Remarks by the Director of the Center for Food Safety and Applied Nutrition

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Good afternoon. As most of you are aware, I will be retiring from FDA at the end of this month, and today is my last time meeting with you as the Director of the Center for Food Safety and Applied Nutrition. Serving as the Center Director, in a role where I have been able to engage everyday with exceptional staff, passionate advocates, and partners committed to advancing public health—some such partners are in the room today—has been the honor of my lifetime.

From implementing FSMA to redesigning the Nutrition Facts label, working to reduce sodium in the food supply and to analyzing outbreak investigations with food safety experts—together we have made tremendous progress toward making the food we feed our families as safe and as nutritious as it has ever been. Traditionally, at the annual FDLI meeting, the Center Director provides updates on the past year—which I will weave throughout my talk today—but I would also like for you to join me in looking back at some of CFSAN's key accomplishments from my eight and a half years leading the center.

FOODBORNE ILLNESS

CFSAN oversees the regulation of almost 80% of the food supply, and chief among our duties is responding to and preventing foodborne illness outbreaks. When I first joined the agency, the Center was busily writing and proposing the first rules of the landmark Food Safety Modernization Act, setting the foundation of our modern regulatory framework. Guided by FSMA, the FDA and the food industry were both transitioning from a posture focused on response and reaction, to one focused on preventing outbreaks and illnesses from occurring in the first place.

Over the last eight years, we have issued nine FSMA final rules and more than seventy guidances to advance food safety. These rules have set new, national standards for ensuring the safety of our food as it moves from farm to fork. One of the last major pieces of FSMA—the food traceability rule—was finalized last November and is expected to facilitate faster identification and rapid removal of potentially contaminated food from the market. I have seen firsthand in our outbreak response the necessity of the traceability rule.

The impact of FSMA goes beyond the legal requirements we have set forth for industry. Since passage of FSMA we have embraced prevention through a myriad of approaches, including expanded surveillance microbiological sampling, building relationships domestically with state partners and internationally with foreign regulatory and public health authorities, and we have expanded and enhanced our

inspectional and compliance activities. Perhaps most important, industry and public health officials alike have moved beyond simple response efforts and are taking more steps than ever to uncover the root cause of food safety issues so that we can learn from the past to build a safer future.

For FDA, this shift toward targeted prevention activities wouldn't be possible without our Coordinated Outbreak Response and Evaluation Network, or CORE. This world class group of food safety experts leads the agency's foodborne illness outbreak response activities, working with our colleagues at the Centers for Disease Control and Prevention and state public health agencies to identify outbreak signals, investigate, and communicate about contamination events. CORE's work has resulted in the identification of 1,124 potential outbreaks, responses to 265 outbreaks potentially linked to food products, and investigations that led to 257 recalls since 2011.

Recognizing the benefits of transparency to both solving foodborne illness events and to preventing future ones, CFSAN's CORE team developed a publicly shared investigation table in 2020 to communicate more information about the potential outbreaks the agency was looking into, even in the early stages before a food vehicle was identified. We tried this as a pilot and it has been so successful that this table that is posted on our website is updated every week.

In recent years, our work has been aided enormously by whole genome sequencing, a tool that we have come to rely on over the last decade for its ability to identify the genetic fingerprint of various pathogens. It is one of the most groundbreaking advancements in food safety, and I could not be prouder of the work done by CFSAN scientists to harness its power to establish and expand the GenomeTrakr network worldwide.

For those of you who might not be familiar with GenomeTrakr, it's a network of laboratories that utilize WGS for pathogen identification and to store isolate sequences at a public database housed at the National Center for Biotechnology Information at the NIH. The data are used for real time comparison and analysis that can speed foodborne illness outbreak investigations and reduce foodborne illnesses and deaths. To date, there are more than 1 million foodborne pathogen sequences that have been uploaded to the database, and the number is growing every day. We estimate that for every 1,000 isolate sequences added to the database for a given pathogen, there is a reduction of approximately six illnesses per year associated with that pathogen. This is genomic epidemiology at its finest.

Taken together—our implementation of FSMA, our expansion of outbreak investigations, our use of whole genome sequencing, our partnerships with other regulatory authorities and other scientific advancements have provided us with more data and information than any other time in history about the pathogens that contaminate food.

