

members, and we welcome new members to further strengthen our advocacy and educational efforts. I encourage folks on the call to either join us at any time, or if you know other organizations who might like to join us, encourage them to get in touch.

For this webinar, Dr. Solomon has agreed to respond to questions submitted by the Alliance, to be followed by ample time for moderator and audience questions. You may submit your questions by clicking on the Q&A button at the bottom of your screen – and that's not the chat box, it's the Q&A box. Now, before introducing Dr. Solomon, we'd like to thank Julianna Wittig and Nicole Williams of his staff. They have collaborated closely with us in preparing this webinar. So, thank you.

And I now have the privilege of introducing our esteemed speaker for today's webinar, Dr. Steven Solomon, Director of FDA's Center for Veterinary Medicine. Dr. Solomon was appointed Director for FDA's Center for Veterinary Medicine in January 2017. He previously served as Deputy Associate Commissioner for Regulatory Affairs and has held a number of policy and leadership positions in the Office of Regulatory Affairs. Dr. Solomon has a Doctor of Veterinary Medicine degree from Ohio State University, and a Master's in Public Health from Johns Hopkins University. He first joined FDA in 1990 as a Veterinary Medical Officer in the Center for Veterinary Medicine. We're incredibly fortunate, and pleased, to welcome Dr. Solomon today, and look forward to his remarks and to questions both from our panel and from the audience. So, with that, I'll turn to Dr. Solomon. Thank you.

Dr. Steven Solomon: Thanks, Kyle, and thanks to the Alliance for having this opportunity. Before I begin talking about the questions, I just want to spend a few minutes – for those not familiar with the work of the Center, I want to give you an overview of what we do at the Center for Veterinary Medicine. Basically, everything you've probably heard about FDA, the Center for Veterinary Medicine is is a microcosm of FDA with the broadest mission. We're the smallest Center in the agency, and our mission is to protect human and animal health. We focus on using a One Health perspective, which I'll be talking about some more; understanding that human health, animal health, plant health, and environmental health are all inextricably linked.

We help to ensure the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness

of animal drugs. As Kyle said, I've been with the agency for over 32 years. What motivates everybody in FDA and at Center for Veterinary Medicine is our mission. And the Center for Veterinary Medicine's staff are tireless public servants. They are committed to public health and they are passionate about animals.

Unlike my counterparts in the other Centers who deal with only one species – humans – our work supports the health of a wide diversity of animal species with often very unique disease conditions. We work to address food-producing animals, companion animals, zoo animals, wildlife animals, all the minor species, fish, and honeybees – just to name a few. As I mentioned, we're the smallest Center. We're around 4% – or we constitute 4% – of FDA, so around 700 FTEs – fulltime equivalents – that support and regulate almost $560 billion dollar industry. That's the total economic impact of the industry.

More than 2/3 of American households own pets. And this totals nearly 400 million pets – dogs, cats, horses, birds, fish, parrots – and, more than 95% of those folks view their pets, as I'm sure many of you do, as part of their family. For food-producing animals, the inventory for cattle is around 94 million, swine around 93 million, and chickens 9 billion, and this provides around 1.2 million jobs out there.

The entire US population, plus many more around the globe – because we have an international reach – depends on Center for Veterinary Medicine ensuring the safety, efficacy, quality manufacturing, and accurate labeling of veterinary products, whether that's pet food for your pets, livestock feed that eventually forms a part of the human food supply chain, or veterinary drugs that fight heartworm in dogs, respiratory illness in pigs, or infections in aquaculture fish, or a reproductive challenge in a rhinoceros.

So, with that background on CVM, I'll sort of go through some of the questions. The first question is related to the present FY2023 budget requests, and some discussion about where these resources are going to go. So, our budget request for FY2023 totals $22.9 million and 47 FTEs – so, fulltime equivalent people, and it's spread across six different areas. I'll briefly walk through each of those areas.

The first, and probably the largest request, is data monitorization,

and enhanced technology. This is for $10.1 million and 8 FTEs. This builds on a request that the carryover from FY2022 of about $0.6 million. This is building on our work that we are handling more and more large data to address and respond to human and animal health emergencies – not just from animal food outbreaks, but all the events that are taking place in society, whether it's a major weather event, the pandemic, geopolitical conflicts, such as the Ukraine/Russia conflict. All of these things have been really impacting the supply chains, which we'll be talking more about.

Some of the questions that we ask ourselves, and I'm sure you ask us, are: What's the impact of the pandemic when it first started in China? Most of our ingredients for drugs come from China and India. What's the impact of that on the ability to have our product – these raw materials – when there are changes? When we have an event like a tsunami that it hits India, what's the impact on any of the products that we need here in the United States? We get most of our vitamins from other countries. What's the impact if there's a shortage there? Who would be affected?

