Statement by
Consumer Brands Association
Submitted to House Oversight Subcommittee on Health Care and Financial Services
"FDA Oversight Part I: The Infant Formula Shortage"
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Consumer Brands champions the industry whose products Americans depend on every day, representing more than 2,000 iconic brands. From cleaning and personal care to food and beverage products, the consumer packaged goods (CPG) industry plays a vital role in powering the U.S. economy, contributing $2 trillion to U.S. GDP and supporting more than 20 million American jobs. As we look to the future of our industry, modernizing and reforming FDA is top of mind for the food, beverage and personal care companies we represent.

Our members' experiences across the CPG industry provide real world evidence of why a modernized FDA is warranted. Companies are halting innovation in food packaging and novel foods because of delays in FDA's review of industry submissions. We hear concerns about an inability to innovate, grow and thrive because FDA lacks streamlined decision-making for the range of products within its jurisdiction. To meet consumers where they are today, FDA rightly should be modernized to keep pace with consumer demand and preference.

Addressing structural and governance issues at the agency, particularly with respect to FDA's food and nutrition program, is foundational to modernizing FDA in this space. Consumer Brands appreciates the committee's attention to these issues, and we are hopeful that this hearing will continue the process of elevating and strengthening FDA's role in supporting the CPG industry in meeting consumer demands and expectations, as well as innovating for enhanced safety and environmental quality in the decades ahead.

Unifying FDA's Food Program Under a Deputy Commissioner for Foods

The CPG industry depends on FDA to perform its regulatory role effectively, efficiently and transparently. We appreciate FDA's past collaboration with our industry, consumer groups and the states in implementing the Food Safety Modernization Act (FSMA) and executing on its New Era of Smarter Food Safety initiative. Unfortunately, problems in the food program's organizational structure, governance and performance are impacting the effectiveness of that relationship. For more than a year, Consumer Brands, as part of a coalition and independently, has called on FDA to elevate and unify its foods program under a fully empowered deputy commissioner for foods, with accountability to the commissioner and authority over the Center for Food Safety and Applied Nutrition (CFSAN), the food and feed safety components of the Center for Veterinary Medicine (CVM), and the human and animal food components and operations of the Office of Regulatory Affairs (ORA). We believe this should be done with urgency to benefit consumers and support industry in delivering safe foods to the marketplace. A unified structure and a full-time deputy commissioner for the FDA foods program also translates into results we all care about - focused leadership, accountability, and effective dialogue with myriad stakeholders.

Consumer Brands believes the expert panel convened by the Regan Udall Foundation (RUF) did an outstanding job completing its mandates and providing bold recommendations for the

agency's consideration. The panel recommended that the FDA foods program be unified under a single leader with direct management authority over the entire program, including the inspection, laboratory and import oversight elements now housed in ORA. This recommendation has been rejected by the agency despite the fact that these field-based elements consume nearly 70% of FDA's food-related budget and are vital to the transformation of FDA's food safety program to align with the prevention oriented focus envisioned by Congress in FSMA. Without direct authority over FDA's frontline field force, it is our belief that any new leader will be unable to overcome the myriad cultural and operational problems documented by the expert panel, or accomplish the transformational, program wide modernization called for by said panel.

Further, we agree with the expert panel that the large, frontline workforce needs to become an integral part of the FDA's foods program, and not remain a separate organization that protects its independence and outdated culture of reacting to food safety problems rather than preventing them.

To be clear, the boxes on the organizational chart and "who reports to whom" matter when redesigning FDA's foods program. Structure (boxes and lines) will send one of two messages: either there is a single FDA foods program or, alternatively, there are three, distinct organizational components with disparate leaders and cultures. We urge FDA not to reward entrenched autonomy by replicating a siloed system. Placing all components of FDA's foods program under the deputy commissioner on an organizational chart lays out the expectation of a single, unified foods program and will facilitate the permanent transformational and cultural changes needed for long term success.

FDA can make this change now. The creation of a deputy commissioner for foods does not require an act of Congress or rulemaking. In fact, the position existed during the Obama administration and worked to ensure programs and oversight work at optimal levels.

Consumer Brands acknowledges that FDA's food program may require increased funding to fulfill its mission. We also appreciate that Congress has provided considerable funding for the FDA food program going back to Fiscal Year 2015. A strategic review and realignment around these enhanced priorities could help FDA, and its stakeholders, make the case for bolstering funding if needed. We will continue working with the FDA and committees of jurisdiction to ensure FDA's funding needs are transparent, understood, requested, and appropriated.

Alternative Approach to FDA's Announced Redesign

Consumer Brands would like to offer an alternative to FDA's human foods program redesign. We are confident this plan would help FDA urgently evolve its foods program to one that is action oriented and that makes timely decisions to assure consumers have access to safe, affordable products. Moreover, these changes do not require an act of Congress and can demonstrate meaningful progress in a relatively short period of time.

- **Proposed ORA Restructuring Strategy**

FDA's vision for ORA modernization appears to be focused on enterprise-wide business flow and data capture improvements through the right IT investments. We are concerned that

consistent workflows and data capture with regard to inspections, compliance follow-up and enforcement will be based on the traditional ORA model of reacting to problems once they occur, which may work for drugs and devices, but not for foods. Consumer Brands is calling on ORA to shift to a prevention-oriented mindset which would transform food-related fieldwork and make the best use of federal and state resources.

