Statement by
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Thank you for the opportunity to appear before this panel today to provide remarks as part of your review of the foods program at the Food and Drug Administration (FDA). My comments will focus on the questions provided in advance to all panelists.

What is Working Well at FDA?

There are many dedicated, public health servants within the foods program who possess immense expertise and a passion for the mission. They care about the work they do and are committed to protecting public health and preventing foodborne illness. While the institution may bestow the program with second class status, the foods program is filled with first class personnel.

There are some external communications components that have worked well and have provided good information, including the import alerts weekly summary and the CORE investigation table.

What are the Key Challenges to the Agency?

It has become evident over recent years that the foods program is in need of a significant culture change that would allow for a focus on illness prevention with improved governance, accountability, and transparency. Between inadequate responses to recalls, a failure to implement a culture of illness prevention, and a failure to move quickly on proposed rules and initiatives, there are a number of questions about whether the FDA is performing its regulatory role effectively. The FDA food program appears to be struggling in its role to protect consumers and is preventing the food industry from operating effectively.

The success of the foods programs and its initiatives depend on all the major program units - the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM),

and the Office of Regulatory Affairs (ORA) – collaborating seamlessly with a common strategic direction, clear priorities, effective resource management, and accountability. Success also requires transparency and robust engagement with industry, consumer groups, state partners, and other stakeholders. This is an element that is currently lacking with the FDA food program.

Another key challenge is the FDA foods program lacks a single, full-time, fully empowered expert leader of all aspects of the food program.

In recent decades, most FDA commissioners have been medical specialists who naturally focus on the programs impacting medical products. This leadership focus is certainly warranted considering the significant impact these programs have on public health, and the pandemic provides an example of this.

However, this usually results in intense competition for the commissioner's time and support, and focus on the food program is typically what has suffered under this dynamic. It has become virtually impossible for an FDA commissioner to possess the bandwidth to provide strategic leadership and management accountability to a large set of offices that regulate approximately 80 percent of our food supply.

The fragmented structure and framework of the food program results in delays in making compliance decisions, including recalls. The duplicative multiple compliance and recall groups within each part of the food program and the lack of unifying leadership often result in these delays and an overall lack of urgency.

Proposed Recommendations

Structure/Leadership/Authority

The fragmented structure within the FDA foods program led an unprecedented coalition of consumer groups, industry trade associations and state and local regulators to join together to call on FDA to unify the food program under a deputy commissioner for foods. This position would have accountability to the commissioner and direct line authority over CFSAN, CVM, and the food-related

components and operations of ORA. The coalition letter urged Commissioner Califf to immediately appoint someone with relevant and appropriate food credentials.

In addition to bringing focused leadership and accountability to the FDA's food program internally, a unified structure and a full-time senior expert leader would strengthen the program's standing externally and its ability to be in effective dialogue with its many stakeholders.

Resources

Another area of broad general agreement among stakeholder groups is the need for increased funding for the FDA food program to fulfill its mission. But, this increased funding should come with more accountability and transparency. Congress has provided considerable funding for the food program, especially for the implementation of the Food Safety Modernization Act (FSMA).

However, the current fragmentation of the food program and the lack of a single, empowered full-time expert leader has caused delays in the implementation of FSMA and questions about how funding is allocated within the FDA food program.

The essence of FSMA was calling for a shift in FDA's culture from one that reacted to food safety situations to one that focused on prevention. This is most critically needed in ORA, which is responsible for inspection and compliance, and receives approximately 70 percent of all FDA food program funding.

ORA is viewed historically as an insular organization that resists change, does not transparently share food resource and program data with food policy leaders in CFSAN and CVM. Under the current governance structure, ORA makes unilateral, unaccountable resource allocation decisions that have resulted in a large overhead structure. Only about a third of its resources are allocated to its food safety and compliance activity.

Despite the funding increases Congress has provided, ORA's domestic food inspections declined significantly in the years following the enactment of FSMA and before the pandemic shutdown in March 2020. Unlike other programs, FDA co-regulates food safety with state and local programs. These programs have found funding capped in recent years, and the agency at times

reducing its commitment to states. ORA also significantly reduced FDA-funded state inspections, which can be conducted at a lower cost. Meanwhile, ORA is seeking to count these state inspections that are conducted without federal funding towards its FSMA mandates.

It has become evident that ORA is taking a dismissive approach to the inspection mandates under FSMA, viewing them as the maximum number of domestic inspections and has used the mandates as an excuse to reduce inspection work by the states. An FDA inspection task force issued a report last year recommending that Congress consider repealing the FSMA inspection mandates. In the absence of a transparent approach to assessing facility risk and clear identification of how "risk-based" inspections would occur, this would be a significant step backward.

Conclusion

The need for reforms within the FDA foods program is extensive and will not be solved by the appointment of an empowered deputy commissioner position alone. However, it would bring focused leadership and accountability, and a unified structure that clearly establishes internal roles and responsibilities and strengthens the program's ability to dialogue effectively with its many internal and external stakeholders. The empowered deputy commissioner and unified structure would also allow for streamlined decision-making and swift responses that would benefit all stakeholders, both in urgent matters and for daily operations.

While we recognize that CVM is excluded from your review, we are concerned that this exclusion demonstrates FDA's unwillingness to address difficult internal issues involving structure and accountability, and could be an attempt to influence this panel's recommendations. It also demonstrates a lack of understanding of how the food system works. Virtually every element of CVM's program relates in some way to the food system, including the animal drug approval program, which mainly applies to human food animals, and the regulation of animal feed, which affects both human and animal health. Excluding CVM from this review increases the potential that this panel's final report and recommendations will be incomplete.

Thank you for your consideration of these comments and the panel's overall work in conducting this review of the FDA foods program.

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