**IN THE UNITED STATES DISTRICT FOR THE NORTHERN DISTRICT OF ILLINOIS CHICAGO DIVISION**

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| KARRIE DEVINE, as Parent, Guardian Ad Litem, and as Next Friend of K.D., a minor,<br><br>Plaintiff,<br>v.<br><br>ABBOTT LABORATORIES, INC.; MEAD JOHNSON & COMPANY, LLC; MEAD JOHNSON NUTRITION COMPANY,<br><br>Defendants. | **Case No.** |

**COMPLAINT FOR DAMAGES AND JURY DEMAND**

**PARTIES, JURISDICTION, AND VENUE**

1. Plaintiff, Karrie Devine, the mother of baby K.D. (hereinafter "K.D."), brings this cause of action against Abbott Laboratories, Inc., ("Abbott" or "Defendant") and Mead Johnson & Company, LLC and Mead Johnson Nutrition Company ("Mead" or "Defendant") to recover for K.D.'s injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous cow's milk-based products.

2. On August 10, 2005, K.D. was born at Memorial Hospital in Bakersfield, California.

3. Defendant Mead Johnson & Company, LLC aka Mead Johnson Nutrition Company, a Delaware corporation with its principal place of business and global headquarters in Chicago, Illinois, manufactures, designs formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula products including Enfamil Human Milk Fortifier and Enfacare Powder.

4. Defendant Abbott Laboratories, Inc., an Illinois corporation with its principal place of business in Chicago, Illinois, manufactures, designs, formulates prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula including Similac Special Care.

5. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a) because complete diversity exists between Plaintiff and Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.

6. This Court has personal jurisdiction over Defendants because Defendants reside in this District because both have their principal place of business in this State, and both are authorized to conduct business and do conduct business in the State of Illinois. Defendants have marketed, promoted, distributed, and/or sold their Cow's Milk-Based Products in the State of Illinois and 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.

7. 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 are headquartered in this District and transact substantial business in this District.

## GENERAL ALLEGATION

8. On August 10, 2005, K.D. was born prematurely.

9. Following the birth, K.D. was placed in the Neonatal Intensive Care Unit (NICU) at Memorial Hospital in Bakersfield, California and Valley Children's Healthcare, Madera, California.

10. K.D. was intravenously fed Similac and Enfamil, while in the NICU.

11. After being fed Similac and Enfamil, on August 14, 2005, K.D. was diagnosed with Necrotizing Enterocolitis ("NEC") while in the NICU.

12. K.D. was subsequently diagnosed with cerebral palsy and failure to thrive. At the time K.D. was diagnosed with and treated for NEC, Plaintiff was unaware of the fact that the Defendant's cow's milk-based products fed to their baby caused or substantially contributed to the development of NEC and resulting injuries.

**THE SCIENCE**

13. 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 K.D. The WHO estimates that approximately 15 million babies are born preterm every year and that number is rising.

14. Nutrition for preterm babies, like K.D., 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.

15. Originally, cow's milk-based products were believed to be good for the growth of premature, low birth weight babies; however, science and research have advanced for decades confirming the significant dangers of the Defendants' cow's milk-based products in causing Necrotizing Enterocolitis ("NEC") 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 babies, yet, the Defendants did nothing to change their product, packaging, guidelines, instructions, and/or warnings. Additionally, advances in science have created alternative formulas and fortifiers that are derived from human milk and non-bovine based products; however, the Defendants continue to promote and sell their defunct cow's milk-based products.

16. As early as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula- fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. Babies born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast milk, but it was 20 times more common in those fed formula only. A. Lucas,

T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

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

18. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and human milk fortifier, these babies were 90% less likely to develop surgical NEC. Sullivan, S., et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products*. (Journal of Pediatrics 2010; 156:562-7.)

19. 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 [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). This same report stated that premature infants who are not breast fed are 138% more likely to develop NEC. Id., Table 1, p. 2.

