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North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Statement for the Hearing Record

The Infant Formula Crisis

House Committee on Appropriations

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) commends Chairwoman DeLauro, Chairman Bishop, Ranking Members Granger and Harris, and Members of the Subcommittee for holding today's hearing on the formula shortage crisis and is grateful for the opportunity to offer the following statement for the hearing record.

NASPGHAN represents more than 2,500 pediatric gastroenterologists 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, liver and nutrition-related diseases and disorders.

Pediatric gastroenterologists are board certified in pediatric digestive conditions, as well as in nutrition. As pediatric specialists, NASPGHAN members regularly care for infants with gastrointestinal disorders related to severe protein intolerance, allergies, malabsorption and poor growth who require specialized (non-standard) formulas to thrive. For example, up to 3-8 percent of infants born worldwide may be affected by a milk protein allergy and require either hypoallergenic extensive hydrolysate or amino acid formulas as their sole source of nutrition — both of which have been in very short supply since February.

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.¹ *C. sakazakii* and *Salmonella* are opportunistic foodborne pathogens.²

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.^{3,4,5} The Food and Drug Administration (FDA) has published recommendations for the preferred use of ready-to-feed (RTF) infant formulas in neonatal intensive care to decrease the risk of *E. sakazakii* infection.⁶ The Centers for Disease Control and Prevention (CDC) has also recommended that when breast milk is not available, the

¹ 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>.

² Bintsis, T., *Foodborne pathogens*. AIMS Microbiol, 2017. 3(3): p. 529-563.

³ Bowen, A.B. and C.R. Braden, Invasive *Enterobacter sakazakii* disease in infants. *Emerg Infect Dis*, 2006. 12(8): p. 1185-9.

⁴ 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).

⁵ Farmer, J.J., 3rd, *My 40-Year History with Cronobacter/Enterobacter sakazakii - Lessons Learned, Myths Debunked, and Recommendations*. *Front Pediatr*, 2015. 3: p. 84.

⁶ 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

RTF formula should be considered whenever possible in preterm infants, newborns less than two months of age and children with weakened immune systems.⁷

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*.⁸ 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.^{9,10} 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.¹¹

IMPACT OF THE FORMULA RECALL

Abbott Nutrition's voluntary recall of the impacted specialty formulas created an abrupt shortage in protein hydrolysate, amino acid-based and metabolic formulas — the effects of which have been far reaching because of the company's dominant market share and the limited capacity of other formula manufacturers to bridge the supply gap. The timing of the formula recall coincided with other pandemic supply chain disruptions. Hospitals, medical supply companies, families, and supplemental nutrition programs, including the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and Supplemental Nutrition Assistance Program (SNAP), have been severely impacted by the formula shortages. Health care providers frequently encounter clinical situations where substitute formulas are either unavailable or poorly tolerated by the patient.

Abbott Nutrition'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 plant closure.

In March 2022, a survey conducted by NASPGHAN of pediatric gastroenterology health care professionals received 371 responses. 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

⁷ Cronobacter Infection and Infants. 2022 [cited 2022 4/30/2022]; Available from: <https://www.cdc.gov/cronobacter/infection-and-infants.html>.

⁸ 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).

⁹ *Ibid*.

¹⁰ Healy, B., et al., Cronobacter (*Enterobacter sakazakii*): an opportunistic foodborne pathogen. *Foodborne Pathog Dis*, 2010. 7(4): p. 339-50.

¹¹ 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.

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, weight loss, rectal bleeding, rapid gastric emptying, acute kidney injury, and electrolyte disturbances which have resulted in increased physician and emergency department visits, as well as increased hospital admissions and delayed hospital discharges. NASPGHAN members also reported the formula shortage has stressed staff resources. The NASPGHAN survey results were gathered within weeks following Abbott's voluntary recall, and, since then, formula shortages have become more dire.

Immediately following the close of Abbott Nutrition's Sturgis facility on February 17, NASPGHAN posted information on its [website](#) classifying categories of affected formulas and alternatives. Those resources are continuously updated, providing physicians and other health care providers, as well as families, with information on how best to navigate the shortage.

The scarcity of formulas and the stress experienced by families have⁷⁴ been made worse by policies and regulatory red tape that have impeded patient access to alternatives to their current formula. Federally funded supplemental nutrition programs, such as WIC and 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. Likewise, insurance companies demonstrated poor flexibility in providing coverage for non-formulary products.

NASPGHAN asks Congress to call upon insurance companies to immediately suspend all prior authorization requirements for patients with a current specialty formula authorization and for which a formula substitution or alternative is prescribed or ordered by the treating physician or other health care professional. Additionally, authorization and coverage flexibility is needed to access out-of-network home health companies when the in-network supplier is unable to provide the prescribed formula or its alternative. Equivalent cost coverage is paramount to avoid excessive out-of-pocket payment.

