Baby formula whistleblower's complaints were known 8 months earlier than acknowledged by Abbott Labs and the FDA

Kevin Reed 9 June 2022

The pediatric nutritionals giant Abbott Labs and the US government agency responsible for regulating the company were both informed of an employee complaint about dilapidated and unsafe manufacturing conditions at the firm's Sturgis, Michigan, baby formula factory eight months earlier than they have previously acknowledged.

The Wall Street Journal reported on Wednesday, based on disclosures from an anonymous government official, that a formal complaint was filed by a former Abbott Labs employee in February 2021. The complaint raised "product safety concerns" under the guarantees of the U.S. Labor Department's Occupational Safety and Health Administration's (OSHA) whistleblower protection program

This was one year before products from the Sturgis plant were recalled from stores and the factory shut down by the Food and Drug Administration (FDA), after an inspection of the facility showed the presence of deadly bacteria and other unsanitary conditions. The closure of the Abbott Labs plant, which produces approximately 20 percent of all baby formula in the US, dramatically contributed to the shortage that has now reached catastrophic proportions across the country.

The *Journal* reported that the employee complaint detailed "failing equipment in need of repair and formula released without adequate evidence that it was safe for consumption." The report also said that the Labor Department "provided the February 2021 complaint to Abbott as well as to the FDA that same month, according to the government official."

The same employee who filed the federal OSHA complaint, as well as a discrimination complaint with

the Michigan OSHA, also submitted the 34-page whistleblower complaint to the FDA in October 2021 that was recently made public. The *Journal* report said the employee was fired in August 2020 and that Abbott Labs said, "the employee was dismissed for violations of food-safety policies and didn't raise product-safety concerns with the company's office of ethics and compliance," while working for the company.

Neither the company nor the government has denied the *Journal* report. Continuing with its belligerent stonewalling and refusal to take responsibility for the baby food shortage or its role in releasing contaminated products to the public, Abbott Labs said, "We investigated the federal OSHA complaint and have not been able to confirm the allegations."

For its part, the FDA refused to address its failure to disclose the existence of the OSHA complaint by claiming it was preoccupied with "addressing the dire need for infant formula in the U.S. market and our teams are working day and night to make that happen" and did not have time to respond to "various questions about the timeline of events leading up to the FDA's warning and Abbott's recall of products manufactured at their Sturgis facility."

The revelations that worker concerns about conditions at the largest baby formula production facility in the US were swept under the rug for more than a year essentially exposes the congressional hearing on May 25 as part of an ongoing coverup of the origins and causes of the baby formula crisis. It demonstrates that the testimony of FDA Commissioner Robert Califf and Abbott Labs senior vice president of US nutrition Christopher Calamari, neither of whom mentioned the February 2021 OSHA complaint, cannot

be trusted as providing a truthful picture of what has been going on at the facility.

Both the pediatric nutritionals giant and the US government regulator received the employee complaint and did nothing about it until reports began to emerge in September that infants who consumed the baby formula were hospitalized after being infected with cronobacter, which is known to cause life-threatening conditions including meningitis. Then only after two babies died from their infections did the FDA force the shutdown of the Sturgis factory.

Furthermore, even after it was clear by February 2022 that an already existing shortage crisis was going to be significantly exacerbated by the shutdown of the Sturgis factory, the Biden administration was too preoccupied with its preparations for a war with Russia in Ukraine to take note of it.

According to a report in *Politico* on Thursday, White House officials concluded that the Abbott Labs recall and plant shutdown "did not warrant involvement by the president and top staff, who were consumed by the early stages of the war in Ukraine." An unnamed White House official said, "There were a million crises going on" and reported that the baby formula crisis was not being brought up in meetings held by Domestic Policy Council head Susan Rice "for weeks after the recall." The official said the baby formula shortage "just wasn't elevated to a top-level crisis."

Meanwhile, the shortage continues to have a devastating impact on families across the US with outof-stock rates climbing to 74 percent on average nationwide and reaching as much as 90 percent in some states, according to Datasembly. Even though the Sturgis facility has restarted production as of last weekend, industry experts expect the crisis to continue for much of the summer.

CNN spoke with Jamie Lackey, founder and CEO of the nonprofit organization Helping Mamas in Norcross, Georgia, that provides services for low income families with babies. Lackey said, "There is a lot of panic. We had a mom come through the distribution site the other day—she had gone to 15 different stores with her child in the car and could not find a single can of formula." She added, "We had another mom show up before the offices opened the other day. It is getting hard, and people are afraid."

Spectrum News 1 spoke with Ines Palacio of Walton,

Kentucky, who said that she has been finding it increasingly difficult to locate formula for her baby who was born in February. Palacio's mother traveled to Canada to buy some formula and brought it home, but her infant could not tolerate the product. Palacio said, "It makes you wonder how one of the most modern nations in the world is dealing with this issue and isn't able to resolve it quickly. It is scary, because when we're dealing with these recalls, you're giving your child something that could potentially be faulty."

On June 6, the *New York Times* published an interview with Cameron Stripling, who lives in Anchorage, Alaska and gave birth to twins in February. They were born 13 weeks before their due date. While the two daughters, who weighed just over one pound each when they were born, have so far avoided major health complications, the Stripling family is still preoccupied with finding baby formula.

Stripling and her husband have so far been able to locate a few cans of the Abbott Labs product NeuroPro EnfaCare, the high calorie formula the twins need to supplement breastfeeding. She said, "Something is not right. There is no way that we should be having this problem."



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