Kyle Kinner: Good morning, everyone. We're going to wait just a minute to make sure everyone's had an opportunity to join the call. And then, I'll kick us off.

All right. Let's get started, if that's all right.

Good morning. I am Kyle Kinner, an Alliance board member and Senior Government Relations Officer at The Pew Charitable Trusts, an organization which uses evidence-based, nonpartisan analysis to solve today's challenges. In that role, I work on a variety of nutrition, food safety, and other FDA regulatory issues.

I am pleased to say I am joined today by Alison Bodor, who is also an Alliance board member and serves as President and Chief Executive Officer of the American Frozen Food Institute, a member-driven national trade association that represents the frozen food and beverage industry. In her role at AFFI, Ms. Bodor leads efforts to advance food safety and other aspects of the frozen food industry's public agenda.

We would also like to welcome Alliance members, the media, and Alliance guests to our webinar with Dr. Susan Mayne, who is the Directors of FDA's Center for Food Safety and Applied Nutrition or CFSAM.

First, a quick word about the Alliance for a Stronger FDA. We are a multi-stakeholder coalition that advocates for increased appropriated resources for the FDA. We have been an important force in the doubling of the FDA's budget authority funding from $1.6 billion to $3.3 billion in recent years.

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 the FDA's mission. Our members include consumer and patient groups, research advocates, health professional societies, trade groups and industry. We have about 150 members, and we welcome new members to join us and further strengthen our advocacy and educational efforts.

For this webinar, Dr. Mayne 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 the Q&A button at the bottom of your screen. And that is not the chat box. It's the Q&A button.

As part of the first section of our program, the self-interview questions, Dr. Mayne will discuss the Politico article that appeared this weekend that focused on the FDA's food and nutrition responsibilities. And now before introducing Dr. Mayne, we would like to thank her staff, especially Natalie Hageman, who has collaborated closely with us in preparing this webinar.

I have the privilege now of introducing our esteemed speaker for today's webinar: Dr. Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition. Dr. Mayne leads the Center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, color additives, and cosmetics. CFSAN's responsibilities also include fostering the development of healthier foods and ensuring that consumers have access to accurate and useful information to make healthy food choices.

As an internationally recognized public health leader and scientist, Dr. Mayne received a BA in Chemistry from the University of Colorado. She earned her Ph.D. in Nutritional Sciences with minors in Biochemistry and Toxicology from Cornell. She came to FDA in 2015 from Yale University, where she 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.

Dr. Mayne, thank you so much for your long-standing commitment to advancing food safety and improved nutrition policies and for agreeing to spend some time with us today. The floor is yours.

Dr. Mayne: Great. Thank you so much, Kyle, and good morning, everyone. I would like to start by just saying how grateful I am for the Alliance's support throughout the years. You've all been key partners in advancing our Center's programs, and I appreciate all that you do to champion our agency.

And so, I do have four questions that I've been asked to respond to, and I will provide responses to those first. And then, I will address some comments about the Politico article. So, the four questions I've been asked, I will read to you, and then I'll dive right in on some of my responses.

The first question is: The FY23 President's Budget was just unveiled. Can you talk a bit about your priorities for the upcoming year in areas where there are critical resource needs?

Second, CFSAN also received a number of increases in the '22 Omnibus. Can you give us any insight into ways in which you will use these new resources? And how do these increases, and in some areas where there were no increases, impact your 23 request?

Third, health equity is a big focus throughout the budget requests. Can you walk us through ways in which the Center is prioritizing this issue?

And finally, supply chain issues rose to the forefront during the pandemic. Can you touch on how supply chain disruptions have impacted CFSAN's work and what measures the Center is taking to improve this issue?

So, let me begin. Again, I'm so grateful for the opportunity, first to take the time today to provide insight into our '23 budget priorities and help answer these other questions as well. So, to start with, I'd like to talk a bit about our new budget request and your question around priorities for the upcoming year and the areas that we've identified as having urgent resource needs.

As you all know and appreciate, our remit is vast, and we oversee nearly 80% of the nation's food supply in addition to the safety and labeling of cosmetics and dietary supplements. And we do all of that work without meaningful user fees. I am now in my eighth year of service as the CFSAN Center Director after having spent almost 30 years in public health, and I have worked hard to put forward a vision that builds on what we have achieved and addresses where resources should be prioritized to tackle public health issues that plague American families.

You've asked me how the recent '22 Omnibus has impacted our request going into '23. We are extremely fortunate that Congress provided increases to several of our programs in '22, including $2 million for our food additives work, $1.7 million for our New Era work, $2 million for dietary supplements, and $1.1 million for infant formula review among others.

So, FY22 was a strong down payment on many of our initiatives.

So, in ’23, we are looking to build on those investments and bridge the resources gaps we have in our programs to ensure that these programs not only keep pace with inflation but match the growth and innovations in our respective regulated industries.

At a high level, we are seeking an additional $33 million for our Healthy and Safe Food for all work that houses our nutrition, Closer to Zero on emerging chemical and toxicological issues, and an additional $9.1 to implement the New Era of Smarter Food Safety.

And before I dive into specifics, I’d like to qualify a few of the numbers you’ll hear me say today. Given the timing of the ‘22 Omnibus and the release of the ’23 budget, the numbers I cite today will reflect the increase we recently received in the Omnibus. In addition to budget priorities for the new year, you also asked me to talk about ways in which we are prioritizing health equity. So, let me start there.

