

United States Senate

WASHINGTON, DC 20510

May 18, 2022

Robert B. Ford
Chairman of the Board and Chief Executive Officer
Abbott Laboratories
100 Abbott Park Road,
Abbott Park, Ill. 60064

Dear Mr. Ford,

We write regarding the alarming and dangerous shortage of infant and nutritional formula in the United States and seek information on how your company's prioritization of profit over safety and public health has created this crisis. As the largest infant formula manufacturer in the United States, with roughly 40% of the market share in an industry dominated by just three companies, Abbott holds disproportionate responsibility for this current crisis.¹ Abbott has repeatedly and brazenly violated safety rules and ignored warnings from the Food and Drug Administration (FDA), leading to a massive recall, temporary closure of its Sturgis, Michigan plant, and an unprecedented shortage in infant formula – even as your stockholders and executives raked in profits.² We are seeking information on how your company has profited from this crisis American families are facing and how you will ensure that it is not repeated.

On February 17, 2022, your company and the FDA announced a recall of Similac, Alimentu, and EleCare – three different types of formula – and shut down the Sturgis facility after reports that two infants were hospitalized and two died as a result of illness from formula contaminated by *Cronobacter* bacteria.³ Families with infants and people with rare medical conditions are now unable to readily find lifesaving and nutrient-rich formula. The nationwide out-of-stock rate for

¹ New York Times, "The Baby Formula Crisis," David Leonhardt, May 13, 2022,

<https://www.nytimes.com/2022/05/13/briefing/baby-formula-shortage-us-economy.html>.

² Politico, "Whistleblower Warned FDA about formula plant months before baby deaths," Helena Bottemiller Evich, April 28, 2022, <https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569>.

³ Food and Drug Administration, "FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022)," May 17, 2022, <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>; White House, "FACT SHEET: President Biden Announces Additional Steps to Address Infant Formula Shortage," press release, May 12, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/fact-sheet-president-biden-announces-additional-steps-to-address-infant-formula-shortage/#:~:text=On%20February%2017%2C%20the%20largest,fell%20ill%20and%20two%20died.>

infant formula is 43%, with 8 states over 50%,⁴ and retailers are rationing formula.⁵ Families are traveling long distances to find formula and often paying exorbitant prices when they are unable to find it in stores.⁶ In some cases, parents reported paying six times the retail cost – sometimes paying hundreds of dollars – to secure the necessary formula for their children.⁷

For the 1.2 million infants⁸ who rely on the United States Department of Agriculture’s (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) for formula, the search is especially difficult, particularly for those living in states like Massachusetts that hold exclusive contracts with Abbott.⁹ On May 16, 2022, your company entered into a consent decree with the Food and Drug Administration to find a pathway to restart production at your Sturgis, Michigan plant,¹⁰ but parents will continue to see empty shelves and shortages in formula for six to eight more weeks.¹¹

The current infant formula shortage is both heartbreaking and preventable. Abbott Laboratories has been cutting corners on equipment and safety protocols for years, padding your profits while putting toddlers, children, and adults reliant on your products at risk. Between September 2019 and September 2021, Abbott Nutrition (the arm of your company manufacturing infant formula) received 17 consumer complaints regarding their infant formula products. Additionally, your company found *Cronobacter* in five environmental samples from January 2019 to August 2021.¹²

⁴ Datassembly, “Datassembly Releases Latest Numbers on Baby Formula,” press release, May 10, 2022, <https://datassembly.com/news/out-of-stock-rate-in-april-2022-copy/>; Washington Post, “Baby formula factory still months away from production,” Laura Reiley and Sam Easter, May 14, 2022, <https://www.washingtonpost.com/business/2022/05/14/baby-formula-shortage-sturgis/>; Insider, “Here are the states facing the worst of the baby formula shortage,” Katie Balevic, May 14, 2022, <https://www.businessinsider.com/here-are-the-states-seeing-worst-of-baby-formula-shortage-2022-5#:~:text=A%20shortage%20of%20baby%20formula,Biden%20has%20met%20with%20manufacturers..>

⁵ Washington Post, “Baby formula factory still months away from production,” Laura Reiley and Sam Easter, May 14, 2022, <https://www.washingtonpost.com/business/2022/05/14/baby-formula-shortage-sturgis/>.

⁶ The Guardian, “‘It’s a nightmare’: baby formula shortage leaves US parents desperate,” Gloria Oladipo, May 9, 2022, <https://www.theguardian.com/us-news/2022/may/09/baby-formula-shortage-abbott>.

