No. 26-29

IN THE

Supreme Court of the United States

MEAD JOHNSON & COMPANY, LLC, *et al.*,

Petitioners,

v.

CLARISSA GREEAR, INDIVIDUALLY AND ON BEHALF OF HER MINOR CHILD B. H., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE APPELLATE COURT OF ILLINOIS, FIFTH DISTRICT

BRIEF OF THE AMERICAN ACADEMY OF PEDIATRICS, ILLINOIS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION, NATIONAL ASSOCIATION OF PEDIATRIC NURSE PRACTITIONERS, PERINATAL RESEARCH SOCIETY, CHILDREN'S HOSPITALS NEONATAL CONSORTIUM, AND MARCH OF DIMES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

The American Academy of Pediatrics (AAP), the Illinois Chapter of the American Academy of Pediatrics (ICAAP), the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), the National Association of Pediatric Nurse Practitioners (NAPNAP), the Perinatal Research Society (PRS), the Children's Hospitals Neonatal Consortium (CHNC), and the March of Dimes (MOD) submit this brief as *amici curiae* in support of petitioner Mead Johnson & Company, LLC.

AAP is a 501(c)(3) nonprofit organization of 67,000 pediatricians dedicated to the health and well-being of all infants, children, and adolescents. For more than nine decades, AAP has served as the Nation's foremost authority on pediatric health, and its evidence-based guidelines, policy statements, and clinical reports establish the medical guidance that physicians nationwide follow. AAP has appeared before this Court as *amicus curiae* in numerous cases implicating children's health and welfare.

NASPGHAN is a world leader in research, education, clinical practice and advocacy for pediatric gastroenterology, hepatology and nutrition in health and disease. Its 3,000 members—physicians, psychologists,

1. Petitioners' and Respondents' counsel were provided timely notice of this brief in accordance with Supreme Court Rule 37.2. No counsel for a party authored this brief in whole or in part, and no party, counsel for a party, or person other than the amici curiae and their counsel made a monetary contribution intended to fund preparation or submission of this brief.

nurses, advanced practice providers, and dietitians—are singularly dedicated to advocating for children with gastrointestinal, liver, and nutrition-related diseases and disorders.

ICAAP is an organization of over 2,000 pediatricians in Illinois, dedicated to improving the health and well-being of infants, children, and adolescents throughout Illinois. ICAAP advocates on behalf of children, families, and health professionals; develops and provides continuing medical education and resources for pediatric professionals; and collaborates with other organizations on programs and projects that improve the health and well-being of children.

NAPNAP is the professional association for pediatric nurse practitioners and advanced practice registered nurses caring for children. Established in 1973 as the first national society of nurse practitioners, its mission is to optimize the health and well-being of infants, children, adolescents, and young adults, and to empower its community of pediatric experts. NAPNAP is recognized as a trusted authority and indispensable resource on pediatric advanced practice nursing.

PRS is a nonprofit, professional research organization comprising pediatricians, obstetricians, and scientists from around the world who lead groundbreaking research programs and collaborate across disciplines to advance perinatal medicine and developmental biology. Its membership, nearly 350 members, represents all academic and professional career stages.

CHNC is a 501(c)(3) nonprofit organization dedicated to improving care and outcomes for the unique population of medically complex neonates and infants in children's hospital Level IV NICUs through sharing of data, information and ideas for benchmarking, research, and development of safety and quality improvement initiatives.

MOD is a national nonprofit organization advocating for the health of all mothers and babies. MOD aims to end preventable maternal and infant death, preterm birth, and maternal health complications. For over 85 years, MOD has pursued that mission through research, community service, education, and advocacy—benefiting families nationwide.

The interests of *amici* in this case are scientific and clinical, not adversarial. Their members and affiliates include the neonatologists, pediatric specialists, and advocates who care for the almost 380,000 premature infants born in this country each year—many of them in neonatal intensive care units (NICUs), where nutrition is a matter of survival. For these physicians and advocates, preterm infant formula, including the formula at issue here, is not an ordinary article of commerce but an essential, and often lifesaving, instrument of neonatal medicine. *Amici* accordingly have a profound institutional interest in ensuring that such products remain available to the physicians and patients who depend on them.

Although appearing in support of petitioner, amici submit this brief as neutral, academic authorities, to help the Court understand the association between the onset of necrotizing enterocolitis (NEC) and preterm infant formula use. *Amici's* members possess specialized

expertise bearing directly on the medical and scientific questions presented in this case, namely, the etiology of NEC. Amici respectfully submit that an accurate understanding of the underlying science, research, and medical literature is essential to a sound resolution of the questions presented.

