



March 28, 2023

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Statement for the Hearing Record

FDA Oversight Part I: The Infant Formula Shortage

House Committee on Oversight and Accountability
Subcommittee on Health Care and Financial Services

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) commends Chairwoman McClain, Ranking Member Porter, and Members of the Subcommittee for holding today’s hearing on the 2022 formula shortage and appreciates the opportunity to offer the following statement for the hearing record.

NASPGHAN represents more than 3,000 pediatric gastroenterologists, nurses and pediatric registered dietitian nutritionists in the United States, Canada, and Mexico and is the only organization singularly dedicated to advocating for children with gastrointestinal (GI), liver and nutrition-related diseases and disorders.

Pediatric gastroenterologists are physicians who are board certified in pediatric digestive conditions, as well as in nutrition. As pediatric specialists, NASPGHAN members regularly care for infants and children with GI disorders related to severe food protein intolerance, food allergies, malabsorption, poor growth and malnutrition who depend on specialized (non-standard) formulas for treatment, growth, and survival. For example, approximately 450,000 (2%) of children under the age of five years in the United States have a dietary milk protein allergy that is managed by either dietary restrictions in a nursing mother or by reliance on “extensively hydrolyzed” or “amino acid-based” hypoallergenic formulas^{1,2} — both of which experienced a significant supply shortage following the 2022 Abbott formula recall.

In fact, NASPGHAN’s experience on the frontlines of pediatric health care illustrates a current lack of national preparedness to respond to disruption in the manufacturing of infant and other specialized formulas. The situation became so dire by April of 2022, inspiring much media coverage, that we believe all of America now understands that specialized formulas are essential sources of nutrition for infants, children, adolescents, and adults with severe allergies, intestinal disorders and diseases, chronic kidney disease and metabolic disorders.

In assessing the national response to the shortage to date, NASPGHAN commends Congress for recognizing the essential nature of specialized formulas by requiring in the *2023 Consolidated Appropriations Act* the establishment of an Office of Critical Foods — defined as infant formulas and medical foods — within the Food and Drug Administration’s (FDA’s) Center for Food Safety and Applied Nutrition. NASPGHAN also applauds other provisions in the bill aimed at improving preparedness against infant formula shortages, including the development of a national strategy on infant formula.

In addition, we call attention steps that NASPGHAN has taken in response to help its members, our pediatric health care colleagues, and our patients. Specifically, soon after the Abbott’s 2022 formula recall, NASPGHAN created information and made it [publicly available](#) — information that was shared with the Administration — regarding safe substitutions for formulas that were in

¹Rona RJ, Keil T, Summer C et al. The prevalence of food allergy: a meta-analysis, *J Allergy Clin Immunol* 2007;120:638

² Host A. Cow's milk protein allergy and intolerance in infancy. Some clinical epidemiological and immunological aspects. *Pediatr Allergy Immunol* 1994;5:1

shortage. The information categorizes formulas by protein type for premature and term infants, as well as for children older than 12 months of age. By categorizing formulas, health care professionals, patients and caregivers can better understand which formulas are comparable and safe to substitute for each other.

NASPGHAN appreciates that marketing and labeling of formulas often make it difficult for consumers to understand and differentiate which formulas can be substituted for others, particularly in high-risk populations who require specialty formulas. A lack of understanding around how to categorize formulas can also lead to parental hesitancy and delays in switching between formulas, even when it is safe to do so. NASPGHAN is pleased the *2023 Consolidated Appropriations Act* requires the publication of a list on the website of the Department of Health and Human Services providing information on how to identify appropriate substitutes for infant formula products in shortage that are relied upon by infants, as well as by individuals with inborn errors of metabolism or other serious health conditions.

Finally, NASPGHAN agrees that protecting against future *Cronobacter sakazakii* (*C. sakazakii*) formula contamination or contamination by other bacteria must become a federal priority, as must designing well-coordinated national responses to future recalls or disruptions in formula manufacturing or the supply chain. Based on the experience of the 2022 formula shortage, NASPGHAN has developed policy recommendations which are outlined later in this statement.

