

Kyle Kinner:

Thanks everyone for attending today's Food Safety and Animal Health webinar sponsored by the Alliance for A Stronger FDA. My name is Kyle Kinner. I coordinate government affairs for Pew Charitable Trusts and I am a member of the Alliance board. Let me briefly introduce our two moderators for this morning's conversation.

I am joined by my fellow Alliance board members, Alison Bodor, who is President and CEO of the American Frozen Food Institute, a respected trade association representing all segments of the frozen food and beverage industry, and also Thomas Gremillion, Director of Food Policy at the Consumer Federation of America where he oversees research, analysis, advocacy, and media outreach for the group's food policy activities. The event today is convened by the Alliance for a Stronger FDA.

The Alliance was founded in 2007 and has been a tireless advocate for the agency and its public health mission. The coalition now includes more than 160 members including patient groups, health professional societies, biomedical, consumer, public health, and pharmaceutical research advocates, individuals, trade associations, law and consulting firms, and companies – truly a diverse group of supporters of the Food and Drug Administration.

In addition to today's webinar for FDA's Food and Animal Health leadership team, just a plug that the Alliance will also host a July 14<sup>th</sup> webinar, planned with the Associate Commissioner for Regulatory Affairs, Judy McMeekin, and a July 22<sup>nd</sup> webinar with FDA's Center for Devices and Radiological Health Director, Jeff Shuren. So, to briefly introduce our panelists, we are very pleased and honored to have all three of our guests with us today.

Our first speaker is FDA's Deputy Commissioner for Food Policy and Response, Frank Yiannas. Deputy Commissioner Yiannas is responsible for a broad array of food safety priorities such as outbreak response, traceback investigations,

produce recall activities, and supply chain innovation. He most recently served as Vice President of Food Safety at Walmart.

Deputy Commissioner Yiannas will be followed by FDA's Center for Veterinary Medicine Director Steven Solomon, an accomplished veterinarian who leads the Center's work to regulate veterinary drugs and devices as well as animal feed and pet food programs. CVM conducts research to ensure the safety of animal drugs and feeds and products made from animals. Dr. Solomon, who we are very pleased to have with us today, served previously as the Associate Commissioner for Regulatory Affairs within FDA's Office of Regulatory Affairs.

And finally, we will hear from FDA's Center for Food Safety and Applied Nutrition Director Dr. Susan Mayne, who leads the Center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, cosmetics, and dietary supplements. Prior to joining FDA, Dr. Mayne was the Winslow Professor and Chair of the Department of Chronic Disease Epidemiology at the Yale School of Public Health and Associate Director of the Yale Cancer Center.

So, before I turn it over to Deputy Commissioner Yiannas, I would like to let our audience know that you can submit questions via the Q and A box at the bottom of your screen for use later in the program. We will try to get to as many questions as we can. We look forward to your lively and engaged feedback and I know we have a great audience this morning, and I think you all will have good questions for our esteemed panel. And we want to get to the question section as soon as we can.

So, our panelists have an all-too-brief opportunity for an introductory series of remarks at the beginning. And so, panelists, just letting you know, we will let you know when your introductory remark period is concluded. And with that, I will turn the virtual podium over to Deputy

Commissioner Yiannas, a friend and tireless advocate for modern- and prevention-focused food safety system. Deputy Commissioner, if you want to take it away, I really appreciate it.

Deputy Commissioner Yiannas:

Yes, well thank you very much, Kyle, for those kind introductions. And thanks everyone for joining us for what is an important conversation. We appreciate the role this Alliance has played in advocating for the agency. And at the end of the day, we realize that it is advocating on behalf of the American consumer. So, what I thought I would do is answer a couple of questions that you had, the first one being, “What are the important priorities that were put forth in the FY 22 President’s Budget related to food safety improvements?”

And then, specifically, I am going to answer them from the Office of Food Policy. The response perspective, you are going to hear from my colleagues on other points that they are emphasizing. But I thought I would begin by presenting a bit of a background. I think it is important to understand the “why” and the landscape that we are living in and operating under before we jump into the budget ask. And I do not think there is any question by those of you listening today that we understand the world is changing very rapidly.

If you have seen what we experienced with the pandemic and just life in general, I think many of us are saying, “We never imagined that we would see these types of changes in our lifetime.” I heard this quote recently that I think is worth repeating. It stated, “The pace of change has never been this fast, yet it will never be this slow again.” And this is true for food too, the conversation we are going to have today. The food system is changing very rapidly.

It has always been changing since the beginning of time because you have heard some people are rejecting that we are going to see more changes in food in the next 10 years than we have seen in the last 20 or 30. I believe that. Some people have

described it as being in a “food revolution.” I do not think that is exaggerating it. I do think we are undergoing a food revolution. As we speak, just pause to think about it. Foods are being reformulated at record paces.

We have new foods evolving and being produced such as cell-cultured food, plant-based foods, and gene-edited foods and crops. We have food systems changing and new production methods being realized, some of them very hopeful and optimistic in terms of leading to more sustainable agricultural practices. We have the food system becoming increasingly digitized. We knew our ability to detect contaminants – you are going to hear some of that both from myself and Dr. Mayne – is getting really good and that is a good thing.