Nutrition is one of our biggest priorities at CFSAN, given the real opportunities to significantly improve public health. Although nutrition is an extraordinarily impactful area on our health, our current nutrition funding accounts for seven percent of CFSAN’s budget. Considering the central goal that nutrition plays in the lives of every American, there is no question: we could do more with more.

In our ’23 request, you’ll see we are seeking an additional $11.6 million for our Improving Health Equity Through Nutrition work, which aligns several nutrition program areas to apply an approach that integrates nutrition, diet, toxicology, and health across the lifespan. There are three separate but related components to our work in this category, including $3.7 million for updating dietary guidance for mothers and children, $2 million in outreach to vulnerable populations, and $5.7 million to modernize nutrition labeling.

We are excited to advance our work in this space, and we have several activities planned with additional resources, including first advancing our partnerships with our sister agencies to develop additional education and outreach efforts around the Dietary Guidelines, which for the first time, included guidance for children under 2 years of age and expanded guidance for those who are pregnant or breastfeeding.

This work helps ensure that those who are pregnant or who might become pregnant, as well as parents and caregivers, are aware of current recommendations for healthy eating patterns. And from our perspective, it's critically important that this advice takes into account FDA's Closer to Zero work on toxic elements.

Second, partnering with our Office of Minority Health and Health Equity to provide tailored education materials to vulnerable populations to better empower them to use FDA's tools for labeling for better nutrition.

And third, using the healthy claim to better reflect current nutrition science and dietary recommendations. This includes research we are conducting on a healthy symbol. We live in a world where people make quick decisions. People are busy and are trying to limit time in a grocery store in the current pandemic. There is building evidence that shows that symbols and other front impact labeling schemes can help consumers make quick, healthy choices, particularly those who have lower nutrition literacy.

Next, I'll touch on our emerging chemical and toxicological work, which covers food additives and substances added to food, chemicals used in food contact such as PFAS, allergens, dietary supplements, and contaminants in cosmetics. All of these issues continue to receive major attention from the public 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 pose potential chronic risks to human health.

Looking to '23, we recognize that increased funding will allow us to expand these programs, hire staff to increase agency oversight in these programmatic areas, and respond to the ever-increasing number of industry submissions and claims. At a high level, we are requesting an additional $16.3 million. And I'll just quickly touch on a few of the ways in which we'd like to use this funding.

First, in our food additives work, $6.1 million. This includes support for our voluntary evaluation program, such as our GRAS program, and our biotech notification program, and programs to keep pace with industry advancements and innovation, such as reviewing cell cultured foods. Additionally, we'd like to support society and industry interests in increasing the use of recycled plastics by ensuring that regulatory systems are in place to evaluate new

recycling technologies intended to be used to generate recycled source material for food packaging, to ensure those materials are safe for consumers.

Just quickly under food additives, I'd like to touch briefly on sodium. We were happy to publish our final short-term study in reduction targets in October. Researchers estimated that lowering U.S. sodium intake by about 40% over a decade could save 500,000 lives and nearly $100 billion in healthcare costs. The short-term targets were a first step in a gradual, iterative approach to sodium reduction.

We plan to monitor the food supply and industry's progress in achieving the targets. While it may not sound like a flashy activity, monitoring is at the crux of developing achievable sodium targets. Monitoring the food supply in a robust way benefits everyone, including industry and public health, because it allows us to develop and refine targets that are more specifically tailored for various food categories. We know a one size fits all approach is not appropriate due to the food safety and technology considerations around sodium.

Next is allergens, $3 million. We are hard at work implementing the FASTER Act, which mandates sesame labeling. And with the infusion of funds from FY21 and 22, we continue to hire additional scientific staff. With an additional $3 million in our '23 request, we plan to continue hiring to ensure we have the necessary capacity to fully implement the FASTER Act and to undertake activities like enhancing the CFSAN Adverse Event Reporting System and other tools for surveillance and monitoring.

Additionally, we'll be updating guidance documents to reflect the addition of sesame as the ninth major food allergen, publishing a draft scientific evaluation framework for how we will identify new allergens of concern beyond the major nine, and developing guidance on labeling controls and manufacturing controls to address cross-contact.

Next is our PFAS work, $2.3 million. Our research, surveillance, and consultation with states continues to expand to better understand dietary exposures to PFAS and to work with our federal partners to ensure that the U.S. food supply remains among the safest in the world. We are grateful that PFAS was another area that received increased support in the Omnibus, with an additional $1.3 million to help us continue our state collaboration efforts as well as help us

expand our analytical capabilities to state and our contract laboratories.

Our request for an additional $2.3 million will enable us to recruit additional experts such as chemists and toxicologist to help detect PFAS in the food supply, understand associated risks, and further reduce the public's exposure to foods that present health risks.

Next is dietary supplements, $3.1 million. The dietary supplement marketplace has exploded exponentially since the enactment of the Dietary Supplement Health and Education Act, or DSHEA, in 1994. And it's grown from an estimated 4,000 products to well over 80,000 products today. And now, with the explosion of novel products containing CBD and hemp, there is no question that we need a modernized approach to overseeing these products.

Thankfully, with Congress's support over the last few years, our office's dietary supplement program's funding has increased significantly, and it's up to about $13 million now, which includes the $2 million in new funding in '22, which is a great help. In the '23 President's budget, we have requested another $3.1 million for this work. These additional resources will go a long way towards our modernization efforts, including setting the groundwork to provide transparency into the supplement marketplace as well as increase our policy, scientific, and compliance workforce.

