TESTIMONY

OF

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EVALUATING FDA HUMAN FOODS AND TOBACCO PROGRAMS

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Introduction

Chair Guthrie, Ranking Member Eshoo, and members of the Subcommittee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA or the Agency) new Human Foods Program (HFP) and our work to help ensure the safety of our food supply and to provide consumers access to science-based information on healthful food choices.

This is an exciting time to testify before this Committee.

On October 1, 2024, FDA will officially launch the new, unified HFP as part of the largest reorganization in FDA's recent history. While the United States benefits from one of the safest and most nutritious food supplies in the world, increasing complexities in our food systems and recent food safety challenges have highlighted the need for the Agency to change how we adapt and approach our responsibility to regulate 80 percent of the U.S. food supply. Just over two years ago, FDA Commissioner, Dr. Robert Califf requested that the Reagan-Udall Foundation for the FDA (the Foundation) convene a panel of independent experts to evaluate FDA's human foods program, to understand where we could strengthen our program and bolster FDA's role as a world leader in regulatory oversight of food.

I was honored to serve on the committee of experts evaluating FDA's regulatory structure for human foods and to work alongside others on the panel to develop recommendations[1] that would enable FDA to more efficiently and effectively carry out our public health mission.

This exposure to the FDA's inner workings, the Agency's strengths and challenges, along with my experience of over 30 years at the U.S. Environmental Protection Agency (EPA), has uniquely positioned me to drive the necessary changes for the HFP as the first Deputy Commissioner for Human Foods. In my first year in this role, I have drawn heavily on my time leading many efforts at the EPA, including the overhaul of our approach to toxicological assessments under the Toxic Substances Control Act (TSCA) and establishing a labeling program to help consumers make informed choices about the safety of everyday household cleaning products. I know firsthand that by working collaboratively with our stakeholders we are better positioned to meet our shared public health goals.

The new HFP is a major restructuring of our form to improve our function. Consistent with the recommendations FDA has received, the new program will improve communication throughout the Agency, streamline leadership decision making, and implement the processes and structures that support us in taking swift action. Importantly, our new organization is intentionally designed to centralize leadership and expertise and support a more consistent and systematic risk management approach focused on microbiological food safety, food chemical safety, and nutrition. Our work in the new HFP will advance our top strategic priorities of preventing foodborne illness; ensuring exposure to chemicals in foods is safe; and decreasing diet-related chronic disease through improved nutrition.

Through our prioritization and risk management approach we will zero in on those issues where intervention has the greatest opportunity for the prevention of disease and illness and for the promotion of wellness. By having clear strategic priorities, we will be better able to address

[1] https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

emerging and immediate potential health risks while engaging in our long-term work to prevent illness and disease through research, initiatives, and regulatory actions.

Along with a renewed focus on accountability, we are well positioned to continue the improvements we have already made to bolster our oversight of the U.S. food supply and to implement the strategies and programs we have planned for the future. For example, the Agency has put in place protocols to ensure that signals of potential food safety situations, such as in consumer and whistleblower complaints, are coordinated, elevated, and addressed more quickly. We are also investing in technology across the Agency that will ensure information reported by external parties is centrally captured, accessible across the Agency, and more easily tracked. FDA has made considerable progress and we will continue to do so as we move into the implementation of our new program.

Our program has an enormous responsibility and the implementation of the HFP is a vital step toward fulling that responsibility. The new HFP streamlines communication, budget authority, and decision making, and better supports alignment of our policy, programmatic, and inspectional activities. Along with a renewed focus on accountability, we are well positioned to continue the improvements we have already made to bolster our oversight of infant formula and to implement the strategies and programs we have planned for the future.

Even as FDA continues to make progress, the reality is that we require new or stronger authorities to carry out our mission. In addition to new authorities, our program's remit is enormous and increasingly complex. New tools, investments, and strategies will be critical to empower the Agency to meet its mission. The Fiscal Year (FY) 2025 President's Budget[2] recognizes FDA's transformative vision for the HFP, providing targeted investments in activities that will protect and promote a safe and nutritious U.S. food supply.

