



MEMORANDUM

May 23, 2022

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Formula Safety and Supply: Protecting the Health of America’s Babies”

On Wednesday, May 25, 2022, at 11 a.m. (EDT), in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco WebEx online video conferencing, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Formula Safety and Supply: Protecting the Health of America’s Babies.” The hearing will examine the nation’s infant formula product recall, shortage, steps taken to increase supply, and what further action is necessary to ensure families’ access to safe formula across the country.

I. BACKGROUND

In recent months, American families have experienced a supply shortage of infant formula.¹ Reports of a shortage first began in January 2022, which was exacerbated by the Abbott Nutrition (Abbott) voluntary recall of certain brands of powdered infant formula in February 2022 following reports of potential *Cronobacter sakazakii* (*Cronobacter*) contamination at its Sturgis, Michigan, facility.² As many as 75 percent of American caregivers partially depend on formula to provide nutrients to their infants up to six-months of age.³ The current shortage has been particularly acute for low-income families, rural families, and infants and children solely reliant on specialty formulas to manage metabolic, gastrointestinal, or allergic disorders.⁴

II. INFANT FORMULA PRODUCTION AND SAFETY IN THE UNITED STATES

Abbott (which manufactures Similac), Reckitt (which manufactures Enfamil), and Gerber Products Company (a Nestlé subsidiary that manufactures Good Start) collectively hold

¹ *U.S. Baby Formula Shortage is Worrying Parents. Here’s What to Know.*, Washington Post (May 11, 2022).

² *Baby Formula is Hard to Find. Brands and Stores Are Divided Over Why*, Wall Street Journal (Jan. 12, 2022); *Why is There a Baby-Formula Shortage? What to Know and What’s Being Done About It*, Wall Street Journal (May 12, 2022); *Baby Formula Recalled by Abbott After Reports of Bacterial Contamination*, Wall Street Journal (Feb. 18, 2022).

³ See note 1.

⁴ See note 1; *I Don’t Know How My Son Will Survive Inside the Dangerous Shortage of Specialty Formulas*, Politico (May 7, 2022).

approximately 95 percent of the domestic market for infant formula, with each company's pre-recall share estimated at 42, 38, and 15 percent, respectively.⁵ In total, these companies operate nine factories domestically, and Abbott operates an additional plant in Ireland that is registered with the Food and Drug Administration (FDA).⁶ These companies collectively distribute more than half of their products to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies and the remainder to retailers, health care providers, and individual consumers.⁷

Infant formula products marketed in the United States must meet stringent nutritional requirements and safety standards.⁸ FDA conducts annual inspections of all infant formula manufacturers in the United States, during which the agency samples infant formula for proper nutrient composition and assesses the safety of the production area.⁹ Internationally produced products must also meet FDA's nutritional and labeling requirements to be imported into the country.¹⁰

III. ABBOTT'S INFANT FORMULA ASSOCIATED CRONOBACTER ILLNESSES, INVESTIGATION, AND RECALL

Between September 20, 2021, and February 17, 2022, FDA and the Centers for Disease Control and Prevention (CDC) received four reports of infant illness related to potential *Cronobacter* infection after consuming infant formula products manufactured at Abbott's Sturgis, Michigan, facility.¹¹ Unlike other foodborne illnesses, doctors and laboratories are not required to report cases of *Cronobacter* infection to their health departments, other than in

⁵ *Major U.S. Retailers Limit Infant Formula Purchases on Shortage*, Reuters (May 10, 2022); *The Baby Formula Crime Ring*, New York Times (May 2, 2018).

⁶ *Id.*; *Baby Formula is Hard to Find. Brands and Stores Are Divided Over Why*, Wall Street Journal (Jan. 12, 2022); Abbott Nutrition, *Abbott Provides Infant Formula Update* (Apr. 15, 2022) (press release); Mead Johnson Nutrition, *Manufacturing Facilities Company* (www.meadjohnson.com/map-category/manufacturing-facilities) (accessed May 13, 2022); Department of Energy, *Better Buildings, Gerber Products* (<https://betterbuildingssolutioncenter.energy.gov/partners/gerber-products-company>) (accessed May 16, 2022).

⁷ Department of Agriculture, *Winner Takes (Almost) All: How WIC Affects the Infant Formula Market* (Sept. 1, 2011) (www.ers.usda.gov/amber-waves/2011/september/infant-formula-market/).

⁸ Food and Drug Administration, *Guidance for Industry: Frequently Asked Questions About FDA's Regulation of Infant Formula* (Sept. 20, 2018) (www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-frequently-asked-questions-about-fdas-regulation-infant-formula); Food and Drug Administration, *Regulations and Information on the Manufacture and Distribution of Infant Formula* (Dec. 19, 2017) (<https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/regulations-and-information-manufacture-and-distribution-infant-formula>).

