

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

OCTAVIA PATTON-ASHLEY, Individually,
and as Next Friend of Minor Child, Baby Boy
S.A.,

Plaintiff(s),

v.

ABBOTT LABORATORIES, INC., MEAD
JOHNSON & COMPANY LLC and MEAD
JOHNSON NUTRITION COMPANY

Defendants.

Case No.:

**PLAINTIFF’S COMPLAINT &
DEMAND FOR JURY TRIAL**

Plaintiff, OCTAVIA PATTON-ASHLEY, Individually, and as Next Friend of Minor Child, Baby Boy S.A., (“Plaintiff”), hereby complains against Defendants Abbott Laboratories, Inc., (“Abbott”), Mead Johnson & Company LLC, (“Mead Johnson”), and Mead Johnson Nutrition Company (“Mead Johnson Nutrition”) and alleges as follows:

Nature of the Case

1. This action is the result of the preventable death of a newborn baby, Baby Boy S.A., who died after developing a horrific and deadly disease caused (or substantially contributed to) by Abbott’s, Mead Johnson’s, and Mead Johnson Nutrition’s cow’s milk-based infant formula or fortifier.

2. Necrotizing Enterocolitis (hereinafter “NEC”) is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that can cause the tissue to necrose—or, in more simple terms, die—and can lead to perforation of the gut. Advanced cases of NEC often result in the need for abdominal surgery to remove the diseased portion of the gut and, in the most severe cases, NEC can cause death.

Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights¹ who are fed cow's milk-based formula or fortifier products.

3. Upon information and belief, the companies who manufacture these cow's milk-based formula or fortifier products, including Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, understand the relationship between consumption of their products and an increased risk that the preterm infant will develop NEC.

4. Nevertheless, upon information and belief, companies who manufacture these cow's milk-based formula or fortifier products, including Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, including physicians like Baby Boy S.A.'s doctors, passing off these deadly products as something safe, effective, and substantially similar to or even superior to human breast milk.

5. Tragically, Baby S.A., who was premature at birth, was fed these cow's milk-based products, developed NEC, and died shortly thereafter.

6. Plaintiff, Octavia Patton-Ashley, Individually, and as Next Friend of Minor Child, Baby Boy S.A., brings this cause of action against Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition for claims arising from the direct and proximate result of their misconduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, or sale of their cow's milk-based baby formula and fortifier products.

¹ For the sake of brevity, the terms "premature" and "preterm" will be used interchangeably throughout this Complaint.

PARTIES

PLAINTIFF & BABY BOY S.A.

7. Baby Boy S.A was born prematurely at Children’s Hospital Colorado Anschutz Medical Campus in Aurora, Colorado, on February 4, 2021. He died on June 20, 2021, after developing NEC.

8. Baby Boy S.A. developed NEC after being fed Defendants’ cow’s milk-based products at home.

9. Plaintiff, Octavia Patton-Ashley, is the mother of Baby Boy S.A., and brings this action for the wrongful death of her son. Plaintiff, Octavia Patton-Ashley, is a resident and citizen of State of Louisiana, and resides in Elm Grove, Louisiana.

DEFENDANT ABBOTT

10. Upon information and belief, Defendant Abbott manufactures, designs, formulates, tests, markets, labels, packages, sells, and otherwise places into the stream of commerce in the United States, including in Colorado, cow’s milk-based baby formula and fortifier products, including Similac Advanced Pro.

11. Upon information and belief, Defendant Abbott is incorporated in Illinois, registered to conduct business in Colorado, and can be served via its registered agent, C.T. Corporation System, at 208 S. Lasalle Street, Suite 814, Chicago, Illinois 60604.

DEFENDANT MEAD JOHNSON

12. Upon information and belief, Defendant Mead Johnson manufactures, designs, formulates, tests, markets, labels, packages, sells, and otherwise places into the stream of commerce in the United States, including in Colorado, cow’s milk-based baby formula and fortifier products, including Enfamil Gentle Ease.

