Making Sense of the Infant Formula Shortage

Moving From Short-term Blame to Long-term Solutions

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Purchasing infant formula became an enormous challenge beginning in early 2022 for families throughout the United States. Faced with a myriad of other challenges in raising newborns came the unexpected reality of not having food in stores that their infants needed to thrive. Quickly, blame was assessed, and less quickly, government and industry solutions to increase supply were set in motion, but the actions taken have not fully resolved shortages. Even more than a year and a half after the severe shortages began, little effort has been made to develop long-term solutions to formula supply issues. It is time for the nutrition community to seriously consider this issue as a major policy agenda and recognize that healthy childhood nutrition starts with secure feeding for all infants regardless of mode or content of feeding. In this article, we will explore what needs to be done in this regard and where the barriers are to implementing long-term solutions to both the formula shortage and supporting breastfeeding families. Nutr Today 2023;58(5):195–200

Abbreviations: AAP: American Academy of Pediatrics, FDA: Food and Drug Administration, WIC: The Special Supplemental Nutrition Program for Women Infants and Children, USDA: US Department of Agriculture

THE SUPPLY CHAIN FOR INFANT FORMULA IN THE UNITED STATES

Infant formula is a unique consumer item in the United States and many other countries. Although breastfeeding is recognized as optimal for infants, with decreases in the risk of numerous health problems for both mother and baby, many families are unable to breastfeed or choose to formula feed. In the United States, the majority of infants will receive some infant formula during the first year of life.[1]

Infant formula is produced by private, for-profit companies. However, its composition and production are primarily regulated by federal legislation embodied in Food and Drug Administration (FDA) rules and regulations. Formula is unique in that it is the only food in the United States that is principally purchased using government resources via the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) or with use of the Supplemental Nutrition Assistance Program benefits. The WIC program contracts with manufacturers account for slightly more than half the formula purchased in this country. The WIC is administered on a state-by-state basis with federal oversight and regulation by the US Department of Agriculture (USDA).[2]

These unique characteristics have led to a loss of competitiveness in the marketplace, as evidenced by 2 companies controlling approximately 80% of the market as of early 2022 and 4 companies controlling well over 90% of the market. As such, production, distribution, and purchase of infant formula largely are based on the operation of these few companies and subject to being severely affected, especially by incidents affecting production at any 1 of the 2 largest companies.[3]

This situation is magnified when considering specialized formulas for infants who have either severe allergies or rare disorders of metabolism. Although the 4 companies that dominated the marketplace in early 2022 each make some or all of these specialized formulas, the supply is tightly limited and is subject to being disrupted easily with little alternative backup available.

Prior to the middle of 2022, virtually no infant formula was imported into the United States because few companies had FDA clearance for their overseas manufacturing facilities or for importing formula produced in them. In fact, most of what was imported likely was imported illegally using the "gray market" to meet the desires of mostly upper-income families who believed that certain European formulas were healthier than US formulas. Relatively little effort was expended by the federal government to stop this from occurring, and pediatricians and other health professionals generally did not attempt to seriously counsel families away from this practice.[4]

This situation led to a perfect setup for the disaster in formula supply that occurred in February 2022. Table 1 shows how these and other related issues played a part in the formula shortages.

THE FORMULA SHORTAGE OF 2022

Although infant formula recalls and production delays have previously occurred in the United States, a unique situation

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TABLE 1 Unique Characteristics of Infant Formula Use Leading to a High-Risk of Harm When Shortages Occur

Unique Characteristic	Vulnerability	Consequence
Marketplace controlled by only a few companies	Manufacturing or other problems at one of the 2 large companies could not be readily overcome	One company closing its largest production facility led to major nationwide formula shortage
WIC program entirely dependent on 3 companies in the US	Inflexibility by states in switching WIC providers	When shortages occurred, WIC recipients were most affected and unable to find formula
Rigorous FDA regulations on formula production and distribution and import restrictions	Inability to import formula readily even from reliable manufacturers overseas	Federal action needed to begin a broad importation effort was very slow to occur
Relatively high use of specialized, hypoallergenic formulas by consumers	Global production of these special formulas is minimal, other countries also use US-manufactured products	When production of these products at a major US factory was stopped, there was no ability on a global basis to compensate for it by production elsewhere
Minimal educational efforts related to infant formula directed to consumers or health professionals	Few families or healthcare providers are highly knowledgeable about formula variations and how to interchange brands	During shortages, families and providers were often confused about identifying similar types of formula as acceptable substitutes
For non-breastfed infants in the first months of life infant formula is the sole source of nutrition	Shortages especially of specialized formulas can lead to growth failure or other harmful health outcomes	During shortages, many families made formula at home or overdiluted formula, both of which are very harmful practices to infant health
High rates of formula-feeding in the US are associated with lack of support for breastfeeding	Difficulty in supporting families of newborns with breastfeeding, especially when returning to workplace	Despite calls for increased breastfeeding, only a small increase occurred during formula shortages

