IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

A.F., a minor, by and through his Parent and Next Friend, SASHA STEWART
5105 Cedgate Rd.
Baltimore, Maryland 21206
Baltimore County

and

SASHA STEWART
5105 Cedgate Rd.
Baltimore, Maryland 21206
Baltimore County

Plaintiffs,

v.

MEAD JOHNSON & COMPANY, LLC
2701 Patriot Blvd.
Glenview, Illinois 60026

Serve:
Corporation Service Company
1201 Hays Street
Tallahasee, FL 32301

and

MEAD JOHNSON NUTRITION COMPANY
2701 Patriot Blvd.
Glenview, Illinois 60026

Serve:
Corporation Service Company
300 Deschutes Way, Suite 208 Mc-Csc1,
Turnwater, WA 98501

Defendants.

Civil Action No.:

COMPLAINT AND JURY TRIAL DEMAND

COMPLAINT FOR DAMAGES

This action arises out of the injuries suffered by a premature infant who was fed Defendants' cow's-milk-based infant formulas and/or fortifiers. *Necrotizing Enterocolitis* (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC may lead to surgery and to death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow's milk-based formula or fortifier products. The companies who manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the healthcare community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, the premature infant was fed these cow's milk-based products, developed NEC and suffered significant injuries, which caused his mother to incur extensive economic and emotional damages.

Plaintiffs, A.F., a minor (hereinafter "Baby A.F."), by and through his parent and next friend Sasha Stewart, and Sasha Stewart, individually (hereinafter "Baby A.F.'s Mother"), bring this cause of action against Defendants for claims arising as the direct and proximate result of Defendants' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendants' cow's milk-based products (collectively "Cow's Milk-Based Products").

GENERAL ALLEGATIONS

1. Plaintiffs bring this Complaint for Damages and Demand for Jury Trial against Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (together "Mead")

(collectively "Defendants"), and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

JURISDICTION AND VENUE

2. This Court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiffs and the Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

3. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct business and do conduct business in the State of Maryland, purposefully direct and/or directed their actions toward and/or within Maryland. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within the State of Maryland, the damages were sustained by Plaintiff within the State of Maryland, and the damages sustained by Plaintiff were a result of Defendants' actions and/or inactions, described herein, that were purposefully directed at and/or within the State of Maryland. Further, Defendants have marketed, promoted, distributed, and/or sold their products described herein in the State of Maryland. Defendants have sufficient minimum contacts with this state and/or sufficiently avail themselves of the markets in the state through their promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

4. Venue of this action is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district, Defendants have sufficient minimum contacts with Maryland, and Defendants intentionally availed themselves of the markets within it through the promotion, sale, marketing, and distribution of their products.

PARTIES

5. Baby A.F. was born prematurely at The Johns Hopkins Hospital in Baltimore, Maryland on September 14, 2019. Baby A.F. developed NEC after being fed Cow's Milk-Based Products while in the Newborn Intensive Care Unit ("NICU"). At all times material hereto, Baby A.F. was domiciled in and a citizen of the State of Maryland.

6. Baby A.F.'s Mother, Sasha Stewart, is a citizen and resident of the State of Maryland and has at all relevant times resided in Baltimore County, MD. Baby A.F's Mother brings this action to recover for Baby A.F.'s injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous cow's milk-based preterm infant nutrition products.

7. 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 manufacture, design, formulate, prepare, test, provide instructions for, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Maryland, premature infant formula and premature infant milk fortifier made from cow's milk under the "Enfamil" brand name.

FACTUAL ALLEGATIONS

The Scope of the Problem

8. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like

Baby A.F. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

9. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

10. Science and research have advanced in recent years confirming strong links between cow's milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products, however, the manufacturers of the Cow's Milk-Based Products continue to promote and sell the Cow's Milk-Based Product versions.