⁷ The Intercept, “BABY FORMULA INDUSTRY SUCCESSFULLY LOBBIED TO WEAKEN BACTERIA SAFETY TESTING STANDARDS,” Lee Fang, May 13, 2022, <https://theintercept.com/2022/05/13/baby-formula-shortage-abbott-bacteria-safety-testing-lobbying/>; Boston Globe, “Parents are grappling with an ‘impossible’ baby formula shortage,” Diti Kohli, May 12, 2022, <https://www.bostonglobe.com/2022/05/12/business/we-dont-know-what-do-formula-shortage-hits-parents-babies-hard/>; Texas Tribune, “Baby formula shortage is making low-income mothers struggle to pay for a product usually covered by the state,” Jason Beeferman, May 13, 2022, <https://www.texastribune.org/2022/05/13/baby-formula-shortage-Texas-WIC/>.

⁸ Washington Post, “Baby formula factory still months away from production,” Laura Reiley and Sam Easter, May 14, 2022, <https://www.washingtonpost.com/business/2022/05/14/baby-formula-shortage-sturgis/>.

⁹ PBS, “Parents face empty shelves as baby formula shortages worsen,” Ali Rogin, April 16, 2022, <https://www.pbs.org/newshour/show/parents-face-empty-shelves-as-baby-formula-shortages-worsen>.

¹⁰ Abbott Laboratories, “ABBOTT ENTERS INTO CONSENT DECREE WITH U.S. FOOD AND DRUG ADMINISTRATION FOR ITS STURGIS, MICH., PLANT; AGREEMENT CREATES PATHWAY TO REOPEN FACILITY,” press release, May 16, 2022, <https://abbott.mediaroom.com/2022-05-16-Abbott-Enters-into-Consent-Decree-with-U-S-Food-and-Drug-Administration-for-its-Sturgis,-Mich,-Plant-Agreement-Creates-Pathway-to-Reopen-Facility>.

¹¹ New York Times, “F.D.A. and Abbott Reach Agreement on Baby Formula to Try to Ease Shortage,” Christina Jewett, May 16, 2022, <https://www.nytimes.com/2022/05/16/health/baby-formula-shortage-fda.html>.

According to a whistleblower complaint, your company’s cost-cutting measures included subpar clean-in-place (CIP) procedures, including the failure to train or hire adequate staff to keep their Sturgis site sanitary, failure to undertake “reasonable measures” to correct deficient training protocols, and falsifying records to cover up breaches.¹³ Even after these problems were discovered by the Food and Drug Administration in inspections last fall and earlier this year, your company failed to act.¹⁴ In a May 16, 2022 filing, the Department of Justice and the Food and Drug Administration wrote that Abbott staff was “unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants,” leading to legal action and further prolonging the shortage.¹⁵

Furthermore, a highly consolidated market has insulated your company from the consequences of its failures, exacerbating your company’s inability to resume safe production and ensuring that any shortage would quickly spiral out of control. Your company’s “iron grip on the market,”¹⁶ which has been boosted by over \$4 million in lobbying in 2020 alone, and over \$95 million since 1998,¹⁷ has effectively reduced competition and restricted the infant formula market to just four companies – Abbott, Reckitt Benckiser, Nestle, and Perrigo, which together account for 89% of U.S. infant formula sales.¹⁸ This corporate concentration, combined with decades of inactivity by regulators, allowed your company to skate by with subpar safety protocols, knowing that consumers did not have the option to easily switch to a competitor. American Economic Liberties Project’s Sarah Miller argued that due to concentration, “Abbott does not fear consumers will flee [...] and it does not fear government” given its lax track record.¹⁹

In addition, corporate concentration created a “fragile” supply chain, which the COVID-19 pandemic further strained, that was too weak to weather the additional shortage caused by the Sturgis facility’s shutdown.²⁰ Last week, eight senators wrote to USDA asking the agency to examine the impact of consolidation in the infant formula market and take steps to increase competition and better protect families.²¹

¹² Food Safety News, “Abbott Nutrition: The gathering storm,” Phyllis Entis, April 16, 2022, <https://www.foodsafetynews.com/2022/04/abbott-nutrition-the-gathering-storm/>.

¹³ Food Safety News, “Former employee blows whistle on baby formula production plant tied to outbreak,” Coral Beach, April 28, 2022, <https://www.foodsafetynews.com/2022/04/former-employee-blows-whistle-on-baby-formula-production-plant-tied-to-outbreak/>.

¹⁴ New York Times, “F.D.A. and Abbott Reach Agreement on Baby Formula to Try to Ease Shortage,” Christina Jewett, May 16, 2022, <https://www.nytimes.com/2022/05/16/health/baby-formula-shortage-fda.html>.

