United States Senate
Washington D.C. 20510

May 18, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, M.D. 20993

Dear Commissioner Califf:

Thank you for your efforts to ensure food safety at the Food and Drug Administration (FDA). For decades, the FDA has been the gold standard for approving and regulating medical products and food. Yet this year, the actions of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) has raised questions regarding its ability to fulfill its core oversight responsibilities. The safety of, and access to, infant formula should be among CFSAN's highest priorities, as this food is vital for the growth and development of infants. To this end, we write to request a response from FDA on its activities that may have contributed to the exacerbated infant formula shortages and specific questions in the following paragraphs. It is our responsibility as U.S. Senators to do everything with our authority to hold the FDA accountable and legislate in areas that will enable the agency to meet the expectations of the American people.

Our hearts and prayers are with the parents and their families whose babies tragically died due to infant formula bacterial contamination. We understand and want to support the FDA in thoroughly evaluating all reported and potential infant formula contaminations. However, based on the timeline and where we are today, it is unclear as to why nearly three months have gone by and the FDA has failed to expeditiously conduct and conclude its investigation. On February 17, Abbott Nutrition initiated a proactive, voluntary recall of three of its powdered formulas manufactured at their facility in Michigan following four consumer complaints of potential *Cronobacter* bacteria contamination.[1]

[1] Abbott, Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant, February 17, 2022, https://abbott.mediaroom.com/2022-02-17-Abbott-Voluntarily-Recalls-Powder-Formulas-Manufactured-at-One-Plant. *See* also U.S. Food and Drug Administration, Company Announcement: Abbott Voluntarily Expands Recall of Powder Formulas Manufactured at One Plant, February 17, 2022, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant.

The following day, FDA warned consumers not to use these products.[2] On April 15, the U.S. Centers for Disease Control and Prevention concluded the bacteria isolated from two of the sick infants and the Michigan facility had no connection. And as of last week, no connection has been found, yet the facility remains idle.[3, 4]

We are also concerned as to why FDA leadership failed to be proactive in mitigating the shortage crisis parents are now facing. The COVID-19 pandemic revealed many vulnerabilities across all sectors of industry, and our food supply chain was woefully unprepared to handle challenges here and from foreign partners. Infant formula supplies at local grocery stores were relatively stable for the first half of 2021. The out-of-stock percentage started to climb steadily in the later half and continued to worsen throughout this year.[5] Abbott Nutrition's voluntary recall exacerbated the shortage, and yet no policies were taken to mitigate the sharp increases to the current out-of-stock 43 percent the Administration is now scrambling to address. It's also concerning that FDA and key officials in the Administration did not anticipate this crisis or take action within days following Abbott Nutrition's voluntary recall considering the company holds 48.1 percent of the U.S. market in infant formula.[6]

Families are getting to the brink of pursuing unsafe and potentially dangerous options to feed their infants including homemade infant formula. And physicians are, once again, running defense on misinformation due to a lack of federal action to get the word out on safe alternatives.[7, 8, 9] In addition, the shortage will trickle into other federal agencies, diverting and stretching resources from other crises like illicit fentanyl. In April, the U.S. Customers and Border Protection (CBP) seized $30,000 worth of unapproved infant formula across 17 shipments at the Philadelphia, Pennsylvania port of entry.[10]

Based on the timeline, it is unclear why federal health agencies have not been able to complete this investigation in a more expeditious manner or plan ahead to mitigate this additional supply chain disruption. Therefore we respectfully request your responses to the following questions:

1. The manufacturing facility in Michigan is segmented where manufacturing designated areas are required to adhere to specific safety and infection control standards. The facility also

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[2] Kansas Department of Health and Environment, KDHE & FDA warn consumers not to use select Similac, Alimentum & EleCare powdered infant formula, February 18, 2022, https://www.kdhe.ks.gov/CivicAlerts.aspx?AID=147.
[3] Abbott, Press Release: Abbott Provides Infant Formula Update, May 11, 2022, https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html.
[4] U.S. Centers for Disease Control and Prevention, Cronobacter and Powdered Infant Formula Investigation, accessed May 12, 2022 (updated May 12, 2022), https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html.
[5] Datasembly, Nation-wide Out-Of-Stock is now at 43% for the week ending May 8th, May 10, 2022, https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/.
[6] IBISWorld, Industry Report: Infant Formula Manufacturing, by Jack Curran, August 2020, https://www.ibisworld.com/united-states/market-research-reports/infant-formula-manufacturing-industry/.
[7] The New York Times, Why Doctors Don't Recommend Homemade Baby Formula, by Catherine Pearson, May 11, 2022, https://www.nytimes.com/2022/05/11/well/homemade-baby-formula.html.
[8] KAKE ABC, Homemade infant formula can be dangerous. Experts share how to feed your baby through the shortage, by Madeline Holcombe, May 11, 2022, https://www.kake.com/story/46472922/homemade-infant-formula-can-be-dangerous-experts-share-how-to-feed-your-baby-through-the-shortage.
[9] Bloomberg, Parents Are Trying Homemade Baby Formula. Doctors Say They Shouldn't, by Allison Nicole Smith and Kelsey Butler, May 12, 2022, https://www.bloomberg.com/news/articles/2022-05-12/why-parents-making-homemade-infant-formula-should-beware-of-serious-health-risks.
[10] U.S. Customs and Border Protection (CBP), Philadelphia CBP Seizes Nearly 600 Cases of Infant Formula Unapproved for Import to the United States, April 5, 2021, https://www.cbp.gov/newsroom/local-media-release/philadelphia-cbp-seizes-nearly-600-cases-infant-formula-unapproved.

maintains areas that are administrative and do not directly handle manufacturing or exposure of open products. Please describe the areas in which the FDA has taken samples and how many samples were taken that would empirically validate the results of the investigation. In your explanation, please also include the expected timeline for each task and if CFSAN has met its obligations.

