Consumer Federation of America

October 4, 2022

Independent Expert Panel
FDA Human Foods Program
Reagan-Udall Foundation for the FDA

Dear Expert Panel Members:

Consumer Federation of America (CFA) appreciates the opportunity to submit the following written comments to inform your external review of the U.S. Food and Drug Administration's food program. CFA is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education.

As you know from the oral testimony given during your deliberations on September 29 and 30 of this year, including my own, FDA's effectiveness in safeguarding the food supply has been hampered by a lack of resources, a lack of transparency, and a lack of willingness to use the agency's full authority to protect public health. These deficiencies feed off one other. For example, without adequate staffing to carry out enforcement actions, a more permissive interpretation of the laws implemented by FDA becomes practically inevitable. However, reform at FDA must start with accountable leadership.

CFA has joined a coalition of consumer advocate, industry, and state regulator stakeholders in calling for FDA Commissioner Robert Califf to create an empowered deputy commissioner for food position that would lead a unified foods program. This position would have direct line authority over all major food program components: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the relevant components of the Office of Regulatory Affairs (ORA). Although no single reform will cure all of FDA's ills, a unified leadership structure will enable a more transparent view into how FDA's food program uses its resources, foster accountability, and enable streamlined decision-making and swift responses that will benefit all stakeholders, both in urgent matters and for daily operations.

CFA was disappointed to learn that CVM was excluded from the panel's review of FDA's food program. CVM's decisions directly affect food safety, and therefore merit consideration of any effort to reform FDA's food program. CVM's failure to withdraw approval of the carcinogenic feed additive Carbadox, for example, imposes an unreasonable and unnecessary health risk on U.S. consumers that the governments of other industrialized countries in the world have long curtailed. Since at least 2016, CVM itself has recognized that "evidence regarding carcinogenic residues in edible tissues of swine treated with carbadox raises serious questions about the human food safety of the drug."[1] Nevertheless, more than

[1] https://www.federalregister.gov/documents/2016/04/12/2016-08327/phibro-animal-health-corp-carbadox-in-medicated-swine-feed-opportunity-for-hearing

six years later, carbadox is fed to more than half of the country's pigs. A deputy commissioner for food with oversight over CVM should take responsibility for addressing this unconscionable delay.

A deputy commissioner should also take responsibility for ORA staff that inspect food facilities and carry out the food program's enforcement activities. The agency's current organization obscures the view into how FDA dedicates resources to the food program, with two different sections of the FDA budget—the food programs budget and the ORA budget—related to food. ORA is responsible for inspecting food facilities, but also for inspecting drug manufacturers and bioresearch facilities and even keeping shipments of opioids and other illicit drugs out of the mail. Placing the relevant sections of ORA under a leader with responsibility for protecting the food supply—and nothing else—will promote transparency and more accountability.

As many others have noted, FDA must operate with more transparency. The Deputy Commissioner for Foods position was eliminated, according to news reports, after the consulting firm McKensey issued a report recommending the reorganization. But that report has not been made available to the public. Nearly six months after submitting a FOIA request, CFA is still waiting for access to it. Unfortunately, the lack of transparency around this McKensey report is emblematic of a deeper, seemingly reflexive inclination of the agency to withhold information from the public.

The agency's policy on disclosing retail consignees of recalled foods provides a telling example, because it directly contrasts with the approach taken by food regulators at USDA's Food Safety and Inspection Service (FSIS). In 2008, FSIS began disclosing the identities of retailers that had sold FSIS regulated food products subject to a Class I recall. In announcing the policy, FSIS concluded that retail consignee information is not confidential. Fourteen years later, FDA has not followed suit, and the agency has not made clear why. Why are consumers privy to the identity of retailers that sold recalled frozen waffle and sausage breakfasts, but not to those who sold recalled frozen waffle breakfasts without sausage? If a legal interpretation is to blame, then FDA leadership should make that clear, and a higher authority should resolve the discrepancy between FDA's and FSIS' reading of the statute. On the other hand, if a lack of resources is to blame, then more transparency could help the agency make the case for more funding.

To its credit, FDA made some progress on the retail consignee issue in 2018 with a guidance announcing a policy to disclose retail consignees of foods that are 1) not easily identified from their packaging (or lack thereof); and 2) likely to remain available for consumption in consumers' homes at the time of the recall. The universe of foods meeting these two conditions is small, since most foods whose origins are not easily identified by packaging, e.g. fresh produce, have short shelf lives and are likely to have been consumed or thrown out by the time a recall is announced. As a result, this policy fails to leverage the power of local media and social media to improve consumer awareness and to "effectuate recalls" that involve products that may be in people's pantries for a long time, like the soy nut butter produce that was recalled a few years back.

This is just one example. Fostering a culture of transparency at FDA will take significant time and effort. As a first step though, FDA leadership should focus on the budget process. The current reporting system gives stakeholders very little insight into what the agency is spending on programs that are not specifically highlighted in the narrative portion of the budget document. Agency leadership should also provide more visibility into the FDA legislative proposal process. FDA's FY 2023 legislative proposals

include several important reforms with respect to remote inspections, dietary supplements, cosmetics, toxins in baby foods, and infant formula. CFA supports these legislative proposals, but there are many other worthwhile reforms not included among them. How FDA determines what makes it on to the list of legislative proposals should be made clearer.

Along with greater transparency, a deputy commissioner for food will be held accountable for FDA's reluctance to use its full authority to protect the public health. This reluctance poses a large obstacle to the agency's success, and to FDA getting the resources it needs. A few examples illustrate how the agency could do much more to protect public health by simply exercising its existing authority. First, FDA can do much more to protect the public from misleading alcoholic beverage labeling. FDA was given jurisdiction over a segment of the alcoholic beverage market in 2008. Recently, many of these FDA-regulated "hard seltzer" type products have begun making vitamin fortification and other illegal claims. But FDA has turned a blind eye, presumably because agency officials do not want to dedicate the resources to enforcement actions.

A second example is infant formula. Abbott Laboratory's Sturgis facility had multiple final product samples test positive for *Cronobacter*, but FDA inspectors did not find out about those test results until they came to the facility for an inspection. Under the existing law, FDA could require real time disclosure of final product testing results from infant formula manufacturers. In particular, 21 U.S. Code § 350a provides that infant formula manufacturers must retain microbiological testing records and that those records "shall be made available . . . for review and duplication upon request" by FDA. FDA thus has authority to request testing records and use the information to prioritize inspections, should the agency choose to invest the time and staff needed to establish such a process.

Finally, FDA must increase its oversight of the chemicals in our food. Admittedly, this is a huge task for which the agency is severely understaffed. However, the workaround that the agency has settled upon—allowing the food industry to make secret determinations of novel food ingredients' safety through the GRAS process—is a pennywise, pound foolish public health strategy. The GRAS process has taken the pressure off Congress and the agency to provide a fix, but it has done a great disservice to consumers. As diet-related disease increasingly suffocates the U.S. economy, this laissez-faire approach will only become more intolerable.

There are many other areas—cosmetics, dietary supplements, front-of-package labeling, agricultural water, genetically modified and other novel food ingredients—where FDA can do more to protect public health using its existing authority. CFA recognizes that finite resources will always necessitate difficult choices at the agency. However, an accountable leadership structure operating with greater transparency will help to ensure that those choices reflect the public interest.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America