



May 24, 2022

The Honorable Diana DeGette
Chair, Subcommittee on Oversight and
Investigations
U.S. House of Representatives
Washington, D.C. 20510

The Honorable H. Morgan Griffith
Ranking Member, Subcommittee on
Oversight and Investigations
U.S. House of Representatives
Washington, D.C. 20510

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

Dear Chair DeGette and Ranking Member Griffith,

I am Kenneth Mendez, President and CEO of the Asthma and Allergy Foundation of America, or AAFA. AAFA is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world.

The formula shortage became acute with a recall of a defective brand this year after at least four babies were hospitalized with bacterial infection and at least two babies died. But the recall has been exacerbated by relentless supply-chain problems and labor shortages. Parents report that formula is difficult, if not impossible, to find. Parents are rationing food as they search for more formula. Some are driving several hours to find formula, without success.

Impact on Families of Babies, Children, and Adults with Food Allergies

For parents with a child on a special formula due to food allergies, the current shortage is especially frightening.

Childhood food allergies are a significant public health issue resulting in relatively high rates of severe allergic reactions and Emergency Department use. About 3% of infants and almost 9% of 1-year-olds are allergic to at least one food.¹ Some allergic reactions can be mild like nasal stuffiness, itching, or coughing; other reactions, anaphylaxis, can be severe and life-threatening.²

Babies who are allergic to components of mainstream infant formula, such as milk or soy, require specialized formula in order to get adequate nutrition without risking a life-threatening allergic reaction. Children with cow’s milk protein allergy (CMPA) have few safe formula options. These options for children with CMPA include:

¹ Gupta RS, Warren CM, Smith BM, et al. The public health impact of parent-reported childhood food allergies in the United States. *Pediatrics*. 2018;142(6):e20181235. doi:10.1542/peds.2018-1235

² Asthma and Allergy Foundation/Kids with Food Allergies, “Food Allergy and Anaphylaxis in Infants and Toddlers” [webinar slides]. Available at <https://www.kidswithfoodallergies.org/media/3330/aafa-kfa-webinar-food-allergy-and-anaphylaxis-in-infants-and-toddlers.pdf>



- **Extensively Hydrolyzed Formulas (e.g., Enfamil® Nutramigen®, Enfamil® Pregestimil®, Similac® Alimentum® or Similac® Expert Care®)**
- **Amino Acid-Based Formulas (e.g., Neocate®, EleCare®, PurAmino™, Alfamino™)**

When these special formulas for food allergies become scarce, babies' lives and health are put at risk. While many healthy, full-term babies can, if necessary, switch from brand to brand of formula, for babies with food allergies no safe alternative may be available.

The impact also goes beyond babies. Children and adults with Eosinophilic Esophagitis (EoE) are also at risk during this shortage. EoE is a type of food allergy that affects the esophagus and a child's or adult's ability to eat. In the case of EoE, amino acid formulas like EleCare® may be a patient's sole source of nutrition and are considered medical foods. Medical foods are nutrition products (usually formulas) that are made to manage a disease or condition. They are prescribed and used under medical supervision. They are not the same as foods recommended by a doctor as part of a diet to manage symptoms.

Below please find examples from people across the country struggling to find specialty formula.

From Lansing, NJ: My child is 11. He survives from an amino acid-based formula. It's impossible to get now. Please do what you can to assist.

From Athens, GA: The story below is about my grandson Maverick he is 4 months old, this is written by his mom who is experiencing this formula shortage first hand. Please fix this problem now...our babies need it!

Mavericks Mom:

I've been very vocal about my frustration and (currently) devastation over the stress of finding formula to feed Maverick. Many, many of you have asked how you can help. This is it. If you're willing, please take a moment to write a note to congress about this issue. You can follow the link in this shared post.

Bradley had CMPA as an infant that manifested at 3 months old in the form of eczema, horrible cradle cap, and mild GI symptoms like constipation and regurgitation.

Maverick has what can only be described as SEVERE CMPA, which manifested as a newborn (from birth, really) in the form of severe GI symptoms including constipation, blood in his stool, enflamed colon (colitis), red puffy eyes, and hours upon hours of screaming. He was not happy a moment in his life before he was put on Puramino at 8 weeks old. Our sweet, smiley Maverick is a perfect example of why specialty formulas MUST be prioritized right now. Any baby can thrive on specialty. Maverick and other children like him will be hospitalized on "normal" formula. He is currently having a reaction to his four-month vaccines which contain NEGLIGIBLE amounts of dairy. I



cannot imagine how detrimental one bottle of milk-based formula would be to his immune system.

