UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

SAMANTHA CLARKE, on her own behalf and as representative of the estate of PHOENIX JEFFRIES, *Plaintiff*, v. ABBOTT LABORATORIES, SERVE: The Corporation Company 120 South Central Avenue Suite 400 St. Louis, MO 63105 And MEAD JOHNSON & COMPANY, LLC, SERVE: CSC-Lawyers Incorporating Service Co. 221 Bolivar Street Jefferson City, MO 65101 And MEAD JOHNSON NUTRITION COMPANY SERVE: CSC-Lawyers Incorporating Service Co. 221 Bolivar Street Jefferson City, MO 65101 *Defendants.*	Case No.: 4:22-cv-144 COMPLAINT JURY TRIAL DEMANDED

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Abbott Laboratories ("Abbott") and Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company (together "Mead")(collectively "Defendants). Plaintiff alleges the following

upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters:

NATURE OF THE ACTION

1. This action arises out of injuries suffered by a premature and high-risk infant (the "Injured Infant") who was given Defendants' cow's milk-based infant feeding products. Defendants' products caused the Injured Infant to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result, this infant was seriously injured, resulting in death or long-term health effects and harm to her parents ("Plaintiff Parents").

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant's consumption of Defendants' unreasonably dangerous cow's milk-based infant feeding products.

PARTIES

3. Samantha Clarke is the mother of Phoenix Jeffries and a citizen and resident of the state of Missouri and has at all relevant times resided in Warrenton, Missouri (located in Warren County). Plaintiff is the mother of decedent Phoenix Jeffries and brings this suit in her personal capacity and as Representative of the Estate of Phoenix Jeffries, deceased.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC (together,

"Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois, with its principal place of business in Illinois. Abbott is a manufacturer of cow's milk-based infant formula products and markets many of these products under the brand name "Similac."

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332 because there is complete diversity of the Plaintiff and the Defendants and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

7. This Court has personal jurisdiction over each defendant because a state court in the State of Missouri would have such jurisdiction pursuant to the Missouri Long-Arm Statute, R.S. Mo. 506.500.

8. Venue is proper in this district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this district in that Plaintiff's claims and injuries arise from Phoenix Jeffries's use of baby formula in this district, which was distributed and sold for use in this district, actually purchased or purchased for use in this district, and being used in this district when the ingestion causing Baby Jeffries's injuries and damages occurred.

FACTUAL ALLEGATIONS

A. Baby Jeffries's Development of NEC

9. Baby Jeffries was born on September 13, 2021 at Mercy Hospital in St. Louis at 31 weeks gestational age weighing just 1535 grams.

10. Phoenix was fed Similac and/or Enfamil cow's milk-based products shortly after her birth.

11. Shortly after she first ingested Defendants' products, Phoenix developed NEC.

12. On September 22, 2021, Phoenix Jeffries exhibited a swollen abdomen and Plaintiff Samantha Clarke was notified that Baby Jeffries would need to be fed with an IV. Plaintiff Samantha Clarke returned to the NICU at Mercy Hospital St. Louis as Baby Jeffries's condition continued to deteriorate and was diagnosed with necrotizing enterocolitis. On September 21, 2021, Phoenix Jeffries endured an exploratory laparotomy, which revealed Necrotizing Enterocolitis *totalis*, a condition where the entirety of the intestinal tract is necrotic and is inoperable. At this point, Phoenix Jeffries was started on comfort care and Plaintiff Samantha Clarke and her family visited the NICU for the last hours of Phoenix Jeffries's life. Phoenix Jeffries passed away from NEC shortly after.

B. Cow's Milk-Based Feeding Products are Known to Cause NEC

13. NEC is a devastating disease that is most frequent and lethal gastrointestinal disorder affective preterm infants. NEC is a gastrointestinal disorder that develops when pathogenic bacteria breach the protective walls of the intestine through a process called bacterial translocation, which results in inflammation and death (necrosis) of portions of the intestine. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

14. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm

and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

15. For example, a 1990 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 fed breast milk alone and ***three times*** more common than in those who received formula plus breast milk. The study showed that babies born after 30 weeks gestation rarely developed NEC when their diet included breast milk but was ***twenty times*** more common in those fed formula only.

16. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and human milk fortifier, these babies were **90% less likely to develop surgical NEC**.

17. Yet another study that analyzed the date from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

18. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warning that **"For vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)."** This same report stated that premature infants who are not breastfed are ***138% more likely*** to develop NEC.

19. The *American Academy of Pediatrics* has advised that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of cow-based formula. This recommendation is based on the "potent benefits of human milk," including "lower rates of … NEC."

20. A study published in 2013 showed that all 104 premature infants participating in

the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and HC gain (weight and head circumference). 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." Thus, inadequate growth was proven to be a poor excuse for feeding cow's milk-based formula.

21. A 2013 multicenter, randomized, controlled trial found that premature and low birth-weight infants fed exclusively human milk-based diets developed NEC only 3% of the time while premature and low birth weight infants fed cow's milk-based formula and fortifier products developed NEC ***21% of the time***.

22. This finding was replicated in a 2014 study of randomized extremely premature infants, where infants fed exclusively human milk-based products developed NEC just 5% of the time while those given cow's milk-based products developed NEC 17% of the time.

C. <u>Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist</u>

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and milk fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets,

demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breask milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. Defendants' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time the Injured Infants were fed Defendants' products, the science clearly demonstrated to Defendants that these products cause and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that Defendants' cow's milk-based products present a dire threat to the health and development of preterm infants, Defendants have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, Defendants have continued to sell their unreasonably dangerous products to unsuspecting parents and healthcare providers, generating huge profits as a result.

D. Defendants' False and Misleading Marketing of Cow's Milk-Based Formula

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to Injured Infants' birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that Defendants' cow's milk-based formulas and fortifiers are necessary for the growth and development of their vulnerable children. These tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. *None* of Defendants' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Defendants know their advertising efforts disincentivize breastfeeding and incentivize the use of formula and that this boosts their profits. Defendants, along with other formula manufacturers, spend exorbitant sums of money to continue this trend. In 2014 alone, formula manufacturers spent $4.48 billion on marketing.

33. In 1981, the World Health Assembly, the decision-making entity for the World Health Organization, recognized the abuse and dangers of infant formula marketing and developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect of

introducing partial bottle-feeding on breastfeeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, including providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, Defendants' aggressive marketing exploits new parents' darkest fears – that the nutrition they are supplying to their child will not provide the best chance of survival – while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a page titled "Infant Formula Marketing" states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed – for medical reasons or otherwise – **infant formula is the only appropriate, safe alternative** to meet babies' nutritional needs." This statement ignores the existence of donor milk and human milk-based formula products.

36. Abbott markets and sells multiple products specifically designed for premature and low birth-weight infants including Liquid Protein Fortifier, Similac Neosure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of

the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Abbott emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and "Includes expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancement in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of **breast milk research** and

multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive **breast milk studies** to date" (emphasis added).

39. Mead recognizes that many countries have adopted the Code as law and thus states on its website, on a page titled "Terms of Use," "Mead Johnson Nutrition endorses the aim of the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes in developing countries, including standards for product integrity, labeling, distribution, and promotion." Mead quotes from the code that "breastfeeding is best for infants," but then contradicts the WHO by stating that "Formula, when used properly, provides a sound nutritious substitute or supplement to breast milk, but it is more expensive."

40. Abbott and Mead have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk, offering free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-of-town families stay while their babies receive long-term treatment in the NICU.

41. Through this early targeting, Defendants create brand loyalty under the guise of a "medical blessing," in hopes that new parents will continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for Defendants. Defendants' gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their health care professionals, and they have been shown to negatively impact breastfeeding rates.

42. Further, when Defendants recognized a shift in the medical community towards providing exclusive human milk-based diets for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier."

These names are misleading as it suggests that the product itself is derived from human milk when in fact it is a cow's milk-based product. For example, one study, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product.

43. Defendants have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider their brand's cow's milk-based products a first choice. This marketing scheme is employed despite Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infants.

E. Defendants' Inadequate Warnings

44. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of preterm infants, the product is in fact extremely dangerous for premature infants. Enfamil products substantially increase the chances of a preterm infant developing potentially fatal NEC.

