



**Statement by
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Before the House Appropriations Subcommittee on Agriculture,
Rural Development, Food and Drug Administration, and Related Agencies
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Chairman Bishop, Dr. Harris, and Subcommittee members, thank you for the opportunity to appear before you today to discuss the factors that contributed to the current shortage of infant formula products in the U.S. and the impact it is having on American families and consumers.

Founded in 1936, Consumer Reports is an independent, non-profit and non-partisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, Consumer Reports advocates for laws and company practices that put consumers first. We are dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

FDA Governance and Performance

When a root cause analysis of the infant formula shortage is conducted, there will be several issues that will be scrutinized to determine what may have contributed to it. First and foremost, the actions of Abbott will need to be thoroughly reviewed, especially given the allegations outlined in the whistleblower report. Another factor to be studied is what impact did market concentration have in causing and exacerbating the infant formula crisis.

However, I would like to focus my testimony on the issue that is most relevant to this subcommittee's jurisdiction, and that is how the organizational structure, governance, and performance of the FDA food program impacted the infant formula recall.

A timeline of FDA's actions throughout the infant formula situation is attached as part of my testimony. As you will see, there are numerous questions that many of you in Congress have – and

many consumers have – about whether FDA performed its regulatory role effectively throughout this process. The evidence seems to suggest that the agency was too slow to act, failed to take this issue seriously, and was not forthcoming with information to parents and caregivers.

There are many stakeholder groups in the food policy community who believe that the infant formula crisis exposed a greater organizational structure and culture problem that has long existed at FDA. The infant formula crisis is merely one symptom of the overall problem and it is becoming increasingly clear that confidence in the FDA food program is eroding among consumers, industry, states and other stakeholder groups.

Fragmented Structure and Poor Governance

A significant reason for the diminished confidence is that the FDA food program has second class status within the agency and it has resulted in serious problems relating to its structure, governance and performance. Another primary reason is the FDA lacks a single, full-time, fully empowered expert leader of all aspects of the food program.

As you know, in recent decades, most FDA commissioners have been medical specialists who naturally focus on the programs impacting medical products. This leadership focus is certainly warranted considering the significant impact these programs have on public health, and the pandemic provides an example of this.

However, this usually results in intense competition for the commissioner's time and support, and focus on the food program is typically what has suffered under this dynamic. It has become virtually impossible for an FDA commissioner to possess the bandwidth to provide strategic leadership and management accountability to a large set of offices that regulate 80 percent of our food supply.

The lack of a single full-time leader affects all aspects of FDA's food program. In addition to the infant formula recall situation, the most significant is the effect of these issues on the implementation of the Food Safety Modernization Act (FSMA).

The success of FSMA depends on all major food program units – Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) – working together with state partners and with a common strategic direction, clear priorities, sound resource management, and internal accountability.

Success also requires transparency and robust engagement with consumers, industry, states, and other stakeholders. This is an element that is currently lacking with the FDA food program.

It is this fragmented structure and dynamic in the FDA food program that led an unprecedented coalition of consumer groups, industry trade associations and state and local regulators to [join together](#) recently to call on FDA to unify the food program under a deputy commissioner for foods. This position would have accountability to the commissioner and direct line authority over CFSAN, CVM, and the food-related components and operations of ORA. The coalition letter urged Commissioner Califf to immediately appoint someone with relevant and appropriate food credentials.

In addition to bringing focused leadership and accountability to the FDA's food program internally, a unified structure and a full-time senior expert leader would strengthen the program's standing externally and its ability to be in effective dialogue with its many stakeholders.

While typically many of the organizations that sent the letter may not agree on a number of issues, we do agree that there are serious problems within FDA's food program as it relates to organizational structure, governance and performance. We are aligned on the importance of the food program for protecting consumers and the ability of the food industry to operate effectively.

The fragmented structure and framework of the food program results in delays in making compliance decisions, including recalls. **Congress and the HHS Inspector General should investigate how FDA's fragmented structure and leadership affected its response to the Abbott infant formula problem.** The duplicative multiple compliance and recall groups within each part of the food program and the lack of unifying leadership often result in these delays and an overall lack of urgency.

FDA's Recent Appointment of a Food Program Overseer

Perhaps sensing this frustration, Dr. Califf recently announced the appointment of Dr. Janet Woodcock, FDA's principal deputy commissioner, to oversee and provide strategic counsel to seven parts of the FDA, including the major food program offices – CFSAN, CVM, and ORA.