We also recognize that in this space, several of our authorities have not kept pace with industry growth and innovation, particularly within the cosmetics and dietary supplement programs. Similar to previous years, we are asking Congress to modernize our authorities within these programs to ensure we have the most up to date regulatory frameworks. These authorities include a mandatory product listing database for supplements, and registration and listing, adverse event reporting, CGMPs, and allergen labeling among others for cosmetics.

We greatly appreciate Congress's interest in modernizing these programs, and we look forward to working with them on it.

Another area of focus for us you'll see highlighted in our budget is on toxic elements. We have heard loud and clear from the public, from industry, and from Congress that we need to make progress here. Supporting patterns of healthy eating while mitigating risk of exposure to toxic elements through investments in nutrition across

the lifespan offers one of our greatest opportunities to have an important generational impact on the nutrition, health, and well-being of our population.

We are grateful for resources to help us do this work that were received in the ’22 Omnibus, which will help us advance our work to improve the health of mothers, infants, and children. With the funds in hand, we expect to make significant progress on a few action levels I’ll touch on in a second and aim to provide related guidance on best practices, sampling, and testing.

We also expect these funds will help us expand our capacity to better manage the current infant formula review workload. As we’ve seen through our close monitoring of the supply chain, considering the recent infant formula recall, it is important that we are fully staffed with experts on infant formula to be able to do all we can to expeditiously complete reviews of new infant formula submissions, which will help to minimize any disruptions to the supply chain and to ensure infants across the U.S. have access to safe, nutritious formula.

The new omnibus funding is enabling us to expand our infant formula review team from nine FTEs to 13 FTEs. Looking at our Closer to Zero request for the ’23 budget, we are requesting an additional $5.1 million, which will help reduce exposure to toxic elements from foods eaten by babies and young children.

We are expecting OMB to issue guidance to industry for an action level for arsenic in apple juice and proposed action levels for lead in various juices. We are also far along on the priority Closer to Zero guidance that will propose draft action levels for lead in categories of food consumed by babies and young children. Further, in addition, we are currently evaluating the science for arsenic and the dose response of cadmium as part of our work to establish interim reference levels for these elements.

Outside of infant formula review, we currently have less than 10 FTEs working on toxic elements. So, with additional resources, we’d prioritize increasing our workforce capacity to help the goal of action levels, conduct marketplace sampling, and carry out appropriate enforcement actions, among others. We believe our regulatory actions, along with research and collaboration with all of our stakeholders: industry, advocacy, policy makers, academia, and consumers, will result in significant reductions in exposures to lead

and other toxic elements among children and have a lasting public health impact. This builds on the success we have seen in reducing inorganic arsenic in infant rice cereal by 29% over a six-year period.

For our broader toxic elements work, we are requesting an additional $2.1 million to expand our capacity for monitoring levels in the broader food supply, including increased sampling for the Total Diet Study and other monitoring efforts and increased laboratory testing for detection of inorganic arsenic. It's important that we have data on toxic elements in foods more broadly, as some of those same foods can also be used to feed babies and young children.

In addition to the need for new resources, we are seeking new authorities to better protect consumers from toxic elements in food. First, we recognize that we have limited tools at our disposal to help reduce exposure to toxic elements in baby food. We are asking Congress to allow us through administrative order to establish contamination limits in food, especially those foods that are consumed by vulnerable populations such as infants and young children, and to allow us to update limits as new scientific information becomes available. This would be a faster and more efficient process to establish binding levels.

Second, we recognize that under current law, manufacturers are not required to test ingredients for levels of toxic elements such as lead and arsenic in baby food prior to market. To address this, we are asking Congress for the authority to require industry to conduct toxic element testing of baby foods prior to going to market and to be able to remotely access these test results to proactively monitor industry progress in reducing toxic element levels. These new authorities will add tools at our disposal to help reduce exposure to toxic elements in baby food and will help us determine where we should better focus our time and our resources.

And lastly, I'll touch on our New Era of Smarter Food Safety request. New Era was another area that received a boost of funding in '22. In total, we received $1.7 million. And with those additions, we plan to advance our IT systems in support of food traceability and further the implementation of the FSMA tracing mandate. Looking to '23, we are requesting an additional $9.1 million. These resources will go a long way in modernizing our approach to food safety by improving prevention-oriented food safety practices, strengthening data sharing and predictive analytics capabilities, and

enhancing traceability to respond to outbreaks more quickly.

Some of the planned activities with this funding include fully implementing the FSMA food traceability final rule, which is to be issued in late 2022, including significant outreach efforts so those that it applies to fully understand the ins and outs of the new rule, working with international regulatory partners to create a common, global food traceability language based upon harmonized data elements and standards, and expanding our root cause analysis work in several ways, including enhancing our communication tools that can quickly and transparently relay the outcomes of root cause analyses, develop a national training curriculum for root cause investigations, and evaluate how we can best use predicted analytics tools to proactively identify food borne outbreaks.

Your last question focused on supply chain issues that rose to the forefront during the pandemic. The pandemic taught us a lot about the supply chain and showed us the conditions of the public health emergency could disrupt our supply chains in ways we hadn't considered previously, including as a result of worker illnesses. But in a concentrated industry with a limited number of producers, it doesn't take something extreme like a public health emergency to impact the supply chain. A food safety issue could have the same impact. Or something like the current Ukraine/Russia conflict.

