

# Protecting The Most Vulnerable

The NEC baby formula litigation, the science, the damages and the fight for justice in state & federal courts.

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September, 2023



This white paper is provided for information purposes only by the authors in their pursuit of justice on behalf of those injured by actions of the makers of Similac and Enfamil. This complex litigation is ongoing in both state and federal courts. For more information, or to discuss a referral or co-counsel relationship for NEC cases with Levin Rojas Camassar and Reck, please contact Paul Levin, Founding Partner at [paul@lrcr.law](mailto:paul@lrcr.law) or (860) 834-3333.



# About NEC Baby Formula Litigation



NEC baby formula is a mass tort that attorneys should closely monitor. Individuals are filing NEC baby formula lawsuits against manufacturers of cow's milk-based formula. Plaintiffs claim these products caused preterm infants to develop necrotizing enterocolitis (NEC), a life-threatening intestinal disease. The core argument is both direct and compelling; cow's milk-based fortifiers and formulas caused or contributed to the injury and death of several thousand infants annually. Moreover, the baby formula manufacturers not only fail to provide warning to the parents of such infants consuming their formula, but instead actively promote and subsidize the use of their products through free provision of product to hospital NICU's, along with a sophisticated digital marketing effort that rivals and mimics in some respects those of Big Tobacco a generation earlier. Manufacturers such as Mead Johnson and Abbott Laboratories who market cow's milk-based formulas assure safety, do not advise against feeding preterm babies these products and imply equivalency if not superiority of their formulation as compared to human breast milk.

Studies have shown for decades that an exclusive human milk-based diet decreases the risk of NEC. Donor milk is commonly available when a mother's own milk is not. And since 2006, human-milk-based formula and fortifiers have been available. The predominant allegations in the Complaints filed sound in strict liability for design defect, strict liability for failure to warn, negligence, negligent misrepresentation, loss of consortium, and claims under certain states' consumer fraud and deceptive practices acts.

Necrotizing enterocolitis is an intestinal disorder primarily affecting premature infants or sick newborns. With NEC, the intestinal tissue dies and falls off, forming perforations in the intestines. Bacteria can then leak into the abdomen or bloodstream through these holes.

# Manufacturers in NEC Baby Formula Lawsuits

Mead Johnson and Abbott Nutrition are the defendants in these NEC baby formula claims. Mead Johnson, based in Indiana manufactures the cow's milk-based formula Enfamil. Abbott Laboratories, headquartered in Illinois, produces the cow's milk-based formula Similac.

## NEC Baby Formula Injuries

Necrotizing enterocolitis (NEC) is a devastating and often lethal gastrointestinal disease that primarily affects premature infants. Although NEC can occur in full-term infants, 9 out of 10 babies who get NEC are preterm. NEC is the leading cause of death in very-low-birth-weight infants. What starts as feeding intolerance and a swollen belly can quickly turn into a lethal systemic infection. NEC is the death of tissue in the intestine. It is widely understood that inflammation of the intestine leads to bacterial invasion of the bowel wall, eventually causing tissue necrosis. Up to half of all infants who develop NEC will require surgical treatment. Overall mortality ranges from 10% to 50%. However, in the most severe cases involving perforation, peritonitis, and sepsis, mortality approaches 100%.

NEC remains a leading cause of death in premature infants, with a mortality rate as high as 35%.

### Symptoms related to NEC include:

- Abdominal pain and swelling
- Changes in heart rate, body temperature, blood pressure, and breathing
- Diarrhea with bloody stool
- Green or yellow vomit
- Lethargy
- Refusal to eat and weight loss

### Injuries related to NEC include:

- Death
- Abdominal infections such as peritonitis
- Sepsis
- Intestinal stricture
- Short bowel (short gut) syndrome
- Growth failure and developmental delays

## Key NEC Cow's Milk-Based Formula Studies

Various research has established a potential link between cow's milk-based formulas and NEC in preterm infants.

One of the first studies to identify a relationship between cow's milk-based formula and NEC was published in the Lancet in 1990. The study found that babies fed solely formula were more than 20 times more likely to develop NEC. Additional studies followed the Lancet publication, unearthing a concerning trend.

In 2012, a study in the Journal of Pediatric Research concluded that infants fed breast milk were anywhere between 40% to 90% less likely to suffer NEC than those given formula.

Another important study in the British Medical Journal that examined manufacturers' clinical trials and conduct will likely play a significant role in NEC baby formula lawsuits. This study found a "universal lack of transparency" and selective reporting between and within formula milk trials. The research suggested that formula trials are unreliable and biased, with manufacturers selectively reporting favorable results.

