IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

ALYHANA CHILDS, as PARENT, NATURAL GUARDIAN AND NEXT FRIEND OF S.S., a minor, 5469 Grove Ridge Way, Rockville, MD 20852.

Plaintiff,

Civil Action No.:

v.

ABBOTT LABORATORIES, 100 Abbott Park Road, Abbott Park, IL 60064

SERVE:

CT Corporation System 1015 15th Street NW, Suite 1000 Washington, DC 20005

and

MEAD JOHNSON & COMPANY, LLC, 225 North Canal Street, 24th Floor, Chicago, IL 60606

SERVE:

Corporation Service Company 1090 Vermont Avenue, NW Washington, DC 20005

and

MEAD JOHNSON NUTRITION COMPANY, 225 North Canal Street, 24th Floor, Chicago, IL 60606

SERVE:

Corporation Service Company 1090 Vermont Avenue, NW Washington, DC 20005

Defendants.

PLAINTIFF'S COMPLAINT AND JURY DEMAND: PRODUCTS LIABILITY INTRODUCTION

This action arises out of the injuries suffered by Plaintiff's premature infant, who was fed Defendants' cow's-milk-based infant formula and/or fortifier. Defendants' products caused the injured infant to develop Necrotizing Enterocolitis (hereinafter "NEC"), a life-threatening and potentially 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 often lead to surgery and even 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 health care community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, baby S.S. (hereinafter "Baby S.S."), who was premature at birth, was fed these cow's milk-based products, developed NEC, and suffered significant injuries as a result.

Plaintiff, Alyhana Childs, as Parent, Natural Parent, and Next Friend of Baby S.S., brings this cause of action against Defendants for claims arising from 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 (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively "Cow's Milk-Based Products").

GENERAL ALLEGATIONS

Plaintiff, Alyhana Childs, as Parent, Natural Parent, and Next Friend of Baby S.S. (hereinafter "Plaintiff"), by and through the undersigned counsel, brings this Complaint against Defendants,

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 3 of 31

Abbott Laboratories; Mead Johnson and Company, LLC; and Mead Johnson Nutrition Company; and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

JURISDICTION AND VENUE

1. This is an action for damages which exceeds the sum of 75,000.00, exclusive of costs, interest, and attorneys' fees.

2. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff 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 District of Columbia. Defendants have marketed, promoted, distributed, and/or sold their Cow's Milk-Based Products in the District of Columbia and 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 (a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Defendants transact substantial business in this District.

PLAINTIFF

5. Baby S.S. was born prematurely at George Washington University Hospital in Washington, District of Columbia. Upon information and belief, Baby S.S. developed NEC after being fed Similac and Enfamil Cow's Milk-Based Products while in the NICU at George Washington University Hospital in Washington, District of Columbia.

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 4 of 31

6. At the time of Baby S.S.'s birth and subsequent NICU treatment, he domiciled in and was a citizen of the District of Columbia.

7. Plaintiff, Alyhana Childs, the mother of Baby S.S., (hereinafter "Baby S.S.'s Mother"), domiciled in and was a citizen of the District of Columbia at the time of Baby S.S.'s birth. Baby S.S. and Baby S.S.'s Mother currently domicile in and are citizens of the State of Maryland, and reside in Rockville in Montgomery County, Maryland. Baby S.S.'s Mother brings this action against Defendants to recover for Baby S.S.'s injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous cow's milk-based products.

DEFENDANTS

8. Defendant, Abbott Laboratories ("Abbott") was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Delaware with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen and domiciliary of Delaware and Illinois. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including the District of Columbia, premature infant formula and premature infant milk fortifier under the Similac brand name.

9. Defendant Abbott advertises that it provides the "#1 Formula Brand, Backed by Science" and claims to have "over 90 years of innovations" in infant formula.