This marriage of science and collaboration to achieve material results is emblematic of our new Prevention Strategies to Enhance Food Safety. These strategies are multi-disciplinary approaches that are undertaken by the FDA and our partners to help limit and prevent future outbreaks linked to certain categories of foods, especially those where we have seen repeat outbreaks or other food safety issues. Since September we have released strategies focused on improving the safety of bulb onions, imported enoki and wood ear mushrooms, powdered infant formula, and, most recently, soft fresh queso fresco style cheeses. I believe this kind of targeted approach to identify the root cause and trends in outbreaks across different commodity groups and to

identify strategies to prevent future contamination is exactly the direction Congress envisioned for our food safety system when they passed FSMA in 2010.

INFANTS AND YOUNG CHILDREN

Let me now pivot to another important aspect of our food system, protecting the health of infants and young children. Having access to safe and nutritious food improves health outcomes throughout a person's lifespan, which is why this work is a priority for us at FDA. From issuing advice to parents of young children on how much and what types of fish they can eat to get the benefits of fish while minimizing exposure to mercury, to building a more resilient infant formula market, we have built on a foundation of research and policy to further advance FDA's efforts to support children's growth and healthy development.

Infant Formula

When I addressed FDLI almost a year ago, we were in the midst of an infant formula shortage that was sparked by a recall due to insanitary conditions at one of the largest infant formula manufacturing facilities. Today, because of the actions we have taken this last year, in-stock rates have reached 90%, which is better than the levels we saw before the 2022 recall. In addition, week after week, production is outpacing demand.

In the past year, FDA has taken many steps to improve the resiliency of the infant formula supply and taken steps to enhance the safety of powdered infant formula through the development of a Cronobacter prevention strategy and the National Strategy to increase the resiliency of the infant formula market. We have set up various workgroups throughout FDA to execute the items noted in these strategies, and we'll be continuing to provide updates on our progress on our newly created Infant Formula webpage.

We have also initiated work with the National Advisory Committee on Microbiological Criteria for Foods, which held a public meeting just yesterday, to help us to address some knowledge gaps about Cronobacter and its implications in food.

Still there is more we need to do and more authorities we need to do them. First, it's important that Cronobacter sakazakii infections become a nationally notifiable disease. Currently, only two states, Minnesota and Michigan, require reporting of Cronobacter infections to public health departments. This lack of mandatory reporting nationwide significantly hampers our ability to fully understand Cronobacter's public health impact. In June, the Council of State and Territorial Epidemiologists will consider this issue, and we fully support them adding Cronobacter to the list of notifiable diseases.

Additionally, we need to better understand the prevalence of Cronobacter in manufacturing environments and the steps manufacturers are taking when they find it. As part of the President's FY24 budget request, we are asking Congress for additional authority to require manufacturers to report positive product samples to us and to conduct additional environmental sampling and retain and make available to us during inspection any Cronobacter isolates that are found. And until we get these authorities, we are asking manufacturers to take these steps voluntarily. These actions are very much needed, but not steps FDA can take alone.

The infant formula market is extremely concentrated, and intolerant of recalls and plant closures, so we are working with the industry and through our call to action for enhanced food safety of this critical commodity.

We would like to work with all of our stakeholders to elevate these issues, implement new approaches, and pursue additional resources, so that together we can protect the health of our youngest, and most vulnerable, populations.

Closer to Zero

Another area where we are actively working to protect infants and young children is through our Closer to Zero initiative to reduce exposure to arsenic, lead, cadmium, and mercury from foods. While the Closer to Zero initiative is relatively new, our work to reduce exposure to harmful levels of environmental contaminants is not.

In fact, one of my first areas of focus upon arriving at CFSAN was our work to reduce exposure to inorganic arsenic from infant rice cereal, since rice cereal is an important source of iron but also the predominant source of exposure to arsenic for infants. Through guidance, we issued draft and final action levels, the impacts of which are already evident; for example, from 2012–2019, inorganic arsenic levels in infant rice cereal decreased by 29%.

Through Closer to Zero, we have expanded our efforts with draft guidance on lead in juice and lead in processed foods commonly consumed by babies and young children, and we are actively working to identify additional action levels for arsenic, along with cadmium, and mercury. Closer to Zero takes an iterative approach to lowering the levels of these contaminants in foods over time to as close to zero as possible. We recognize the challenges in reducing the levels of these contaminants that may be in foods because they are in the environment, either naturally or from human activities, and our approach ensures that the action levels we identify are health protective and also achievable, so that families have continued access to foods they rely on to support the health and development of their children.

