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INSIGHT

Preterm Infant Formula and Necrotizing Enterocolitis Litigation

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Hundreds of lawsuits allege that certain infant formula products caused preterm infants to develop necrotizing enterocolitis (NEC), a life-threatening gastrointestinal condition. To date, plaintiffs have won two large verdicts and Abbott, one of the largest manufacturers, has signaled that it may discontinue the relevant products if it continues to lose cases—prompting concerns about a potential shortage. This Insight provides background on NEC in preterm infants, summarizes recent litigation, and concludes with select considerations for Congress.

Background

Preterm infants—babies born before 37 weeks of gestation—typically require specialized nutrition to compensate for growth and developmental shortcomings. Maternal or donor breastmilk, widely considered the optimal nutritional sources, may be unavailable or limited. In such cases, preterm infants (and sometimes low-birthweight infants) may consume specialized formulas along with specially fortified breastmilk or as their sole source of nutrition. In these circumstances, human breastmilk and preterm infant formulas are typically optimized for preterm infant nutrition with one of two types of fortifiers: bovine (cow-based) milk-derived fortifiers (BMF) or human milk-derived fortifiers (HMF).

NEC is characterized by the infection, inflammation, and degradation of the intestinal lining, which can lead to severe illness or death. NEC is among the leading causes of illness and death across all infants (**Figure 1**), though it is most common among preterm infants. The direct causes of NEC are not well understood. Current scientific literature points to a combination of risk factors, rather than causal factors. These factors include the immaturity of a preterm infant's digestive system, the composition of certain intestinal microbiota, a weakened immune system, and enteral feeding (i.e., the use of a feeding tube), but gaps in knowledge remain. These gaps link to a range of research challenges, including different NEC definitions and the disease's similarity to other gastrointestinal conditions, which can make it challenging to diagnose and establish clear, definitive causes.

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Figure 1. Top 15 Causes of Infant Death

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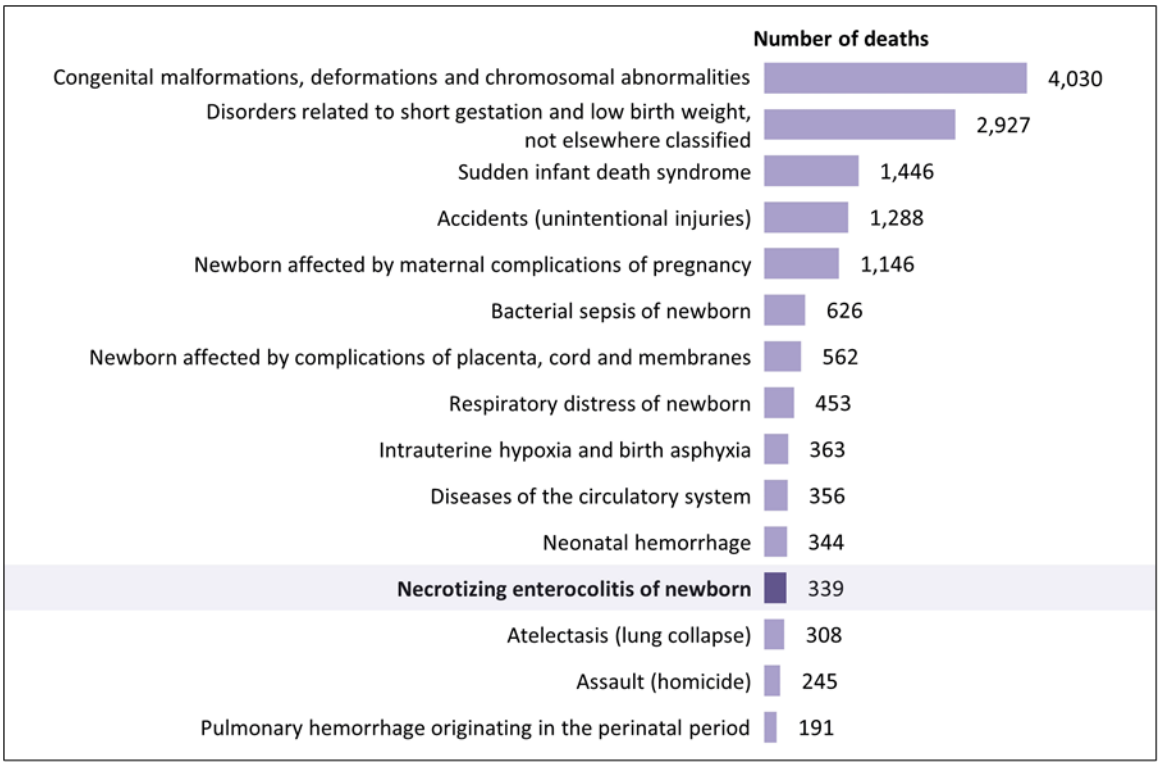

Source: Figure developed by CRS using vital statistics data accessed at http://wonder.cdc.gov/ on July 29, 2025.

