



**Statement by
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Rural Development, Food and Drug Administration, and Related Agencies
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Chairwoman Baldwin, Ranking Member Hoeven, and Subcommittee members, thank you for the opportunity to appear before you today to discuss the FDA food program.

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

I would like to focus my testimony on how the organizational structure, governance, and performance of the FDA food program impacts food recalls and food policy decisions. Between inadequate responses to recalls, a failure to implement a culture of illness prevention, and a failure to move quickly on proposed rules and initiatives, there are a number of questions about whether the FDA is performing its regulatory role effectively. The FDA food program appears to be struggling in its role to protect consumers and is preventing the food industry from operating effectively.

There are many stakeholder groups in the food policy community who believe that the recent infant formula crisis exposed a greater organizational structure and culture problem that has long existed at FDA. It has become 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 approximately 80 percent of our food supply.

The lack of a single full-time leader affects all aspects of FDA's food program. 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. 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 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. But, this increased funding should come with more accountability and transparency. 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.

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](#) significantly in the years following the enactment of FSMA and before the pandemic shutdown in March 2020. Unlike other programs, FDA co-regulates food safety with state and local programs. These programs have found funding capped in recent years, and the agency at times reducing its commitment to states. ORA also significantly reduced FDA-funded state inspections, which can be conducted at a lower cost. Meanwhile, ORA is seeking to count these state inspections that are conducted without federal funding towards its FSMA mandates.

It has become evident that ORA is taking a dismissive approach to the inspection mandates under FSMA, viewing them as the maximum number of domestic inspections and has used the mandates as an excuse to reduce inspection work by the states. An FDA inspection task force issued a report last year recommending that Congress consider repealing the FSMA inspection mandates. In the absence of a transparent approach to assessing facility risk and clear identification of how "risk-based" inspections would occur, 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 assertions about investing in technology to leverage oversight

activities certainly makes sense. 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 at the same level with drugs, devices, biologics, and tobacco at FDA.

Recommendations

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

- 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.
- Seek detailed answers from FDA 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.