20. 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 pre-term 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-e841 (2012).

21. A study published in 2013 showed that, out of 104 the premature infants participating in the study receiving an exclusive human-milk-based diet, all 104 exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, et al., *Human Milk Feed Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6-459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding cow's milk-based products, but the practice continued largely due to extensive and aggressive marketing campaigns conducted by infant formula companies.

22. In another study published in 2013 it was reported: "This is the first randomized trial in EP [Extremely Premature] infants of exclusive HM [Human Milk] vs. PF [Preterm Formula]. The significantly shorter duration of TPN and lower rate of surgical NEC support major changes in the strategy to nourish EP infants in the NICU." Cristofalo, E.A., et al., *Exclusive Human Milk vs. Preterm Formula: Randomized Trial in Extremely Preterm Infants.* (J Pediatr 2013 Dec; 163(6): 1592-1595.)

23. In a study published in 2014, it was reported: "Necrotizing enterocolitis (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." Good, Misty, et al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*. (Expert Rev Clin Immunol. 2014 July; 10 (7): 875-884.)

24. In that same article it was reported: "Necrotizing enterocolitis (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. 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. 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."

25. In that same article it was reported: "A wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing necrotizing enterocolitis. There have been several meta-analysis reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC. By determining the specific ingredients in breast milk that are protective against NEC, it is our hope that this devastating disease will one day be preventable."

26. In a study published in 2016 it was reported: "Extremely premature infants who received an exclusive HUM diet had a significantly lower incidence of NEC and mortality. The HUM group also had a reduction in late-onset sepsis, BPD, and ROP. This multicenter study further emphasizes the many benefits of an exclusive HUM diet, and demonstrates multiple improved outcomes after implementation of such a feeding protocol." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet.* (Breastfeeding Medicine. 2016, Nov. 2, 11(2):70-75.)

27. In a study published in 2017, it was reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis. Infants who receive greater than 50% of mother's own milk (MOM) in the 2 weeks after birth have a significantly decreased risk of NEC. An additional factor in the recent declining rates of NEC is the increased utilization of donor human milk (DHM). This creates a bridge until MOM is readily available, thus decreasing the exposure to cow milk protein. Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora. Ideally, preterm infants should be fed human milk and avoid bovine protein. A diet consisting of human milk-based human milk fortifier is one way to provide

the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a human milk diet." Maffei, Diana, Schanler, Richard J., *Human milk is the feeding strategy to prevent necrotizing enterocolitis!* (Semin Perinatol. 2017 Feb; 41(1):36-40.).

28. In another study published in 2017, it was reported: "In summary, HM [Human Milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs [Randomized Clinical Trials] on preterm infants weighing between 500 and 1250 g at birth compared the effect of bovine milk-based preterm infant formula to MOM or DHM on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence of NEC. A Cochrane systematic review that evaluated the effect of DHM or bovine milk-based formula on health outcomes for preterm infants also determined that formula significantly increases the risk of NEC." Shulhan, Jocelyn, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*. (ASN. ADV Nutr 2017; 8:8-0.91.)

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

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

31. Further, when Defendants recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier." Similar to the "Human Milk" formula, these names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that 91.2 percent of parents surveyed in the NICU

interpreted "human milk fortifier" as potentially meaning breast milk-based product.

32. Abbott's packaging directs users to: "Add only to human milk—do not add water." This direction is convoluted by Abbott's misleading use of the term human milk. The fortifier can be added to Abbott's "Human Milk" formula, as well as breast milk. There is no indication that the fortifier is only meant to be added to breast milk, and even if this was the intended direction, the widespread misapplication of the fortifier to Abbott's "Human Milk" formula would be its own doing by deliberately conflating and misdirecting the delineation of "human milk."