10. Defendants, Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company, (collectively "Mead Johnson") are companies based in Illinois that manufacture, design, formulate, prepare, test, provide instructions, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including the District of Columbia, premature infant formula and premature infant milk fortifier under the Enfamil brand name. Mead Johnson Nutrition Company was at all times material hereto and is now a corporation duly organized, incorporated, and existing

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 5 of 31

under the laws of the State of Delaware with its principal place of business and global headquarters in the State of Illinois, and is thus a resident, citizen, and domiciliary of Delaware and Illinois. Mead Johnson & Company, LLC was at all times material hereto and is now a limited liability company duly organized and existing under the laws of the State of Delaware with its principal place of business and headquarters in the State of Illinois. Upon information and belief, at all times material hereto, the sole member of Mead Johnson & Company, LLC is Mead Johnson Nutrition Company.

11. Mead Johnson Nutrition Company self-proclaims to be recognized as "a world leader in pediatric nutrition" and traces its history back to the company's founding in 1905 by Edward Mead Johnson, Sr. It claims to be the "only global company focused primarily on infant and child nutrition" and that its "singular devotion has made our flagship 'Enfa' line the leading infant nutrition brand in the world." Boasting "more than 70 products in over 50 countries," it claims that its "products are trusted by millions of parents and healthcare professionals around the world."

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

12. 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 S.S. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

13. 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.

14. 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

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 6 of 31

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 versions.

15. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was <u>six to ten times more</u> common in exclusively formula-fed babies than in those fed breast milk alone and <u>three times more common</u> 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 <u>20 times more common</u> in those fed cow's milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990) (emphasis added).

16. A study published in 2009 evaluated the health benefits of an exclusively human milkbased diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were <u>90% less likely</u> to develop surgical NEC as compared to a diet that included some cow's milkbased products. 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).

17. 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, <u>formula feeding is associated with higher rates</u> of necrotizing enterocolitis (NEC)." 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). This same report stated that premature infants who are not breast-fed are <u>138% more likely</u> to develop NEC. *Id*.

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 7 of 31

18. 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." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e84l (2012).

19. 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 <u>infants can achieve and mostly exceed targeted growth standards when receiving</u> <u>an exclusive human milk-based diet</u>." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants* ≤ 1250 *Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendants.

20. 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 <u>significantly higher rate</u> 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 (Newborn Intensive Care Unit). E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

21. 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

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 8 of 31

by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al.*, *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* 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. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease**." *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

22. In yet another study, published in 2014, it was reported that an exclusive human milk diet, devoid of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

23. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an <u>exclusive human milk diet is associated with "significant benefits"</u> for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were <u>no feeding-related adverse outcomes</u>." Hair, *et al, Beyond Necrotizing*

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 9 of 31

Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

24. 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 as to the rate of NEC. Both trials found that an **exclusive human milk diet resulted in a much lower incidence of NEC**. While the 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 increase 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. Further, NEC survivors accrue substantially higher outpatient costs. 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).

25. 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 breast-milk 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." Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

26. 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,

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 10 of 31

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]." (emphasis added). In Article 5.2, the Code states that "manufacturers and distributors should not provide, <u>directly or indirectly</u>, 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 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..." *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

27. 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 "<u>a major</u> <u>factor undermining efforts to improve breastfeeding rates is continued and aggressive</u> <u>marketing of breast-milk substitutes</u>," 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." *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).

28. Recognizing a shift in the medical community towards an exclusive 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.

29. The Defendants have designed competing, systematic, powerful, and misleading

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 11 of 31

marketing campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk-Based Products a first choice. Similarly, the Defendants market their products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk-Based Products and failing to warn of the deadly disease of NEC and risk of death.

30. Thus, despite the existence of alternative and safe human milk-based products, these Defendants continue to market and/or sell the Cow's Milk-Based Products under the guise of being a safe product for their newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like Baby S.S.

The Inadequate Warnings

31. 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.

32. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC and death, 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 or death.