For example, Ukraine is the world's largest producer of sunflower oil, which is an ingredient in many foods as well as in infant formulas. While the FDA foods program doesn't commonly deal with supply chain issues of medically necessary products, we do have that situation when it comes to infant formula. Certain infant formulas are specialty or medical formulas. For example, they are effectively treatment for babies who have inborn errors of metabolism. We recognized early during COVID that disruptions in the supply chain for food, especially infant formula, could cause significant harm to vulnerable populations.

So, we are asking Congress to help us shed light on when these shortages occur, so we can take action to promote the continued availability of these foods. Our concerns about disruption to the infant formula supply chain have only been heightened following a large recall of powdered infant formula and the Ukraine crisis.

Our assessment indicated that mandatory shortage and supply chain disruption reporting at any time, not just during a public health

emergency, would help us get ahead of the curve in these situations involving infant formula, instead of relying on the good will of infant formula manufacturers. And better information on other food supply chain challenges during a public health emergency would have been very helpful over the past two years.

So now, I'm going to transition to some remarks about the Politico article. These are just a few highlights of our FY23 request, but before I stop for questions, I do want to take a few minutes to talk about the article that you may have seen about the FDA foods program. Let me begin by saying we take any and all criticism seriously as we work to execute our mission. However, it's important for me to say that the U.S. has one of the safest food supplies in the world. Most people in the U.S. eat their food without giving much thought to safety and without having any issues, which speaks to the effectiveness of our food safety system.

But there are some very real challenges, some of which were identified in the story. Resources is a big one. You've heard me talk about that today. How many of you knew that FDA had fewer than 10 employees working on toxic elements in foods and fewer than 10 working on infant formula? Our entire nutrition group, which includes our nutrition program staff, food standards and labeling, which includes allergen labeling, infant formula and medical foods, is fewer than 70 people. For context, tobacco and poor nutrition similarly contribute to chronic disease burdens. However, FDA's Center for Tobacco Products budget is nearly 30 times larger than the budget allotted to CFSAN's nutrition work.

A preliminary analysis came out this month that suggests life expectancy in the U.S. is now five years lower than our peer countries, and nutrition is a significant contributor to chronic disease. We do have an opportunity to make a generational improvement in the nation's nutrition and thus our life expectancy. And the resources we have requested in our '23 budget will be crucial for that work.

Also, regulatory agencies have to act within the authorities they have. Some of the authorities we are seeking in the '23 budget will streamline our regulatory work and make it faster and more efficient. For example, as you heard earlier, we anticipated vulnerabilities in the infant formula supply chain in the early days of the pandemic and are seeking new authorities to have information about that to protect the supply chain for our most vulnerable

consumers.

But I also feel the need to convey my perspective on what I see in CFSAN in the foods program. I see a program that has gotten more done in the past seven years than probably any time in its history, without having any significant increase in size, and despite being under a deregulatory administration for four of those years and an ongoing global pandemic. I see a huge overhaul in the nation's food safety system with FSMA, with a program publishing eight foundational rules and more than 50 guidances to transform the system to a prevention-oriented framework to help industry prevent unsafe foods every day.

I see some of the most important nutrition policies to ever come out of FDA, multiple ones. And those have come out in recent years. Think about the Nutrition Facts label update with added sugars for the very first time, elimination of trans fats from our food system, menu labeling so consumers can access not just calories but also additional nutrition information like sodium when ordering foods outside the home, and of course, our work on sodium reduction more broadly. In addition to packaged food targets, the sodium reduction guidance includes targets for restaurant foods.

This is innovation other countries are seeking to emulate. Our guidance recognizes the need to reduce sodium broadly across the food supply in order for palates to adjust. WHO and others have told us that FDA's work on trans fat and sodium is enormously impactful in leading policies around the globe for healthier foods.

We've also advanced food safety science in ways that are leading the world. Our work on GenomeTrakr using whole genome sequencing has been described as the most important paradigm change in food safety ever. We are now detecting more outbreaks and food safety issues, including many with small numbers of cases that would have alluded detection in the past. We are solving outbreaks with 10 or fewer cases.

Beyond the molecular biology and genomics, CFSAN has a strong laboratory presence. Our analytical labs are recognized as top-notch and some of the best in the world. Because we regulate largely in a post-market environment, our labs our critically important for us to survey the U.S. food system using sampling plans designed to represent the foods most representative of what is consumed in the U.S., for example, through our Total Diet Study. It takes resources

to collect and analyze the data, and we make it all publicly available.

Our analyses of those data lead to our policies, guidances, and regulations. Because we have to collect all the data, it does take time, but it leads to scientifically grounded policies. We also respond to more than 2,000 inquiries every month in our Food and Cosmetic Information Center. People care about our work. And of course, we respond to all types of emergencies, whether it be COVID, or an outbreak, or an oil spill that may impact seafood, or hurricanes and flood damage to food, with ramifications to food safety.

We have the busiest compliance job at FDA, but we do that with fewer employees than other Centers. And I must mention the employees. The work ethic I see of our employees is second to none. So, we can do more with more. More resources, more authority to streamline our work. And that is why I am so pleased to be able to come and speak with you today.

So, I will stop at that point, and I look forward to taking your questions. Thank you.

