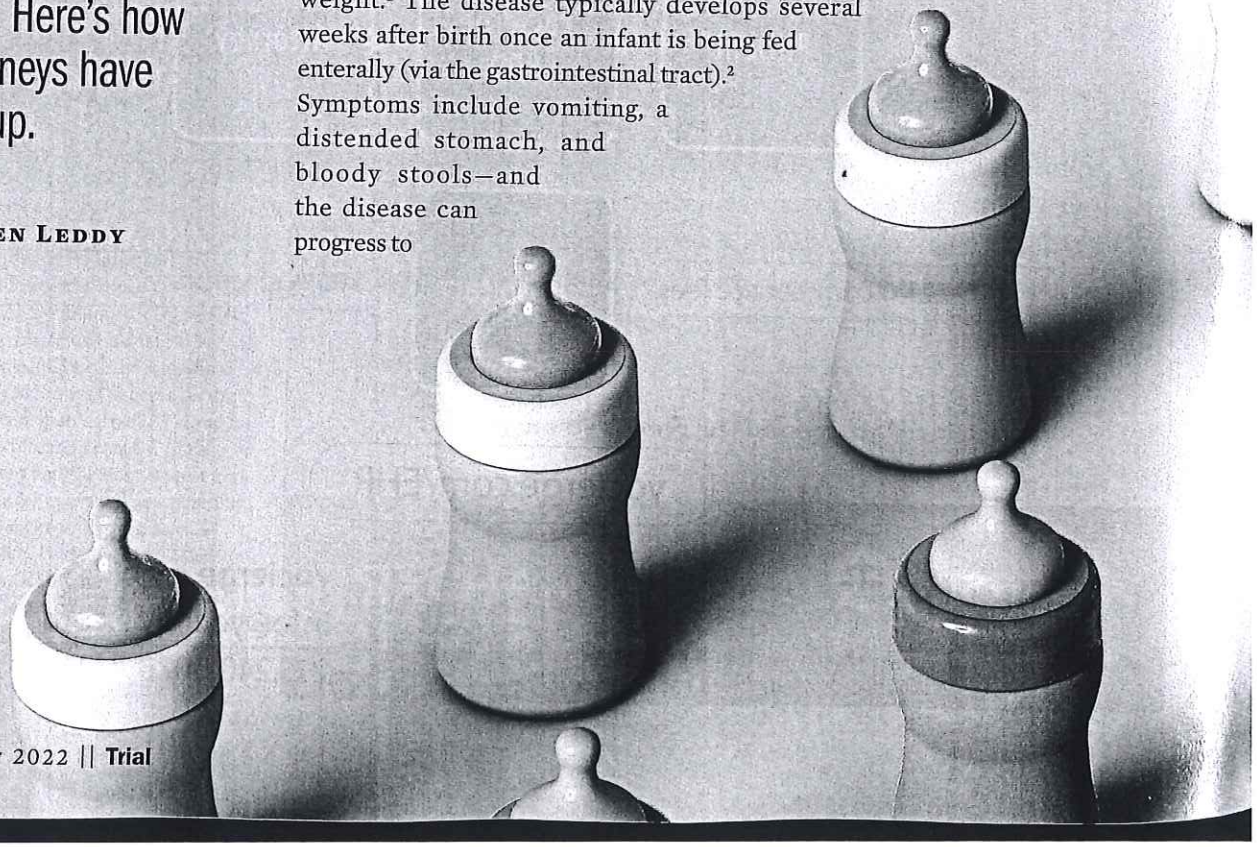
THE INFANT FORMULA CRISIS

An unchecked infant formula industry is putting babies' lives at risk with unsuitable ingredients and contaminated products. Here's how trial attorneys have stepped up.

By || **MAUREEN LEDDY**

When North Stonington, Conn., attorney Stephen Reck met with a distraught mother at a McDonalds five years ago, he had no idea that the meeting would lead to a nationwide effort to make infant formula safer. Tomika Knight had just lost her daughter, TyLea, who was born prematurely and lived only 48 days, all of which were spent in Yale New Haven Hospital's neonatal intensive care unit (NICU). TyLea had developed the intestinal infection necrotizing enterocolitis (NEC), and despite emergency bedside surgery, she died from the infection.