Notes: Causes of death reflect standardized International Classification of Diseases (ICD) codes.

Preterm Infant Formula and NEC

Some research suggests that human breastmilk can reduce the risk of NEC, though the underlying biological mechanisms require further study. Some studies have examined whether certain kinds of preterm infant formula are linked to NEC, but the evidence is generally considered inconclusive. Researchers have also questioned whether NEC risks may vary by the type of fortifier used in either formula or breastmilk. Some hypothesize that HMF, rather than BMF, may decrease NEC risk; however, robust, high-quality data are limited. A prevailing theory is that the absence of human milk increases NEC risk, rather than pointing to a causal link between preterm infant formula (or certain fortifiers) and NEC. A 2024 consensus statement from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention, and National Institutes of Health, which drew upon a Eunice Kennedy Shriver National Institute of Child Health and Human Development-led advisory council report, also recognized this observation and recommended further research.

Litigation

Hundreds of lawsuits allege that certain preterm infant formula products caused infants to develop NEC. Two types of claims that are often asserted in these lawsuits are negligence and strict liability.

To prevail on a negligence claim, a plaintiff must establish, by a preponderance of the evidence, that (1) the manufacturer owed the plaintiff a duty of care, (2) the manufacturer breached that duty, (3) the defendant's breach was the "proximate cause" of the plaintiff's injury, and (4) the plaintiff suffered

damages. Generally, an infant formula manufacturer owes a duty of care to all foreseeable users of the product, and the manufacturer would breach that duty by failing to use "reasonable care" in designing, manufacturing, labeling, or marketing the product. If the evidence establishes that the manufacturer exercised the requisite "reasonable care," the plaintiff's negligence claim would not succeed, even if the product caused the injury.

By contrast, to establish a strict liability claim, a plaintiff does not need to establish that the infant formula manufacturer acted unreasonably in breach of the duty of due care. To establish strict liability, a plaintiff must show that the product contained a "defect" that made it "unreasonably dangerous" and that it caused the plaintiff's injury. An infant formula product is defective if it contains a manufacturing defect, a design defect, or is defective due to inadequate instructions or warnings.

Two negligence and strict liability lawsuits brought by parents of injured infants against formula manufacturers in Illinois and Missouri state courts resulted in a $60 million and a $495 million jury verdict, respectively. Another Missouri jury returned a verdict in favor of the infant formula companies. Following this verdict, the judge granted the plaintiffs' motion for a new trial due to several erroneous evidentiary rulings at trial. Additionally, hundreds of lawsuits have been consolidated in a single federal proceeding called a multidistrict litigation (MDL). The parties selected four cases to proceed to trial as test cases. In the first of these, the trial judge granted summary judgment to the infant formula company, in part because no donor milk or HMF was available at the hospital, meaning that an adequate warning would not have made a difference in this case. The court's order emphasized that its decision "has limited direct application to other claims in the MDL." The trial in the second test case is set to begin in August 2025.

Considerations for Congress

Some stakeholders have expressed concern that the lawsuits against infant formula manufacturers may cause formula supply shortages and nutrition deficiency issues, particularly as Abbott has signaled that it may pull its products at issue from the market if it continues to lose cases. In the 119th Congress, some bills aim to incentivize infant formula manufacturers to remain in, or enter, the market. For example, H.R. 2300 would temporarily preempt certain lawsuits against preterm infant formula manufacturers while the FDA conducts further study. H.R. 2008 would provide tax credits to certain new and expanding infant formula manufacturers. Other congressional action seeks to improve public awareness of the benefits of human donor milk and HMFs for vulnerable infants or, separately, require mandatory, no-cost coverage of HMF-based products by Medicaid, the Children's Health Insurance Plan, and private insurance plans (H.R. 4569).

Other stakeholders emphasize expanding access to fortified donor breastmilk, rather than relying on formulas. Additionally, some researchers suggest the need for further investigation into the relative protective or harmful effects of HMFs and BMFs. Recent data indicate that the relatively high U.S. preterm birth rate remains stagnant, which may signal the need that additional attention be focused on preterm birth prevention and related maternal and infant health issues.

Author Information

Dorothy C. Kafka
Legislative Attorney

Alexandria K. Mickler
Analyst in Health Policy

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