Abbreviations: FDA, Food and Drug Administration; WIC, The Special Supplemental Nutrition Program for Women Infants and Children.

developed in February 2022 when the largest manufacturer of formula in the United States recalled formula from its principal factory producing powder and specialized formula and closed that factory for an extended period.

The reasons why this happened have been widely discussed and investigated by the FDA, by Congress, and the media.[5] Of note is that since the initial recall of one company's products in February 2022 by March 2023, 3 additional recalls from 3 different US manufacturers of infant formula have occurred related to concern about bacterial contamination. The focus of this article is on the consequences of this initial recall and ultimately the prevention of these consequences from future recalls. We will begin by a discussion of the issue of powder formula and how it related to the ensuing events.

SPECIAL ISSUES RELATED TO POWDERED INFANT FORMULA

Infant formula can be provided to the consumer, whether at home or in the hospital, as either a powder or liquid. Liquids can be provided either at the final used dilution or as a concentrate requiring the addition of water. Although the nutritional benefits provided by powders and liquids are very similar, there are some crucial differences.

The first of these differences is that infant formula provided as a powder is not subject to end of production sterilization. Although stepwise processes during manufacturing are done with careful attention to cleanliness and sterility, contamination can be introduced in production or packaging of the final formula product. In addition, powdered formula requires the addition of water and mixing of the final product in the home or hospital. Although infectious contamination is rare, it does occur, most seriously from bacteria known as *Cronobacter sakazakii*. In contrast, liquid formula is subject to end-product sterilization and does not require addition of water (except when it is in the form of concentrates).[6] Risks of infectious contamination are much lower from liquids, although some risk exists due to unclean bottles or nipples.

The second major difference is product cost. Generally, consumers will pay considerably more for liquids compared with powder, due in part to their greater bulk and consequent shipping and storage expenses. Many brands are available only as powder due to consumer preference for lower-cost products. Most liquid formula is used as ready-to-feed in small bottles in the hospital both for

healthy infants and those in neonatal intensive care units or other hospital wards.

These differences require extreme attention to detail in all formula production and distribution, but especially so for powdered formula. They leave open the possibility that contamination events can both cause harm to individual babies and lead to major disruptions in the source of formula nationally. Inadequate redundancy in the system, especially for specialized formulas, contributes to this risk.

SHORT-TERM SOLUTIONS

The response to the factory closure and recall in February 2022 was slow and inadequate. The failure of a large range of systems to identify and respond to the crisis occurred and has been well-documented.[7] Ultimately, extreme public pressure, in part generated by social media, led to national awareness and industrial and government actions.

Industry initially responded by attempts to increase formula from other US factories and provide reassurance that the problem was short-term and would quickly improve. The federal government generally followed this line until it reached the point where in many locations no formula was available for purchase, and families resorted to dangerous approaches such as using homemade formulas and overdilution of what formula they could find. Hospitals using hypoallergenic and other specialty formulas faced a similar crisis that was critical due to the unique nature of these formulas for many of the infants under their care.

Approximately 3 months into the shortage, the government announced a series of actions designed to improve infant formula supply. The most important of these was called "operation fly formula" and consisted of the FDA granting temporary registration (the equivalent of approval to import) to some infant formulas produced outside the United States that were not otherwise registered with the FDA, and the federal government provided flights to bring the formula to the United States. These formulas and companies were fully vetted by the FDA, and it was effective in providing safe options and additional formulas, including specialized formulas.[8]

Although the actual volume of formula imported via this program was relatively small, over time this importation and increased production by all US manufacturers gradually improved the situation. However, even a year after the initial recall in early 2022, persistent shortages exist, multiple additional recalls have occurred, and the situation is not ideal, especially for families using the WIC program who cannot purchase formula online and those infants needing specialty formulas.[9] Clearly, long-term solutions are needed.

