FDA Oversight Hearing Part 1: The Infant Formula Shortage

Subcommittee on Health Care and Financial Services
Committee on Oversight and Accountability
United States House of Representatives

Statement for the Record

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Chairwoman McClain and Ranking Member Porter, we appreciate this opportunity to submit a statement for the record of the subcommittee's oversight hearing on last year's infant formula shortage.

From 2007 to 2018, we each served as FDA's top food safety leader. We have worked throughout our careers on the challenge of providing Americans a safe and abundant food supply. We know what a challenge that is for the people who grow and process our food and for the people at FDA who work on food safety every day. We have the greatest respect and gratitude for what they do.

We applaud your oversight of the events leading to the recall of Abbott's infant formula and the resulting shortages. The reported lapses of time between FDA's findings of insanitary manufacturing conditions and receiving infant illness reports and FDA's recall are concerning and serve as lessons for how FDA responds to safety signals about infant formula. We urge you, however, to examine the infant formula crisis in the larger context of ongoing efforts to modernize FDA's Food Program.

During the period we served, illness outbreaks and contamination incidents cast doubt on FDA's ability to protect American consumers from hazards as diverse as *E. coli* in leafy greens, *Salmonella* in peanut butter, and contaminated food imports. Congress responded on a bi-partisan basis, with broad industry and consumer support, by enacting the Food Safety Modernization Act of 2011 (FSMA). This law directed FDA and the food industry to implement modern approaches to preventing food safety problems, which required an overhaul of FDA's traditional culture and its focus on detecting and reacting to problems rather than systematically preventing them.

The infant formula events are one sign that FDA has not accomplished the food safety transformation FSMA envisioned and is not organized for success on food safety, but there are many others. Last April, POLITICO thoroughly documented the management and performance "dysfunction" in FDA's Food Program as a whole, including but not limited to food safety. The problems begin with the program's low priority in the FDA commissioner's office and include its fragmented organizational structure, insular culture, bureaucratic infighting, slow decision making, and failure to follow through on FSMA implementation. In response, a rare coalition of consumer organizations, industry trade associations, and FDA's state regulatory partners came together to affirm POLITICO's findings and call for an organizational overhaul of the Food Program, including a fully impowered deputy commissioner to unify and lead it.

FDA Commissioner Robert Califf responded by engaging an independent expert panel to analyze the program's problems and recommend solutions. The report of this panel, which included a former FDA commissioner, other former government leaders, and food safety experts, also

documented the problems in the program and recommended sweeping organizational and cultural change. Like the stakeholder coalition, they called for FDA to unify the program under a single leader with full line management authority to lead its essential culture change and program modernization.

Inexplicably, FDA leadership has rejected this recommendation. The steps they have announced create a new deputy commissioner position (Deputy Commissioner for Human Foods) but with authority over only parts of the program. By leaving out animal food, this continues the organizationally divided implementation of FSMA at FDA headquarters. Even more critically, the Deputy Commissioner for Human Foods does not even have authority over all of FDA's human food components. That is because the large field-based units within FDA that manage food inspections, field laboratories, and import oversight – and consume some two-thirds of FDA's food-related budget – remain organizationally separate, with no direct management accountability to the new deputy commissioner.

From our personal experience trying to lead FDA's Food Program within its fractured structure and divided lines of management accountability, we know this will not work. FDA's inspectors and other field staff are dedicated and hardworking, but the culture of the field organization is insular and tradition bound. The matrix management approach Dr. Califf touts from his private sector experience has been tried and failed at FDA, as we know from our personal experience and as exemplified by the lags in FDA's action on infant formula.

For FDA to succeed on food safety, its large frontline workforce needs to become a fully integrated component of a unified Food Program, not remain a separate organization that protects its independence and its outdated culture of reacting to food safety problems rather than preventing them.

It is unclear why FDA leadership has rejected the recommendations of its stakeholders and independent experts who have deep experience and expertise on food matters. One possibility is that, while the agency's top leaders are highly expert in medical product oversight, they lack personal experience and expertise on food safety and what it will take to transform the Food Program's culture and performance.

Medical products certainly deserve all the attention they get at FDA, and for years that's been the focus of FDA's top leadership, which helps explain why food regulation has a lower priority within FDA and is chronically underfunded. The focus of FDA leadership on medical products may also explain why the commissioner's proposed reorganization of the Food Program is patterned after the model that works for drugs and other medical products but won't work for food.

Another possible explanation for the half steps the Commissioner has proposed is that, like any major organizational change, the needed unification of the Food Program will encounter internal questions and resistance. These should be taken seriously and managed, but the stakes are too high to let bureaucratic issues block progress that is so vital to America's health and to public confidence in FDA's oversight of food safety.

Ideally, the Commissioner would change course and replace the announced reorganization with one that truly unifies the Food Program and empowers the new deputy commissioner position. Absent that, Congress must act by directing FDA to make these critical changes. Or Congress could elevate and reset the Food Program by removing food from FDA altogether and creating a separate agency under a Commissioner for Food Safety and Nutrition.

With decisive action now, Americans can get the unified, efficient and forward-leaning food program they deserve and expect. With half steps, disunity and dysfunction that was so evident during the infant formula crisis will persist and history will surely repeat itself.