CHEMICALS IN FOOD

Our work on food chemical safety goes beyond foods commonly consumed by babies and young children and extends beyond the four heavy metals that are prioritized in Closer to Zero. Protecting consumers from harmful exposure to chemicals is part of the very fabric of the FDA. As those of you who know your FDA history are aware, it was the push to protect consumers from harmful exposure to chemicals in the food supply that paved the way for the passage of the Food, Drug, and Cosmetic Act and the very creation of the FDA. While exposure to lethal chemicals intentionally added to foods, such as formaldehyde-tainted milk, are a thing of the past, chemicals that have contaminated our environment and are unintended contaminants in our foods is very much a modern-day concern. In addition, many consumers are also worried about chemical ingredients used in food. Food chemical safety is therefore not only an area that will benefit from additional research, but also from consumer education. All food is made up of chemical substances.

Chemicals when used safely in food, food packaging, and other food contact surfaces enable products to last longer and be less vulnerable to microbial contamination. Of course, chemicals in the modern food supply also make food more desirable by enhancing the color, texture, or flavor.

At FDA, we consider the levels of chemicals found in food and consumer consumption patterns as we evaluate the safety of both chemicals that are intentionally added and those that enter the food supply through contamination, using the latest science and regulatory tools, and adapting to and incorporating new information and approaches as they become available. We are working on a framework to

systematically review the post-market safety of authorized uses of chemicals in food, drawing upon extensive curated information about chemical toxicity, so that we can continuously protect public health as the science evolves around these chemicals.

An example of our work in this area is our effort to better understand and reduce exposures to PFAS in the food supply. PFAS are a diverse group of human-made chemicals that have been used for decades in a wide range of applications across diverse industries and uses.

Because of the chemical composition of PFAS, they do not break down easily and have become ubiquitous in the environment. While this is well-documented, PFAS in the food supply is an area where there are still more questions than answers. The FDA has been a leader in advancing the science of testing for PFAS in the food supply, and since 2019, we have tested hundreds of foods in the general food supply as well as those from areas of known contamination—in the latter category we made sure certain products coming from areas of known environmental contamination have not entered the market. With regard to the general food supply, what we have found is that with the exception of seafood, our testing has found that almost all samples tested have no detectable PFAS. Our sampling is limited, and so there is still much work for the agency to do to in continuing to test the food supply and reduce dietary exposure to PFAS.

ADDRESSING DIET-RELATED CHRONIC DISEASE

Making sure food does not make us sick goes beyond making sure it is not contaminated. For decades we have all been witness to the epidemic of diet-related chronic diseases in our country. The interplay between nutrition and health status is complex. But we are making progress, and I have had the honor of being in a position to lead work out of FDA that has advanced policies and initiatives that through improved nutrition address diet-related diseases such as cardiovascular disease, diabetes, and arthritis.

There are two sides of the nutrition coin—making the food itself more nutritious and helping people to make food choices that support their health. On both fronts, FDA has made important progress. In the last several years we have removed Partially Hydrogenated Oils, a major contributor to heart disease, from our food supply. We have also set voluntary sodium reduction targets for a wide variety of processed, packaged, and prepared foods. Our targets are complemented by a suite of sodium reduction initiatives. With reductions in sodium intake, we expect to see reductions in high blood pressure, heart disease, and strokes.

To help consumers make more informed choices, we now require menus and menu boards at chain restaurants to include information like calories. Further, for the first time in over twenty years, we have updated the Nutrition Facts Label with a refreshed design to communicate nutritional information as well as new features, like the declaration of added sugars for the first time.

While each of these efforts has the potential to prevent hundreds of thousands of premature deaths and other illnesses, we know there is more we can do government-wide to help make healthier food choices the easy choice. This last year I was fortunate to participate in the White House Conference on Hunger, Nutrition, and Health. This Conference, and the National Strategy that came out of it, has brought a much needed, renewed focused to the role that diet and nutrition play in our health. The strategy prominently features FDA nutrition initiatives, including front of package labeling,

updating the criteria for "Healthy," and facilitating reductions in both sodium in the food supply and intake of added sugars.

In coordination with the conference last September, FDA issued a new proposed definition of the "Healthy" nutrient content claim that consumers can see on the front of food packages. The definition is being updated to align with current nutrition science and the Dietary Guidelines for Americans. For example, current dietary guidelines focus on the importance of healthy dietary patterns and the food groups that comprise them, the type of fat in the diet rather than the total amount of fat consumed, and the amount of sodium and added sugars in the diet.

We are also developing a "Healthy" symbol to represent the definition so that consumers can quickly find foods that meet the definition. We know that most people's eating patterns do not align with current dietary recommendations, so we believe updating the "Healthy" claim and having a symbol could provide information to help consumers improve eating patterns.

