

# The Infant Formula Shortage: Impact, Responses, and Lessons Learned

Susan A. Berry, MD, FAAP  
August 30, 2022

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



# Susan A. Berry, MD, FAAP, FACMG

- Professor, Division of Genetics and Metabolism, Department of Pediatrics, University of Minnesota.
- Dual Boarded in Pediatrics and Genetics/Clinical Genetics.
- Member of the American Academy of Pediatrics Council on Genetics.
- No conflicts of interest to disclose.



# The Infant Formula Shortage

The recall of select Abbott Nutrition formulas has caused drastic formula shortages across the country for thousands, including for those who rely on specialty formulas.

Unfortunately, many of these specialized formulas are manufactured only at Abbott's Sturgis plant.



# What We've Heard from Providers

- Pediatricians overwhelmed with calls and inquiries from desperate parents.
- Pediatricians rationing their supply of formula.
- Often no choice but to make creative substitutions based on what's available.
- Often requires engagement with insurance companies to allow for these substitutions.



# What We've Heard from Providers

- Alternative product lines are very limited.
- Some states exploring suspending/revising authorized formulas requirement.
- Severity of shortage and level of concern variable by location.



# Impact on Children and Families

- Concern/stress/desperation regarding infant children's health, nutrition, and well being.
- Infant hospitalizations have occurred with weight loss and dehydration due to dilution and homemade formulas.
- For children with phenylketonuria (PKU) and maple syrup urine disease (MSUD), amino acid-modified formula is crucial, and Abbott's Phenex and Ketonex have been in short supply.
- Formula switching fatigue.



# Impact on Patients and Clinics

- GMDI conducted a brief survey in June of metabolic dietitians to understand how the formula crisis was affecting patients and clinics.
- Most respondents followed 100-300 patients with metabolic conditions.
- Formula Coverage: 50% from a state-run formulary; 50% through insurance
- When a medical food change was required, the top barrier for patients was unacceptable taste, followed by an inappropriate nutritional profile for that patient's needs.



# From Prescription to Consumption

- Health team determines appropriate formula and dose.
- Prescription is sent to DME or Pharmacy (may take multiple tries based on insurance)
- DME/Pharmacy request authorization from insurance
  - May need additional documentation from health team
  - If denied will require appeal process
- Once approved DME/Pharmacy ships from warehouse or directly from manufacturer.
  - If formula is backordered DME may or may not inform the patient and typically does NOT inform health team
- Any change in formula needs the whole process to start over.

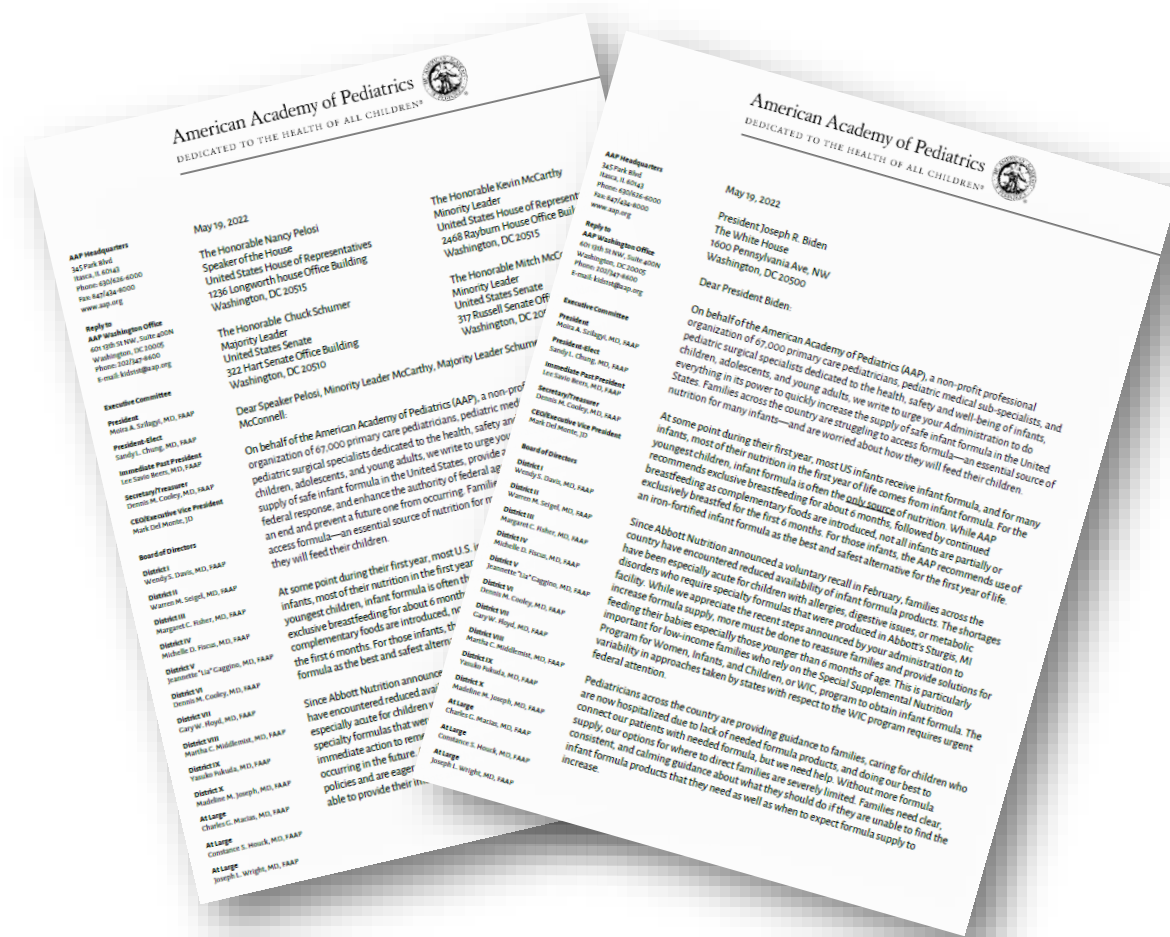
*Typical time from prescription to formula in hand 1-4 weeks*