Kyle Kinner: Dr. Mayne, thank you for those remarks. And now, I'll turn it over to Alison for a moderator question.

Alison Bodor: Thank you, Dr. Mayne. And thank you especially for at the end there, your comments reiterating the safety of the U.S. food supply. I think that's really important for everyone to understand, that despite the pandemic, despite the supply chain disruptions that we've all faced, we do have the safest food supply in the world, and that is a partnership with the agency and industry working very hard and prioritizing food safety.

Given the pandemic – let me kick us off – you mentioned that the supply chain, and Ukraine, and the pandemic, and other issues, even cyber-attacks, can have an impact on the supply chain. Let's zero in on the pandemic a little bit because that's been such a big issue for us in this last two years. And we've learned a lot in how to deal with disruption, to put it mildly. How has this changed how CFSAN operates, and what do you expect – what changes do you think will persist within the agency, and which ones will be revisited? Where do you see the new normal heading?

Dr. Mayne: And thank you for that. And yes, we have learned a lot through this global pandemic, and it has changed how CFSAN operates in many

ways. As you pointed out, we really have to think about the supply chain. And what we know is the supply chain is a global intertwined one. Even if case counts are dropping here, for example, and we start to adjust to some new normal, what happens across the globe with respect to the pandemic or other crises still has an impact on supply chains and availability of products.

Even though case counts have been lower here, the same is not true for Asia, and the current lockdown in Shanghai is affecting one of the world's busiest and largest shipping ports, which is having continued ripple effects across the entire global supply chain. And we know that disruptions to the supply chain are wide-ranging and complex. It not only impacts the availability of ingredients but also packaging materials and labeling stock. There are labor shortages and shipping disruptions on top of this.

And we understand that the challenge facing companies like yours are anticipated to continue for months if not longer. And that is why in the early months of the pandemic, FDA issued temporary guidance that provided flexibility on certain food labeling and other requirements for various segments of the food industry to help support the food supply chain and to meet consumer demand. And these flexibilities are still in place today.

And we want to assure you and the others on the call that the flexibilities will remain in place as long as necessary to support the food supply. And when the time is right, and we have returned to more normal operations, both flexibilities won't immediately be removed. We plan on taking a phased approach to the transition, and we will provide appropriate lead time on any plans. We will communicate regularly, and we hope to engage an ongoing dialogue with industry and other stakeholders throughout this entire process, as we have been throughout the pandemic.

What we need from industry to help support these supply chains is information and data. We need to hear from industry about what is happening on the ground. We need to understand the ongoing challenges and how things are shifting. We need data on the impact this is having on industry and consumers. All of this information is critical to our understanding and will help us as we make determinations and decisions moving forward.

In addition to those flexibilities, the FDA has made changes to our inspectional activities due to the pandemic, taking a risk-based,

deliberative approach to foreign and domestic inspections, ensuring we could carry out our public health mission while protecting our workforce and the workforces of those we regulate. Mission critical inspections were prioritized, and routine surveillance activities were temporarily postponed.

FDA successfully implemented alternative tools and approaches where inspections were or are not currently feasible, including remote interactive evaluations. For example, remote livestreaming video of operations, teleconferences or screensharing, record request, and leveraging information from trusted regulatory partners. All of these activities were outlined in the report we released last year, Resiliency Roadmap for Inspectional Oversight.

And as we move forward, and we adjust to a new normal, FDA will continue to use every available approach and resource to meet our regulatory responsibilities and to achieve optimal public health outcomes. We will work to modernize and support innovation to our regulatory role, integrating new oversight methods and new tools. We will enhance our coordinated approach to inspections, leverage mutual reliance, information sharing, and collaborative approaches to help us better face challenges in the future.

Alison Bodor: Thank you, Dr. Mayne, and I appreciate your comment about the need for data by the agency, where we are seeing problems in the supply chain. I think we've had that conversation before through the Food and Beverage Issues Alliance that we are committed to providing you with that. Kyle?

Kyle Kinner: Before I continue, just reminding the audience if you have a question for Dr. Mayne, feel free to include that in the Q&A button. If you click that button, a popup box will emerge, and you can type that in, and send it in, and we'll be able to communicate that to Dr. Mayne.

I'll ask a question, Dr. Mayne, about workforce issues. Recruiting the modern, highly qualified workforce that CFSAN needs to implement programing like the Food Safety Modernization Act, or IT Modernization, or the New Era programming will require the agency to genuinely go out and hire the best and brightest.

Do you feel like you have the tools you need to successfully compete with private employers and even other FDA divisions to hire the next generation of scientists and other experts you need to achieve your mission? Are there other authorities – I'm thinking about the

medical centers and their utilization of the 21st Century Cures authority, for example – that you think would help CFSAN recruit a modern workforce?

Dr. Mayne: So, we are fortunate that CFSAN has maintained a very low attrition rate that has averaged around five to six percent over the last three years. In 2021, during the pandemic, our attrition rate was 5.7%. But as we lose people, including due to retirement, we have to replace them with new staff with advanced scientific and technical skills, including things like data sciences, to support the growing innovation we see broadly across our regulated industries.

However, for these types of positions, CFSAN is increasingly competing with industry and even other parts of FDA to hire and retain staff. So, CFSAN would benefit if we had the agile hiring authorities that FDA's medical product centers received in 2016. Modern hiring authorities would enable CFSAN to recruit talented scientific staff on par with the private sector. We'd be able to get out offers more quickly than under our current hiring authorities. This really would be transformative for CFSAN. We'd be able to bring on the talent we need to address the increasingly complex and exciting innovation in our program area and do it more quickly.