We are strong advocates for better detection methods and improved public health surveillance. But there is a lot of change. And while we are grateful for the progress that they made over the last 10 years, specifically under the auspices of the Food Safety Modernization Act, modernization is not something that you can do just once a day. And so, we are committed to continued modernization. I think you are going to hear that theme today.

In terms of specifically the budget asked, we have actually said that the updated budget is broken down into three areas: 1.) Critical public health infrastructure, 2.) core FDA medical and food program activities, and 3.) public health issues in general. **[Audio cuts out] [00:06:30]**

Dr. Solomon:

Great. So, this is Steve Solomon. Good morning, everyone. Thanks for the invitation to meet with the Alliance today and discuss the Center for Veterinary Medicine’s budget and activities. I will take a slightly different approach on this. We are very excited about the CVM budget for FY 22. We have got an increased request of \$19.8 million. It is spread across five different initiatives that I will walk through.

And these are both our priorities for now, and I

hope you will appreciate they are investments that will be paying dividends in the future. So, the five areas we are going to talk about are the New Era of Smarter Food Safety, animal food safety oversight, medical product supply chains, data modernization and enhanced technology, and an Initiative for Pay Cost Increases. So, I am going to say a little bit more about each one. When Frank comes back, he is going to be talking more about New Era, so I do not want to repeat a lot of that.

But it is an important area that we are focused on, on, “How do we move in the future?” is along Frank’s comments about how fast everything is changing and the New Era for Smarter Food Safety’s importance. But we also recognize there is still a lot of Food Safety Modernization Act work that needs to be completed or bolstered, and particularly in the animal food space. So, let me switch over to animal food safety oversight, and we are requesting \$16.4 million for this.

I think this may be the biggest FSMA request in a while for a program area that has historically been underfunded is Animal Food Safety. Our request includes \$14.1 million going to the Office of Regulatory Affairs. That money is primarily to fund cooperative agreements with our states. And for those who are not familiar, under the animal food program, states do 80% of our animal food inspection work. And then we have \$2.3 million for CVM to oversee that Animal Food Safety work.

When I talk about animal food safety, I feel like I am often saying the same thing again and again. All animal food should be safe. We continue to see too many animals and people getting sick from pet food, too many livestock illnesses and deaths due to preventable errors. In 2019 – just to give some examples – 154 people in 34 states, including 27 children under five, got sick from handling pet treats contaminated with salmonella.

Just this year, we have had over 130 pet deaths and hundreds of pet illnesses due to pet foods

contaminated with oxytocin. Getting the formulation to controlled contaminants correct is critical to cause complete diet formulations, often the only things animals are eating. That is their sole diet. They do not eat the varied diet that we do. And so, when things go wrong with an animal food diet, they often go wrong in a big way.

So, with this funding, we will continue to address contaminants such as pathogens in pet food and repeating illnesses such as overdoses of vitamins or mineral imbalances. I have been with the agency for over 31 years and two areas where I think the American public cares the most are always issues dealing in children and pets. And this investment supports what people really care about in those two areas.

We will also be using this increase to expand our efforts to modernize, harmonize, and transform the US animal food safety system into one that is comprehensive and prevention-oriented. We at CVM recently released our new comprehensive animal food compliance program. We designed this comprehensive inspectional approach that bases our animal food facility inspections on risk and public health impact.

It also consolidates all requirements that apply to a specific facility into a single FDA or state inspection, rather than the previous practice which was visiting the site multiple times to address one requirement at a time versus looking at all hazards when you go into the facility at one time. Switching over to the medical product side of the house, we have a request for medical supply chain issues of \$2.3 million.

A lot of this request comes from our lessons learned during COVID-19 and the adaptations that we have had to make to continue to ensure the supply chain for animal drugs. For example, making sure that we continue to have antimicrobials to treat infections and maintenance drugs that animals need to treat chronic conditions. Sponsors of human drugs have the requirement to alert FDA about potential drug

shortages. Animal drug sponsors don't. This is a huge gap.

And in an attempt to close that gap, we have provided ways that the animal drug industry could voluntarily advise us of potential shortages or supply chain disruptions. During the first year of COVID, we received three times more the potential animal drug shortage reports than we typically do, however we worked closely with industry. We were able to avert 86% of these animal drug shortages reported to us.

Our budget request will continue strengthening our capacity to detect data gaps and mine data to help identify, anticipate, and mitigate the effects of any public health emergency on the animal drug supply. Emerging diseases shifting trends in the marketplace also result in vulnerabilities for unapproved, fraudulent products. The lesson learned is that when people are anxious, as they are during COVID, they often will turn to animal drugs, even when the risks are high and the data is sparse, as we have seen with ivermectin and chloroquine.

And there are always unscrupulous actors out there that are waiting to prey on an unsuspecting public with fraudulent products. At best, these products might take your money. But at worst, the impact is far greater. The increased request will help CVM continue to monitor the product for more fraudulent and harmful products and protect both humans and animals.