⁹ Food and Drug Administration, *Compliance Program: Infant Formula Program – Imports and Domestic* (July 10, 2018) (www.fda.gov/media/71695/download).

¹⁰ *What's Behind America's Shocking Baby Formula Shortage?*, The Atlantic (May 12, 2022).

¹¹ Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022) (accessed May 16, 2022).

Minnesota.¹² As a result, FDA and CDC would not have become aware of such cases through normal reporting channels and must rely on consumer complaints and doctors' voluntary reports to learn about *Cronobacter* infections. In a previously scheduled, routine FDA inspection of the facility between September 20–24, 2021, FDA found objectionable conditions or practices and issued a decision of voluntary action indicated, leaving the decision of any corrective actions to the facility.¹³ The Sturgis facility is one of the country's biggest manufacturing facilities for infant formula, including specialty formula for children with certain metabolic or allergic conditions.¹⁴

FDA began an additional inspection on January 31, 2022, after receiving two additional reports of *Cronobacter* cases and a whistleblower report.¹⁵ FDA did not issue a public warning on the potential risk of contaminated infant formula until February 17, 2022, the same day that Abbott initiated a voluntary recall of powder infant formulas for its Similac, Alimentum, and EleCare brands.¹⁶ Abbott later expanded its recall to include its specialty formula for infants with impaired renal function.¹⁷ FDA concluded its series of 24 visits to the Sturgis plant on March 18, 2022.¹⁸ The agency found that the facility failed to establish processes to prevent formula contamination and to maintain surfaces that could lead to product contamination.¹⁹ FDA found *Cronobacter* in five environmental samples at the plant, but not in the product samples.²⁰ None of the five strains found in the environmental samples matched the two patient samples CDC analyzed.²¹

¹² Centers for Disease Control and Prevention, *Cronobacter Frequently Asked Questions* (www.cdc.gov/cronobacter/technical.html) (accessed May 6, 2022).

¹³ Food and Drug Administration, *Firm Profile: Abbott Laboratories dba Abbott Nutrition* (<https://datadashboard.fda.gov/ora/firmprofile.htm?FEI=1815692>) (accessed May 12, 2022); Food and Drug Administration, *FMD86: Establishment Inspection Report Conclusions and Decisions* (Jan. 2014) (www.fda.gov/media/87643/download); *Michigan baby formula plant owner reaches deal with FDA to restart production*, The Detroit News (May 16, 2022).

¹⁴ *Major U.S. Retailers Limit Infant Formula Purchases on Shortage*, Reuters (May 10, 2022).

¹⁵ Food and Drug Administration, *Form FDA 483: Inspectional Observations* (Mar. 18, 2022) (www.fda.gov/media/157073/download); *Whistleblower Warns FDA About Formula Plant Months Before Baby Deaths*, Politico (Apr. 28, 2022).

¹⁶ Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (Feb. 17, 2022) (press release); Abbott, *Recall Notice: U.S. / Puerto Rico* (Feb. 17, 2022) (press release).

¹⁷ Abbott, *Recall Notice: U.S. / Puerto Rico* (Feb. 28, 2022) (press release).

¹⁸ Food and Drug Administration, *Form FDA 483: Inspectional Observations* (Mar. 18, 2022) (www.fda.gov/media/157073/download).

¹⁹ *Id.*

²⁰ Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022) (accessed May 12, 2022).

²¹ Centers for Disease Control and Prevention, *Cronobacter and Powdered Infant Formula Investigation* (www.cdc.gov/cronobacter/outbreaks/infant-formula.html) (accessed May 16, 2022).

IV. THE NATION'S FORMULA SHORTAGE

The February 2022 Abbott recall and subsequent decreased availability of Similac, Alimentum, and EleCare brands exacerbated prior infant formula shortages due to the coronavirus disease of 2019 (COVID-19) pandemic-related supply-chain challenges.²² While methods of assessing stock supply vary, according to Datasembly, which relies on the variety of stock-keeping units (SKUs) available to determine an out-of-stock (OOS) rate, in the first half of 2021, the infant formula OOS rate was relatively stable at two to eight percent, but increased to 23 percent by January 2022.²³ By May 8, 2022, 43 percent of infant formula SKUs were sold out at major retailers across the country.²⁴ Surveys measuring the OOS rate based on rates of purchase estimated the OOS rate at 21 percent by the end of that same week.²⁵