33. In fact, neither of the Defendants provide any warning in their labeling, websites, or marketing that discusses the risk of NEC and death with use of their Cow's Milk-Based Products with preterm infants.

34. The warning on Similac Human Milk Fortifier, an Abbott Cow's Milk-Based Product specifically marketed for use with preterm infants states:

Precautions

- Add only to human milk—do not add water
- This product is nutritionally incomplete by itself and is designed to be added to human breast milk
- Additional iron may be necessary
- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk
- Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk
- Not intended for feeding low-birth-weight infants after the reach a weight of 3600 g (approximately 8 lb) or as directed by a physician

Preparation and Use

Follow directions as specified on carton. Improper dilution may be harmful.

35. The warning on Enfamil Human Milk Fortifier, a Mead Johnson Cow's Milk-Based

Product specifically marketed for use with preterm infants states:

WARNING: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although this powder is formulated for premature infants, nutritional powders are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

Follow hospital rules or your baby's doctor's instructions for the safe handling of human milk. To aid mixing, agitate the human milk well. Pour the desired amount into a sterile container and warm to feeding temperature.

- 1. Remove vials from foil pouch and separate number of vials needed.
- 2. Store remaining vials in foil pouch at room temperature. Once pouch has been opened, vials must be used within 24 hours.
- 3. Shake vigorously to mix contents. Firmly hold vial UPRIGHT by bottom tab and slowly twist top off completely. Add fortifier to breast milk.

Some liquid may remain in cap and vial; disregard [sic] this liquid. Discard opened vial and cap promptly. Do not use product that has unusual characteristics.

- 1. Failure to follow these instructions could result in severe harm. Once prepared, fortified breast milk can spoil quickly. Either feed fortified breast milk immediately or cover and store in refrigerator at 35-40°F (2-4°C) for no longer than 24 hours. Agitate before each use.
- 2. For bottle feeding: Pour only the amount of fortified breast milk to be fed into a feeding container and feed immediately. Do not use fortified breast milk if it is unrefrigerated for more than a total of 2 hours. After feeding begins, use fortified breast milk within one hour or discard.
- 3. For tube feeding: Once fortified breast milk is prepared, it can remain at room temperature for no longer than a total of 4 hours.

Warning: Do not use a microwave oven to warm the fortified human milk. Serious burns may result.

Storage: Store unopen pouches in carton at room temperature. Avoid excessive heat. Do not freeze.

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 13 of 31

Warning: Not for parental (I.V.) use. Fortifier is designed to be mixed with breast milk; do not administer directly.

36. The warning on Enfamil Premature Formula, a Mead Johnson Cow's Milk-Based

Product specifically marketed for use with preterm infants states:

Your baby's health depends on carefully following the instructions below. Proper hygiene, preparation, use and storage are important when preparing infant formula. Use as directed by your baby's doctor. Ask your baby's doctor about the need to boil a clean nipple in water before use. Inspect each bottle for signs of damage. 1. Wash hands thoroughly with soap and water before preparing bottle for feeding.

- 2. SHAKE BOTTLE WELL and remove cap.
- 3. Attach nipple unit (not included).

WARNING: Do not use a microwave oven to warm formula. Serious burns may result.

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

Storage: Store unopened bottles at room temperature.

Avoid excessive heat and prolonged exposure to light. Do not freeze.

DO NOT ACCEPT IF PACKAGE HAS BEEN OPENED. DO NOT USE IF CAP RING IS BROKEN OR MISSING.

USE BY DATE ON CARTON AND BOTTLE LABEL.

37. Thus, Defendants do not warn the users, the parents, or the medical providers and

staff that these Cow's Milk-Based Products can cause NEC or death, nor do they provide any guidance

on how to avoid or reduce the risks of NEC or death while using their products.

Baby S.S. and the Dangerous, Defective Products

38. Baby S.S. was born at George Washington University Hospital on May 12, 2007. Baby

S.S. was born preterm at 30 weeks gestation age with a low birth weight of 1265 grams (2 pounds 12.6 ounces) and a length of 15 inches.