LONG-TERM SOLUTIONS

The formula shortages led to a broad range of investigations and recommendations, some generated at the congressional level and others largely by the FDA. The media has been instrumental in keeping the pressure on the FDA and government officials. However, few of these recommendations have been implemented to date. We will suggest what needs to be done and what is likely to occur in this section. These are summarized in Table 2 and considered individually below.

Increased Diversity in Formula Options Through Importation

It is widely understood that families wish and need to have more options in formula selection than the pre-2022 domination of the market by 2 companies. This can best be accomplished through allowing additional high-quality, properly vetted companies to import infant formula products produced outside the United States, as well as enhancing the development and operation of new domestic formula suppliers. Accomplishing this requires a process for registration of new formulas and factories that is consistent with long-standing FDA regulation and feasible for companies to undertake. There are numerous barriers to importation and opening new domestic production that must be overcome to make this a practical solution. This includes, for example, changing archaic rules related to animal protein studies being required for FDA registration.

The FDA has partly acknowledged this issue and created a pathway for new importation.[8] However, the process of FDA formula registration remains overly cumbersome and needs substantive revision for both imported and domestic products. Furthermore, tariffs on imported formula decrease the options, especially for lower- and middle-income families to purchase and use imported formulas.

Overall, there is improvement in this area, but a long-term unbiased review of the formula marketplace is needed to develop policies that will ensure and protect formula supplies.

Major Revisions in WIC Program Contracting

Approximately half of the formula purchased in the United States is via the USDA-managed WIC program. The WIC operates via state-by-state (with some state groupings) contracts that selects companies using lowest-bidder competitive bidding based on preset standards set by the USDA. Three companies hold all the WIC contracts in the United States with the 2 largest holding all but a few state contracts.

Opening the WIC contracting process to ensure more companies are involved as WIC providers would be difficult and potentially costly to the government. Mandating that companies work together or that they separate out various types of formulas with different contracts (eg, goat milk, partial hydrolysates) is possible. However, the loss of exclusivity in the WIC contract to use one company for nearly all the different types of formulas may lead to lower rebates to states in the competitive bids. Although being discussed in Congress, it seems unlikely that any meaningful changes

TABLE 2 Long-term Approaches to Improving Formula Availability and Breastfeeding Support

Solution	Who Must Act to Make It Happen?	Is It Likely to Occur?
Increased diversity in formula options through importation of brands not available in the US before the middle of 2022	FDA primarily regulates this process, but input from Congress and the White House is important.	Yes. However, there are hurdles and challenges to be overcome in ensuring a range of options for families.
Major revisions in WIC program contracting procedures (eg, states obtaining deep discounts if they designate a single company as a sole provider of formula for WIC)	USDA and likely also congressional action	No. As it currently exists, WIC contracting saves the government money because formula is obtained at a much lower price for use in WIC, and there is little will in government to change this and increase costs.
Increased postpartum support for breastfeeding including parental paid leave increases	Congress likely would need to act, but individual states could act as well.	Minimal. However, positive changes are appearing on the horizon. This has not become the public issue it should be yet, however.
Substantial changes in FDA processes and handling of infant nutrition	FDA primarily with congressional oversight	Maybe. This is being discussed, but real changes appear to be in the distant future.
Improved education of healthcare providers related to formula choices	Organizations such as the AAP, ASN, AND, and ASPEN	Minimal. There is inadequate interest in this topic generally, and concerns about healthcare providers being accused of formula advocacy and bias limit this training and education.
Mandatory reporting requirements for infant formula safety issues that may impact production or distribution	FDA, CDC, Congress, and individual states	Yes. This seems to be on the horizon at all levels. However, how much will occur is uncertain. Mandating reporting of clinical *Cronobacter sakazakii* infections nationally is the first key goal as is mandatory notification to the FDA of all batches of formula that have evidence of *Cronobacter* species even if not marketed.

Abbreviations: AAP, American Academy of Pediatrics; AND, Academy of Nutrition, and Dietetics; ASN, American Society for Nutrition; ASPEN, American Society for Parenteral and Enteral Nutrition; FDA, Food and Drug Administration; WIC, The Special Supplemental Nutrition Program for Women Infants and Children.

in the WIC program related to formula companies and contracting will occur for an extended period.

Increased Postpartum Support for Breastfeeding Including Parental Paid Leave Increases

During the formula shortages, nutrition advocates and others, including pediatricians, were generally cautious about recommending increased breastfeeding as a solution to the problem. This was due to concerns that families who were no longer breastfeeding would feel guilty about this, and it would not effectively address the short-term shortages of obtaining appropriate formula.