Several of the raw materials used in formula production (such as milk and vegetable oil) and in packaging final products (such as plastic and tin) have experienced supply chain disruptions in recent months.²⁶ Price spikes in raw materials due to global conflicts, labor shortages, and transportation and logistics challenges are also contributing factors in the current shortage.²⁷ Further, panic-buying has contributed to the shortage in recent weeks, collectively leading to rationing of infant formula sales by some stores, higher prices, and scams.²⁸

Other reporting points to WIC's exclusive contracting mechanism, international import taxes and restrictions, and existing health and safety regulations as contributing factors to the limited domestic manufacturing base.²⁹ Inconsistent consumer demand for infant formula during the pandemic—influenced by such factors as workforce participation, fertility rates, availability of disposable income, and consumer preferences—has made it difficult for manufacturers to plan production schedules.³⁰ Although formula sales skyrocketed as consumers stockpiled necessities

²² See note 1; *What's Behind America's Shocking Baby Formula Shortage?*, The Atlantic (May 12, 2022).

²³ Datasembly, *Datasembly's Data Reveals 31% Out-of-Stock Rate in April 2022 for Baby Formula; Up 11% Compared to November 2021* (Apr. 14, 2022) (<https://datasembly.com/news/out-of-stock-rate-in-april-2022/>).

²⁴ Datasembly, *Datasembly Releases Latest Numbers on Baby Formula* (May 10, 2022) (<https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/>).

²⁵ IRI (@iriworldwide), Twitter (May 13, 2022, 5:55 PM) (<https://twitter.com/iriworldwide/status/1525233244538605569>).

²⁶ See, e.g., *Baby Formula is Hard to Find. Brands and Stores Are Divided Over Why*, Wall Street Journal (Jan. 12, 2022); *Russia Bans Sunflower Seed Exports, Imposes Quota on Sunoil*, Reuters (Mar. 31, 2022); *Vegetable Oil Prices Soar, Far Outstripping Other Food Inflation*, Washington Post (May 11, 2022); Department of Agriculture, *Daily Market News at a Glance: Week of May 9 -13* (www.ams.usda.gov/mnreports/dyweeklyreport.pdf) (accessed May 13, 2022); Coriolis Research, *Understanding the Infant Formula Value Chain* (Jan. 2014).

²⁷ See, e.g., Infant Nutrition Council of America, *Infant Formula & Supply Chain* (<https://infantnutrition.org/parents-if-you-dont-have-the-baby-formula-you-need-heres-what-to-do/>) (accessed May 12, 2022); *Russia Bans Sunflower Seed Exports, Imposes Quota on Sunoil*, Reuters (Mar. 31, 2022).

²⁸ *Baby Formula Shortage: What's Causing It?*, TIME (May 13, 2022); *A Baby Formula Shortage Leaves Desperate Parents Searching for Food*, New York Times (May 10, 2022).

²⁹ See note 7; *What's Behind America's Shocking Baby Formula Shortage?*, The Atlantic (May 12, 2022).

³⁰ *Id.*

in the early days of the pandemic, they subsequently fell as families consumed their supplies.³¹ The current shortage is concurrent with declining rates of breastfeeding, as well as a slight uptick in the birthrate following a significant national decline in births during the first year of the pandemic.³²

Since Abbott is the exclusive supplier for more than half of the WIC agencies nationwide, low-income parents and children have been disproportionately impacted by the infant formula recall.³³ For some families, the inability to secure specialized formulas means having to go to the hospital to receive feeding through IV total parenteral nutrition (TPN).³⁴ This not only presents additional health care access disparity and burden for families, but TPN itself requires a valve that is also in short supply and placed on an allocation plan by the manufacturer.³⁵

V. ACTION TO INCREASE FORMULA SUPPLY

A. Federal Action

On May 18, 2022, the House of Representatives passed a \$28 million emergency spending bill to help increase the U.S. supply of infant formula as well as a bill intended to protect the WIC program from future recalls and shortages.³⁶ On the same day, President Biden invoked the Defense Production Act (DPA), requiring suppliers to direct needed resources to infant manufacturers, and launched “Operation Fly Formula” to expedite the importation of formula into the country and into stores.³⁷ Since then, two Operation Fly Formula missions have been approved to transport the equivalent of 1.5 million eight-ounce bottles of Gerber formula into the United States.³⁸ On May 22, 2022, HHS Secretary Xavier Becerra authorized the first two DPA priority orders: the first for Abbott to secure raw materials including corn syrup and sugar and the second for Reckitt to acquire single-use products such as filters.³⁹ These actions followed conversations on May 12, 2022, between President Biden, manufacturers, and retailers. The meeting led to the announcement of steps to increase supply without compromising safety, including cutting red tape to get infant formula onto shelves faster and calling on the Federal

³¹ *Id.*

³² *What’s Behind the Baby Formula Shortage*, National Review (May 9, 2022).

