



## AMERICA'S BABY FORMULA CRISIS

American families are experiencing an unprecedented shortage of baby formula. Countless grocery stores stand bare with empty shelves, creating a health crisis for babies in the world's wealthiest nation as a result.

### BACKGROUND

The United States produces about 98% of its infant formula.<sup>1</sup> Abbott Nutrition alone manufactures about 48% of the domestic baby formula supply. Over the past year, the Food and Drug Administration (FDA) received complaints of a potential contamination at Abbott's Sturgis, Michigan facility linked to a rare bacterial infection and organ damage in four infants,<sup>2</sup> which led to two fatalities. The manufacturer voluntarily ceased production following the complaints.<sup>3</sup>

As a result, American families are struggling to obtain baby formula. Compounding this crisis, the average cost of the most popular baby formula products – already costing some families up to \$1,500 per year<sup>4</sup> – increased by 18% over the past year, during a time when Americans were emerging from the pandemic and experiencing crushing inflation.<sup>5</sup> Meanwhile, the Biden Administration was caught flat-footed at every turn.

A brief timeline of the Biden Administration's mismanagement is as follows:

- **February 2021:** A whistleblower files an Occupational Safety and Health Administration (OSHA) complaint about conditions at Abbott Nutrition's Sturgis facility. The Labor Department notifies the FDA and Abbott of the OSHA complaint that same month.<sup>6</sup>
- **October 19-20, 2021:** A whistleblower warned the FDA of negligent cleaning and safety practices at Abbott's Sturgis facility in a 34-page report in October 2021.<sup>7</sup> The whistleblower mailed the report by FedEx to seven senior FDA officials, including then-Acting FDA Commissioner Woodcock.<sup>8</sup>
- **October 21, 2022:** Three of the seven senior FDA officials are notified of the report via email. FDA officials confirmed receipt "in a detailed email" the same day.<sup>9</sup>
- **December 7, 2021:** The FDA claims this as the first date the agency reached out to the whistleblower to schedule an interview. Due to scheduling issues, the whistleblower is unable to interview until December 22, 2021.
- **January 31, 2022:** FDA inspects Abbott Nutrition's facility in Sturgis, Michigan.
- **February 2022:** FDA Commissioner Califf testified to Congress that the whistleblower report got lost in FDA's mailroom and did not reach senior officials until mid-February 2022.<sup>10</sup> Commissioner Califf is confirmed by the Senate on February 15. Abbott voluntarily shuts down the Sturgis facility and recalls certain powdered formulas on February 17. The FDA and CDC announce a joint investigation into the facility. Abbott expands its recall on February 28.
- **April 2022:** President Biden claims he "became aware" of the formula shortage in April 2022.<sup>11</sup> At least six states report over half of their formula stockpiles are exhausted, and 26 states report 40-50% out of stock rates.<sup>12</sup>
- **May 2022:** 43% of infant formula was reported out of stock across the U.S. as of May 9. FDA Commissioner Califf appoints Dr. Woodcock to lead the agency's internal review of food operations during this month.<sup>13</sup>

- **June 2022:** Abbott reopens the Sturgis plant under FDA oversight in June but is forced to close the facility again on June 15 due to rain and flooding.<sup>14</sup>

## **Big Government Drives Mass Shortage**

**The WIC program creates a national duopoly of manufacturers.** The federal Women, Infants, and Children (WIC) nutrition program is the largest purchaser of formula in the U.S. About half of all babies in the U.S. qualify for WIC, and the program accounts for more than half of domestically-produced formula. Currently, only two companies – Abbott Nutrition and Mead Johnson – serve about 90% of the infants in the program, due in part to WIC’s contract award practices.<sup>15</sup> States are required by federal law to award a sole-source contract to a manufacturer in exchange for rebates to lower costs. These rebates represent one-quarter of funding for the WIC program, or about \$1-\$2 billion annually in revenues.<sup>16</sup> Accordingly, Abbott Nutrition is the sole source WIC provider in 23 states and Washington, D.C. and is the only supplier of specialty formulas.<sup>17</sup> Allowing more free market competition may help prevent a shortage crisis of this scale in the future, if a facility were to close.

