

Congress of the United States

Washington, DC 20510

May 13, 2022

Commissioner Robert M. Califf M.D.
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf,

We write today to express alarm and concern about the continued lack of access to infant formula impacting parents and caregivers across the country. On February 17, 2022, the Food and Drug Administration (FDA) took action to recall Abbott’s Similac, Alimentum, and EleCare infant formulas due to apparent bacteria growth at the company’s Sturgis, Michigan plant, which resulted in infant deaths and illnesses.¹ We have long expressed concerns with the speed and efficacy of the FDA’s food and safety nutrition center, and the protracted delay in issuing a recall in this chilling case has exacerbated those concerns. While we must address the issues the led to this failure, at this point in the crisis, it is just as critical that we urgently focus on getting safe and affordable infant formula to the families that need it.

Approximately three in four babies are given formula in the first six months of their life², and approximately one in five receive formula in just their first two days of life.³ For some infants, the nutrition support provided by certain formulas, like EleCare, is essential— infants with medically complex needs may rely on prescribed formulas due to allergies, feeding tubes, or nutritional deficiencies.⁴ Formula supply was already limited due to global supply chain disruptions, but since the recall in February, formula access has further declined to alarmingly low levels: in March, 29% of formula inventory was out of stock, and by May, that number had climbed to 40%⁵; some metro areas have seen much higher numbers.⁶ Not only has supply of the recalled formulas—Similac, Alimentum, and EleCare—dropped, but other brands have seen availability disruptions as families have flocked to purchase the remaining stock—a switch that in and of itself can often result in negative health outcomes.⁷

¹ “Powdered Infant Formula Recall: What to Know,” U.S. Food and Drug Administration, last modified April 29, 2022, <https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know>.

² Centers for Disease Control and Prevention, “Breastfeeding Report Card United States, 2020,” <https://www.cdc.gov/breastfeeding/pdf/2020-Breastfeeding-Report-Card-H.pdf> (accessed May 11, 2022).

³ CDC, “Breastfeeding Report Card.”

⁴ Parija Kavilanz, “Baby Formula Shortage has Some Families Scrambling,” *CNN* February 8, 2022, <https://www.cnn.com/2022/02/08/business/baby-formula-shortages/index.html>.

⁵ Kavilanz, “Baby Formula Shortage.”

⁶ Ryan Nickerson, “As Houston’s Baby Formula Shortage Worsens, Parents Scramble to Find Food for Newborns,” *Houston Chronicle* (Houston, TX), May 10, 2022, <https://www.houstonchronicle.com/news/houston-texas/trending/amp/baby-formula-shortage-17133468.php>.

⁷ Anna Guizerix, “‘SO STRESSFUL’: Vicksburg Families Impacted by Baby Formula Shortage,” *The Vicksburg Post* (Vicksburg, MS), April 29, 2022, <https://www.vicksburgpost.com/2022/04/29/so-stressful-vicksburg-families-impacted-by-baby-formula-shortage/>.

Families are feeling the impact. Caregivers have described traveling to Target, Walmart, CVS, and other stores in search of formula, only to come up empty handed—forced to go without for a day, or more. If they can find the formula that their child relies on, they are often limited in the number of products they can purchase. As a result, some parents have even resorted to diluting formula to make it last longer, which doctors warn can have extremely dangerous health repercussions for infants. Other families, including some in Connecticut, have reported price gouging online, particularly on eBay and other marketplaces where they are desperately searching.⁸ Raising an infant is a stressful enough experience without wondering whether or not you will be able to find—or afford—the food your child desperately needs to grow, thrive, and stay healthy.

While the FDA has recently noted that the agency will “continue [its] discussion with Abbott Nutrition and other infant formula manufacturers... to support the supply of infant formula products,”⁹ parents need concrete solutions and answers now. The agency cannot rely on or defer to Abbott and their promises to “consider release of [the] products on a case-by-case basis.”¹⁰ As such, we respectfully request answers to the following questions:

1. When does the FDA expect formula supply shortages to be mitigated and to return to pre-recall levels?
2. How has the FDA engaged with retailers to support replacement supplies for formula and prevent price gouging?
3. How was the FDA working with formula suppliers prior to the recall to eliminate shortages related to the pandemic and global supply chain disruptions?
4. How is the FDA actively working with Abbott, and other suppliers, to increase infant formula production now that the recall has further impacted supply?
5. Is the FDA taking specific steps to improve shortages of specialized infant formula often needed by children with medically complex needs? If yes, what actions is the agency taking?
6. How is the FDA ensuring that the safety of product distributed by Abbott on a case-by-case basis is prioritized?

We respectfully ask that you reply to these questions by May 27, 2022. These shortages are of critical concern to families in Connecticut and across the country, and we must work quickly to ensure that all infants have access to the nutrition they need.

Sincerely,


RICHARD BLUMENTHAL
United States Senate


ROSA DELAURO
Member of Congress

⁸ Amber Diaz, “Baby Formula Shortage Forces Connecticut Mothers to Go to the Extreme,” *NBC Connecticut* (West Hartford, CT), April 27, 2022, <https://www.nbcconnecticut.com/news/local/baby-formula-shortage-forces-mothers-to-go-to-the-extreme/2771731/>.

⁹ “Powdered Infant Formula Recall: What to Know.”

¹⁰ *Ibid.*