TESTIMONY

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"FDA OVERSIGHT PART II: RESPONSIBILITY FOR THE INFANT FORMULA SHORTAGE"

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INTRODUCTION

Chairwoman McClain, Chairman Comer, Ranking Member Porter, Ranking Member Raskin, and members of the Subcommittee, thank you for inviting me to testify about the Food and Drug Administration's (FDA's or the Agency's) work on infant formula. FDA is committed to doing everything we can within our authorities to help avoid future supply shortages and ensure parents and caregivers have access to an abundant supply of safe and nutritious infant formula. To that end, we are taking significant actions to continually strengthen our own operations and working across the government to optimize supply chains and access, while holding industry accountable.

BACKGROUND

The United States has one of the safest food supplies in the world. Most people in the United States eat their food without having to give much thought to safety and without encountering any safety issues, which reflects the effectiveness of our current food safety system. Indeed, independent experts have recognized the U.S. food supply as being among the safest in the world. For example, *The Economist* publishes an annual report that measures the Global Food Security Index (GFSI), which considers food affordability, availability, quality and safety, and sustainability and adaptation, across 113 countries. In the 2022 GFSI Report, the United States received its highest ranking for the "food quality and safety" category—ranking third in the world in this category behind Canada and Denmark.[1] The report states this ranking is supported by the United States' score of 100 percent on several indicators in this category, including food safety and nutritional standards.[2] Further, the report notes that the United States has moved up 25 positions for the food safety indicator since 2012 and is now tied for first.

At the same time, we recognize that our system is not perfect. FDA is an important part of the food quality and safety system of the United States, as we regulate about 78 percent of the food supply. Our job as regulators is to follow the science, set standards, and then verify that industry is doing their part to meet those standards. Other key parts of the nation's food quality and safety system include the producers and manufacturers of our food. They are on the frontline, with the ultimate responsibility of safeguarding the safety, quality and availability of our nation's food. As a nation, we all suffer when they do not meet that responsibility, as illustrated by last year's infant formula recall and shutdown of Abbott Nutrition's Sturgis, Michigan facility. These actions were taken following several reports of *Cronobacter* infections in infants who had reportedly consumed powdered infant formula from that facility, a confidential disclosure document from a whistleblower who worked there, and egregious findings from an FDA inspection.

Shortly after the voluntary recall by Abbott and associated Sturgis facility shutdown, parents and caregivers began experiencing shortages of infant formula products. FDA worked with Abbott, other infant formula manufacturers, and federal partners to address the shortage. Since 2022, FDA has engaged in several actions to address the issues identified and distill key lessons learned, as outlined in more detail below. In addition, FDA engaged in two reviews of the

[1] *See* "United States," *Global Food Security Index 2022*, ECONOMIST IMPACT, available at https://impact.economist.com/sustainability/project/food-security-index/explore-countries/united-states.
[2] *See id*.

Agency's infant formula response: an internal review of the Abbott recall and a comprehensive external evaluation of the Human Foods Program by the Reagan-Udall Foundation (RUF). Based on these reviews and the lessons learned from 2022, the Agency is committed to taking actions to strengthen our own operations, to work with our federal partners to optimize supply chains and access to safe and nutritious infant formula, and to hold industry accountable to ensure a safe and reliable infant formula supply.

LESSONS LEARNED

FDA has reflected on the Abbott recall and infant formula shortage, and we would like to share with the Subcommittee some of the key lessons learned.

First, there are additional actions that the infant formula industry needs to take to ensure the safety of the food they produce. FDA has reviewed conditions during recent inspections of powdered infant formula manufacturers and has identified numerous areas for improvement across the industry. We outlined these areas in a March 8, 2023, letter to infant formula manufacturers, packers, distributors, exporters, importers, and retailers, which was a call to action for all members of the infant formula industry to help better protect our most vulnerable population. Among other things, FDA is urging industry to evaluate established systems of production and in-process controls and to ensure that appropriate controls are implemented at any point, step, or stage in the production process where control is necessary to prevent adulteration of infant formula.[3] While FDA has a regulatory role in setting safety standards and verifying compliance, industry bears the responsibility to produce to the highest possible standards and maintain their facilities so recalls and shutdowns are minimized.

Second, the U.S. infant formula market is concentrated, and the high concentration in the infant formula industry means any interruption could have outsized market effects. There are only three major domestic producers of infant formula—only two of which produce specialized medical formulas. This means that any potential disruption—whether it be a recall or a natural disaster—can, and did, place outsized stress on the infant formula supply. This is why the first lesson learned is so critical: one important way to prevent future shortages in such a concentrated industry is through a stronger focus on food safety.

