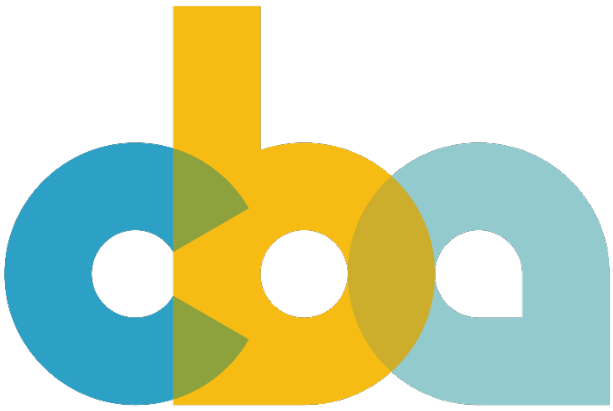

CONSUMER
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U.S. Senate Committee on Appropriations

Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies

"Food Safety and the Food and Drug Administration"
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Statement of Sarah Gallo
Vice President of Product Policy
Consumer Brands Association

Powering every day.

Chairwoman Baldwin, Ranking Member Hoeven and members of the subcommittee, thank you for the invitation to testify at today's hearing. My name is Sarah Gallo, and I serve as vice president of product policy for the Consumer Brands Association.

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.

There is a considerable range of issues currently affecting CPG products. Consumer Brands has been laser focused on supply chain and packaging sustainability for several years, as both issues impact the entirety of the CPG industry and require continued attention. 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.

To meet consumers where they are today, FDA rightly should be modernized to keep pace with consumer demand and preference. 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.

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. The aggressive modernization of FDA's medical products programs that took place several years ago should serve as model and imperative for FDA's food program to keep pace with industry innovation and consumer demands.

We are hopeful that today's hearing can begin a process to elevate and strengthen FDA's role in supporting the CPG industry in meeting consumer demands and expectations and 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. Specifically, the lack of a single, full-time, fully empowered, expert leader affects all aspects of the FDA's food program. Inefficient decision making has slowed reviews, hindering progress and even rendering innovation obsolete. Inexperienced and undertrained inspectors are being sent into the field. A split and siloed food program undercuts communication and collaboration at the expense of efficiency and responsiveness. Each of FDA's major food program units, the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM) and the Office of Regulatory Affairs (ORA), stands to benefit from a common strategic direction, clear priorities, sound resource management and internal accountability that could result from unifying the program under an expert leader who is accountable and responsible for the program.

Consumer Brands is calling on FDA to unify its food program under a deputy commissioner for foods, with accountability to the commissioner and direct line authority over CFSAN, CVM and the food-related components and operations of ORA. There is an urgent need for this change to be made, and the appointee should have relevant and appropriate food credentials to quickly implement modifications that will benefit consumers and our industry. A unified structure and a full-time senior leader translate into results we all care about — focused leadership, accountability and effective dialogue with myriad stakeholders. We believe that the ultimate success of FSMA, as well as execution of the New Era of Smarter Food Safety blueprint, requires transparency and robust engagement with industry, consumer groups, state associations and other stakeholders. This is lacking under the current structure and governance model.

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.

I have made several references to accountability and want to note that 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 this committee to ensure FDA's funding needs are transparent, understood, requested and appropriated.

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.

We are in the process of articulating these policies with our member companies and look forward to sharing our plan with you in the coming months. Certainly, policies related to modernizing inspections, labeling and recall processes, new policy formulation to address e-commerce and the use of technology and new models for FDA-industry collaboration will be included.

Modernizing the agency is business-critical for our industry. FDA must develop and implement a structured, prioritized regulatory agenda for its food program, utilizing a transparent process that allows for stakeholder input and includes a public process for rulemaking and issuance of guidance.