Like many other employers during the pandemic, we've had to shift how we function and embrace the fully remote environment for most of our employees. We are starting to initiate our return to facilities, but that's not to say our work weeks will look like what they did prior to 2020 with us being in the office traditionally five days a week. On par with our sister agencies like HHS, under HHS, we will be moving to a more flexible work week, where depending on their roles, staff will have the opportunity to do more telework and work remotely. We are exploring how to maximize our productivity and also our job satisfaction. Every business is doing that.

Many of the flexibilities we have come to appreciate during the pandemic will continue as we emerge from the pandemic because FDA understands that these changes will enable us to recruit for positions more competitively and to hire a more diverse workforce. And I know we did have employees working remotely before the pandemic where it made sense for the employee and for the Center.

Kyle Kinner: Thank you. Alison?

Alison Bodor: Dr. Mayne, could you talk a little bit more – you mentioned that you

would be advancing partnerships with sister organizations on nutrition education. And that seems so smart because nutrition and health-related chronic diseases are not and should not be FDA's responsibility alone. It should be a whole health system approach. So, could you expand upon the vision there?

Dr. Mayne: Yes. I think the vision is to really develop tools, and many of those tools need to be developed by FDA because they are our labeling authorities that we need to communicate to consumers. And then, really leverage those with our federal partners. Of course, that includes folks like CDC, and NIH, and others. Really leverage those tools, but also, as you know, with other partners including private industry.

We have had a public private partnership that has been operational through the Reagan-Udall Foundation to help amplify some of our nutrition messaging. We are not resourced to do a major educational campaign, but we can certainly develop quality tools that can be amplified by others, contributing to what we know we need to do to help reduce the risk of diet-related chronic diseases that plague our country today, that contribute to our healthcare costs, and we know that we need to do more to address that.

And the COVID-19 pandemic has really highlighted that – as we've seen, the people who have been most vulnerable, including many of the people who are working in food industry establishments – many of them are more vulnerable to the adverse effects of COVID-19 given that they have diet-related chronic diseases and most likely to have additional morbidity and mortality.

So, we need to do more around nutrition. We need to have more of the federal government, all of government approach, and we need to explore other partnerships, including public private partnerships, as I just spoke about.

Kyle Kinner: Dr. Mayne, CFSAN has experienced – we talked about the budgets in past years and now, the FY23 requests. CFSAN has experienced some budget growth over the past few years but candidly, not substantially. Your FY15 BA was around $900 million, and your FY22 BA is about $1.1 billion, reflecting cumulative growth over seven years of around 25%, not adjusted for inflation. By contrast, USDA, sort of a sister agency, has seen its budget grow considerably faster over the same period. Their budget, I think, has nearly doubled.

You have an extraordinarily broad mission to ensure that Americans have access to safe and healthy foods. You have regulatory oversight of over 80% of the food supply, cosmetics, dietary supplements, etc. It seems like we're asking a lot, but additional resources are needed.

Based on what you said, is it your assessment that CFSAN's limited growth in BA funds and lack of user fee resources has constrained what the agency is able to do relative to what you'd like to do?

Dr. Mayne: And I'd say that's accurate. And the statistics you gave, Kyle, are across the foods program. That $1.1 billion includes across the foods program. Within CFSAN, we account for about 33% of those resources. And with that 33%, what that gives us is around 1,100 people. Our budget is around $345 million to regulate all of the areas that you mentioned along with supporting all the scientific enterprises that I spoke about earlier.

I mentioned that two-thirds of that funding goes to the Office of Regulatory Affairs Field Operations for those inspections of food facilities. And we have more regulated industries that we have to oversee than any other part of the FDA. And unlike most Centers that do receive significant funding through user fees, 97% of our budget comes from budget authority, which makes us an outlier at FDA and has meant that our funding often doesn't correlate to the level of work we have relative to the scope of our mission, in contrast to most FDA Centers.

In those other Centers, they receive user fees. They can scale up as the volume of incoming work increases. And in our case, we have to just somehow manage as best we can to absorb that work because we can't scale up as the volume goes up without new appropriations.

For example, prior to the passage of PDUFA, the Prescription Drug User Fee Act, FDA's food and drug programs were about the same size. Today, CDER is roughly five times as large as CFSAN. CFSAN's modest budget compared with the scope of our mission means that CFSAN is not always able to meet consumer expectations for our oversight of the nation's supply of food, cosmetics, and dietary supplements. And thus, we have to prioritize.

Another issue we are discovering is while our systems and programs are advancing, such as with the work of the GenomeTrakr Network

that I highlighted, that means we're going to pick up more and more issues, more and more outbreaks with GenomeTrakr and that we need to devote attention to – and this can be a drain on our already limited resources.

We reiterate our commitment to do all possible to keep consumers safe, including leveraging all advancements in science and technology. However, we know we can do more with more. And we'd ideally like to see those efforts paired with new resources to better align with what we need.

Kyle Kinner: Thank you. Alison?

Alison Bodor: Just a little bit of a follow-up: Do you feel based on that, that you've asked for sufficient funding in 2023?

Dr. Mayne: Well, I think we can always do more with more. We have to go through a process, as I'm sure you are well aware, of how the budget process rolls out across the federal agencies. We can always do more with more.