Depending on the study, the risk of NEC is anywhere from 3-10x greater when formula is used on preemies. It is notable that the NEC cases we are pursuing are all "surgical NEC." The statistics relative to "surgical NEC" are particularly compelling and show a 10x risk factor. To put this in perspective, comparative research shows the NEC risk factor beats Roundup. Roundup, for example, has been shown to increase the risk of cancer in the range of 41%



## Alternatives

As a result of the strong epidemiology showing the increased risk to premature infants associated with cow's milk-based formula, Prolacta Biosciences brought a product to market specifically designed for premature infants and made entirely of human milk instead of cow's milk. Studies have shown that this product provides all of the nutrients required by premature infants while significantly reducing the risk of NEC when compared to cow's milk-based formula. Prolacta has been available in hospitals since 2006. Other companies have since emerged. (for example, LactaLogics.)

## Outcomes of infants diagnosed with NEC.

Understanding the science of how infant formula causes NEC is critically important because of the impact that necrotizing enterocolitis has. Just one case of surgical NEC has been estimated to cost between \$300,000 and \$600,000 in medical and related care. A NEC diagnosis is only the beginning of a long list of possible outcomes: from bloody stools to cerebral palsy, NEC can lead to a myriad of health effects.

Even minor cases of NEC that are treated through antibiotic therapy can have a lifetime of consequences for the sufferer. As the injured gut heals, scar tissue can form strictures in the intestine. If they are severe enough, surgery is often required to remove the bowel obstructions. Even mild structures can cause constipation, intestinal impactions, and other gastrointestinal upsets.

Often, premature infants who require bowel resections are later diagnosed with a condition called short gut syndrome (SGS). After having significant portions of their bowels removed, the children do not have enough intestines left to properly digest food. They are left to suffer a lifetime of nutrition deficiencies, dehydration, growth delay, and motor developmental delay and are at an increased risk of sepsis and prolonged hospitalization. In severe cases, the infant will require supplemental nutrition via an IV through childhood. In more recent years, surgical bowel elongation and tapering surgeries have become an option for those with the most severe forms of SGS, but they come with a long list of potential complications.

The long-term complications associated with NEC are, unfortunately, not limited to the gastrointestinal system. Infants with NEC are significantly more likely than infants of similar age and gestation who did not develop NEC to be neurodevelopmentally impaired, including a higher risk of cerebral palsy.

## NEC Baby Formula Status of Litigation

In April 2022, the Judicial Panel on Multidistrict Litigation consolidated NEC baby formula claims. The JPML consolidated federal NEC baby formula lawsuits into MDL-3026 in the Northern District of Illinois, with Judge Rebecca R. Pallmeyer presiding. Abbott Laboratories and Mead Johnson supported the centralization of these claims.

As of February 2023, 105 actions are pending under MDL-3026. Plaintiffs, defendants, and the court have selected twelve Similac and Enfamil cases for potential bellwether trials as part of Judge Pallmeyer's "bellwether program." Fact discovery for these 12 cases should conclude in April 2023, and the trials may begin in 2024.



## NEC Baby Formula litigation Procedural status

We are still in the discovery phases of this litigation and there have not been any NEC baby formula verdicts or settlements at this time. The litigation is proceeding well in both State Court and Federal Court. Close to two million documents from the defendants have been reviewed. Earlier in the litigation MDL judge, Rebecca Pallmeyer, encouraged cooperation between state and federal court attorney constituencies. Jose Rojas from the Law Firm of Levin, Rojas, Camassar & Reck, in addition to being Co-lead of the MDL was appointed as a state court liaison along with Beth Kavaney. Documents and deposition transcripts obtained in each may be fully shared amongst the Law Firms pursuing state and federal litigation, subject to the applicable protective orders in place. In this regard,

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### State Court.

The main activity in this case has transitioned to St. Clair County. Judge Foley has taken the lead in St. Clair and has ordered the first trial in February 2024. It is widely expected that Mark Lanier will be the lead trial counsel in that case. There have been approximately 50 depositions taken in state court. Illinois has a very useful procedure that allows for "discovery depositions", meaning that the state court litigants get two bites at each witness. The depositions in state court have all been discovery depositions, so the lawyers there have not fully confronted the witnesses with the very best documents. They are saving that confrontation for the next round. Additionally, most of the bellwether plaintiffs have been deposed.

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### Federal Court.

In the MDL we have completed approximately 15 depositions of Mead and/or Abbott representatives, and these will be rapidly continuing through September and October. In the bellwethers, several plaintiffs have also been deposed. So far, no physicians have been deposed. The final bellwether selections were scheduled to transpire on September 14, 2023. The leadership team is working well together. The five leads have developed a good bond and mutual trust and respect. There will be considerable pressure on the Defendants to produce remaining documents and witnesses in order to firm up a Bellwether trial schedule in the MDL.