**The U.S. restricts access to foreign infant formula manufacturers.** FDA regulations are the most extensive in the world. Domestic and foreign manufacturers must meet high bars for nutritional ingredient requirements, as well as comply with specific labeling guidelines.<sup>18</sup> Once FDA-approved for import, these products are subject to high tariffs (up to 17.5%) and tariff-rate quotas (TRQs). TRQs are additional duties that increase the tariff rate, and can be placed on goods once total imports pass a certain level.<sup>19</sup> Newly-approved retailers and those who have modified their product must also then wait 90 days before marketing the baby formula product.<sup>20</sup>

Many European countries are substantial producers and exporters of infant formula. Further, many European formulas meet or exceed FDA nutritional requirements<sup>21</sup> but are unable to comply with FDA’s labeling guidelines and are, therefore, barred from exporting products to the U.S.<sup>22</sup> In April 2021, for example, Customs and Border Protection (CBP) seized \$30,000 worth of European baby formula for not meeting FDA labeling guidelines and regulatory requirements.<sup>23</sup>

In 2021, U.S. imports of infant formula represented about 1.5% (or \$28.8 million) of the estimated domestic demand of \$1.8 billion, according to the Congressional Research Service, as shown below.<sup>24</sup>

**Table 1. Sources of Imports of Infant Formula in 2021**

| Country        | Quantity of Imports (kilograms) | Value of Imports (U.S. Dollars) | Average Cost per Kilogram (U.S. Dollars) |
|----------------|---------------------------------|---------------------------------|--|
| Ireland        | 2,297,934 kg                    | \$17,191,723                    | \$7.48                                   |
| Chile          | 1,179,763 kg                    | \$3,296,057                     | \$2.79                                   |
| Netherlands    | 551,802 kg                      | \$7,092,049                     | \$12.85                                  |
| Brazil         | 183,171 kg                      | \$325,245                       | \$1.78                                   |
| Venezuela      | 43,143 kg                       | \$110,104                       | \$2.55                                   |
| Serbia         | 36,486 kg                       | \$35,272                        | \$0.97                                   |
| Mexico         | 18,377 kg                       | \$514,488                       | \$28.00                                  |
| Australia      | 8,244 kg                        | \$230,838                       | \$28.00                                  |
| Greece         | 1,620 kg                        | \$15,034                        | \$9.28                                   |
| Denmark        | 518 kg                          | \$6,728                         | \$12.99                                  |
| El Salvador    | 480 kg                          | \$6,000                         | \$12.50                                  |
| United Kingdom | 9 kg                            | \$2,223                         | \$247.00                                 |
| Sum            | 4,321,547 kg                    | \$28,825,761                    | \$6.67 (average)                         |

**Source:** U.S. Census Bureau.

**Notes:** Infant formula only. See shaded box for HTSUS codes.

**Federal regulations prevent domestic startups from competing.** In 2022, ByHeart, located in Pennsylvania, became the first new domestic formula manufacturer in the U.S. since 2007.<sup>25</sup> It reportedly took ByHeart over \$190 million in premarket funding and five years to start production. ByHeart’s CEO attributed the lack of new market entry to spending “years trying to study and understand FDA regulations. We also heard a lot of ‘you guys are nuts.’”<sup>26</sup>

## POLICY SOLUTIONS

Congress enacted the Access to Baby Formula Act in May 2022.<sup>27</sup> The law increased flexibility for WIC participants to purchase other formula products other than sole-source contractors. In addition, Congress should conduct oversight of WIC's contracting practices and assess other options to promote competition among formula manufacturers supplying the program.<sup>28</sup>

The House of Representatives passed H.R. 8351, the Formula Act, sponsored by Rep. Blumenauer (D-CT) on July 15, 2022. The Formula Act would temporarily suspend tariffs on infant formula products. Congress may consider other long-term reforms to lower tariff rates to ease import restrictions and regulations.

The 2020 United States-Mexico-Canada Agreement (USMCA) imposed new restrictions on Canadian global exports of formula due to preexisting U.S. concerns that Canada was “‘dumping’ powdered milk products, including baby formula.”<sup>29</sup> The U.S. did not import any formula from Canada in 2021.<sup>30</sup> Ironically, the Department of Agriculture reported that U.S.-manufactured formula accounted for the largest amount (22%) of dairy exports to Canada that same year.<sup>31</sup> Congress may consider other trade reforms to ease import restrictions.

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<sup>1</sup> Abbott Nutrition, Mead Johnson, and Nestle account for 98% of domestic manufacturers. Perrigo supplies the remainder, as a domestic producer of store brands for several retailers, such as Walmart, CVS, and Target, and a very small amount is imported.

