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

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I. Introduction

Chairs DeGette and Pallone, Ranking Members Griffith and McMorris Rodgers, Members of the Subcommittee, thank you for the opportunity to participate in today's hearing. My name is Chris Calamari, and I am the President of Nutrition North America and Senior Vice President for U.S. Nutrition at Abbott. I lead Abbott's U.S. nutrition business, which includes our portfolio of infant formula products.

I was born in the Bronx and grew up in Yonkers, New York. My father was a firefighter, and my mother was a homemaker. They instilled in me the values of integrity, empathy, and accountability as well as the importance of caring for those in need. I attended college and business school on scholarship and financial aid and have always been drawn to the health care industry and the incredible ways it can better people's lives. I joined Abbott in 2005 because of its values and extraordinary portfolio of products, and I have had the privilege of serving in a number of roles, including Vice President for Pediatric Nutrition.

I am pleased to be here on behalf of Abbott today to speak about the national formula shortage and the aggressive steps we are taking to address it. On behalf of all of us at the company, I want to express our extraordinary disappointment that this situation has occurred and our dedication to ensuring that it is addressed as soon as possible. As a parent, I know firsthand how important a reliable supply of infant formula can be for a family, and all of us at Abbott regret the stress that this shortage has caused for parents. To all of the families who depend on us for a reliable supply of formula—we let you down. We are deeply sorry and are committed to making sure that a shortage like this never happens again.

Since initiating the recall in February, we have worked to mitigate supply issues and get as much product into the hands of parents as we can. We are also working closely with our regulators on the steps necessary to resume production at our facility in Sturgis, Michigan. We appreciate the work of the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA"), the Biden Administration, governors, and policymakers throughout the country in helping to reach this point and address the shortage as it has evolved.

As we move forward, we know that we must work to re-earn the trust that parents and caregivers have placed in our formulas for decades. It will take time, but we can assure you all that more supply is on the way. By the end of June, we expect to supply more formula to Americans than we were in January before the recall.

II. Abbott's Longstanding Commitment to America's Parents and Children

Abbott is a global healthcare company that provides life-changing technologies and services to help people live healthier, fuller lives. Our products remove the regular pain of finger sticks as people manage their diabetes and connect patients to doctors with real-time information monitoring their hearts. They also help to ease chronic pain and movement disorders and test half the world's blood donations to ensure a healthy supply. Our purpose is to make the world a better place by bringing our products to the people who need them. Abbott proudly employs more than 110,000 people globally, over 35,000 of which are spread across offices and manufacturing facilities throughout the United States.

Created in 1903, Abbott Nutrition is a division of our broader company that provides resources to help people live their best lives. Every day, our team of scientists and experts works hard to discover and develop nutrition products that improve life for people of all ages. As a leader in nutrition science, research, and development, our goal is to deliver nutrition products and education that meet the changing needs of families across the world. We make products to help babies and children grow, that work to keep bodies strong, and that support the unique nutritional and therapeutic needs of adults.

The origins of our infant formula business date back to 1903, when Harry C. Moores and Stanley M. Ross founded the Moores & Ross Milk Company in Columbus, Ohio. Originally dedicated to bottling milk for home delivery, the company later created an infant formula with a milk base, which became known as Similac in 1927. Similac proved to be very popular, and in 1928, the company sold its traditional milk operations, changed its name to M & R Dietetic Laboratories, and began to focus solely on infant formula. By the late 1940s and early 1950s, Similac became a widely used formula in the United States, and the company established a second facility in Sturgis to help meet product demand. The company then created Ross Laboratories in 1956 to continue improving its infant formulas, and that entity merged with Abbott Laboratories in 1964, making us a leader in nutrition.[1]

Since that time, Abbott has continued to serve parents and infants with high-quality formula products that meet the highest of health and safety standards. Over the years, we have invested billions of dollars in growing our production capacity, enhancing safety and quality, further refining our complex nutritional formulas, and creating new specialized products.

For more than 90 years, we've helped give babies a strong start with our Similac line of infant formulas, employing the latest nutrition science to support healthy growth and development of babies' eyes, brains, and immune systems. Abbott was also the first company to introduce a formula with 2'-FL human milk oligosaccharide ("HMO"), an ingredient that helps a baby's immune system be more like that of a breastfed infant. In late 2021, we announced the approval of Similac 360 Total Care, the first and only infant formula in the United States with a blend of five different HMOs.

[1] "M & R Dietetic Laboratories," Ohio History Connection: Ohio History Central, https://ohiohistorycentral.org/w/M_%26_R_Dietetic_Laboratories.

Approximately 1.1 million babies in the United States are fed with Similac each year, and our Sturgis facility produces about 40 percent of our Similac supply, representing roughly one in six formula-fed babies. We also support 36 states and the District of Columbia through the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"), which feeds an estimated 580,000 babies in places where Abbott has a WIC contract. We take immense pride in providing for the nutritional needs of these infants, and we are doing everything we can responsibly do to address the current shortage so that they will continue to receive the food they need.

