

October 12, 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,

I write today regarding alarming new reports about the aggressive tactics Abbott Nutrition, a subsidiary of Abbott Laboratories, has deployed to avoid disclosure of and accountability for potentially contaminated infant formula that caused permanent health consequences for numerous children and culminated in the disastrous 2022 infant formula shortage.<sup>1</sup>

Earlier this year, I wrote to you about your company's troubling record of cutting corners on equipment and safety protocol while padding its own profits, causing an unnecessary and tragic shortage for families across the country.<sup>2</sup> You failed to provide meaningful responses to my questions.<sup>3</sup> The new reports indicate that Abbott Nutrition was aware of these risks for decades, and that the company worked to cover up the consequences by "deploying scorched earth legal tactics" to "grind down – and in some cases attack" families seeking compensation for the harm caused and using legal settlements to force impacted families to stay silent.<sup>4</sup> It is deeply troubling that Abbott appears to have been using abusive legal tactics and non-disclosure agreements to avoid accountability for the health and safety risks from its unsafe products, and I write to seek on the information about what Abbott Nutrition kept hidden from the public and the legal tactics the company used against families seeking justice.

As early as 2003, a representative from your company acknowledged that *Cronobacter* was "a little bit more ubiquitous" in the powdered infant formula than previously known.<sup>5</sup> However,

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<sup>1</sup> New York Times, "How Abbott Kept Sick Babies From Becoming a Scandal," David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>2</sup> Letter from Senator Elizabeth Warren to Abbott CEO Robert B. Ford, May 18, 2022, <https://www.warren.senate.gov/imo/media/doc/2022.05.18%20Letter%20to%20Abbott%20Laboratories%20on%20Infant%20Formula%20Shortage.pdf>.

<sup>3</sup> Cite to Abbott July response.

<sup>4</sup> New York Times, "How Abbott Kept Sick Babies From Becoming a Scandal," David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>5</sup> Washington Post, "The fight to keep little-known bacteria out of powdered baby formula," Laura Reiley and Jacob Bogage, September 6, 2022, <https://www.washingtonpost.com/business/2022/09/06/cronobacter-sakazakii-bacteria-baby-formula/>.

despite an outbreak in 2011 and several lawsuits against Abbott alleging that its powdered formula contained *Cronobacter*, information about these risks failed to reach many new parents and your company continued to cut corners and operate under lax safety measures.<sup>6</sup> The use of aggressive legal tactics and settlements that required families “to keep quiet” undoubtedly played a role in limiting the public’s knowledge of the health risks to babies from *Cronobacter* and shielded your company from scrutiny even as consumer complaints and citations by federal regulators grew.<sup>7</sup>

In cases brought by families harmed by *Cronobacter*, Abbott Nutrition brought “the resources and tactics of Big Law” against “poor families and their overwhelmed lawyers,” using aggressive tactics in a case that one judge called “the worst by a factor of 10.”<sup>8</sup> Following a “seven-year legal battle” for one family whose infant suffered “debilitating brain damage,” your company successfully sought a court order sealing trial testimony and evidence regarding Abbott’s testing and food safety protocols in its Sturgis, Michigan plant – seven years before consumption of unsafe formula resulted in the deaths of several infants and a nationwide infant formula shortage.<sup>9</sup> Between September 2019 and September 2021, Abbott Nutrition found *Cronobacter* in five environmental samples in this same plant.<sup>10</sup> In the injunction filed against Abbott in May 2022, the Department of Justice alleged “ongoing inadequacies in manufacturing conditions and practices.”<sup>11</sup> Judge Mark Bennett, who oversaw a 2013 *Cronobacter* case against Abbott Nutrition, argued that Abbott’s court victories directly fed into this cover-up, noting that a large verdict would have generated “national publicity” about *Cronobacter*, alerting parents across the country to the danger.<sup>12</sup>

The use of these legal tactics to keep potential risks out of the public eye is part of a broader strategy your company employed to actively cover up inadequate safety practices. A whistleblower complaint from October 2021 charged that Abbott actively falsified records regarding the testing, expiration dates, and maintenance records to “limit or avoid oversight.”<sup>13</sup> The whistleblower alleged that during the 2019 Food and Drug Administration (FDA) inspection, “active efforts were undertaken and even celebrated [...] to keep the auditors from learning” of potential contamination of micros, and files underwent “sanitizing” before being

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<sup>6</sup> *Id.*

<sup>7</sup> New York Times, “How Abbott Kept Sick Babies From Becoming a Scandal,” David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>8</sup> New York Times, “How Abbott Kept Sick Babies From Becoming a Scandal,” David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>9</sup> New York Times, “How Abbott Kept Sick Babies From Becoming a Scandal,” David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>10</sup> Food Safety News, “Abbott Nutrition: The gathering storm,” Phyllis Entis, April 16, 2022, <https://www.foodsafetynews.com/2022/04/abbott-nutrition-the-gathering-storm/>.