39. After he was born, Baby S.S. was sent to the Neonatal Intensive Care Unit (NICU) at George Washington University Hospital.

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 14 of 31

40. Following his birth, his mother successfully pumped her own breast milk for her baby's nutrition.

41. From May 13, 2007 until May 26, 2007, Baby S.S. was fed with his mother's breast milk, fortified breast milk, or Enfamil Premature Infant Formula.

42. On May 27, 2007, Baby S.S. developed bright red stools with increasing abdominal distention.

43. Baby S.S. was diagnosed with NEC on May 27, 2007. He was put on bowel rest and was started on triple antibiotics.

44. On June 11, 2007, oral feeds were restarted slowly after 14 days of bowel rest.

45. Baby S.S. was fed Enfamil Premature Infant Formula and breast milk between June 11, 2007, and June 14, 2007.

46. On June 15, 2007, Baby S.S. again developed a distended abdomen, and he was put on bowel rest. Over the next few days, Baby S.S.'s condition did not improve. He was diagnosed with NEC a second time.

47. Due to the imminent need for surgical consultation, Baby S.S. was transferred to Children's National Hospital in Washington, District of Columbia, on June 22, 2007.

48. On June 30, 2007, Baby S.S. was forced to undergo an exploratory laparotomy. Multiple perforations in the bowel and a severe stricture were discovered. He underwent a resection of the terminal ileum and cecum.

49. At the time he was diagnosed with and treated for NEC, Baby S.S.'s parents were unaware of the fact that the Defendants' Cow's Milk-Based Products he was fed caused or substantially contributed to his development of NEC and resulting injuries.

50. As a result of developing NEC, Baby S.S. lost large portions of his bowel, causing permanent injury. He continues to suffer today with chronic bowel-related distress, pain, suffering,

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 15 of 31

mental and emotional anguish and distress.

COUNT I: STRICT LIABILITY AS TO DEFENDANT ABBOTT'S DESIGN

51. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

52. At all times material to this action, Defendant Abbott was engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers, including Baby S.S.

53. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

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

55. Defendant Abbott specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like Baby S.S..

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

57. Prior to May 12, 2007, Defendant Abbott was aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, as nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

58. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 16 of 31

significantly increased the risk of NEC.

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

60. Despite the foregoing, the Defendant continued to sell and market its defective and/or

unreasonably dangerous products to preterm infants.

61. The products were defectively manufactured and/or 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 in preterm infants significantly increased the risk of NEC;
- 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 S.S., to risks of serious bodily injury;
- c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;
- d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;
- e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;
- f. Defendant failed to adopt an adequate or sufficient quality control program; and/or
- g. Defendant failed to inspect or test their products with sufficient care.
- 62. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable

dangerous condition, Baby S.S. suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against

Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest,

and trial by jury.

COUNT II: NEGLIGENCE AS TO DEFENDANT ABBOTT

63. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

64. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

65. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

66. Defendant Abbott, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

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

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- 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 to determine if its products were safe for preterm infants;
- d. Failing to collect data to determine when and how its products could be used safely;
- e. Failing to utilize the significant peer reviewed research to develop instructions;
- f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 18 of 31

- g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
- h. Failing to stop or deter its products from being fed to preterm infants like Baby S.S.;
- 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 update its warnings and/or instructions based upon currently available data, research, and studies;
- k. Failing to take reasonable steps to prevent preterm infants from developing NEC and/or death;
- 1. Failing to take reasonable precautions to prevent preterm infants from developing NEC and/or death;
- m. Improperly creating agreements with hospitals whereby its products would be over utilized to the detriment of the preterm infants;
- n. Improperly promoting continued use of its product in hospitals despite knowing of the great harm it was causing;
- o. Failing to develop comprehensive mitigation strategies to reduce the risk of NEC and/or death in its products;
- p. Intentionally promoting a culture of silence whereby the harmful effects of its products were never being communicated to the parents or the public;
- q. Failing to insert a warning or instruction to healthcare professionals in the NICU that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed cow's milk-base products;
- r. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC and death in premature infants;
- s. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
- t. Failing to adopt an adequate or sufficient quality control program; and/or
- u. Failing to inspect or test their products with sufficient care.
- 68. Defendant Abbott knew or should have known that its products were to be used as

nutrition and nutritional supplements with preterm infants, like Baby S.S..

69. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 19 of 31

Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

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

71. As a direct and proximate result of the negligence of Defendant Abbott, Baby S.S. suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: FAILURE TO WARN AS TO DEFENDANT ABBOTT

72. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

73. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

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

75. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 20 of 31

health care staff, of the significant dangers in its Cow's Milk-Based Products.

76. Defendant owed a duty to provide warnings and instructions on its Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care 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 health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

77. Rather than provide adequate warnings, Defendant Abbott developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

78. Defendant Abbott was and remains aware that parents are never warned or informed that feeding the product could cause their baby to develop NEC, become seriously ill, require sections of their bowel to be removed, and die.

79. Defendant Abbott supports and encourages this practice of silence because it does not want its Similac brand name to be linked with NEC and death.

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

81. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

82. Defendant Abbott, through their own testing and studies, consultants, and experts,

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 21 of 31

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.

83. Defendant Abbott, through its knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC and death.

84. Defendant Abbott breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's Milk-Based Products, including but not limited to the following acts:

- a. Providing <u>no warnings</u> regarding the risk of NEC;
- b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;
- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the defendant's Cow's Milk Product;
- e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that its Cow's Milk-Based Products could cause their baby to develop NEC;
- 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 fail to provide any details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk-Based Products are known to significantly increase the risk of NEC when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked its Cow's Milk-Based Products to NEC in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;
- j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

- k. Failed to send out "Dear Dr." letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- 1. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or
- m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants; and/or
- n. Intentionally hid the dangers of its products from parents, doctors, nurses, and hospitals.
- 85. As a direct and proximate result of Defendant Abbott's failure to warn, Baby S.S.

suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against

Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest,

and trial by jury.

COUNT IV: STRICT LIABILITY AS TO MEAD JOHNSON DEFENDANTS' DESIGN

86. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

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

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

89. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed and/or sold by Defendants Mead Johnson, were in a defective and/or unreasonably

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 23 of 31

dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

90. Defendants Mead Johnson specifically marketed and created their Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like Baby S.S.

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

92. Prior to May 12, 2007, Defendants Mead Johnson were aware or should have been aware that their Cow's Milk-Based Products were not safe for use, as they were used, as nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

93. Defendants Mead Johnson knew or should have known that the use of their Cow's Milk-Based Products with preterm infants were unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC.

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

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

96. The products were defectively manufactured and/or 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 in preterm infants significantly increased the risk of NEC;
- 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 S.S., to risks of serious bodily injury;

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 24 of 31

- c. The products failed to meet legitimate, commonly held, minimum safety expectations of the products 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 the products;
- 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.
- 97. As a direct and proximate result of the Cow's Milk-Based Product's unreasonable

dangerous condition, Baby S.S. suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT V: NEGLIGENCE AS TO MEAD JOHNSON DEFENDANTS

98. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

99. Defendants Mead Johnson, as the manufacturers and/or sellers of Cow's Milk Product, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and/or to distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

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

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

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 25 of 31

102. Defendants Mead Johnson breached the duty owed to Plaintiff and acted negligently

in their actions, including, but not limited to, the following:

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- 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 to determine if its products were safe for preterm infants;
- d. Failing to collect data to determine when and how its products could be used safely;
- e. Failing to utilize the significant peer reviewed research to develop instructions;
- f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
- g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
- h. Failing to stop or deter its products from being fed to preterm infants like Baby S.S.;
- 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 update its warnings and/or instructions based upon currently available data, research, and studies;
- k. Failing to take reasonable steps to prevent preterm infants from developing NEC and/or death;
- 1. Failing to take reasonable precautions to prevent preterm infants from developing NEC and/or death;
- m. Improperly creating agreements with hospitals whereby its products would be over utilized to the detriment of the preterm infants;
- n. Improperly promoting continued use of its product in hospitals despite knowing of the great harm it was causing;
- o. Failing to develop comprehensive mitigation strategies to reduce the risk of NEC and/or death in its products;
- p. Intentionally promoting a culture of silence whereby the harmful effects of its products were never being communicated to the parents or the public;
- q. Failing to insert a warning or instruction to healthcare professionals in the NICU that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed cow's milk-base products;

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 26 of 31

- r. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC and death in premature infants;
- s. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
- t. Failing to adopt an adequate or sufficient quality control program; and/or
- u. Failing to inspect or test their products with sufficient care.
- 103. Defendants Mead Johnson knew or should have known that their products were to be

used as nutrition and nutritional supplements with preterm infants, like Baby S.S.

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

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

106. As a direct and proximate result of the negligence of Defendants Mead Johnson, BabyS.S. suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VI: FAILURE TO WARN AS TO MEAD JOHNSON DEFENDANTS

107. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

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

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 27 of 31

NEC.

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

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

111. Defendants Mead Johnson owed a duty 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 dangers and safe use of the product to health care 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 health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

112. Rather than provide adequate warnings, Defendants Mead Johnson developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

113. Defendants Mead Johnson were and remain aware that parents are never warned or informed that feeding the product could cause their baby to develop NEC, become seriously ill,

Case 1:22-cv-00711 Document 1 Filed 03/15/22 Page 28 of 31

require sections of their bowel to be removed, and die.

114. Defendants Mead Johnson support and encourage this practice of silence because it does not want its Enfamil brand name to be linked with NEC and death.

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

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

117. Defendants Mead Johnson, 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.

118. Defendants Mead Johnson, through their knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC.

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

- a. Providing **no warnings** regarding the risk of NEC and death;
- b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products and preterm infants, including but not limited to NEC;
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;

- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendants' Cow's Milk-Based Products;
- e. Failed to provide instructions to consumers and health care that the Defendants' products carried a significant risk that its Cow's Milk-Based Products could cause their baby to develop NEC;
- 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 details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk-Based Products are known to significantly increase the risk of NEC when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked its Cow's Milk-Based Products to NEC in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its product;
- j. Failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;
- k. Failed to send out "Dear Dr." letters warning of the risks NEC and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- 1. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or
- m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers' health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants; and/or
- n. Intentionally hid the dangers of its products from parents, doctors, nurses, and hospitals.
- 120. As a direct and proximate result of Defendants Mead Johnson's failure to warn, Baby

S.S. suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against

Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays 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

Plaintiff hereby requests a trial by jury on all issues triable by jury.

Dated: March 15, 2022

Respectfully submitted,

PAULSON & NACE, PLLC

<u>/s Christopher T. Nace</u> Christopher T. Nace, Esq. (Bar No. 977865) 1025 Thomas Jefferson St., NW Suite 810 Washington, DC 20007 202-463-1999 (Tel.) 202-223-6824 (Fax) <u>ctnace@paulsonandnace.com</u>

LEVIN, ROJAS, CAMASSAR, AND RECK, LLC Stephen M. Reck, Esq. *Pro Hac Vice Forthcoming* Jose M. Rojas, Esq. *Pro Hac Vice Forthcoming* P.O. Box 431 North Stonington, CT 06539 860-535-4040 (Tel.) 860-535-3434 (Fax) attorneyreck@yahoo.com rjoas@ctlawyer.net

Counsel for Plaintiffs