SUMMARY OF ARGUMENT

This petition presents questions of immense consequence for nearly 380,000 premature infants born in the United States each year—and for the medical professionals who care for them. The decision below would permit Illinois courts to exercise personal jurisdiction over claims brought by thousands of out-of-state plaintiffs. It would invite forum shopping and allow plaintiffs to aggregate their claims in a favorable forum, imposing tort liability on a manufacturer of preterm-infant formula based on allegations that the product caused NEC. That theory conflicts with current medical science. If accepted, it would also jeopardize the availability of a product on which neonatal medicine depends.

Amici submit three propositions, each within the compass of their scientific and clinical expertise, that warrant the Court's attention.

First, preterm infant formula's availability to physicians is critical to preterm infant care. Infants born at very low birth weight (VLBW) rely on specialized nutrition for survival. A mother's own milk (MOM) is the preferred source, but it is frequently unavailable in adequate volumes or within the required time. Pasteurized donor human milk (PDHM) remains constrained by

supply, cost, and distribution limits. In light of these limitations on human milk, preterm formula provides necessary nutrition for infants who would otherwise face malnutrition, impaired neurological development, or morbidity. Critically, the medical literature indicates that it is the absence of human milk, not the presence of formula, that is associated with an elevated risk of NEC. This distinction is scientifically fundamental. Physicians and neonatologists are best positioned to determine each infant's unique nutritional needs and implement the appropriate feeding regimen.

Second, scientific evidence does not support the conclusion that preterm infant formula *causes* NEC. NEC is a serious, potentially fatal, multifactorial disease whose precise pathophysiology remains incompletely understood, and it can occur even among infants fed an exclusive human milk diet. The medical literature indicates that the increased risk of NEC among preterm infants is associated with the absence of human milk—not the presence of formula. That risk is driven primarily by prematurity. Recent data only reinforces the point: improvements in NEC rates have stalled since 2015 despite increased use of human milk, underscoring both the disease's multifactorial nature and the impropriety of attributing it to any single cause. These are basic scientific distinctions, yet the theory underlying plaintiffs' claims in these cases ignores them.

Third, the consequences of allowing plaintiffs to concentrate their claims in a notoriously friendly forum extend far beyond the parties now before the Court. The substantial verdicts already entered in other cases, together with the thousands of similar claims now pending,

pose a grave threat to the preterm formula supply. Should that supply diminish or be withdrawn, neonatologists and pediatric clinicians would lose an essential instrument of care and with foreseeable consequences: increased infant mortality, impaired neurological development, and permanent degradation of the standard of care for the Nation's most vulnerable patients.

The decision below, if permitted to stand, risks harming the medical care of premature infants born in this country. For the foregoing reasons, *amici* respectfully submit that the Court should grant the petition for a *writ of certiorari.* Doing so will allow plaintiffs' claims to be resolved in appropriate forums upon a sound scientific foundation, and will help preserve the availability of a life-saving medical product.

ARGUMENT

I. PRETERM INFANT FORMULA'S AVAILABILITY TO PHYSICIANS IS CRITICAL TO PRETERM INFANT CARE

Preterm infant formula is an indispensable component of neonatal medicine. Infants born VLBW rely on specialized nutrition for survival. MOM is the preferred source, but it is frequently unavailable in the volumes, or within the time, these infants require, and PDHM remains constrained by limitations in supply, cost, and distribution. Preterm formula fills that gap for infants who would otherwise face malnutrition, impaired neurological development, or morbidity. Critically, the medical literature indicates that it is the absence of human milk, not the presence of formula, that is associated with

an excess risk of NEC. This distinction is scientifically fundamental. The physicians and neonatologists entrusted with preterm infants' care are best positioned to determine each child's unique nutritional needs and implement the appropriate feeding regimen.