All of these are questions that we need data systems, that are currently stove-piped, in order to be able to answer these questions, and that's what this investment is about. I'm sure many of you who own pets have been to the pet store and may have seen that your recent foods may be in short supply, or your favorite brands. These are issues that we're trying to help address.

So, the Center for Veterinary Medicine scientists need the tools from this investment so they can focus on research and analysis to bring critical drugs to market faster, ensure unsafe drugs are removed more quickly from the market, address disease outbreak, identify food ingredient shortages or food contamination impacts at the speed that these events continue to unfold, which has increased – growing more rapid. This is investment not only in technology, but in business modernization, and it'll will improve our abilities to answer these questions by refining how we access and analyze large amounts of data.

The second request is for premarket animal drug review. This is $5 million. Congress – Center for Veterinary Medicine is the only Center that has this split between having user fees for medical products and non-user fees for animal food. So, we get user fees under the Animal Drug User Act and the Animal Generic Drug User Fee Act. They were last passed by Congress and the President

signed them into law in 2018.

The User Fee Act supplements the appropriated budget authority (BA) portion of the new animal drug review process, and supports the timeliness and efficiency of both pioneer and generic animal drug reviews that are currently in negotiations for the Animal Drug User Fee Act – this is the fifth version – and the Animal Generic Drug User Fee Act – the fourth version.

We've seen a tremendous increase in the generic animal drugs submissions over the past few years. We saw a 50% increase in workload in under AGDUFA 2, and another 50% under the current authorization. It is a real challenge for us to keep up the number of increasing animal drug submissions. Once again, user fees pay part of that, but we also need to have budget authority. So, this request is to hire additional people to meet this demand to make sure we meet our performance commitments to help industry increase the availability of safe and effective drug products.

The next portion is a continuation of some of the requests from 2022. From the medical product supply chain, this is $0.8 million. This is to identify data gaps and review existing data for the quality for our animal drug and manufacturing system. We leveraged some COVID-19 supplemental funding we got to create this system of – the new animal drug and manufacturing system – to retrieve information on animal drug products, the acquisition of pharmaceutical ingredients, and the status of manufacturing sites. We got $1.5 million in FY2022, so we need people to make sure that we're looking at this data, and the quality of the data that's in the system.

The new area that we've been looking at is reducing animal testing through alternative methods. The present request is for $0.7 million. While most of the Centers are doing research and animal studies – most of those in support of the human approval of the products. At CVM we're doing animal studies in support of the animal approval of these products. And, once again, animal studies can be resource intensive. They can be complex to implement. There is lots of concern about items like 'can we find alternative methods to improve animal welfare by adopting new methods that can help us replace, reduce, or refine animal testing'? This is often abbreviated as the three R's.

So, we're developing state of the art technology as alternatives to

traditional animal research. We would love to be moving more in this direction. It's now possible to use stem cells to create a mouse with the same immune system as a dog. In this case, we wouldn't have to then use dogs in studies, but could use mice to replace them. And we're also doing a current study to prove the safety and effectiveness of some animal drugs. We're actually using dogs in this study, but we did something very unique in that the animals are going to be adopted out at the end of the study. And, right now, volunteers from Center for Veterinary Medicine are spending time socializing these dogs. While the study is going on, they're taking them for walks, they're playing with them, so that at the end of the study, all these animals are going to be adopted out. And we're happy that so far ten have already been spoken for.

The other areas of funding. You've probably heard about already from Frank Yiannas: It's the new era of smarter food safety. This is $4.6 million. This new era initiative was launched in July in 2020. It's built on the Food Safety Modernization Act, promoting new ways to advance food safety. We're requesting funds as part of the Center for Veterinary Medicine portion of it to help expand our root-cause analysis when there are animal food outbreaks, better use of predictive analytics on outbreaks, trying to reduce the time it takes to trace the origin of a contamination event, so we learn from those. We're also looking to advance traceability.

In our mutual alliance efforts, which I'll be speaking a lot about during this time today. We really need to continue to strengthen our response to working with our state partners in making sure we're leveraging each other's data when contaminated animal food is identified. We cannot handle these issues alone. We need our state, local, territorial, and tribal partners.

And the last area is an increase in pay, costs $1.8 million. It's important that we have the necessary staffing and personnel to keep our programs going. We need the people who have the great scientific expertise. We're taking more and more of a total product life cycle approach. We look at pre- and post-market activities, and we have a pretty large portfolio of drugs, foods, devices – all for the various species I mentioned earlier.

But what we've been experiencing over the years, and has been particularly **severe** at Center for Veterinary Medicine, is erosion. When our funding of programs remains flat, we have increased payroll costs, benefits, cost of living, retirement costs. This has cost us, over the past ten years, around $26 million in what we've

had to absorb at Center for Veterinary Medicine. And the impact of that erosion is that certain programs are impacted more than others. And the impact has primarily been on our post-market surveillance and our research area due to this erosion. So, getting support for the payroll increases is really important.

