

Abbott Reaches Agreements To Resolve A Portion Of Litigation Involving Its Specialty Formulas For Preterm Infants

- Agreements will resolve the *Gill* case and claims involving approximately 2,000 other individuals
- Abbott and the medical community stand by the safety of preterm infant formulas
- Regulators and medical professionals recognize that these products are safe and necessary, and there is no reliable scientific evidence that they cause necrotizing enterocolitis

ABBOTT PARK, Ill., Aug. 20, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) has reached agreements with three law firms to resolve the *Gill* case and claims involving approximately 2,000 other individuals relating to the company's specialty formulas for preterm infants.

In July 2024, a St. Louis jury awarded the plaintiff in the *Gill* case \$495 million in damages. Abbott appealed the verdict to the Missouri Court of Appeals in December 2024, but the appeal was denied. Rather than continuing to appeal or paying approximately \$600 million, representing the *Gill* judgment plus accrued interest to date, Abbott entered into agreements to resolve the *Gill* case as well as necrotizing enterocolitis (NEC) claims asserted on behalf of approximately 2,000 additional infants for an aggregate amount of approximately \$670 million.

These agreements are a compromise of disputed claims and not in any way an admission of liability. Abbott stands by the safety of these products and the essential role they play in helping the medical community care for preterm infants. The Food and Drug Administration, National Institutes of Health, Centers for Disease Control and Prevention, American Academy of Pediatrics, NEC Society, neonatologists and other medical professionals recognize that these products are safe and necessary, and that there is no reliable scientific evidence that they cause NEC.

The agreements follow a series of favorable rulings for preterm formula manufacturers in federal and state courts, including victories in all three federal Multidistrict Litigation (MDL) bellwether cases. In July 2026, the U.S. Court of Appeals for the Seventh Circuit affirmed a pretrial judgment for Abbott in the first federal MDL bellwether case involving the company's preterm infant formulas. In June 2026, the Illinois Appellate Court reversed a \$60 million verdict against Mead Johnson, finding that the trial court failed to properly apply the learned intermediary doctrine governing a manufacturer's duty to warn, a defense relevant in a substantial number of cases. In March 2026, a Florida state court, applying the learned intermediary doctrine, also dismissed claims involving preterm infant formula.

While Abbott remains confident in the safety of these products and the science supporting them, the company believes these agreements are in its best long-term interest and represent a constructive step toward substantially resolving the overall litigation.

Following these agreements, there are roughly 1,700 lawsuits pending in federal and state courts involving claims on behalf of approximately 12,700 individual infants. That population includes claims on behalf of individuals who named both Abbott and Mead Johnson without identifying which manufacturer's formula was administered, individuals diagnosed with NEC before receiving any formula, individuals who were never diagnosed with NEC, and individuals who appear in multiple lawsuits in different jurisdictions. Abbott continues to work to identify and eliminate such claims and others like them.

Frequently Asked Questions

What is NEC?

Necrotizing enterocolitis, or NEC, is an inflammatory intestinal disease, which typically affects premature infants. Challenges associated with prematurity – such as an underdeveloped intestinal tract and immature immune system – can combine to lead to NEC, which explains why infants born the most prematurely are at the highest risk of NEC.

Does preterm infant formula cause NEC?

No. Numerous scientific papers and NEC authorities have made clear that preterm infant formula does not cause NEC. Indeed, a 100-page [report](#) authored by a blue-ribbon Working Group of 24 doctors and eight government officials organized by the Department of Health and Human Services explained that "[a]vailable 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."

Earlier this year, the [AAP confirmed that](#) "[p]reterm infant formula is recommended when [mother's own milk] is not available and [pasteurized donor human milk] is either not available or the family declines use." [Dr. Mark Corkins](#), division chief of pediatric gastroenterology at the University of Tennessee Health Science Center, said: "There is no evidence that the formulas cause NEC. That is why these court cases make no sense to the folks who understand the actual science."

What is preterm infant formula?

Preterm infant formulas are specialty formulas that are designed to meet the unique nutritional needs of preterm and low-birth-weight infants, who need more calories and nutrients than full-term infants to survive and thrive. Thus, these products differ from infant formulas for full-term infants that are sold in stores directly to parents and caregivers. For decades, Abbott has researched, developed and produced these specialized nutrition products, and today Abbott is one of only two companies in the U.S. providing these products. FDA regulates preterm infant formula and has not asked for changes or additions to the ingredients or label. Abbott complies with all applicable FDA regulations.