A. Nutrition for Preterm Infants Is Critical

Approximately one in ten infants in the United States is born preterm, and preterm birth remains the leading cause of neonatal mortality. Beth Ellen Davis et al., *Primary Care Framework to Monitor Preterm Infants for Neurodevelopmental Outcomes in Early Childhood*, 152 Pediatrics e2023062511, at 1 (2023). Among the most serious complications these infants face is NEC, a condition involving inflammation and necrosis of intestinal tissue that occurs in 3% to 9% of preterm infants and carries mortality rates as high as 30%. *See Id.* at 7; Mark A. Underwood, *The fifty billion dollar question: does formula cause necrotizing enterocolitis?*, 45 J. Perinatology 565, 565 (2025). Every infant, including preterm infants, must be fed as soon as is medically feasible, because "[n]utrition is vital for brain and organ development, and prolonged fasting increases risk factors for other serious conditions." *Necrotizing Enterocolitis (NEC) in Preterm Infants Working Group of the National Advisory Council of Child Health and Human Development (NACHHD) Report to the Secretary, Department of Health and Human Services*, ii (Sept. 16, 2024) [hereinafter "Working Group Report"]. The Working Group cautioned that intravenous feeding may increase the risk of bloodstream infections. *Id.*

To this end, three sources of nutrition are available for preterm infants: MOM, PDHM, and preterm infant formula. Margaret G. Parker *et al.*, Am. Acad. of Pediatrics, Comm. on Fetus & Newborn, Section on Breastfeeding & Comm. on Nutrition, *Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant: Clinical Report*, 157 Pediatrics e2025073625, at 2 (2025) [hereinafter "Parker et al."].

It is recommended "that [VLBW] infants receive human milk, preferably from their own parent." Working Group Report, *supra*, at 14. However, human milk, be it MOM or PDHM, is not always available or sufficient. *See id.* at 4. One notable statistic highlighting this fact is that human milk provision at discharge among VLBW infants stands at only 52%. Parker et al., *supra*, at 2. Parker et al. further links inequities in MOM provision to practical barriers to lactation support, including transportation barriers, access to efficient double electric breast pumps, peer lactation support, interpreter services, and unmet basic household needs that affect lactation. Parker et al., *supra*, at 9. Many mothers also face physiological barriers to lactation because of shortened pregnancy and related medical morbidities. *Id.* at 3.

Donor human milk, the second source of specialized nutrition for preterm infants, also faces substantial limitations. *See* Working Group Report, *supra*, at 4 ("Unfortunately, human breast milk, including donor milk, is not always available."). PDHM often must be fortified after pasteurization, because unfortified human milk and standard infant formula "are not sufficient for optimal growth of preterm infants." *Nutritional Needs of the Preterm Infant*, in Am. Acad. of Pediatrics,

Pediatric Nutrition 123, 138 (9th ed. 2025) [hereinafter *Pediatric Nutrition* ch. 5]; *see Breastfeeding*, in Am. Acad. of Pediatrics, *Pediatric Nutrition* 53, 72 (9th ed. 2025) [hereinafter *Pediatric Nutrition* ch. 3] ("Preterm infants who weigh less than 1500 g[rams] at birth require a human milk fortifier . . . to provide adequate nutrients to support growth.").

And, although donor milk supply may be statistically sufficient in the aggregate for the highest-risk infants, PDHM is not available in every NICU, remains subject to cost and reimbursement barriers, and may be inequitably accessed. *See* Working Group Report, *supra*, at 19 (stating that there appears to be sufficient donor human milk supply for premature infants at highest risk for NEC, but identifying hospital participation, expense, reimbursement, financial-strain, and access barriers); Parker et al., *supra*, at 3, 9 (explaining that PDHM is not available in every NICU caring for VLBW infants, that PDHM access may be limited locally or nationally, and that prioritization for VLBW infants may be needed). These limitations underscore the critical need for an alternative nutritional source when human milk is unavailable or insufficient.

The nutritional demands of preterm infants are extraordinary. VLBW infants require substantially higher caloric density, protein, calcium, phosphorus, and micronutrients than term infants, and standard infant formula intended for term infants is not sufficient for optimal growth of preterm infants. *See Pediatric Nutrition* ch. 5, at 138–44. Randomized prospective trials further demonstrate that preterm infant formulas "result in significant improvements in growth and cognitive

development compared with standard formulas for term infants." *Pediatric Nutrition* ch. 5, at 138 (citing Ruth Morley & Alan Lucas, *Influence of Early Diet on Outcome in Preterm Infants*, 83 Acta Paediatrica 123 (Supp. 405 1994)). Also, when compared to alternatives, such as non-preterm formula or intravenous (IV) feeding[2], "[p]reterm infant formula is substantially superior" to "prolonged (weeks to months) parenteral nutrition or non-preterm infant formulas that do not support the nutritional requirements of VLBW infants." Parker et al., *supra*, at 3. This underscores the unique and specialized nutrition preterm infants require.