Consumer Brands believes the only plausible rationale for the agency's rejection of the expert panel's advice is that ORA performs certain support functions for field staff that are common across food, medical product, and tobacco programs, and that efficiencies may be lost if these services are managed separately. This includes facilities, travel, and human resource support. For the record, we agree that the deputy commissioner should not be managing day-to-day administrative activities. To the extent such support services can be performed more efficiently by an administrative unit serving all FDA programs, we encourage this approach. Importantly, in a shared services environment, services required to support the foods program should be paid from resources appropriated by Congress to the foods program. FDA must acknowledge that in exploring enterprise-wide processes and procedures, medical products and food are vastly different. FSMA directed FDA to transition from reacting to food safety problems to preventing them in the first place.

The two elements of ORA that manage the foods program's large inspectorate and laboratory operations are already lodged within separate ORA offices – namely, the Office of Human and Animal Food Operations (OHAFO) and the Office of Human and Animal Food Laboratory Operations (OHAFLO). The reporting lines for these offices could readily be changed from ORA's Associate Commissioner for Regulatory Affairs to the foods program's Deputy Commissioner for Foods.

ORA's oversight of food imports might require a hybrid approach. It is currently managed through the ORA Office of Enforcement and Import Operations that oversees a two-step process involving initial computer screening and selective field exams and/or sample collections of imported food shipments to verify regulatory compliance. The initial screening is currently performed on a centralized basis by a staff that screens all incoming FDA-regulated products. If it's the most efficient way to perform this initial step, it could continue on a shared services basis. Staff performing field exams and sampling could be assigned to OHAFO and be integrated into a unified foods program.

The foods program's information and data analysis systems need to be overhauled and modernized to meet today's food safety needs, which differ from the medical product and tobacco industries. FDA announced a goal of "strengthening our enterprise information technology and analytical capabilities to fulfill the promise described in the New Era of Smarter Food Safety and support the improvement in workflow that will accompany these changes." This necessary modernization will be paid for by the foods program budget and must be directed and managed in line with foods program needs and priorities. An enterprise-wide information system that meets medical product specifications but does not fully meet foods program needs, will be a bad investment.

- **Proposed CVM Restructuring Strategy**

ORA created a specialized human and animal food inspectorate and human and animal food regulatory laboratories under program alignment to deliver on FSMA. We believe the human and animal policy contingents also should be combined. This would facilitate FDA delivering on its commitments to the One Health initiative. By linking humans, animals and the environment, One Health can help address the full spectrum of disease control – from prevention to detection, preparedness, response and management. Further the federal, state, local, tribal and territorial national integrated food safety system envisioned and called for in FSMA involves both human and animal food safety. It simply does not make sense to create an Office of Integration for human foods that does not include the oversight of animal feed and pet food. We remain convinced that the pet food and feed safety components of CVM should be included in the redesign of FDA foods program given the overlap and circularity of issues that exist.

We recognize that CVM does important medical products and nutrition work with regard to pets and food producing animals, and we have never stated those components should be pulled under the deputy commissioner for foods position.

We suggest, as an alternative to FDA's redesign plan, that CVM's Office of Compliance, report to the deputy commissioner for foods. A dotted line to the CVM Director could be drawn if viewed necessary. In addition, if there are shared services that CVM could provide to this component, they could remain in play through appropriate foods program budget reimbursement mechanisms.

Challenges with Matrix Management

We disagree with FDA's proposed use of matrix management as the tool to unify its foods program at the highest levels of the organization. We acknowledge the appropriate application of matrix management to manage multiple, discrete projects or tasks that require diverse subject matter expertise, to coordinate staff functions, and importantly, to speed decision making. But it only works *if* the right structure is established. Additionally, we question the use of matrix management to drive cultural and performance transformation across a large program.

Publications on the topic suggest that matrix management often fails at the senior most management levels of an organization. The matrix approach to FSMA implementation has proven that. For example, a 2014 high level FSMA implementation strategy document focused on transforming how the field force would work under FSMA remains on ORA's website today. It describes principles to guide a new one-mission, one program approach to field implementation of FSMA's prevention framework. ORA concurred with the strategy in word only, but never seriously pursued implementation.

Modernizing the Agency

Organizing under a deputy commissioner for food is step one, not the only step. Consumer Brands set a goal to define a series of high value, product-related policies that embrace technological advancements and reframe FDA's food program operations. A decade ago, we would have thought about modernizing FDA to move at the speed of business. Years later, it is essential that FDA is reformed to move at the speed of the consumer, meeting their rapidly changing preferences and demands.

Last year, Consumer Brands recommended a series of procedural and policy reforms that embrace technology and reframe FDA's foods program operations. The major categories and tactics targeted for reform are detailed in our Consumer Agenda for FDA Modernization and include, in part: labeling modernization, chemicals management modernization, modernization, including hiring staff with appropriate subject matter expertise, to facilitate food packaging innovation, and modernization to streamline the review of industry submissions including food additive petitions, food contact notifications, and requests for letter of no objections.

Conclusion

The CPG industry is accountable to and responsible for the consumers it serves. Working at the speed of the consumer requires a strong, modernized FDA — one that is structured, governed, and funded for success. That may not be the case today, but it is also not the fate of tomorrow if FDA chooses to make smart, needed changes.

Consumer Brands does not believe the FDA's proposed redesign goes far enough. Much more is needed to tackle the food program's structural vulnerabilities that resulted in the infant formula shortage and are putting consumers' health at risk. We request the agency revisit the recommendations of the RUF expert panel, specifically those calling for the commissioner to elevate, integrate and unite the foods program under a fully empowered deputy commissioner.

Our industry stands ready to respond to and partner with the FDA to meet the essential, daily needs of American families. We believe there is ample opportunity for industry, Congress and the administration to work together and deliver a modernized FDA food program. We look forward to working with the committee to achieve this goal.