III. Addressing the Current Formula Shortage

We know the recall and suspension of operations at our Sturgis facility have impacted the availability of formula, and we have implemented numerous measures to increase supply. As discussed below, we are working closely with the FDA to restart operations at Sturgis. We continue to make progress on corrective actions and will be implementing additional measures as we work toward addressing items related to the recent recall. Since February, we have also taken aggressive action to increase supply:

- We have used our global network to create additional supply for American families, air shipping millions of cans of Similac into the country from our facility in Cootehill, Ireland. Since February, that facility has produced nearly 11 million pounds of Similac for the United States. In June alone, we intend to produce an additional 4.7 million pounds for the United States. We are up to nearly 50 flights per week coming into 12 airports spread across the country. We are averaging six to eight flights per day, each carrying approximately 132,000 cans. The Cootehill facility is FDA-registered and sources ingredients from approximately 1,000 dairy farms in the local area. Following stringent quality and safety processes, each batch of infant formula undergoes extensive quality checks before it reaches stores. This year, we will more than double the amount of Similac Advance powder formula we're bringing in from Ireland.

- We have converted liquid manufacturing lines and increased production of Similac and Alimentum liquid that is ready to feed. Columbus, Ohio is the headquarters for Abbott's U.S. nutrition business and is home to one of our five manufacturing facilities that produce infant formula for the United States. At this facility we've made significant changes to ensure we can prioritize production of Similac Ready-to-Feed liquid formula, a product that can be used directly from the bottle. In the second quarter of the year, we expect to produce nearly two times more Similac Ready-to-Feed liquid formula than we did during the same period of time last year.

- In addition to the changes in Ohio, we have been prioritizing the production of infant formula at our other manufacturing facilities in Arizona and Virginia to help replenish the supply in the market.

- We are offering increased value of coupons available for all our infant formula products, including Similac Ready-to-Feed, to enable families to purchase formula from stores either free or deeply discounted.

- Since the recall, we have been working with the USDA and WIC agencies to pay rebates on competitive products in states where Abbott holds a WIC contract when Similac is not available. Abbott has committed to continue to pay rebates for competitive products through at least August 31. This means WIC families will continue to be able to obtain formula free of charge, whether it is Similac or formula from another manufacturer. We greatly appreciate the partnership of state WIC administrators and the flexibility they have provided as we work through this shortage.

- For those babies with specialized needs, we worked with the FDA and obtained authorization to release metabolic formulas that were on hold to those in need. Additionally, we contacted other manufacturers to provide information regarding supply constraints for specialty formulas so they can address the demand, where possible. We have been engaging with healthcare providers to identify potential alternative formulas whenever we can. We are also establishing a $5 million fund that will be independently administered to help families who rely on our specialty formula EleCare with medical and living expenses as they weather this storm.

As we do the hard work to increase supply, we have been truly inspired by our employees across the country, who have done everything they can to get formula into parents' hands—employees like sales representatives Kathie, Tolanda, and Alex who each made long drives to deliver formula to those in need, or Director of Customer Service Operations, Lee, who arranged to have formula delivered same-day to Alaska so that it could be air shipped to families of active duty servicemembers in outer parts of the state.

For parents, we have established a hotline to assist with addressing product shortages as best we can. We expect this hotline will become increasingly useful as supply increases prior to normalizing. Parents can reach the hotline at 1-800-986-8540. We have also posted information regarding our recall on our website[2] as well as a page outlining how customers can make urgent product requests for specialty formulas.[3] Parents with concerns about their child's nutritional needs should also discuss them with a doctor or other healthcare professional.

IV. Moving Forward at Abbott's Sturgis Facility

In addition to the actions outlined above, we have also been working around the clock to bring the Sturgis facility back online, which will further increase capacity by 40 percent. The facility has been shut down since February when we initiated a voluntary recall. The voluntary recall involved four complaints of *Cronobacter sakazakii*, a common environmental bacteria, found in infants who consumed formulas produced in our Sturgis plant. Two infants became sick, and two tragically passed away. There is nothing more terrible and tragic than what the families of these four children have experienced. Nothing can be said to make that pain subside. That's why we wanted to make sure we had all the information we could get and worked to ensure that the situation was thoroughly investigated.

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2 https://www.similacrecall.com.

3 https://abbottnutrition.com/metabolics.

During its inspection, the FDA took 292 environmental swabs throughout the factory and four tested positive for *Cronobacter sakazakii*. The four swabs that tested positive were from areas that do not come into direct contact with product. As part of our own investigation, we also found *Cronobacter sakazakii* in non-product-contact areas of the facility.

We did everything we could to remove product from shelves as fast as we could, to notify customers, and to ensure that those who had bought product could quickly get refunded. We believe this was the right thing to do. Safety must be a top priority, especially when it comes to the most vulnerable.

Since the recall, we have conducted significant and thorough analysis and investigation in parallel with the FDA and Centers for Disease Control and Prevention ("CDC"). After a thorough review of all available data, we continue to believe that there is no conclusive evidence to link our formulas to these infant illnesses.

Abbott conducts microbiological testing on products prior to distribution, and no Abbott formula distributed to consumers tested positive for *Cronobacter sakazakii* or *Salmonella*. Additionally, all testing of finished product by Abbott and the FDA during the inspection of the Sturgis facility came back negative for *Cronobacter sakazakii* and *Salmonella*, and no *Salmonella* was found at the Sturgis facility.