This also underscores the undeniable fact that preterm infant formula occupies a clear and necessary place in preterm infant clinical care, because these specialized formulas are a medical necessity for preterm infants in the absence of other nutritional options. *See* Am. Acad. of Pediatrics, *AAP Statement In Response to NEC Lawsuit Verdicts* (July 27, 2024) [hereinafter "AAP Statement"] (describing provision of special preterm formula as "a routine and necessary part of <u>care</u> of these preterm infants," (emphasis in original) and noting insufficient donor milk supply to serve as the sole nutrition source); U.S. Dep't of Health & Human Servs., FDA, CDC, NIH Consensus Statement on Recent Advisory Council Report on Premature Infants and Necrotizing Enterocolitis, at

2. Prolonged parenteral, intravenous nutrition carries substantial risks including bloodstream infections and cholestatic liver disease. *See* Working Group Report, *supra*, at ii (noting that "[f]eeding intravenously may increase the risk of bloodstream infections"); *Pediatric Nutrition* ch. 5, at 134–36 (discussing cholestasis and parenteral-nutrition-associated cholestatic disease in preterm infants receiving parenteral nutrition).

2 (Oct. 3, 2024) [hereinafter "FDA/CDC/NIH Consensus Statement"] ("**For infants where the supply of human milk is insufficient, these formulas are part of the standard of care for premature infants.**" (emphasis in original)).

Against this backdrop, preterm infant formula not only serves an essential function but is integral to preterm infant care and recommended when MOM and PDHM are unavailable. *See* Parker et al., *supra*, at 3 ("In this situation or when parents decline PDHM, preterm infant formula is recommended and provides essential nutritional requirements for VLBW infants.") (citing Frank R. Greer & Steven A. Abrams eds., *Pediatric Nutrition* (9th ed. Am. Acad. of Pediatrics 2025)).

B. Prematurity and NEC

In 2022, 356 infants in the United States died from NEC, and 38% of surgical NEC survivors demonstrate severe developmental disabilities. Working Group Report, *supra*, at i; Davis et al., *supra*, at 7 (citation omitted). The predominant risk factors for NEC include gestational age less than 32 weeks, birth weight below 1,500 grams, and cardiac complications. Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, 8 Advances in Nutrition 80, 81 (2017). These risks stem from the physiological immaturity characteristic of preterm birth, including underdeveloped cardiovascular, respiratory, gastrointestinal, and immune function. *Id.* In particular, infants born before 32 weeks gestation frequently exhibit pulmonary insufficiency that compromises oxygen delivery to tissues. *Id.*

Approximately 85% of NEC cases occur in infants born before 35 weeks gestation, while only 7–15% of cases occur in late-preterm or term infants. *Id.* NEC is a devastating but relatively uncommon illness among preterm infants—the very population for whom preterm infant formula is designed and, in many clinical circumstances, medically necessary. *See* AAP Statement, *supra* (describing provision of special preterm formula as "a routine and necessary part of care of these preterm infants").

What makes NEC particularly challenging is that its precise causation is not fully understood. As a leading neonatology researcher explained, NEC is "likely not a single discrete entity, but rather a final pathway to intestinal inflammation and necrosis with multiple starting points." Underwood, *supra*, at 565. NEC is best understood as "a perfect storm at the intersection" of "immature intestinal anatomy, physiology, immune responses, intestinal dysbiosis, and inconsistent intestinal perfusion and oxygenation." *Id.* The Working Group similarly concluded that "[t]he causes of NEC are not well understood" and "[t]he relationship between feeding and development of NEC is unclear." Working Group Report, *supra*, at 3, iv.

The disease manifests in stages, from mild indications that an infant "may have" NEC, to definite NEC diagnosis, and finally to advanced NEC. Working Group Report, *supra*, at 4–5. The Working Group emphasized that NEC is "a multifactorial disease with many associated risk factors," *Id.* at iv, 13, including, among others, prematurity, microbial dysbiosis, impaired intestinal perfusion, and an exaggerated pro-inflammatory immune response. *Id.* at 7–8. NEC is also seen in human milk-fed preterm infants,

although at a lower rate than in preterm infants who are not fed human milk. *See id.* at 8, 20–23 (explaining that human milk exposure lowers NEC risk, that premature infants receiving only human milk can still develop NEC, and that PDHM significantly reduced but did not eliminate NEC risk compared with formula feeding); Parker et al., *supra*, at 3 (stating that "human milk-based feedings do not confer absolute protection against NEC," and that NEC rates "among VLBW infants [receiving] exclusively human milk. . . ranged from 4.2% to 9.3%" in randomized trials); Underwood, *supra*, at 565–66 (describing studies showing lower NEC incidence among preterm infants receiving MOM and reporting that donor human milk reduces NEC risk compared with infant formula).