The next question talks about the 2022 Omnibus Budget, and what we're doing with that budget. I spoke a lot about that already because many of the new budgets are carryovers, but I'll go into a little more detail. In 2022, our enacted budget was $181 million, of which $129 million was budget authority, and $52 million was user fees. While I think I was, at many others were, sort of disappointed with the omnibus process – there were House, and Senate markups that were getting significantly additional funds to Center for Veterinary Medicine – the process sort of didn't work when they went through the omnibus process. To be sure, folks did work hard to try to get House, and Senate appropriation support but had some challenges through the Omnibus process. So, we will use the funds we got, which was $6.2 million to continue to protect and promote human and animal health. We got less than a third of what we requested. We did get $2.3 million for animal food safety oversight, and additional $1 million for animal food ingredient review, $1.5 million for medical product supply chain I talked about, and $0.5 million for the data modernization I talked about. And $0.9 million to cover a portion of the FY 2022 cost of living adjustment, so some of the resources.

I'd like to spend a little bit more time on the animal food safety piece. What I find is, working around 32 years, I've worked on the human side and the animal side – and the American public care the most about children and pets. And this investment in Animal Food Safety supports what people really care about. Animals have died and humans have been sickened because animal foods have been contaminated. While Center for Veterinary Medicine got $2.3 million, a big part of that request was $11.2 million for Animal Food Safety Oversight from my colleagues in the Office of Regulatory Affairs. And that funding is really important because it's used to expand our funding to our state partners, and strengthen our mutual reliance efforts with states. When I talk about animal food safety, I feel like I continue to say the same thing: all animal foods should be safe. I continue to see too many animals and their owners or other people getting sick from unsafe pet foods, too many livestock illnesses, and deaths due to preventable food mixing errors.

A couple of examples: in 2019, 154 people in 34 states, including 27 children under five, got sick from handling pig ear pet treats that were contaminated with salmonella. In 2021, it was not a good year. We had 170 pet deaths, and hundreds of pet illnesses due to pet food contaminated with aflatoxin. In formulation, control of contaminants is critical, because animals are typically eating the same food all the time. Making sure their diet formulations are correct is important. We as people eat a very diverse diet, so what we see when something goes wrong in animal food, it often goes wrong in a very big way.

And, partnering with our states is critical, and is needed to implement a modernized, comprehensive, and prevention-oriented inspection system in the animal food safety system. I've long been an advocate for an integrated national food safety system. Typically, the states do 80% of the animal food inspections, while FDA does 20%. We provide funding for the states. The National Association of States Department of Agriculture issued a report a couple years ago that we really needed to expand our work with them, and they needed $20 million to expand the Animal Food Preventive Control regulations.

So, this additional funding would expand mutual reliance efforts, build upon the $2.3 million that we got, and help continue to transform the animal food safety systems to make it safer. In addition, we received $5 million in 2020. In 2022, we received an additional $1 million to hire and train additional reviewers, implement process improvements to strengthen our capability to review biotechnology plants, and enhance the premarket animal food program. This animal feed ingredient review is going to help enable innovation and address challenges and opportunities in the animal food industry.

The 2022 budget had a congressional report language that charged the Center for Veterinary Medicine to look at our food ingredient policy to support hanges to allow more food claims. We're going to report back to Congress, but we're hoping that we can make a positive statement on that. With that addition, we really do anticipate a significantly increased workload. New claims will also present the need for new expertise. So, additional funding in this area is very critical.

The pandemic was the next area of questioning. I'll start off, and

it's have to say: The only positive note I found from the pandemic was that there was increased adoption of animals from animal shelters. And I think that's important because it demonstrates the importance from a One Health perspective of the human/animal bond that's so important and critical to peoples' wellbeing. That people adopted lots of pets from shelters is a very positive thing.

We also gave a lot of flexibilities during the pandemic, and many of those are in place for the duration of the public health event, which still goes on. And we have to make decisions on how and when to change those flexibilities, or which ones we're going to keep, or which ones we're going to change.

We also changed. Some of the other changes were that we weren't able to conduct routine regulatory inspections during part of the pandemic, and so we implemented lots of new tools using remote regulatory inspection. So, I think that's a positive tool, and one that's going to last, that we can use remote records access, where we have that authority, such as on the drug side, and using remote regulatory assessments on the veterinary feed side, as we've looked at veterinary feed directives. We think these tools have long-term value and can help increase our productivity. So, I think those are areas that we will save time over the long haul.