<sup>11</sup> Case 1:22-cv-00441, [https://www.marlerblog.com/files/2022/05/abbott\\_complaint\\_0.pdf](https://www.marlerblog.com/files/2022/05/abbott_complaint_0.pdf).

<sup>12</sup> New York Times, “How Abbott Kept Sick Babies From Becoming a Scandal,” David Enrich, September 6, 2022, <https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html>.

<sup>13</sup> Confidential Disclosure re Abbott Laboratories’ Production Site in Sturgis Michigan, October 19, 2021, [https://www.marlerblog.com/files/2022/04/Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021\\_Redacted-1-1.pdf](https://www.marlerblog.com/files/2022/04/Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021_Redacted-1-1.pdf).

provided to auditors.<sup>14</sup> According to FDA Commissioner Robert Califf, the 2022 FDA inspection found similarly “shocking” conditions that included standing water, cracks in essential safety equipment, and even inadequate handwashing and staff sanitation that gave the agency “no confidence in the integrity of the Abbott Quality Program at this facility.”<sup>15</sup>

Even as your company continued attacking families in court and cutting corners on equipment and safety, barreling towards the crisis that has harmed infants, children, and adults across the country, you were raking in record profits. In the second quarter of 2021, Abbott Laboratories doubled its profits from the year before.<sup>16</sup> 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,<sup>17</sup> and raising your compensation from approximately \$20.5 million in 2020 to nearly \$25 million in 2021.<sup>18</sup> In May 2022, you wrote that the company would make “significant investments” in safety and quality processes to “ensure this never happens again” – omitting that the company repeatedly failed to make the investments before the crisis started.<sup>19</sup>

In order to address our concerns about your company’s long record of covering up public health risks and your role in the infant formula shortage, we ask that you provide answers to the following questions by October 26, 2022:

1. Please provide a list of all litigation against Abbott Nutrition since 2003 alleging the spread of *Cronobacter* through powdered infant formula.
  - a. For each of these cases, please provide information on the following:
    - i. Any motions filed to seal documents or evidence from the public record;
    - ii. Any motions Abbott Nutrition filed to recoup costs from the plaintiff.
2. Please provide a list of settlements Abbott Nutrition has entered into regarding alleged *Cronobacter* infections from powdered infant formula since 2003.
  - a. For each settlements, please provide the following information:
    - i. The amount Abbott Nutrition paid to families impacted by *Cronobacter*;

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<sup>14</sup> *Id.*

<sup>15</sup> House Committee on Energy & Commerce, Hearing, May 25, 2022, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s>.

<sup>16</sup> 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>.

<sup>17</sup> Securities and Exchange Commission, Abbott Laboratories, Form 10-K, February 18, 2022, <https://www.sec.gov/ix?doc=/Archives/edgar/data/1800/000110465922025141/abt-20211231x10k.htm>.

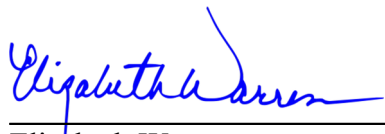
<sup>18</sup> New Yorker, “The Baby-Formula Blame Game,” Jessica Winter, May 28, 2022, <https://www.newyorker.com/news/daily-comment/the-baby-formula-blame-game>; Securities and Exchange Commission, Abbott Laboratories, Proxy Statement, March 18, 2022, <https://www.sec.gov/Archives/edgar/data/0000001800/000120677422000778/abt3910011-def14a.htm#d391001a017>.

<sup>19</sup> Washington Post, “Abbott CEO: We’re sorry about the formula shortage. Here’s what we’re doing to fix it.” Robert Ford, May 21, 2022, <https://www.washingtonpost.com/opinions/2022/05/21/abbott-ceo-robert-ford-formula-elevil/>.

- ii. Any non-disclosure agreements included in the settlements;
- iii. Whether these settlements were disclosed to any federal regulators of powdered infant formula;
- iv. Whether these settlements were approved by the Abbott Board of Directors.

Thank you for your attention to this matter.

Sincerely,



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Elizabeth Warren  
United States Senator