Separate from NEC risk, human milk alone, including both MOM and PDHM, is nutritionally insufficient to meet the demands of VLBW infants without fortification. "[N]utritional requirements cannot be met with human milk alone using the volumes of milk that are generally tolerated by VLBW infants, because requirements exceed those of healthy term newborn infants with respect to protein, energy, fatty acids, minerals, and micronutrients." Parker et al., *supra*, at 9; *see also Pediatric Nutrition* ch. 5, at 153 (noting that in unfortified human milk, "all nutrients are present in inadequate concentrations to meet the nutritional needs of the preterm infant."). That no single source of nutrition can independently sustain optimal growth in preterm infants underscores the need for a comprehensive nutritional strategy—one in which human milk, fortification, and, when necessary, preterm infant formula each play an essential role.

This multifactorial understanding is critical to evaluating any association between NEC and preterm infant formula. NEC occurs even among infants fed an exclusive human milk diet, its precise causation remains incompletely understood, and no single nutrition source can independently meet the demands of VLBW infants. A disease with multiple contributing causes cannot be attributed to any single factor without rigorous scientific evidence establishing independent causal responsibility, which evidence does not exist with respect to preterm infant formula. *See* Underwood, *supra*, at 569 ("The scientific evidence supports a role of human milk in decreasing the risk of NEC, but not the role of infant formula in *causing* NEC." (emphasis added)).

C. Scientific Evidence Does Not Support the Conclusion That Formula Causes NEC

The central scientific question underpinning plaintiffs' claims in the case below is whether preterm infant formula *causes* NEC. Based on the current scientific evidence, that causation has not been established. The distinction is critical: while there is strong evidence that human milk is protective against NEC, conclusive evidence that formula causes NEC is lacking.[3] This scientific reality undercuts the causation theory on which the plaintiffs' claims rest.

Dr. Mark A. Underwood, MD, frames the issue this way: "The central question is whether this difference [in NEC rates] is due to protective factors in human milk that

3. "There is no conclusive evidence that preterm infant formula causes NEC." FDA/CDC/NIH Consensus Statement, *supra*, at 2.

are not in the formula or whether preterm infant formulas contain one or more toxic components that trigger NEC." Underwood, *supra*, at 567. Regarding bovine milk protein, the ingredient most commonly alleged to be causative, Underwood states that "[d]ata from preterm infants suggesting that bovine milk protein is a trigger for NEC are lacking." *Id.* at 568. He further explains that if intact bovine proteins or peptides commonly triggered NEC, one would expect extensively hydrolyzed formula to reduce NEC risk, yet a meta-analysis of 11 small clinical trials involving 665 preterm infants found no difference in NEC between extensively hydrolyzed and standard formula. *Id.* A recent review also found few prognostic studies of NEC and did not identify infant diet as a significant prognostic factor. *Id.* at 569.

The Working Group reached a similar conclusion: "Available evidence supports the hypothesis that it is the absence of human milk—rather than the exposure to formula—that is associated with an increase in the risk of NEC." Working Group Report, *supra*, at 15. In other words, there is no evidence that formula itself causes NEC; rather, the evidence supports the protective effects of human milk. Consistent with that distinction, Parker also explains that while human milk-based feedings are associated with lower NEC rates, human milk does "not confer absolute protection against NEC," noting NEC rates of 4.2% to 9.3% among VLBW infants receiving exclusively human milk as the base diet in randomized control trials. Parker et al., *supra*, at 3.

Summarizing the science, Underwood concludes that "[t]he scientific evidence supports a role of human milk in decreasing the risk of NEC, but not the role of

infant formula in causing NEC." Underwood, *supra*, at 569. The NEC risk reduction associated with a human milk-based diet is "likely secondary to the immunologic and antimicrobial components in human milk." *Pediatric Nutrition* ch. 5, at 155 (citations omitted). Appreciating this distinction is vital to the issue: the premise that human milk is protective does not itself establish that formula causes NEC. The evidence thus supports human milk's protective role, not a causative role for formula. *See* Underwood, *supra*, at 569; Working Group Report, *supra*, at 15. Human milk contains immunoglobulins, lactoferrin, human milk oligosaccharides, and other bioactive components with antimicrobial, anti-inflammatory, prebiotic, and barrier-function effects. Underwood, *supra*, at 567 tbl. 3. The absence of these protective factors is analytically distinct from the presence of a causative toxic component, which has not been proven to exist in preterm infant formula. *See* Working Group Report, *supra*, at 10–11, 15.