We did spend that time doing a real review and overhaul of our inspection program for animal food. We used to look at inspections on a hazard-by-hazard basis. We're now moved to a comprehensive inspection model which incorporates all the food safety regulations into a single inspection. We also used the time to help improve our inventory and our risk models so that we now can do better work planning. And so, I think the pandemic had some impact – still has a lot of impact, so we used that time to do a number of things.

The next area that I got a question about was about infrastructure costs and what that really means. Once again, I think I've talked a little bit about the data monitorization enhanced technology. I can't overemphasize how important that investment is. And, just to give some advanced examples of it: We're now looking at the Ukraine/Russian conflict, and there, Ukraine is the largest supplier of sunflower oil that's used in both human foods and some animal foods. So that's going to affect the food supply. We need modern systems to be able to access what alternative food sources can be used and where we get things.

Russia provides a lot of the Cobalt-60 that's used in sterilization of certain veterinary drugs and devices. These type systems were developed on individual areas and stove-piped – our systems don't talk to each other. So, this investment will allow our analysts and our scientists to quickly generate responses to the pressing public health and animal health questions. And, right now, they need to do this work by going into each system and downloading spreadsheets and doing a lot of manual work in multiple databases and linking the data, ensuring the quality of the data sources, and generating reports. That's not the way to do work.

The other infrastructure invest is really our Office of Research is now over 25 years old. We've been doing work on a lab assessment to evaluate our existing space and are going to need significant renovations to it. We're also updating our agricultural facilities. We have unique work that's not done anywhere else other than in our agricultural facility. We have all sorts of agricultural species: goats, we have the beagles that I talked about, and others, all on our research campus.

The One Health area is one where I would really like to spend time. Once again, One Health recognizes that human, animal, plant, and environmental health are interconnected. And the focus is on using that and cutting across discipline sectors to solve complex public health problems. It's a collaborative framework. It's uniting education, research, industry, government agencies, health officials at local, regional, national, and global levels. And it's foundational to tackling the public health problems like antimicrobial resistance, **zoonotic** diseases such as COVID-19, and others.

We've been working with 17 other agencies during the COVID-19 outbreak on understanding the impact on animal species, making sure we have diagnostic tests that work and recognizing susceptible species. As you might imagine, we've gotten a lot of momentum coming out from the global pandemic for One Health, and we're very engaged in this process. Our mission of protecting human and animal health is grounded in a One Health approach. We need to work with our other Centers on the safety and efficacy of the products we regulate for both humans, and animals. We also need to work under the National Environmental Policy Act on the environmental piece.

Just thinking of a few examples that that will bring to mind: mad cow disease, or BSE, which was a variant of Creutzfeldt-Jakob disease – was one disease that the Center for Veterinary Medicine was very involved in to protect humans from getting mad cow disease. Monkeypox was a foreign animal zoonotic disease that came over from imported African rodents**]** from Africa and had 47 human cases in six states in the United States. You all may remember the issue of melamine, which was a contaminant in pet food, but it relates from a human health perspective because the following year, it was found in infant formula in China. And, because of Center for Veterinary Medicine's discovery of melamine and developing a method of detection, we didn't have any of that problem here in the United States.

You may even recall the issue of Heparin contaminated with over-sulfated condroitin sulfate. The reason that there was a contamination event was because heparin comes from the intestines of pigs, and there was an outbreak of porcine reproductive and respiratory syndrome in heparin – in pigs in China – which decreased the pig population. So, once again, One Health is sort of everywhere you look around it.

It's also translational medicine. The drug ivermectin was developed for use in animals, but actually became useful in Africa for treating some parasitic diseases in Africa. And we've approved drugs, like in 2018 a new class of drugs which actually reduces ammonia emissions from cattle. And ammonia emissions can cause atmospheric haze, and noxious odors, and eutrophication of bodies of water, and algae deaths. And so this was a new class of drugs that has a positive effect on the environment.

The One Health principles are core to FDA's work, and our work with other agencies. We're co-leading a steering committee with the Office of Chief Scientists of FDA, and we're really trying to promote that we develop an FDA Center for Excellence for One Health. We've been talking to budget and legislative requests for a period of time. Other agencies such as USDA and CDC support our One Health efforts, and they have One Health offices. This would help us serve as a nexus for where to come in with One Health issues if there's a specific One Health Center for Excellence. It would allow us to better integrate across FDA in the depth and breadth of the work that we do there.

So, we're really looking to refine resources and develop an FDA

Center for Excellence. It is funding that is requested as part of the pandemic preparedness portion of the 2023 budget request.

And then, the last area I think that asked a specific question was our role on antimicrobial resistance. This is an area that the Center for Veterinary Medicine has been very active in for decades. We outlined our plans, and what we call our Five-Year Plan, for supporting antimicrobial stewardship in veterinary settings which uses the One Health principles. We focus our goals into aligning antimicrobial drug product use with the principles of antimicrobial stewardship, fostering stewardship of antimicrobials in veterinary settings, and enhancing monitoring of antimicrobial resistance and antimicrobial drug use.

