

Thank you for the invitation to speak with you today. Food safety is a thankless profession, and my comments today are not meant to diminish anyone's commitment to food safety rather share a consumer perspective. I am here on behalf of all individuals and families that continue to be impacted by foodborne disease. Stop Foodborne Illness, or STOP, is a national public health organization that was born out of tragedy almost 30 years ago. It was the same tragedy that launched Mr. Marler's practice. Parents, who lost their children to a foodborne pathogen they had never heard of, wanted answers. Through their pain, STOP's founding mothers and fathers learned that deadly bacteria were legally allowed to be present in the food they fed to their children.



These courageous individuals activated and advocated for change; their singular focus was preventing this from happening to others. Sharing their individual stories of pain and loss, they engaged regulatory leadership. Those leaders understood change was not only needed but necessary to restore trust in the system. The response was to take appropriate action against the devastating outcome of the Jack in the Box O157:H7 outbreak. *E. coli* O157:H7 was declared an adulterant in ground beef – the first meat and poultry reforms in 88 years.

The list of issues that STOP has advocated since its inception is long and if you review the timelines, change comes as a reaction to a tragedy. STOP fully engaged and supported of the passage of the 2011 Food Safety Modernization Act (FSMA) because its focus is on prevention. Our constituent advocates publicly stood to share their stories of illness, permanent injury, and loss of life to put a face on foodborne disease, to underscore that it is unacceptable to die from eating, and that we are all susceptible. The message, which we continue to share, is consumers and public health must be the focus during the decision-making process and prevention is key to reducing illness and death.

Eleven years later, consumers still wait for the culture shift from reactionary to prevention. As evidenced in the powdered infant formula recall from Abbott Nutrition, the culture is reactive, the process lacks clarity, and the system is not structured for swift, urgent action to protect consumers. The FDA released its internal review of its response to the infant formula crisis last week. Upon reading it, as a consumer it alarms me; as the leader of a national public health organization, it has me questioning the goal of the exercise.

The internal review recounts the missteps including lack of proper training and lack of clarity of roles - both of which are essential for performing job duties. However, it does not provide any substantive call for change nor any findings regarding the fragmented leadership structure that, based on evidence, is in large part core to the failure to respond to the powdered infant formula crisis with urgency. The report falls far short of seriously addressing the full scope of the culture issues within the agency and provides what I call ‘recommendations lite’. I say that because the recommendations speak of *developing* policies and *evaluating* procedures and *consider* having after-action meetings. Yes, these activities should occur if they do not currently; however, there is no discussion of root cause analysis or making the internal cultural shift toward prevention. The FDA has the authority to create a singular leader – with food safety expertise - of the food program now. It must take the opportunity to unite the food program and begin to tackle the findings in the internal review.

I want to share some bright spots in our current engagement with FDA. STOP’s work centers on building collaborative coalitions to increase the safety of the food supply and that includes working with federal agencies. The New Era for Smarter Food Safety blueprint has provided opportunities to engage with FDA – specifically on recall modernization and food safety culture. Those individuals we have been working with to bring the New Era to life have provided thought leadership in a truly collaborative manner. And STOP, with our partners NCSU and Cultivate SA, worked with Michael Roger’s team to design and deliver 24 3-hour live food safety culture courses to 1200 Consumer Safety Officers – who are part of the Office of Regulatory Affairs.

Yesterday at the WH Conference on Hunger, Nutrition and Health, President Biden stated that that no one should die of a disease that can be prevented; foodborne disease is preventable. Consumers want to trust that the foods that they feed their families are safe. The slow pace of implementation of FSMA, the same foods regularly being recalled, and the ongoing powdered infant formula crisis have eroded that trust. Consumers are trusting that this process, that you have undertaken, will have meaningful impact on their safety. Consumers cannot wait 88 years and continue to suffer the consequences of resistance to change.

Thank you.

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