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Subcommittee on Health Care and Financial Services

On Causes and Effects of the Recent Powdered Infant Formula Shortage

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I want to thank Chairwoman McClain, Ranking Member Porter, and other committee members for inviting me as a witness on behalf of the Center for Science in the Public Interest (CSPI). CSPI is an over 50-year-old advocacy group that acts as a watchdog on food and health issues on behalf of US consumers. We do not accept donations from either government or industry. I am its President and Executive Director and a former Associate Commissioner at the Food and Drug Administration (FDA). While there I worked on drug shortages, with which the powdered infant formula shortage situation shares many similarities.

If we are to apportion blame for the now-resolving powdered infant formula crisis, we should start at the Abbott Nutrition plant in Sturgis, MI that produced the formula associated with an outbreak tied to four hospitalizations, including two deaths. It was there that infant formula contaminated with *Cronobacter sakazakii* was destroyed years before the outbreak without FDA being notified. It was there that, according to a whistleblower, there were lax cleaning practices, falsified records, and relevant information hidden from FDA inspectors. And it was there that

repeated FDA inspections revealed standing water, decaying dryers, failure to follow sanitary practices and, eventually, multiple environmental samples on medium- and high-care areas positive for *Cronobacter sakazakii*. While many questions remain about the outbreak, including how the *Cronobacter* may have entered the product (the outbreak strain was not one of those captured among the environmental strains FDA detected), these conditions, the increasing numbers of cases, and the deadly nature of *Cronobacter* infection left FDA with little choice but to insist that the company recall affected product.

If the U.S. infant formula market had been characterized by vigorous competition, the ensuing recall of Abbott formula would likely not have catapulted the market into a full-blown shortage, with parents having to go from shop to shop in search of dwindling supplies. But, prior to the recall, Abbott was estimated to control about 40% of the U.S. formula market, with about half of that coming from the Sturgis plant. Moreover, just four companies controlled about 90% of the domestic market. This left the U.S. with few alternative suppliers as the recall hit. Market concentration is one of the factors behind the ongoing drug shortage problem as well.

These conditions had existed for years, but it took the addition of a pandemic, with its own supply chain problems, Abbott Nutrition's deficient manufacturing practices, and, later, the war in Ukraine, to produce a full-blown shortage. Much of the FDA response was entirely appropriate and drew from its drug shortage experience. The agency convened an Agency-wide Incident Management Group, sought to identify alternative suppliers that could increase their production, exercised enforcement discretion on a case-by-case basis to allow product to reach

the market, facilitated the importation of products from abroad, and used a risk-benefit approach to release the most critical products, such as specialty metabolic and amino acid formulas. Other parts of the government contributed, too, including invoking the Defense Production Act to give formula suppliers priority access to critical ingredients and Operation Fly Formula in which the Department of Defense flew in formula from abroad.

In other respects, FDA's performance failed to live up to the high standards American consumers expect and deserve from the agency responsible for keeping our food supply safe. A whistleblower report went undelivered to senior agency staff for months and the agency took too long to schedule a repeat inspection of the Sturgis facility, even as *Cronobacter sakazakii* cases continued to be reported, thus delaying the resultant recall. The agency ordered an internal review of its own response but that report, while offering many strong recommendations, failed to provide a clear account of the events surrounding the recall or the mistakes made by agency officials.

Better prevention and management of future crises requires at least three elements: authority, funding, and an effective organizational structure. On the first, the Food and Drug Omnibus Reform Act provided FDA with some important additional authorities. It required formula and medical food manufacturers to develop a redundancy risk management plan to identify and evaluate risks to their supply. It mandated the creation of an Office of Critical Foods at FDA, which will manage the regulation of infant formula and medical foods. Perhaps most critically, it

required critical food manufacturers to notify FDA of interruptions in manufacturing likely to lead to meaningful disruptions in supply.

To better protect U.S. infants, the agency needs additional authorities. It should have the authority to require manufacturers to notify the agency of positive test results for relevant pathogens and to require more frequent environmental testing in production facilities. FDA should also have the authority to compel manufacturers to submit supply chain data, allowing the agency to analyze and respond to evolving issues. In addition, the Office of Critical Foods should be able to designate additional foods in a public health emergency and require notification of potential shortages related to those foods. Finally, the Council of State and Territorial Epidemiologists and Centers for Disease Control and Prevention should add *Cronobacter* to its list of nationally notifiable diseases and conditions and more states should join Minnesota and Michigan in including *Cronobacter* as a reportable disease.

Second, the food program at FDA requires more funding. Despite efforts by Congressional appropriators to boost funding for FDA's Center for Food Safety and Applied Nutrition (CFSAN) and to fully fund the Food Safety Modernization Act, rising costs have left the food program with a number of FTEs similar to what it had in 1978. Yet, not only has the food industry evolved dramatically since the 1970s, but FDA has been given more and more responsibilities from Congress, including broad new mandates over infant formula, dietary supplements, food labeling, and food safety.

The President's FY 2024 budget calls for $152 million in necessary new funding for FDA's foods program, which will allow the agency to hire 195 additional FTEs. This amount will include $64 million for Healthy and Safe Food for All, including support for improved oversight of infant formula, as well as $12 million for Nutrition, a critical funding stream as FDA seeks to establish a Center for Nutrition that will house its Office of Critical Foods. CSPI believes the number dedicated to nutrition in the Presidents' budget is in fact too small, and a figure closer to $24 million is needed to adequately fund this important work. Adequately funding the food program is critical to assuring an optimal infant formula supply. Such funding would support increased review capacity for infant formula premarket notifications, improving surveillance of formula-related adverse events, the development of laboratory methods for *Cronobacter sakazakii*, and more rapid review of inspection findings.

Finally, Americans deserve a food program that is transparent, effective, and accountable. The formula crisis laid bare the high level of dysfunction, breakdowns in communication and lack of clear lines of authority that characterized the agency's response. The reorganization plan announced by FDA Commissioner Robert Califf on January 31, 2023, is an important step on the path towards addressing these issues. This proposal follows from a report on the human foods program ordered by Dr. Califf and conducted by the Reagan-Udall Foundation. The proposed reorganization captures the spirit of the Reagan-Udall Foundation report, addresses the most critical problems identified, and does so in a manner that minimizes internal disruption:

- It elevates the food program to the Deputy Commissioner level (higher than any other FDA product Center).

- It dissolves a dysfunctional structure whereby three senior officials with authority over the human foods program all reported to the Commissioner and none had clear authority over the program.
- It clarifies the relationship between the human foods program and the Office of Regulatory Affairs, which inspects facilities. FDA has stated that "the Deputy Commissioner would set the priorities for field activities, direct how the resources will be used, what risks will be prioritized, and inspection strategy."
- It establishes a new Center for Excellence in Nutrition.
- It creates a new Office of Critical Foods.

While additional detail on exactly how these new structures will be operationalized is still necessary, this proposal is a significant step forward, creating a foods program led by a leader who is more empowered and accountable than any food program leader in recent history. The proposal lays a strong foundation for a newly enhanced food program at FDA, one that could ensure a safer and healthier food supply for us all. No mother, no father, should ever again face a desperate, store-by-store search for a product to nourish their infants.