We put out various guidance documents like Guidance for Industry (GFI) 263. We give our guidance documents numbers. This guidance which transitions medically important antimicrobials currently available over-the-counter to prescription status so that we can increase stewardship by having veterinarians controlling them. We're looking at the ranking criteria for ranking antimicrobial drugs based on their importance in human medicine. We're working to launch stewardship projects to enhance our resources available to veterinarians.

We work with our surveillance work under the National Antibiotics Resistance Monitoring System, characterizing resistant bacteria by sampling additional animal species such as veal, shrimp, and salmon. And we are now working with EPA on testing the various watersheds. We're now in a Phase 2 of that plan. We're working to solidify an approach to finding durations of use of approved medical antimicrobial drugs. We're looking to build an approach to collect better antimicrobial use information on animals.

We're looking at advancing our NARMS strategic plan to enhance our sampling of foodborne pathogens, and we're now starting to look at antimicrobial resistance, not only to food-producing animals, but also in companion animals. So, that's part of the strategic plan – that five-year plan that's out there. We're also part of the president's National Action Plan for combating antimicrobial resistant bacteria. That's just been extended out through 2025. And we need to continue to work on developing, with our stakeholders, how we measure progress, and are we having an impact on slowing the impact of antimicrobial

resistance.

So, let me pause there. I know that was a whirlwind tour, but I want to leave plenty of time for questions.

Kyle Kinner: Thank you, Dr. Solomon. I'll turn it over to our panel moderators, who have some questions.

Peter Lurie: Well, hi, Steve. Good afternoon. Maybe I'll jump in first, Allison, if that's okay. Let me follow up on the One Health theme because I know how important that is to you and ask you to talk a little bit about that in the context the COVID-19 pandemic. It's not about eradicating infections that have animal hosts. So, can you tell us a little bit about what Center for Veterinary Medicine is doing in its research to establish the existence of animal hosts, and what, if anything, you're able to do in terms of perhaps reducing levels of infections among animals.

Dr. Steven Solomon: So, thanks for the question, Peter. It's good to see you again. So, we're doing many different things on that. So, we actually are part of an interagency program with 17 other government agencies looking at COVID-19. One of the approaches in One Health is that it's not one agency in charge; we each bring in our resources and the expertise we have to the table. One of the areas that Center for Veterinary Medicine was clearly in charge – focused on – was the diagnostic testing. While our Center for Devices and Radiological Health was focused on testing for humans, we wanted to make sure the tests for animals were accurate, and that people could do it.

So, we did some inter-lab comparison exercises – three, and we're working on a fourth – inter-laboratory comparative exercises to make sure that veterinary diagnostic labs were capable of being able to diagnose COVID-19 as the different strains were coming forth.

We worked on – Some of the areas that we worked a lot on is that every time there's a pandemic, or other event out there, there are unscrupulous people who try to take advantage of others on these issues. So there have been lots of fraudulent products, often using animal drugs for either treating animals for COVID-19 or treating humans.

And probably the two best examples were the chloroquine, where unfortunately, a family actually took some animal chloroquine and, unfortunately, the husband passed away. The wife was in the ICU. And then another drug was ivermectin, and people were using

animal ivermectin to treat themselves or as a preventative. And many people ended up in the hospital. And we spent a lot of our time trying to get messages out to people about "Don't use animal drugs." You may recall our tweet that became viral that says, "You're not a horse. You're not a cow. Seriously, y'all. Stop it." Don't use animal ivermectin. which actually was one of our more effective messages out there.

We've also closely followed with our colleagues, the issue of transmission to animals. So, there was a lot of concern when COVID-19 first started that we started seeing companion animals – dogs and cats – and, the concern was: How badly does it affect our pets? And, what we found was a relatively mild illness in dogs and cats. So, we did work to make sure we could fund necropcies, or autopsies, and diagnostic testing of some of those animals because what we didn't want people to do is to get rid of their animals because they were fearful that they could transmit it back. And we've seen no evidence that companion animals could transmit COVID-19 back.

Where we have seen some interesting findings is that it first started in Europe, where we found mink that are very susceptible to COVID-19, and caused a lot of deaths of mink populations, and various countries have used various approaches to try to resolve that issue. But we have seen transmission back from mink into humans, and that's a concern. And, more recently, we've seen deer populations in the US and Canada also having it. And some recent information still being studied whether there can be transmission back, but these wildlife populations could serve as an animal reservoir where these viruses could continue to mutate. And if they can transmit back to people, it could continue to spill over back from animal populations. It could be a real concern that it's going to keep the COVID-19 various mutations not only reoccurring in people, but also in animal populations. So, in this One Health group, we spend a lot of time sort of studying which species are susceptible, which species are susceptible as we go through the various variants, whether it's alpha, or delta, or omicron, or the new versions that are now popping up. We need to understand what's the impact on animal populations.

