

September 12, 2023

The Honorable Gene Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Mr. Dodaro,

The Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), which represents the largest expansion and overhaul of U.S. food safety law since the 1930s, was signed into law in January 2011.¹ Among other things, FSMA shifted FDA regulators' focus from responding to foodborne illness outbreaks to trying to prevent them from occurring in the first place. According to FDA, the agency has finalized nine major rules to implement this comprehensive act. Each rule specifies actions that farmers, food manufacturers, importers, or others must take at certain points along the food chain – from production to sale – to prevent contamination. However, we remain concerned that FDA's oversight of our nation's food supply continues to be inadequate to protect Americans from preventable foodborne illness outbreaks.

While the U.S. food supply is among the safest in the world, according to the Centers for Disease Control and Prevention (CDC), foodborne illness remains a costly and common public health problem. Each year, roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die as a result of foodborne illness.² The FDA is responsible for overseeing the safety of 80 percent of the U.S. food supply. However, it is clear from recent events, like the infant formula crisis, there are serious deficiencies that have prevented the agency from acting quickly to address food safety issues.

Following the infant formula crisis of 2022, the Reagan-Udall Foundation conducted an independent investigation of FDA's response. Released in December 2022, the final report describes several issues with the agency's organizational culture, leadership structure, access to resources, and regulatory authorities.³ We understand FDA has since taken steps to address some of these issues, including proposals to restructure the agency's Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR), and Office of

¹Pub. L. No. 111-353, 124 Stat. 3885 (2011).

²“Burden of Foodborne Illness: Findings,” Centers for Disease Control and Prevention (2018)

³ U.S. Library of Congress, Congressional Research Service, *FDA's Independent Evaluation of Its Food Safety Programs*, by Amber Nair, IN12083 (2023).

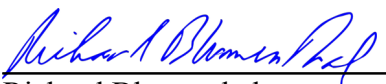
Regulatory Affairs.⁴ Given the importance of FSMA to FDA’s goal of reducing foodborne illness in the United States, as well as the increases in funding for food safety, and the recent changes at the agency we request that GAO undertake a review that focuses on the following questions:

- 1) What have been the key trends in foodborne illness since FSMA was enacted in 2011?
- 2) To what extent has FDA assessed its own effectiveness in implementing FSMA to reduce foodborne illness in the United States, and what metrics, if any, does FDA use to measure FSMA’s success?
- 3) What challenges, if any, does FDA face as it implements FSMA, and what barriers, if any, does FDA face in achieving its goal of further reductions in foodborne illnesses?
- 4) What impact, if any, have the recommendations in the Reagan-Udall report and FDA’s subsequent proposed changes had on the agency’s food safety efforts?
- 5) What new resources or authorities does FDA require from Congress to more effectively reduce foodborne illness in the United States?

All of us have an interest in ensuring the food we eat is as safe as possible, and we are committed to working to ensure all Americans have access to safe and accessible food supplies. More than a decade after FSMA was enacted, it is important to ensure FDA has the resources and authority necessary to carry out its vital mission of protecting our nation’s food supply.

Thank you for your consideration of this request.

Sincerely,



Richard Blumenthal
United States Senator



Richard J. Durbin
United States Senator

⁴ U.S. Food and Drug Administration, “FDA Provides Update on Proposal for Unified Human Foods Program, including New Model for the Office of Regulatory Affairs,” press release, June 27, 2023, <https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposal-unified-human-foods-program-including-new-model-office-regulatory>.