

**HEARING BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**

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Chairwoman DeGette, Ranking Member Griffith, Chairman Pallone, Ranking Member McMorris Rodgers, and distinguished members of the Subcommittee, thank you for the opportunity to testify before you today. My name is Scott Fitz, and since 2018, I have served as Vice President of Technical and Production at Gerber Products Company (“Gerber”). In that role, I am responsible for all of Gerber’s manufacturing operations and corporate technical functions in the United States. On behalf of Gerber, I thank the Committee for holding this important hearing to discuss the infant formula shortage the United States is currently experiencing.

At Gerber, our mission is “anything for baby” and that promise has driven our business for generations. As a father myself, I can only imagine the strain and anxiety being felt by parents who rely on formula for their little ones right now. While Gerber is a small manufacturer in the U.S. infant formula market with 8.1 percent market share, we are working tirelessly to help parents and caregivers get the formula they need so their babies can thrive. In the wake of the Abbott Nutrition (“Abbott”) recall, we have taken actions to redirect our resources to rapidly increase consumer supply. In March and April, we increased availability of our infant formula in the market by roughly 50 percent.

All babies deserve the best possible start in life. While breast milk is unquestionably the best nutrition for a baby, for those infants who are not breastfed, infant formula is the only suitable alternative recognized by medical authorities like the American Academy of Pediatrics. This makes infant formula a critically important product for parents, caregivers, and babies. For this reason, we must all come together to address this shortage and ensure families have the formula they need.

***Gerber: Who We Are***

Our mission is to serve children and families the highest quality food so they can grow up healthy and happy; this has been the guiding principle behind our operations since our founding over 90 years ago.

With manufacturing facilities in Eau Claire, Wisconsin, Fremont, Michigan, and Fort Smith, Arkansas, Gerber employs approximately 1,350 people across the United States. We are a multi-generational company made up of moms, dads, grandparents, and caregivers. Our employees take pride in advancing our mission and supporting one another, our communities, and all Gerber babies and parents.

## ***Gerber's Quality and Compliance Standards***

At Gerber, the quality and safety of our products and the health and well-being of infants and young children have always been our top priorities. To fulfill our uncompromising commitment to food safety and quality, we have stringent procedures and controls in place at all levels of production, from the sourcing of raw materials and ingredients to the processing and distribution of our products. This includes thorough quality checks and rigorous testing at each of our food and formula facilities. Specifically, our infant formulas undergo as many as 500 quality and safety checks, and every finished batch of infant formula and other specialty formula is tested for the presence of bacteria. Our quality and safety standards are among the strictest in the world, and many of our measures exceed U.S. Food and Drug Administration ("FDA") requirements.

In the spirit of continuous improvement and innovation, we continue to review, revise, and strengthen our already strict compliance policies and procedures. In 2020, Gerber's parent company Nestlé welcomed the Call to Action on breast milk substitutes from the World Health Organization, UNICEF, and other civil society organizations. The Call to Action provides companies with a platform for raising breast milk substitute marketing standards. Specifically, by the end of 2022, Gerber will unilaterally stop promotion of formula for babies aged 0-6 months in the U.S., where no relevant regulations currently exist (the company will continue to manufacture and sell infant formula). Our Call to Action compliance program includes training for all Gerber employees who work in infant nutrition, regular internal and external independent audits of our practices, and implementation of grievance and reporting procedures. We publicly report on our compliance record each year.

We remain strongly committed to working with the FDA, public health and consumer groups, and other members of the industry, as well as our supply chain and business partners, to continue to promote and improve food safety. This is essential to building trust with parents who rightfully want to be assured that the products they buy are safe and of the quality they expect and deserve.

## ***The Infant Formula Shortage: How We Got Here***

Like most industries, the infant formula industry is not immune to global supply chain challenges related to the COVID-19 pandemic. Gerber has faced challenges procuring necessary ingredients and packaging supplies, and we have had to identify alternative suppliers. Given our high safety and quality standards and the highly regulated nature of this industry, adding new suppliers or changing ingredients or packaging materials is a rigorous and time-intensive process. We have also faced constraints related to availability of labor and transportation for product distribution. These challenges were exacerbated by the recent recall in the infant formula space.