Third, the Abbott recall was not the only contributor to the formula shortage. The infant formula supply was already under strain due to labor and supply chain challenges associated with the COVID-19 pandemic and the conflict in Ukraine, which decreased access to crucial formula ingredients. The situation was also exacerbated by a lack of meaningful risk management plans from manufacturers to prepare for unforeseen manufacturing or supply chain disruptions, often making it difficult or impossible to switch production of specific formulas to different lines or plants in the near-term to respond to these disruptions. Furthermore, lower volume and less variety of formula on store shelves contributed to consumer purchasing behavior, which can be driven by media exposure. Specifically, with regard to the infant formula shortage, there was a

[3] *See* "March 8, 2023, Letter to Infant Formula Manufacturers, Packers, Distributors, Exporters, Importers, and Retailers," FOOD AND DRUG ADMINISTRATION, available at https://www.fda.gov/media/166044/download.

large spike in infant formula purchases which peaked in May 2022 and contributed to increased draw down of formula inventories and further depleted product that was in the supply chain.[4]

Fourth, extensive data gaps surrounding *Cronobacter* and associated infections exist, including epidemiology, genomics, and prevalence of contamination in varying environments. This is largely due to the fact that the vast majority of states do not require *Cronobacter* infection to be reported to state health departments. Also, *Cronobacter* infection is not a nationally notifiable condition unlike many illnesses caused by foodborne pathogens, meaning that states are also not reporting most cases to the Centers for Disease Control and Prevention (CDC). CDC and FDA do receive some notifications of *Cronobacter* infection outside of the process used for most other foodborne pathogens that are nationally notifiable. Further, *Cronobacter* bacteria are commonly found in a number of environments, including in homes, and since infections are seemingly rare, the source of infections is not well understood. With limited reporting of an infection that is seemingly rare, public health agencies have extremely limited data in libraries of genomic sequences of these pathogens compared with foodborne pathogens like *Salmonella*. Robust genomic data libraries are needed to maximize the ability to definitively link clinical samples to their source and to identify repeat sources of clinical illnesses.

Finally, FDA's internal evaluation of agency activities and decision-making, as well as the external, independent evaluation of FDA's Human Foods Program convened by the RUF, highlight the need for operational improvements within FDA. We support the findings of these evaluations and are actively working to implement their recommendations.

PATH FORWARD

FDA Actions

FDA is committed to doing everything within our authorities to ensure the safety and availability of infant formula. For instance, when the infant formula shortage became apparent in 2022, FDA sought to provide relief by enabling available, safe, and nutritious products to enter the U.S. market by temporarily exercising enforcement discretion, on a case-by-case basis, for certain infant formula requirements.[5] Twelve manufacturers brought their infant formula products into the U.S. market under this flexibility.[6] In September 2022, FDA issued an Infant Formula Transition Plan guidance that outlines a path for interested firms marketing products in the United States under the exercise of enforcement discretion. The path outlined in the guidance aims to bring those products into compliance with U.S. requirements to facilitate longer-term

[4] *See* "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market," FOOD AND DRUG ADMINISTRATION, pg. 5, available at https://www.fda.gov/media/166520/download.
[5] *See* "Guidance for Industry: Infant Formula Enforcement Discretion Policy," FOOD AND DRUG ADMINISTRATION, May 2022, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy.
[6] *See* "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," FOOD AND DRUG ADMINISTRATION, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

availability and help diversify manufacturers providing products in the U.S. market.[7] As a result, the number of manufacturers providing formula to the U.S. market has doubled. These flexibilities, combined with increased production from existing manufacturers, have resulted in in-stock rates returning to levels that exceed the levels before the recall.[8]

We have also made many operational improvements at FDA in response to recommendations in the internal review and the RUF report. To highlight a few since the Abbott recall, FDA has:

- Engaged in a broad, Agency-wide effort to reorganize and strengthen the Human Foods Program;
- Revised the internal consumer complaint procedure to strengthen the escalation process, thus better defining when certain consumer complaints need to be escalated to the most senior officials;
- Expanded and significantly improved a required infant formula training course for investigators to ensure every infant formula inspection is robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process;
- Initiated hiring for key positions to support the new Office of Critical Foods that is required to be established under the Food and Drug Omnibus Reform Act, including a Chief Critical Foods Officer and a critical foods investigator cadre specializing in infant formula and medical foods using recently expanded hiring authorities under the 21st Century Cures Act;
- Met our infant formula inspectional targets, including inspecting all infant formula facilities, both domestic and foreign, annually;
- Strengthened our risk-based approach to the timing and periodicity of infant formula facility inspections, helping to minimize any possible disruptions to the supply chain; and
- Strengthened our compliance oversight by holding more regulatory meetings, inspecting facilities at greater frequencies, conducting more environmental and product testing during those inspections, adding more expert analysis to the complaint review process, and enhancing our review of firms' sanitation records, resulting in smaller, more targeted recalls.