A third use of this request also stems from COVID when you talk about how we prioritize inspections and how we are going to anticipate catching-up and doing those inspections and using a risk-based approach. The next budget area is one that I know the Alliance has been very engaged in, and that is data modernization and enhanced technology. We are pleased to be part of the Agency's data-wide enterprise data modernization effort with a targeted increase of \$10.7 million for CVM.

We spent the past year doing an assessment of all

CVM's business processes and IT systems that supports our critical mission sanctions like our premarket animal drug review, our post-market monitoring activities, and our regulatory science. Unfortunately, we found out the Center is increasingly falling behind in the way we engage with drug sponsors, veterinarians, animal producers, consumers, and other stakeholders in the digital world. And we need a comprehensive digital transformation.

This request will help modernize our outdated and disparate IT systems and business processes to increase efficiency and effectiveness, reduce overall cost, and provide the flexibility needed to meet the challenges of evolving regulatory landscape. It is closely aligned with the agency's data modernization and technology modernization action plans that I know you have been hearing about.

We want to increase CVM's ability to keep pace with advances in bioanalytical evaluation with humans and animal food contaminants and advances in DNA sequencing and editing, as Frank talked about when we were talking about biotechnology. The last area I just want to highlight is "Initiative for Pay Cost Increases." What we are really trying to address here is the significant impact of budget erosion in our ability to carry out the mission.

At present, seeking a pay raise of 2.7% for federal employees, FDA's request to Congress includes approximately half of what is needed to cover the increase. This funding is critical to avoid continued program erosion as has happened over time. In programs, funding remains flat, but the cost of payroll increases. We must either reduce the number of staff or reduced the programmatic efforts that allow us to carry out this mission.

Over the past 10 years, CVM has had to absorb \$26 million in budget authority to cover these rising payroll costs, and they impact our ability to regulate the animal food supply and veterinary medicine products available in the country. So, let me stop



there. Let me turn it over to Dr. Mayne.

Dr. Mayne: Alright, thank you. Can everybody hear me okay?

Alison Bodor: Yes, thank you, Susan.

Dr. Mayne: Alright, thank you. So, good morning, everyone. I join Frank and Steve in sharing my appreciation to the Alliance's really important support of our work. And I am really grateful to have this opportunity to share my priorities for the Center for Food Safety and Applied Nutrition as outlined in our FY 22 budget request. To provide some more context, I will walk you through the questions you had for me, starting first with what I see as the most important priority for CFSAN in the FY 22 President's Budget.

A more than \$55 million increase included for CFSAN, it is the Center's largest request ever. And as I will share with you, these areas would help ensure our programs across the board are keeping pace with the tremendous change and innovation currently occurring in food system as you heard Frank speak about. As the only FDA center without significant user fees and whose work is primarily focused in the post-market space, it is doubly important that we use the budget process to resource our programs.

I have served as CFSAN director for almost seven years after spending almost 30 years in public health work, and I can assure you that the areas we have identified are areas where there is great need and also great passion for the new work we would like to accomplish with new resources. Specifically, the Center is requesting funds that would allow us to make targeted investments in two overarching areas, \$18 million focused on maternal and infant health and nutrition, and \$19.5 million to address emerging chemical and toxicological issues.

We also have requested \$8.6 million in resources under the New Era of Smarter Food Safety. And Frank will cover those when we get his audio back on. So, let me first talk about our maternal and

infant health and nutrition proposal. This is a body of work I am particularly engaged in as is our Acting Commissioner. This request bridges food safety and nutrition, and it will allow us to support healthy eating patterns while also mitigating exposure to naturally occurring toxic elements like lead and arsenic.

Also, within this bucket, the Infant Formula Review request is a prime example. There, with just a small infusion of resources, we will be able to help protect our youngest and most vulnerable consumers while supporting industry innovations in infant formula. Approximately 75% of infants in the US receive infant formula or other non-breastmilk nutrition by six months of age.

The additional \$1.1 million requested will allow us to hire four new reviewers to add to the existing team of nine staff members and expand our capacity to review the increasing number and complexity of infant formula submissions. So far this year, we are on track to double the submissions we received in 2020.

The second category that we have highlighted in our request, “Emerging Chemical and Toxicological Issues,” will provide increases for several areas: food additives and substances added to food, chemicals used in food contact which include PFAS and other contaminants more broadly, allergens, dietary supplements, and cosmetics. All of these issues continue to receive major attention as new potential health concerns emerge.

They share a critical need for resources to modernize and streamline regulatory frameworks for products or ingredients that, in certain cases, can pose potential chronic risk to human health. But these have not benefited from the FSMA budget increases. So, the resources requested in this budget are a meaningful step forward in catching up some of these most under-resourced programs in CFSAN. We are already making progress in this area as evidenced by our work to remove certain PFAS used in food contact.

But frankly, we need additional resources to conduct similar evaluations for many of the thousands of other chemicals present in the food supply. As we have seen with PFAS, sometimes new data become available that require FDA to reconsider previous safety designations. Ensuring the continued safety of foods requires that we prioritize our post-market efforts. For this, we have requested the largest amount in this category, \$8.3 million, to support work to assess safety of food additives and chemicals.