Throughout the pandemic and the recent recall, Gerber has demonstrated resilience and maintained high in-stock rates despite significant challenges. In the six months prior to the Abbott recall, our average in-stock rate was 86 percent. In the period since Abbott's February recall, Gerber has maintained an average in-stock rate of roughly 90 percent.<sup>1</sup> This increase reflects the significant measures Gerber has taken to increase the availability of our infant

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<sup>1</sup> Based on data through May 15, 2022.

formula. We also remain dedicated to providing accurate and reliable information to parents and caregivers in an empathetic manner.

### ***Gerber's Response to the Infant Formula Shortage***

Many of us at Gerber are parents ourselves, and we recognize the gravity of the current shortage and the impact it is having on families and babies around the country. With near empty shelves and high out-of-stock rates across the United States, families are concerned about their ability to get the formulas their babies rely on, and we understand and share those concerns. And we have taken decisive action to increase the amount of supply to meet the current market need.

We have taken steps across our factories to increase production of infant formula. Our factories run at full capacity—24 hours a day, 7 days a week—and we have optimized our processes to increase production and make formula as efficiently as possible while maintaining our uncompromising product safety standards. We are constantly adapting our production schedules as circumstances and needs change. We have simplified our product portfolio and reorganized our production schedule to increase production of key products, prioritizing the most in-demand routine formulas, as well as specialty formulas that have been in critically short supply. Finally, we have enlisted experts from Nestlé's Global Center of Excellence to help us optimize output.

We also responded rapidly to provide more formulas for infants who have a cow's milk protein allergy, as these products are in especially short supply in the wake of the recent recall. We accelerated the production of Gerber® Good Start® Extensive HA® formula, originally planned for later in the year, and rushed shipments via air freight from the Netherlands. Our Nestlé Health Science team is producing four to six times the normal volume<sup>2</sup> of its hypoallergenic amino acid-based formula Alfamino® and is shipping the product via air from Switzerland.

We have recently partnered with the Biden Administration to get infant formula to parents and caregivers even faster. As part of Operation Fly Formula, we will expedite the import of 132 pallets of specialty formulas Alfamino® Infant and Alfamino® Junior and 114 pallets of Gerber® Good Start® Extensive HA®. This will add the equivalent of approximately 1.5 million 8-ounce bottles of formula into the U.S. market for babies. The first of these shipments arrived in Indiana this past Sunday. Under FDA's new import guidance, we have submitted our first request for enforcement discretion to import Nestlé NAN Supreme Pro Stage 1, which Nestlé produces in Germany for the Australian market. We are preparing a second submission that will allow us to import a larger size of our Gerber® Good Start® Gentle for the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"). We also continue to look for ways to tap into Nestlé's global nutrition network to help.

Gerber's efforts to significantly increase the amount of infant formula available to families go beyond increasing production. For example, we have accelerated e-commerce availability, which provides consumers with quick, direct access to the formula they need. We also released what we call safety stock—product we hold in reserve to protect against unexpected market surges—to

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<sup>2</sup> Variable according to availability of raw ingredients and packaging materials.

get these products to families who need them now. We have delayed new product trials and medical sampling to help ensure the formula we make is available to address immediate needs in the market. As noted above, because of these actions and others, we increased availability of our infant formula in the market by roughly 50 percent in March and April. We know more must be done, but we believe the steps Gerber has taken over the past several months have made a real difference and enabled more babies to receive the formula they need.

We are also working through our Parent Resource Center,<sup>3</sup> our Ask Nestlé page,<sup>4</sup> Gerber.com, social media, and industry groups to provide essential information to parents and caregivers. We are committed to being part of the solution for parents in this difficult situation, and we understand the importance of having fast, accurate, reliable information and compassionate support when it comes to children’s health and well-being. Our Parent Resource Center, at 1-800-4 GERBER, has baby feeding experts available 24/7 to address ongoing consumer questions and concerns, including where to find and purchase products, alternative options if a family’s preferred formula is not available, and information about what to expect when transitioning to a different formula. We are also communicating directly with healthcare providers to provide information on Gerber’s best formula substitutions.