I am leading the new HFP with the support, expertise, and commitment of thousands of federal workers. Ultimately our goal is that all people in this country can live better, longer, and more productive lives—free of the burden of preventable food and diet-related illness, disease, and death. We cannot achieve this goal alone, and I am firmly committed to working collaboratively with this Committee and Congress, with our regulatory partners, and with all of those who have a stake in the safety and nutrition of the U.S. food supply, to tackle head-on the challenges we face in our increasingly complex food system.

Strategic Priority I: Preventing Foodborne Illness through Advancements in Microbiological Food Safety

When we worked with this Committee to enact the FDA Food Safety Modernization Act (FSMA), the central tenet was building a food safety system centered on preventing foodborne diseases. One of FDA's most important actions has been to improve the tools we use to surveil the food supply to identify risks early, and to work collaboratively with industry, academia, and federal and state, local, tribal and territorial partners to identify and implement prevention and mitigation measures. In 2022, we launched the development of a series of 'prevention strategies' —based on data that identify the most effective risk management interventions to address food

[2] https://www.fda.gov/about-fda/reports/budgets

safety risks associated with a particular food. Most recently we have published prevention strategies, that include fact sheets and resources for manufacturers, on Soft Fresh Queso Fresco-Type Cheese,[3] Bulb Onions,[4] and Powdered Infant Formula[5] in response to repeated foodborne outbreaks over the years associated with these commodities.

Food safety is a shared responsibility, and collaboration with industry and external stakeholders is paramount during emerging or active food safety situations. Industry is a key partner in preventing foodborne illness, including identifying opportunities for best practices for enhanced food safety prior to outbreaks and illness. Our commitment to increased transparency and engagement is enormously valuable to our prevention strategies. We have seen promising progress on data sharing initiatives and we have engaged with industry to inform our prevention strategies.

The need for this partnership and an example for its success has been highlighted in the recent outbreak of Highly Pathogenic Avian Influenza (HPAI) in dairy cattle. From the first identified illnesses by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service, to on-going efforts by FDA, states, industry, and our U.S. government partners, it has been essential to work with updated and complete information as we collaborate to address new developments.

Ensuring the safety of the U.S. food supply is among our top priorities, and as we implement the HFP reorganization, we will continue to collaborate closely with others to advance prevention strategies that reduce the burden of pathogen-related foodborne illness.

Increasing oversight of infant formula industry

As part of the work the Agency did to unify and strengthen the HFP, we took a close look at those issues that were highlighted during the infant formula shortage in 2022. In addition to the Foundation's evaluation of the program overall, FDA completed and publicly released our own internal review of the Agency's infant formula response,[6] as well as carefully reviewed the findings of the HHS Office of the Inspector General's (HHS OIG) audit.[7]

The safety of infant formula is a long-term priority for the Agency. The Food and Drug Omnibus Reform Act (FDORA) established a new Office of Critical Foods, which is responsible for overseeing infant formula and medical foods. Under this new office, which will be part of the Nutrition Center of Excellence, we will continue to advance our work in this area by

[3] https://www.fda.gov/food/new-era-smarter-food-safety/summary-fdas-strategy-help-prevent-listeriosis-outbreaks-associated-soft-fresh-queso-fresco-type
[4] https://www.fda.gov/food/new-era-smarter-food-safety/summary-fdas-strategy-help-prevent-salmonellosis-outbreaks-associated-bulb-onions#:~:text=Increasing%20strategic%20and%20targeted%20sample,the%20State%20of%20Chihuahua%2C%20Mexico.
[5] https://www.fda.gov/food/new-era-smarter-food-safety/summary-fdas-strategy-help-prevent-cronobacter-sakazakii-illnesses-associated-consumption-powdered
[6] https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/progress-update-fdas-evaluation-infant-formula-response
[7] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000708.asp

consolidating many of the infant formula oversight functions that are currently spread throughout the foods program, allowing us to provide more focused oversight of this vital commodity.

To ensure the expertise and continuity required for inspections, we have established a dedicated cadre for conducting infant formula inspections and provided our investigators with specialized training based on current science. Further, we have updated our infant formula compliance program for FDA investigators, including instructions for environmental sampling when conducting an inspection of a powdered infant formula manufacturer.