In brief, we would note that events of microbial contamination of formula have historically and sporadically occurred over the past 30 years, leading to various smaller formula recalls that have not resulted in mass shortages. However, the pace and scope of these recalls has now increased. Subsequent to the Abbott recall of 2022, there have now been a series of at least five more recalls of formula batches from various other manufacturers, including Kate Farms, ByHeart and Reckitt Mead Johnson, and the supply chain remains fragile leading each of these formula recalls to further stress the system. NASPGHAN strongly believes that implementing new recommendations and creating better policies around monitoring and responding to microbial contamination of infant formulas are essential to national security. New policies that ensure all infants and those with GI disorders have prioritized access to nutrition will ensure that the United States can meet demand, even in event of future disruptions in market share and product supply.

BACKGROUND

Contamination of pediatric and infant formula has been shown in both epidemiological and microbiological studies to primarily be invasive *C. sakazakii* and *Salmonella* infections in young

newborns and preterm infants.³ *C. sakazakii* and *Salmonella* are opportunistic foodborne pathogens.⁴

Published cases of invasive *C. sakazakii* have mostly involved preterm infants, neonates (age <2 months), and older children who were immunocompromised, for example, those having undergone a bone marrow transplant.^{5,6,7} The FDA has published recommendations for the preferred use of ready-to-feed (RTF) infant formulas in neonatal intensive care units (NICUs) to decrease the risk of *C. sakazakii* exposure and infection.⁸ The Centers for Disease Control and Prevention (CDC) has also recommended that when breast milk is not available, the RTF formula should be considered whenever possible, especially in preterm infants, newborns less than two months of age, and children with weakened immune systems.⁹

The manufacturing process of RTF and liquid concentrate formulas involves a pasteurization step using ultra-high temperatures that essentially eliminate contamination with all bacterial microorganisms, including *C. sakazakii*.¹⁰ In contrast, the manufacturing process for powdered formula is not sterile because the addition of thermally sensitive ingredients such as vitamins, minerals, amino acids, and fatty acids *that may potentially be contaminated* occurs after the pasteurization step.^{11,12} Contamination with *C. sakazakii* may also occur post-manufacturing at any stage of formula reconstitution through the use of contaminated water, utensils, work surfaces, or enteral tubing.¹³

³ FAO/WHO. *World Health Organization. (2006). Enterobacter sakazakii and Salmonella in powdered infant formula : meeting report. World Health Organization. <https://apps.who.int/iris/handle/10665/43547> 2006 [cited 2022 4/30/2022]; Available from: <https://apps.who.int/iris/handle/10665/43547>.*

⁴ Bintsis, T., *Foodborne pathogens*. AIMS Microbiol, 2017. 3(3): p. 529-563.

⁵ Bowen, A.B. and C.R. Braden, Invasive Enterobacter sakazakii disease in infants. *Emerg Infect Dis*, 2006. 12(8): p. 1185-9.

⁶ Henry, M. and A. Fouladkhah, Outbreak History, Biofilm Formation, and Preventive Measures for Control of Cronobacter sakazakii in Infant Formula and Infant Care Settings. *Microorganisms*, 2019. 7(3).

⁷ Farmer, J.J., 3rd, *My 40-Year History with Cronobacter/Enterobacter sakazakii - Lessons Learned, Myths Debunked, and Recommendations*. *Front Pediatr*, 2015. 3: p. 84.

⁸ I Himelright, E.H., V Lorch, M Anderson, Univ of Tennessee Medical Center at Knoxville; T Jones, A Craig, Tennessee Dept of Health. M Kuehnert, T Forster, M Arduino, B Jensen, D Jernigan, Div of Healthcare Quality Promotion, National Center for Infectious Diseases, CDC. *Enterobacter sakazakii Infections Associated with the Use of Powdered Infant Formula --- Tennessee, 2001*

⁹ *Cronobacter Infection and Infants*. 2022 [cited 2022 4/30/2022]; Available from: <https://www.cdc.gov/cronobacter/infection-and-infants.html>.