45. The Enfamil products Mead markets specifically for premature infants are commercially available at retail stores and online and do not require a prescription.

46. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC and the resulting complications associated with Enfamil products or the magnitude of this increased risk. Furthermore, Mead did not provide instructions or guidance for how to prevent NEC.

47. Mead does not cite any medical literature or research to guide the use of its products.

48. Mead deceived the public, parents, physicians, other medical professional, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are commercially available at retail stores and online and do not require a prescription.

52. Despite knowing of the risk of NEC, the packaging of Abbott's products does not warn of the significantly increased risk of NEC and the resulting complications associated with Enfamil products or the magnitude of this increased risk. Furthermore, Abbott did not provide instructions or guidance for how to prevent NEC.

53. Abbott deceived the public, parents, physicians, other medical professional, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

F. Safer Alternative Designs

55. Defendants' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. Defendants could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

56. Prolacta Bioscience manufacturers and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

57. Upon information and belief, Abbott and Mead were aware of the significantly increased risk of NEC, devastating injuries, and/or death associated with its cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

COUNT I: STRICT LIABILITY – DESIGN DEFECT
(Against All Defendants)

58. Plaintiffs incorporate by reference each of the preceeding paragraphs as if fully set forth herein.

59. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

60. Defendants also owed a duty to the consuming public and Plaintiffs in particular to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for the intended use.

61. Abbott and Mead knew that their products would be used to feed premature infants, like the Injured Infants, and knew or reasonably should have known that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

62. The Injured Infants ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infants outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

63. Abbott and Mead knew or reasonably should have known that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that Defendants' products do.

64. Abbott's and Mead's products contained cow's milk, cow's milk derivatives, and cow's milk proteins at the time they left Defendants' manufacturing facilities and at the time they left Defendants' control.

65. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious

injury, and death, even though doing so was economically feasible and even though pasteurized breast milk was an available alternative.

66. Abbott's and/or Mead's products were fed to the Injured Infants, which directly and proximately caused their NEC and led to injury and death.

67. As a further direct and proximate result, Plaintiff Parents incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and/or other harms. Their lives have been significantly affected by the Injured Infant's injuries and/or death.

COUNT II: STRICT LIABILITY – FAILURE TO WARN
(Against All Defendants)

68. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

69. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their cow's milk-based formula products in the feeding of premature infants, including the risk of NEC, serious injuries resulting from NEC, and death.

70. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Defendants undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

71. Abbott and Mead breached their duty to warn of the foreseeable risks of the infant formula and fortifier products at issue because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause such infants to develop NEC, severe injury, or death, yet Defendant failed to provide adequate warnings of those risks. Among other risks, Defendants:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature infants; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of safety and security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to carry 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 breast milk in premature infants; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants' products, notwithstanding the substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the baby's parents and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

72. Abbott's and Mead's products contained cow's milk ingredients and thus were defective at the time they left the control of Defendant.

73. At the time of manufacturing, the likelihood that Abbott's products would cause NEC, serious injury, and death, and the seriousness of those harms, rendered the included warnings inadequate, and Abbott could have included adequate warnings about the risk of these harms.

74. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendants' products, the Injured Infant was fed cow's milk-based products, which caused them to develop NEC.

75. The risks Defendants failed to warn of are not of a kind that an ordinary consumer would expect. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infants these products. Had Plaintiff Parents known of the significant risks of NEC as a result of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to their children.

76. As a direct and proximate result of Defendants' failure to warn, Plaintiff Parents incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and/or other harms. Their lives have been significantly affected by the Injured Infant's injuries and/or death.

COUNT III: NEGLIGENCE
(Against All Defendants)

77. Plaintiffs incorporate by reference each of the follow paragraphs as if fully set forth herein.

78. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

79. At all times relevant to this action, the Injured Infant's health care providers used the products at issue in their intended manner and for their intended purpose.

80. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and Plaintiffs.

81. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant formula and fortifier products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty to the consuming public in general and Plaintiffs by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Carrying warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to carry 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 breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the baby's parents; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

82. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

83. As a direct and proximate result of Defendants' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused her to develop NEC.