This is another issue where consumer groups, industry and state and local regulators agree – this move is disappointing and needs reconsideration. Dr. Woodcock's extensive FDA career has focused on policies impacting medical products but she has no significant food policy credentials or standing in the food policy community. Appointing someone with a medical products background to oversee the food program is a solution that demonstrates the insular and dismissive approach that FDA too often takes toward the food program; it virtually ensures that the food program will continue to have second class status at FDA.

From an operational perspective, this new arrangement does not provide any food program integration, no full-time food expert leader, and no more genuine accountability for ORA, CFSAN and CVM than what exists now. Dr. Woodcock's new role goes far beyond the food program, including leadership of the commissioner's signature digital transformation initiative and oversight of all of FDA's budget and administrative program. It is not plausible that she or anyone would have the capacity to provide meaningful operational accountability or provide the sustained leadership required for the culture change that is needed in the food program.

FDA Resource Management and Food Program Funding Transparency

Another area of broad general agreement among stakeholder groups is the need for increased funding for the FDA food program to fulfill its mission. This subcommittee, and Congress in general, has provided considerable funding for the food program, especially for the implementation of the Food Safety Modernization Act (FSMA).

However, the current fragmentation of the food program and the lack of a single, empowered full-time expert leader has caused delays in the implementation of FSMA and questions about how funding is allocated within the FDA food program. This is an issue that Chairwoman DeLauro and Chairman Bishop have led in seeking these answers.

The essence of FSMA was calling for a shift in FDA's culture from one that reacted to food safety situations to one that focused on prevention. This is most critically needed in ORA, which is responsible for inspection and compliance, and receives approximately 70 percent of all FDA food program funding.

ORA is viewed historically as an insular organization that resists change, does not transparently share food resource and program data with food policy leaders in CFSAN and CVM. Under the current governance structure, ORA makes unilateral, unaccountable resource allocation decisions that have resulted in a large overhead structure. Only about a third of its resources are allocated to its food safety and compliance activity.

Despite the funding increases Congress has provided, ORA's domestic food inspections declined by 30 percent in the years following the enactment of FSMA and before the pandemic shutdown in March 2020. ORA also significantly reduced FDA-funded state inspections, which can be conducted at a lower cost.

ORA also has taken a dismissive approach to the inspection mandates under FSMA, viewing the mandates as the maximum number of domestic inspections and has used the mandates as an excuse to reduce inspection work by the states. An inspection task force led by Dr. Woodcock issued a report last year recommending that Congress consider repealing the FSMA inspection mandates. This would be a significant step backward.

The questions this subcommittee needs to be asking about ORA are: How does ORA allocate food program funding? and Is ORA making the best use of these resources?

The success of FSMA, and the FDA food program overall, requires a full-time, empowered, expert leader who can lead culture change and ensure accountability for resource management across ORA, CFSAN, and CVM.

We are fortunate to have a person with immense expertise and abilities like Dr. Califf serving as FDA Commissioner. His recent testimony about investing in technology to leverage oversight activities certainly make sense, especially given his recent background at Google.

However, investing in technologies, and implementing structural changes for improved governance are not mutually exclusive opportunities. We are not going to be able to algorithm our way out of the existing problems in the FDA food program. We also need structural and governance changes, stronger leadership and a higher priority that puts food in the FDA's front seat, along with drugs, devices, biologics, and tobacco.

Recommendations

Below are recommended actions that the subcommittee can take to address the systemic problems at FDA that exacerbated the infant formula recall situation.

- Investigate how FDA's fragmented structure and leadership affected its response to the Abbott infant formula problem.
- Urge Dr. Califf to reconsider the appointment of Dr. Woodcock to oversee seven parts of the FDA, including the major food program offices. Dr. Woodcock has no significant food policy credentials and no standing in the food stakeholder community. In addition, Dr. Woodcock was acting commissioner and overseeing the agency's actions when the Abbott infant formula situation developed into a crisis.
- Urge Dr. Califf to unify the food program under a deputy commissioner for foods that would have accountability to the commissioner and direct line authority over CFSAN, CVM, and the food-related operations of ORA. This unified structure and a full-time senior expert leader with relevant and appropriate food credentials would strengthen the program's standing externally.
- Continue the investigation initiated by Chairwoman DeLauro and Chairman Bishop seeking detailed answers on how ORA allocates food program funding to determine whether ORA is making the best use of these resources.

Thank you for the opportunity to testify today. I look forward to any questions.