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

34. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary. As seen above, Abbott's packaging failed to give any precaution to use the product under the direction of a physician, however, newer packaging includes such a caution: "To be used only under the supervision of a doctor." The packaging seems to be changed recently to include this warning and products with the older packaging are still widely available to buy online.

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

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

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

38. On information and belief, Abbott was aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott has continued to use cow's milk as the foundation of their products. Abbott fails to mention "cow's milk" anywhere on its packaging, and surreptitiously refers to cow's milk under its ingredients as "Nonfat Milk." The words "cow's milk" or "cow" are nowhere to be found on any of the packaging or marketing for its product.

***Abbott's Failure to Provide Adequate Warnings, Instructions or Guidelines***

39. Defendant Abbott Laboratories, Inc. manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula and fortifier.

40. Abbott's Similac product contained only the following packaging information guidelines, instructions and warnings:

"Similac Special Care 20 – Precautions:

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician"

"Similac Special Care 24 – Precautions:

- Very low-birth weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician"

"Similac Special Care 24 High Protein – Precautions:

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued.
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician

"Similac Special Care 30 – Precautions:

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Use this product only after feedings of lower caloric density are well- established. For improved tolerance, it is best to increase caloric density slowly, by 2- to 4-Cal/fl oz increments
- Hydration status should be monitored
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician"

"Similac Special Care Premature 20 calorie and 24 calorie and High Protein Precaution:

- If signs of intolerance develop, slow feeding or discontinue.
- Not intended for low-birth-weight infants after they reach a weight of 3600 grams (approx. 8 lb.) or as directed by a doctor."

"Similac Special Care Premature 30 calorie – Precaution:

- Use once feeding tolerance is established
- If signs of intolerance develop, slow feeding or discontinue.
- Hydration status should be monitored
- Not intended for low-birth-weight infants after they reach a weight of 3600 grams (approx. 8 lb..) or as directed by a doctor."

41. Defendant Abbott's product, Similac Alimentum and Similac Alimentum Expert Care, contain only the following packaging information warnings and instructions:

Safety Precautions: Never use a microwave oven to warm mixture. Serious burns can result.
Warning: Powdered infant formulas 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.

42. Defendant Abbott's range of Human Milk Fortifiers contain only the following packaging information warnings and instructions:

Similac Human Milk Fortifier Concentrated Liquid: 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

Similac Human Milk Fortifer Hydrolyzed Protein Concentrated Liquid: 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 Hydrolyzed Protein Concentrated Liquid can be added to human milk
- Not intended for feeding low-birth-weight infants after they reach a

weight of 3600 g (approximately 8 lb..) or as directed by a physician

Similac Human Milk Fortifier Powder: Precautions

- Add only to human milk—do not add water
- 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 Power can be added to human milk (see Preparation, page 29)
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb.) or as directed by a physician

1. Barrett-Reis B, et al. Pediatrics. 2000;106:581-588. 2. Chan GM. J Perinatol. 2003;23:620-623.

3. *Escherichia coli, Staphylococcus, Group B Streptococcus, and Enterobacter sakazakii (now Cronobacter sakazakii).

Liquid Protein Fortifier: Precaution

- If signs of intolerance develop, slow feeding or discontinue.

43. Science and research have advanced in recent years confirming the dangers of the defendant's cow's milk-based product in causing NEC and death in premature infants, yet the Defendant did nothing to change its product, packaging, guidelines, instructions and warnings.

44. The warnings and instructions are overly broad and vague, and do not ever mention that the product significantly increases the risk of NEC and death, nor provide any detailed instructions or evidence on when and how to feed the infants and how to avoid NEC and death when feeding its products.

45. None of this medical literature properly warns the user that its product causes NEC and death nor does it provide guidance on how to avoid NEC or death while using its product.

46. Despite knowing that its product significantly increases the risk of NEC and death, Abbott Laboratories, Inc. deliberately chose to omit a specific warning of NEC or death, and deliberately failed to provide any detailed instructions or guidance on how to avoid NEC or death when feeding Similac.