2. As noted in the paragraph above, the CDC concluded that the samples taken did not match the bacteria in the facility. How does the FDA partner with other agencies at the federal, state, and/or local level to expedite investigations to forestall potential supply chain crises? To what extent do other agencies or organizations advance or hinder a timely investigation?
3. Why has it taken more than three months to complete the obligations required to finalize a safety inspection?
4. At what point did the FDA alert the White House of the bacteria and the product recall?
5. Did the FDA, along with the White House, have a strategic plan in place to mitigate formula shortages? If yes, please provide a brief description, date of implementation, actions the agency has taken, and expected timelines to enable manufacturers to produce, process and deliver food during supply chain disruptions.
6. Did or has the FDA made any recommendations to the White House about what actions the agency can take to prepare or handle the shortage?
7. The manufacturing facility in Sturgis, Michigan is the only Abbott plant to produce specialized formula for infants with metabolic disorders. How is the FDA going to work with Abbott and other formula manufacturers to ensure that the special medical needs of infants can be met?
8. Abbott Nutrition, along with other infant formula manufacturers, have registered domestic and foreign sites to manufacture infant formula for interstate commerce in the U.S. Abbott Nutrition's facility in Ireland is an FDA-registered facility. It also has several other facilities in the Netherlands, Spain, and France that manufacture infant formula. What steps has FDA taken to increase importation by accrediting more manufacturing facilities overseas?
9. At what point was the White House made aware that these importation options were available to ease the strain on domestic capacity?
10. Whose decision was it to ease these requirements on formula from foreign manufacturers?
11. In White House press briefings last week, the Press Secretary and others within the Biden Administration appeared to blame Abbott Nutrition for the deaths and shortages, despite the fact that the investigation is not concluded.[11, 12] Did the FDA state to the White House that Abbott Nutrition was responsible for the illnesses or deaths?

The shortage, felt by all families in need, is disproportionately impacting vulnerable populations. As you know, Medicaid is a major source of coverage for low-income vulnerable populations including pregnant women, infants, and children. In 2020, Medicaid covered 42 percent of births.[13] In addition,

[11] The Hill, White House goes on defense on baby formula shortage, by Alex Gangitano, May 13, 2022, https://thehill.com/news/administration/3487765-white-house-goes-on-defense-on-baby-formula-shortage/.
[12] The Hill, Buttigieg points blame at Abbott for baby formula shortage, by Monique Beals, May 15, 2022, https://thehill.com/news/administration/3489439-buttigieg-points-blame-at-abbott-for-baby-formula-shortage/.
[13] March of Dimes, Health Insurance/Income, https://www.marchofdimes.org/peristats/data?reg=99&top=11&stop=154&lev=1&slev=1&obj=18.

49 percent of infants born in the U.S. participate in the Special Supplemental Nutrition Program for Women, Infants, and Children.[14] While breastfeeding has been on the rise, many infants rely on formula partially or as their sole source of food.

The FDA must do everything within its statutory authority to ensure it facilitates access to safe, quality foods. We would appreciate a reply no later than Wednesday, May 25, 2022. Thank you for your attention to this matter and please do not hesitate to reach out to us or our staff should the agency require resources or cooperation from other agencies to fulfill its obligations.

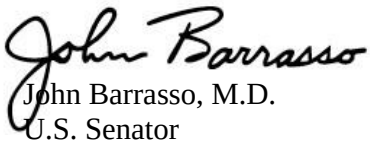
Sincerely,

Roger Marshall, M.D.
U.S. Senator

Shelley Moore Capito
U.S. Senator

Susan M. Collins
U.S. Senator

Mike Braun
U.S. Senator



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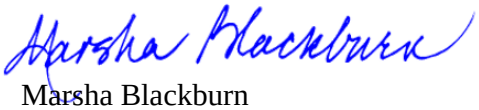

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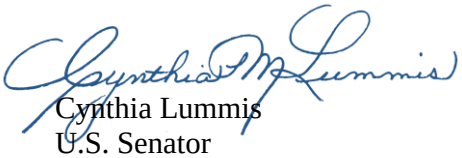
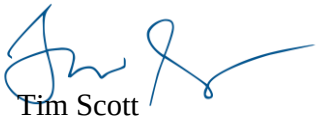


Cynthia Lummis
U.S. Senator



Tim Scott
U.S. Senator

[14] National WIC Association, The State of WIC: Investing in the Next Generation, February 2022, page 40, https://s3.amazonaws.com/aws.upl/nwica.org/state-of-wic_2022.pdf.

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