Timeline of FDA Actions on Infant Formula Situation

- **September 2019:** FDA detects *Cronobacter* in Abbott's Sturgis facility, and also [found](#) it had failed to test a representative sample for Salmonella at the final stage of production cycle.
- **September 2021:** FDA [learns](#) that a Minnesota infant had been hospitalized for three weeks with *Cronobacter sakazakii*, and that the infant had consumed powdered infant formula manufactured by Abbott.
- **September 2021:** The same week that the FDA learned about the Minnesota case, the agency [conducts](#) an inspection of Abbott's Sturgis facility. However, it is not conclusive whether this was a routine inspection or a response to the Minnesota case.
- **October 2021:** FDA [receives](#) a report from a whistleblower that outlines allegations of wrongdoing at the Sturgis facility, including: falsification of records; releasing untested infant formula; hiding information from the FDA; and lax sanitation practices. The report was sent to principal deputy commissioner Dr. Janet Woodcock, CFSAN director Dr. Susan Mayne, ORA associate commissioner Judith McMeekin, and Office of Criminal Investigations associate commissioner Catherine Hermsen; it was not sent to deputy commissioner for food policy and response Frank Yiannas.
- **December 1, 2021:** FDA reportedly [receives](#) a second complaint about a case in Ohio that resulted in a death.
- **December 2021:** FDA [interviews](#) whistleblower – two months after receiving it.
- **January 11, 2022:** FDA reportedly [receives](#) a third complaint about a cronobacter case.
- **January 31, 2022:** FDA [begins](#) an extensive inspection of the Sturgis facility – over three years after first encountering cronobacter at the facility; almost five months after learning of the Minnesota case; almost four months after receiving the whistleblower report.
- **February 1, 2022:** FDA [confirms](#) presence of *Cronobacter* at Sturgis facility.
- **February 2022:** The whistleblower report is [shared](#) with FDA's deputy commissioner for food policy and response Yiannas, four months after FDA received it and two months after FDA interviewed the whistleblower.
- **February 17, 2022:** FDA [issues](#) warning to consumers not to use certain powdered infant formula manufactured at Sturgis facility. Abbott announces its voluntary recall of these products. These actions occur two years and five months after FDA first detected cronobacter at the Sturgis facility; and over four months after learning of the Minnesota case.
- **March 2022:** FDA principal deputy commissioner Dr. Woodcock [announces](#) that her office will lead the internal investigation into FDA's actions and response to the infant formula situation involving the Sturgis facility. Dr. Woodcock served as FDA Acting Commissioner during this time, creating an inherent conflict of interest.

- **March 4, 2022:** Chairwoman DeLauro [requests](#) that the HHS IG investigate FDA's handling of the Abbott infant formula recall.
- **April 1, 2022:** FDA [establishes](#) an Incident Management Group to work on issues surrounding the infant formula recall and shortage.
- **April 8, 2022:** FDA [receives](#) Abbott's corrective action plan to address the problems outlined in the investigation that began January 31, 2022.
- **April 29, 2022:** FDA [allows](#) Abbott Nutrition to release recalled products to individuals needing urgent, life-sustaining supplies of specialty formulas on a case-by-case basis.
- **May 10, 2022:** In announcing the actions it is taking to improve supply, FDA [challenges](#) the notion that there is a shortage, noting that more infant formula was purchased in April than in the month prior to the recall.
- **May 16, 2022:** A proposed consent decree between FDA and Abbott is [announced](#) in which Abbott agreed to take corrective actions following FDA's inspection of the Sturgis facility.
- **May 16, 2022:** FDA [announces](#) a guidance that outlines increased flexibilities regarding importation of certain infant formula products in an effort to increase supply.
- **May 19, 2022:** Dr. Califf [testifies](#) before the House Agriculture-FDA Appropriations Subcommittee that it will take another two weeks for the Sturgis facility to open. He estimates that it will take another eight weeks after the plant's opening for supply to reach store shelves.
- **May 19, 2022:** During the same [hearing](#), Dr. Califf confirms the appointment of Dr. Woodcock as an overseer of the food program at the FDA. As FDA Acting Commissioner, Dr. Woodcock oversaw much of the agency's response to the infant formula crisis.

