



**Statement for the Record Submitted by
Jennifer Sedlmeyer, Senior Director, Professional Education, March of Dimes
Hearing of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights of the
Senate Committee on the Judiciary
“Baby Formula and Beyond: The Impact of Consolidation on Families and Consumers”
Wednesday, June 15, 2022, 2:30 P.M.**

Chairwoman Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights, thank you for your commitment to addressing the nation’s baby formula shortage crisis. March of Dimes commends you for holding this hearing to examine this topic of utmost importance to maternal and child health.

On behalf of March of Dimes, the nonprofit organization leading the fight for the health of all moms and babies, we appreciate this opportunity to submit testimony for the record. We began that fight more than 80 years ago as an organization dedicated to eradicating polio in the U.S., a goal that we achieved. We continue that fight today as we work to address some of the biggest threats to moms and babies, such as premature birth and maternal mortality, through research, education, programs and advocacy.

March of Dimes’ ongoing work to improve maternal and infant health is more important than ever as our nation is in the midst of a dire maternal and infant health crisis. Rates of preterm birth are increasing, the U.S. is one of the most dangerous places to give birth in the developed world, and there are unacceptable disparities in birth outcomes between women and infants of color and their White peers.

We know, the health and well-being of mothers and infants are inextricably linked. By improving the health of women before, during and between pregnancies, we can improve outcomes for both them and their infants. This is certainly true when it comes to addressing the baby formula shortage hitting the nation.

As a Master’s prepared nurse, with specialty certifications in maternal, newborn, and neonatal intensive care, I bring over 20 years’ experience in neonatal and perinatal care, nursing education, hospital management and public health administration to this issue. Before discussing the recent shortage of infant formula, I would like to say, on behalf of March of Dimes, that our hearts go out to the families who have lost babies due to contaminated powdered formula and those whose infants suffered devastating health consequences from the contaminated product.

This has been a very stressful time for so many families dealing with the pandemic and now this stress has become more intense due to a lack of available nutrition for many babies who do not have access to and who cannot receive human milk. We are especially concerned for lower income families who are already struggling enough in this very challenging time with the economy and inflation not having access to nutrition.

The bipartisan “Access to Baby Formula Act of 2022,” which was signed into law by President Biden, will expand access to the supply under the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to address the shortage that many families are facing. This legislation is positive and should help to increase the supply for many families so that they can have adequate nutrition for their newborn babies. WIC typically is only able to purchase a certain type of baby formula for its clients, along with a certain sized can. Although the government has since come out with waivers for WIC, meaning clients can now purchase a wider variety of formulas, the shortage has still hit the families on WIC very hard.

There have been reports of price gouging which is obviously very concerning. Some states, such as California, have passed executive orders banning excess price hikes on baby formula through the end of the summer.

We are encouraged to see that there are some suppliers who have increased their production and we certainly believe that the shipments that are coming as a result of Operation Fly Formula, to bring needed formula over from Europe to the U.S., will start to relieve some of the pressure that many families are facing. It will take weeks to see relief. Even with production restarting at the Abbott’s Sturgis, Michigan factory, it will be weeks before it actually hits the shelves and there is relief at scale for many families.¹ Reaching lower income families who are already strapped with respect to financial resources should be a priority.

The Impact of the Baby Formula Shortage

There are system-wide reasons for this shortage, but what is most important to understand right now is how parents are struggling if they are impacted by this crisis. This is a very distressing time for parents and caregivers and they need our support.² As the Food and Drug Administration (FDA) continues to work to address the shortage of baby formula, there are reports that parents and caregivers who depend on formula to feed their babies are feeling forced to take drastic measures to provide them with the nutrition they need to stay healthy. This includes diluting formula, which can have dangerous health consequences for the baby such as causing an electrolyte imbalance that can lead to seizures and other severe health problems, and reducing nutrients levels and slowing developmental growth.³

¹ <https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html>

² <https://www.bostonglobe.com/2022/05/12/business/we-dont-know-what-do-formula-shortage-hits-parents-babies-hard/>

³ https://www.upi.com/Health_News/2022/05/18/dilute-infant-formula-danger/8071652885773/

Datasembly found that during the last week of May, 74% of formula products were out of stock at some point. In nine states, including many in the South, more than 90% of formula products were not always available, which means families are still on the hunt.⁴ Nine states across the U.S., including California, Florida, Georgia, Louisiana, Mississippi, Nevada, Rhode Island and Tennessee have topped 90% out-of-stock rates, with Arizona hitting a 94% out-of-stock rate during the week of May 22-29.⁵

Initially, this problem affected those with babies on more specialized formulas or with nutritional issues. Then the gap, or the emptiness on the shelves, increased to the point where it's now any formula. It's now any parent of any baby. You can go to any grocery or pharmacy and the shelves are just empty. Even as the government airlifts massive amounts of formula in from other countries and Abbott reopens a factory that produces almost half the powdered formula sold in the U.S., getting regular supply back to retailers could take weeks or months. Parents and caregivers continue to feel the pain of store shelves that are cleaned out of baby formula, and many are turning to hospitals and community organizations for help.