The *Cronobacter sakazakii* that was found in environmental testing during the investigation was in non-product contact areas of the facility and has not been linked to any known infant illness. Moreover, genetic sequencing on the two available samples from ill infants not only failed to match the strains of *Cronobacter sakazakii* found in our plant, they also failed to match one another. In all four cases of infant illness, the state, FDA, and/or CDC tested samples of the Abbott formula that was used by the child, and in all four cases, all unopened containers tested negative.

Open containers from the homes of the infants were also tested in three of the four cases; two of the three tested negative. The one positive test was from an open container from the home of the infant, and it tested positive for two different strains of *Cronobacter sakazakii*, one of which matched the strain that caused the infant's infection, and the other which matched a strain found on a bottle of distilled water in the home used to mix the formula. Again, neither strain matched strains found in our plant.

Per the request of the FDA during the inspection, independent, third-party food-safety experts reviewed the food safety plans and procedures, environmental testing, and finished product testing programs as well as the documentation of a portion of the specialty product (metabolic) batches manufactured at Sturgis. The analysis and report determined the food safety plan, processes, and procedures in place met all requirements and was submitted to the FDA on the same day the report was completed on March 31, 2022.

The FDA concluded its inspection with a letter on March 18, listing observations that pointed out where Abbott did not consistently follow our processes and identified areas where we can improve our systems and protocols. We take this very seriously and we responded to the letter in early April. Even before our formal response, we began working to address issues, and we

immediately implemented corrections to address the items the FDA raised in its letter. We have also been making upgrades to the plant.

Abbott is committed to upholding the highest standards for manufacturing of all nutrition products. We have been implementing corrective actions and enhancements at the facility and strengthening our existing processes, to give parents and customers renewed confidence in the quality of manufacturing at our Sturgis plant. Our actions include:

- Installing non-porous, easily cleanable sanitary floors;
- Increasing our finished product testing, which already meets or exceeds regulatory requirements;
- Confirming process consistency by validating the dry-out test method and verifying the dry-out procedures;
- Enhancing the environmental monitoring program by increasing the sampling of non-product contact areas by two to three times;
- Improving and implementing revised traffic control patterns to further control the manufacturing non-product contact environment from microbial introductions.

In addition, on May 16, we entered into a consent decree with the FDA related to the Sturgis plant. The decree is an agreement between the FDA and Abbott on the steps necessary to resume production and maintain the facility and does not affect any other Abbott plant or operation. This is a major step forward to reopening the facility and restarting production that will help to ease the nationwide formula shortage. And we are working to ensure that Sturgis can continue to be one of the nation's preeminent formula manufacturing hubs, meeting the most rigorous of health and safety standards.

We plan to resume production at the Sturgis facility the first week of June. From the time we restart production at the site, it will take approximately six to eight weeks before product is available on shelves. And we'll do everything we can to get product into the hands of families who need it most as soon as possible. When we are operating our Sturgis facility at full capacity, we will more than double our current production of powdered infant formula for the United States.

For the families of hospitalized children, we wish we could provide them the formula they need today and are working to identify ways to do so. We will prioritize EleCare when manufacturing resumes and get that out the door first. In the meantime, we're establishing a $5 million fund that will be independently administered to help these families with medical and living expenses.

V. Learning From the Shortage

As we near the reopening of Sturgis and begin looking to the future, we know there is much to be learned from this situation, and we have begun to reflect on the lessons that can be drawn from the shortage to inform our planning so that this does not recur. We believe that, at its core, this is an issue of capacity rather than concentration. Prior to the recall and shut down of Sturgis, formula purchasing patterns changed during the pandemic, and manufacturing capacity began to reflect those new trends. Supply chain issues also created a new dynamic, as ingredients and other materials needed to produce our formulas became harder to find. Then, issuing the recall and taking Sturgis offline further impacted formula availability.

The shortage has made clear that we and perhaps others making different critical products need to build additional capacity resilience in our supply chain, consistent with FDA requirements, and we stand ready to partner with you here in Congress in that effort. We plan to expand both capacity and redundancy. This will increase the nation's formula supply and create the redundancy we need to never have to stop production of critical products like EleCare again. We will also continue to invest in upgrading our safety and quality processes and equipment. In the meantime, we will continue to invest heavily in building out our global manufacturing network and arranging for additional redundancies throughout our formula business. We are making significant investments to ensure this never happens again.

VI. Conclusion

At Abbott, we are honored to provide formula to millions of families across the United States, and we regret the stress and anxiety the current shortage has caused for families. We are doing everything we can to address it. We are increasing capacity as much as we are able, and our manufacturing facilities are running 24 hours per day, seven days per week. We are airlifting millions of cans of product from our FDA-registered facility in Ireland to partially alleviate lack of supply. We have converted manufacturing lines to boost production of ready-to-feed liquid formula. We are redoubling our commitment to the WIC program, including making additional supply available for WIC families. And we are working around the clock to prepare our Sturgis facility for reopening. Thank you.