¹⁵ *Id.*

¹⁶ The American Prospect, “Monopolies and the Baby Formula Shortage,” David Dayen, May 10, 2022, <https://prospect.org/blogs-and-newsletters/tap/monopolies-and-the-baby-formula-shortage/>.

¹⁷ Open Secrets, Abbott Laboratories, website accessed May 14, 2022, <https://www.opensecrets.org/orgs/abbott-laboratories/summary?id=D000000383>.

¹⁸ The American Prospect, “Monopolies and the Baby Formula Shortage,” David Dayen, May 10, 2022, <https://prospect.org/blogs-and-newsletters/tap/monopolies-and-the-baby-formula-shortage/>.

¹⁹ New York Times, “The Baby Formula Crisis,” David Leonhardt, May 13, 2022, <https://www.nytimes.com/2022/05/13/briefing/baby-formula-shortage-us-economy.html>.

²⁰ The American Prospect, “Monopolies and the Baby Formula Shortage,” David Dayen, May 10, 2022, <https://prospect.org/blogs-and-newsletters/tap/monopolies-and-the-baby-formula-shortage/>.

²¹ Senator Cory Booker, “Booker, Duckworth, Klobuchar Lead 8 Senators in Urging USDA to Address Infant Formula Shortages,” press release, May 13, 2022, <https://www.booker.senate.gov/news/press/booker-duckworth->

Even as your company ignored warnings from whistleblowers, parents, and the FDA, you continued to rake in record profits. In the second quarter of 2021, Abbott Laboratories doubled its profits from the year before.²² Rather than investing in safety or training, Abbott Laboratories used their increased profits to spend over \$800 million to purchase over 6.5 million shares of its stock in buybacks in 2021,²³ and raised your compensation from approximately \$20.5 million in 2020 to nearly \$25 million in 2021, over 250 times that of the average Abbott employee.²⁴ Your company had a choice, and rather than prioritizing public health and ensuring that the nation's families had a safe and plentiful infant formula supply, you cut corners, reaped billions in profits for shareholders and executives. It is disappointing that your failures have directly harmed so many American families.

In order to address our concerns about your company's decisions leading up to the infant formula shortage, we ask that you please provide answers to the following questions by June 1, 2022:

1. Please provide a list of all Abbott stock buybacks in the last five years, including the number of shares purchased, the cost, and the impact of these buybacks on share prices.
2. Please provide a list of all compensation for all top company executives, including Robert Ford, Robert Funk, Jr., Hubert Allen, Daniel Salvadori, Andrea Wainer, and Miles White, for each of the last five years, including:
 - a. Salary
 - b. Bonuses
 - c. Other compensation
 - d. For all bonuses, please provide a list that describes the type and amount of the bonus received.
 - e. Specifically, did executive compensation include any bonuses related to meeting food safety and quality standards? If so, what executives received these bonuses, and how much were they?
3. Please provide a list of all FDA inspections or audits of the Sturgis facility from 2017 to the present and the results of these inspections.
4. Please provide a list of all inspections or audits by any other local, state, or federal regulator at the Sturgis facility from 2017 to the present, and the results of these inspections.
5. Did any other third party conduct an inspection or audit of the Sturgis facility from 2017 to the present? If so, please provide a copy of the results of these inspections.

[klobuchar-lead-8-senators-in-urging-usda-to-address-infant-formula-shortages](#).

²² Forbes, "Abbott Labs Profit Doubles On Strong Device And Covid Test Sales," Bruce Jepsen, July 22, 2021, <https://www.forbes.com/sites/brucejepsen/2021/07/22/abbott-labs-profit-doubles-on-strong-device-and-covid-test-sales/?sh=6d44f71e5542>.

²³ Securities and Exchange Commission, Abbott Laboratories, Form 10-K, p. 21, February 18, 2022, <https://www.sec.gov/ix?doc=/Archives/edgar/data/1800/000110465922025141/abt-20211231x10k.htm>.

²⁴ Securities and Exchange Commission, Abbott Laboratories, Proxy Statement, p. 54, March 18, 2022, <https://www.sec.gov/Archives/edgar/data/0000001800/000120677422000778/abt3910011-def14a.htm#d391001a017>.

6. Did Abbott employees conduct any internal inspections or audits of the Sturgis facility from 2017 to the present? If so, please provide a copy of the results of these inspections.
7. Were Board members made aware of any concerns about the ability of the company to meet safety standards for infant formula produced at the Sturgis facility? If so, please provide copies of these communications.
8. Did Abbott or any other third party conduct any Cronobacter testing of infant formula at the Sturgis facility prior to the recall? If so, please provide a list of any and all positive tests, including the date of the test and the affected products.

Sincerely,



Elizabeth Warren
United States Senator



Cory A. Booker
United States Senator