However, in the long term, we must face the reality that most infants in the United States will receive formula at some time during the first year of life, and as documented in many places including a report by the US Surgeon General several years ago, there are major systematic impediments to breastfeeding in the United States.[9] The most important of these is likely the lack of extended paid postpartum leave for mothers and caregivers as well as the challenges of pumping and storing milk in most workplaces. The US lags far behind most industrialized countries in this regard.

Although this topic has generated increasing public attention, there seems little likelihood of meaningful changes soon. Smaller changes in rules, support for public breastfeeding, and increased support for human milk banks and pumping milk in the workplace are occurring, but a real change in public policy to support breastfeeding seems unlikely in the next few years.

Substantial Changes in FDA Processes and Handling of Infant Nutrition

As was necessary after the recall in early 2022, the FDA has undertaken a detailed review of its actions related to the recall and shortages and its regulatory environment for infant formula. Significant problems have been identified in management practices within the FDA, which contributed to the situation that developed. Although this is an important step, the interventions to improve formula supply and deal

with recalls and factory closures remain limited at present. This is an area of great interest to Congress, and it is likely that substantial reorganization within the FDA will occur to enhance food safety management, including infant formula.

Nonetheless, the FDA infant formula division is badly understaffed, and it remains to be seen whether changes will be implemented effectively within the FDA. It is likely that there will be improvements to ensure that the type of slow, ineffective response in early 2022 is not repeated. Other federal agencies, such as the USDA, must also evaluate their processes to ensure equity in provision of formula during shortages.

Improved Education of Healthcare Providers Related to Formula Choices

Infant formula education, both at the public and health provider level, is woefully inadequate. Although experts exist, mostly pediatric and neonatal dietitians and a small number of physicians, generally, little effort is provided to educate physicians, nurses, and other healthcare providers about the appropriate uses of different infant formula types and the interchangeability of brands.

This caused a major problem for many families during the shortages when hypoallergenic formulas were in short supply. It became clear that healthcare providers were overly recommending these formulas when the products were not medically indicated.[10] Moreover, many providers were unfamiliar with similarities between different brands and types of formulas as well as options such as lower-cost store brand formulas.

The underlying cause of limited formula education for providers is both an overemphasis on training providers only in breastfeeding/breast milk–related issues and the reality that nearly all education on infant formulas is provided by formula companies, especially the 3 largest ones in the United States. Concern that this education may discourage breastfeeding may also contribute.

Fixing this will not be easy. Although organizations such as the American Academy of Pediatrics provide lectures at national meetings on infant formula, this is not a broadly effective educational strategy. Because the US does not follow the World Health Organization guidance, which limits the interaction of formula companies with healthcare providers (or families), it is certain that in the foreseeable future the companies will control the discussion and education of healthcare providers, and this is not ideal. By allowing companies to directly market, especially to families, misleading information may be transmitted that undermines breastfeeding and leads to overuse of specialized or higher-cost formulas.

Mandatory Reporting Requirements for Infant Formula Issues

Formula recalls occurred both in 2022 and at other times largely due to concerns about the risk of or specific cases of bacterial contamination and infections occurring due to the formula. Surprisingly, there is no mandatory national reporting system for *C sakazakii* infections, and companies have a limited obligation to inform the government of supply or manufacturing problems that would lead to formula shortages. In March 2023, the FDA released a letter asking companies marketing formula in the United States to "voluntarily notify the Agency any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed."[11] The FDA has indicated that it does not have statutory ability to mandate this reporting. There is no national plan for how to handle this type of crisis and little interaction among companies related to aiding each other when needed because of production problems.

Proposals to resolve these issues including mandatory national reporting of *C sakazakii* infection are being discussed, and it is likely that there will be additional reporting requirements for infant formula manufacturers related to factory closures or production line problems. However, the time frame and how these will be handled are not certain.

CONCLUSIONS

Americans were shocked to discover in early 2022 that a critically needed product they assumed would always be readily available to them was unavailable and that government and industry protection of the safety and supply of infant formula was inadequate. Small short-term solutions have been done to support the formula industry and supplies, but the situation will recur if more substantial long-term solutions are not implemented. Some of these, especially those that are not costly to government or industry, are being strongly considered or undertaken. Other, more costly, and fundamental changes seem far away now, until this crisis occurs again and brings the issues back to the forefront of the public's concern. Advocacy within the nutrition community is needed on an ongoing basis to help improve these long-term responses.

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