New resources will allow us to acquire new tools so that we can leverage new and evolving data sources that support premarket safety evaluations and help us prioritize our post-market safety review efforts in a science-based, systematic way that will focus on the substances that have the greatest potential for public health impact. We need to use science to be more proactive than reactive.

Recognizing the need already, we have been developing something called the Expanded Decision Tree, which is a tool for screening chemicals based on the latest toxicology data and risk. To date, we have curated safety data on over 1,900 chemicals to build the Decision Tree, but we need more resources to make it a fully functional tool. One of your questions was, “How do these requests in FY22 compare to our long-term priorities?”

This work to more systematically help us prioritize our post-market safety reviews based on risk is a good example of how we see these resources requested in these categories being a down payment on funding needs that are likely to continue. Another question you asked about was CFSAN’s role in nutrition and our key priorities there. As some of you know, my academic background is in nutritional sciences, and the science supports that investments to improve nutrition can have profound and enduring public health benefits.

As mentioned earlier, the maternal and infant health

and nutrition request includes resources to develop educational materials for consumers and public health professionals on the risks from toxic elements in foods. And it would provide for us to partner with others in HHS and USDA to explore opportunities to emphasize the new dietary guidelines aimed at caregivers of infants from birth to 24 months, including the importance of eating a diverse diet while reducing exposure to toxic elements.

I am also deeply committed to advancing our initiatives under the Nutrition Innovation Strategy or NIS. We launched NIS a little over three years ago with the goal of using our tools and our authorities to help reduce the burden of nutrition-related chronic disease. Among our NIS accomplishments, we launched a comprehensive education campaign on the updated nutrition facts label.

The pandemic has only highlighted the need to address diet-related chronic diseases and work towards ensuring healthy food options are available for all Americans. We have a lot of exciting nutrition work lined up this year, including the “healthy” proposed rule, more on standards of identity and product naming, and taking further steps to address sodium based upon the National Academies’ DRI report. I will wrap up just briefly covering our food safety requests under New Era.

I was asked specifically about the data modernization request, so I will focus on the needs we identified there. We have requested \$7.3 million as part of the data modernization initiative. This request compliments our New Era request and will enable the Center to leverage new and emerging technologies and data-driven approaches to strengthen our predictive capabilities, accelerate prevention, and speed traceback. A key element of the request is focused on tech-enabled traceability.

This will help us enhance preparations for implementation of the FSMA Food Traceability final rule to be issued in late 2022. It will also help

us meet the FSMA requirements to enhance IT systems to receive traceback data directly from stakeholders in certain situations. Investments in data and analytics will help position the FDA and the foods program for a more modern and efficient regulatory system for the future. These are some highlights of our FY22 requests, and I look forward to taking your questions.

So, thank you to Tom and Alison and I will turn it back to you.

Alison Bodor:

Thank you, Susan. Frank, do you want to continue where you left off? You left off talking. You had mentioned all the different changes in our food system and talking about under FSMA being under continual change also.

Deputy Commissioner Yiannas:

Great. Let me make sure – do a sound check. Can you hear me fine?

Alison Bodor:

Yes.

Deputy Commissioner Yiannas:

Awesome, okay. Not sure what happened, but nevertheless, happy to reconnect. So, hopefully, you have heard from my colleagues, and they persuaded you that there is a lot of change happening, and we just have to keep up with the rate of change that is happening in the marketplace and the food system in general. If you look at the specific asks set forth under the New Era, it is \$45 million in particular. And it is broken down into the four core elements outlined in our blueprint. I think by now, people are familiar, “The New Era of Smarter Food Safety.”

Again, let me emphasize what we have tried to do is paint a vision on how FDA wants to modernize for the next 10 years. So, it the long view. We know that, to go to Congressional leaders and ask for funding, they expect us to have a long-term view or plan, and it is not really wise for us to come back every year with a cafeteria approach of funding. So, we do have a long-term view of how we want to modernize.

Of the \$45 million under the New Era, I will tell you that about half of that is coming from the data modernization of the technology portion of the budget. You have heard that from previous speakers. Over half of it is about tech-enabled food safety. You will hear me speak that it is not really about the technology. I want to share it is not just about updated systems. It is more importantly how we are going to use that technology to solve some of the public health challenges.

But the way the \$45 million is broken down is about \$6.1 million of that will go to tech-enabled traceability. Many of you know that I believe that a lack of traceability is an Achilles' heel in today's food system. I have seen that my entire 30-year career in the private sector. Most of the big incidents, whether you think of the PCA, or whether you think of it as romaine lettuce, or whether you think about some of these imported works, we just do not have enough transparency and visibility into food system. And this is absolutely sorely needed.

Traceability, to me, is not a reactive tool, since we are trying to respond to health risks quicker and shorten epidemic curves. But it is about providing a new level of transparency in the food system that can be a game changer in terms of influencing behaviors and understanding how changes need to be made to strengthen prevention. You know we have issued a proposed tech-traceability rule, which was part of FSMA last year, but there is still work to be done. And CFSAN will be doing a lot of work with finalizing the food traceability rule.