Earlier this year we released draft guidance for industry on their use of Dietary Guidance Statements on food labels to help people understand how a food or food group can contribute to a healthy eating pattern. Examples of Dietary Guidance Statements are "make half your grains whole grains," and "eat a variety of vegetables." Our guidance would help with more consistent use of such statements to benefit consumers.

Our work on front-of-package information doesn't stop there. We are also working on a front-of-package—or FOP—labeling system to quickly and easily communicate nutrition information. Use of these schemes has increased dramatically around the world in recent years. FOP systems can promote equitable access to nutrition information and provide consumers with additional context and information to help them make healthier choices.

And while a central focus of FDA's nutrition work is aimed at reducing diet-related chronic disease, I would be remiss if I didn't talk about some of our nutrition and labeling work to address more immediate adverse health impacts, like allergens. During my time as Center Director, the FDA has taken steps to make foods safer for those with common food allergies and sensitivities, including enhancing gluten-free labeling requirements, taking enforcement actions on manufacturers that have repeatedly produced foods with undeclared food allergens, and conducting informative sampling such as our work to evaluate dairy-free dark chocolate for the presence of milk. Earlier this year, sesame was added as the ninth major food allergen when the FASTER Act became effective, requiring that it be listed on food labels as an allergen. Just yesterday we issued a draft Compliance Policy Guide to provide guidance for FDA staff on the FDA's enforcement policy regarding major food allergen labeling and cross-contact. We are aware that some manufacturers are intentionally adding sesame to products that previously did not contain sesame and are labeling the products to indicate its presence. We recognize that this practice may make it more difficult for sesame allergic consumers to find foods that are safe for them to consume—an outcome that the FDA does not support. We are engaged with various stakeholders on this issue.

INTERSECTION OF FOOD SAFETY AND NUTRITION

Before I move off the topic of nutrition, I would like to take a moment to discuss the important intersection between nutrition and food safety. Because my prior

research at Yale included the study of both beneficial and adverse components of foods in relation to health outcomes, I was well aware of that intersection, but my understanding of the importance has only grown over the last several years. Whether it be Closer to Zero—which involves maximizing nutrients and healthy foods for infants and young children while minimizing exposure to toxic elements—or microbial food safety to reduce pathogen contamination in fresh fruits and vegetables, or assuring that powdered infant formula as a sole source of nutrition is safe from microbial contamination, nutrition and food safety ARE intertwined and policy makers must consider both.

One important example of this intersection is our work on dietary supplements. Dietary supplements can help consumers get their daily requirement of essential vitamins and nutrients needed to maintain their health, but unlike drugs, the FDA doesn't evaluate new dietary supplements to ensure they are safe and effective before they can be sold. Over the last twenty years, we have seen the number of dietary supplements on the market, including those sold on-line through popular retailers, expand exponentially. In 2015, we established the Office of Dietary Supplement Programs to better oversee this expanding field. Through the leadership of this office, the FDA has taken critical steps to enhance the safety of dietary supplements, educate consumers about taking supplements safely, and acting to remove unscrupulous manufacturers selling so-called miracle cures from the market. Just this year, the office launched a new Dietary Supplement Ingredient Directory where the public can learn more about ingredients that are often used in products sold as dietary supplements and can see what the FDA has said in the past about the ingredient. Much like our nutrition initiatives, this action will help consumers to make more informed choices about the supplements they choose to take.

FUTURE OF THE HUMAN FOODS PROGRAM

And finally, as you know, the foods program at FDA is undergoing changes. First, the cosmetics program is moving out of CFSAN and into the Office of the Chief Scientist, which will be responsible for carrying out the implementation of the Modernization of Cosmetics Regulation Act, the most significant update to the FDA's authority to regulate cosmetics since the passage of the FD&C Act in 1938. I am so pleased this act passed; I have been advocating for this during my tenure, which included testifying in a hearing on the Hill about this topic. Second, the FDA is moving forward with a broad reorganization of the human foods work, which I believe will be pivotal to ensuring that the FDA is able to continue to support the food safety system in our country well into the future.

We all know the world around us is changing rapidly. Today, you can order a salad on an app and have it delivered in twenty minutes. Scientists can rapidly interrogate genetic data to link a case of foodborne illness to a pathogen found years earlier in a production environment, advancing our ability to investigate foodborne illness. New companies are innovating in the production of meat and poultry products using cultured animal cells, and genome-edited crops offer new and accessible solutions to the problems created by issues such as climate change. And every day, products grown or processed from all corners of the earth end up on our dinner table.