¹⁰ Henry, M. and A. Fouladkhah, Outbreak History, Biofilm Formation, and Preventive Measures for Control of Cronobacter sakazakii in Infant Formula and Infant Care Settings. *Microorganisms*, 2019. 7(3).

¹¹ Ibid.

¹² Healy, B., et al., Cronobacter (Enterobacter sakazakii): an opportunistic foodborne pathogen. *Foodborne Pathog Dis*, 2010. 7(4): p. 339-50.

¹³ Kalyantanda, G., L. Shumyak, and L.K. Archibald, Cronobacter Species Contamination of Powdered Infant Formula and the Implications for Neonatal Health. *Front Pediatr*, 2015. 3: p. 56.

IMPACT OF THE FORMULA RECALL

Abbott's voluntary recall of the impacted specialty formulas created an abrupt shortage in protein hydrolysate, amino acid-based and metabolic formulas. The effects of the recall were far reaching because of the company's dominant market share and the limited capacity of other formula manufacturers to bridge the supply gap.¹⁴ The timing of the formula recall coincided with other pandemic-related supply chain disruptions.

Abbott's Sturgis facility produced 25 different formulas, including standard formulas used for healthy term infants and specialized formulas used by infants and children with food allergies, renal failure, intestinal failure, and various metabolic disorders. Many of the specialized formulas have either no alternatives available in the United States or extremely limited supplies of alternatives that were rapidly depleted following the surge in demand after the February 2022 plant closure.

In March 2022, a survey conducted by NASPGHAN of pediatric gastroenterology health care professionals received 371 responses within one week. Of the respondents, 97 percent indicated their practices had been negatively impacted by the formula shortage resulting from the Abbott recall. The most impacted formulas were the amino acid-based formulas (90%), followed by the extensively hydrolyzed formulas (55%). Respondents reported that parents and caregivers were in distress about the ability to feed their children, and there was widespread frustration with the absence of adequate and uniform guidance.

Among the reported medical consequences of the recall were feeding intolerance of substitute formulas, weight loss, gastrointestinal bleeding, decreased intestinal function, acute kidney injury, and electrolyte deficiencies, which resulted in increased physician and emergency department visits, as well as increased hospital admissions and delayed hospital discharges.

The scarcity of formulas and the stress experienced by families was worsened by policies and regulatory red tape that impeded patient access to formula alternatives. The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Supplemental Nutrition Assistance Program (SNAP) experienced major bureaucratic documentation and emergency approval barriers that impeded their ability to quickly issue non-contract brand formula in settings of specific product shortages. NASPGHAN members also reported that insurance companies demonstrated poor flexibility in providing coverage of non-formulary products or by requiring new prior authorization for alternatives to the formulas in shortage.¹⁵

¹⁴ Sentongo T, Velez DS, Huynh P, Abdelhadi R, Chan A, Goday P, Karjoo S, Kinberg S, Merritt R, Pai N, Quiros-Tejeira RE, Duro D. Managing the Impact of *Cronobacter sakazakii*, the Nemesis of Powdered Formula. *J Pediatr Gastroenterol Nutr.* 2022 Aug 1;75(2):113-115. doi: 10.1097/MPG.0000000000003508. Epub 2022 Jun 6. PMID: 35666843.

¹⁵ Ibid.

OBSERVATIONS AND RECOMMENDATIONS

The Abbott formula recall revealed how vulnerable the supply of specialized nutrition products is to interruptions in the manufacturing and supply chains. The salient effect of the recall was an abrupt and widespread shortage of essential sources of nutrition for infants, children and adolescents with severe allergies, intestinal failure, chronic kidney disease and metabolic disorders.

Several critical systemic gaps were exposed following the recall, including a lack of capacity to quickly escalate production of essential specialty nutrition products when a major manufacturer was sidelined, a limited ability of health care professionals to rapidly identify suitable and available nutrition substitutes, poor tolerance of some of these substitutes and a need for policies or practices that mitigate evolving disruption in supplies of medically essential nutritional products.

