

Congress of the United States

Washington, DC 20510

July 13, 2022

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to express our strong concern over the fragmented organizational structure and lack of coordination across the food safety programs at the Food and Drug Administration (FDA). To better unify the FDA food program, we urge you to appoint an empowered Deputy Commissioner for Foods—with authority over the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) food component. Further, we request that you prioritize the reorganization of the FDA's food programs to ensure the FDA succeeds in its critical food mission to protect, promote, and advance public health.

The FDA food program plays a crucial role protecting American consumers by enforcing food safety regulations. The foods program regulates nearly 80 percent of the American food supply and ensures the food industry operates responsibly and sanitarily to protect public health. Over a decade ago, the Food Safety Modernization Act (FSMA) was enacted into law to increase support for and modernize the FDA's food program. However, the agency has yet to issue several key safety standards required by the law such as regulating the water to keep pathogens away from fresh produce and implementing traceability across the food industry. Other initiatives such as heavy metals and other toxic elements in baby food and sodium reduction have languished for years. Despite increased resources to the Office of Regulatory Affairs to fund inspections, the number of food safety inspections performed has been going down each year. In 2011, the FDA inspected nearly 11,000 facilities, but only inspected 3,300 facilities so far in 2022.¹ These delays and deficiencies actively endanger the health and safety of the American people. More than 128,000 people are hospitalized and 3,000 people die from foodborne illnesses every year.²

In April 2022, Politico published a detailed report alleging that the FDA suffers from severe leadership and management problems and has failed to prioritize food safety with slow responses to foodborne illness outbreaks dating back to 2011.³ The report details poor coordination and mismanagement due to the agency's failure to prioritize the food program. For example, the

¹ Environmental Working Group., *FDA food safety inspections plummet, despite congressional mandate*, EWG, (May 25, 2022) (online at <https://www.ewg.org/news-insights/news/2022/05/fda-food-safety-inspections-plummet-despite-congressional-mandate/>).

² Centers for Disease Control and Prevention., *Estimates of Foodborne Illness in the United States*, CDC, (November 5, 2018) (online at <https://www.cdc.gov/foodborneburden/>).

Center for Food Safety and Applied Nutrition (CFSAN) suffers from a “deep-seated culture of avoiding hard decisions and near-paralyzing fear of picking serious fights with the food industry” and leadership is plagued by turf battles between CFSAN and the Office of Food Policy and Response.⁴ One former Commissioner of the FDA described the food side of the FDA as “on the back burner” for the agency. Other officials described the food program as “impossible,” “broken,” and “byzantine.”

This “back burner” approach was reflected in the FDA's response to the infant formula shortage. Even though the FDA first received a whistleblower report alleging safety problems at the Abbott infant formula plant in October 2021, the FDA's Deputy Commissioner for Food Policy and Response supposedly didn't learn about the whistleblower complaint until four months later. It took over four months for the FDA to re-inspect the plant.⁵ And after its inspectors confirmed the contamination, the FDA waited for nearly three weeks before alerting the public. This communication breakdown within the FDA hampered the response to the infant formula shortage and weakened public confidence in the FDA's ability to respond to foodborne illness outbreaks promptly.

The lack of a unified Food and Drug Administration's (FDA) food program under a single empowered Deputy Commissioner continues to contribute to the ongoing challenges facing the FDA food program. We call upon you to reform the FDA food program's governance by appointing an empowered Deputy Commissioner for Foods with direct line authority over the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs' (ORA) food component. This unified program under an empowered deputy commissioner would strengthen all aspects of the FDA's food program, external affairs capacity, and its ability to work efficiently with its many stakeholders. In fact, this exact role at the FDA was established in 2010 to address the agency's fragmented organizational structure around food safety but has been left vacant since 2018. This leaves the FDA without a senior leader to manage the response to food safety events like the current infant formula shortage and the hepatitis A outbreak. Filling this position with an individual who has a strong and relevant background in food safety is essential to an improved FDA food program.

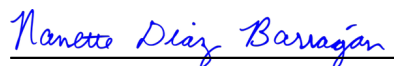
Thank you for your consideration of this request.

Sincerely,

³ Helena Bottemiller Evich., *How the FDA's Food Division Fails to Regulate Health and Safety Hazards*, Politico, (April 8, 2022) (online at <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/>).

⁴ Id

⁵ Kimberly Kindy et al., *Whistleblower Report on Baby Formula Didn't Reach Top FDA Food Safety Official*, Washington Post, (May 25, 2022), (online at <https://www.washingtonpost.com/politics/2022/05/25/whistleblower-fda-yiannas-report-abbott-baby-formula/>).



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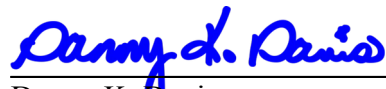
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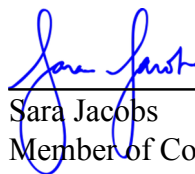
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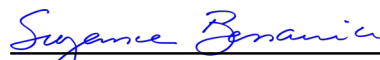
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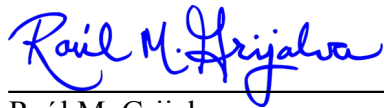
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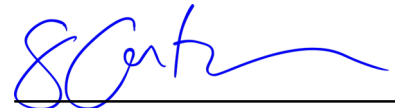
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