Overhauling the Structure and Governance of FDA's Food Program

A Submission to the Reagan-Udall Independent Expert Panel

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Introduction

In April 2022, a coalition of major FDA stakeholders – representing consumers, the food industry, and state food regulators – wrote to Commissioner Robert Califf noting serious problems in the Food Program's structure, governance, and performance. To address these problems, they asked him to unify the program by creating a Deputy Commissioner for Foods position with clear line authority over the program's three separately-managed operating units – the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the food related elements of FDA's field force, now in the Office of Regulatory Affairs (ORA).

The goal of the request was to establish a common strategic direction, clear priorities, sound resource management, and enhanced transparency and accountability throughout the Program.

Commissioner Califf commissioned the Reagan-Udall Foundation (RUF) to conduct an independent review and make recommendations for change. This process has elicited broad support for the coalition's proposed structural change and has also raised questions about why such major change is necessary. As individuals who have played senior leadership roles on food safety within FDA, USDA, state food regulatory programs, and the food industry (brief bios provided below), we strongly support the stakeholder coalition in calling for an overhaul of the structure and governance of FDA's Food Program.

In this submission to the RUF Independent Expert Panel, we spell out why the overhaul is required and describe key elements of the needed transformation of the Food Program. We also provide our vision for the roles of the deputy commissioner and Center directors and express what we see at stake for FDA if the governance overhaul does not happen in a way that equips the Food Program to succeed in its food safety mission. *The public's health and FDA's credibility and standing on food safety are at stake.*

In an Addendum, we explain how the leadership and governance needs of the Food Program differ from the needs of FDA's three medical product programs. The concept of symmetry with the structure and governance model that works for medical products should have no bearing on doing what's right for food.

Why FSMA Necessitates a Governance Overhaul

The challenges of implementing the Food Safety Modernization Act of 2011 (FSMA) drive the need for an FDA governance overhaul of the kind the coalition recommended. Other components of the Food Program, including nutrition activities and toxic elements, are also in need of a strategic and governance overhaul, but they are not the focus of our submission.

Here's why successful implementation of FSMA and responsible management of Food Program resources necessitates a new governance model.

FSMA Implementation

- FSMA changed everything about FDA's food safety mission. It transformed FDA's mission from reacting to problems occurring mainly in U.S.-based food manufacturing facilities to preventing contamination risks and foodborne illnesses across the entire food system.

- For the first time, FDA was charged with regulating produce farms in the U.S. and overseas and the practices of thousands of food and feed importers; inspecting tens of thousands of foreign food facilities; and partnering with states to build a "national integrated food safety system" to, in part, leverage resources to inspect the roughly 100,000 domestic food facilities in operation today. The agency was also charged with establishing new programs for defending the food and feed supply from intentional adulteration and improving the traceability of food and feed.

- And Congress mandated in FSMA that human food, pet food, and feed for food animals all be regulated under the same framework of regulatory standards for prevention, making CVM an integral part of the Food Program along with CFSAN and ORA.

- ORA's food facility inspection and enforcement role will always be important, but the mission mandated by FSMA requires so much more of the Food Program as a whole and particularly ORA, including:

    - ORA's cultural transformation from inspection and reaction as ends in themselves to an ethos of public health prevention pursued on a global basis;

    - CFSAN, CVM, and ORA working seamlessly and flexibly on new strategies to incentivize prevention and the implementation of best practices across the food system, and on conducting timely investigations of the root causes of illness outbreaks to prevent their recurrence;

    - ORA being on the forefront of actively collaborative partnerships with state agencies and foreign food safety counterparts in furtherance of a Food Program prevention strategy;

- ORA collaborating with CFSAN and CVM on development of the FSMA-mandated National Integrated Food Safety System, which is intended to take full advantage of the states currently conducting about 60% of manufactured food inspections and most domestic animal food and produce farm inspections; and

- Greater ORA transparency and a common platform for data sharing across the entire Food Program.