There have been a lot of zoological animals and wildlife animals that have caught it, and there's some well-known science about which animals are more susceptible to COVID-19 than others.

Kyle Kinner: All right. Thank you.

Allison Phipps: If I might jump in with a quick question, Dr. Solomon? And thank you again for your time today to join the Alliance for this webinar. You talked about the real scope of expertise that's at the Center for Veterinary Medicine. So, I was wondering if you could speak a little bit about how the Center approaches recruitment of employees and talent to be able to meet the expertise that's needed.

Dr. Steven Solomon: Thanks for the question, Allison. We really have a great culture at Center for Veterinary Medicine, and unlike many of the other components, we don't seem to have – We have fairly low attrition, and we have a lot of people who want to work for the Center for Veterinary Medicine. Unfortunately, we don't have the resources to be able to hire all the people out there. But we really do work very hard on the culture of our organization, and recruitment out there. We need to look at, you know, we do a lot of horizon-scanning to see 'what are the new issues, and what types of scientific expertise are we gonna need in the future?'.

So, like I talked a little bit, we're going to probably need new expertise in looking at animal food ingredients. So, in the animal, plants, biotechnology, and animal biotechnology, we need expertise, or have expertise in geneticists, bio-informaticists, animal scientists, like you have a background in, and statisticians. Statistics is an area where people are in high demand. Our problem for folks is often people are moving into other Centers, particularly the statisticians that are really in great demand. So, have a whole lot of challenges in pay equity.

We have really interesting work. People like the way that we have our culture where our organization. I just met this morning with five or six new people. They had such interesting backgrounds. One person had 30 years of industry experience working for a pharmaceutical company. One person had been –in academia. Some had worked for other Centers. So, we really look at where we're going, what type of expertise we're going to need, recruit for that expertise, and we have people who really want to come, and work for us.

I'm still on the line. I may have dropped off the picture. I can't tell.

Peter Lurie: Yeah, your picture is – No. You're off the picture now. In fact, are you still there? Oh, there we go. Do you want to just say a word so

we can make sure we hear you, Steve?

Dr. Steven Solomon: I should be back now.

Peter Lurie: You are. Okay. Super. So, let me ask a couple of budget-related questions. One of the attendees just asks that you, just for clarity, repeat the FY 2023 budget request, and the 2022 Omnibus budget as well. If you could just remind folks of what the magnitude of those was, and, while you're doing that, I'll ask you a related question, if you're able to answer it. I understand if you can't. You mentioned that you're in negotiation for ADUFA and AGDUFA as we speak. Is there much you can tell us about how that is going, or particular needs that you see arising in the context of that?

Dr. Steven Solomon: So, we had public meetings. We just actually had one last week, I think, or the week before, and the meeting minutes from each of the negotiations are posted. Beyond that, I'm really not at liberty to say much more about that. But, to answer the first part, for the 2023 request, the total request was $22.9 million. That was $10.1 million for data monitorization and enhanced technology. It was $5 million for premarket animal drug review workload. It is $0.8 million for the medical product supply chain, $0.7 million for reducing animal testing through alternative methods, $4.6 million for the New Era Smarter Food Safety on the root cause, and the traceability, and $1.8 million to cover the increase pay costs.

The 2022 Omnibus that we received was $6.2 million. That included $2.3 million for animal food safety oversight, $1 million for animal food ingredient review, $1.5 million for medical products supply chain, and $0.5 million for data monitorization, and enhanced technology, and $0.9 million to cover a portion of the payroll costs.

Kyle Kinner: Okay. Thanks.

Allison Phipps: Dr. Solomon, there is certainly a lot that the Center is working on right now, but if we're to look into the future, and thinking about what the next five years hold. Can you speak a little bit to Center for Veterinary Medicine's goal, and where you'd like to see the Center move over the next five years?

Dr. Steven Solomon: Thanks for the question, Allison. So, we're very active in the continued work on the antimicrobial resistance area. That work is going to continue, so I think it's an area of continued focus for us.

In order to fulfill our mission, the type of challenges we're getting are just increasing exponentially. Whether they are responding to an animal food outbreak, whether it's a new type of technology like intentional genetic alterations, or regenerative medicine activities, we're going to see more and more innovative products going out there. So, in order to meet our mission, we really need to focus on our human capital, getting some people.

