ALLIANCE FOR A STRONGER FDA

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Testimony of the Alliance for a Stronger FDA

To the Resources Session of Reagan-Udall Foundation's Public Meeting of the Independent Experts Panel on Human Food Safety on September 30, 2022

Delivered by Steven Grossman

I am Steven Grossman, executive director of the Alliance for a Stronger FDA. On behalf of the Alliance for a Stronger FDA, I want to express our strong support for your efforts.

The Alliance is a diverse coalition of agency stakeholders---consumers, patients, research groups, trade groups and companies—who work together to advocate for FDA's resource needs.

In December 2007, the FDA Science Board, a group of outside advisors to the Commissioner, produced a report, entitled: *FDA Science and A Mission at Risk* (here). Their charge was to look at FDA and produce a far-ranging set of recommendations about agency science.

The report and a subsequent Congressional hearing (here) were galvanizing.

In part because of the report and the alarm it raised, FDA received a $325 million increase in BA (taxpayer) funding in FY 2009. For FY 2010, FDA received an additional $306 million increase in BA funding.

As other panel members have described, it is hard for FDA to receive significant additional funds during the appropriations process. However, it is not impossible. Appropriators and other Members of Congress want safe food just as much as their constituents.

How do we get there? It starts with a strong report from you. Propose the changes that are needed. Recognize that under resourcing of human food programs is a significant contributor to the current situation.

More resources will not solve all the problems. However, no set of solutions can be successfully implemented without a larger budget, more personnel, and improved technology.

Here are some additional points we hope you will consider:

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Resist the call for "changes first, resources afterward." There needs to be a common plan, but once implementation begins, additional resources have to be ready. With no new resources, FDA leadership would have the impossible task of setting up new operations while maintaining the integrity of the existing programs. Many changes will also require skills and experiences for which CFSAN will need to recruit.

Explore the small office problem. The House Appropriations Committee's FY 2023 report contains the following:

> "This bill was developed during the infant formula shortage in the spring of 2022. That crisis revealed the FDA had only nine people in the office that regulates infant formula. This raises a concern about how many other key offices at the agency are also severely understaffed. The Committee will be in dialogue with the agency throughout the year about critical staffing needs."

Given the number and breadth of FDA's responsibilities, we find this a credible concern and believe that CFSAN is particularly vulnerable. We hope the Independent Expert Panel will reach out to the House Appropriations Committee to share notes.

Highlight Science at CFSAN. Regulating human food safety with risk-based decision-making and other tools requires science and emerging technologies. This tends to be underappreciated. That hurts CFSAN internally, diminishes its credibility with policymakers, and undercuts its ability to recruit the skillsets required. We urge you to highlight the importance of science at CFSAN and help achieve more respect for CFSAN's mission and scientific role.

Change Requires Operational and Financial Flexibility. Leadership in human food safety needs goals, supportive structure, and resources. Some of your recommendations may be painfully precise in what they require. The risk is that the process of mapping out a better future turns into a prescriptive exercise, where future leadership is working from a checklist without the flexibility to adjust to changing circumstances.

Keep in mind that more change is coming: no federal agency's mission and responsibilities are more affected by advances in science, technology, innovation, and social trends than the FDA.

To conclude our thoughts: When a complex regulatory system is under resourced—as is the case with human food safety at FDA--you get what you get: mostly good, but very vulnerable.

Properly resourcing the food safety components of FDA would allow the agency to develop and maintain a system that is intentionally excellent. Why would anyone want anything less?

Please help the Commissioner, and eventually Congress, to get this right.

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