13. Upon information and belief, Defendant Mead Johnson is incorporated in Delaware, registered to conduct business in Colorado, and can be served via its registered agent, Corporation Service Company, at 135 North Pennsylvania Street, Suite 1610, Indianapolis, Indiana 46204 or via its other registered agent, Illinois Corporation Service Company at 801 Adlai Stevenson Drive, Springfield, Illinois 62703.

DEFENDANT MEAD JOHNSON NUTRITION

14. Upon information and belief, Defendant Mead Johnson Nutrition manufactures, designs, formulates, tests, markets, labels, packages, sells, and otherwise places into the stream of commerce in the United States, including in Colorado, cow's milk-based baby formula and fortifier products, including Enfamil Gentle Ease.

15. Upon information and belief, Defendant Mead Johnson Nutrition is incorporated in Delaware, registered to conduct business in Colorado, and can be served via its registered agent, Corporation Service Company, at 135 North Pennsylvania Street, Suite 1610, Indianapolis, Indiana 46204 or via its other registered agent, Illinois Corporation Service C at 801 Adlai Stevenson Drive, Springfield, Illinois 62703.

JURISDICTION AND VENUE

16. This is a serious wrongful death case and the amount in controversy, exclusive of interest and costs, exceeds the \$75,000.00 jurisdictional minimum.

17. This Court has jurisdiction over this case because Abbott, Mead Johnson, and Mead Johnson Nutrition market, promote, and sell products, including the products at issue in this case, in Colorado, avail themselves of the benefits and

protections of the laws of Colorado, and regularly transact business in Colorado. Additionally, many of the events which led to the untimely death of Baby Boy S.A. occurred in the State of Colorado.

18. Venue of this action is proper because Abbott, Mead Johnson, and Mead Johnson Nutrition transact substantial business in Colorado, a substantial number of the events giving rise to Plaintiff's claims occurred in Colorado, and the corresponding documentary and testamentary evidence regarding Plaintiff's claims are, also, located in Colorado.

FACTUAL ALLEGATIONS

A. The Science Connecting Cow's Milk-Based Products to NEC

19. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Baby Boy S.A. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

20. Nutrition for preterm babies, especially those with a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams) like Baby Boy S.A., is significantly important. Because the United States ranks in the top ten countries in the world with the greatest number of preterm births, the U.S. market for infant formula and fortifiers is particularly vibrant.

21. Despite historical thinking that cow's milk-based products were good for the growth of premature, low-birth-weight babies, advances in science and research have proven just the opposite is true. Indeed, current science and research confirms strong links between cow's milk-based products and a significantly increased risk of

developing NEC, which can cause death in premature infants, along with many other health complications and long-term risks to the infant. And contrary to Defendants' representations that their products were superior to human breast milk, advances in science show that, in reality, a human breast milk diet is superior to a formula-based diet.

22. As early as 1990, a prospective multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula-fed babies than in those who were fed breast milk alone and three times more common than in those who received formula plus breast milk. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519–23 (1990). This study also found that while NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk, it was 20 times more common in those fed cow's milk-based formula only. *Id.*

23. In a study published in 2007 it was reported: "The use of an exclusive HUM [Human] diet is associated with significant benefits for extremely premature infants <1259 g BW. The benefits include decreased NEC rates, mortality, late-onset sepsis, PDA, BPD, ventilator days, and ROP. Importantly, while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes. This study demonstrates that an exclusive HUM diet provides important benefits beyond NEC." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*. (Breastfeeding Medicine. 2016, Nov 2., 11(2):70-75.)

24. A separate study published in 2010 evaluated the health benefits of an

exclusive human milk diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. S. 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*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010). The results showed that preterm babies fed an exclusive human milk diet were **90% less likely to develop surgical NEC** as compared to a diet that included some amount of cow's milk-based products. *Id.* (emphasis added).

25. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "[f]or vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." Office of the Surgeon General, *The Surgeon General's Call to Action to Support Breastfeeding*, U.S. DEP'T OF HEALTH & HUMAN SERV., p.1 (2011), *available at* <https://www.ncbi.nlm.nih.gov/books/NBK52682/>. This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id.* at 2.