The Scientific Evidence Mounts

11. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was **six to ten times more** common in exclusively formula-fed babies than in those fed breast milk alone and **three times more common** than in those who received formula plus breast milk. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk, but was **20 times more common** in those fed cow's milk-based formula only.[1]

12. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in

[1] A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, Lancet, 336: 1519-1523 (1990) (emphasis added)

extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were **90% less likely** to develop surgical NEC as compared to a diet that included some cow's milk-based products.[2]

13. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, **formula feeding is associated with higher rates** of necrotizing enterocolitis (NEC)."[3] This same report stated that premature infants who are not breast-fed are **138% more likely** to develop NEC.[4]

14. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used."[5]

15. Further, 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 weight and head circumference gain. The authors concluded that "this study provides data showing that **infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet**."[6] Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Products, but the practice has largely

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[2] S. Sullivan, et al, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added)

[3] U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added)

[4] *Id*

[5] *Breastfeeding and the Use of Human Milk*, Pediatrics, 129:e827-e841 (2012)

[6] A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added)

continued due to extensive and aggressive marketing campaigns conducted by infant formula manufacturers such as Defendants.

16. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a **significantly higher rate** of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU.[7]

17. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant morbidity and mortality**. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk."[8] The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death.[9] The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies.[10] The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease**."[11] Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is

[7] E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added)
[8] Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added)
[9] *Id.*
[10] *Id.*
[11] *Id.*

recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC."[12]

18. In yet another study published in 2014, it was reported that an exclusively human milk-based diet, void of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants.[13]

19. In 2016, a large study supported previous findings that an exclusively human milk-based diet in extremely preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first multi-year study to compare rates of NEC at various institutions after implementation of a feeding protocol using exclusively human milk. The authors concluded that the use of an **exclusively human milk-based diet is associated with "significant benefits"** for extremely preterm infants, and while evaluating the benefits of using an exclusively human milk-based protocol, they noted that "it appears that there were **no feeding-related adverse outcomes**."[14]

20. A publication by the American Society for Nutrition, in 2017, noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow's milk-based preterm infant formula to human milk in relation to the rate of NEC. Both trials found that an **exclusively human milk diet resulted in a much lower incidence of NEC**. While the

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[12] *Id.*
[13] Steven Abrams, *et al*., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014)
[14] Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet,* BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added)

study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **cow's milk-based products significantly increased the risk of NEC and death**. The study also noted the **"exponential" health care costs** associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and nearly doubles to $313,000 per infant for surgically treated NEC. Additionally, NEC survivors accrue substantially higher outpatient costs.[15]

21. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breastmilk substitutes. The WHO Director concluded the meeting with the following statement, "**In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement**."[16]

22. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast Milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast milk substitutes is specifically prohibited: "**There should be no advertising or other form of promotion to the general public** [of breast milk substitutes]." In Article 5.2, the Code states that "manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of

[15] Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added)
[16] Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added)

samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…"[17]

23. The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "**a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast milk substitutes**," noting that in 2014, the global sales of breast milk substitutes amounted to **US $44.8 billion** and "is expected to rise to **US $70.6 billion** by 2019."[18]

24. Recognizing a shift in the medical community towards an exclusively human milk-based diet for preterm infants, the Defendants began heavily promoting "human milk fortifiers," a name which misleadingly suggests that the product is derived from human milk, instead of being derived from cow's milk.

25. The Defendants have designed competing, systematic, powerful, and misleading marketing campaigns to persuade physicians and parents to believe that: (1) cow's milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breast milk; and (3) physicians consider their Cow's Milk-Based Products the first choice. Similarly, the Defendants market their products for preterm infants as necessary for growth and perfectly safe for preterm infants, despite knowing the extreme risks posed by Cow's Milk-Based Products.

[17] *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3
[18] *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added)

The Inadequate Warnings

26. Defendants promote the use of their preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

27. Despite the knowledge of the health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC, Defendants did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendants provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC.