These technology enhancements can really collect and analyze a vast amount of data that we need, and we need to work on strategies to address the various emerging issues. I wish I could say that the pandemic we're going through is the last one, but I can tell you that we need to invest to try to make sure that the next zoonotic disease outbreak doesn't become a pandemic.

On the animal food side, we really need spend more activities getting more oversight. My goal is, once again, to not see any animal die from animal food safety issues. So, we need to get that investment to look at pet food safety, and try to avoid pathogens in pet food, trying to enhance our mutual reliance with the states that I talked about, and our public health response.

We really need to invest in our post marketing surveillance on the drug side. The Center for Veterinary Medicine has the largest pharmaceutical vigilance database in the world. When a product is approved, that's not the end of the life cycle of the drug. The drug – It's exposed during clinical trials to a subset of animal populations, but we always learn more when it goes to larger populations. And we really – We get 100,000 adverse event reports every single year, and we haven't got the resources to look at them. We're only able to look at around 25% of those. We prioritize what we look at – that's some of the new products out there – but we really need to spend more time looking at all those products.

We need to do some more work on how we have oversight of industry. And the inspection process and the routine surveillance inspections are critical. Reauthorization of the ADUFA 5 and the AGDUFA 4 are critical next year for those activities. The animal food industry that I talked about is really undergoing significant innovations. Lots of new products coming down the line. We need to be prepared for those. So, there's a lot coming down the pike. A lot of innovation, both on the drug side, the animal food side of the house, and we need the investment in IT systems, the right people, to be prepared for those because the rate of what we're trying to

deal with is just increasing at a very rapid rate.

Peter Lurie: So, let me follow up on that, if I might. You mentioned innovation in the animal drug sphere, and without disclosing the contents of any application, what do you see as the most exciting areas of innovation in animal medicine? I'm especially interested in your examples of animal medicines that ultimately turned out to be useful in humans, even if some humans didn't understand the distinction completely. But I'm curious as to what kinds of resources you might need to stay on top of these innovations, and what you see them as being.

Dr. Steven Solomon: Right. Thank you. So, as you probably heard from my colleague, Peter Marks at the Center for Biologics, on the animal side, veterinary regenerative medicine is a really active area of research. Developing new cells, and new therapies – tissue therapies for animals. We call this area our Animal Cells Tissues, and Cell and Tissue-Based Products. We abbreviate that as ACTPs. They consist of animal stem cells, differentiated cells, and tissues such as blood, platelet, and plasma amnion. They're intended to be implanted, transplanted, infused, or transferred from a donor into an animal.

Sometimes they're the same animal/donor recipient. Sometimes, they're different species. We're making significant advances, but this is an area of really developing research and very innovative therapies. They hold great promise for future safe and effective treatment for many animal diseases. We do work closely with our human counterparts. But we need good, high-quality data from well-conducted, well-controlled, well-designed scientific studies.

Animal agriculture. We're working hard on intentional genetic alterations (ITAs) in animals. This is using molecular techniques. CRISPR is the most common one right now to introduce changes into the genome of the animal. They really provide great opportunities to foster risk-based, science-based programs to oversee this beneficial technology that can benefit human health, animal health, animal nutrition, and animal welfare.

Just a recent example, earlier in March, we made a low-risk determination for the marketing of two genome-edited beef cattle, and their offspring that are known as the PRLR Slick Cow. They were used – CRISPR technology, and they are animals that have extremely short, slick hair coats, and potentially able to better

withstand hot weather, which in kind of a climate change issue, animals that have less temperature related stress may result in better welfare conditions.

We've worked recently in improving intentional genetic alterations in a pig called the GalSafe pig. This pig had alterations to reduce alpha-gal sugars on it. This is valuable in two different areas. One would be the people that suffer from alpha-gal syndrome. They've been bitten by a certain type of tick – the Lonestar tick – and become allergic to red meat, and they can't eat it without having allergic reactions – some mild, some very significant. So, it serves as a dual source of the GalSafe pig for food source, but also as a potential source for xenotransplantation.

And you've probably recently read two different transplantations. There was a heart from a related pig, not the GalSafe pig, that was used for a patient in Baltimore, and a recent kidney transplant. So, the possibility for xenotransplantation is out there.

And we just approved – we think another really growing area is monoclonal antibodies, so we approved the drug Solensia just recently. The first treatments of the control of pain associated with osteoarthritis in cats. It's a cat-specific monoclonal antibody that recognizes impacts to nerve growth factor that's involved in regulation of pain. This is a current research area on veterinary medicine.

So, in these areas, we need the type of things I talked about before. We need investment in our research infrastructure. We need investment in our business processes and technology to support the review processes. And we've really tried to help these companies along by developing for the innovative products, what we call the Veterinary Innovation Program, or the VIP program. And that's recognizing that we're often dealing with people who are in academia or startups that really don't know the regulatory process. So, this program really helps hold their hands, and we have 46 products currently enrolled in that program.