26. Similarly, the American Academy of Pediatrics issued a 2012 policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of cow's milk-based products. A. Eidelman, *et al.*, *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129(3): e827–41 (2012). "The potent benefits of human milk are such that all preterm infants should receive human milk" and that "[i]f [the] mother's own milk is unavailable . . . pasteurized donor milk should be used." *Id.* at e831.

27. A study published in 2013 showed that every one of the 104 premature

infants receiving an exclusive human-milk-based diet exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that “this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet.”

A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants \leq 1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013). This is a clear indication that inadequate growth is a poor excuse for prioritizing cow’s milk-based formula over human breast milk, but the practice continued largely due to extensive, aggressive marketing campaigns conduct by infant formula companies.

28. Multiple scientific studies throughout the 2010s overwhelmingly concluded that the risks of NEC are increased by the consumption of cow’s milk-based products and decreased by an exclusive human milk diet.

29. In 2013, the first randomized trial in extremely premature infants of human milk versus preterm cow’s milk-based formula found a significantly higher rate of surgical NEC in infants receiving the cow’s milk-based preterm formula and supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU. E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592–95 (2013).

30. A 2014 study reported that NEC is a devastating disease of premature infants associated with significant morbidity and mortality, and while the pathogenesis of the disease remains incompletely understood, it is well established that the risk of NEC is increased by the administration of infant formula and decreased by the administration of breast milk. Misty Good, *et al.*, *Evidence Based Feeding Strategies Before and After*

the Development of Necrotizing Enterocolitis, EXPERT REV. CLIN. IMMUNOL., 10(7): 875–84 (2014). The same study found that NEC “is the **most frequent and lethal** gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* (emphasis added). “NEC affects 7–12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease.**” *Id.* (emphasis added). The study concluded that advances in formula development have made it possible to prevent NEC, and the “exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC.” *Id.*

31. In another study published in 2014, it was reported that an exclusive human milk diet, devoid of cow’s milk-based products, was associated with lower risks of death, NEC, NEC requiring surgery, and sepsis in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MED., 9(6):281–86 (2014). This study concluded that the use of an exclusive human milk-based diet, using a nutritionally appropriate human milk-based fortifier, was the best option for extremely preterm infants. *Id.* at 286.

32. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both

medical and surgical NEC. A. Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MED., 11(2): 70–74 (2016). This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with significant benefits for extremely preterm infants and found that an exclusive human milk-based protocol produced no feeding-related adverse outcomes. *Id.* at 74.

33. A 2017 study reported that human milk is the preferred diet for preterm infants, protecting against a multitude of NICU challenges and especially NEC. D. Maffei and R. Schanler, *Human milk is the feeding strategy to prevent necrotizing enterocolitis!*, SEMINARS IN PERINATOLOGY, 41(1):36–40 (Feb. 2017). The study found that infants who receive greater than 50% of their mother’s breast milk in the two weeks after birth have a significantly decreased risk of NEC and that a factor in declining rates of NEC was the increased utilization of donor human milk. *Id.* at 36. “Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora.” *Id.* The study concluded that preterm infants should ideally be fed human milk and avoid bovine protein, adding that human milk-based fortifiers “can provide additional nutritional supplements necessary for adequate growth.” *Id.*

34. A 2017 publication by the American Society for Nutrition noted that

human milk has “been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC.” Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):89 (2017). This study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow’s milk-based preterm infant formula to human milk on rates of NEC occurrence. Both trials found that an exclusive human milk diet resulted in a much lower incidence of NEC. *Id.* at 87–89. While the study noted that cow’s milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products in the short-term, the cow’s milk-based products ***significantly increase the risk of NEC and death***. *Id.* at 84, 89. The long-term health care costs associated with NEC, however, were exorbitant—from 2011 to 2012, the cost of NEC in the U.S. ranged between \$180,000 and \$198,000 per infant and nearly doubled to \$313,000 per infant in cases of surgically treated NEC. *Id.* at 82. Further, NEC survivors accrue substantially higher outpatient costs. *Id.* at 82.