28. In fact, Defendants did not provide any warning on their labeling, websites, or marketing materials that warns that their Cow's Milk-Based Products exponentially increase the risk of NEC in preterm infants, or that human breast milk, donor breast milk, and human breast milk-based formulas and fortifiers are much safer for preterm babies than their Cow's Milk-Based Products.

Safer Alternative Design

29. Plaintiffs allege there were reasonable, safe, and economically and technologically feasible alternative designs of Cow's Milk-Based Products for premature infants available to Defendants when the formulas and fortifiers at issue in this case were sold. Moreover, Plaintiffs allege that human milk-based products from donor breast milk are safer alternatives to cow's milk-based formulas and fortifiers for premature infants, particularly premature infants in the low to extremely low birth weight category such as Baby A.F. Prolacta Bioscience manufactures and sells breast milk-based feeding products specifically for premature infants which contain no cow's milk. This alternative design provides the nutrition necessary for growth and development

without the unreasonably dangerous and deadly effects associated with Defendants' products. Further evidence of the safer alternative design will be presented by Plaintiffs' expert witnesses.

Baby A.F. and the Dangerous, Defective Products

30. Baby A.F. was born prematurely at 29 weeks gestation at The Johns Hopkins Hospital (hereinafter "Johns Hopkins") in Baltimore, MD on September 14, 2019. At birth, Baby A.F. weighed 1340 grams, or less than three pounds.

31. After he was born, Baby A.F. was sent to the NICU at Johns Hopkins. On September 20, 2019, he was started on low-volume trophic feedings of maternal breast milk or donor breast milk.

32. Baby A.F. began to transition from breast milk to formula on October 4, 2019. Medical records show the premature infant formula given to Baby A.F. via continuous feedings was **Enfamil Premature Infant Formula 24 Calories**. By October 6, 2019, he had advanced to full-volume feeds, with half of those feeds consisting of Defendants' preterm formula. By October 8, 2019, it was noted that he was no longer consuming breast milk and had completed the transition to "full formula" or "100% PE 24."

33. On or about October 11, 2019, while still consuming Defendants' formula, Baby A.F. began to develop symptoms indicative of NEC, including a distended abdomen, bloody stools, and x-ray imaging showing dilated loops of bowel. Serial films later revealed abnormal accumulations of gas in the intestinal wall and portal vein—ominous radiological signs called *pneumatosis intestinalis* and portal venous gas, respectively. Baby A.F. was diagnosed with stage II NEC, immediately taken off formula feedings, given a blood product transfusion, and prescribed triple antibiotics.

34. Suffering from worsening respiratory failure and sepsis, along with ever-increasing abdominal distension, Baby A.F. required intubation and was cleared for an urgent abdominal

exploration by the pediatric surgery department. On October 12, 2019, he underwent an exploratory laparotomy in which a segment of completely necrotic distal ileum was resected. An ileostomy and mucous fistula were also created during the procedure.

35. Due to the nature of his injuries and the invasive procedure that was necessary to save him, Baby A.F. was not released from Johns Hopkins until December 11, 2019—88 days after his birth.

36. Baby A.F. was discharged from Johns Hopkins and immediately transferred and admitted into Mount Washington Pediatric Hospital (hereinafter "Mount Washington") in Baltimore, MD for continued management of his ileostomy, tube feedings, and infection. He remained at Mount Washington until February 17, 2020, at which point he was readmitted to Johns Hopkins for another exploratory laparotomy to re-anastomose his bowels and take down the previously created ileostomy.

37. After the surgery, Baby A.F. was returned to Mount Washington on February 21, 2020 for his second round of post-operative recovery and care. Baby A.F. was finally discharged to his home on March 5, 2020—the culmination of an almost six-month ordeal involving four total hospitalizations, two open-bowel surgeries, two different facilities providing round-the-clock care, and an immeasurable amount of hardship for Baby A.F.'s mother.

38. At the time he was diagnosed with NEC, Baby A.F.'s Mother was unaware of the fact that the Defendants' Cow's Milk-Based Products, which he had consumed for an entire week via continuous tube feedings prior to his diagnosis, could have caused or substantially contributed to his development of NEC and resulting injuries.

