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HAWAII

United States Senate
WASHINGTON, DC 20510-1104

COMMITTEE ON ARMED SERVICES
COMMITTEE ON ENERGY & NATURAL RESOURCES
COMMITTEE ON THE JUDICIARY
COMMITTEE ON SMALL BUSINESS & ENTREPRENEURSHIP
COMMITTEE ON VETERANS' AFFAIRS

May 11, 2022

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10902 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf,

As Democrats work to address the supply-chain crisis, families continue to experience difficulties in accessing critical supplies, including baby formula. It is critical that the Food and Drug Administration (FDA) expeditiously investigates and resolves the outstanding concerns with Abbot Nutrition's Sturgis facility and ensure safe production resumes as quickly as possible. Additionally, the FDA must take steps to prevent a recurrence of this kind of shortage.

According to recent reports, starting the week of April 24, the amount of formula available on shelves was 40 percent below normal inventory levels, up from 31 percent three weeks prior and 11 percent in November. In an industry that has become increasingly consolidated, we cannot afford to have such a high-volume factory producing unsafe formula or going offline for prolonged periods of time.

In the United States, almost three-quarters of all babies—2.7 million a year—will rely on formula for some portion of their nutrition. Even babies who successfully breastfeed often need additional nutritional support from formula, 19 percent of breastfed newborns receive formula supplementation within the first 2 days of life.

Decreased supply is threatening the health and safety of infants across the country, particularly infants with health issues and infants from families with low-incomes and families of color. The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) limits recipients to a few brands of formula, and with Abbot as a major contract holder their shutdown creates an untenable situation for many families. Further, babies, older children, and adults with life-threatening allergies, metabolic issues, or feeding tubes can only tolerate certain formulas leaving them in a dire situation when supply becomes scarce.

Reports indicate that families are taking drastic measures to feed their babies including making risky substitutions or diluting formula to make it last longer, and even using recalled formula. The longer formula scarcity exists, the more likely families are to take these dangerous steps.

The closure of Abbott's facility, supply chain issues, and the impact of rising food costs have all made it increasingly difficult for families to find and afford formula – a problem that is even more dire in high cost of living states like Hawaii.

Understanding the responsibility and authority of FDA will help address the current crisis and prevent future threats to infant safety. Thus, I request your responses to following questions:

1. Please outline FDA's authority over safety and supply of formula.
2. Please provide details regarding the agency's investigation, steps to address the immediate crisis, timeline, and coordination with other federal agencies.
3. Please detail the agency's long-term plan to alleviate future problems with supply and distribution, including any coordination with other federal partners.

I ask that FDA treat this problem with the urgency it requires, and hope we can work together to ensure formula is safe, accessible, and affordable for families in Hawaii and across the country. Please provide us with a response to this urgency request no later than May 25, 2022.

Sincerely,

Mazie K. Hirono

United States Senator