We are also committed to advancing the science of *Cronobacter sakazakii*. On November 15, 2022, FDA published an outline of our Strategy to Help Prevent *Cronobacter sakazakii* Illnesses Associated with Consumption of Powdered Infant Formula to explore options for strengthening food safety throughout the product's lifecycle. This prevention strategy is intended to help limit or prevent contamination, recalls, and any possible illnesses associated with adulterated powdered infant formula.[9]

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[7] *See* "Guidance for Industry: Infant Formula Transition Plan for Exercise of Enforcement Discretion," FOOD AND DRUG ADMINISTRATION, Sept. 2022, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-transition-plan-exercise-enforcement-discretion.

[8] *See supra* n.4.

[9] *See* "Outline of FDA's Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula," FOOD AND DRUG ADMINISTRATION, available at https://www.fda.gov/food/new-era-smarter-food-safety/outline-fdas-strategy-help-prevent-cronobacter-sakazakii-illnesses-associated-consumption-powdered.

Since February 2022, the Agency has had ongoing and extensive engagement with the infant formula industry to identify and implement opportunities to strengthen preventive control practices and engage on the development and refinement of the prevention strategy moving forward. FDA food safety experts have engaged with industry, state, international, and other partners to explore environmental factors that may contribute to contamination in facilities; review issues related to specific foodborne hazards to identify potential mitigation measures or knowledge gaps; review regulations to identify provisions that may be strengthened; identify prevention measures that can be taken to reduce future incidences of foodborne illness; and expand our understanding of food safety issues and limit recurrences of underlying root causes responsible for contamination.

FDA food safety experts have advanced a charge through the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to gain scientific insight on possible industry and public health interventions to address *Cronobacter* infections associated with powdered infant formula. We have engaged with the Council of State and Territorial Epidemiologists (CSTE) and CDC about elevating reporting for *Cronobacter* infection in infants less than 1 year of age to a nationally notifiable disease.

We appreciate the resources and authorities recently granted to us by Congress in the Fiscal Year (FY) 2023 Consolidated Appropriations Act, including, as noted earlier, the creation of a new office for oversight, coordination, and facilitation of activities related to critical foods such as infant formula. We are working to implement new authorities and to leverage new resources, including requiring that manufacturers of infant formula notify FDA of discontinuances and interruptions in supply that could lead to a meaningful disruption of the supply chain, enhancing our IT systems to streamline review processes, and working with the National Academies of Sciences, Engineering, and Medicine on a study of the U.S. infant formula market and comparison with the European Union to examine and report on challenges in the supply, market competition, and regulation of infant formula in the United States. We are also actively improving our staffing through the hiring enhancements expanded under the 21st Century Cures Act and have hired additional infant formula staff. The Agency has also posted hiring announcements for several key positions, including for the Deputy Commissioner for Human Foods and the Chief Critical Foods Officer. Lastly, in March 2023, we released the Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market, which outlines immediate actions FDA took to address the infant formula shortage and details the Agency's plans for improving the resiliency of the infant formula supply, while noting multiple issues beyond the purview of FDA.[10]

We believe these actions are important steps forward, but additional resources and authorities are still needed to help FDA effectively prevent disruptions in the infant formula supply chain and ensure the safety of these products. Importantly, the President's FY 2024 Budget includes $21.4 million in new funding to improve surveillance and monitoring of adverse events; refine laboratory methods for detecting certain bacteria; and hire additional staff and experts to increase review capacity and stay current on innovation within the industry and the evolving science of infant nutrition. FDA is also seeking statutory changes through the FY 2024 budget request to require that, among other things, manufacturers report to FDA final product positive test results

[10] *See generally supra* n.4.

for relevant pathogens, conduct more frequent environmental monitoring in their facilities to identify relevant pathogens, and maintain the results of such testing for FDA inspection, either in person or remotely. Such changes would better enable FDA to work with firms in real time to resolve issues around product positive findings, provide much-needed data about contamination prevalence and pathogen genomics, and help ensure that infant formula is being produced under the safest possible conditions.

