RICHARD BLUMENTHAL
CONNECTICUT

COMMITTEES:
AGING
ARMED SERVICES
COMMERCE, SCIENCE, AND TRANSPORTATION
JUDICIARY
VETERANS' AFFAIRS

United States Senate
WASHINGTON, DC 20510

706 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-2823
FAX: (202) 224-9673

90 STATE HOUSE SQUARE, TENTH FLOOR
HARTFORD, CT 06103
(860) 258-6940
FAX: (860) 258-6958

915 LAFAYETTE BOULEVARD, SUITE 304
BRIDGEPORT, CT 06604
(203) 330-0598
FAX: (203) 330-0608

http://blumenthal.senate.gov

June 15, 2022

The Honorable Christi A. Grimm
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Grimm,

I write today to raise concerns with the Food and Drug Administration's (FDA) actions related to the nationwide infant formula shortage. Though the Administration has been working steadily to restore formula supply following the recall of Abbott formulas on February 17, 2022, more information has come to light that necessitates a special review from the Office of the Inspector General (OIG).

We now know that formulas produced at Abbott's Sturgis, Michigan plant were linked to at least nine infant deaths and countless illnesses, an increase over what was previously reported by the FDA.[1] The February recall was long-overdue, and its delay—coming nearly a year after the first whistleblower report which we know now was in February of 2021[2]—was alarming and disgraceful. Though I am pleased that your office has begun an investigation into the cause of this long delay in reviewing the whistleblower report, conducting an audit, and alerting consumers, I remain concerned about the FDA's failure to adequately track the illnesses and deaths linked to the formula, and failure to be transparent with the public. I would ask that throughout your investigation into the recall, which you announced on June 2, 2022[3], you pay special attention to the circumstances that led to these additional infant deaths, and why they were not originally reported by the FDA.

[1] Phyllis Entis, "Nine Baby Deaths Reported to FDA during Abbott Nutrition Investigation," Food Safety News, last modified June 8, 2022, https://www.foodsafetynews.com/2022/06/nine-baby-deaths-reported-to-fda-during-abbott-nutrition-investigation/.
[2] Jesse Newman and Peter Loftus, "Abbott Received Former Employee's Warnings on Baby-Formula Plant Earlier Than Previously Known," *Wall Street Journal* (New York, NY), June 8, 2022, https://www.wsj.com/articles/abbott-received-former-employees-warnings-on-baby-formula-plant-earlier-than-previously-known-11654716316.
[3] "Food and Drug Administration's Actions Regarding the Abbott Infant Formula Recall," U.S. Department of Health and Human Services Office of the Inspector General, last accessed June 15, 2022, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000708.asp.

In addition, I have concerns regarding the possible health and safety implications of the FDA's expeditious application of enforcement discretion to speed formula imports. On May 16, the FDA announced it planned to exercise enforcement discretion for certain requirements to allow for increased imports; in under two weeks, two companies had already received notice of enforcement discretion.[4] The office reviewing applications and applying enforcement discretion remains small—the work of the FDA has long been underfunded—and I am concerned that with the pressure to restore stock and approve products, warning signs could be missed. Additionally, the information requested through this process is limited, and I believe it is critical that your office conduct a full review into how these applications have been reviewed and accepted. As such, I am joining my colleague, Representative Rosa DeLauro in asking your office to commence a secondary investigation into the processes followed by FDA staff when reviewing applications and choosing to apply the necessary enforcement discretion.[5] It is essential that, while addressing this urgent crisis, we do not put more infants at risk.

I applaud your office's steadfast commitment to reviewing the failures at the agency that delayed the Abbott recall and contributed to the death of nine infants, but I encourage you to do more. While we focus on getting formula on shelves, we must also focus on ensuring enforcement discretion is applied in an organized and safe manner with the health and safety of all infants and families at the forefront. Thank you for your attention to this matter.

Sincerely,

Richard Blumenthal
United States Senator

[4] "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," U.S. Food and Drug Administration, last modified June 10, 2022, https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

[5] Office of U.S. Representative Rosa DeLauro, "DeLauro Requests HHS Office of Inspector General Review FDA's Enforcement Discretion Approval of Imported Infant Formula," press release, June 3, 2022, https://delauro.house.gov/media-center/press-releases/delauro-requests-hhs-office-inspector-general-review-fda-s-enforcement