NEC affects 1 in 1,000 live births and is most prevalent in premature infants, especially those with very low birth weight.[1] The disease typically develops several weeks after birth once an infant is being fed enterally (via the gastrointestinal tract).[2] Symptoms include vomiting, a distended stomach, and bloody stools—and the disease can progress to



bowel perforation and necrosis.[3] NEC kills about 15% of the babies it afflicts, and many more survive but have long-term health effects including short bowel syndrome, neurodevelopmental impairments, and growth issues.[4]

After TyLea died of NEC, Knight suspected something was amiss in her feedings, Reck said. In the weeks leading to her death, NICU providers transitioned from feeding TyLea exclusively breast milk to breast milk mixed with cow's milk-based formula, including Enfamil Human Milk Fortifier and EnfaCare powders. The week before TyLea's death, she was fed Similac Special Care, a cow's milk-based formula, sometimes with breast milk and sometimes alone.

After the meeting, Reck dug through scientific studies and found that Knight was on to something—researchers had linked cow's milk formula and NEC incidence in extremely premature infants.[5] Why was a hospital feeding cow's milk formula to NICU patients? And why were manufacturers producing and marketing cow's milk-based formulas for premature infants?

But this unsuitable ingredient in formula specially designed for premature infants wasn't the end of the story—it's become clear that there is a larger problem in the formula industry generally. In late 2021, the FDA began receiving complaints that infants who consumed powdered formula manufactured at Abbott Nutrition's Sturgis, Mich., plant had been infected with Cronobacter sakazakii and Salmonella Newport.[6] These bacterial infections are linked to gastrointestinal distress, and Cronobacter is linked to sepsis and meningitis in infants—with a mortality rate for Cronobacter meningitis of up to 40%.[7] Those sickened were not premature infants in NICUs—they included otherwise healthy infants whose parents purchased and prepared powdered formula in their homes. Researchers have linked over 90% of Cronobacter infections in infants to powdered formula.[8]

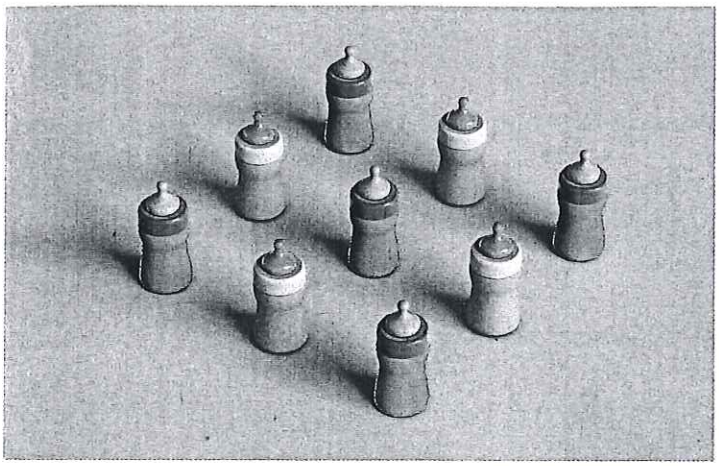
Abbott recalled powdered formulas that were manufactured at the Sturgis plant—including Similac, Alimentum, and EleCare—but claimed that it conducted routine pathogen testing and found no evidence of the contaminants and that Cronobacter "is commonly found in the environment and a variety of areas in the home."[9]

However, according to FDA Commissioner Robert Califf's May 2022 testimony before a U.S. House of Representatives subcommittee, FDA investigators' swabs of multiple locations in the plant tested positive for Cronobacter, and Abbott's internal records indicated Cronobacter contamination had been found in formula batches in 2019 and 2020—both of which Abbott destroyed.[10]

Investigators also observed "serious cracks in the firm's spray dryers," "water leaks and condensation" where powdered formula was produced, inadequate employee handwashing, and a lack of "process controls . . . to ensure that infant formula does not become adulterated due to the presence of microorganisms."[11] Abbott entered into a consent decree with the FDA in May 2022, agreeing to quality control and testing requirements, as well as auditing for four years.[12]

"Infant formula companies have a virtual monopoly and are insulated from free market forces," said Pensacola, Fla., attorney, E. Samuel Geisler, who represents plaintiffs in NEC and contamination claims. Abbott, Mead Johnson Nutrition, Nestlé USA, and Perrigo Co. control nearly 90% of the U.S. formula market,[13] and Abbott's Sturgis plant produces about 20% of the U.S. formula supply.[14]

Geisler added that the formula safety crisis is particularly acute for those in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The Sturgis plant



PLAINTIFFS ARGUE THAT COW'S MILK IS DANGEROUS TO PREMATURE INFANTS AND FORMULA MAKERS HAD A DUTY TO WARN OF RISKS.

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produces about half the nation's formula provided under WIC, Geisler said.