We have also implemented a combination of strategies to prevent contamination of infant formula and our efforts to support market sustainability have resulted in increased safety and availability of this critical food. For example, we called on industry to improve the microbiological safety of powdered infant formula in a letter[8] highlighting science-based prevention strategies for those areas where our inspections, along with input from stakeholders, highlighted gaps in implementing safety standards. In addition, we are conducting more research on *Cronobacter* so that we can provide additional science-based guidance to industry to help control for this specific pathogen in the manufacturing environment. These efforts, combined with elevating *Cronobacter* to a nationally reportable disease, will help to increase our scientific understanding and help to tailor our prevention efforts moving forward.

We are encouraged by the in-stock rates of infant formula that, since early 2023, have held steady at around 85 percent, we know the supply is still highly concentrated in a small number of manufacturers. We have also been focused on improving diversification of the infant formula supply, and, since 2023, we have worked with manufacturers of 19 new formulas under the transition plan, two of which have already successfully transitioned to full compliance with FDA requirements We also continue to prioritize review of new infant formula submissions, and our work with new manufacturers to help them come into compliance with all applicable requirements.

Just over a year ago in March 2023, we issued our as required under FDORA and are now evaluating the findings of a report[9] we commissioned from the National Academy of Science, Engineering and Medicine on challenges in supply, market competition, and regulation—which will inform our long-term national strategy to increase the resiliency of the U.S. infant formula supply.

Our efforts to date to significantly improve the safety of infant formula will result in safer products, but there is more that must be done. In the FY 2025 President's Budget, we requested authority to ensure the safety of foods by, among other things, establishing binding contamination limits in foods via an administrative order process, and requiring infant formula manufacturers to report to FDA positive test results for pathogens regardless of whether the product has left the facility. We have also proposed strengthening the shortage notification provision provided by Congress for critical foods by clarifying the information that is required to

[8] https://www.fda.gov/media/166044/download?attachment

[9] https://www.nationalacademies.org/our-work/challenges-in-supply-market-competition-and-regulation-of-infant-formula-in-the-united-states

be reported by manufacturers when there is a meaningful disruption in the U.S. supply as well as extending the notification requirement to other nutritionally important food products.

Striving to Optimize Oversight under FSMA to Manage Increasing Demands

FSMA directed FDA to inspect tens of thousands of domestic manufacturing facilities at 3- and 5-year risk-based frequencies. This translates to approximately 5,500 high-risk and 11,200 non-high-risk inspections annually. Given resource limitations, the complexity of preventive controls inspections under FSMA, and reduced inspectional capacity during the COVID-19 pandemic, it has been challenging to meet this timeline. FSMA directed FDA to significantly expand its cadre of food inspectors to 5,000 to accomplish the increased inspections required to fulfill the mandates; however, funding has never been provided to support that level of increased staffing.

The oversight of imported food is subject to similar resource constraints. The volume of food imports grows steadily each year, and now amounts to around 20 million shipments annually, from over 200 countries.

FDA has only been able to inspect a fraction of foreign and domestic food manufacturing facilities. FDA is optimizing deployment of its resources to meet Congress's charge to better protect the food Americans eat, but we need the necessary resources from Congress, as requested in the FY 2025 Budget, to fulfill that mission.

Strategic Priority II: Strengthening the Oversight of Food Chemical Safety

FDA's Regulatory Authority for Assessing Chemicals and Actions to Protect Public Health

More than 10,000 chemicals are authorized for use in food or in contact with food in the United States. The food industry is responsible for ensuring the safety of the chemicals they use in foods, including food packaging and other food contact materials, and FDA's ability to assess the safety of these ingredients in the food supply is both reliant on and limited by the availability of this safety data. The proliferation of new food ingredients, food contact materials, and production techniques has not only increased the workload in this area but has also increased the complexity of the work.