We will have to do a lot of outreach, education, and training. And just like we have always stated, we want to educate before and while we regulate. We also want to develop technology platforms to receive that traceability data. We have already started working on a prototype.

If I were to demo it for you, you would be really impressed on how it is able to receive traceability data in digital form, how we can really accelerate connections on tracebacks, have computing power

tell us which traceability links have more statistical power, and legally we can accelerate that so that can happen in days and not weeks, which is usually the case. The second area is “Smarter Improvement Approaches to Prevention.” I believe that we are on the cusp of adding new tools to our toolbox in how we are receiving safely.

It is not simply inspections, not simply training and testing. One of the things we want to do is continue our work on predictive analytics. Again, it is not about machine learning or AI. It is about us further strengthening our ability to predict which foods might be violative or worse to the American consumer. So, we launched a pilot, as may of you know, using AI on the PREDICT System for safety imports, but we want to expand this to, basically, all areas of how we do food safety. Strengthening predictive analytics is good for not only imports.

It is good for helping us prioritize inspections. It is good for helping us determine what samples we might want to take. And so, we really are excited about the progress of predictive analytics, we think, like AI and machine learning. Under “Smarter Tools and Approaches,” we want to strengthen root cause analysis. We really formalized this and shared these approaches with the states so that we could deplore them in a rapid fashion.

The reality, root cause analysis is a fundamental scientific trend that is in a lot of disciplines, if we think about the airline industry, if we think about hospitals. Meanwhile, we think that the food industry is supportive of root cause analysis. If you ask food safety professionals both inside and outside government, they will define root cause analysis very differently. And so, the Agency wants to play a leadership role in really formalizing the root cause in food and food safety in general.

And we also want to just work on inspection modernization. You are going to hear a little bit more about that from Judy McMeekin, but the reality is, we believe that we are living in a new day of data. And with better data, we can further

modernize how we deal with an inspection or compliance oversight. Let me be clear. This is not about doing less inspections. I think, if anything, everyone on this call would say, “We want to do more inspections.”

But it is about using the right data insights, identifying the right attributes of the establishments that we regulate so that we can do a better job overseeing health and safety for ones regulated by FDA. The third area is what we call “New Business Model: The Retail Modernization.” Really quickly, before the pandemic many of you know that it was projected that about one out of every \$5.00 spent on food was spent on an online platform. The pandemic really changed and caused people to stay at home and start ordering online.

So, those statistics have been blown clearly out of the water. And you might ask yourself, “What does the e-commerce business model have to do with food safety?” I will give you a pop quiz and say, “What do you think are the top three things that are changing, again, food safety due to ecommerce?” There are more than three, but number one is the world is becoming the grocery store. You no longer have to rely on brick and mortar where you walk into an establishment and find maybe 50,000 foods.

Consumers will increasingly be able to go online, order what they want from anywhere in the world. And so, huge proliferation will happen after we get through this economic hardship. Think about how you communicate with customers. They are no longer going into a store and talking with someone. There is a lot of work that we want to do that we want to hold a business model – e-business model – summit.

I request more information that we could work with both the private sector and our state departments to make sure we are identifying what are the food safety challenges, identifying the appropriate standards of care, and making sure we create a regulatory framework to deal with the way the food system is changing. And then the last one I will



mention really briefly. We have a little bit of money dedicated to "Food Safety Culture." Some of you know that I have been an advocate for this idea my entire career.

I have said that a Food Safety Culture is a prerequisite for effective food safety management systems. Rules and regulations are critical but getting people to actually put them in practice is what matters most. And so, we really want to start leveraging proven behavioral science principles, concepts of organizational culture – which is a science in itself – blending them with food science so that the FDA's food safety programs can be more effective.

And so, we have planned to do a broad, wide literature search, bring in experts that are not food safety or food science experts to work with us, and we have even identified to hear more from Judy in ORA the need to do training of our original staff and maybe make such training available to regulators across the country. The second question that I asked is, "Well, tell us about FSMA and what has FSMA achieved." And I would tell you it is a great question.

I would say it has been 10 years. FSMA was a monumental undertaking in seeing what we have done in terms of the preventive control and the foundational rulings such as PC for animal food and human foods. The best way I can answer, "What has FSMA done for the US food system?" is number one, growers.

Remember there was a day when we were not too focused on produce and farms, but we know from attribution what important part it plays in foodborne disease, while clearly really important for healthy products. We helped growers and processors of all types, both in the U.S. and abroad, importers that are bringing foods from other countries and serving them to the consumers in the United States, transporters. We are all taking concrete steps every day to minimize the risk of contamination and make sure that foods are safe.

That is a big accomplishment. That happened because of FSMA. Another way I like to answer it: well, because of FSMA, we are having a bigger conversation about food safety in general. That conversation, as we know, started in halls of Congress 10 years ago with bipartisan support. It then traveled to farms – conversations about farms that were not had in the past, happening at food processing plants around the world.