But modernizing the agency also should be business-critical for the agency. Reforms stand to position FDA as a leader and subject matter expert in facilitating innovation, assisting industry in meeting state mandates on issues related to packaging materials and enabling data to drive decision making. We are encouraged that Commissioner Califf noted in testimony before House Oversight and Investigations subcommittee that he will be looking at the overall food program from the perspective of reforming it. Consumer Brands calls on FDA to convene an

independent, outside panel of experts to address modernization of food program policy and procedures.

Applying Lessons Learned from the COVID-19 Crisis

The COVID-19 pandemic created unprecedented challenges for the CPG industry, demanding new approaches to manufacturing processes and temporary changes to government policies and regulations. Many of these crisis-driven actions have proven as safe and more efficient at achieving the goals of pre-crisis public policy and should be made permanent. The experience of the pandemic demonstrates that regulators like FDA and industry can work together to improve the regulatory environment.

Here are a few policies that worked during the pandemic and that continue to work in today's changed operating environment, producing better results for consumers and businesses alike:

1. Develop and Implement Modernized Routine Inspection and Third-Party Audit Models That Include Remote Regulatory Assessments

   COVID-19 illustrated it is possible to facilitate efficient regulatory oversight by inspectors — and verification of suppliers by auditors — through alternative approaches that replace certain in-person practices. Incorporating remote regulatory assessments in modernized inspection approaches has the potential to save hours of time for individual facilities and days for companies with multiple facilities, as well as for government agencies and departments.

2. Expand Government Capabilities to Provide "Speed of Business" Regulatory Responses to Stakeholder Inquiries and Emerging Issues

   During the COVID-19 crisis, regulators provided timely and complete responses and solutions to stakeholder questions and problems. Most regulatory agencies and departments have mechanisms in place for this type of stakeholder engagement, but typically the speed of the response and the provision of practical solutions take weeks. The process deployed during the pandemic for addressing industry's questions and solving problems in real time should be the new normal post-pandemic.

3. Expedite Creation of Just-In-Time Best Practice Documents

   During the COVID-19 crisis, multiple just-in-time industry best practice documents were created by trade associations, including Consumer Brands, that were "blessed" by agencies – CDC and FDA in particular. A process for expeditiously creating these documents, clearing them, subsequently sharing with appropriate federal and state government agencies for their concurrence (as opposed to clearance) and then posting on the web was established and implemented. These documents were fit for use, timely, ensured consumer safety and served to help numerous individual facilities and establishments. This process and expectation should be the new normal and the federal government should partner with industry to achieve this goal.

4. Maintain Food Labeling Flexibility

Labeling flexibilities provided by the FDA during the pandemic to address persistent supply chain challenges were critical to the CPG industry's ability to deliver essentials to consumers, particularly when they were homebound. From allowing minor ingredient substitutions without corresponding label changes to permitting the diversion of product labeled for one use (i.e. restaurants) to be redirected to an area of greater need (i.e. grocery store shelves), these flexibilities make supply chains more nimble, allowing us to better navigate shortages and ensure consumer access *and* safety.

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.

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.

I look forward to your questions and appreciate the opportunity to present our perspective.

Sarah Gallo

VICE PRESIDENT, PRODUCT POLICY

Sarah Gallo is vice president, product policy, at the Consumer Brands Association. In her role, Sarah oversees Consumer Brands' policy leadership on smart regulation issues from advocacy through education to marketplace solutions. She facilitates innovative, productive and strategic partnerships with thought leaders, influential organizations and companies.

Prior to her current role, she served as vice president, agriculture and environment, for the Biotechnology Innovation Organization. There, Gallo led the organization's strategy across agriculture, food systems, energy and bio-based manufacturing.

Gallo has held roles with CHS Inc., where she represented the company's interests on issues related to trade, agriculture, and agronomy at the federal level; the National Corn Growers Association; and as agriculture counsel with the U.S. House of Representatives Committee on Small Business.

Gallo graduated from Boston University with a bachelor of arts in marine biology. She resides in Arlington, Virginia.