Statement by
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FDA Oversight: The Infant Formula Shortage
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Chairwoman McClain, Ranking Member Porter, and subcommittee members, thank you for the opportunity to provide a written statement for today's hearing on the Food and Drug Administration's (FDA) oversight of the infant formula shortage, and the proposal to reform the Foods Program at FDA.

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 Foods Program: Fragmented Structure and Second Class Status

In reviewing the factors that contributed to the infant formula situation, there are several issues to scrutinize in determining what may have contributed to it. First and foremost, the actions of Abbott will need to be thoroughly reviewed, especially after the FDA first detected problems at Abbott's Sturgis, MI facility in 2019, and given the allegations outlined in the whistleblower report that was released in February 2021.

I would like to focus my testimony on how the organizational structure, governance, and performance of the FDA food program impacted the infant formula recall and how FDA's recent plan to restructure the foods program will be inadequate in preventing another similar crisis.

There are numerous questions about whether FDA performed its regulatory role effectively throughout this process. The evidence suggests 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 stakeholders in the food policy community who believe that the infant formula crisis is merely one symptom of a greater organizational structure and culture problem that has long existed at FDA. It is becoming increasingly clear that confidence in the FDA foods program continues to erode among consumer and industry groups.

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 who could provide transparency, accountability, and robust engagement with consumers, industry, states, and other stakeholders. In addition to the infant formula situation, the lack of a full-time leader has had an effect on the implementation of the Food Safety Modernization Act (FSMA).

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 last year 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 the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the food-related inspection and testing operations of the Office of Regulatory Affairs (ORA).

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.

FDA Rejects Expert Panel Report Recommendations

In response to the criticism the agency received about its handling of the infant formula crisis, FDA Commissioner Robert Califf ordered an independent, external review of the Foods Program to be conducted by the Reagan-Udall Foundation. A report issued by the Foundation in December 2022 validated many of the concerns about the Foods Program raised by the diverse coalition of groups.

In its review of the program, the report concluded that the agency's culture, organizational structure and governance model have undermined its effectiveness, and is inhibiting its ability to effectively accomplish its goals. The report also asserted that the lack of a single clearly identified person to lead the Foods Program has adversely impacted the organizational culture and led to overlapping roles and competing priorities that has resulted in constant turmoil.

However, although the report formally acknowledged that serious problems exist within the FDA Foods Program and recommended that the program be unified under a single leader, the FDA has chosen to reject the report's recommendations. The so-called matrix management plan that the FDA is proposing will simply perpetuate the existing dysfunctional structure in the Foods Program that led to its inadequate response to the infant formula crisis.

Based on recent announcements issued by the FDA over the past two months, it is encouraging that Commissioner Califf appears to be aligned with the thinking that a significant restructuring of the FDA Foods Program is necessary, and that a deputy commissioner should have full management and operational authority over all aspects of the foods program and its resources. However, based on the details provided, the plan would fail to truly unify the Foods Program.

The FDA's plan does include the creation of a new deputy commissioner position with authority over certain functions currently housed under the CFSAN, and the Office of Food Policy and Response (OFPR). However, the core food inspection, laboratory, compliance and import oversight would remain under the Office of Regulatory Affairs (ORA).

Essentially, the new so-called empowered deputy commissioner will possess the title of leader of foods at FDA, but that person will not be fully in charge of inspections, testing, or investigations. Thus, the position also would not have oversight authority over two-thirds of the Foods Program budget. The best analogy that could be applied to this situation would be if a person was presented with a brand new car, was told that it belonged to them, but then discovered that other people also have keys to the vehicle and believe they are the owners too.

Thank you for the opportunity to provide a written statement for today's hearing.