I can also say that it's not unusual; it can happen that folks can advocate for resources that exceed what is in the President's budget. And so, I think what we've tried to do here today is really lay out some of the resource challenges we have and with hope – with advocates like the Alliance for Stronger FDA, hopefully we can do more with more and receive some of those resources that would really improve our ability to do more with more.

Alison Bodor: Thanks, Dr. Mayne. We have a comment from the audience on the FSMA, the ag water proposal. FDA's collected data on the new proposal. Can you comment now on the timing of when this would be finalized?

Dr. Mayne: So, with regard to the agricultural water proposal, we had an open public comment period; we've had public meetings, in terms of all of this to get where we are with ag water. And as most of you know, we are unable to specifically comment on timelines. But what I can tell you is the processes we use are to always take the public comments that we get very seriously. Agricultural water is a tough one. We have to look at all the different ways that agricultural water is used across the entire food system.

And so, we have gotten a lot of information and comment on that.

We will take all that into account as we move forward with regard to agricultural water. And we do recognize it is one important thing that we need to address in the Produce Safety Rule; it is not the only one. There are a myriad of different things that we have in the Produce Safety Rule to help get to better produce safety. And that is the commitment we have, not just to support food safety, but also to support better nutrition because we know consuming produce is the foundation of the healthy dietary pattern. So, that food safety work really helps to support the nutrition work by getting greater confidence in the safety of produce.

Kyle Kinner: Dr. Mayne, the enactment of the Food Safety Modernization Act in 2011 was a historic step forward for food policy and for the Food and Drug Administration's approach to foodborne outbreaks and a reorientation away from a reaction to an approach that focused on prevention. I wonder if you now, sort of five years on, want to think about out loud kind of the impacts of FSMA, and how we should view that group of regulations that FDA has implemented over time, and kind of where we are in our goal of sort of transforming food safety and making the American food supply safer.

Dr. Mayne: Yes. I'd say we are very far along with regard to FSMA implementation. Eight different foundational rules are out, 50 guidance documents – more than 50 guidance documents. So, we've been working very hard. But we still have more. FSMA is a complicated overhaul of the U.S. food safety system.

Two things we are critically working on right now are the food traceability rule. We have a deadline to get that food traceability final rule out by this fall. And some of the resources we are requesting here in the '23 budget will help lead to that implementation that is envisioned within FSMA. Our ability to trace foods back through the supply chain will facilitate more rapid responses when we have foodborne illness outbreaks.

So, all of that is critically important to achieve the vision of FSMA, and it takes time, and it takes stakeholder engagement. These FSMA rules are complicated rules, and like most rules, they take a while to get done. On average, rulemaking takes about five years from conception to a final rule.

So, there's a lot of work we do engaging with our stakeholders and the scientific community, all of that. We go through notice and comment, rulemaking requirements, and compliance with federal

law. We also go through an intra-governmental review process as we work on all of these FSMA rules like the traceability rule, to ensure that all feedback is considered and implemented as appropriate from different parts of government. The feedback and insight of our government partners helps make our policy stronger and more comprehensive.

And of course, we have to work really closely with our stakeholders, including industry, to ensure the policies that we put in place are feasible to implement once enacted. If we don't take the time to make sure our rules can be enacted in the real-world setting, then they won't be successful like we want. And at the same time, we're not afraid to act decisively when science supports decisions, even if we know that certain stakeholders may not support that.

But those are just some general comments about FSMA. We are well into FSMA. The early foundational rules, preventive controls for human food, preventive controls for animal food, produce safety rules, those are well being implemented at this point in time with all the guidance and compliance timelines underway, but there still is more to be done. And I mentioned the traceability final rule as an example of additional work ahead with regard to FSMA.

Kyle Kinner: Great, thank you. Alison?

Alison Bodor: Can you talk a bit about the technology needs and opportunities at CFSAN for regulating foods and for ensuring food safety?

Dr. Mayne: Yes, there's so many different ways that technology can assist us. And I can give you multiple examples of where we are using data analytics and new technology tools to try to do more with more. And we know that's happening across all industries. Private industry, government is utilizing technology and innovation to make our job easier.

A couple of examples I'll highlight for you is just how we do our work at the borders and when we choose to screen particular products as having a higher likelihood of being violative. And of course, we screen all lines that come in across our borders, but some of those will be flagged, and they will be sampled, and they will be scrutinized. And we are trying to use additional sources of data and information, and approaches like machine learning and artificial intelligence to do better with how we target violative products coming across our borders. And so, using data, using technology,

using analytics to get more bang for the buck with the work we are doing. That's one example.

Some other examples of where we're using data and analytics across the board: it's really understanding what's happened in some of these foodborne outbreak investigations. We see some certain chronic issues, and leafy green safety is one of those. So, looking across all these outbreaks that occurred over time, can we look to see: are there common data elements that might help us better understand what contamination might have occurred?

So, using data, and analytics, and modeling to really try to get to root cause of what happened in many of these outbreaks when we have especially challenging situations like leafy greens. Those are some examples where we use data and analytics.

The last example I want to use for you is really on the chemical side of food safety as well. And so, there are a lot of different chemicals that can be added into foods. Many of them are Generally Recognized As Safe. Many of them have gone through our food additive petition process, or they've gone through our food contact notification process. In the future, we need to continually look to make sure that those chemicals still remain safe. And so, we need a science-based, data-drive approach to look across that whole sphere of chemicals to make sure we're making the best regulatory decisions and utilizing our resources in the best possible way.