Another issue, Reck said, is "how embedded Abbott and Mead Johnson are in the medical community—providing funds for everything from grants to research to seminars." Reck added that whereas "formula typically is covered by government services programs, donor milk is not."

The formula industry is valued at $55 billion globally, according to the World Health Organization (WHO), and the industry engages in "systematic and unethical marketing strategies" to "influence parents' infant feeding decisions."[15] This is despite the World Health Assembly's 1981 adoption of the "International Code of Marketing of Breast-milk Substitutes," which aims to protect and promote breastfeeding while "ensuring the proper use of breast-milk substitutes."[16] A 2022 status report on the implementation of the code showed a bleak picture for the United States—it had adopted no legal measures while 74% of WHO member states had some sort of legal measure in place on formula marketing.[17]

NEC Cases

Reck believes his claim on behalf of TyLea was the first NEC claim filed in the United States against a formula manufacturer—he filed suit in Connecticut state court in 2019, and the case was then removed to Connecticut federal district court. The plaintiff alleged Abbott and Mead Johnson violated the Connecticut Product Liability Act and brought claims for failure to warn and instruct and strict liability design defect, among others.[18] In particular, the plaintiff pointed to the formula makers' packaging and warning labels, which did not warn of the increased risk of NEC and death or provide instructions on how to avoid those outcomes.[19]

Preemption. Abbott and Mead Johnson moved to dismiss the case, countering that the plaintiff's design defect claim was barred by impossibility preemption.[20] The FDA allowed the formula makers to market the cow's milk formula for use in infants with low birth weight, they argued, and so they "cannot 'unilaterally remove' cow milk from their products because 'such a change requires FDA review.'"[21]

The federal district court applied Connecticut's "risk-utility" test for design defects. Under that test, defendants are liable if "a reasonable alternative design was available that would have avoided or reduced the risk of harm" or the product is "unreasonably dangerous" such that the consumer would not have purchased it if informed of the risks.[22] The court then looked at "whether federal law expressly prohibits the Defendants from complying with state law."[23]

The court considered the defendants' argument that the FDA's registration and notification process for infant formula is "identical in all important respects" to the pre-approval process for drugs and noted a "statutory mismatch"—though Congress explicitly required FDA pre-approval of drugs that undergo a "major change," it only set forth a notification procedure under the Infant Formula Act (IFA).[24] In addition, said the court, it's unclear whether "replacing cow milk with another ingredient would be a 'major change' within the meaning of the IFA."[25]

Abbott and Mead Johnson have continued to advance the preemption argument, but they have lost repeatedly and in multiple jurisdictions.[26]

Learned intermediary. Hartford, Conn., attorney Jose Rojas, co-counsel with Reck in several NEC cases, said the other major argument is that cow's milk is dangerous to premature infants and that formula makers "had a duty to warn parents and health care providers of the increased risk."

On the failure-to-warn claim in TyLea's case, Abbott and Mead Johnson argued that the learned intermediary doctrine applies, so they had a duty to warn only TyLea's doctors of the risks of cow's milk-based formula—not her parents. Under that doctrine, "prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment."[27] Noting the potentially broad effect of a decision, the federal court certified the question of whether the learned intermediary doctrine applied in the plaintiff's case to the Connecticut Supreme Court.[28]

In another case, *Sanchez Juan v. Abbott Labs*, a Florida federal district court went further—in response to the defendant's argument that the learned intermediary doctrine applies, that court permitted the plaintiff to overcome a motion to dismiss by pleading in the alternative and proceeding under both a learned intermediary and direct duty to plaintiff theory.[29] *Sanchez Juan* also involved an extremely premature infant, Reina, who died of NEC after she was fed cow's milk-based formulas—this despite her mother pumping her own breast milk and instructing NICU staff to feed Reina only breast milk.[30]

The NEC cases now are largely consolidated into an MDL in the Northern District of Illinois.[31] In early September, Judge Rebecca Pallmeyer, who was assigned to oversee the MDL, set forth a process for bellwether case selection, ordering 12 cases to be selected for discovery by late November, with four to ultimately be selected for bellwether trials.[32] Reck says that four plaintiff picks and four random picks by the court have already been selected

for bellwether discovery. While about 100 plaintiffs are currently in the MDL, Reck, who is on the plaintiffs' steering committee (PSC), and Rojas, who is co-lead counsel in the MDL, expect it will ultimately involve more than 1,000 claims.

