UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARCIA LAWARY, INDIVIDUALLY AND AS NEXT FRIEND TO L.M., A MINOR, ***Plaintiffs*,** **v.** **MEAD JOHNSON & CO. LLC AND MEAD JOHNSON NUTRITION COMPANY,** ***Defendants*.**	**CIVIL ACTION NO. _____** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs bring this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Co. LLC and Mead Johnson Nutrition Company (collectively, "Defendants"). Plaintiffs allege the following upon personal knowledge as to Plaintiffs' own acts and experiences and upon information and belief, including investigation conducted by Plaintiffs' attorneys, as to all other matters.

NATURE OF ACTION

This action arises out of the injuries suffered by a premature infant, L.M. (the "Injured Infant"), who was given Defendants' cow's milk-based infant feeding products. Defendants' products cause 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 both physical pain and long-term health effects. As a result of these injuries the Injured Infant's parent also suffered

emotional distress psychological injury, and financial harms. Plaintiffs bring these causes of action against Defendants to recover from 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

1. Plaintiff Marcia Lawary (the "Plaintiff Parent") is a natural person and a resident of North Carolina.

2. Plaintiff L.M. is a minor child born on August 30, 2013. L.M. is the child of Marcia Lawary.

3. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the state of Delaware. Its principal place of business is in Indiana.

4. Defendant Mead Johnson & Co. 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.

5. Defendants Mead Johnson Nutrition Company and Mead Johnson & Co. LLC, (collectively, "Mead Johnson") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 USC §1332 because Plaintiffs are residents of North Carolina, neither of the Defendants are residents of North Carolina, and the amount in controversy is over $75,000.00.

7. Venue is proper in this District pursuant to Case Management Order No. 11 of MDL 3026 stating that any plaintiff whose case would be subject to transfer to MDL 3026 may file his

or her case directly in MDL 3026 in the Northern District of Illinois. *See* Dkt. 296, Case 1:22-md-3026-RRP. Additionally, venue is appropriate in this district as a significant portion of the facts giving rise to this claim occurred in this district.

8. If not for Case Management Order No. 11, Plaintiff would have filed, and venue is proper, in the United States District Court for the Middle District of North Carolina.

FACTUAL ALLEGATIONS

L.M.'s NEC Diagnosis

9. L.M. was born prematurely at Cone Health Women's & Children's Center at Moses Cone Hospital in Greensboro, North Carolina on August 30, 2013.

10. L.M. was fed Enfamil cow's milk-based formula shortly after her birth.

11. Shortly after L.M. first ingested Defendants' product, she developed NEC.

12. L.M. was forced to undergo surgery, suffered NEC symptoms and accompanying harm, and has continued to suffer long-term health effects.

Cow's Milk-Based Feeding Products Are Known To Cause NEC

13. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria invade the walls of the intestine causing local infection and inflammation that can ultimately destroy the intestinal wall. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30% 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 numerous 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, in one randomized multicenter study of 926 preterm infants, NEC was ***six to ten*** times more common in exclusively cow's milk-based formula fed babies than in exclusively breast milk-fed babies and ***three times*** more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks' gestation, NEC was ***twenty times more common*** in those only fed cow's milk-based formula than in those fed breast milk.

16. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were ***90% less likely*** to develop surgical NEC (NEC that requires surgical treatment) compared to preterm babies fed a diet that included some cow's milk-based products.

17. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with the 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 the breast milk-based fortifier.

18. A Surgeon General report, *The Surgeon General's Call to Action to Support Breastfeeding* warns that "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are ***138% more likely*** to develop NEC.

19. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that ***all*** premature infants should be fed either of their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This

recommendation is based on the "potent benefits of human milk," including "lower rates of…NEC."

20. A multicenter randomized controlled trial found that premature and low birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low birth-weight infants receiving cow's milk-based formula suffered ***NEC 21% of the time***.

21. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The baby's given cow's milk-based products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

22. 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.

23. 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 breast 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 breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

24. 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.

25. 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.

