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

Submitted by

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Chairwoman McClain and Ranking Member Porter, I appreciate this opportunity to submit a statement for the record of the subcommittee's oversight hearing on food safety.

No one should worry about the safety of their food. While food companies have ultimate responsibility to address the pathogens, heavy metals and toxic chemicals that contaminate our food, the safety of our food supply remains at risk when the Food and Drug Administration (FDA) lacks the resources, organization, and determination to make food safety a top priority.

The contamination of infant formula unveiled important failures at the FDA, which are well documented by the Reagan-Udall Foundation's expert panel. The Reagan-Udall Foundation panel confirmed that cultural and organizational flaws and resource needs are contributing to the failures that make our food less safe.

Creating an empowered deputy commissioner for Human Foods who will have "full management and operational authority over all aspects of the food program and its resources," including field operations, is an important first step. As detailed in a March 9 letter from FDA Commissioner Robert Califf (attached), the new deputy commissioner will be empowered to make all decisions related to food safety, including those related to the field, and will be the "lead official establishing priorities for food program activities, including risk prioritization for

inspections and compliance activities and a clear movement toward the preventive controls regime directed by the Food Safety Modernization Act."

To succeed, the deputy commissioner must be empowered to set priorities for all food safety activities, including inspections. To do so, Commissioner Califf writes that "concept of operations documents and processes will be created that will clarify roles and responsibilities in such a way to dispel any doubts about my intentions to empower the Deputy Commissioner with the authority to oversee and manage the human foods program in its entirety." Dr. Califf intends to define decision rights and make other changes "from stem to stern" that will transform the entire field workforce.

These changes are critical first steps, and Congress should ensure that they are not only implemented but that they succeed in breaking down the organizational silos that needlessly contributed to the contamination of infant formula supplies. The serious organizational, structural and cultural obstacles documented by the Reagan-Udall panel require the leadership of a single food safety leader who will be charged with making food safety a top priority. Every option the Reagan-Udall panel provided called for unifying all elements of the program under a new deputy commissioner with direct line management authority and accountability for the program's success.

Simply changing the organizational structure of FDA's food programs, as Dr. Califf has proposed, will not be sufficient if FDA does not also make it a cultural and organizational priority to prevent the illness caused by pathogens, heavy metals, and toxic chemicals. While Congress has directed FDA to make prevention of illness the agency's "north star," the prevention mandate enshrined in the Food Safety Modernization Act has not been fully embraced by FDA's workforce, and FSMA's command to protect consumers from pathogens in produce has simply been ignored.

To succeed, FDA's Food Program will also need more resources. As the Reagan-Udall panel documented, the number of FDA employees dedicated to food safety and nutrition has not increased since 1978, despite significant new demands on FDA. But more resources alone will not ensure that FDA will be able to meet our food safety challenges. The Reagan-Udall panel made equally clear that the fragmented leadership at the top of the agency hampers FDA's ability to make risk-based decisions about how to best employ these resources.

In particular, the FDA has systematically failed to address the risks posed by toxic chemicals added to food and food packaging. EWG recently found that nearly 99% of the new food chemicals that entered commerce since 2000 were approved by the chemical companies, not the FDA, and that many of the chemicals approved by the FDA many decades ago have not been reassessed, even when there is evidence of health harms. Consumers frequently place the chronic

risks posed by food chemicals, such as the increased risk of cancer and reproductive harm posed by some of them, ahead of the risks posed by food pathogens.

Consumers trust and respect the FDA, but the agency must make important cultural changes if it hopes to retain that trust and respect. The FDA must be more transparent with consumers, industry, consumer organizations and Congress. By providing more oversight, as you have today, Congress can help bring greater transparency to FDA's food program. Indeed, a recent House Oversight Committee investigation into toxic metals has reinvigorated FDA's efforts to reduce the amount of lead, arsenic, and other toxic metals in baby food.

Thank you for the opportunity to submit testimony for the record.