I can tell you from experience, it is happening in corporate boardrooms, something I did not see in the first 25 years in my career. And so, FSMA has really raised awareness of food safety. And I would say, bottom line is, there is no question I think you will agree, FSMA has resulted in safer food for the consumer. There is no question. I do not think we can argue that. Now, some of you might say, “Well, Frank, if you look at foodborne diseases, it is pretty much solved, and funding is getting better.”

I think we all understand that better detection is at play here and playing a role and as I stated earlier, we are strong proponents of better detection, and we will not use that as a crutch. But when we speak about a New Era of Smarter Food Safety, it is just an idea that just like we have used new, innovative technologies to get better at detecting foodborne illness – and that is wonderful, and we have been leaders in that space – we have to use the same type of innovate, creative, and technological approach to prevent foodborne illness.

And this is a bit of this dynamic race as far as our ability to detect and prevent foodborne disease. And so, I wanted to answer that question in terms of what has been achieved. And then the very last question that you had for me is this question about New Era Smarter Food Safety Initiative and, really, “What would be the role of technology?” Let me round up here so we can close and take additional questions.

But let me be clear, because, quite frankly, I get a little frustrated when I hear people just talk about,

"We need to make investments in technology platforms." It is never about platforms. You should always insist, "FDA, what is the public health challenge you are trying to solve? And if you get the funding, show us how it has improved processes in improving public health outcomes." But I will give you just a few examples.

When we talk about distributive ledger technology or blockchain, it is not about blockchain, but it is the idea that we have a very decentralized and distributed food system. And investing in technology such as the distributed ledger technology where everyone does not have to get into a centralized database – they can get into different distributive databases and share information in a trusted and a democratic way – that is good for the US food system.

And it will allow us to track and trace foods really quickly, in seconds as opposed to days. When we talk about machine learning or AI, it is not about machine learning or AI. But would it not be good if the FDA had a tool that could tell our inspectors or our staff and say, "Listen, of the tens of millions of food shipments or containers that are coming across the border every year, these are the ones that you should really focus on." That is an example of how we envision using technology.

Here is another one. In the 20th century, we called that an "Industrial Age." We are in the 21st Century. People are calling it the "digital age."

I envision 50 years from now – you might think, "Frank, honestly, you are a blue sky" – but I envision 50 years from now, the paradigm on compliance changes dramatically. It is no longer about writing rules for establishments and then periodically doing a check, but it is about real-time monitoring because foods and establishments are digital assets that you can do. Think about your vehicle and the way maintenance on your vehicle has changed dramatically. You no longer have to mark it on your calendar.

And so, we are excited. We have to modernize. We have learned through the pandemic that food security is national security. And we thank you for your support. We appreciate it.

Alison Bodor:

Thank you, Frank. And thank you, Susan. And thank you, Steve. I have a question now for all of you, and I think you guys can answer it in turn or you can answer it together with some dialogue. But what lessons has the Food Program learned from COVID-19? And what impact do you see that having on your work moving forward?

Deputy Commissioner Yiannas:

Well, I can start. And I will try to be succinct then. Alison, great question. It has been really a learning experience. Some of us have had the unfortunate experience of dealing with crises before, whether they be earthquakes, tsunamis, tornados. But this one was different in that it was long and just never let up. I like to say, "The US food system has just experience the biggest test on the food system in 100 years." And we passed the test. Now granted, we did not pass it with flying colors.

We all know that early on in the pandemic, there were supply chain destructions, there was some food outages in the center of the store items. And so, we learned a lot about the supply chains. I would say, a couple of really clear lessons learned. 1.) private-public collaboration needs to approach a new level. In the early days of the pandemic, I will tell you, the Agency learned a lot about what was happening in food in private-public collaboration. And it was not just getting in a room and talking like we have done in FSMA.

But we were sharing data and information and necessary. And so, private-public collaboration is critical, certainly in normal times, but in times of crisis, and it has to increasingly involve data sharing. Number two, I would say that today's food system is really marvelous. It is very interconnected, interdependent. And while that leads to a lot of efficiencies such as just-in-time inventory and getting special products, but it has some vulnerabilities. And we learned that through

the pandemic.

And so, I believe that we have to continue to digitize the food system, understanding interdependencies and interconnections. One of the things we did early in the pandemic, we made a bet, and we developed a technology platform called “21 FORWARD.” I cannot imagine going through the pandemic without that platform. But to manage the pandemic, we needed better data and insights.

And so, I think you are going to hear a lot more, Alison, over the next couple of years – certainly even most recently with the cyber-attack on meat producers – on supply chain resilience and the need to modernize and digitize. And then the last thing I would say is we have the strategy to create an interoperable food system. Early on the pandemic, when we had to close restaurants and institutions and theme parks, etc., what we had was we did not have a lack of food, we just had food in the wrong places. We had supply chain logistical issues.

And there were rules that prevented us from moving food that was perfectly safe and nutritional and wholesome from certain types of foodservice establishments to retail. And so, this concept of having an interoperable food system is one that I learned. And then I am sure you are going to hear from some of my colleagues on the need for further strengthening and collaboration at the federal level and state level. But with that, I will let some of my colleagues weigh in on that question. It is a very good one.

