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INSIGHT

FDA's Independent Evaluation of Its Food Safety Programs

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The U.S. Food and Drug Administration (FDA) has primary responsibility for the safety of about 78% of the U.S. food supply. The combined efforts of the food industry and government regulatory agencies often are credited with making the U.S. food supply among the safest in the world. In 2010, the 111th Congress passed the Food Safety Modernization Act to improve FDA's ability to minimize incidences of foodborne illness. Nevertheless, the Centers for Disease Control and Prevention (CDC) report that each year about 48 million people become sick from contaminated food in the United States with an estimated 128,000 hospitalizations and 3,000 deaths.

Major foodborne illness events, such as the 2020 leafy greens outbreak and 2022 powdered infant formula incident, have heightened public and media scrutiny of FDA's Human Foods Program and magnified congressional interest in foodborne illness outbreaks. An April 2022 Politico report cited FDA failures to safeguard U.S. food supplies and organizational dysfunction. Recent Congresses have held multiple hearings and introduced several bills addressing food safety (see, for example, the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies' hearing on FDA and food safety, H.R. 8358, and S. 2958).

In response to increased media and congressional scrutiny, FDA Commissioner Dr. Robert Califf requested that the Reagan-Udall Foundation—an independent organization created by Congress to advance FDA's mission—convene an independent expert panel to comprehensively evaluate FDA's Human Foods Program.

The Reagan-Udall Foundation published its evaluation report in December 2022. It describes numerous shortcomings within the agency's organizational culture, leadership structure, access to resources, and regulatory authorities. The report makes recommendations for improvement, some of which may require congressional action if they are to be implemented.

Reagan-Udall Evaluation

The commissioner requested the scope of the panel's evaluation include the Office of Food Policy and Response (OFPR), the Center for Food Safety and Applied Nutrition (CFSAN), and relevant parts of the Office of Regulatory Affairs (ORA). A summary of the panel's key findings follows.

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Culture. The report found the cultural factors contributing to the Human Foods Program's shortcomings include a lack of a clear vision and mission, competing priorities, lack of a single leader, decisionmaking based on consensus, and risk aversion.

Structure. Under FDA's current organizational structure, OFPR, CFSAN, and ORA each report to the commissioner and are independent of one another. The report found FDA's Human Foods Program lacks a formal definition and clear leader or decisionmaker, outside of the commissioner. The report concluded that the lack of a clear, overarching leader has contributed to a culture of indecisiveness and inaction and created disincentives for collaboration between OFPR, CFSAN, and ORA.

Resources. The report found that financial resources, personnel, and information technology resources have remained relatively flat over the past decade and flat compared with expansion of these resources for other FDA programs, such as the Human Drugs Program. The report asserts that congressional appropriations have not kept pace with the Human Foods Program's needs, and user fees (e.g., reinspections fees) cover about 1% of its $1 billion budget. The report concluded that recent FDA initiatives, such as the Technology Modernization Action Plan (2019), Digital Modernization Action Plan (2021), and Enterprise Modernization Plan (2022), will require adequate resources to be implemented in a manner that would positively affect FDA's Human Foods Program.

Authorities. The report concluded that the Human Foods Program lacks key enabling authorities to successfully perform its mission. The report recommends authorities related to hiring and salary flexibility; data reporting and sharing with state, local, territorial, and tribal authorities to achieve better coordination and cooperation; and allowing appropriations to be available over multiple fiscal years.

Issues for Congress

The Reagan-Udall Foundation's evaluation report makes recommendations that FDA can implement on its own. Other recommendations, if they are to be implemented, may need congressional action. Report recommendations that may need congressional action to implement include

- Create an entity where all elements of the Human Foods Program are defined and have clear lines of authority. The report identifies several possible structures, including keeping the entity within a restructured FDA or creating a new food-safety-focused Department of Health and Human Services operating division separate from FDA.
- Provide sufficient funding through annual appropriations and user fees. The report acknowledges that attempts to implement user fees in this program have failed in the past and such implementation faces opposition from industry and "significant skepticism" from the public interest community.
- Authorize "until expended" funding for the Human Foods Program, particularly for funding infusions intended to address longer-term challenges (e.g., information technology).
- Establish hiring authorities and salary flexibility (similar to those provided to FDA's Human Drugs Program by the 21st Century Cures Act, P.L. 114-255) to improve FDA's ability to recruit, hire, and retain personnel with expertise and skills to support the Human Foods Program.
- Amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) to allow FDA to disclose nonpublic information to state, local, tribal, and U.S. territorial government agencies with counterpart functions related to FDA-regulated products by preempting related state, local, or territorial disclosure laws. The report asserts that this would allow

- FDA to work more closely with its regulatory partners and effectively leverage their oversight capabilities and resources.
- Authorize FDA to establish notification requirements when designated food categories, such as medical foods/infant formula, are likely to experience shortages or when supply chain disruptions are anticipated or occur.

These recommendations vary in the degree of complexity required for implementation. For example, previous Administrations have proposed a restructure of FDA's Human Foods Program, which would require a coordinated effort among several federal agencies whose authorities and jurisdictions may be affected (e.g., U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, and U.S. Environmental Protection Agency). Other recommendations, such as authorizing "until expended" funding, may be more straightforward to legislate and implement. Congressional discourse on the Human Foods Program is likely to be shaped not only by the evaluation report's recommendations but also by perspectives of other food-safety stakeholders and decisionmakers on issues and policy alternatives to advance U.S. food safety.

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