Finally, we are working closely and collaboratively with our government partners. This includes the six states where Gerber has contracted to provide rebated products through WIC to help ensure sufficient supply. While Gerber is a small manufacturer in this space, we are proud to serve our WIC states. We share WIC’s commitment to safeguard the health of low-income infants and children by providing nutritious and safe foods for infants, toddlers, and young children. Where possible, we are also working to assist other states that require support during this formula shortage.

### ***Need for Government Solutions***

Although many important steps have been taken, much more needs to be done to ensure every baby can get the formula he or she needs, both now and in the future. We are grateful for our collaboration with the FDA, the U.S. Department of Agriculture (“USDA”), and the National Economic Council to address the infant formula shortage and get critical formula to parents and babies who rely on it.

Gerber appreciates the efforts taken by the FDA to date. The agency has been expediting routine notification reviews and has helped expedite customs clearance for our imported products. We welcome the agency’s efforts to give companies temporary flexibility on the import of certain infant formulas, and we are actively pursuing opportunities to import more formula as noted above.

We also support the temporary waivers USDA has granted to state WIC agencies, which have provided the flexibility needed right now to help WIC participants access infant formula during this shortage. These waivers allow states to broadly offer alternate formula sizes, forms, and

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<sup>3</sup> Found at 1-800-4-GERBER and <https://www.gerber.com/mygerber-baby-expert>.

<sup>4</sup> <https://www.nestleusa.com/ask-nestle/infant-formula-shortage>.

brands when the contract formula is not available. They also allow stores to accept exchanges of formula purchased with WIC benefits.

Any potential solutions to expedite the availability of infant formula in the short and long term must preserve the quality and safety requirements that are essential to keeping babies safe and healthy. In the immediate term, we would ask for the FDA's continued assistance to expedite the customs clearance process at the U.S. border for the products we import from our FDA-registered facilities abroad. We would also ask that the FDA expedite the review of our submissions for formulas that we produce for other markets under its newly released guidance.

Over the longer term, we believe that it is imperative that the FDA has appropriate resources to review routine notifications from manufacturers, such as those relating to new products, registration of new facilities, or product reformulation. We would also recommend that, in the future, the FDA be granted authority to provide greater transparency on the anticipated severity and duration of a recall when critical products are involved, so that companies like Gerber can respond more quickly to help fill gaps. Transparent and timely information is at the center of how we make business decisions to meet changing demand, and we rely on timely information from the FDA to understand the impact of a particular recall.

We respectfully offer two potential solutions through which the federal government and state WIC agencies might improve access to specialty formulas for infants with food allergies or specific medical needs. We suggest that the USDA request that state WIC agencies include all eligible specialty infant formulas and medical nutrition products in their WIC formularies. This would allow healthcare providers to prescribe any formula on that list based on a patient's medical or nutritional need rather than being limited to prescribing the options listed.

Today, in certain states, WIC participants can only access specialty formulas in retail pharmacies. As a result, WIC participants in these states have been the most affected by the current shortage. State WIC agencies could address such challenges by establishing secondary patient access avenues for these formulas. As a manufacturer, we have the capability to control logistics for state agencies that use a different patient access model other than retail pharmacies, such as direct-to-agency or WIC-authorized durable medical equipment providers. If each state agency had a previously established secondary patient access avenue, companies would have been able to more efficiently direct specialty formulas where needed for WIC clients.

We are currently evaluating the implications of the Biden Administration invoking the Defense Production Act on our ability to source higher quantities of raw materials and packaging materials and accelerate their delivery to our facilities. To the extent that our infant formula manufacturing sites can be given priority access, this could help alleviate challenges in our supply chain.

We appreciate the role that the federal government, including the Administration, FDA, Congress, and others, in addressing this shortage and the risk of similar shortages, both in the short term and going forward, as we work together to do all we can to ensure an event of this magnitude never happens again.

## *Conclusion*

In closing, we want to assure the members of this Committee and the American people that we are deeply committed and taking decisive action to do our part to ensure parents and caregivers have access to the formula they need for their babies to grow and flourish. We look forward to continuing to work with all necessary parties to ensure that all families are able to nourish their little ones. Thank you and I look forward to your questions.