From Chicago, IL: My name is Nicole from Chicago and I would like to share my experience. Please ensure that infants, children, and adults managing food allergies and other digestive and metabolic disorders are adequately considered as Congress acts to address this crisis. Our son is 7 and still needs a special formula because of his allergies and other medical conditions. Formula is his main source of nutrition and vitamins. Please consider all aspects of the shortage and action is needed now.

From Wayne, PA: My name is Megan from Wayne, PA and I would like to share my experience. I am a mom of four kids and my youngest is 7 months old. My three oldest children all had food allergies and I had to rely on specialty formula to keep them safe, healthy and growing. I am also a working mom in the middle of a pandemic. I cannot fathom the fear and anxiety that moms are currently facing with this shortage. Please ensure that infants, children, and adults managing food allergies and other digestive and metabolic disorders are adequately considered as Congress acts to address this crisis.

From Tacoma, WA: My name is Angela Robinson from Tacoma Washington 98407. I would like to share my experience. Please ensure that infants, children, and adults managing food allergies and other digestive and metabolic disorders are adequately considered as Congress acts to address this crisis. My child depends on medical formula (EleCare) as he deals with multiple food allergies, and Eosinophilic Esophagitis. We ran out, and desperately waiting for more to be available. I feel for so many families like mine that are forced to wait months, and be without or have to try something that may not work for them. Thank you!

From Tobyhanna, PA: My name is Janine from Tobyhanna, Pennsylvania and I would like to share my experience. I have a 7-week-old whom I cannot find her formula. I have driven 3 and 4 hours searching days end. I cannot afford to keep driving with the gas prices. Please, please do something.

From Hoschton, GA: My name is Laura from Hoschton, GA and I would like to share my experience. All 3 of my children have relied on hypoallergenic formula for proper growth and development due to various but severe food allergies. The current formula shortage has caused our family a lot of stress as we currently have an 8-month-old using formula. We are having to utilize a vast network of individuals searching for any hypoallergenic formula they can find. It takes hours of my week making sure my baby can be fed. Regardless of political affiliation, politicians including yourself should be ashamed to have sat back with no action items in the works as this has been ongoing since the Abbott nutrition recall towards the beginning of the year. The plant shut down as part of the recall was a major supplier of specialty formulas that many families rely on. Even finding formula prior to the recall was a challenge due to supply chain shortages. The greatest nation in the world shouldn't be facing these issues and as a human being you should be outraged and appalled by this crisis!



More Must be Done, Especially for Babies, Children, and Adults with Food Allergies

AAFA is encouraged to see the recent actions that have been taken to meet the ongoing shortage of formula:

- The Administration has invoked the Defense Production Act that would allow formula producers to have priority for ingredients, and to accelerate flying in formula from overseas suppliers.
- The FDA and Abbott Nutrition have reached a deal to restart operations at its factory in Sturgis, Michigan. But the FDA said that may take several weeks.
- House Democrats passed a \$28M spending bill that would boost FDA funding to inspect domestic and international formula producers.
- The US military is flying in planes carrying shipments of infant formula, as part of the Administration's "Operation Fly Formula" to import the product from Europe and address a critical shortage in the United States. Importantly, the early flights are carrying infant formula, made for children who have allergic reactions to protein and cow milk.
- The Agriculture Department is urging more states to take advantage of the waivers the USDA has been offering in the WIC program, allowing participants access to a broader range of sizes and brands of formula.
- The FDA said it would approve new types of formula from foreign and domestic sources on a case-by-case basis.

However, we remain concerned that the situation remains acutely difficult, particularly for families of babies, children, and adults with food allergies. For the people that depend on amino acid formula, there is often no safe alternative. We urge Congress and the FDA to develop a specific taskforce addressing current availability of allergy formulas and to prioritize their production and distribution to the babies, children, and adults for whom alternatives do not exist. Policymakers may also need to consider approaches to ensure that formulas for babies with allergies are reserved for those with medical need, particularly in times of national shortage.

Conclusion

Thank you for the opportunity to share our thoughts with the Subcommittee. We would be happy to continue working with Congress and the FDA to share our community's experience and help develop policy solutions. Please do not hesitate to reach me at kmendez@aafa.org.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America