We have heard from many parents and there is still a lot of panic with parents having gone to multiple stores with a baby in the car who cannot find a single can of formula. One parent characterized the stress this way, "As parents, one of our biggest biological drives is feed your child, feed your child, feed your child. That's what we think about. Make sure they're growing and getting enough nutrition." Having this formula shortage is a horrible stress and strain for these families.

Even when it is possible to find some formula, it may not be the kind children have been used to. That may not sound like a big deal, but for tiny tummies, it can be a serious concern. One mother switched her daughter's formula six times, which led to rashes and diarrhea. In her words, she said "She was screaming in pain, and there was nothing you could really do. That feels really helpless. You just want to help your child."⁶

One mom stopped breastfeeding her daughter when she was three months old. She switched to formula when she went back to work as it was too difficult to find time to pump enough milk for her child during the day. Her baby was doing great on formula until the shortage really took hold in February. She recently started trying to get her milk supply back, or re-lactate, so she wouldn't have to worry. This is stressful and challenging for her and her baby.

Children's hospitals have noticed an increase in calls from worried parents. Families call in and even come to the ER looking for formula. Food banks are also getting a heavy volume of calls every day. Families are seeking formula online and on social media platforms. They are driving miles and paying exorbitant prices to get a hold of the formula that they need. One OB-GYN at a women's clinic, said postpartum visits are lately filled with questions over how to increase milk

⁴ <https://datasembly.com/news/latest-numbers-on-baby-formula/>

⁵ <https://abcnews.go.com/GMA/Family/parents-baby-formula-shortage-hurting-families/story?id=85212333>

⁶ <https://www.cnn.com/2022/06/06/health/families-struggle-formula-shortage/index.html>

supply, where to get safe baby formula, and whether it's OK to use formula with lot numbers listed in the recall.

How the Shortage has Affected Babies with Special Formula Needs

Neonatal Intensive Care Unit (NICU) families who have medically prescribed recipes for higher calorie formula for their baby's needs are at an increased risk during this formula shortage, as these recipes for 'fortification' use a higher formula to water ratio, and a container of formula is used on a faster timeline than the average baby would use with the container recipe. If fortification is prescribed, it is an essential part of the baby's proper nutrition and growth.

Additionally, specialty formulas for children with allergies, digestive, and metabolic issues are extremely hard to find. Families looking for a specific product are having to drive hundreds of miles in some cases to find the formula they need. Some have been able to work with hospital nutritionists to find substitutes until their regular product is back in stock. However, in some cases there simply is no substitute available.

For example, Abbott makes the only infant formula for babies with kidney problems Similac 60/40, which has fewer minerals than other products. When Abbott's Sturgis, Michigan, factory shut down, the means to make it went away, too. We have heard from parents that formulas for babies with kidney problems and preterm infants have been some of the hardest to track down. Hospitals have had to mix other commercially available products, essentially compounding formula, to try to find something that will work for these fragile infants. This is done by professionals, under carefully controlled conditions in the hospital's formula room and is not something families should try to do at home.

Barron's story highlights the acute nature of the shortage: Barron, who was born at just 27 weeks, or three months early, spent the first several months of his life in a NICU. He struggled with eating since birth. He is now two and has to be fed through a feeding tube. His daily nutrition comes from Neocate Jr., an amino acid-based prescription formula. The formula is expensive and he can easily go through 16 cans of formula in a one-month time span. And now the formula is mostly on back order. After Barron's mother "spent all day long trying to reach out to her resources to see if they had extra cans," she found another mom online, who gave her 17 cans because her son switched to a different formula. That's a month's worth so they can "breathe for a month."⁷

March of Dimes is Working to Support Families Affected by the Shortage

At March of Dimes, we are using forums such as our Healthy Moms Strong Babies webinar series to advise families to be careful during this time about making accommodations with respect to nutrition. It is very important to make sure that babies are well fed and that they

⁷ https://www.newsandtribune.com/news/out-of-stock-experts-family-weigh-in-on-baby-formula-shortage/article_0241710c-e020-11ec-bbf1-4f1c2230a8a2.html

have access to proper nutrition.⁸ March of Dimes is also communicating safety standards through our website.⁹ We caution against watering formula down or using substitutes such as homemade or imported formula or other milks and drinks. Infants up to one year of age need formula, which is fortified with certain vitamins and nutrients that help babies grow and develop. We advocate for breastfeeding, but know this is not possible for some, making this an extremely difficult time for so many families across our country who are worried about feeding their children. We know there are many reasons why a mom may not be able to breastfeed, including physical, personal, social, economic and environmental factors. For babies who are reliant on formula feeding, we encourage parents and caregivers to consider milk banks that follow Human Milk Banking Association of Northern America standards (HMBANA) to provide their babies the nutrition they need. Before accepting any donated formula, we advise parents to make sure it is unused, unopened, and in clear packaging indicating it is not expired, and not on the recall list. We are instructing families who have extra unopened, unexpired formula, to donate it to hospitals or a food banks in their community.