By statute, any substance that will be added to food is subject to premarket approval by FDA unless it is generally recognized, among qualified experts, to be safe under the conditions of its intended use. Therefore, industry is required to submit a premarket safety assessment of any new food or color additive intended for use in food, including food contact materials. Moreover, there are generally no post-market obligations to submit safety assessments to FDA or for FDA to conduct post market safety assessments. If FDA has concerns about a particular chemical, we must either conduct studies ourselves, rely on studies conducted in academia or by regulatory counterparts, or ask industry to volunteer data. This is a significant barrier for critical post-market safety work. Last year, we committed to the review of 21 food ingredients, food contaminants and food contact substances. Over the years, we have seen an increase in the need for safety reviews—either through petition requests or new data coming to light—and, as such, we see the clear need to build a systematic process for conducting post-market assessments of chemicals in food. Post-market assessments include ingredients considered generally recognized as safe (GRAS), food additives, color additives, food contact substances, and contaminants. A

systematic process will allow us to better prioritize safety reviews based on risk and will provide transparency on what is under review with the resources available. This effort is a cornerstone of our commitment to enhancing our focus on food chemical safety.

Congress, state legislatures, and stakeholders have made clear that chemical safety is a priority we need to address. We agree, and we have made food chemical safety one of our top priorities. However, there are also important gaps that need to be addressed as we undertake the work to strengthen our food chemical safety activities. Ready access to safety information and consumer exposure data on chemicals in need of review would help us conduct faster and more robust safety evaluations and reassessments. Access to this data would allow FDA to take any necessary regulatory actions in a timely manner to protect consumers and help ensure food safety.

FDA is committed to leading the way on food chemical and additive safety. Working with our available resources, under the HFP, we will have a newly dedicated office to evaluate our original determinations of safety against the best available science. In just a few weeks, FDA will host a public meeting to share the Agency's thoughts on the framework for this systematic process for post-market assessment of chemicals in food and hear stakeholder perspectives on our thinking. This information will help inform our next steps and further the development of the process and our post-market chemical safety program.

FDA's Continuing Commitment to Reduce Exposure to Chemical Contaminants in Food

Another area of concern is the presence of contaminants—such as lead, cadmium, and arsenic—in food, especially in food marketed for consumption by infants and young children. While most of FDA's testing for contaminants has consistently shown that levels in foods are not an immediate health risk, reducing exposure to these chemicals in the food supply is a priority for the agency given the potential associated health effects, particularly for the very young.

We continue to advance our work under our *Closer to Zero* plan to reduce exposures to heavy metals in foods commonly consumed by babies and young children. This includes finalizing action levels for lead in foods and juice commonly consumed by babies and young children, and we are actively working on proposing action levels for arsenic and cadmium. These heavy metals can be introduced during processing, but they can also be taken up from the environment, so we are collaborating with USDA to tackle the issue at the root by identifying solutions and techniques that can be employed as crops grow to prevent the uptake of heavy metals.

Seafood represents the primary (and predominant) source of dietary exposure to methyl mercury. FDA, along with our governmental co-sponsors, worked with the National Academies of Sciences, Engineering, & Medicine (NASEM) on the "Role of Seafood Consumption in Child Growth & Development," which concluded a few months ago. FDA will use this work to inform whether and how to update the FDA/EPA Fish Advice.

Throughout this work, it is crucial that we are very intentional about how we communicate the risk surrounding a potential contaminant in food. Children with good nutrition are better protected against heavy metal exposure—since nutrients, such as iron and zinc, can reduce the physiological impact of certain contaminants. Because the potential impact of heavy metal exposure is mitigated by foods that supply vital nutrients, as we work with industry and our

regulatory partners to reduce exposure to these contaminants, we will also provide consumers with information on the role of nutrition in the health and development of children.

Lead in Cinnamon Applesauce

In October 2023, FDA in collaboration with state and local partners, initiated an investigation in response to reports of children with elevated blood lead levels. This investigation identified certain cinnamon applesauce products as the source.

Within a few days of learning of the extremely high levels of lead in certain imported cinnamon applesauce products, FDA worked with state and territorial officials, the manufacturer, and our Ecuadorian regulatory counterparts—the product's country of origin—to implement a recall of the product and to collect data and information to quickly share product contamination information with the public. States assisted in the identification of the hazard by collecting additional information to investigate the source of lead contamination, in the removal of products from store shelves when the recall was not sufficiently effectuated by a retailer of the recalled products and increasing screening of applesauce and ground cinnamon products. Based on current information, the FDA believes that this contamination was likely the result of economic adulteration.