84. Had Abbot and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

85. As a further direct and proximate result, Plaintiff Parents incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and/or other harms. Their lives have been significantly affected by the Injured Infant's injuries and/or death.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against All Defendants)

86. Plaintiffs incorporate by reference each of the preceeding paragraphs as if fully set forth herein.

87. At all times relevant to this litigation, the Injured Infant and her caretakers used the products at issue in their intended manner and for their intended purpose.

88. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, full information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

89. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein each of whom were foreseeable and intended recipients of this information.

90. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

91. Abbot and Mead knew or reasonably should have known those misrepresentations to be false.

92. Defendants' misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including the Injured Infant's hospital and health care providers, to provide their infant products to babies, including the Injured Infant.

93. Plaintiff Parents were not aware that these misrepresentations were false and justifiably relied on them. Defendants' misrepresentations induced Plaintiff Parents to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Abbot and Mead not committed these intentional misrepresentation, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

94. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, causing her NEC and subsequent health impacts and death.

95. As a further direct and proximate result, Plaintiff Parents incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and/or other harms. Their lives have been significantly affected by the Injured Infant's injuries and death.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against All Defendants)

96. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

97. At all times relevant to this action, the Injured Infant, by and through her physicians, medical professionals, medical staff, nurses, and their families, used the products at issue in their intended manner and for their intended purpose.

98. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, and complete information about the risks and benefits of using its products when used in the intended manner and for the intended purpose.

99. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

100. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated bases and prior to the time the Injured Infant were fed Defendants' products:

a. That its cow's milk-based products were safe and beneficial for preterm infants; and/or

b. That it's cow's milk-based infant formula products were necessary to the growth and nutrition of preterm infants; and/or

c. That its products have no serious side effects; and/or

d. That cow's milk-based infant formula products are safe for preterm infants; and/or

e. That cow's milk-based infant formula products are necessary for optimum growth; and/or

f. That cow's milk-based infant formula products are similar or equivalent to breast milk; and/or

g. That Enfamil Premature was safe and more like breast milk than other infant formula products; and/or

h. That its products were based on up-to-date science, which made them safe for preterm infants.

101. Abbott and Mead were negligent or careless in not determining those representations to be false.

102. Defendants' misrepresentations were intended to and did in fact induce hospitals and healthcare providers, including the Injured Infant's hospital and health care providers, to provide their products to premature infants, including the Injured Infant.

103. Defendants' misrepresentation induced, and were intended to induce, Plaintiff Parents to allow their children to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, Defendants' messaging.

104. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

105. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, causing her NEC and the subsequent health impacts.

106. As a further direct and proximate result, Plaintiff Parents incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and/or other harms. Their lives have been significantly affected by the Injured Infant's injuries and death.

COUNT VI: LOSS OF CONSORTIUM
(Against All Defendants)

107. Plaintiffs incorporate by reference each of the preceeding paragraphs as if fully set forth herein.

108. Loss of filial consortium is a derivative claim. It is derivative of each of the claims and allegations above.

109. At all relevant times Plaintiff Parents were the Injured Infant's lawful parents.

110. As a result of Defendants' tortious conduct, Plaintiff Parents suffered a loss of affection, companionship, society, and consortium of their children.

COUNT VII: SURVIVAL ACTION
(Against All Defendants)

111. Plaintiffs incorporate by reference each of the preceeding paragraphs as if fully set forth herein.

112. Plaintiff Parents of each Injured Infant Decedent, or their Estates, are entitled to damages for the harms inflicted upon the decedent, as provided under applicable state law.

COUNT VIII: WRONGFUL DEATH ACTION
(Against All Defendants)

113. Plaintiffs incorporate by reference each of the preceeding paragraphs as if fully set forth herein.

114. Plaintiff Parents of each Injured Infant Decedent, or their Estates, are entitled to damages for the harms inflicted upon the decedent, and for harms inflicted on herself, as provided under applicable state law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

115. For compensatory damages in an amount to be proven at trial;

116. For 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 Defendants' conduct;

117. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

118. For interest as permitted by law, both prejudgment and post-judgment;

119. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

120. For such other further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Respectfully submitted,

[redacted]