End.

## About the authors:



### Jose Rojas, Founding Partner

On May 26, 2022 Chief Judge Rebecca Pallmeyer appointed Mr. Rojas as Co-Lead Counsel in MDL 3026, Preterm Infant Nutrition Products Liability Litigation. This appointment followed a twenty-five-year career as a trial lawyer.

Mr. Rojas graduated from law school in 1997. Following law school, he was recruited and commissioned as a First Lieutenant by the United States Army, Judge Advocate General's Corps, and was swiftly promoted to Captain seven months later.

Later, Mr. Rojas was appointed Special Assistant United States Attorney and was entrusted with the awesome responsibility of representing the United States as a federal prosecutor. He prosecuted and tried cases such as rape, child molestation, homicide and larceny. Mr. Rojas quickly earned the respect of his superiors, who described him in the Official Evaluation Report as “the best, most aggressive prosecutor in this very busy legal office.” Before leaving public service, Mr. Rojas was awarded a certificate of appreciation by the Director of the FBI for his “outstanding prosecutive skills” and was made an honorary Agent with the Army Criminal Investigation Division.

Beginning in 2000, Mr. Rojas spent five years representing large corporate and governmental clients at one of Connecticut’s largest and most prominent firms. His work at this law firm focused on complex civil litigation, with an important focus on product liability.

In 2005, Mr. Rojas switched sides, and never looked back. Fed up representing big industry and big government, and driven by a desire to represent real people, Mr. Rojas founded his own firm. Mr. Rojas handled cases involving personal injury, medical malpractice and defective products, frequently taking cases to verdict.

In 2020, Mr. Rojas and his partners formed Levin, Rojas, Camassar & Reck, LLC. The firm was formed after founding what is now known as MDL 3026, Preterm Infant Nutrition Products Liability Litigation. But before the litigation achieved national prominence, Mr. Rojas and his partners litigated the cases alone for well over a year. The early success Mr. Rojas and his partners achieved in the litigation was the foundation for what would later become one of the most significant mass torts in the country.

Mr. Rojas has been featured or quoted in numerous news outlets, including the evening news (NBC30), the Connecticut Law Tribune, the Hartford Courant, and AAJ’s Trial Magazine.

Mr. Rojas has also been asked to speak at important national conferences, including the American Association for Justice Convention, Mass Torts Made Perfect (MTMP), National Trial Lawyers Summit and various seminars and conferences for the Connecticut Trial Lawyers Association.

Mr. Rojas is rated “AV Preeminent” by Martindale Hubbell, “superb” by Avvo (9.9 out of 10 rating), National Trial Lawyers Top 100 and has been repeatedly recognized as a “Super Lawyer” by SuperLawyer.com.

## About the authors:



### Stephen M. Reck, Founding Partner

Named a Super Lawyer for five consecutive years, is a “Lawyer of Distinction”, and is a member of the American Association for Justice

Attorney Reck is the first lawyer in the country to file a lawsuit against the makers of Similac and Enfamil alleging that their products increase the risk of NEC in premature infants.

It all started when a concerned mom called the office and explained what had happened to her daughter. Since that day, Stephen has dedicated his time to these cases, working tirelessly to try to stop the dangerous practice of feeding cow’s milk-based formulas and fortifiers to preemies in the NICU. If you think this may have happened to your child, call our office today or fill out the “contact us” form, we’ll be happy to listen to your child’s story and see if we can help.

In 1991, Stephen M. Reck received his J.D. Magna Cum Laude from the Quinnipiac College School of Law, where he was Editor-in-Chief of the Law Review. He obtained his LLM Degree in 1995 from Columbia University School of Law, where he was designated a Harlan Fiske Stone Scholar.

Ever since, Attorney Reck has been practicing law in southeastern Connecticut. He is admitted to practice in Connecticut state and federal courts, as well as in Rhode Island, New York, New Jersey and Pennsylvania. He established the Law Firm of Stephen M. Reck, LLC in 2006.

He is a member of the Connecticut Trial Lawyers Association and the New London County Bar Association. Attorney Reck is also a frequent seminar presenter to attorneys and bar associations on topics such as jury selection and trials. He served as adjunct professor at Quinnipiac College School of Law where he instructed students in “Legal Skills” for several years.

Attorney Reck has worked with medical experts, economists, and liability experts, whom he can call upon during trials to help strengthen your position. He can provide numerous examples of cases in which insurance companies offered his clients nothing or almost nothing, yet he was able to win financial compensation by taking the cases to trial. Attorney Reck has the highest dog bite verdict in the State of Connecticut.