Several cases also have been filed in state courts—particularly in Illinois where Abbott and Mead Johnson are based.[33] Rojas explained that cases are advancing both in the MDL and state tracks. State litigation likely will proceed more rapidly, he said. Suits in some Illinois state court jurisdictions have been consolidated before one judge for pretrial proceedings to avoid "duplicative discovery and pretrial litigation" and to "prevent inconsistent pretrial rulings."[34]

The Contamination Cases

The first cases alleging that babies were sickened by bacterial contamination of powdered infant formula were filed earlier this year, following news of the unsanitary conditions at the Sturgis plant and Abbott's recall of powdered formula made there.[35] The plaintiffs allege breach of warranty, failure to warn, negligent recall, strict products liability, and unjust enrichment, among other claims.[36] These cases are largely in federal court and were consolidated into an MDL in August under Judge Matthew Kennelly, also in Illinois federal district court.[37]

Marjorie Levine, who is on the PSC for the MDL, recounted her first client in the litigation—the family of a baby who consumed the recalled formula from the Sturgis plant and developed a bacterial infection that left lasting neurological effects. "Abbott knew about this contamination since at least 2019," Levine said, "yet it failed to protect these babies."

Levine expects spoliation to be a big hurdle in the litigation, given the content of a whistleblower complaint from a former Sturgis plant employee alleging that Abbott falsified records, released untested formula, had lax cleaning policies, and failed to comply with current "Good Manufacturing Practices."[38] The whistleblower also alleges the Sturgis plant's automatic labeler frequently failed, creating product tracing issues.[39]

West Palm Beach, Fla., attorney John Romano, who is on the NEC MDL PSC, said he and his clients' goal is to remove cow's milk-based formula from NICUs. He also wants to ensure that parents and health care providers are "warned and educated on the dangers" of this formula for premature infants—ultimately, preventing any more babies from being harmed.

Reck reflected on TyLea's case: "From the time I learned about the link between NEC and cow's milk-based infant formula in 2017, I couldn't stop thinking that I had to do something. Saving the lives of babies is the most important work I'll ever do."

"The end goal for both litigations is accountability," added Geisler, who is co-lead counsel on the contamination MDL. "The court system is the only way to effect change when industry and regulators aren't doing their jobs."

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NOTES

1. NORD (Nat'l Org. for Rare Disorders), *Necrotizing Enterocolitis*, https://rarediseases.org/rare-diseases/necrotizing-enterocolitis/. NEC is a leading cause of death in extremely premature infants. *See* Ravi M. Patel et al., *Causes and Timing of Death in Extremely Premature Infants From 2000 Through 2011*, 372 N. Engl. J. Med. 331 (Jan. 2015).
2. NORD, *supra* note 1.
3. *Id.*
4. *Id.*
5. Sandra Sullivan et al., *An Exclusively Human Milk-based Diet is Associated With a Lower Rate of Necrotizing Enterocolitis Than a Diet of Human Milk and Bovine Milk-based Products*, 156 J. Pediatrics 562, 566 (Apr. 2010), https://tinyurl.com/2p9yy32n ("[F]or extremely premature infants, an exclusively human milk-based diet is associated with a significant reduction in the rates of NEC and surgical NEC compared with dietary exposure to bovine milk–based products.").
6. U.S. Food & Drug Admin., *FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022)*, https://tinyurl.com/mrxw7bu8; Ctrs. for Disease Control & Prevention, *Powdered Infant Formula Investigation*, https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html.
7. Ctrs. for Disease Control & Prevention, *Cronobacter, Frequently Asked Questions*, https://www.cdc.gov/cronobacter/technical.html.
8. Gautam Kalyantanda et al., *Cronobacter Species Contamination of Powdered Infant Formula and the Implications for Neonatal Health*, 3 Frontiers in Pediatrics 56 (July 2015), https://tinyurl.com/ycyhjm2x.
9. Abbott, *Press Release: Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant* (Feb. 17, 2022), https://tinyurl.com/3fc5ezpr.
10. Testimony of Robert M. Califf, M.D., *Infant Formula Crisis: Addressing the Shortages and Getting Formula on Shelves*, 2 (May 26, 2022), https://www.fda.gov/media/158736/download. For more on the history of contaminated powdered formula, see David Enrich, *How Abbott Kept Sick Babies From Becoming a Scandal*, N.Y. Times (Sept. 6, 2022), https://tinyurl.com/533asppb.
11. *Califf Testimony*, *supra* note 10, at 2–3; *see also* Rep. Rosa DeLauro (D-Conn.), *DeLauro Statement on Abbott Facility Reopening* (June 6, 2022), https://tinyurl.com/4whcpp66.
12. Consent Decree of Permanent Injunction, *United States v. Abbott Labs.*, No. 1:22-cv-441 (W.D. Mich. May 16, 2022), https://tinyurl.com/yc2vmb2k.
13. House Comm. on Oversight & Reform, *Press Release: Chairs Maloney and Krishnamoorthi Press Infant Formula Manufacturers on Plans to Address Nationwide Shortage* (May 13, 2022), https://tinyurl.com/ydnrm6mt.
14. Meredith Lee & Helena Bottemiller Evich, *How the Baby Formula Shortage Links Back to a Federal Nutrition Program*, Politico (May 19, 2022), https://tinyurl.com/3ejhamxz.
15. World Health Org., *More Than Half of Parents and Pregnant Women Exposed to Aggressive Formula Milk Marketing—WHO,*