<sup>2</sup> Congressional Research Service [hereinafter CRS], IF12123, *Infant Formula Shortage: FDA Regulation and Federal Response*, May 21, 2022, at <https://crsreports.congress.gov/product/pdf/IF/IF12123>.

<sup>3</sup> U.S. Food and Drug Administration [hereinafter FDA], “Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant,” Feb. 17, 2022, at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant>

<sup>4</sup> U.S. Dep’t of Health and Human Services [hereinafter HHS], “Breastfeeding: Surgeon General’s Call to Action Fact Sheet,” 2011, at <https://www.hhs.gov/surgeongeneral/reports-and-publications/breastfeeding/factsheet/index.html>.

<sup>5</sup> Megan Cerullo, CBS News, “The nationwide baby formula shortage is getting worse,” May 10, 2022, at <https://www.cbsnews.com/news/baby-formula-shortage-rationing-national-crisis/>.

<sup>6</sup> Jesse Newman and Peter Loftus, Wall Street Journal, “Abbott Received Former Employee’s Warnings on Baby-Formula Plant Earlier than Previously Known,” June 8, 2022, at <https://www.wsj.com/articles/abbott-received-former-employees-warnings-on-baby-formula-plant-earlier-than-previously-known-11654716316>.

<sup>7</sup> See whistleblower report here <https://www.documentcloud.org/documents/22051317-confidential-disclosure-re-abbott-laboratories-production-site-in-sturgis-michigan> and <https://s3.documentcloud.org/documents/22051317/confidential-disclosure-re-abbott-laboratories-production-site-in-sturgis-michigan.pdf>.

<sup>8</sup> Helena Bottemiller Evich, Politico, “Whistleblower warned FDA about formula plant months before baby deaths,” April 28, 2022, at <https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569>.

<sup>9</sup> Rep. Rosa DeLauro (D-CT), Chairwoman of the House Appropriations Committee, Press Release, “Congresswoman DeLauro Details Transmission of Infant Formula Whistleblower Report in Response to FDA’s Claims,” May 25, 2022, at <https://delauro.house.gov/media-center/press-releases/congresswoman-de-lauro-details-transmission-infant-formula-whistleblower>.

<sup>10</sup> Testimony of Robert M. Califf, M.D., et. al, Commissioner, FDA, before the Subcomm. On Oversight and Investigations, Cmte. On Energy and Commerce, U.S. House of Representatives, Hearing, “Formula Safety and Supply: Protecting the Health of America’s Babies,” May 25, 2022, at

<https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Testimony%20ECOI%20Infant%20Formula%205.25.2022%20final.pdf>.

<sup>11</sup> C-SPAN, “President Biden Meets with Infant Formula Manufacturers,” June 1, 2022, at <https://www.c-span.org/video/?520693-1/president-biden-meets-infant-formula-manufacturers>.

<sup>12</sup> Texas, Tennessee, Missouri, Iowa, and the Dakotas reported out-of-stock rates of 50%. See CBS News, *supra* at 5, and Rob Wile, NBC News, “Over 40 percent of America’s baby formula supplies are out of stock,” May 9, 2022, at <https://www.nbcnews.com/business/consumer/baby-formula-shortage-recall-low-inventory-rcna27937>.

<sup>13</sup> Helena Bottemiller Evich, Politico, “Amid infant formula fallout, FDA turns to agency veteran with little food experience,” May 19, 2022, at <https://www.politico.com/news/2022/05/19/infant-formula-fallout-fda-woodcock-00033699>.

<sup>14</sup> Laura Reiley and Timothy Bella, Washington Post, “Abbott baby formula plant closes again because of flooding,” June 16, 2022, at <https://www.washingtonpost.com/business/2022/06/16/abbott-baby-formula-plant-closes-flooding-elecare/>.

<sup>15</sup> Meredith Lee and Helena Bottemiller Evich, Politico, “How the baby formula shortage links back to a federal nutrition program,” May 19, 2022, at <https://www.politico.com/news/2022/05/19/baby-formula-shortage-federal-contracts-00033581>.

<sup>16</sup> Christina Szalinski, Kaiser Health News, “For Many Low-Income Families, Getting Formula Has Always Been a Strain,” June 3, 2022, at <https://khn.org/news/article/low-income-families-baby-formula-strain-wic/>, and Victor Oliveira, Economic Research Service, U.S. Dep’t of

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Agriculture [hereinafter USDA], Newsroom, “Winner Takes (Almost) All: How WIC Affects the Infant Formula Market, Sep’t 1, 2011, at <https://www.ers.usda.gov/amber-waves/2011/september/infant-formula-market/>.

