

December 15, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903-0002

We write to share our comments and suggestions regarding your next steps based on the analysis and recommendations from the Expert Panel convened by the Reagan-Udall Foundation, and request a meeting as soon as possible to discuss them with you.

As a diverse coalition of FDA stakeholders, we thank you for commissioning the Foundation's independent expert review of the Human Foods Program in the Food and Drug Administration (FDA). The Expert Panel seriously considered the input it received from both external stakeholders and internal foods program employees in producing a candid report.

We believe the Expert Panel report the Foundation issued on December 6 accurately captures the problems involving the structure, leadership, culture, transparency, and accountability within the FDA's foods program, all of which are preventing the agency from doing its best to protect consumers and enable industry to innovate. We also appreciate the Expert Panel's conclusion that having a single leader who is empowered and accountable for the success of the foods program is central to its success; it is noteworthy that all of the panel's options for structural change include this critical element. We also agree with the Expert Panel's recognition that the inspection and compliance functions of the Office of Regulatory Affairs (ORA) needs to be integrated with the policymakers that reside in the FDA's Centers.

We continue to believe that the option of placing an empowered food expert in a deputy commissioner position with line authority over all elements of a unified Human and Animal Foods Program is the critical element of a successful organizational and leadership structure. We also recognize that a range of options for doing this is on the table, all of which warrant discussion.

For example, while we think option E (an empowered deputy commissioner) is the simplest and most expedient way to achieve the needed structural and leadership change, Options A and B also deserve discussion and consideration. We do not consider Option C -- the CFSAN director and a political appointee leading the foods program -- to be viable because no one person would have the bandwidth to both manage CFSAN and provide management oversight of CVM, food elements of ORA, and possibly a new Center for Nutrition.

Moreover, under Option C, operational leadership of the program would remain divided and potentially politicized by an appointee in the commissioner's office. Changing appointees and/or vacancies in the position would also be detrimental to the program. Finally, we do not consider Option D -- relying on the commissioner and an advisor in his office to provide the sustained, integrative leadership the program needs -- to be a viable option due to the tremendous competing demands on the commissioner's time.

We urge you to announce your commitment to an empowered deputy commissioner model (Option B or E) in February, and name an expert food safety leader who could begin serving in that role immediately on an acting basis while deliberations and dialogue continue on how best to implement such a model. This would expedite FDA's reform process while also balancing urgency and the need for further stakeholder dialogue. Formal reorganization of FDA will take time, but culture change can and should begin immediately.

We appreciate the sense of urgency reflected in your intent to announce a new vision for the Food Program by the end of January and a new structure by the end of February. However, we urge you to seriously engage external stakeholders – consumers, industry, and state and local partners – in genuine dialogue before announcing your decision.

The analysis and recommendations of the Expert Panel to establish the structure and leadership the foods program needs to be fully leveraged, and this can be accomplished more effectively through genuine dialogue with your stakeholders.

Thank you for your attention to this issue. We look forward to a meeting and further discussion with you as soon as possible.

Sincerely,

American Bakers Association
American Frozen Food Institute
Association of Food and Drug Officials
Center for Food Safety
Consumer Federation of America
Consumer Reports
Consumer Brands Association
Corn Refiners Association
Environmental Defense Fund
Environmental Working Group
FMI – The Food Industry Association
Global Cold Chain Alliance
Healthy Babies Bright Futures
International Dairy Foods Association
International Fresh Produce Association
National Confectioners Association
National Grocers Association
National Seasoning Manufacturers Association
Natural Resources Defense Council
North American Millers' Association
Peanut and Tree Nut Processors Association
STOP Foodborne Illness
Western Growers