COUNT I: STRICT LIABLITY – DESIGN DEFECT

(Against All Defendants)

39. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

40. At all times material to this action, Defendants were engaged in the sale of and sold their Cow's Milk-Based Products in the course of their business, including the Enfamil Premature Infant Formula 24 Calories fed to and ingested by Baby A.F.

41. Defendants' Cow's Milk-Based Products fed to and ingested by Baby A.F. were used in a manner reasonably anticipated by Defendants.

42. Defendants' Cow's Milk-Based Products were in a defective condition and were unreasonably dangerous when put to the reasonably anticipated use by consumers, including Baby A.F. and Baby A.F.'s Mother.

43. Plaintiffs were damaged as a direct result of the defective condition of Defendants' Cow's Milk-Based Products, which existed when the Products were sold.

44. Defendants, as the manufacturers and/or sellers of their Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to design, manufacture, distribute and sell their Cow's Milk-Based Products in a manner that was not unreasonably dangerous and are liable despite any care exercised to design a safe product.

45. Defendants' Cow's Milk-Based Products designed, manufactured, distributed and sold by Defendants were in a defective and unreasonably dangerous condition at the time the Products were placed in the stream of commerce for nutritional use and consumption by preterm infants.

46. Defendants specifically created, designed, and sold their Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants like Baby A.F.

47. Defendants' Cow's Milk-Based Products were expected to and did reach the user without substantial change affecting their defective and/or unreasonably dangerous condition.

48. Prior to 2019, Defendants were aware or should have been aware that their Cow's Milk-Based Products were not safe for use as nutrition or nutritional support for preterm infants, yet they took no steps to prevent the use of these products in such situations.

49. Defendants knew or should have known that the use of their Cow's Milk-Based Products on preterm infants was unreasonably dangerous in that these products significantly increased the risk of NEC and death.

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

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

52. The Products were defectively designed and/or unreasonably dangerous, including, but not limited to, the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements for preterm infants significantly increased the risk of NEC and death;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Baby A.F., to risks of serious bodily injury and death;

c. The products failed to meet the legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase and/or use the product;

f. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants failed to inspect or test their products with sufficient care.

53. As a direct and proximate result of the Cow's Milk-Based Products' defective design, which rendered the products unreasonable dangerous, Baby A.F. has suffered and will continue to suffer severe bodily injury, pain and suffering, developmental delays leading to potential disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

54. As a direct and proximate result of the Cow's Milk-Based Products' defective design, which rendered the products unreasonable dangerous, Plaintiffs have suffered and will continue to suffer emotional harm, distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages,

including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT II: NEGLIGENCE

(Against All Defendants)

55. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

56. Defendants, as the manufacturers and/or sellers of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care in designing, testing, manufacturing, inspecting, labeling, marketing, promoting, distributing, selling and warning regarding Cow's Milk-Based Products that were free of unreasonable risk of harm to users and patients, including Plaintiffs, when used in their intended manner.

57. Defendants, as the manufacturer and/or seller of their Cow's Milk-Based Products, had a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

58. Defendants negligently and defectively designed, tested, manufactured, inspected, labeled, marketed, promoted, distributed, sold and warned regarding the subject Cow's Milk-Based Products.

59. Defendants breached the duty owed to Plaintiffs and acted negligently, including, but not limited to, the following actions:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data, study and test to determine if their products were safe for preterm infants;

d. Failing to collect data, study, and test to determine when and how their products could be used safely;

e. Failing to utilize the significant peer-reviewed research to develop instructions and warn of all known risks and complications associated with products made from cow's milk;

f. Failing to develop and/or provide evidence-based guidelines or instructions to decrease the risk of their products causing NEC and death;

h. Failing to stop or deter their products from being fed to extremely preterm infants like Baby A.F.;

i. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;