<sup>17</sup> .....and The White House Briefing Room, “FACT SHEET: President Biden Announces Additional Steps to Address Infant Formula Shortage,” May 12, 2022, at <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/fact-sheet-president-biden-announces-additional-steps-to-address-infant-formula-shortage/>.

<sup>18</sup> FDA, FDA-2014-D-0033, Guidance Document, *Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for “Eligible” Infant Formulas*, June 2014, at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-demonstration-quality-factor-requirements-under-21-cfr-10696i-eligible-infant>. See also FDA, “FDA Issues Guidance for the Labeling of Infant Formula,” September 2016, at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidance-labeling-infant-formula>.

<sup>19</sup> U.S. International Trade Commission, Harmonized Tariff Schedule, 2022 Revision 7, at <https://hts.usitc.gov/current>. See also The Software Report, “How Government Policies Have Contributed to the Baby Formula Shortage,” June 9, 2022, at <https://www.thesoftwarereport.com/how-government-policies-have-contributed-to-the-baby-formula-shortage/>.

<sup>20</sup> 21 U.S. Code § 350a, at <https://www.law.cornell.edu/uscode/text/21/350a>.

<sup>21</sup> Christina Szalinski, New York Times, “Why US Parents Are Choosing European Baby Formula,” March 12, 2021, at <https://www.nytimes.com/wirecutter/blog/us-parents-european-baby-formula/>, and Dina M. DiMaggio et. al, North American Society for Pediatric Gastroenterology, Hepatology & Nutrition, *Comparison of Imported European and US Infant Formulas: Labeling, Nutrient and Safety Concerns*, October 2019, at <https://naspghan.org/wp-content/uploads/2019/10/October-2019-Article-B.pdf>.

<sup>22</sup> Elizabeth Nolan Brown, Reason, “FDA Will Ease Enforcement of Baby Formula Regulations To Address Shortage,” May 17, 2022, at <https://reason.com/2022/05/17/fda-will-ease-enforcement-of-baby-formula-regulations-to-address-shortage/> and The Software Report, *supra*, at 19.

<sup>23</sup> U.S. Customs and Border Patrol, Press Release, “Philadelphia CBP Seizes Nearly 600 Cases of Infant Formula Unapproved for Import to the United States,” April 5, 2021, at <https://www.cbp.gov/newsroom/local-media-release/philadelphia-cbp-seizes-nearly-600-cases-infant-formula-unapproved>.

<sup>24</sup> CRS distinguishes between infant formula (babies 12 months and younger) and child formula (children at least 12 months old, but not older than 12 years old). CRS, IN11932, *Tariffs and the Infant Formula Shortage*, May 23, 2022, at <https://crsreports.congress.gov/product/pdf/IN/IN11932>.

<sup>25</sup> Scott Lincicome, CATO Institute, *The Infant Formula Crisis Argues for Less Government Intervention, Not More*, June 16, 2022, at <https://www.cato.org/blog/infant-formula-crisis-argues-less-government-intervention-not-more>.

<sup>26</sup> Sharon Terlep and Annie Gasparro, Wall Street Journal, “Baby-Formula Shortage Has Spurred Competition, but Tough Road Remains to Unseat Similac, Enfamil,” June 12, 2022, at <https://www.wsj.com/articles/enfamil-and-smaller-baby-formula-brands-test-dominance-of-abbotts-similac-11655026203>.

<sup>27</sup> P.L.No. 117-129

<sup>28</sup> National Public Radio, “The government program that contributed to the baby formula shortage,” May 23, 2022, at <https://www.npr.org/transcripts/1100825714>.

<sup>29</sup> U.S. Trade Representative, Fact Sheet, *United States-Mexico-Canada Trade Fact Sheet Agriculture: Market Access and Dairy Outcome of the USMC Agreement*, at <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/fact-sheets/market-access-and-dairy-outcomes> and Sara Swann, PolitiFact, “Importing baby formula to the U.S. is allowed, albeit uncommon,” May 24, 2022, at <https://www.politifact.com/factchecks/2022/may/24/facebook-posts/importing-baby-formula-us-allowed-albeit-uncommon/>.

<sup>30</sup> CRS IN11932, *supra*, at 24.

<sup>31</sup> Economic Research Service, USDA, “Value of U.S. dairy product exports to Canada grew by nearly 50 percent in just over a decade,” March 23, 2022, at <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=103549>.