And the last area is we're really trying to push out new guidance to help industry encourage sponsors to develop innovative **approaches**. So, we put out four final guidances on the use of biomarkers and surrogate endpoints, adaptive designs, real world data, and encouraging pathways for using foreign data. So, a lot of innovation going on. A lot of it related to the human side. We work

closely with our counterparts on the human side on those issues.

Allison Phipps: Perhaps, Kyle, I can ask one more question if you don't mind – of Dr. Solomon? I think, Kyle, you might be on mute, but I'm going to take that as a yes. Thank you.

Well, Dr. Solomon, you know, one of the areas that you had touched on earlier in your introduction was supply chain, and I was curious to know if there have been any challenges around supply chain, either with animal products, food, or drugs?

Dr. Steven Solomon: Thanks for that question. Yeah, we've really had significant challenges on supply chains. We typically have shortages of products, maybe a dozen per year. During the pandemic, we had well over 100. Lots of different reasons for it, including industry staffing and production issues, manufacturing challenges, raw ingredients shipments, manufacturing equipment, packaging, transportation, the whole worker shortages – all these issues across all areas.

So, we've seen a significant increase in the needs and the shortages that have taken place on supply chains. We've really worked hard with industry to try to mitigate those shortages to the extent we could. The more we know about those earlier rather than later really helps.

We're dealing with significant issues coming up on the animal food side of health. The animal food industry has been fairly resilient during the outbreak to be able to reformulate products for animal feed. But we're now seeing some real challenges, particularly with competition for issues. The fuel ethanol issues has had ripple effects.

We're now seeing, as we sort of have competing demands for green energy and biodiesel fuels, it's causing a diversion of fats and oils that are essential for animal foods going to biofuels. And we're very concerned, as the industry is, that it's gonna have a major impact on the animal food industry's ability to sustain and provide these products, and what the cost is gonna be. If you're a pet owner, you've probably been to the store and seen shortages of some of your favorite products or short supplies of them.

So, we really need to spend more time looking at these issues as they come forth. But we think they're gonna continue to do it –

even the issue of the Ukraine conflict, we expect if that continues, it's gonna have an effect on agricultural production, and production of wheat that could have an effect on both human, and animal use. So we're expecting supply chain issues to continue. And we have been impacted. One of the issues we suffer from at Center for Veterinary Medicine is some of our products, or some of our manufacturing equipment has been prioritized for production of COVID-19 vaccine, or other areas which causes challenges for the veterinary pharmaceutical side of the house.

Kyle Kinner: I think we have time for one more question. Peter, do you want to frame, possibly, the question in the Q&A?

Peter Lurie: Yeah, sure. I'd be happy to do that. I do have a question from one of the audience members, Steve, who just asks about the recently finalized compounding guidance, and he just wants to know – she – what activities are needed from the states or from DOJ to make appropriate enforcement of this kind successful.

Dr. Steven Solomon: Great question. We just did – Thank you for touching on that. So, we did just issue a compounding guidance – final guidance. It's been in the works for a long period of time. One of the aspects of it is there is a lot of misinformation that circulated at animal drug compounding. Unfortunately, there's not enough animal drugs for all the species I've talked about. Therefore, it's important that veterinarians have the ability to compound, but they need to do it in a way that doesn't undermine human and animal safety, or undermine the animal drug approval process, which demonstrates the safety and efficacy. These products are all unapproved animal drugs.

So we've built in a timeframe for education of folks on the compounding for the pharmacists, the compounding pharmacists for the veterinarians. And, so, we've delayed taking any inspectional activities to the beginning of next fiscal year to allow for that education period. We will be reaching out and doing a lot of education and outreach over the next several months. And we will engage the states, and others on that program.

Kyle Kinner: Dr. Solomon, thank you. I see we've come to the end of our time today, and I really want to express our appreciation on behalf of the Alliance for your giving us a full hour on, I'm sure, a busy day to talk with us about Center for Veterinary Medicine, and about your work. And, I really just want to express my appreciation, and

maybe Peter, or Allison, if there is anything you want to say?

Peter Lurie: Just appreciate your time, Steve, and your dedication. I'm just struck again by the huge breadth of stuff that you need to deal with, and really quite how fascinating it is. So, thanks for all of your efforts.

Dr. Steven Solomon: Thank you.

Allison Phipps: Certainly. I echo my colleagues, and just thank you for your time. It's been a pleasure talking with you today, and I hope that you have a nice weekend as well.

Dr. Steven Solomon: Thanks. I appreciate all of you, and the Alliance for giving me the time. It's important that we get the message out, so I appreciate the opportunity. Have a great weekend.

Kyle Kinner: Thank you so much. Have a great day.

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Duration: 60 minutes