In response to finding the elevated levels of lead in the cinnamon applesauce, FDA took additional steps to further ensure that cinnamon available at retail locations meets FDA safety standards. We are working with our state partners to test cinnamon for contamination and, where necessary, to then remove adulterated products with elevated levels of lead from the market. This work resulted in a recall of several ground cinnamon products. We also sent a warning letter to the cinnamon applesauce manufacturer for causing the introduction of adulterated food into interstate commerce and for failing to comply with the FSMA preventive controls regulation prior to the recall by not appropriately identifying and evaluating a known or reasonably foreseeable hazard—in this case, lead—to determine whether that hazard required a preventive control.

This case highlights the importance of ensuring imported products meet FDA's standards for regulatory compliance. Imported products represent about 15 percent of the U.S. food supply — with some segments, such as produce and seafood, having a much greater share. The HFP reorganization will better align the inspectorate and FDA to improve its strategic oversight of imported food, including comprehensive utilization and coordinated deployment of the many tools afforded by FSMA.

When contamination events happen, whether related to microbial or chemical contamination, FDA relies on partnerships with state, local, and U.S. territorial entities to address the situation effectively and efficiently. There is, however, more that can be done to strengthen our partnerships. Currently, we are restricted by statute from sharing certain nonpublic information with regulatory partners related to FDA-regulated products. This is further limited by some regulatory partners' disclosure laws. These limitations can sometimes prevent FDA from taking swift action to protect supply chain integrity. The FY 2025 President's budget requests expanding information disclosure authority for FDA, which would allow FDA to share regulated commodity information seamlessly and in real time with state, local, and U.S. territorial entities.

Advancing Dietary Supplement Safety

The dietary supplement market has grown more than ten times the size it was when the Dietary Supplement Health and Education Act (DSHEA) was enacted in 1994. Estimates[10] indicate that three out of four Americans use dietary supplements daily. FDA authorities and resources have not kept up with this quickly expanding marketplace. There are virtually no barriers to entry to the dietary supplement market. Bad actors have continued to exploit the halo created by the quality work of legitimate manufacturers by continuing to distribute and sell dangerous products that put customers at risk. As requested in the FY25 President's budget, we are committed to working with Congress on authority to require dietary supplement manufacturers to list their products, including the ingredients in their products, with FDA. FDA is confident that an improved framework to regulate dietary supplements would bring significant benefit to public health by promoting consumer safety, allowing FDA to quickly identify dangerous or illegal products on the market to take appropriate action, and increasing regulatory transparency.

Strategic Priority III: Decreasing Diet-related Chronic Disease through Improved Nutrition

Each year, significantly more Americans are sickened or die from diet-related diseases than from foodborne illness or otherwise contaminated food. The Centers for Disease Control and Prevention (CDC) estimates that approximately 3,000 people die from foodborne illness annually, while 804,009 die from heart disease and stroke, 608,371 from cancer, and 101,209 from diabetes.[11] Racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas disproportionately experience these diet-related chronic diseases. The National Strategy on Hunger, Nutrition, and Health[12] highlights the role of nutrition in overall health and broadly seeks to ensure coordination and collaboration across the Federal Government, the private sector; state, tribal, local, and territory governments; academia; and nonprofit and community groups to help promote public health.

The cost of diet-related disease is estimated at more than $1 trillion annually. FDA's Center for Food Safety and Applied Nutrition's (CFSAN) programs provide a strong return on investment (ROI), but the ROI for every dollar invested in our work on nutrition is approximately 10 times that for food safety[13]. Given the prevalence of diet-related chronic disease in this country, relatively modest investments can have broad public health impacts.

FDA has a number of important nutrition initiatives underway, which will soon be led by FDA's Nutrition Center of Excellence in the HFP. We are committed to continuing to find new ways to help consumers build healthy eating patterns, including through improved information about the foods they eat.