We know from experience that the needed level of Food Program cohesion and collaboration is not achievable in today's fragmented management structure, which allows ORA and other components of the program to work autonomously in silos and within disparate cultures.

Resource Management

- More strategic and efficient resource management is essential to the success of FSMA, and more so because Congress has appropriated far less than what the Congressional Budget Office said was needed for FSMA implementation.

- ORA receives nearly two-thirds of all the money Congress appropriates for FDA's Food Program, but it decides unilaterally how most of that money is spent, without transparency or accountability to the current Deputy Commissioner for Food Policy and Response or the leaders of CFSAN and CVM, despite their day-to-day responsibility for the overall success of the program.

- Only about a quarter of ORA's food-appropriated funds are available for programming by CFSAN and CVM for inspections. A significant but unknown share of ORA resources go to headquarters overhead for overseeing compliance, work planning, operational policy development, and other functions that often duplicate CFSAN and CVM functions.

We believe the Food Program needs a unified budget that aligns with the program's overall strategic direction and provides transparency and accountability for how the money is spent. ORA's resistance to budget transparency and accountability combined with the fragmentation of the current program structure and leadership prevents this from happening.

The Roles of the Deputy Commissioner and Center Directors

Some have portrayed the proposed Deputy Commissioner for Foods (DCF) position as an unneeded layer between the CFSAN and CVM Directors and the Commissioner. We see it as recognizing that FDA commissioners typically come from the medical community, lack food safety expertise, and are stretched too thin to provide the sustained, integrative leadership the Food Program needs.

We also see the DCF position elevating the priority and power of the Food Program within FDA and enabling the Program to speak with a unified voice and consistent message. This elevation and unification of the Food Program can only enhance the power and impact of the Centers and

their directors, both internally in the oversight of ORA and competition for FDA resources and externally in engaging stakeholders and state regulatory partners.

Role of the Deputy Commissioner

The DCF would report directly to the Commissioner, who would remain responsible to the administration and Congress for the success of the Food Program. To be successful, the Commissioner should empower and support the Deputy Commissioner to act as the Commissioner's surrogate for day-to-day and strategic leadership of the Program. The DCF's roles should include:

- Providing fulltime, integrative leadership to the Food Program's three operating units;
- Leading program-wide culture change in collaboration with an Executive Team comprised of the Center directors and the head of food field operations;
- Ensuring that the Food Program is building and implementing program-wide and adaptable strategies for prevention;
- With the Executive Team, establishing strategic priorities for the Food Program, defining tactics for achieving the priorities, and putting in metrics to measure success;
- Ensuring important policy and regulatory decisions are made on a timely basis and, as needed, serving as the final decision maker with input from the Executive Team;
- With the Executive Team, developing and communicating to stakeholders a proactive regulatory agenda for the Food Program;
- Overseeing development by the operating units of a unified Food Program budget that is aligned with Program priorities and plans, including fulfillment of FSMA's prevention mandate;
- Advocating for the Food Program and its funding with stakeholders, the administration, Congress, and the media, based on a unified message;
- Leading program-wide response to significant outbreaks and food-related emergencies, including communications with the public and engagement with external stakeholders.

None of these roles are being played effectively or are realistically possible within the current culture and governance model of FDA's Food Program.

Role of the Center Directors

The success of the Food Program depends on CFSAN and CVM being strong, vibrant, forward-leaning organizations that bring leadership and innovation to the fulfillment of their central

science, policy, and regulatory roles. The Center directors are key to the success of the Food Program. They are:

- The frontline leaders and managers of the Program's core scientific, policy, and regulatory functions and directors of the daily operations of CFSAN and CVM;

- Members of the Food Program Executive Team, sharing with the DCF both leadership and responsibility for the overall success of the Food Program;

- Leaders in the development of Food Program strategies and priorities in collaboration with the DCF;

- The primary interface with leaders of the Food Program field force;

- Leaders of collaborative dialogue with the food industry to advance prevention strategies and solve food safety problems; and

- Prominent representatives of their Centers and the Food Program in engagement with stakeholders, the administration, Congress, and the media.