Moreover, a Cochrane systematic review of fourteen randomized controlled trials involving 1,551 VLBW infants found that delaying enteral feeds "may not reduce the risk of necrotising enterocolitis" and "probably increases the risk of invasive infection." Lauren Young et al., *Delayed Introduction of Progressive Enteral Feeds to Prevent Necrotising Enterocolitis in Very Low Birth Weight Infants*, Cochrane Database Systematic Reviews, Issue 1, Art. No. CD001970, at 10, 16, 17 (2022). This finding is significant: infants whose feeds are delayed remain at risk for NEC even without formula exposure. If formula were causative, such infants would not face an independent NEC risk. The persistence of NEC risk in this population further supports the conclusion that

it is the absence of human milk's protective properties, rather than the presence of formula, that is associated with NEC risk.

That distinction also has legal significance: a product is not defective merely because an alternative may offer superior protection against a disease. The scientific record here is that, when human milk is insufficient, preterm formulas remain "**part of the standard of care for premature infants.**" FDA/CDC/NIH Consensus Statement, *supra*, at 2 (emphasis in original).

D. The Crucial Role of Physicians in Determining Appropriate Nutrition

Several authorities establish a clear hierarchy for preterm infant feeding: MOM is the most preferred nutritional and protective source, followed by PDHM, with preterm infant formula recommended when neither is available or sufficient. *See* Parker et al., *supra*, at 1–3; Working Group Report, *supra*, at ii, 13–14. These are individualized clinical decisions because each infant—and the nutritional options available to them—is unique. Federal regulations likewise recognize the physician's indispensable role. The U.S. Food and Drug Administration has promulgated regulations specific to infant formulas used in hospital and clinical settings, acknowledging that such formulas are "typically . . . prescribed by a physician" and "requested from a pharmacist." 21 C.F.R. § 107.50(c)(1). *Amici* believe clinicians and families are best positioned to assess a patient's individualized feeding plan "in the context of human milk availability, specific patient needs, and individual family preferences," and ultimately determine the proper feeding regimen for each

infant. *See* AAP Statement, *supra*, at 2. Preterm infant formula is and should continue to be an option for these practitioners. That option may be at risk now.

The Illinois Appellate Court recently confirmed the centrality of the physician's role in *Watson v. Mead Johnson & Co.*, 2026 IL App (5th) 240936 (June 12, 2026), a case arising from the same coordinated NEC infant formula litigation as *Toles*. In *Watson*, the Fifth District reversed a $60 million jury verdict, holding as a matter of law that the learned intermediary doctrine applied to the preterm infant formula as administered in the NICU. *Id.*, slip op. at 44–45. The court emphasized that the preterm infant formula "was available to [the infant] only at the direction of his neonatologists and other healthcare providers, who evaluated the risks and benefits of the available feeding products." *Id.* at 43–44. The court further explained that the financial evidence admitted at trial created "a substantial risk that the jury would infer culpability from Mead Johnson's wealth rather than from evidence related to defect, causation, or adequacy of warnings." *Id.* at 48.

Clinical guidance and federal regulations thus support treating preterm formula use as an individualized clinical decision, informed by milk availability, infant nutritional needs, clinical condition, and family preferences.[4]

4. *S*ee *Parker,* et al., supra, at 1, 3; Am. Acad. of Pediatrics, AAP Statement in Response *to NEC L*awsuit Verdicts 2 (July 27, 2024) (both recommending individualized feeding decisions based on milk availability and patient needs); *see al*so 21 C.F.R. § 107.50(c)(1) (2026) (exempt infant formulas "typically are prescribed by a physician").