[10] https://www.crnusa.org/newsroom/three-quarters-americans-take-dietary-supplements-most-users-agree-they-are-essential
[11] https://www.cdc.gov/nchs/fastats/deaths.htm
[12] https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf
[13] https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

First, we are very encouraged by efforts to help reduce Americans' sodium intake and thus improve health outcomes. Excess sodium increases risk for hypertension, heart disease and stroke – the leading causes of death and disease in the U.S. Before 2021, average sodium intake by Americans was almost 50 percent more than the daily limit recommended to reduce risk of disease. Following examples that have shown success in other countries, FDA issued final guidance for industry with voluntary sodium reduction targets for 163 categories of processed, packaged and prepared food – the first phase of a data-driven, step-wise approach to help reduce sodium across the food supply. Preliminary data from 2022 show that about 40 percent of these targets had been reached or were very close; an encouraging sign of progress. And building on that first set of targets, FDA issued a new draft guidance[14] with a second set of lower targets, which is now available for public comment.

FDA is also working to finalize updates to the definition of the "healthy" nutrient content claim to reflect current nutrition science. The definitions for this voluntary claim were established in 1994, and updates will allow better alignment with today's Dietary Guidelines for Americans and our updated Nutrition Facts label. Claims like "healthy" on food labels can convey information to busy shoppers with a quick glance and are important to helping consumers make more informed food choices.

Front-of-package (FOP) labeling can also help Americans quickly and easily identify foods that support a healthy diet. Nutrition information is typically detailed in the Nutrition Facts on the back of a food package. FOP labeling would complement these Nutrition Facts by displaying simplified information right on the front of the package. To undertake FOP labeling development, FDA engaged in an extensive scientific literature review, considered consumer research to determine which types of labels are the clearest to consumers, examined the experiences of other countries that have implemented FOP labels, and carefully reviewed feedback from a wide range of interested parties. We have posted our scientific literature review on our website and look forward to sharing the additional results of our research that will inform our proposed rule.

Finally, FDA is closely following the science on ultra processed foods (UPF). While there is currently no single definition for these foods, scientific evidence shows an association between the intake of foods that may be considered UPF and diet-related diseases and poor health outcomes, but there are still many gaps in our understanding. We recently announced a joint initiative with NIH to host a scientific workshop in December 2024 on nutrition regulatory science, including UPF. We plan to discuss key priorities and critical next steps for research in this area. Additional research is needed to understand the exact mechanisms of these foods' impacts on health to help determine causal links.

Conclusion

A safe and nutritious food supply is among our country's highest priorities. While we enjoy one of the safest food supplies in the world, many Americans have lost trust in our food supply and in FDA's oversight. We are committed to increasing public trust by delivering impactful

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2

regulations and initiatives that support our priorities of preventing foodborne illness, ensuring exposure to chemicals in foods is safe, and reducing diet-related chronic disease through nutrition. Trust is also built on communication. As we move forward, it is essential that FDA is more transparent about the challenges we and the food supply face and our work to address those challenges.

FDA is committed to sharing information early and often with the public. That means providing greater visibility into our approach and actions, even when we do not have all the answers; sharing where we as an agency should be held accountable, where there is shared responsibility, and when the responsibility lies elsewhere. In addition, as we move into our new HFP, we will make our communications clearer and look for opportunities to communicate outside of specific food safety events or the rollout of regulations to industry, when doing so will help the public better understand the complexity of our food supply and also the robustness of our food safety system.

Before I close, I want to reiterate my sincere commitment to FDA's public health mission. We at FDA shoulder an enormous responsibility, but we do not act alone. The food system is a shared responsibility across government and industry, based on the mutual understanding that it is in everyone's best interests for the U.S. food supply to be safe and nutritious. Together with others that have a stake in the U.S. food supply, we have made tremendous progress in our food safety and nutrition goals. The HFP represents a tremendous step forward. I am confident that with Congress' support to ensure we have the authority and resources we need, we will be better able to carry out our mandate. We will continue to keep this committee informed of our progress and significant developments.

Thank you for the opportunity to testify today. I will be happy to answer your questions.