Dr. Mayne:

And I can add a few things on top of what Frank highlighted, all of which impacted CFSAN. How consumers are now purchasing their food post-pandemic – you heard about supply chain disruptions. I am going to speak about that briefly. And another one is the concerning health outcomes associated with those who have poor nutrition – obesity, nutrition-related chronic diseases – after getting infected with SARS-CoV-2.

So, first was on the issue of needing to shift food

from where it was originally in the restaurants and large food service operations. That had to pivot very quickly to help get that food to consumers. FDA had an important role to play here because of many of the regulatory requirements around labeling. And of course, there were numerous logistical issues as well. So, FDA and USDA as well had to issue labeling flexibility guidance to allow that food to be shifted.

And the tremendous shift to online purchasing of food is something of great interest for our labeling work moving forward because we all know that that shift is not going to go away post-pandemic. Next, you heard about supply chain disruptions. One of the things that it caused us to really think about is the importance if there were potential disruptions of foods of critical nutritional value, like infant formula, which is the sole source of nutrition for many infants. So, things to consider there.

And lastly, again, I highlighted the importance of better nutrition given the increased risk for severe symptoms and death from COVID-19 from folks who have obesity or nutrition-related chronic disease. The virus also further shined light on the stark manifestations of health inequities among racial and ethnic minority groups. So, we have been making steady progress on implementing our nutrition innovation strategy.

And we are very much looking forward to ways to further address the issues that the pandemic has revealed and, in many cases, exacerbated it.

Dr. Solomon:

Let me just add on – so, many of the same challenges that Frank and Susan talked about on the human side were also on the animal side. So, one of the main examples might be just the understanding of the interconnection between the human food supply and the animal food supply or the impact of other aspects of supply chain. So, when we found out that people were not driving as much, it stopped ethanol production.

Well, coming out of ethanol production is a product

called “dried distiller grains” which is an important component of animal food. And so, animal feed manufacturers had to reformulate their products without this dried distiller grains, and the animal food sector showed tremendous resilience going throughout the pandemic. While there may have been shortages of specific products at various times, they showed tremendous ability to adjust to the situation and adjust the supply chains over time.

Let me switch, though, a little bit, since CVM talks not only just about food side and the drug side, and talk to you a little bit about one of the lessons learned about the relationship between the COVID-19 and One Health. For those of you who are not familiar with the concept, the concept of One Health is that human health, animal health, and environmental health are all linked. And COVID-19 was clearly a very pointed lesson in that as a zoonotic disease.

We participated in a federal One Health interagency group with CDC who leads this with, I think, 22 other agencies – the Agriculture and Interior and Homeland Security and Defense and Commerce and many others. And this network focused their attention on COVID-19. And while, obviously, much of the attention was on the human side, there was also impact from the animal side of the house. So, there were hundreds of reports of positive-COVID animals that sort of mimicked the evolution of the pandemic.

As we started seeing various variants happen in the human side, we also started seeing those variants on the animal side of the house. So, there were over 215 animals that had been diagnosed in the US, plus there were a number of mink farms. Mink seem to be a species that are very susceptible to COVID-19. We also needed to make sure, like we did on the human side, to monitor animal diagnostics and testing from outbreak response activities and investigations and work on issues like wildlife markets.

Within FDA, we focused a lot of attention on One

Health. And it is really gaining momentum within FDA. We are trying to build a One Health center for excellence in the FDA. We see some support for this in what some of the COVID supplemental funding, particularly for our Veterinary Laboratory Response Network, which we call the “Vet-LIRN network.” This is 46 veterinary diagnostic labs around the country.

And their critical role was not only doing animal testing, but they were able to pick up when there was a shortage of human testing for COVID-19. This group was able to get their certification through some of the work that CVM did in order to be able to continue testing out there. So, I think one of the real lessons to me was COVID showed me the importance of taking a One Health approach to solving really challenging public health problems. Like, this pandemic was getting us ready for the next pandemic.

So, we are really trying to really work within here at the lesson for the One Health Center for Excellence as an initiative within FDA that we are going to need sustained funding for it to be able to keep us prepared for not only a pandemic, but other public health emergencies. Let me stop there.

Tom Gremillion:

Okay. Thank you, Dr. Solomon. Yes, that is a great place to stop. And we wanted to have a chance to get to some of our Alliance member and audience questions. And so, I will start off with one. Dr. Solomon, you mentioned 80%, I believe, of funding for inspections going to the states. I wanted to ask Dr. Mayne – states also do extensive work in produce safety and retail. How does the budget request that you all have been discussing relate to supporting states to do the critical inspection work that you are engaged in?

Dr. Mayne:

And it is beyond inspection work. I mean, the states are critical regulatory partners across the board on so many of our issues. And I will give you one that is directly related to one of our resource requests, and that is the work that the federal and the states are doing together with regard to environmental



contamination with PFAS.