47. The cow's milk-based product, Similac, is dangerous to premature infants in that it significantly increases the risk that the baby will develop NEC.

48. The cow's milk-based product, Similac, is dangerous to premature infants in that it significantly increases the risk that the baby will develop NEC and die.

49. The Defendant, Abbott Laboratories, Inc., failed to properly warn that its product, Similac, can significantly increase the risk that the premature infant will develop NEC and suffer catastrophic injuries as occurred to K.D.

50. Based on information and belief, Abbott Laboratories, Inc.'s cow's milk-based product, Similac, did cause K.D. to develop NEC.

51. The Defendant, Abbott Laboratories, Inc. was aware, or should have been aware, that its product was not safe for use, as it was used, in the premature infant, K.D., yet they took no steps to prevent its use in such a situation.

52. The Defendant, Abbott Laboratories, Inc. did foresee, or should have foreseen, that its product would be used as it was in the case of K.D. and knew or should have known, that such use would significantly increase the risk of NEC in K.D., yet it took no steps to prevent such use.

53. The product, Similac, was not safe to be used as it was in the case of K.D., and the Defendant knew, or should have known, it was unsafe, yet it failed to properly instruct, or warn the FDA, NICUs, hospitals, doctors and parents that its product was not safe.

54. The product, Similac, was not safe to be used as it was in the case of K.D. and the Defendant knew or should have known it was unsafe, yet it failed to provide detailed instructions or guidelines on when and how its product would be safe to use in a premature infant like K.D.

55. The Defendant, Abbott Laboratories, Inc, has marketed its products as safe and beneficial for premature infants like K.D.

56. Because the Defendant Abbott Laboratories, Inc.'s product is specially designed as food for vulnerable premature infants and contains no warning that it causes death or NEC, it is viewed as safe by physicians and parents of premature infants.

57. Because the Defendant Abbott Laboratories, Inc.'s product is specially designed as food for vulnerable premature infants and requires that no warning of NEC or death be given to parents or an informed consent be provided by hospitals or doctors, it is viewed as safe by

physicians and parents of premature infants.

58. The Defendant, Abbott Laboratories, Inc. has promoted its product for premature infants and claim its product increases the baby's weight and caloric intake and its product is more beneficial than harmful.

59. Notwithstanding strong medical evidence establishing the extreme dangers that cow's milk-based products pose for premature infants, Abbott Laboratories, Inc. has marketed its cow's milk-based products as an equally safe alternative to breast milk and has promoted its products as necessary for additional nutrition and growth. The Defendant has specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants*, when indeed its product poses a known and substantial risk to these babies.

60. Moreover, Abbott Laboratories, Inc. has also attempted to market its products specifically to *premature infants*, who are the infants at highest risk from the dangers of the product.

61. As of 2016, Abbott Laboratories, Inc. marketed and sold seven products specifically targeting "Premature/Low Birth-Weight Infants": Liquid Protein Fortifier, Similac® NeoSure®, Similac® Human Milk Fortifiers, Similac® Special Care® 20, Similac® Special Care® 24, Similac® Special Care® 24 High Protein, and Similac® Special Care® 30.

62. With the proliferation of the internet, the Defendant, Abbott Laboratories, Inc., has updated its tactics to advertise heavily online and through its own website.

63. In this promotional website, there is no mention of the risk of necrotizing enterocolitis. The promotional web page expressly and implicitly represents that its cow's milk-based products are safe for use with premature infants. This is false and misleading. Abbott Laboratories, Inc. advertisements claim to give proper nourishments but fails to disclose the risk.

64. Thus, despite the existence of alternative and safe human milk-based formulas and fortifiers, Defendant Abbott continues to market and/or sell its cow's milk-based products under the guise of being safe for newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like K.D.

65. Abbott Laboratories, Inc. knew or should have known that its product would be used in the way it was used on this premature infant, K.D.