We believe a structure that elevates the Food Program's leadership within FDA and makes the field force an integral part of a unified Program will enhance, not diminish, the power and impact of the Center directors.

What's at Stake for FDA

The FDA Food Program is at a critical juncture in its history and bold action is needed to ensure its future success and protect consumers. Here are a few reasons why.

- Progress on protecting consumers from preventable risks are lagging: 16 years after the spinach *E. coli* outbreak that helped spark FSMA, leafy green outbreaks are recurring for the same reasons the spinach outbreak occurred in 2006. Today, 60% of all *E. coli* O157:H7 cases and 40% of all Salmonella cases in the United States are attributed to fresh produce.

- FDA's role on food safety is at a turning point in terms of loss of confidence among stakeholders and Congress. The agency risks loss of support for its food budget, especially if transparency and accountability in budgeting and resource management are not established.

- Industry and congressional discussion of removing food from FDA's jurisdiction is serious. To maintain its food safety leadership role, FDA needs to elevate the program's priority and invest in modernizing it from top to bottom.

- If FDA can't decisively and promptly address the Food Program's governance model using the powers of the commissioner and the HHS Secretary, we would support moving the program outside FDA.

We consider the status quo at FDA to be unsustainable, and the stakeholders aren't going away. At greatest risk are consumers.

ADDENDUM

FDA's Medical Product Programs are Not a Governance Model for Food

Some have asked why the operating model and the relationship between ORA and the medical product programs won't work for food. The answer lies in fundamental differences between the medical product and food programs in their missions and implementation challenges and in the role ORA plays.

The structure and new governance model for the Food Program should be considered through the lens of food, not medical products, and be based on the challenges of implementing FSMA and FDA's overall food safety mission.

Different Mission and Implementation Challenges

- The medical product programs and mission are scientifically complex and challenging, but are well-defined by law and user fee expectations, consisting mainly of timely reviews of INDs and NDAs to ensure safety and effectiveness and ORA oversight of product quality through GMP inspections and compliance.

- While FDA's food safety goal under FSMA is clear – prevention of foodborne illness – what it must do operationally each day to achieve the goal is not clearly defined by law. Rather, the food safety mission requires:

    - applying a diverse regulatory toolkit on a largely discretionary basis to a wide range of agricultural producers, manufacturers, retailers, foreign food establishments, and importers;

    - actively partnering on inspection, compliance, and prevention efforts with state agencies and foreign governments; and

    - providing guidance, education, and leadership to foster voluntary compliance and prevention across a vast global food safety community.

These differences require a leadership structure and governance model that can integrate the CFSAN, CVM, and ORA food safety activities and respond nimbly on strategy and resource deployment to address the broad range of evolving food safety challenges.

ORA's Role and Culture

As the frontline interface between FDA, the food industry, and state regulatory partners, ORA has a much more central role on food safety and FSMA implementation than on medical product safety and efficacy. The success of ORA on its food role requires transformation in ORA's internal culture and how it interacts with CFSAN and CVM.

- ORA plays an important but relatively limited role in FDA's medical product program, consuming 12% of the resources available for FDA's human drug, device, and biologics programs.

- ORA is central to the food safety program, consuming 69% of all dollars Congress appropriates to FDA's human food program.

- ORA has a deep tradition and culture of focusing on inspection numbers and compliance actions and reacting to non-compliance and product quality problems, which may work for medical products but not for food.

- In FSMA, Congress mandated a shift to a culture of prevention within FDA and across a highly diverse food industry, which requires a top-to-bottom transformation of the mindset and culture of ORA.

- ORA has a management culture of insularity, lack of transparency, and resistance to change, which makes the needed ORA transformation unlikely without a structure that integrates ORA with the Food Program organizationally and provides program-wide leadership and accountability for implementing FSMA's prevention vision.