And so, our budget request does include \$3.5 million for new resources to help build our capacity to address many of the concerns, better understand the risks, determine appropriate next steps, and communicate with the public. So, let me give you an example of where we have been doing this right now. We have been supporting one state in the sampling of foods from a contaminated area over the past two years. We have been analyzing many samples, averaging just under one time per month, as well as providing a lot of technical assistance.

Most states do not have the capability to test for PFAS at this time. So, with new resources, that will help us continue to provide support to our state regulatory partners to make sure we can provide that science-based assistance as they are working to ensure the safety of foods produced in proximity to these local contamination sites.

So, we think there is a really critical role for states in helping us monitor and address issues involving chemical contaminants, like PFAS, like the toxic element work in the food supply. And our FY22 requests will help support this really important partnership with our states.

Alison Bodor:

Thank you, Susan. And I have got a question here that I think, Frank, I am going to pose to you because of your role in COVID and working in some of the interagency processes. What did FDA learn about working with other agencies such as CDC and OSHA during the COVID-19 pandemic?

Deputy Commissioner Yiannas:

Well, we learned a lot. We learned that it was critical. At the height of the pandemic, we were saying it was an all-in government response. And so, one of the things we learned, quite frankly, was at times it did not matter that you followed traditional roles and responsibilities.

I think if you look back at the pandemic, you might, say, "FDA really tested the limits with its authority, putting out documents that seemed to be

Occupational Safety and Health-related,” because we learned early on that worker safety and supply chain continuity were two sides of the same coin. So, constant communication was needed. Granted, Alison, I would say there was some additional opportunity there with closer communication at the federal level.

I would also say that we learned that one of the real opportunities is communicating at the state and local level. The reality is the US food system is regulated by the states and the feds. It is really fragmented. And it was challenging to get harmonized messages out to every single state, every single local health department. And so, those were the challenges, and we learned. And we also learned that we have to take a new look at how we communicate.

I think the industry in general was probably bombarded with a tsunami of information – too much information, sometimes guidance changed, and we got feedback, “We cannot keep up with it all.” And so, hopefully, if something like this happens again – which I hope it does not – we have learned our lesson that we might streamline communication in terms of how we get that message out to regulators. There was a ton of lessons learned.

I will tell you that there have been action plans here to take those lessons learned and try to memorialize them, so we do not have experience them again. But there has been quite a few. The other thing is, I had mentioned it earlier – food security is national security. We really, really need to step up as a country and develop these supply chain continuity and resilience plans. We really need to do that.

Dr. Solomon:

I guess, just a quick note to build on Frank’s – one of the foundations of the One Health approach is it is a collaboration across disciplines. And so, just the example that the One Health federal agency group I talked about, 22 different agencies working across to try and address some of the COVID issues on the animal side of the houses – just one of the

real lessons learned, and it is the foundation of the One Health approach. Thanks.

Kyle Kinner:

Thanks, Dr. Solomon. I think we have may be time for one more question. There have been a couple questions about sodium. Dr. Mayne, you might want to address, in particular, the guidelines and the timelines for those and the extent to which FDA is coordinating with USDA's Food and Nutrition Service on sodium standards in school food programs. You could talk about that.

Dr. Mayne:

Okay. So, the question on sodium, asking for clarity on timelines, like when we are going to finalize them – we, unfortunately, are not able to provide any precision on timelines for any of our actions and that is because many of those timelines are not even within the Agency's control. So, the details on what that is going to look like, I obviously cannot get into. But what I can say is it remains a top priority for FDA under our Nutrition Innovation Strategy, so that is a piece of it.

How we coordinate with USDA – we coordinate with USDA on so many different issues, including nutrition issues. And so, we are in regular communication with USDA in different parts of USDA – the Food Nutrition Service, AMS, FSIS, and ARS. We work with so many different faces of USDA. So, we are in regular communication on those issues.

Alison Bodor:

Here is one more and this is for you, Dr. Mayne. Can the FDA make available the Expanded Decision Tree for new chemicals?

Dr. Mayne:

Yes. So, we are developing this right now. And we have presented the concept and where we are at several scientific meetings. We are also preparing a manuscript for a peer-reviewed publication that will continue to communicate to the world where we are on the Expanded Decision Tree. So, we have made some significant process. It is building on the Cramer Decision Tree that people may be familiar with in toxicology. But as we continue to evolve this, we do need resources.

And that is part of our chemical ask is to really build out the Decision Tree, get it to a point where we can use it more nimbly, where others could use it more nimbly. That is part of our chemicals resource request. So, yes, we are committed to transparency as we are continuing to develop this Expanded Decision Tree.

Tom Gremillion:

Okay. Well, I think with that, we have reached our time. I want to thank our speakers from FDA – Deputy Commissioner Yiannas, Dr. Solomon, Dr. Mayne – and remind everyone to be on the lookout for the July 14<sup>th</sup> event that the Alliance for a Stronger FDA will be holding with Judy McMeekin, Associate Commissioner for Regulatory Affairs. Thank you all for attending.

Dr. Mayne:

All right, thanks, everybody.

Dr. Solomon:

Thank you all.

Alison Bodor:

Thank you all.

**[End of Audio]**

**Duration: 58 minutes**