So, we think developing an expanded decision tree that takes into account all the curated data we have on a host of different chemicals, and we are using that to prioritize those chemicals that we might have concerns about from a public health perspective, and really use our limited resources to prioritize on those. And it's using data, analytics, all the information we have about certain classes of chemicals, to inform the actions that we take.

And some of the resources we are requesting would really strengthen our ability to have that post-marketing oversight of chemicals in the food supply. And I reiterate our point that we do have the safest food supply out there. There are certain chemicals in the food supply. If there are ones that are of concern, we want data and science to really prioritize, and if we do have concerns, take action on those chemicals. It's all critical to ensure we have confidence in the food supply.

Kyle Kinner: Dr. Mayne, we have a question from an audience member. They ask about the experience that FDA had with reacting to a specific instance of toxic substances in baby food. They ask: To what extent was FDA aware of issues in relation to the Abbott infant formula concern in September of 2021? And then, why was there a period of time that elapsed until a recall in February of 2022?

Dr. Mayne: Okay, so I think there were two questions in there. The first one is about toxic elements in baby food. And this is an area of our program that we have been working on for a very long time. As an example, as we communicated when we put our action level out – sorry, not the action – action plan, Closer to Zero – what we've seen is a decrease, for example, in lead exposure in babies and young children 1 to 3 years old of 97%. The toxic element exposures in our babies and young children have been reduced, and in some cases have been reduced dramatically.

Some of that is based upon FDA action, not all of it. Some is because of the removal of lead in gasoline, which as we know, led to foil contamination, which led to food contamination. So, that's an example where there has been significant progress made. FDA had a role to play here as well through the use of eliminating lead in soldering cans that was contributing through food contact to lead exposure. That, of course, was eliminated, and we have made great progress.

I mentioned inorganic arsenic in regard to infant rice cereal. We prioritized that because that is a toxic element where one particular food accounted for the biggest source of exposure. And that was based upon our science and data. So, to utilize our resources, we focus in on where we can have the greatest public health impact.

So, in that case, we worked on inorganic arsenic in infant rice cereal because it was the most important source of exposure for babies and young children. As you know, we have put out action levels, and we have reduced exposure, as I highlighted, by 29% over a six-year window of time.

We need to do more with some of these other toxic elements. We need to work on cadmium. We need to do more in that area. But what we have learned using the science and data that we have generated in the center – we have tested foods. We have looked at those foods. We have published all of that data, and we've estimated intakes using national data from, for example, What We Eat in

America National Health and Nutrition Examination Survey.

And what that data showed is that there's not one particular food category that we would target next to continue moving these exposures closer to zero. Rather, we needed to target categories of food, and that is what we are doing with Closer to Zero now. I mentioned a guidance document for lead, for a variety of different juices that is in OMB final stages of clearance. I also mentioned the guidance document on lead in different categories of baby foods is very far along.

So, we can, and we have been working to reduce these exposures to as close to zero as we can get.

You also asked me about the Abbott Nutrition situation. As the agency has indicated, when we get questions about this, we are committed to protect consumers. We understand the criticality of infant formula for our youngest consumers. But at this moment in time, we are still in an open investigation. And so, I am not able to answer specific questions at this moment in time about an open investigation involving the recall of some formula from Abbott Nutrition.

But our commitment is always to use our full regulatory levers to protect those infants, to protect the supply chain. I spoke about the infant formula supply chain and our work in that regard. And when we are able to tell more about the scenario and where we have been with this infant formula recall, we will do so. But at this moment in time, because it's an open investigation, I'm not able to share those details with you today.

Kyle Kinner: Thank you.

Alison Bodor: Thank you, Dr. Mayne. Appreciate that as well. I think with that, we're coming to the end of the hour. Dr. Mayne, are there any final comments that you'd like to make or share with the audience?

Dr. Mayne: Well, I think our purpose in coming here today was to speak to you about some of our resource needs and our authorities. I think you have heard that there is a need for resources that could help us do more to meet consumer expectations. I think I just want to put an exclamation point on that. That was identified in the Politico article that it's challenging to do everything we are expected to do, and we have very few staff in some of these areas.

So, with additional resources and with your support, we can and will do more with more. And we take those resources very seriously. We track and utilize those resources consistent on how they are appropriated to us. We put in monitoring systems and tracking. So, we know that the activities that we take with these resources remain on track. We monitor them on a weekly basis to make sure that we are utilizing those resources as effectively as possible.

So, with that, we can go ahead and wrap up the call. And thank you again to the Alliance for hosting me today.

Alison Bodor: You're welcome. And thank you for joining us. Thank you for being here today and sharing your thoughts, your perspective, FDA's perspectives on the 2023 budget. We, I think, hear you loud and clear on the resources that are needed at the agency, and we're pleased that the Alliance has been supportive of the agency's budget in the past and will continue to be.

Kyle, do you have any comments to end?

Kyle Kinner: Just echo the thanks for your time today. It's been enlightening. I know our audience has appreciated the opportunity to hear more about your priorities, about your budget. We look forward to staying in touch, and look forward to your interest in these issues, and your help on the work to make sure that it's well funded.

Dr. Mayne: Great. Thank you so much.

Kyle Kinner: Take care.

Alison Bodor: Thank you.

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Duration: 61 minutes