26. At the time the Injured Infant was fed Defendants' products, the science clearly demonstrated to Defendants that these products cause and greatly increased the likelihood that a baby will develop NEC, leading to severe injury and often death.

27. 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.

Defendants' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

28. Mead Johnson has aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

29. Mead Johnson'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. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. *None* of the defendants marketing materials, including their promotional websites, referenced the science showing how significantly their products increased the risk of NEC.

30. 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.

31. Undoubtedly aware of the impact of their advertising, Defendants, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

32. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly - the decision-making body of the World Health Organization - 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 on breastfeeding of introducing partial bottle feeding, 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, as well as providing sample products to mothers or members of their families.

33. While Mead Johnson acknowledged The Code 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're supplying their child will not provide the best chance of survival - wholly failing to warn that their products come with significantly increased risk of NEC.

34. Mead Johnson 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, Mead Johnson 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 noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

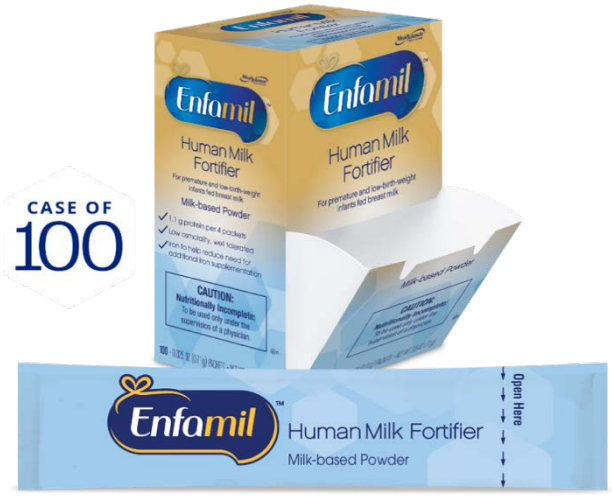
35. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has

inspired the advancements 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).

36. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer 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.

37. Through this early targeting, Defendants create brand loyalty under the guise of a "medical blessing," in hopes that new parents 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.

38. Further, when Defendants recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Mead Johnson developed "Enfamil Human Milk Fortifier." The name is misleading because it suggests that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, 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. The packaging appears as:



39. 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 Defendants' cow's milk-based products to be 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 Infant.

Defendants' Inadequate Warnings

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

41. The Enfamil products Mead Johnson markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

42. Despite knowing of the risk of NEC, the packaging of Mead Johnson's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or

death) associated with Mead Johnson's products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

43. Mead Johnson cites no medical literature or research to guide the use of its products.

44. Despite knowing of the risk of NEC, Mead Johnson did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

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

46. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead Johnson 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.

Safer Alternative Designs

47. Mead Johnson's 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.

48. Prolacta Bioscience manufactures 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.

49. On information and belief, Mead Johnson was aware of the significantly increased risk of NEC and death associated with their cow's milk-based products. Instead of warning of the dangers, or removing them altogether, Mead Johnson has continued to use cow's milk as the foundation of their products.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT

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

51. Defendants 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.

52. Defendants also 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 merchantable and reasonably suited for the intended use.

53. Defendants knew that their products would be used to feed premature infants like the Injured Infant 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.

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

55. Defendants knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

56. Defendants' products contained cow's milk at the time they left the manufacturing facility.

57. Defendants 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 and technologically feasible and even though pasteurized breast milk was an available alternative.

58. Defendants' products were fed to the Injured Infant, which directly and proximately caused their NEC and led to long-lasting injuries.

59. As a further direct result, Plaintiff Parent incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiffs' lives have been significantly affected by the Injured Infant's injuries.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN

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

61. Defendants, 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 products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

62. Defendants' 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.

63. Specifically, Defendants breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation 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 those infants to develop NEC, severe injury, or death, yet they 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 those babies; and/or

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

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

d. Failed to insert 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 their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns; and/or

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

64. Defendants' products contained cow's milk at the time they left the manufacturing facility.

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

66. The unwarned of risks 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 Infant those products. Had Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, Plaintiff Parent would not have allowed such products to be fed to her child.