Delays in safe formula substitutions also occurred in 2022 due to myriad of structural factors in the private and public sectors. In particular, many private payers — if they cover specialized formulas — require prior authorization (PA) by name and manufacturer for medical coverage. Although NASPGHAN members and all U.S. pediatricians are accustomed to the PA process, such requirements at individual insurance plan levels remained in place throughout the shortage adding significant delays in patient access to available substitutes.

Most plans require about 48 hours to two weeks before approval is granted for coverage of specific specialty formulas. During the shortage, many patients switched often in accordance with availability and with *each* switch, new PA paperwork for the substituted formula was required for the same medical indication, and the plan policy for waiting time again was applied. Delays in access due to the PA process to these critical formulas were and are a particularly serious medical issue in infants <6 months of age with food protein intolerance and allergies who, for developmental reasons, rely on these specialized formulas for sole source nutrition. This process also tremendously strained our nation's pediatric health care providers, offices, and hospitals, who were forced to dedicate extraordinary additional time and efforts to overcome redundant PA processes.

For infants enrolled in WIC and SNAP, each individual state WIC/SNAP office needed to recognize the problem and adjust their individual bureaucratic processes to allow for substitutions without delaying access to patients. While NASPGHAN appreciates efforts by the Biden Administration to guide private payers, as well as WIC/SNAP, to adjust their administrative processes around formulas in times of shortage, there have been no policies put forward that will ensure that such emergency procedures will be followed again should a shortage recur.

In addition to necessary policy changes, NASPGHAN strongly encourages Congress to allocate additional resources to the FDA to provide necessary oversight of formula products. Other

regulatory considerations identified by NASPGHAN members¹⁶ to mitigate or prevent a formula shortage crisis in the future and to ensure the safety of infants, children and adults who depend on these formulas could include:

- prompt mandatory reporting of foodborne illnesses caused by *C. sakazakii*. A national reporting requirement that specifically mandates inclusion of *C. sakazakii* (i.e. inclusion for this organism in the CDC's Food Safety outbreak investigation reporting system: <https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/report-illness/healthcare.html>) should lead to earlier recognition of and opportunities to intervene in possible outbreaks of foodborne illnesses due to this bacteria;
- focusing formula recalls on populations considered to have the greatest risk of invasive infection. Generally, children younger than five years are considered to be at the greatest risk for acquiring foodborne illnesses and related complications. However, in the absence of data, defining the risk of illness solely based on age is a complicated message to generalize in a risk-averse environment;
- requiring formula manufacturers that control a significant market share to have a backup supply plan to ensure a non-disrupted supply of their products or buy enough time to allow substitute products to be made available;
- encouraging hospitals, durable medical equipment (DME) suppliers, WIC, and SNAP to broaden their selection and coverage within each formula category;
- providing greater flexibility to federal supplemental nutrition programs, such as WIC and SNAP, in making non-contracted brands of formula available during a shortage; and
- requiring insurance companies to provide coverage for non-formulary products when there is a shortage of formulary products. Furthermore, insurance companies should be mandated to provide coverage of specialized formulas, or critical foods, for individuals with GI and metabolic diseases and disorders.

CONCLUSION

NASPGHAN appreciates this opportunity to share its perspectives on the formula shortage and preventing shortages in the future and stands ready to serve as a resource to this Subcommittee. For more information or questions, please contact NASPGHAN policy advisor Camille Bonta at cbonta@summithealthconsulting.com or at (202) 320-3658.

¹⁶ Sentongo T, Velez DS, Huynh P, Abdelhadi R, Chan A, Goday P, Karjoo S, Kinberg S, Merritt R, Pai N, Quiros-Tejeira RE, Duro D. Managing the Impact of Cronobacter sakazakii , the Nemesis of Powdered Formula. J Pediatr Gastroenterol Nutr. 2022 Aug 1;75(2):113-115. doi: 10.1097/MPG.0000000000003508. Epub 2022 Jun 6. PMID: 35666843.