Is preterm infant formula part of the standard of care?

Yes. [The AAP has explained](#) that "[p]roviding special formula is a routine and necessary part of care of these preterm infants." Likewise, [the NEC Society](#) – a non-profit focused on eradicating NEC – explained that "[s]ometimes, formula is necessary and chosen by the baby's care team as the best available plan of care." Preterm formula is especially important because mothers of premature infants may have trouble expressing a sufficient supply of breast milk and donor human milk is not always available. In these situations, preterm infant formula is a critical option.

[In a brief filed on Aug. 7, 2026, to the U.S. Supreme Court](#) the AAP, 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 wrote: "Preterm infant formula is an indispensable component of neonatal medicine" and that "[t]he medical community universally regards preterm formula as an essential, life-saving component of neonatal care."

What have federal health authorities and the medical community said about preterm infant formula?

The FDA, CDC and NIH, the AAP, and the NEC Society agree that preterm infant formulas are a vital necessity in caring for premature infants and that feeding decisions should be made in neonatal intensive care units (NICUs), not in courtrooms.

[In October 2024, the FDA, CDC and NIH said:](#) "There is no conclusive evidence that preterm infant formula causes NEC." Instead, "[a]vailable 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." [These groups also said:](#) "These formulas can be critical for premature infants for whom parental or donor milk is not an option, or where a supplement to parental or donor milk is necessary for the health of the infant."

[In September 2024, the American Academy of Pediatrics said:](#) "Specialty formulas and fortifiers provide an essential source of nutrition for premature infants. While breastmilk is preferred, it does not eliminate the risk of NEC, and there is not always enough supply from a parent or donors."

[In July 2024, the American Academy of Pediatrics said:](#) "Courtrooms are not the best place to determine clinical recommendations for the care of infants. Feeding decisions should be made by clinicians and families. These need to be individualized in the context of human milk availability, specific patient needs, and individual family preferences."

[In July 2024, the NEC Society said](#) "Feeding decisions should be made in the NICU, not in courtrooms."

[In April 2024, the NEC Society said:](#) "In the ICU, feeding decisions are medical decisions. It is imperative for medical decisions to be made by those who practice medicine in partnership with patient-families. The medical team, in collaboration with patient-families, should decide how babies are fed in the ICU. These medical feeding decisions aim to protect against NEC while providing optimal nutrition for discharge and long-term health outcomes. Neonatal feeding decisions should be made at patients' bedsides, not in courtrooms."

Why does access to preterm infant formula matter?

About 1 in every 10 infants born in the U.S. is premature, per the CDC. [But per the AAP:](#) "there is not always enough [human milk] supply from a parent or donors" for premature infants. As Judge Rebecca R. Pallmeyer, the judge in the federal MDL has recognized, "[t]his means that cow's-milk-based formulas, including [Similac Special Care 24], will remain essential products until the production of human-milk formula is sufficient to eliminate any risk of shortfalls in all NICUs nationwide." And "[f]ormula is designed to serve as a replacement whenever donor milk or mother's milk is unavailable, so the product's utility is categorical, not marginal." To use the Court's analogy, it is a "lifeboat" product.

Is the medical community concerned about continued access to preterm infant formula?

Yes. [As the AAP has said:](#) "Feeding decisions should be made by clinicians and families," not litigants. When these decisions are taken from clinicians, [physicians](#), [medical organizations](#) and [policymakers](#) have expressed concern about continued access to preterm infant nutrition products. These groups have warned of potential impact on availability if manufacturers cannot continue supplying them given the threat of unending litigation.

[In a brief filed on Aug. 7, 2026, to the U.S. Supreme Court](#) the AAP, 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 wrote: "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."

What is the learned intermediary doctrine?

In both *Watson v. Mead Johnson* (Ill. App. Ct. 2026) and *Ennix v. Abbott* (Fla. Cir. Ct. 2026), courts held that the learned intermediary doctrine applies to preterm formula used in the NICU. That doctrine provides that a manufacturer's duty is to communicate to doctors, not directly to the patient, because it recognizes that doctors – not manufacturers – are in the best position to evaluate risks and benefits and advise parents accordingly.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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