# AAP Response – Federal Advocacy

- Letters to the White House and Congress urging immediate action
- Constant, ongoing communication with FDA, USDA, CDC, and the White House to share expertise
- Regular briefings of the health care provider community hosted by the White House in partnership with NASPGHAN



# AAP Response – Pediatricians and Families

- Provided pediatricians, families, and the media with accurate information and recommendations for navigating the shortage.
- Resources continually updated as new information emerges.



# AAP Response – Pediatricians and Families

- *AAP News* article:

“AAP experts offer advice on how pediatricians can help parents through formula shortage.”



The screenshot shows a webpage from AAP News. At the top left is the logo "AAP News" and at the top right are links for "Latest News" and "Collections". Below the header is a "SHARE" section with icons for Facebook, Twitter, and LinkedIn. The main content area features a photograph of a hand holding a blue measuring spoon over a baby bottle, with a can of formula in the background. Below the photo is the article title "AAP experts offer advice on how pediatricians can help parents through formula shortage", the date "May 19, 2022", a "Download PDF" link, the article type "News", and a list of topics: "Fetus/Newborn Infant, Metabolic Disorders, Nutrition, Public Health".

# AAP Response – Pediatricians and Families

- HealthyChildren.org Resources

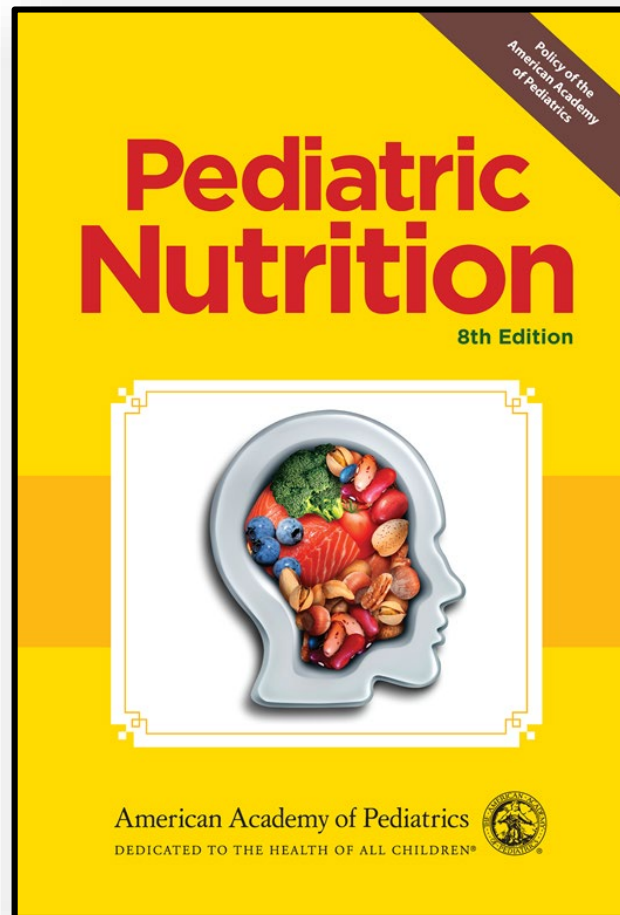
AAP's parent and family-facing web site.