Stories submitted to Consumer Reports

- **Out of time.** *I breastfed my son for 6 months. After much thought and consideration we successfully transitioned him to formula for his next 6 months before switching to milk. Now, with only a couple months before his first birthday, they've turned into the most stressful time in his life. In my husband and my lives. I do not have the option to go back to breastfeeding, and now I don't have a means of giving my son what he needs -which should be a basic physiological need. I pray no mother goes through the stress of when or how her child will get what they need. This shortage is the new pandemic and must come to an end.— **Meghan, IL***
- **Twins.** *My daughter has twin boys and they were born 6 weeks premature. We watch them during the day. She was using Aldi formula. Now you can not find anything. Everyday my husband and I visit the 3 Aldis within a 10 mile radius to see if they have had a shipment. Since she has 2 babies it is very scary when we go 2x a day to check to see if they got a shipment and the shelves are empty. So far she has had to change their type just to feed them. Hopefully they do not have a reaction. They had stomach issues due to being premature. This is ridiculous. — **Kathleen, NY***
- **Frustration Mode.** *My story begins back in mid November just before Thanksgiving. I had only 1 week supply of Similac ready to feed sensitive formula for my 4 month old grandson Aidan. I drove for over 2 hours going from King Kullen to Stop and Shop and several CVS stores only to find they did not receive any shipment of formula. I spoke to a CVS store Manager in Wantagh and recommended that I contact the manufacturer directly. So the following morning I called Abbott directly and was able to order formula online with them. For a while that was working out and Target and Walmart supply was hit and miss. They were more times out of stock than had a supply and limited how many bottles you could order. I needed one 32 oz bottle for each day a month's supply costs close to \$300.00. In mid January again stores were out of stock even Abbott. I texted Abbott on January 11th asking when they expected Similac Pro sensitive to be available to order. They answered that they had no timeline because shipping delays and issues with staff shortages. But assured they were making every effort to make improvement with their distribution center. Well things got worse we had to have friends from out of state purchase for us as many as they could get. About that time in February there was a recall in Similac powder formula which we had on hand. So that could not be used so everyday I was on the computer checking Target Walmart and Abbott several times a day. Last month I called the American Pediatrics Society spoke in length of this crisis the lady said there was nothing they could do. I suggested maybe I should contact The NY Times or my Congressman. She agreed. The following week a story came out on ABC news but didn't get much attention. But then more and more states were being hit but this crisis. This was a health crisis but no body seemed to want to do anything to resolve it. I felt so frustrated and feeling how could this be allowed to happen. In 2 months my grandson can turn to milk but I worry about all those families raising little babies. It is a disgrace that our Government is so slow to act. Congress should why it's costs \$9.00 for a 32 oz bottle of liquid formula — **Patricia, NY***

- **Low supply needs formula to supplement.** *Unfortunately, I am a mother that would like to breastfeed exclusively, but I have low supply and make about 1/3 milk production of what my baby needs. I use formula to supplement the additional nutrition my 4 week old baby needs. We didn't have a huge supply of formula as she was just born and didn't know how she would react to different brands. It is incredibly stressful to be tied to a pump 9x a day, breastfeeding, doing/eating all the things to increase supply, and not be able to produce enough. Then add the extra stress of the formula shortage on top, just makes my low supply dip even more. It has been a scramble to find formula and most shelves are bare near where I live. Online retailers are all sold out. I have had to call on friends and family to search in their neighborhood to send what they can find to help us get about a month supply. We have had to just use what we can get, versus the ones most appropriate for her and what we would want to buy. Hearing that this could go on for another 8 weeks at least is incredibly frustrating considering my baby's intake of formula is rising as she grows. So many families are worse off than we are and that devastates me to hear as a mother. – Mollie, CO*
- **Fear my baby will go hungry.** *My son had an issue gaining weight because I was not producing enough breast milk. My son was in the 3rd percentile in weight at 3 months, before I introduced formula. On formula, my son thrived and jumped to the 24th percentile by 6 months. But now, the formula I have been feeding him is gone (Similac Advance Pro) and I am struggling to find formula of any kind. My son NEEDS this formula or he will not make it. I have had to ask parents, friends, co-workers to look for formula and buy it for me. This has been incredibly stressful and my son should not be at risk of going hungry, because there is NOTHING else I can feed him. Please fix this!!! — Chantel, CA*
- **Military mom.** *I'm a mom who combo feeds, I breastfeed and use formula. My daughter needs formula for weight gain, it's so stressful. There are days when I don't pump enough milk and have to rely on formula. My daughter also need a special kind, this is really stressful — Kieyesa, VA*
- **Special needs.** *Our twins have developmental delays due to prematurity. We rely on Alimentum as our main source of calories. In February our twins had profuse diarrhea for a week straight. I suspected the formula, as the diarrhea smelled like spoiled milk. We stopped the formula immediately. Luckily we were able to supplement with puréed fruit and almond yogurt. They will eat nothing else, and have lost so much weight as a result. Our littles have a milk allergy, and there is nothing else on the market they will drink. We've tried everything. We pray this shortage is resolved for the countless families that depend on these formulas as a food source. -Mirtha, CA*

Resource for Consumers

- **What to Do If You Can't Find Baby Formula.** For parents who need to find baby formula now, experts offer advice for tracking it down. Read the advice [here](#).