

STATEMENT OF

ROBERT CLEVELAND

BEFORE THE

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

CONCERNING

**FORMULA SAFETY AND SUPPLY:
PROTECTING THE HEALTH OF AMERICA'S
BABIES**

PRESENTED ON

MAY 25, 2022

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Chair DeGette, Ranking Member Griffith, and distinguished Members of the Subcommittee, thank you for the invitation to appear before you. It is an honor to be here to discuss our efforts to address the urgent infant formula shortage in the United States today.

Background

My name is Robert Cleveland, and I am the Senior Vice President for the Nutrition Business Unit covering North America and Europe at Mead Johnson Nutrition (“MJN”), a company fully owned by the Reckitt group. I oversee our Nutrition business in the U.S. and other markets and have worked in pediatric nutrition for over a decade, beginning as a marketing director at MJN and holding positions of increased operating responsibility in the United States and globally. I also served my country in the United States Navy, and I am the proud father of two daughters.

MJN was founded in the United States in 1905 and has been a premier producer of pediatric nutrition since that time. Our company’s founder, Edward Mead Johnson, founded the first pediatrician-recommended baby formula after his own son, who was born with a congenital health defect and growing weaker, was failing to thrive. His son survived and went on to run the company years later. MJN now produces routine infant and specialty formulas under well-known brands such as Enfamil and Nutramigen. Our major manufacturing facilities are in Northern Michigan and Southern Indiana, where we employ over 1,200 people.

We are enormously proud of the work we do to feed and support the healthy growth of infants and other vulnerable populations. In the United States, numerous families rely on MJN products for their children. We recognize the huge responsibility we have to nourish infants across the country, and we take that responsibility very seriously.

MJN's Response to Formula Shortage

At MJN, we recognize that the formula shortage is a very serious issue, because we understand the responsibility we have in making the single source of nutrition for so many infants and other vulnerable people. As a father, I understand that nothing is more important than the ability to feed and nurture one's children.

That is why we are working around the clock and coordinating closely with the federal government and others to do whatever is possible to address the shortage. My team spans a wide range of functions that includes supply, procurement, regulatory, nutrition science, and medical. I am immensely proud of the extraordinary work all of them have done to address the formula shortage, and I am proud of their dedication to serving our customers. As a result of my team's exceptional efforts, we have increased supply by more than 30% compared to this time last year.

Cause of Shortage

You have asked for our perspective on the origin and causes of the current formula shortage. For context, supply has remained relatively consistent over many years. In fact, we are not aware of any shortage of this nature in MJN's history.

Over the past two years, MJN, like other manufacturers, experienced some supply chain challenges related to the pandemic, but we were able to manage them and keep our supply up. For example, throughout the pandemic, the industry experienced increased demand associated primarily with pantry loading and a slight increase in birth rates. At the same time, COVID-related supply issues affected production, but production remained sufficient to meet demand during this period. Consumers may not have found their preferred product at their preferred retailer, but until the recall, sufficient feedings were available to ensure all infants had access to necessary nutrition.

The Abbott recall event was the precipitating event of the current supply situation. That sudden supply loss, compounded with continuing challenges with supply chain inputs and residual pantry loading connected with the COVID-19 pandemic, has led to the crisis we are dealing with today.

MJN's Efforts to Address Shortage

In response to the shortage that resulted from the Abbott recall, we are doing everything possible to put more products on shelves while always maintaining the highest standards of safety and quality.

We have all hands on deck working around the clock to get product to families who need it. The steps we are taking include the following:

- We have added shifts and unlimited overtime to run our plants 24/7.
- We cut our time to market almost in half (about 40%) by having trucks ready to load the minute we roll products out of our facilities.
- We are working with our retail partners to ensure that trucks carrying our infant formula are unloaded first.
- We are simplifying our supply chain by focusing on most efficient formats to maximize output. We have purposely reduced the number of different products we make, focusing on those sizes and formats that allow us to get the most product out in the shortest time period. Focusing on fewer products allows us to run our factories more efficiently, with fewer interruptions.
- For our specialty formula Nutramigen specifically, we have limited products to a single packaging size in order to streamline our supply chain.

Overall, this has allowed us to supply 30% more formula so far this year as compared to this time last year. We are now providing over half the infant formula in the United States, which means we are providing nutrition for 211,000 more infants than we did before the recall.

We are taking all of these measures while keeping a close eye on quality and safety. Infant formula requires near pharmaceutical grade levels of safety, and quality control has always been paramount. Our focus on safety has not changed at all as we undertake efforts to meet the current demand.

We are continually looking for other ways to increase supply while ensuring the highest levels of safety and quality. We are pursuing the Food and Drug Administration's ("FDA") import exception with respect to our overseas facilities. We hope to move quickly to gain approval to import formula from those sites into the United States. We realize the incredible responsibility we have in providing the sole nutrition for infants, and there can be no short cuts for this vulnerable population.

Collaboration with Federal Government

In addition to the steps MJN is taking in our production and supply chain, a large part of our response has involved working with the federal government at all levels. We have been working closely with the White House, the FDA, and the Department of Agriculture ("USDA") to take every measure we can to end this shortage as quickly as possible. On May 12, 2022, infant formula manufacturers, including MJN, met with President Biden at his request to discuss how the federal government can help address the formula shortage. President Biden and his Administration have been very helpful in supporting our efforts to address the shortage, including by invoking

the Defense Production Act to address manufacturing supply shortages and implementing Operation Fly Formula, which directs the use of military aircraft to import formula from overseas. Both of these actions will assist us in increasing our production and in reliably providing a consistent supply of formula to the market.

We have been working extremely closely with the FDA, including on ways to expedite review and approval of some of our infant formulas manufactured at our facility in Delicias, Mexico. Accelerating this process, while still ensuring high safety and quality standards, would allow us to significantly increase supply to U.S. consumers.

Finally, we have also been working with the USDA to expand the availability of formula under the Women, Infants, and Children (“WIC”) program. We have been a proud partner of the WIC program since it started more than 40 years ago. Nourishing every child for their best possible start in life is core to our purpose. We believe the program is vital to the health and well-being of American infants, and our team has worked incredibly hard to supply infant formula to this important population and to fill the void left by the recall.

We proposed several adjustments to the WIC program that we believe will help alleviate the current shortage. First, we recommended that the USDA provide a universal waiver allowing WIC participants to use vouchers for any size formula at the shelf. Typically, the WIC program is administered using one specific product, which works well during normal times to keep WIC and non-WIC products from competing at the shelf. We also recommended requesting that all manufacturers prioritize their WIC commitments when allocating their volume to ensure that WIC mothers do not bear the brunt of the current shortage. We are pleased that Congress passed and the President signed the Access to Baby Formula Act implementing these changes. To further support this effort, we recommended eliminating retailers’ minimum WIC stocking requirements of WIC-specified products, so they maximize formula on the shelf with any size they can order and distribute.

With these adjustments, the WIC program will be better positioned to ensure that the infants in the WIC program receive the nutrition they need.

We also applaud the efforts of Congress to consider other legislative changes to prevent such a shortage from ever happening again. We would be happy to work with you in that important effort.

Conclusion

Thank you to the Subcommittee for the opportunity to speak with you today about this important issue and about how we can best meet the needs of families who rely on infant formula to feed their children. We are intensely focused on resolving the shortage as quickly and as safely as possible and on getting formula into the homes of families who need it. We appreciate the Subcommittee’s efforts to assist in this essential effort.