All of this, and more, is quite literally changing the landscape of our food system, and the FDA is being asked to do more to protect it. With every scientific

advancement, innovation, or disruption in our food supply, we are faced with new challenges to our oversight.

I'll admit, while the science underlying this innovation excites me at its potential, the acceleration of these changes has made it challenging to keep up the last few years as the regulator of emerging innovation—and I don't foresee there being any slowing down. The FDA currently regulates over 200,000 registered food facilities, which I would suggest is just the baseline of our oversight. We also regulate importers of food and produce farms, and work with states to ensure that restaurants and retail food settings are safe. The scope and breadth of our oversight is vast, and continuously expanding. Which is why, now more than ever, we need a modern, regulatory infrastructure that can keep pace to protect public health. Therefore, I fully support the new vision that Dr. Califf has outlined for the Human Foods Program.

Under this new program, human food-related functions at FDA will be united under a new Deputy Commissioner. The reorganization will better align our work across the agency, remove redundancies, and enable the agency to oversee human food more efficiently and effectively. As part of the reorganization plans, the Commissioner has laid out his vision for a new Nutrition Center of Excellence, which would elevate and empower action on nutrition science, policy, and initiatives to reduce diet-related chronic diseases and improve health equity.

The Nutrition Center of Excellence will also house a new Office of Critical Foods, which will be tasked with leading a new strategic vision to enhance our oversight of infant formula and medical foods. Using our new Title 21 hiring authorities, we have already begun the process of filling leadership roles for this new office, but our budget request for fiscal year 24 will be key to getting that Office off the ground with solid footing and in executing the vision for the Center of Excellence.

Restructuring alone will not enable the agency to keep pace with our evolving food system. The Reagan-Udall Foundation's evaluation of the human foods program at FDA earlier this year observed, and I quote, "Relatively modest increases in federal budget authority, flat staffing levels, and lack of sustained and sufficient commitment to upgrading IT, contrasting with the rapidly changing food industry, have constricted the ability of the human foods program to carry out its mission efficiently and effectively." The FY23 budget provided us with more support than we have seen in a decade, but a one-time increase will not be enough.

We don't have to look much further than our consumer complaint and adverse event systems to see that these upgrades are needed. Each year we receive nearly 10,000 consumer complaints and adverse event reports regarding FDA-regulated foods and dietary supplements. Modernized upgrades to our IT systems will allow us to collect additional data with these reports, like pictures or UPC codes, and can help us to streamline and speed processing so that we can identify and address significant issues—like those we have experienced with infant formula—more quickly.

The FY24 budget request calls for $106.7 million in new funding for CFSAN, which would be a historic investment to strengthen the FDA's food safety and nutrition capacity. Being well-funded means we can better meet our mission while also addressing challenging events like those associated with the COVID-19 pandemic or infant formula recalls and shortages. While we have been able to navigate tough situations, it has often meant having to pivot staff away from routine work such as issuing guidance, drafting regulations, or monitoring other factors in the food supply. This new funding would help us to better meet our core mission and the public's expectation of our critical role in protecting public health.

The Reagan-Udall evaluation also found that investing in our program yields a tremendous return on investment. For example, our food safety budget in 2021 was $284 million but provided a total public health benefit valued at $3.1 billion. In addition, the CFSAN nutrition budget was $24 million in FY20–21, which contributed public health benefits valued at $2.8 billion. This means that for every $1 spent, we see a $119 return on investment through improved nutrition. These are numbers that directly impact families across the country, including yours and mine.

CLOSING

To close I will leave you with just a few parting thoughts.

The evolution of our food safety system is a story of challenge and opportunity. We will continue to be faced with new challenges, whether it be the discovery of new pathogens or chemicals that can impact the safety of our food or shifts in the way we produce food due to the impact of climate change on our environment. These challenges will stress the system, but science, innovation, and partnerships will—as they have before—create a pathway for advancements that will continue to allow us to protect public health. We can continue to overcome these challenges by working together. Each major transformation in our food safety system was the result of industry, academia, regulators, and consumer advocates working together. As we continue to plan for the implementation of a new, stronger, Human Foods Program, I trust that by working together we can create a regulatory system that will offer the greatest protection to our food supply in our nation's history.

I am humbled by all the work we have been able to accomplish together these last eight years and immensely thankful for the opportunity I was given to lead such an exceptional and dynamic Center. My time at FDA has been without question the highlight of my career. I am passing the baton to new leaders at FDA and remain confident that with continued support the future of the human foods program at FDA is equipped and ready to meet the challenges of tomorrow.

Thank you.