³³ *‘Please Help’: A Nationwide Baby Formula Shortage Worsens*, New York Times (May 11, 2022).

³⁴ Letter from Mark Wietecha, Chief Executive Officer, Children’s Hospital Association, to Robert M. Califf, M.D., Commissioner, Food and Drug Administration (May 10, 2022).

³⁵ *Id.*

³⁶ *House Passes \$28m to Bolster FDA Amid Baby Formula Shortage*, Politico (May 18, 2022).

³⁷ The White House, *Fact Sheet: President Biden Announces New Actions to Address the Infant Formula Shortage* (May 18, 2022) (press release).

³⁸ The White House, *President Biden Announces First Two Infant Formula Defense Production Act Authorizations* (May 22, 2022) (press release).

³⁹ *Id.*

Trade Commission and State Attorneys General to crack down on price gouging or unfair market practices.⁴⁰

On April 1, 2022, FDA established an incident management group to coordinate its work on the infant formula supply chain and food safety issues.⁴¹ FDA has been monitoring formula availability and compiling data on trends for in-stock rates at both national and regional levels to direct products to areas of greatest need.⁴² In addition, the agency has been working with Abbott to allow for the immediate release of specialty and metabolic formulas on a case-by-case basis.⁴³ FDA also has been meeting regularly with formula manufacturers to understand production capacity, expediting its review of manufacturing changes, streamlining its import entry review procedures, and using greater discretion in its review of minor labeling errors.⁴⁴ Other agencies are engaged to help increase families' access to formula, such as the Department of Agriculture working with states to allow WIC recipients to use their benefits on a wider variety of products and relax requirements on formula capacity in retail outlets.⁴⁵

On May 16, 2022, Abbott entered into a proposed consent decree with FDA for its Sturgis facility, under which it agreed to retain outside expert assistance to bring its facility into compliance with FDA laws and regulations, develop plans designed to reduce and control the risk of bacterial contamination, and be subject to periodic compliance evaluations.⁴⁶ FDA also released guidance to help major manufacturers seek approval to safely import formula that is not currently being produced for the domestic market.⁴⁷ In addition, FDA Commissioner Robert Califf announced that the agency plans to investigate the timeliness of its response to safety lapses at Abbott's Sturgis plant.⁴⁸

B. Manufacturer Action

According to FDA, production expansion by Reckitt and Gerber has compensated for Abbot's lost production, with production in the last four weeks outpacing production in the four

⁴⁰ The White House, *Fact Sheet: President Biden Announces Additional Steps to Address Infant Formula Shortage* (May 12, 2022) (press release).

⁴¹ Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022) (accessed May 17, 2022).

⁴² Food and Drug Administration, *FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products* (May 10, 2022) (press release).

⁴³ See note 36.

⁴⁴ See note 37.

⁴⁵ See note 35.

⁴⁶ Department of Justice, *Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula* (May 16, 2022) (press release).

⁴⁷ See note 36.

⁴⁸ *FDA to Investigate Delay in Baby Formula Plant Inspection, Commissioner Says*, CNBC (May 16, 2022).

weeks before the recall.⁴⁹ On March 22, 2022, Abbott announced efforts to increase production of Similac at its other manufacturing facilities in the United States, to import Similac from its Ireland plant, and to prioritize production of other liquid formulas.⁵⁰ On May 11, 2022, the company announced that it could restart its Sturgis plant within two weeks with FDA approval, which would put products onto shelves six to eight weeks later.⁵¹ Commissioner Califf has since echoed that the facility could be up and running by late May 2022.⁵²

VI. WITNESSES

The following witnesses have been invited to testify:

PANEL I

Robert M. Califf, M.D.

Commissioner
Food and Drug Administration

Frank Yiannas, M.P.H.

Deputy Commissioner
Food Policy and Response
Food and Drug Administration

Susan Mayne, Ph.D.

Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration

PANEL II

Christopher J. Calamari

President, U.S. and Canada Nutrition
Senior Vice President
Abbott

Scott Fitz

Vice President
Technical and Production
Gerber Products Company

Robert Cleveland

⁴⁹ See note 35.

⁵⁰ Abbott Nutrition, *Abbott Provides Infant Formula Update* (May 22, 2022) (press release).

⁵¹ Abbott Nutrition, *Abbott Provides Infant Formula Update* (Mar. 11, 2022) (press release).

⁵² *FDA Chief: "Quite Likely" Abbott Baby Formula Plant Could Be Up and Running Again in Two Weeks*, The Hill (May 16, 2022).

Senior Vice President
Nutrition, North America and Europe
Reckitt