American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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May 19, 2022

The Honorable Nancy Pelosi
Speaker of the House
United States House of Representatives
1236 Longworth house Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader Schumer, and Minority Leader McConnell:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, we write to urge you to act quickly to increase the supply of safe infant formula in the United States, provide additional funding to bolster the federal response, and enhance the authority of federal agencies in order to bring this crisis to an end and prevent a future one from occurring. Families across the country are struggling to access formula—an essential source of nutrition for many infants—and are worried about how they will feed their children.

At some point during their first year, most U.S. infants receive infant formula, and for many infants, most of their nutrition in the first year of life comes from infant formula. For the youngest children, infant formula is often the only source of nutrition. While AAP recommends exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, not all infants are partially or exclusively breastfed for the first 6 months. For those infants, the AAP recommends use of an iron-fortified infant formula as the best and safest alternative for the first year of life.

Since Abbott Nutrition announced a voluntary recall in February, families across the country have encountered reduced availability of infant formula products. The shortages have been especially acute for children with allergies, digestive issues, or metabolic disorders who require specialty formulas that were produced in Abbott's Sturgis, MI facility. Congress must take immediate action to remedy the current shortage and to prevent a similar supply issue from occurring in the future. At a minimum, we urge you to take immediate action on the following policies and are eager to work with you on other ways to ensure families across the country are able to provide their infants and children with the nutrition they require.

Additional Resources for FDA

The Food and Drug Administration (FDA) desperately needs additional resources in order to address the current shortage of FDA-regulated infant formula and certain medical foods, ensure the safety of these products, and prevent future shortages. Currently FDA has only 13 staff members who regulate and monitor production of infant formula products and no staff to respond to supply chain issues. Increased funding is necessary to enable the agency to strengthen and increase the number of FDA inspection staff and to provide resources for personnel working on formula issues including: reviewing applications for new products to come to the U.S. market, helping the agency stop fraudulent baby formula from entering the marketplace, and improving data collection on the infant formula marketplace. FDA's current limited capacity to monitor safe manufacturing practices at infant formula production facilities must be remedied. This is especially important as new products will be entering the U.S. market in order to increase the supply of infant formulas available to families throughout the country.

Advanced Notification

Given that infant formulas and specialty medical formulas are often the only source of nutrition for children across the country, FDA needs the authority to adequately prepare for, and if necessary, respond to potential supply disruptions. Manufacturers of infant formulas and other specialized medical foods should be required to proactively manage risk and develop risk management plans for supply of their product. Further, these manufacturers should be required to notify FDA and communicate with the agency if they expect a meaningful disruption in their domestic supply. This information also should be available to the U.S. Department of Agriculture (USDA) given their role in administering food assistance programs such as the Special Supplemental Program for Women, Infants, and Children, or WIC. Currently, no law requires manufacturers of infant formulas or essential medical foods to notify FDA when they become aware of a circumstance that could lead to a shortage of these products. FDA does, however, have the authority to require manufacturers of drug products to notify the agency of potential shortages, which has enabled it to prevent or mitigate drug shortages including those labeled for use in children. Requiring similar advanced notification for infant formulas and other medical foods would allow FDA to take earlier steps to promote the continued availability of these foods.

Role of WIC

WIC provides nutritious food (including infant formula), nutrition education, breastfeeding support, and referrals to health care and social services for millions of low-income women, their infants, and young children who are determined to be nutritionally at-risk. In the United States, 53% of all infants younger than 1 year are served by WIC, and about half of infant formula nationwide is purchased by participants using WIC benefits. Waivers from the USDA and contract flexibilities exercised by State WIC Agencies have allowed for flexibility in the program during the current shortage, including alternate container sizes and different forms and brands of formula. This has given WIC families more options to obtain infant formula amid limited supply on the shelves. While several waivers are currently available, not all states who could benefit from them have chosen to request them. The variability in approaches taken by states with respect to the WIC program requires urgent federal attention. Further, USDA relied on its pandemic authority in issuing these waivers; if we were not currently in a public health emergency, USDA would not have had the authority to immediately issue these waivers. Congress must act to ensure that in future disasters, emergencies, or times of product recalls or supply chain disruptions, USDA can immediately act to increase the number of infant formula products available to WIC participants nationwide. Congress should consider a more nationwide approach to waivers and ensure that USDA is aggressively and proactively providing technical assistance to states. Infant formula companies who contract with WIC should also be required to have a plan in place for how to provide needed formula to families in the event of a future shortage.

Donor Human Milk

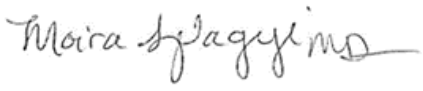
The use of pasteurized donor human milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established milk banks. Donor milk banks, such as those accredited by the Human Milk Banking Association of North America, represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in Neonatal Intensive Care Units and other settings. However, accessibility to donor milk in the U.S. continues to be substantially limited in terms of supply, cost, and distribution. Congress should ensure greater federal regulatory oversight of donor human milk by the FDA. There is no current federal requirement for insurance coverage of donor milk, which often leaves families, especially families with preterm infants, responsible for the costs. Congress should ensure that families can access donor human milk on the basis of medical necessity, not financial status. Further, Congress can dedicate resources and raise awareness for donating and receiving safe donor human milk.

Insurance Coverage for Medical Nutrition

Many of the families who are searching for specialized formulas to meet their children's medical needs are the same families who frequently face denials for coverage of such products by their insurance. While medically necessary nutrition is sometimes the best or only treatment for a digestive or metabolic condition, insurance companies often deny coverage. Insurance companies will typically cover pharmaceuticals or biologics for treatment of these diseases; however, they are often used off label or may not be recommended by the treating physician as first line therapy. Further, pharmaceuticals and biologics are often costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer. Even when an insurance company does cover medically necessary nutrition, it often comes with the stipulation that the formula be administered through a feeding tube (for example, a nasogastric tube, placed through the nose into the stomach or a gastrostomy tube, surgically placed directly into the stomach). Surgery to place a feeding tube is expensive and these tubes carry additional risks. Congress should require both public and private insurance to cover medically necessary foods, such as highly specialized formulas, as a treatment option. Congress has previously recognized the importance of providing coverage for medically necessary nutrition and required TRICARE coverage for such therapies in the 2016 National Defense Authorization Act. We urge Congress to expand this requirement for other insured populations with rare digestive and metabolic conditions.

Thank you for your attention to this urgent issue and know that we stand ready to work with you to ensure that families have access to the infant formula that they desperately need. If we can be of further assistance, please contact Tamar Magarik Haro at tharo@aap.org.

Sincerely,



Moira A. Szilagyi, MD, PhD, FAAP
President

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