B. Defendants’ Strategy to Conceal the Dangers of Their Cow’s Milk-Based Formulas From Healthcare Providers and Parents

35. Recognizing a shift in the medical community towards an exclusive human milk-based diet for preterm infants, upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition began heavily promoting “human milk fortifiers,” a name which suggests the product is derived from human milk. But it is not. Defendants’ human milk fortifiers were, in fact, still cow’s milk-based products.

36. Upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition also designed competing, ongoing, systematic, and misleading marketing

campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians should consider their Cow's Milk-Based Products a first choice.

37. To further disseminate these messages throughout the scientific and medical community, upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition provided substantial monetary support to various organizations, purportedly dedicated to the research and study of relevant infant health topics, like dietetics and nutrition.

38. Upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition used their positions of prominence and power in these organizations to ghostwrite favorable publications and to silence dissenting scientific voices that might reveal the true risks associated with consuming products like Abbott's, Mead Johnson's, and Mead Johnson Nutrition's, which were derived from cow's milk.

39. Similarly, upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition marketed their products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing this was untrue and unsupported by the data.

40. Thus, despite the existence of alternative and safe human milk-based fortifiers—some of which are actually made by Abbott, Mead Johnson, or Mead Johnson Nutrition—Defendants, at all relevant times, and to this day, continue to market or to sell their Cow's Milk-Based Products, claim these products are safe, and fail to alert healthcare professionals and parents of the significant health risk posed by

ingesting these products, especially to preterm, low weight infants like Baby Boy S.A.

41. Upon information and belief, Abbott's, Mead Johnson's, and Mead Johnson Nutrition's marketing and public relations campaigns, which touted the safety, necessity, and superiority of their cow's milk-based products were motivated, at least in part, by a desire to create brand loyalty amongst doctors and parents, and ultimately to profit from the sale of their infant formula products.

42. Upon information and belief, Abbott's, Mead Johnson's, and Mead Johnson Nutrition's misinformation campaigns were incredibly successful.

43. Indeed, The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*, Geneva: World Health Org., p.2 (2018). "[A] major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to \$44.8 billion was expected to rise to \$70.6 billion by 2019. *Id.*

44. The WHO's most recent Status Report in 2020, again, took issue with these aggressive marketing tactics, recommending that legislators "recognize their obligations, both under international human rights law and international agreements, to promote and protect breastfeeding, and to eliminate inappropriate marketing practices" because "far too few countries have legal measures in place to effectively stop harmful marketing of [breast-milk substitutes]." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2020*, Geneva: World Health Org., pp.

viii, 26 (2020). The WHO also criticized “[m]anufacturers and distributors of [breast-milk substitutes]” for continuing to “target health workers for promotion of their products.” *Id.* at 23.

C. Defendants Did Not Warn Doctors or Parents That Their Cow’s Milk-Based Products Were Dangerous

45. Upon information and belief, at all relevant times and to this day, Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition promote the use of their cow’s milk-based products to parents, physicians, hospitals, and medical providers as safe and, specifically, necessary to help promote adequate growth in premature infants.

46. But Abbott, Mead Johnson, and Mead Johnson Nutrition know all three claims are untrue, upon information and belief.

47. Indeed, at all times relevant hereto, Abbott, Mead Johnson, and Mead Johnson Nutrition were aware that their cow’s milk-based products significantly increased the risk that any premature infant, like Baby Boy S.A., could develop NEC (and even die) as a result, upon information and belief.

48. Despite understanding that their products significantly increased the risk of developing NEC, Abbott, Mead Johnson, and Mead Johnson Nutrition deliberately chose to omit a specific warning regarding this risk.

49. Defendants’ cow’s milk-based products do not include any instructions or warnings detailing the risks of NEC presented by the product, namely that ingestion of cow’s milk-based product significantly increases the risks of NEC and, consequently, of death.

50. In fact, Abbott, Mead Johnson, and Mead Johnson Nutrition do not

provide any warning whatsoever—in their labeling, websites, or other marketing or promotional materials—that their cow’s milk-based products exponentially increase the risks of NEC and death in preterm infants, or that human breast milk, donor breast milk, human breast milk-based fortifiers, and non-cow’s milk-based formulas are much safer for preterm babies than their cow’s milk-based products.

