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May 17, 2022

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

Dear Commissioner Califf,

I write today regarding the acute nationwide shortage of infant formula. The Food and Drug Administration (FDA) is tasked with protecting the nation's public health, but also regulating commercially available infant formulas in liquid and powder forms. I am increasingly concerned that not only has FDA failed to uphold either of these responsibilities, but it is woefully unprepared for future shortages of essential products like infant formula.

There are millions of infants whose sole source of nutrition comes from infant formula, as well as some children and adults who have severe allergies or metabolic conditions that prevent them from consuming any other foods. The current shortage of infant formula is impacting countless families in West Virginia, who are being forced to scour stores or drive hours across state lines only to find shelves empty and no formula to be found. Much of this could have been forestalled if the FDA had acted proactively after initially identifying contamination of certain infant formulas.

According to the FDA's Data Dashboard, which publicly displays data on inspections of facilities across the United States, Abbott's Sturgis facility was inspected 19 times between 2009 and 2021.[1] During a 2010 inspection, investigators found deficiencies in manufacturing conditions, safety assurance, and lack of effective pest exclusion. During a 2019 inspection, investigators found that final infant formula products were not being tested to ensure they met certain biological standards. Finally, during a September 2021 inspection, at which time consumer complaints involving contaminated infant supply were starting to be submitted to Abbott Nutrition, investigators found additional deficiencies and cited personnel working directly with infant formula, packaging, equipment and other materials who had not washed their hands.

On February 17, 2022, the FDA announced it was investigating complaints of illnesses related to powdered infant formula products manufactured at Abbott Nutrition's facility in Sturgis, Michigan, [2] that were received as far back as September 1, 2019. On the same day the FDA made the announcement that it was investigating, Abbott announced it would voluntarily recall

[1] https://datadashboard.fda.gov/ora/firmprofile.htm?FEIi=1815692
[2] https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility

certain infant formula products, including similac, alimentum and elecare products,[3] while FDA recommended that consumers avoid purchasing or consuming certain powdered infant formula products produced at this facility.

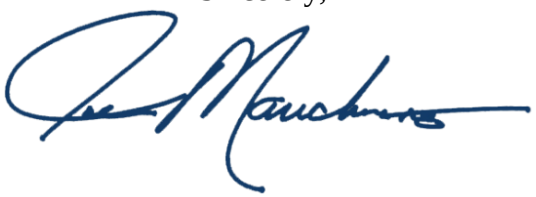
It took the FDA until May 10, 2022 to announce the steps it would take to improve the supply of infant formula products in the United States,[4] almost three months after the FDA began its investigation into contaminated infant formula manufactured at the Sturgis facility and an additional four months after undertaking the 2021 inspection of the Sturgis facility that found serious lapses in safety and health conditions.[5] Additionally, the FDA had a 34-page whistleblower report from October 2021, that outlined serious allegations about data falsification.[6] Over those seven months, the FDA could have and should have taken decisive action to quickly address the shortage it knew would come by allowing other facilities to produce higher quantities of infant formula, beginning the process of importing foreign supplies of FDA-approved infant formula, or clearing formula that had been produced but kept at the Sturgis facility in storage. In addition, the FDA could have established an Incident Management Group (IMG) immediately following the initial announcement instead of waiting for news reports to come out regarding lack of supplies.[7]

At every step of this crisis, the FDA has been caught flat-footed. Now, parents and children face a crisis that is putting their infants and family members at risk. The FDA has long advised parents and caregivers against diluting infant formula and against making their own formula recipes at home, but parents and families are desperate. They are running out of options. I urge you to use every power at your discretion to address this dire situation now and ensure a situation like this cannot happen again in the future. Specifically, if you could let me know:

- What is the current status of the Incident Management Group in responding to this crisis?
- Is the FDA reviewing their response to this crisis, and how will the FDA ensure this never happens again?
- What further steps need to be taken to ensure families have access to the nutrition they need?

I look forward to working with you to address this shortage for the sake of our children.

Sincerely,



Joe Manchin III
United States Senator

[3] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant
[4] https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products
[5] https://www.marlerblog.com/files/2022/04/APPLIED-FOI-II-BR-Abbott-Nutritions-FEI-1815692-9-2021-EIR..pdf
[6] https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569
[7] https://www.iowawatch.org/2022/03/03/this-is-their-only-food-formula-recall-forces-iowa-families-to-adapt/