The screenshot shows the HealthyChildren.org website interface. At the top left is the logo for healthychildren.org, with the tagline "Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics". A search bar is located at the top right. Below the logo, there is a navigation menu with "MENU" and a hamburger icon. The main content area is titled "Tips & Tools" and includes a list of resources: "Ask the Pediatrician", "Find a Pediatrician", "KidsDoc Symptom Checker", "Newsletters", "HealthyChildren Magazine", "Texting Program", and "Webinars". The "Ask the Pediatrician" section is active, showing a question: "With the baby formula shortage, what should I do if I can't find any?". The question is attributed to Steven A. Abrams, MD, FAAP. Below the question is the "Answer" section, which begins with "Since the outbreak of COVID-19, there have been significant shortages of infant". A partial image of a woman's face is visible at the bottom right of the screenshot.



# AAP Response – Pediatricians and Families



- AAP's *Pediatric Nutrition, 8th Edition* policy manual includes chapters on:
  - Formula Feeding of Term Infants
  - Inborn Errors of Metabolism
  - Federal Regulation of Foods and Infant Formulas



# AAP Response – Pediatricians and Families

The screenshot shows the HHS.gov website. At the top, there is a search bar with the text "I'm looking for..." and a magnifying glass icon. Below the search bar is a navigation menu with links for "About HHS", "Programs & Services", "Grants & Contracts", and "Laws & Regulations". The main content area is titled "Information for Families During the Formula Shortage". It includes a paragraph about the importance of formula for babies and families, a section for "Find Safe Substitutes" with a link to "Try a New Brand of Formula", and a sidebar with the heading "Read this page in:" and links for "Spanish / Español", "Vietnamese / Tiếng Việt", "Creole / Kreyòl", and "Navajo".

- Worked with the White House on HHS.gov/formula information.



# AAP Response – Pediatricians and Families

- Amplified messaging across AAP's social media channels and through press outreach.



American Academy of Pediatrics  
@AmerAcadPeds

The current infant formula shortage has led to recipes for homemade baby formula circulating online. These are dangerous and can have deadly consequences. Here are the facts parents should know 📖:

A screenshot of social media posts and a news release. At the top is a tweet from the American Academy of Pediatrics (@AmerAcadPeds) stating: "As the national shortage in infant formula continues, we wrote to federal officials urging immediate action at every level of government to increase the supply of safe infant formula in the United States. Our press release: ...". Below the tweet is a link preview for aap.org with the text "American Academy of Pediatrics Urges White House, Congress to Take Comprehensive, Urgent Action to...". At the bottom is a news release banner from wbur with the headline "Can't find baby formula? Pediatrician shares the do's and don'ts of navigating the shortage" and a play button icon.

News Release

## American Academy of Pediatrics Urges White House, Congress to Take Comprehensive, Urgent Action to Address Infant Formula Shortage

[Home](#) / [News Room](#) / American Academy of Pediatrics Urges White House, Congress to Take Comprehensive, Urgent Action to Address Infant Formula Shortage

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



# AAP Response – Messages to Families

- Contact your pediatrician. Local WIC office may also be a resource.
- Check smaller stores and drug stores.
- Consider online from well-recognized distributors.
- For most babies, it is OK to switch to any available formula. There are exceptions for babies on special formulas. If unsure, talk with your pediatrician.
- Check social media groups.
- Consider borrowing from a friend.
- Limit to a 10-day to 2-week supply of formula to ease shortages.





# Alternative Formulas / Science of Substitution

- By focusing on protein type, it is possible to create categories of formulas that generally can be considered interchangeable.
- However, patients with conditions requiring specialized formulas must work with their medical specialists if they are facing shortages.
- NASPGHAN resource categorizes US FDA-reviewed formulas by protein type. <https://naspghan.org/recent-news/naspghan-tools-for-hcps-affected-by-formula-recall/>
- Even if nutritionally equivalent, infants resist change.



# Imported Formula

## Helpful facts about imported baby formula

For most babies, it is fine to switch to any available formula during the shortage. But if you use imported baby formula, keep the following in mind:

Some labels use “stages” for age groups.



Make sure to use the scoop that comes with the imported formula. Be sure to use the correct number of scoops.



Milliliters (mls) are used instead of ounces (oz).  
30 mls = 1 oz.



You may see “teat” referred to instead of the bottle’s nipple.

**Read labels carefully and contact your pediatrician with any questions.**

Learn more at  
[HealthyChildren.org](http://HealthyChildren.org)



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



American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



# Conclusion

- Broad issues identified regarding affordability and access to formula for people with metabolic and digestive disorders.
- Need to continue efforts to pass the Medical Nutrition Equity Act (MNEA).
- Pediatricians can't do it alone. We will continue working together with the federal government and other partners to make sure that no matter a family's zip code, or means, no matter their child's health condition or age, they can find the formula they need.
- Current strategies to provide formula will continue to impair delivery even when shortages are alleviated.

