Congress of the United States

Washington, DC 20510

January 30, 2023

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing regarding the Reagan-Udall Foundation's critical review of the Food and Drug Administration's (FDA) Human Foods Program. You previously stated that this review would help inform a "new vision" for FDA that will be announced at the end of this month. As part of this "new vision," we encourage you to embrace the significant leadership and structural reforms that the Foundation recommended in its report. American families cannot afford for FDA to continue its inadequate food oversight, especially when we now have a comprehensive analysis of how to start to remedy the agency's food safety failures.

In addition to its other duties, FDA is responsible for the oversight of nearly 80 percent of food in the United States—from peanut butter, to lettuce, to infant formula. Too often, however, the FDA has failed to protect Americans from dangerous food pathogens and outbreaks. Every year, more than 48 million Americans are sickened, 128,000 are hospitalized, and 3,000 lose their lives because E. Coli, Norovirus, Salmonella, or some other bacteria or virus in their food. This pain, suffering, and loss of life is unacceptable; and, even more infuriating, it can be prevented.

In 2011, the *FDA Food Safety Modernization Act* (FSMA), legislation we crafted to transform our nation's approach to foodborne illnesses, was signed into law. It had a simple premise: FDA was too reactive to foodborne illness outbreaks, acting only after a problem had arisen and people had been sickened. We worked with bipartisan Members of Congress, consumer organizations, and food companies to turn FDA into an organization that would prevent outbreaks in the first place. The FSMA empowered the FDA with new authorities, resources, and funding to accomplish this goal. But, as outlined in the Reagan-Udall report, FDA has not lived up to its end of the bargain, despite the FSMA's passage more than a decade ago.

For example, in October 2021, FDA was alerted to significant compliance issues at Abbott Nutrition's Sturgis, Michigan, facility—a facility responsible for manufacturing infant formula. However, despite the vulnerable population that consumes the products manufactured at this facility, FDA did not follow up and inspect the facility until January 2022, upon which it found several samples to suggest the presence of *Cronobacter*. Even then, FDA did not request that Abbott initiate a recall of their infant formula—nor warn consumers—until mid-February 2022. It's difficult to explain why FDA moved this slowly, even when this issue hospitalized at least four infants, claimed two of their lives, and had the potential to harm the health and well-being of other infants across the nation.

Americans deserve better than what FDA has done to ensure food safety. That is why we introduced a bill last Congress to create a new, independent "Food Safety Administration" responsible for taking over FDA's food oversight responsibilities. In the Reagan-Udall Foundation's report, this proposal was included as their first option for structural reform at FDA. We understand that this change would require congressional action and would be difficult to accomplish in a divided Congress. However, FDA should take this recommendation to heart and begin undertaking meaningful steps to improve the Human Foods Program in the meantime.

As was outlined in the report, the Human Foods Program must be unified under a single leader and restructured. To this end, we urge you to empower a Deputy Commissioner for Foods with authority over the Human Foods Program; separate the Center for Food Safety and Applied Nutrition (CFSAN) into a "Center for Food Safety" and a "Center for Nutrition;" and directly integrate the Office of Regulatory Affairs' (ORA) food-related inspectional and compliance responsibilities within the Human Foods Program.

As commissioner, you have the power to turn the FDA into an organization that meets its mission and prevents foodborne illnesses and outbreaks—saving and improving lives nationwide. Now is the time for real reform at FDA—it is not the time for half measures or more excuses. We look forward to learning more about your "new vision" for FDA's Human Foods Program later this month.

Sincerely,

Richard J. Durbin
United States Senator

Rosa L. DeLauro
United States Representative