- Program alignment was intended to clarify and strengthen the policy and planning leadership roles of the Centers. CDER and ORA were able to agree on a Concept of Operations to address their respective roles on inspection coordination and compliance decision making. A parallel effort between CFSAN and ORA failed because of ORA's resistance to transparency and genuine accountability and its commitment to protecting its prerogative to make unilateral resource management decisions.

- On food safety, ORA maintains an arms-length relationship with the Centers and the current Office of Food Policy and Response, as though it were a separate agency with interests of its own separate from CFSAN and CVM.

FDA will not succeed on FSMA implementation until ORA sees itself and functions as an integral part of the Food Program as a whole.

BIOS

Dr. David Acheson is the Founder and CEO of The Acheson Group (TAG), which applies scientific expertise and extensive experience to strengthen the food safety programs of food

companies and protect public health. Dr. Acheson has held many food safety leadership positions in the federal government, including Chief Medical Officer at USDA's Food Safety and Inspection Service and FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Director of CFSAN's Office of Food Defense, Communication and Emergency Response. In addition, as the Assistant and then Associate Commissioner for Foods he provided agency-wide leadership role for all food and feed issues and led development of the 2007 Food Protection Plan, which served as the basis for many of the authorities granted to FDA by FSMA.

Steven Mandernach is the past president and current executive director of the Association of Food and Drug Officials (AFDO). AFDO represents state and local food safety regulatory officials in working collaboratively with FDA, USDA, the food industry, and consumer groups to improve the uniformity and effectiveness of food safety regulations and programs. In this role, Mr. Mandernach leads AFDO's efforts to work toward the National Integrated Food Safety System mandated by Congress in the Food Safety Modernization Act. Prior to becoming executive director in 2018, he led Iowa's food safety regulatory program as bureau chief for food and consumer safety at the Iowa Department of Inspections. Mr. Mandernach contributes to food safety training and education as a member of the board of directors for the International Food Protection Training Institute (IFPTI) and the Partnership for Food Safety Education.

Dr. Stephen Ostroff retired from the Food and Drug Administration in 2019 after a distinguished career of service to the nation's health. Before joining FDA, Dr. Ostroff worked at the Centers for Disease Control and Prevention (CDC) in Atlanta for more than 20 years on infectious disease surveillance and outbreak investigations, much of that time as the Associate Director for Epidemiologic Science in the National Center for Infectious Diseases (NCID) and finally as the Deputy Director of NCID. He joined FDA in 2013, and served as FDA's Chief Scientist, Deputy Commissioner for Foods and Veterinary Medicine, and, for two extended periods, as the agency's Acting Commissioner.

Michael Taylor is a board member of STOP Foodborne Illness, which supports and represents victims of foodborne illness and their families. He served from 2010 to 2016 as Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration, where he led implementation of the Food Safety Modernization Act of 2011. He served previously at FDA as a staff attorney (1976-80) and as Deputy Commissioner for Policy (1991-94) and at USDA as Administrator of the Food Safety and Inspection Service and Acting Under Secretary for Food Safety (1994-96).

Roberta Wagner is vice president of regulatory and technical affairs at the Consumer Brands Association, which advocates for many of the largest U.S. food companies. Before that she spent 33 years in public service, focused on food safety, including senior leadership positions at FDA and USDA. At FDA, Wagner worked for 20 years in the Baltimore Field Office on all aspects of FDA field operations and later held senior leadership positions in FDA headquarters, including in the Office of Regulatory Affairs (ORA) as Assistant Commissioner for Operations, and in FDA's Center for Food Safety and Applied Nutrition (CFSAN) as Deputy Director for Regulatory Affairs. She completed her FDA career leading CFSAN's implementation of the Food Safety Modernization Act. At USDA, Wagner was a member of the Food Safety and Inspection Service executive team as Deputy Administrator of the FSIS office that oversees the FSIS inspection force and head of the FSIS policy office.