The Baby Formula Shortage is a Wake-Up Call that Demands More Action

March of Dimes remains engaged with Congress on bipartisan legislative opportunities on preventing baby formula shortages. As mentioned, we support bipartisan efforts like the Access to Baby Formula Act which provides much-needed help to WIC families, who we know purchase about half the baby formula in the U.S. The bill is aimed at expanding pandemic-era flexibilities granted to WIC participants, allowing them flexibility to buy different kinds of formula they otherwise would not be allowed to get under WIC. We also have supported actions taken by the Biden administration, including invoking the Defense Production Act to ensure that manufacturers have the necessary ingredients to make safe, healthy infant formula here at home. Additionally, the launching Operation Fly Formula is helping to speed up the import of infant formula and get more formula to stores as soon as possible.¹⁰ While these efforts are positive, there are clearly more long-term steps needed to address the shortage and prevent it from reoccurring in the future.

Largely a result of long-standing market concentration among four main production competitors, this crisis did not happen overnight, and disproportionately impacted low-income families and those with other socioeconomic challenges, who are least supported in establishing and maintaining breastfeeding. According to the Centers for Disease Control and Prevention (CDC), most infants start breastfeeding (84.1%) but only 58.3% of infants are still breastfeeding at six months. Furthermore, the percentage of breastfed infants supplemented with infant formula before two days of age is 19.2% so many babies are not exclusively breastfed.¹¹

⁸ https://www.hhs.gov/formula/index.html?utm_source=news-releases-email&utm_medium=email&utm_campaign=june-12-2022

⁹ <https://www.marchofdimes.org/baby/feeding-your-baby-formula.aspx>

¹⁰ <https://www.whitehouse.gov/formula/>

¹¹ <https://www.cdc.gov/breastfeeding/data/reportcard.htm>

There are huge disparities based on race and income, with lower rates among low-income mothers participating in WIC and low-income non-Hispanic Black mothers. We must consider ways in which more families would not be so severely impacted by this type of shortage in the future, and actions that can be taken to make sure all families have access to the best infant nutrition, and ensure that infants have the best chance at receiving human milk. March of Dimes recommends Congress and the Biden administration consider the following steps:

- Examine market consolidation impediments to access and consider ways to incentivize the entry of new competitors and expand on the number of factories making infant formula;
- Increase oversight of facility inspections requiring more frequent inspections by baby formula safety and supply chain experts;
- Require manufacturers to warn the FDA of supply chain disruptions and establish risk mitigation strategies from both the FDA and formula manufacturers;
- Enhance data collection on baby formula production and establish more rigorous reporting from manufacturers to identify potential shortages so that they can be mitigated and resolved much sooner;
- Provide supplemental emergency funding to give the FDA the resources it needs to address the urgent infant formula shortage;
- Encourage the Federal Trade Commission (FTC) to address actions that deceive, exploit, or scam families trying to buy formula through online secondary markets; encourage online marketplaces to better protect consumers during the formula shortage, and take swift action on abusive tactics in online marketplaces;
- Improve support for breastfeeding by advancing workplace supports for moms pumping. For many new moms, breastfeeding and returning to work can be hard. This is a common reason many women stop breastfeeding or pumping milk for their babies. The Affordable Care Act (ACA) included provisions that required certain employers to provide break time and a place for most hourly wage-earning and some salaried employee to pump at work. The bipartisan Providing Urgent Maternal Protections (PUMP) for Nursing Mothers Act of 2021 would extend those supports to the 9 million employees that were excluded from the ACA's protections. These nurses, teachers, retail workers, and managers across a number of industries deserve the same protections as other working mothers;
- Expand coverage and reimbursement by Medicaid plans and commercial insurance for International Board Certified Lactation Consultation (IBCLC) Services, breast pumps, and supplies such as Milk Collection Kits for those struggling with breastfeeding, wanting to maintain breastfeeding or wanting to re-lactate;
- Support policies to ensure that all insurance companies cover donor human milk for families who need it. Medically necessary donor human milk should be covered and reimbursed by state Medicaid plans and commercial insurance, and expansions of what is medically necessary may be needed should this crisis persist;

- Expand on the recent flexibilities added to WIC by enacting legislation providing the authority to uniformly support online ordering, pickup, and delivery of WIC benefits without the presence of a cashier allowing for online ordering as a permanent option under the program;
- Expand on critically-needed mental health care services for families confronted with the strain of the baby formula shortage through the Health Resources & Services Administration's (HRSA) Screening and Treatment for Maternal Depression and Related Behavior Disorders Program. This program provides real-time psychiatric consultation, care coordination, and training for front-line providers to better screen, assess, refer and treat pregnant and postpartum women for depression and other behavioral health conditions; and
- Finally, continue to provide funding support, as well as a legislative authorization, for the new maternal mental health hotline, so that it can be staffed with qualified counselors 24 hours a day and conduct outreach efforts to raise awareness about maternal mental health issues.

March of Dimes thanks the Subcommittee for focusing attention on the nation's baby formula shortage crisis. With your help, we can prevent families from having to face this problem in the future, and address the multi-factorial reasons that contributed to the crisis so it does not repeat itself. March of Dimes stands ready to work with you.