j. Failing to continuously and vigorously study their Cow's Milk-Based Products in order to avoid NEC and death in premature infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for preterm infant formula and fortifier;

l. Failing to adopt an adequate or sufficient quality control program;

m. Failing to warn consumers, including Plaintiffs, healthcare providers, the FDA, and the general public of all known risks and complications associated with their Cow's Milk-Based Products;

n. Marketing and promoting their Cow's Milk-Based Products in a misleading, inadequate and deceptive manner;

o. Failing to provide periodic or yearly safety reports and risk-benefit analyses;

p. Failing to develop and provide a protocol and/or guidelines to hospitals, physicians, and parents regarding the proper and safe use of the products on preterm infants;

q. Failing to perform the necessary scientific process of collection, detection, assessment, monitoring, and prevention of the adverse effects of feeding products made with cow's milk to preterm infants; and/or

r. Failing to inspect or test their products with sufficient care.

60. Defendants knew or should have known that their Cow's Milk-Based Products were to be used as nutrition and nutritional supplements for preterm infants, like Baby A.F.

61. Defendants knew or should have known that the use of their Cow's Milk-Based Products on preterm infants was unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC and death.

62. Furthermore, scientific data and well researched studies have concluded that these products carried unreasonable risks of NEC and death, which far outweighed the products' benefits for premature infants like Baby A.F.

63. Had Defendants not committed negligence, as set forth herein, Baby A.F. would not have been exposed to Defendants' unreasonably dangerous Cow's Milk-Based Products and would not have developed NEC and the resulting medical conditions and injuries.

64. As a direct and proximate result of Defendants' negligence, described herein, Baby A.F. has suffered and will continue to suffer severe bodily injury, pain and suffering, developmental delays leading to potential disability, emotional harm and distress, loss of enjoyment of life and economic damages.

65. As a direct and proximate result of Defendants' negligence, described herein, Plaintiffs have suffered and will continue to suffer emotional harm, distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY - FAILURE TO WARN

(Against All Defendants)

66. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

67. At all times material to this action, Defendants were engaged in the sale of and sold their Cow's Milk-Based Products in the course of their business, including the Enfamil Premature Infant Formula 24 Calories fed to and ingested by Baby A.F.

68. Defendants' Cow's Milk-Based Products were unreasonably dangerous at the time of sale.

69. Defendants' Cow's Milk-Based Products were unreasonably dangerous when put to the reasonably anticipated use by consumers, including Plaintiffs, who were without knowledge of their unreasonably dangerous characteristics.

70. Defendants' Cow's Milk-Based Products fed to and ingested by Baby A.F. were used in a manner that was reasonably anticipated by Defendants.

71. Defendants failed to adequately warn consumers, including Plaintiffs, healthcare providers, the FDA, and the general public of all known risks and complications associated with their Cow's Milk-Based Products, including NEC and resulting medical conditions, complications and injuries.

72. Plaintiffs were damaged as a direct result of Defendants' Cow's Milk-Based Products being sold without an adequate warning.

73. Defendants, as the manufacturers and/or sellers of their Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, as well as healthcare providers, to properly warn and provide adequate warnings and instructions about the dangers, risks and complications associated with the use of products made with cow's milk on preterm infants, specifically including but not limited to the risk of NEC and death.

74. Defendants, as the manufacturers and/or sellers of their Cow's Milk-Based Product, were unreasonable in relying upon any intermediary, including physicians and/or other healthcare providers and/or healthcare staff, to fully warn the end user, including Plaintiffs, of the hidden risks and dangers associated with its Cow's Milk-Based Products, as the magnitude of the risk

involved in using Defendants' Cow's Milk-Based Products on preterm infants is significant and involves the real danger of serious bodily injury and death.

75. Defendants, as the manufacturers and/or sellers of their Cow's Milk-Based Product, failed to fully warn and instruct any intermediary, including physicians, other health care providers, and/or health care staff, of the significant risks and dangers in their Cow's Milk-Based Products.