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.

NASPGHAN strongly encourages Congress to pass legislation this year authorizing the FDA to work with formula manufacturers to avoid, adequately prepare for, and, if necessary, respond to potential supply disruptions in the future. Congress should also act swiftly to provide added resources to the FDA to perform all tasks necessary to address the current shortage and prevent shortages in the future. **Other regulatory considerations 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:**

- Required reporting of *C. sakazakii* infections by all states.
- Genetic profiling of regulated pathogens detected in manufacturing facilities.
- Communication between manufacturing plants and FDA at regular intervals with sharing of standardized data.
- A streamlined approach to incident investigation by CDC and FDA. Specific criteria are needed to define when a formula can be deemed to be a threat to health.
- Development of sterile liquid formulas for high-risk patient populations should be encouraged.
- Establishing a national stockpile of powder infant formulas for which substitutes may not be readily available. Regulation must be sensitive to the limited shelf-life of these products.
- Formula distribution outlets like WIC, SNAP and hospitals should diversify their vendors of powdered specialized formulas.
- Manufacturers of powdered specialized formulas that have a dominant market share must have a back-up supply plan.
- Importation of similar formula products when shortages are developing or anticipated. Standardized criteria and durations for such waivers could be developed before a shortage develops, not in response to a new shortage.
- Modification of “use by” dates to increase product availability. These formula products do not spoil, but risk some nutrients falling below a label claim. A modest extension of the expiration date poses much less risk than having no product, when recently expired product is available.

- Recalls could be limited to high-risk populations. For example, there are well-defined age and medical risk factors for *C. sakazakii*. Not all infants and children appear to be at equal risk, and many patients could continue on their usual formula without much risk of an adverse event.
- A professionally developed, up-to-date, readily accessible list of clinical indications for the use of exempt infant formulas and a list of potentially suitable formulas categorized by age for those indications is needed.

PASSAGE OF THE MEDICAL NUTRITION EQUITY ACT

The current formula shortage is a significant crisis, but it will be resolved. However, there are patients who were in crisis before the shortage because coverage of the same formulas that are currently in shortage have been and continue to be denied coverage or to be restricted by health insurance companies. If Congress does not resolve these persistent access issues through enactment of the *Medical Nutrition Equity Act*, patient access to critical life-saving medical nutrition will continue to be in jeopardy long after the shortage crisis has subsided.

The bipartisan *Medical Nutrition Equity Act* would require coverage of these specialized formulas for patients with specific diseases and disorders of the gastrointestinal system and inherited metabolic disorders. It is narrowly drafted to focus on individuals for whom medically necessary nutrition is a major part of the treatment for their diseases.

For some of the covered disorders, the legislation simply establishes treatment parity. For example, medically necessary nutrition is routinely denied by insurance companies for the management of Crohn's disease, while more costly treatments that put children at risk of medical complications, most often stemming from a suppressed immune system, are approved. As the current formula shortage has demonstrated, specialty formulas are not a luxury for the individuals who rely on them — they are a validated medical treatment and are necessary. When an insurance company does cover a medically necessary formula, it typically comes with the stipulation the formula be administered through a surgically placed tube. These types of coverage policies are not based on medical science, are not cost-effective, may create situations that put patients at risk for more harm than benefit from unnecessary procedures, and interfere with physician medical decision making and patient well-being.

Nearly 40 states require some level coverage of medically necessary nutrition, but coverage is highly variable from state to state and does not reach patients enrolled in health plans covered by the Employee Retirement Income Security Act (ERISA).

There is precedent for this legislation. In December 2016, Congress improved coverage for medically necessary nutrition for TRICARE beneficiaries through passage of the *National Defense Authorization Act*. The *Medical Nutrition Equity Act* extends coverage of medically necessary, or essential, nutrition to those covered under Medicaid, the Children's Health Insurance Program, Medicare, the Federal Employee Health Benefit Program, and private

insurance. NASPGHAN strongly urges Congress to pass the *Medical Nutrition Equity Act* this year.

CONCLUSION

NASPGHAN appreciates this opportunity to share its perspectives on the formula shortage crisis, its ideas about how to avoid this situation in the future and to comment on what Congress can do to make sure children with gastrointestinal and metabolic diseases and disorders are guaranteed coverage and access to medically necessary lifesaving medical foods and formulas in the future.

For more information or questions, please contact NASPGHAN policy advisor Camille Bonta at cbonta@summithealthconsulting.com or at (202) 320-3658.