United States Senate
Washington D.C. 20510

September 20, 2022

**VIA ELECTRONIC TRANSMISSION**

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

Commissioner Califf:

Thank you for responding to our letter regarding the U.S. Food and Drug Administration's (FDA) investigation of Abbott Nutrition's facility and the infant formula shortage crisis. Despite the numerous flexibilities and resources provided by Congress and temporary import flexibilities outlined in your letter, the infant formula crisis persists nationwide.[1, 2, 3] Some of the FDA's flexibilities are set to expire at the end of this month and Operation Fly-Formula, while alleviating some issues, cannot run indefinitely. American families need permanent long-term solutions, and that includes increasing capacity and competition in the U.S. market.

The infant formula market has consolidated over the years due to manufacturing-related issues and consumer demand so any disruption in an oligopoly will undoubtedly lead to supply chain shortages. Over 80 percent of the market is largely comprised of three manufacturers including Abbott Nutrition, Mead Johnson, and Perrigo. Abbott Laboratories lead with 49.5 percent, followed by Mead Johnson at 20.6 percent, and Perrigo with 11.9 percent.[4] Abbott Nutrition recently announced it will restart its Similac® infant formula production at its facility in Sturgis, Michigan.[5] We understand

[1] MarketWatch, Baby-formula shortage is finally easing, although some states are still seeing high out-of-stock rates, by Zoe Han, August 22, 2022, https://www.marketwatch.com/story/baby-formula-shortage-is-finally-easing-although-some-states-are-still-seeing-high-out-of-stock-rates-11660833270.
[2] KSHB Kansas City, Local mothers still struggle to find baby formula amid ongoing shortage, by JuYeon Kim, August 26, 2022, https://www.kshb.com/news/local-news/local-mothers-still-struggle-to-find-baby-formula-amid-ongoing-shortage.
[3] KFYRTV, Baby formula shortages persist, by Christa Kiedrowski, September 5, 2022, https://www.kfyrtv.com/2022/09/05/baby-formula-shortages-persist/.
[4] IBISWorld, Industry Report: Infant Formula Manufacturing (OD4287), Jack Curran, June 2022, https://www.ibisworld.com/united-states/market-research-reports/infant-formula-manufacturing-industry/.
[5] Abbott, Press Release: Abbott is Restarting Similac Production at Sturgis, August 26, 2022, https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html.

FDA did not establish or rule out a direct link between the deaths and the formula produced at the plant. But we now know that any disruption from one manufacturer – including one that makes up almost half of the infant formula market – can devastate families and cascade into a whole-of-government approach to resolve. Given the delicate nature of the infant formula supply chain, it's become even more apparent that we need to diversify our commercial capacity by providing other industry manufacturers the opportunity to compete. This is especially necessary for manufacturers of infant formula products that cannot be reasonably substituted by currently available products.

Despite this significant crisis, to date, under the enforcement discretion authorized by President Biden's May Executive Orders to address the formula crisis, the FDA approved only 23 infant formula products, or base powder, from 10 unique manufacturers out of dozens of ex-U.S. based formula and milk companies that have applied for short-term FDA approval to provide infant formula to the U.S. marketplace. Of the products approved, 13 were approved for infants who rely on "regular" formula products, and only three are for special nutrition needs. In addition to these products intended for infants who rely on "regular" formula, the agency has approved just 6 specialty products, or bases, from 5 unique manufacturers. The last application granted by FDA for enforcement discretion was August 10, over a month ago.

What's most concerning is FDA's decision last month to defer further review of pending applications after taking over a month to respond.[6, 7] We understand from several manufacturers that FDA has still not indicated any attempt to review or prioritize increasing domestic production through competition.

Given the above, it is unclear why the Center for Food Safety and Applied Nutrition has chosen to ignore so many applications for more manufacturers to market infant formula products for interstate commerce. Therefore, we respectfully request your responses to the following questions:

1. Over the last several months, how many applications for infant formula products has the FDA received, and what were the committed quantities in these applications?
2. For the 16 products approved, what is the current status of manufacturers' production capacity and committed quantities?
3. Of the 10 unique manufacturers applications that FDA approved, which manufacturers delivered on committed quantities?
4. For manufacturers the FDA approved, have any of their authorizations been withdrawn? If so, please describe the reason.
5. How many applications are currently pending? Starting from the submission dates, what is the timeline of each application's status based on FDA's classification of its stages for approval?
6. Are there applications pending, deferred, or denied that aimed to bring to market specialty infant formula?
7. Has the FDA provided reasonable flexibilities in its communications with applicants?
8. Can you provide a clear explanation as to why no additional applications for regular infant formula have been approved since August?

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[6] Just-Foods, New Zealand's A2 Milk Co. thwarted in plan to export infant-formula to US, by Andy Coyne, August 10, 2022, https://www.just-food.com/news/new-zealands-a2-milk-co-thwarted-in-plan-to-export-infant-formula-to-us/.

[7] Agri-Pulse, Infant formula shortage is easing, but not likely to be resolved quickly, by Sara Wyant, August 11, 2022, https://www.agri-pulse.com/articles/18110-infant-formula-shortage-is-easing-but-not-likely-to-be-resolved-quickly.

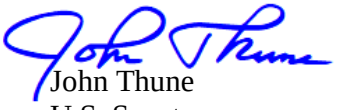
The FDA has the opportunity to learn from this crisis and ensure this does not happen again. We would appreciate a reply no later than Wednesday, October 5, 2022. Thank you for your attention to this matter and please do not hesitate to reach out to us or our staff should the agency require resources or cooperation from other agencies to fulfill its obligations.

Sincerely,

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

Shelley Moore Capito
U.S. Senator

John Boozman
U.S. Senator



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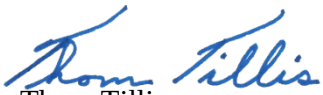

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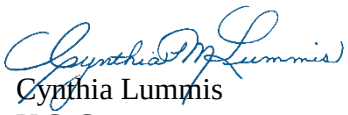

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