51. Abbott also does not provide any detailed instructions on how to more safely use the product, such as instructions on when and how to feed preterm infants, so as to avoid an increased risk of NEC and death when using its Similac Pro-Sensitive product.

52. For example, Abbott’s Similac Pro-Sensitive contains only the following packaging information warnings and instructions:

Similac Pro-Sensitive Precautions:

- Never use a microwave oven to warm formula. Serious burns can result.
- Not For infants or children with galactosemia.

53. Mead Johnson and Mead Johnson Nutrition also do not provide any detailed instructions on how to more safely use the product, such as instructions on when and how to feed preterm infants, so as to avoid an increased risk of NEC and death when using their Enfamil product.

54. For example, Mead Johnson’s and Mead Johnson Nutrition’s Enfamil Gentle Ease contains only the following packaging information warnings and instructions:

Enfamil Gentle Ease Precautions:

- Warning: Do not use a microwave oven to warm formula. Serious

burns may result.

- Failure to follow these instructions could result in severe harm. Once prepared, infant formula can spoil quickly. Either feed immediately or cover and store in refrigerator at 35-40 F (2-4 C) for no longer than 24 hours. Do not use prepared formula if it is unrefrigerated for more than a total of 2 hours. Do not freeze prepared formula. After feeding begins, use formula within one hour or discard.

D. Circumstances of Baby Boy S.A.’s Death

55. Baby Boy S.A. was born prematurely, at 34 weeks gestation, on February 4, 2021, at Children’s Hospital Colorado Anschutz Medical Campus, in Aurora, Colorado. Baby Boy S.A. was sent home with his parents on February 8, 2021.

56. At first, Baby Boy S.A. was given human breast milk. But when she became unable to continue to breastfeed, she started feeding Baby Boy S.A. Similac Advanced Pro, at her physician’s suggestion, based on the false and misleading representations of Abbott that this product was safe and substantially similar to human breast milk.

57. In April 2021, Baby Boy S.A. was switched from Similac Pro-Sensitive to Enfamil Gentle Ease based on his doctor’s recommendation—which was, again, based on fraudulent and misleading representations by Defendants Mead Johnson and Mead Johnson Nutrition that such products were safe and substantially equivalent to human breast milk.

58. Baby Boy S.A. was continued on Mead Johnson’s and Mead Johnson Nutrition’s cow’s milk-based products until June 17, 2021, when he was transported via ambulance to the hospital, where he was diagnosed with septic shock.

59. For the next three days, Baby Boy S.A. was treated in the PICU, where

his doctors fought to save his life.

60. Despite their best efforts, including multiple resuscitations, Baby Boy S.A.'s doctors were unable to save him. Tragically, after less than four days in the hospital, Baby Boy S.A. succumbed to his injuries and was pronounced dead on June 20, 2021.

61. Plaintiff, Octavia Patton-Ashley—Baby Boy S.A.'s mother—was unaware of the fact that Abbott's cow's milk-based formulas, including Similac Advanced Pro, fed to Baby Boy S.A., were capable of causing NEC.

62. Plaintiff, Octavia Patton-Ashley—Baby Boy S.A.'s mother—was unaware of the fact that Mead Johnson's and Mead Johnson Nutrition's cow's milk-based formulas, including Enfamil Gentle Ease, fed to Baby Boy S.A., were capable of causing NEC.

63. Had Plaintiff been made aware of the facts, data, and science that linked Abbott's cow's milk-based formulas, including Similac Advanced Pro, and other cow's milk-based products to an increased risk of NEC, she would have insisted on donor breast milk, refused to feed her son a cow's milk-based formula, and/or would have requested a different non-cow's milk-based formula.