II. LOSING ACCESS TO PRETERM FORMULA POSES GRAVE RISKS TO THE HEALTH AND SURVIVAL OF VULNERABLE INFANTS

A. Preterm Infants Face Unique and Urgent Nutritional Vulnerabilities

Almost 380,000 infants are born prematurely, under 37 weeks gestation, in the United States each year. Michelle J.K. Osterman et al., *Births: Final Data for 2024*, 75 Nat'l Vital Stat. Reps., no. 2, at 35 tbl.10 (June 9, 2026). These infants have complex nutrition needs to support critical growth and development. Optimal nutrition is critical to brain and organ development and improves survival in preterm infants.

As the Working Group emphasized, "all infants, including those in the neonatal intensive care unit (NICU), must be fed as soon as is medically feasible by whatever means are available. Nutrition is vital for brain and organ development, and prolonged fasting increases risk factors for other serious conditions." Working Group Report, *supra*, at ii. HHS likewise stated that ensuring vulnerable children have access to safe and nutritious food is a top priority for FDA, CDC, and NIH. *See* FDA/CDC/NIH Consensus Statement, *supra*, at 2. For some preterm infants, preterm infant formula is a critical option when parental or donor milk is unavailable or insufficient. *See Id.*

Human milk, though preferred, is not always available. *See* Working Group Report, *supra*, atii, 14; Parker et al., *supra*, at 1–3. Many mothers of VLBW or very preterm infants face barriers that can delay lactogenesis or reduce milk production. Parker et al., *supra*, at 3. National

data show that only 52% of VLBW infants received any human milk at discharge, with persistent disparities by race/ethnicity and geography. *Id.* at 2. And PDHM, as discussed, faces its own access limitations. *See id.* at 9.

Preterm infant formula fills that clinical gap when human milk is unavailable or insufficient. As the AAP has emphasized, these specialized formulas are "a routine and necessary part of care" for preterm infants. AAP Statement, *supra*, at 1 (emphasis in original). Any threat to the availability of these products therefore implicates not merely commercial interests but the health and survival of the Nation's most vulnerable patients.

B. Even Minor Disruptions to the Formula Supply Would Cause Devastating Harm to the Infants Who Depend on It

Infant formula has become a subject of national concern. The 2022 formula shortage exposed deep vulnerabilities in the domestic supply chain. In response, FDA Commissioner Dr. Marty Makary and Nicholas Diamantas, director of the FDA's Office of Critical Foods, announced "Operation Stork Speed," an initiative to overhaul infant formula safety and availability as part of President Trump's "Babies First" policy agenda. The preterm infant formula market is particularly fragile: only two companies in the United States are primary producers of formula for premature infants, and litigation untethered to the science could devastate access. *See* AAP Statement, *supra*, at 2. *Amici* already sees the landscape evolving around this issue: two 2024 jury verdicts against formula companies totaled about $555 million, and thousands of similar claims had been filed as of mid-2025. Underwood,

supra, at 565. The Illinois Appellate Court recently reversed the $60 million *Watson* verdict, holding that the learned intermediary doctrine applied as a matter of law to the preterm infant formula at issue, as administered in the NICU. *Watson*, 2026 IL App (5th) 240936, ¶¶ 44–45. Even so, the AAP has warned that "[r]ecent court cases . . . may jeopardize the availability of these formulas." AAP Statement, *supra*, at 2. This case presents the same concerns and warrants this Court's review.

If access to preterm formula were threatened, neonatologists could face fewer options when MOM and PDHM are unavailable or insufficient. Alternative feeding methods cannot adequately fill that gap. The Working Group warned that intravenous feeding may increase bloodstream-infection risk, and *Pediatric Nutrition* ch. 5 discusses cholestasis and liver-disease concerns previously associated with IV feeding. Working Group Report, *supra*, at ii; *Pediatric Nutrition* ch. 5, at 134–35. *Pediatric Nutrition* ch. 5 further states that unfortified human milk and standard term formula are not sufficient for optimal preterm growth, and that preterm formulas significantly improve growth and cognitive development compared with standard term formulas. *Pediatric Nutrition* ch. 5, at 138–39. These facts underscore preterm infant formula's place in preterm infant care. Parker et al., *supra*, at 1, 3, likewise explains that, where MOM and PDHM are unavailable or declined, preterm infant formula is recommended and provides essential nutritional requirements for VLBW infants.

Reduced access to preterm formula could exacerbate existing gaps in neonatal nutrition. Parker reports that human milk provision at discharge among VLBW infants

is lowest among non-Hispanic Black and American Indian/Alaska Native populations and in the southern United States. Parker et al., *supra*, at 2. The Working Group identifies donor-milk access as a healthcare disparity and notes that hospitals with more than 75% Medicaid recipients and hospitals with high proportions of African American or Hispanic patients are less likely to use donor milk than other hospitals. Working Group Report, *supra*, at 19. These access limitations are not inevitable. Continued availability of preterm infant formula thus remains essential for the clinicians and patients who depend on it.