UNICEF (Feb. 22, 2022), https://tinyurl.com/2x7k9sw5.

16. World Health Org., *International Code of Marketing of Breast-Milk Substitutes* (Jan. 27, 1981), https://www.who.int/publications/i/item/9241541601; World Health Org., *International Code of Marketing of Breast-Milk Substitutes Frequently Asked Questions*, 2 (2017), https://tinyurl.com/yvwfx4d4.
17. World Health Org., *Marketing of Breast-Milk Substitutes: National Implementation of the International Code, Status Report 2022*, 12 & 36 (May 12, 2022), https://www.who.int/publications/i/item/9789240048799. The report also raised concerns globally about social media promotion practices—particularly through the use of influencers, "baby clubs," and "data harvesting for message targeting." *Id.* at 20.
18. *Ferry v. Mead Johnson & Co.*, 514 F. Supp. 3d 418, 426 (D. Conn. 2021).
19. *Id.* at 427–29.
20. *Id.* at 436.
21. *Id.*
22. *Id.* at 439.
23. *Id.* at 440.
24. *Id.* at 442.
25. *Id.* at 443.
26. *See Hunte v. Abbott Labs.*, No. 3:20-cv-1626-SRU (D. Conn. 2020); *Sanchez Juan v. Abbott Labs.*, No. 6:21-cv-502-RBG-EJK (M.D. Fla.); *Simmons v. Abbott Labs*, No. 2021-L-00000144 (Ill. Cir. Ct. 2021).
27. *Ferry*, 514 F. Supp. 3d at 433 (citing *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001)).
28. *Id.*
29. Order Denying Motion to Dismiss, *Sanchez Juan v. Abbott Labs., Inc.*, No. 6:21-cv-502-RBG-EJK (M.D. Fla. Aug. 2, 2021).
30. *Id.* at 2.
31. *In Re Abbott Labs. Preterm Infant Nutrition Prods. Liab. Litig.*, MDL No. 3026 (N.D. Ill.); Transfer Order, *In Re Abbott Labs. Preterm Infant Nutrition Prods. Liab. Litig.*, 2022 WL 1053663 (J.P.M.L. Apr. 8, 2022).
32. Protocol for Selection of Initial Bellwether Discovery Cases and Initial Bellwether Trial Cases and Authorization of Plaintiff Profile Forms, *In re Abbott Labs. Preterm Infant Nutrition Prods. Liab. Litig.*, MDL 3026 (N.D. Ill. Sept. 7, 2022).
33. Mead Johnson has recently successfully asserted that it is headquartered in Indiana. *See Alexander v. Mead Johnson & Co.*, 2022 WL 2156140 (S.D. Ill. June 15, 2022).
34. *See, e.g.*, Motion to Transfer and Consolidate Cases for Pre-trial Purposes Only Under Illinois Supreme Court Rule 384 at 6, *Jupiter v. Mead Johnson & Co.*, No. 2021-L-000560 (Ill. Dec. 14, 2021).
35. *See, e.g., Suarez v. Abbott Labs., Inc.*, No. 1:22-20506 (S.D. Fla. 2022); *Deffebaugh v. Abbott Labs.*, No. 1:22-cv-01079 (N.D. Ill. 2022).
36. *Id.*
37. Transfer Order, *In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, MDL No. 3037 (J.P.M.L. Aug. 5, 2022), https://tinyurl.com/yv23vfar.
38. Confidential Disclosure Re Abbott Laboratories' Production Site in Sturgis, Mich. 2–3 (Oct. 19, 2021), https://tinyurl.com/2p992ymt.
39. *Id.* at 3 & 27.