76. Defendants failed to provide warnings and instructions on their Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the risks, dangers and safe use of the products to healthcare providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing healthcare providers and administering healthcare staff and to specifically warn of the risks and dangers associated with the use of Cow's Milk-Based Products on preterm infants, specifically including, but not limited to, the risk of NEC and death.

77. Upon information and belief, rather than providing adequate warnings, Defendants developed relationships which included incentives and financial gain to healthcare providers and facilities for using their Cow's Milk-Based Products within the NICU, such that healthcare providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

78. In addition and/or in the alternative, if healthcare providers and healthcare staff had been properly instructed and warned of the risks associated with the use of products made from cow's milk on preterm infants, they would not have used such dangerous products.

79. Defendants, as the manufacturers and/or sellers of their Cow's Milk-Based Products, have a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and were presumed to know the result of all such advances.

80. Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in "The Science and Scope of the Problem" Section, knew of the significant risk of NEC with preterm infants and death.

81. Defendants, through their knowledge, review, and survey of the scientific literature, as detailed in "The Scope of the Problem" and "The Scientific Evidence Mounts" sections, knew that the use of Cow's Milk-Based Products on preterm infants could cause severe injury, including but not limited to NEC and death.

82. Defendants failed to provide proper warnings and/or instructions regarding their Cow's Milk-Based Products, including but not limited to as follows:

a. Provided no warnings regarding the risk of NEC and death;

b. Provided inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products on preterm infants, including but not limited to NEC and death;

c. Failed to provide proper instructions, guidelines, studies or data on when and how to feed their products to preterm infants in order to decrease the risk of NEC and/or death;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of Defendants' Cow's Milk-Based Products;

e. Failed to provide instructions to consumers and healthcare providers that Defendants' preterm infant nutrition products carried the significant risk that their Cow's Milk-Based Products could cause babies to develop NEC and die;

f. The warnings and instructions are severely inadequate, vague, confusing and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk-Based Products significantly increasing the risk of NEC and death and fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that their Cow's Milk-Based Products are known to significantly increase the risk of NEC and death when compared to human milk in preterm infants;

h. Failed to provide well-researched and well-established studies that linked products made from cow's milk to NEC and death in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of their products;

j. Failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants their Cow's Milk-Based Products;

k. Failed to send out "Dear Doctor" letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for preterm infants;

l. Failed to advise physicians and healthcare providers that their Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

m. Failed to contain sufficient instructions and warnings on their Cow's Milk-Based Products such that healthcare providers and healthcare staff were not properly warned of the dangers of NEC associated with the consumption of products made from cow's milk by preterm infants.

83. If Defendants had fully warned and instructed the intermediary(ies), including physicians, other health care providers, and/or health care staff who provided care and treatment to and/or fed Defendants' Cow's Milk-Based Products to Baby A.F., of the significant risks and dangers associated with products made from cow's milk, including NEC, the intermediary(ies) would not have fed Defendants' Cow's Milk-Based Products to Baby A.F.

84. If Defendants had fully warned and instructed Plaintiffs on the significant risks and dangers associated with products made from cow's milk, including NEC, Baby A.F.'s Mother would not have fed, nor would she have allowed others to feed, Defendants' Cow's Milk-Based Products to Baby A.F.

85. As a direct and proximate result of Defendants' failure to warn, which rendered their Cow's Milk-Based Products unreasonably dangerous, Baby A.F. has suffered and will continue to suffer severe bodily injury, pain and suffering, developmental delays leading to potential disability, emotional harm and distress, loss of enjoyment of life and economic damages.

86. As a direct and proximate result of Defendants' failure to warn, which rendered their Cow's Milk-Based Products unreasonably dangerous, Plaintiffs have suffered and will continue to suffer emotional harm, distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit,

attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT IV: NEGLIGENT MISREPRESENTATION

(Against All Defendants)

87. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

88. Defendants provided misleading and false information and/or omitted information in labeling, marketing, distributing, selling and warning regarding their Cow's Milk-Based Products.