The answer to scientific uncertainty is continued research and broader nutritional access—not the loss of an option that *amici*, federal agencies, and scientists all describe as necessary when human milk is unavailable or insufficient. The Working Group issued 17 recommendations to improve the evidence base on NEC risk factors, nutritional support, feeding practices, disparities, and long-term outcomes. Working Group Report, *supra*, at 24–27. *Amici* calls both for expanded access to PDHM and for protecting the preterm infant formula supply for infants who need it.

Amici cannot stand by while ongoing litigation jeopardizes the availability of preterm infant formula, "stripping neonatologists and clinicians of" a vital—and at times sole—tool for treating some of the most critically ill infants in their care.

III. STALLED NEC IMPROVEMENTS UNDERSCORE THE ABSENCE OF CAUSATION AND THE NEED TO PRESERVE ALL TREATMENT OPTIONS

Recent data shows that improvements in NEC have stalled. Horbar and colleagues analyzed 447,396 infants at 888 U.S. hospitals from 1997 to 2021. *See* Jeffrey D. Horbar et al., *Trends in Mortality and Morbidities for Infants Born 24 to 28 Weeks in the US: 1997–2021*, 153 Pediatrics e2023064153, at 3 (2024) [hereinafter Horbar et al.]. NEC decreased from 10.0% to 6.8% over the full period, but rates were stable from 2015 to 2021. *Id.* at 3–4, tbl.2. Horbar et al. concluded that "[i]mprovements in mortality and morbidity have slowed, stalled, or reversed in recent years" and cautioned that the data "do not permit causal explanations" for observed trends. *Id.* at 4, 6.

This data should be used as outcome-trend benchmarks, not as proof that any single dietary factor explains NEC's trajectory. *See id.* at 6. As the AAP has observed, "the causes [of NEC] are multifaceted and not completely understood" and "[o]ur science does not tell us exactly how to prevent it." AAP Statement, *supra*, at 1. The Working Group likewise describes NEC as multifactorial and recommends research across epidemiology, mechanisms, feeding practices, and disparities. Working Group Report, *supra*, at iii, 24–27.

The cited medical and federal sources distinguish human milk's protective effect from proof that preterm formula causes NEC. *See* FDA/CDC/NIH Consensus Statement, *supra*, at 2; Working Group Report, *supra*, at 15; Underwood, *supra*, at 569; AAP Statement, *supra*, at

1. AAP and FDA sources recognize preterm formula as necessary when human milk is unavailable or insufficient. *See* AAP Statement, *supra*, at 2; FDA/CDC/NIH Consensus Statement, *supra*, at 2. The *Watson* reversal confirms that courts must scrutinize the clinical basis for claims in these cases. *See Watson*, *supra*, at 44–45. This Court should grant certiorari to resolve the personal jurisdiction question enabling this forum-shopping, and ensure that tort liability in this area rests on sound science, not speculation.

CONCLUSION

Amici curiae represent the physicians, advanced practice nurses, scientists, and advocates who care for and champion this nation's most vulnerable patients. *Amici* write with a single purpose: to ensure that this Court understands the medical science of NEC and the catastrophic consequences of a decreased or eliminated preterm infant formula supply.

The scientific evidence is clear. There is no conclusive evidence that preterm infant formula causes NEC. There is strong evidence that human milk is protective, but protection and causation are not logical inverses. The medical community universally regards preterm formula as an essential, life-saving component of neonatal care.

The decision below, if left undisturbed, would let Illinois courts continue exercising personal jurisdiction over the claims of thousands of out-of-state plaintiffs, fueling forum-shopping that threatens to destroy the supply of a product on which almost 380,000 premature infants depend each year. No adequate substitute exists.

The consequences for infant mortality and morbidity would be devastating.

This Court's review is warranted because the personal-jurisdiction question in these cases is of exceptional national importance and will recur in thousands of similar claims brought by out-of-state plaintiffs. Absent this Court's guidance, plaintiffs will continue to concentrate their claims in notoriously plaintiff-friendly courts, seeking massive liability based on a causation theory the scientific community has expressly rejected, and ongoing harm to the preterm infant formula supply and the infants who depend on it.

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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