64. Had Plaintiff been made aware of the facts, data, and science that linked Mead Johnson's and Mead Johnson Nutrition's cow's milk-based formulas, including Enfamil Gentle Ease, and other cow's milk-based products to an increased risk of NEC, she would have insisted on donor breast milk, refused to feed her son a cow's milk-based formula, and/or would have requested a different non-cow's milk-based formula.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

65. Abbott willfully, wantonly, intentionally conspired, and acted in concert to withhold information from Plaintiff, Baby Boy S.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

66. Abbott, Mead Johnson, and Mead Johnson Nutrition willfully, wantonly, intentionally conspired, and acted in concert to withhold safety-related warnings from Plaintiff, Baby Boy S.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

67. Abbott, Mead Johnson, and Mead Johnson Nutrition willfully, wantonly, intentionally conspired, and acted in concert to withhold appropriate feeding instructions from the Plaintiff, Baby Boy S.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

68. Upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition willfully, wantonly, intentionally conspired, and acted in concert to ignore relevant safety concerns and deliberately not study the safety and efficacy of cow's milk-based formulas.

69. Upon information and belief, Abbott, Mead Johnson, and Mead Johnson Nutrition willfully, wantonly, intentionally conspired, and acted in concert to call into question scientific and medical literature that disputed or otherwise undermined their primary message that cow's milk-based formula was safe.

70. Due to the absence of any warning by Abbott, Mead Johnson, and Mead Johnson Nutrition as to the significant health and safety risks posed by their cow's milk-

based infant formula, Plaintiff was unaware that Similac and Enfamil could cause serious injuries, including NEC, as this danger was not known to Plaintiff or the general public.

71. Given the foregoing, Abbott, Mead Johnson, and Mead Johnson Nutrition are estopped from relying on any statute of limitations defenses.

COUNT I: STRICT LIABILITY — DESIGN DEFECT

72. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

73. At all times material to this action, Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition were engaged in the sale, or marketing or design, or manufacture, or distribution of Cow's Milk-Based Products, which are defectively designed or unreasonably dangerous to consumers, including Baby Boy S.A.

74. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as manufacturers, have a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

75. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed or sold by Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, were in a defective or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

76. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition specifically marketed and created their Cow's Milk-Based Products for use as nutrition

and nutritional supplements for preterm infants, like Baby Boy S.A.

77. Defendants' Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective or unreasonably dangerous condition.

78. Prior to Baby Boy S.A.'s death in June 2021, Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition were aware (or should have been aware) that their Cow's Milk-Based Products were not safe for use, as they were used, for nutrition or nutritional support in preterm infants, yet took no steps to prevent the use of these products in such situations.

79. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition knew or should have known that the use of their Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC and death.

80. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants like Baby Boy S.A.

81. Despite the foregoing, the Defendants continued to sell and market their defective or unreasonably dangerous products to preterm infants.

82. The products were defectively designed or unreasonably dangerous, including, but not limited to the following particulars:

- a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner,

such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC and death;

- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Baby Boy S.A. to risks of serious bodily injury and death;
- c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;
- d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;
- e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;
- f. Defendant failed to adopt an adequate or sufficient quality control program; or
- g. Defendant failed to inspect or test their products with sufficient care.

83. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonably dangerous condition, Baby Boy S.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

WHEREFORE, Plaintiff demands judgment against Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition for all applicable wrongful death damages,

costs of this action, post-judgment interest, and trial by jury.

COUNT II: STRICT LIABILITY — FAILURE TO WARN

84. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

85. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition as the manufacturers or sellers of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC and death.

86. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as the manufacturers or sellers of Cow's Milk Product, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in their Cow's Milk- Based Products, as the magnitude of the risk involved is using Defendant's Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

87. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as the manufacturers or sellers of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers of their Cow's Milk-Based Products.

88. Defendants owed a duty to provide warnings and instructions on their Cow's Milk- Based Products marketed or sold for use with preterm infants that

adequately communicated information on the dangers and safe use of the product to health care providers recommending these products and to parents feeding their children at home. Defendants should have taken into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and parents and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC and death.

89. But rather than provide adequate warnings, Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition developed relationships, which included financial incentives to health care providers and facilities for using and recommending their Cow's Milk-Based Products, such that health care providers and facilities had an incentive to withhold any instructions or warnings from the end user, upon information and belief.

90. Additionally, or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not recommended such a dangerous product.

91. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as manufacturers, have a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

92. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, through their own testing and studies, consultants and experts, or knowledge of the

scientific literature, as set forth above, knew of the significant risk of NEC with preterm infants and death.

93. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, through their knowledge, review, and survey of the scientific literature, as detailed above, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC and death.

94. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition breached the foregoing duties and failed to provide proper warnings or instructions of their Cow's Milk-Based Products, including but not limited to the following acts:

- a. Providing **no warnings** regarding the risk of NEC and death;
- b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed their products to preterm infants in order to decrease the risk of NEC or death;
- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's Cow's Milk Product;
- e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that their Cow's Milk-Based Products exponentially increased their baby's risk of developing NEC and death;

- f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn that the use of Cow's Milk-Based Products significantly increasing the risk of NEC and death, and they fail to provide any details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that their Cow's Milk-Based Products are known to significantly increase the risk of NEC and death when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked their Cow's Milk-Based Products to NEC and death in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of their products;
- j. Failed to otherwise warn physicians, healthcare providers, or parents—the ultimate end users of the product—of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;
- k. Failed to send out "Dear Doctor" letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants;
- m. Failed to warn parents of early signs and symptoms of NEC, so that parents could discontinue formula use and seek medical attention

immediately;

n. Failed to instruct parents on how to safely use their products at home so to avoid or minimize the risk of NEC, to the extent such safe use is possible; or

o. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

95. As a direct and proximate result of Defendants' failure to warn or properly instruct, Baby Boy S.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

96. WHEREFORE, Plaintiff demands judgment against Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: NEGLIGENCE

97. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

98. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as the manufacturers or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute products free of unreasonablerisk of harm to users and patients, when said products are used in their intended manner.

99. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, as

manufacturers, have a duty to hold the knowledge and skill of an expert, and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

100. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition, directly or indirectly, negligently, or defectively made, created, manufactured, designed, assembled, tested, marketed or sold the subject Cow's Milk-Based Products.

101. Defendants breached the duty owed to Plaintiff and acted negligently in their actions, including, but not limited to, the following:

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design or manufacture amounted to or resulted in a defect failure mode of the products;
- c. Failing to collect data to determine if their products were safe for preterm infants; Failing to collect data to determine when and how their products could be used safely;
- d. Failing to utilize the significant peer reviewed research to develop instructions;
- e. Failing to develop evidence-based guidelines or instructions to decrease the risk of their products causing NEC and death;

- f. Failing to provide evidence-based guidelines or instructions to decrease the risk of their products causing NEC and death;
- g. Failing to stop or deter their products from being fed to extremely preterm infants like Baby Boy S.A.;
- h. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;
- i. Failing to continuously and vigorously study their cow's milk-based products in order to avoid NEC and death in premature infants;
- j. Failing to utilize economical and technically available safer manufacturing or design alternatives for the preterm infant formula and fortifier;
- k. Failing to adopt an adequate or sufficient quality control program; or
- l. Failing to inspect or test their products with sufficient care.

102. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Baby Boy S.A.

103. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition knew or should have known that the use of their Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC and death.

104. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition had a duty to warn parents of early signs and symptoms of NEC, so the parents could discontinue formula use and seek medical attention immediately, but did not.

105. Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition had a duty to instruct parents on how to safely use their products at home so to avoid or minimize the risk of NEC, to the extent such safe use is possible, but did not.

106. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits for premature infants like Baby Boy S.A.

107. As a direct and proximate result of Defendants Abbott's, Mead Johnson's, and Mead Johnson Nutrition's failure to warn or properly instruct, Baby Boy S.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

WHEREFORE, Plaintiff demands judgment against Defendants Abbott, Mead Johnson, and Mead Johnson Nutrition for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury.

**COUNT IV: VIOLATION OF THE ILLINOIS
UNIFORM DECEPTIVE TRADE PRACTICES ACT**

27. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

28. At all times relevant, the Illinois Uniform Deceptive Trade Practices Act ("Illinois UDTPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including . . . misrepresentation or the concealment, suppression or omission of any material fact, with the intent that others rely upon the concealment, suppression or omission of such material fact." 815 Ill. Comp. Stat. Ann. 505/2.