89. Defendants, as the designers, manufacturers, sellers and distributors of their Cow's Milk-Based Products, had a duty to the general public and to Plaintiffs to provide truthful, accurate and complete information about the risks and benefits of using their products.

90. Defendants failed to exercise reasonable care by failing to provide truthful, accurate and complete information about the risks and benefits of using their Cow's Milk-Based Products.

91. Because of Defendants' failure to exercise reasonable care, the information provided to consumers, including Plaintiffs, regarding their Cow's Milk-Based Products was misleading and/or false, including, but not limited to, the following:

a. Defendant misrepresented that their Cow's Milk-Based Products were safe and beneficial for premature infants when they knew or should have known that the products were unreasonably dangerous and could cause NEC, devastating injuries and/or death in premature infants;

b. Defendants misrepresented to parents, physicians and healthcare providers 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;

c. Defendants misrepresented that their Cow's Milk-Based Products had no serious side effects, when they knew or should have known the contrary to be true;

d. Defendants negligently misrepresented that their Cow's Milk-Based Products were similar or equivalent to human milk;

e. Defendants negligently misrepresented that their Cow's Milk-Based Products were based on current up-to-date science, which made them safe for premature infants;

f. Defendants negligently omitted the material fact that their Cow's Milk-Based Products significantly increase the risk of NEC in premature infants; and

g. Defendants' negligently misrepresented that their Cow's Milk-Based Products are specially designed to be similar to and a reasonable substitute for breast milk specifically for preterm infants.

92. The information was provided by Defendants to Plaintiffs in the sale of their Cow's Milk-Based Products to Plaintiffs, who justifiably relied on the information and have suffered pecuniary loss as a result.

93. As a direct and proximate result of Defendants' negligent misrepresentations, described herein, Baby A.F. has suffered and will continue to suffer severe bodily injury, pain and suffering, developmental delays leading to potential disability, emotional harm and distress, loss of enjoyment of life and economic damages.

94. As a direct and proximate result of Defendants' negligent misrepresentations, described herein, Plaintiffs have suffered and will continue to suffer emotional harm, distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT V: BREACH OF EXPRESS WARRANTY

(Against All Defendants)

95. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

96. Defendants expressly warranted that their Cow's Milk-Based Products, including Enfamil Premature Infant Formula, were safe and effective to members of the consuming public, including Plaintiffs and other premature infants like Baby A.F. Moreover, Defendants expressly warranted that the Enfamil Premature Infant Formula was "specially formulated to meet the unique nutritional needs" of preterm neonates.

97. Members of the consuming public, including consumers such as the Plaintiffs, were the intended third-party beneficiaries of the warranty.

98. Defendants' Cow's Milk-Based Products do not conform to this express representation because consumers cannot safely use them in the intended manner without risk of the product causing NEC and subsequently leading to grave complications, invasive surgery and/or death.

99. Baby A.F.'s Mother had a reasonable expectation that the formula consumed by Baby A.F. was properly designed and manufactured, free from defects of any kind, and that it was safe for its intended, foreseeable use of providing specialized nutrition for vulnerable, underweight, preterm babies.

100. Baby A.F.'s injuries were the direct and proximate result of Defendants' breach of their express warranties.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI: BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

(Against All Defendants)

101. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

102. Defendants manufactured, supplied and sold their Cow's Milk-Based Products, including Enfamil Premature Infant Formula, with an implied warranty that they were fit for the particular purpose of providing nutrition to preterm children.

103. Members of the consuming public, including consumers such as Plaintiffs, were the intended third-party beneficiaries of the warranty.

104. Defendants' Cow's Milk-Based Products, including Enfamil Premature Infant Formula, were not fit for the particular purpose as a safe means of feeding vulnerable preterm newborns in the NICU due to the unreasonable risks of bodily injury and death associated with their use.

105. The Plaintiffs in this case reasonably relied on Defendants' representations that their products were an effective and safe means of nourishing preterm infants.

106. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries and damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants)

107. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

108. At the time Defendants marketed, distributed, and sold their Enfamil Premature Infant Formula to Plaintiffs, Defendants warranted that their Cow's Milk-Based Products were merchantable and fit for the ordinary purposes for which they were intended.

109. Members of the consuming public, including consumers such as Plaintiffs, were the intended third-party beneficiaries of the warranty.

110. Defendants' products were not merchantable and fit for their ordinary purpose because they had the propensity to lead to the serious personal injuries as described herein in this Complaint.

111. Baby A.F.'s Mother allowed Baby A.F. to consume and Baby A.F. subsequently consumed Cow's Milk-Based Products, specifically Enfamil Premature Infant Formula, with the reasonable expectation that they were properly designed and manufactured, free from defects of any kind, and that they were safe for their intended, foreseeable use as a form of nourishment specifically for preterm babies.

112. Defendants' breach of implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injury and damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII: PUNITIVE DAMAGES

(Against All Defendants)

113. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

114. Baby A.F.'s injury was the result of misconduct of Defendants that manifested a flagrant disregard of the safety of preterm infants who might be harmed by their Cow's Milk-Based Products.

115. Defendants fraudulently withheld information known to be material and relevant to the harm that Plaintiffs suffered or misrepresented the information of that type.

116. Defendants engaged in fraudulent and malicious conduct towards Baby A.F.'s medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiffs and the public.

117. Defendants are liable to Plaintiffs for punitive damages for their wanton, reckless and/or willful conduct in manufacturing, designing, formulating, preparing, testing, providing instructions for, marketing, labeling, packaging, selling, and/or placing into the stream of commerce a product that is defective.

118. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

119. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

120. Defendants had knowledge of, and were in possession of, evidence demonstrating that their Cow's Milk-Based Products were defective and unreasonably dangerous and were associated with a substantially higher incidence of NEC than other preterm infant nutrition products on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiffs or their health care providers of the dangers and higher incidence of NEC associated with their Cow's Milk-Based Products;

b. Establish and maintain an adequate quality-control program and/or post-market surveillance system which kept abreast of scientific developments and peer-reviewed research studies regarding NEC and preterm infant nutrition products made from cow's milk;

c. Cease specifically targeting, marketing and selling their Cow's Milk-Based Products to preterm infants, their parents and the hospitals that serve them;

d. Reformulate their Cow's Milk-Based Products so as to decrease the exponential risk of contracting NEC;

e. Recall their Cow's Milk-Based Products from the market due to the fact that they dramatically increased the risk of NEC and death in preterm infants.

121. Defendants acted to serve their own interests and consciously disregarded the substantial risk that their Cow's Milk-Based Products might kill or significantly harm preterm

infants and consciously pursued a course of conduct despite having actual knowledge that such conduct created a substantial risk of significant harm to consumers.

122. As a direct, proximate and legal result of Defendants' acts and omissions as described herein, Baby A.F. has suffered and will continue to suffer severe bodily injury, pain and suffering, developmental delays leading to potential disability, emotional harm and distress, loss of enjoyment of life and economic damages.

123. As a direct, proximate and legal result of Defendants' acts and omissions as described herein, Plaintiffs have suffered and will continue to suffer emotional harm, distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

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

2. 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;

3. 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;

4. For interest as permitted by law;

5. For attorney's fees, expenses, and recoverable costs incurred in connection with

this action; and

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby request a trial by jury on all issues triable by jury.

Dated: October 4, 2022

Respectfully submitted,

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Pro Hac Vice to be Requested

COUNSEL FOR PLAINTIFFS

CERTIFICATE OF GOOD STANDING

In accordance with Maryland Rule 1-313, I hereby certify that I am a member in good standing of the Maryland Bar and licensed to practice law in the State of Maryland with an office address in the District of Columbia.

/s/ Christopher T. Nace
Christopher T. Nace