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CLIFFORD'S NOTES

# TAKING SHAPE

## Baby formula cases starting to move in Northern District

**By BOB CLIFFORD**

A premature twin in downstate Illinois became ill and died from necrotizing enterocolitis (NEC) after consuming baby formula. In what was the first trial involving Enfamil formula on behalf of infant Chance Dean, born at 31 weeks, the jury returned a verdict of $60 million on March 13 following a month-long trial in St. Clair County, Illinois. (*Jasmine Watson v. Mead Johnson & Co., LLC,* 21 L 1032).

The company was accused of not doing enough to warn parents about the increased risk of the deadly disease in premature babies who were given its formula.

NEC is a serious gastrointestinal problem that most seriously attacks premature babies. The condition inflames intestinal tissue that can cause it to die or create a hole in the intestine. Bacteria can leak through this hole, causing serious abdominal infections. Some infants need surgery to remove the damaged intestine.

The defendants marketed the products as being nutritionally equivalent to breast milk. The lawsuits allege the formula makers knew of the risks involving their cow-milk-based products yet failed to inform the consuming public of the dangers.

For years, studies indicated cow milk could cause serious gastrointestinal problems, particularly for premature infants. The Lancet Journal first published about the possible link between bovine baby formulas and NEC in 1990, finding that formula-fed babies were 20 times more likely to develop NEC. Ten years later, a study in the Journal of Pediatrics reached similar conclusions and found infants fed with breast milk or human milk fortifiers were 90% less likely to develop NEC compared to those fed with traditional formula. Additional studies, such as one published in 2020 by Cambridge University Press, have suggested that makers of infant formulas have conflicts of interest given their funding of biased and unreliable clinical studies, as well as holding corporate decision-making seats on dietary advisory committees with no transparency to the public.

Certain Similac and Enfamil baby formula products from Abbott Laboratories and Mead Johnson & Co., headquartered in Chicago, are the subject of suits involving cases of NEC in infants who consumed these products. Hundreds of babies suffered injury and some have died. Parents sued for answers and justice. As of press time, 389 NEC cases were consolidated in the U.S. District Court for the Northern District of Illinois by Chief Judge Rebecca R. Pallmeyer. *In Re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation,* MDL 3026.

Plaintiffs in the NEC litigation plan to demonstrate the major baby formula makers were aware of these studies yet continued to manufacture and market the products to unsuspecting parents. On Nov. 1, 2023, Pallmeyer selected four key "bellwether" cases to go to trial. These trials are intended to gauge potential jury reactions to the presented evidence. Of these four cases, two name both Abbott (makers of Similac) and Mead Johnson (makers of Enfamil) as defendants, one names only Mead Johnson, and another only Abbott. Three of these lawsuits are wrongful death claims attributed to NEC after their formulas were consumed. Another involves an infant who survived NEC but experienced severe complications requiring multiple surgeries.

Who can forget the baby formula shortage due to tainted products during the COVID pandemic? Recently, thousands of cans of Reckitt/Mead Johnson Nutrition's infant formula sold in the U.S. were recalled after Israeli health authorities confirmed the bacteria Cronobacter sakazakii was present in cans being imported into Israel from the U.S. The recall includes 675,030 cans sold in the U.S., the FDA said, which were produced at Mead Johnson's plant in Zeeland, Michigan, starting in June 2023. Cronobacter also was behind the outbreak linked to Abbott's infant formula in 2022 which amounted to millions of recalled cans. The bacteria can cause severe life-threatening infections such as meningitis, according to the recall alert. Symptoms may include poor feeding, irritability, temperature changes, jaundice, grunting breaths and abnormal movements.

The U.S. Food and Drug Administration in October announced it had adopted guidelines in response to the massive baby formula recall and shortage in 2022 linked to a deadly pathogen. Authorities say new federal guidelines aimed at strengthening oversight and regulation of the U.S. powdered infant formula market are making an impact. In August 2023, the FDA issued letters of warning to three infant formula manufacturers as part of the agency's ongoing commitment to enhance regulatory oversight to ensure the industry is producing infant formula under the safest conditions possible.

This isn't the first time baby formula makers have come under scrutiny. In July 2022, Mead Johnson agreed to an $8.4 million settlement on the grounds that the company deceptively marketed Enfamil formula. The suit alleged fewer servings of formula were in each container than what was represented and parents overpaid for the amount of formula they received.

Once again, an example of lawyers becoming the voice for the voiceless. CL

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