29. Upon information and belief, as discussed herein, Abbott, Mead Johnson,

and Mead Johnson Nutrition, at all relevant times, engaged in unfair and deceptive acts by concealing and omitting significant and material facts in connection with their labeling, advertisement, and sale of their cow's milk-based infant formulas, including Similac and Enfamil.

30. Upon information and belief, as discussed herein, Abbott, Mead Johnson, and Mead Johnson Nutrition, at all relevant times, misrepresented the benefits of cow's milk-based infant formulas, including Similac and Enfamil, by omitting significant and material facts in their marketing, promotion, sale, and labeling of their cow's milk-based infant formulas, including the fact that their cow's milk-based infant formulas significantly increased the risk of developing NEC. In fact, the entire time Baby Boy S.A. was prescribed and ingested Abbott's, Mead Johnson's, and Mead Johnson Nutrition's cow's milk-based infant formula, the label (and corresponding advertisements and marketing materials) contained no warnings concerning NEC at all.

31. Instead of including applicable warnings or appropriate instructions, Abbott, Mead Johnson, and Mead Johnson Nutrition misleadingly advertised only the purported benefits of cow's milk-based infant formulas, but did not disclose any risks relative to NEC. Indeed, Abbott, Mead Johnson, and Mead Johnson Nutrition did not disclose any warnings associated with use of the product, including, but not limited to, the increased risk of developing NEC, which could lead to severe complications including death.

32. Upon information and belief, Abbott's, Mead Johnson's, and Mead Johnson Nutrition's advertisements and marketing materials concerning cow's milk-based infant formulas, including Similac and Enfamil, which were created and

disseminated by Abbott, Mead Johnson, and Mead Johnson Nutrition, were intended to induce healthcare providers to prescribe cow's milk-based infant formulas, including Similac and Enfamil, and parents to feed their infants cow's milk-based infant formulas, including Similac and Enfamil.

33. And indeed, Baby Boy S.A.'s parents and his healthcare providers detrimentally relied on the information contained in Abbott's, Mead Johnson's, and Mead Johnson Nutrition's labeling, advertising, and other marketing materials. Such statements though, in reality, deceptive and untrue formed, at least in part, the basis of Baby Boy S.A.'s physicians' decision to recommend and prescribe a cow's milk-based infant formula, like Similac and Enfamil, as well as the decision of Plaintiff—Baby Boy S.A.'s mother—to feed her infant a cow's milk-based infant formula, like Similac and Enfamil.

34. Such advertisements and statements with respect to cow's milk-based infant formulas, including Similac and Enfamil, were misleading, demonstrably false, and violated the Illinois UDTPA.

35. As a result of violating the Illinois UDTPA, Abbott, Mead Johnson, and Mead Johnson Nutrition caused Baby Boy S.A.'s doctors to recommend cow's milk-based infant formulas, including Similac and Enfamil, and Baby Boy S.A. to be fed cow's milk-based infant formulas, including Similac and Enfamil, which caused severe injuries and damages as previously described herein.

36. Additionally, and in the alternative, as a result of violating the Illinois UDTPA, Abbott, Mead Johnson, and Mead Johnson Nutrition also caused Baby Boy S.A.'s injuries to be more severe than they otherwise would have been, if Baby Boy

S.A.'s doctors had been given appropriate instructions, adequate safety information, and been advised to stop formula feeds, seek medical treatment, or medical intervention sooner.

37. Accordingly, Plaintiff is entitled to damages under the Illinois UDTPA.

PRAYER FOR RELIEF

38. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate Plaintiff:

- a. Baby Boy S.A.'s medical expenses, physical pain and suffering, and other compensatory damages to be proven at trial;
- b. Damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Abbott's, Mead Johnson's, and Mead Johnson Nutrition's conduct;
- c. Past, present, and future out-of-pocket costs, lost income, revenue, profits, or business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended for Plaintiff;
- d. Attorney's fees, expenses, and recoverable costs incurred in connection with this action;
- e. Plaintiff's Loss of Enjoyment of Life;
- f. Pre- and Post-Judgment Interest;
- g. Exemplary and Punitive Damages;