67. As a further direct result, Plaintiff Parent incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiffs' lives have been significantly affected by the Injured Infant's injuries.

COUNT III: NEGLIGENCE

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

69. Defendants, 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.

70. 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.

71. Defendants, 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.

72. Specifically, although Defendants knew or reasonably should have known at the time of production that their cow's milk-based infant 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:

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 contra-indicated for premature infants like the Injured Infant; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that Defendants 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 insert 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 parents of newborns; and/or

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

73. In addition, although Defendants 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.

74. 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 him to develop NEC.

75. Had Defendants 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.

76. As a further direct result, Plaintiff Parent incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiffs' lives have been significantly affected by the Injured Infant's injuries.

COUNT IV: INTENTIONAL MISREPRESENTATION

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

78. At all times relevant to this action, the Injured Infant (and their caretakers) used the products at issue in their intended manner and for their intended purpose.

79. Defendants, 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, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

80. Defendants 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.

81. Specifically, upon information and belief, Defendants 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 were 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.

82. Defendants knew or reasonably should have known those misrepresentations to be false.

83. 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.

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

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

86. As a further direct result, Plaintiff Parent has incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiff's lives have been significantly affected by the Injured Infant's injuries.

COUNT V: NEGLIGENT MISREPRESENTATION

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

88. At all times relevant to this action, the Injured Infant used Defendants' products at issue in their intended manner and for their intended purpose.

89. Defendants, 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 their products when used in the intended manner and for the intended purpose.

90. In the course of their business, Defendants 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 recipients of this information.

91. Specifically, upon information and belief, Defendants 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 their cow's milk-based products were safe for premature infants; and/or

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

f. That their 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 were 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.

92. Defendants were negligent or careless in not determining those representations to be false.

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

94. Defendants' misrepresentations induced, and were intended to induce, Plaintiff Parent to allow her child to be fed Defendants' infant products, in justifiable reliance on all the messaging received about formula feeding, including, directly or indirectly, from Defendants' messaging. Had Defendants not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

95. As a direct and proximate result, Defendants' products were fed to the Injured Infant, causing him NEC and the subsequent health impacts.

96. As a further direct result, Plaintiff Parent incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiffs' lives have been significantly affected by the Injured Infant's injuries.

COUNT VI: BREACH OF EXPRESS WARRANTY

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

98. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting its cow's milk-based feeding products, which are defective and unreasonably dangerous to consumers, including Plaintiffs. These actions were under the ultimate control and supervision of Defendants.

99. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of cow's milk-based feeding products, including a duty to:

a. Ensure that their products did not cause the user unreasonably dangerous side effects; and/or

b. Warn of dangerous and potentially fatal side effects; and/or

c. Disclose adverse material facts, such as the true risks associated with the use of and exposure to cow's milk-based feeding products, when making representations to the FDA (Food and Drug Administration), consumers, and the general public, including the Plaintiff.

100. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with its products is not limited to representations made on the labeling.

101. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Mead Johnson's cow's milk-based feeding products were safe for premature babies' health, effective, fit, and proper for their intended use.

102. Defendants advertised, labeled, marketed, and promoted its products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its cow's milk-based formula products would conform to the representations.

103. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Mead Johnson's cow's milk-based formula products. Defendants knew and/or should have known that the risks expressly included in the warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that its cow's milk-based formula products were safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective as preterm baby formula.

104. The representations about Mead Johnson's cow's milk-based products, as set forth herein, contained, or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

105. Defendants placed its cow's milk-based products into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of premature babies developing injuries associated with the ingestion of cow's milk-based products.

106. Defendants breached these warranties because, among other things, its cow's milk-based products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe

for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that its products were safe, and intentionally withheld and concealed information about the risks of premature babies developing serious injuries associated with the use of cow's milk-based formula products; and

b. Defendants represented that its products were safe for use and intentionally concealed information that demonstrated that human breast milk was a safer alternative than cow's milk-based formula.

107. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of cow's milk-based products in deciding to consume the product. Plaintiffs reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products. Plaintiff would not have ingested products had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of disclosure.

108. Defendants had sole access to material facts concerning the nature of the risks associated with their products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiff Parent could not have reasonably discovered that the risks expressly included in its warnings and labels were inadequate and inaccurate.

109. Plaintiff had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning its cow's milk-based products.

110. Plaintiff was exposed to cow's milk-based products as manufactured, tested, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

111. Had the labels, advertisements, or promotional material for its products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information, and warranting that the products were safe for their intended use, Plaintiff could have avoided the injuries complained of herein.

112. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs have sustained pecuniary loss and general damages in a sum exceeding this court's jurisdictional minimum.

113. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great personal injury and damages.

114. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

COUNT VII: BREACH OF IMPLIED WARRANTY

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

116. At all relevant times, the Defendants controlled its cow's milk-based products. Defendants designed, developed, tested, labeled, packaged, distributed, marketed and/or sold their cow's milk-based products, including the products ingested by Plaintiff.

117. At all relevant times, Defendants intended premature babies to ingest their cow's milk-based products, and Defendants impliedly warranted their cow's milk-based products to be of merchantable quality and fit for consumption.

118. Injured Plaintiff was foreseeable user of cow's milk-based products.

119. The Defendants knew or had reason to know that Plaintiff Parent would rely on the Defendants' judgment and representations regarding the safety of their cow's milk-based products for premature babies.

120. The Defendants' cow's milk-based products were expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was labeled and sold by the Defendants.

121. The Defendants breached various implied warranties with respect to its cow's milk-based products in that they were not fit for its intended purpose or ordinary use, and specifically, that the Defendants represented that their cow's milk-based formula product was safe for premature babies and would not cause NEC when ingested.

122. In reliance upon the Defendants' implied warranty, Plaintiff ingested the products in a manner normally intended, recommended, promoted, and marketed by the Defendants.

123. The Defendants' breach of their implied warranty regarding their cow's milk-based formula products was a substantial factor in causing Plaintiffs' injuries.

COUNT VIII: DECEPTIVE TRADE PRACTICES

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

125. By the conduct described in detail above and incorporated herein, Defendants engaged in unfair or deceptive acts that violated North Carolina G.S. 75-1.1.

126. Plaintiffs used Defendants' products for personal use and thereby suffered ascertainable losses because of Defendants' actions.

127. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have used Defendants' product and would not have incurred related injuries and damages.

128. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monetary gain from Plaintiffs for the Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

129. Defendants engaged in unfair methods of competition and deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have; and

b. Failing to disclose information concerning goods or services that was known at the time of the transaction inducing the consumer into a transaction into which the consumer would not have entered if the information had been disclosed; and

c. Defendants intended for Plaintiffs to rely on their representations and advertisements regarding the Products in order to achieve monetary gain from Plaintiffs through her purchase of the Products. Plaintiffs was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at Plaintiffs and other consumers was to create demand for and sell the Products.

130. Defendants' intentional, deceptive, unconscionable, and fraudulent representations and material omissions to Plaintiffs, physicians, and consumers, constituted unfair and deceptive acts and trade practices.

131. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or has made false representations.

132. Defendants have actual knowledge of the defective and dangerous condition of Defendants' products and failed to take any action to cure such defective and dangerous conditions.

133. Plaintiffs relied upon Defendants' misrepresentations and omissions in determining which product to use.

134. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to Plaintiffs and other consumers constituted deceptive acts and practices.

135. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs, suffered ascertainable losses and damages.

136. As a direct and proximate result of Defendants' violations of consumer protection laws, Plaintiffs sustained economic losses including medical care.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgement as follows:

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

138. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained by Plaintiffs because of Defendants' conduct.

139. 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 will likely be, recommended.

140. For interest as permitted by law.

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

142. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Dated: November 14, 2024

RESPECTFULLY SUBMITTED,

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