Industry Responsibility

I would like to emphasize that manufacturers of infant formula are in the best position to prevent future recalls and shortages. FDA does not make food; we set safety standards and verify that industry is meeting them. It is industry's responsibility to produce safe food and infant formula, and these companies must do more to prevent contamination of their facilities and products. Over the past year, while we have not encountered any other facilities that approach the conditions that we found in our January 2022 inspection of Abbott's Sturgis facility, we have seen certain common issues at other firms. In our March 8, 2023, letter to industry, we translated our findings into a call to action to urge manufacturers to consider ways to better control water in plants; perform more frequent environmental monitoring for *Cronobacter*; conduct the most robust root cause analyses possible; embrace the latest science and technology, including whole genome sequencing when food safety problems occur; and strengthen supply chain controls for health hazards. By encouraging industry to deal more aggressively with issues when they are smaller, we seek to avoid facing a situation like the one with Abbott where there was a large recall and months of facility shutdown to correct conditions.

As we make our own operational improvements outlined above, I want to be clear that the Agency intends to take more actions: more inspections; more actions toward industry aimed at improving the safety of their production practices; more communications like our letter to industry; and other targeted actions, so that if recalls become necessary, they are smaller. These actions are intended to recalibrate an entire industry, drive safety forward, and challenge industry to be more preventive.

However, there is no regulatory or enforcement action that we can take that will be faster or more effective than having a firm take the most appropriate food safety actions before product ever leaves their doors. That is why our March 8, 2023, letter to industry asked firms to voluntarily notify us as soon as they have detected a product positive—because that is how we can make a real change, working with firms before product leaves their facilities, obviating the need for a recall.

The need for our call to action is exemplified by events that occurred in the months prior to issuance. Two firms—Perrigo and Reckitt—released infant formula product into the market without fully evaluating the intervening sanitation breaks before and after the production of the implicated product.[11] If Perrigo and Reckitt had notified FDA at the time the positive samples

[11] *See e.g.,* "Perrigo Announces Voluntary Recall of Limited Quantity of Gerber® Good Start® SootheProTM Powdered Infant Formula," available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-announces-voluntary-recall-limited-quantity-gerberr-good-startr-sootheprotm-powdered-infant;

were found, we could have worked with the firms to assess the potential impact of the findings on other product and to affirm that the appropriate steps were being taken to ensure that no potentially contaminated product entered the market.

Thankfully, compared to the Abbott recall and the temporary closure of the Sturgis facility, the recent recalls were much narrower in scope, only impacting a few weeks of product with no additional facility closures. Nevertheless, these recalls highlight the need for industry to do more to find *Cronobacter* in the production environment through environmental monitoring, performing root cause analyses if product contamination occurs, and using that information to prevent future contamination.

We encourage Congress to also examine the current state of the infant formula industry, including voluntary compliance with actions to improve the safety of infant formula laid out in our letter to industry, efforts to improve and modernize manufacturing facilities and equipment, and compliance with the supply disruption notification requirements included in the FY 2023 Consolidated Appropriations Act.

All of Government Approach

FDA is a food safety agency and works to support improved nutrition, including for our youngest consumers. As such, the Agency has limited authority and ability to impact market concentration and monitor supply chains in real time in the way that industry can. We are working to do all we can within our authorities and with our partners to prevent future shortages, but recognize there are other factors affecting the market that are beyond our control. FDA continues to engage with agency partners and other stakeholders as they pursue efforts to improve the infant formula supply chain, and we are committed to providing support to any efforts which may benefit infant health and nutrition in the United States.

CLOSING

Last year's infant formula shortage reflected an industry failure to produce infant formula in a sanitary way, putting FDA in the difficult situation of recommending a voluntary recall of certain products, knowing that there would be supply chain ramifications. Avoiding this situation in the future will require not only the actions by FDA that I have highlighted in my testimony, but also action from the infant formula industry, other U.S. government (USG) partners, and Congress.

We appreciate our interactions with industry, stakeholders, and our USG partners, which have all contributed to improvements in the supply of safe infant formula. It will take continued cooperation among all the players and additional authorities and resources to help us achieve our vision for a modernized regulatory approach to infant formula safety, contributing to an infant formula supply with greater resilience to withstand any future challenges.

We look forward to working with you all to make this a reality.

"Reckitt Recalls Two Batches of Prosobee 12.9 oz Simply Plant Based Infant Formula Because of Possible Health Risk," available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/reckitt-recalls-two-batches-prosobee-129-oz-simply-plant-based-infant-formula-because-possible.