66. The way in which the Defendant Abbott Laboratories, Inc. product was fed to K.D. was extremely dangerous and caused an unreasonably high risk that he would develop NEC, yet the defendant, Abbott Laboratories, Inc., provided no detailed instructions or warnings to prevent or alter the way this product was used.

67. The Defendant, Abbott Laboratories, Inc. has learned that its cow's milk-based product was causing NEC, devastating injuries, and death in premature infants, yet Defendant Abbott did nothing to change its product, packaging, guidelines, instructions and warnings.

68. The mother, Karrie Devine, was never told that the Similac product could cause her baby to develop NEC.

69. The mother, Karrie Devine, was never told that the Similac product could cause her baby any harm.

70. The mother, Karrie Devine, was never told that the Similac was made from cow's milk.

71. The mother, Karrie Devine, was never told of the studies showing cow's milk-based product was extremely dangerous to her baby.

72. Had the mother, Karrie Devine, been made aware of the facts, data, and science that linked Similac to NEC, she would not have allowed her daughter to be fed Similac.

73. The FDA requires manufacturers of prescription medications to study their medications and perform drug trials and collect data to determine the safety and efficacy of their drugs and to determine the likelihood of side effects and to continuously study the drug's use to review adverse outcomes and create proper warnings and instructions; however, because baby products, such as Similac, are not drugs, the manufacturer, Abbott does not perform such trials and does not collect data on when and how the product should be fed. Despite knowing for decades that the products are significantly increasing NEC and death in premature infants, and are far more dangerous than most prescription drugs, Abbott is doing nothing to stop or lessen NEC or death.

74. If Abbott had performed the pharmacovigilance required by drug manufacturers for their premature infant formulas and fortifiers, these products would not have been fed to K.D. and he would not have developed NEC and he would not have suffered the devastating effects of NEC.

75. There are human milk-based formulas and fortifier products which are feasible alternatives to the premature infant formula and fortifier products.

***Mead Johnson's Failure to Provide Adequate Warnings, Instructions, or Guidelines***

76. The Defendant, Mead Johnson & Company, LLC and/or Mead Johnson Nutrition Company manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula including Enfamil Human Milk Fortifier and Enfacare Powder.

77. Defendant Mead's product, Enfamil Human Milk Fortifier, contained only the following packaging information guidelines, instructions and warnings:

> 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 if 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.
> Caution: Nutritionally Incomplete: To be used only under the supervision of a physician.
> Caution: Regarding use in extremely low-birth-weight infants (ELB.W
> -1 kg or less): Hypercalcemia has been reported in some of these infants on full enteral feeds of human milk supplemented with human milk fortifiers.

78. The product, Enfacare Powder, contained only the following packaging information guidelines, instructions and warnings:

> "Warning: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilation, use or storage may result in severe harm. Although this powder is formulated for infants born prematurely, powdered infant formulas 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. Ask your

baby's doctor which formula is appropriate for your baby."

79. Defendant Mead cited no medical literature or research to guide the user for its product, Enfacare Powder, nor that its product causes or significantly increases the risk of NEC or death.

80. As previously discussed, science and research have advanced in recent years confirming the dangers of the Defendant Mead's cow's milk-based product in causing NEC and death in premature infants, yet Defendant Mead did nothing to change its product, packaging, guidelines, instructions and warnings.

81. The warnings and instructions are overly broad and vague, and do not ever mention that the product significantly increases the risk of NEC and death, nor provide any detailed instructions or evidence on when and how to feed the infants and how to avoid NEC and death when feeding its products.

82. Despite knowing that its product significantly increases the risk of NEC and death, Defendant Mead deliberately chose to omit a specific warning of NEC or death, and deliberately failed to provide any detailed instructions or guidance on how to avoid NEC or death when feeding Enfamil.

83. Enfamil contains bovine or cow's milk-based formula.

84. The cow's milk-based formula product, Enfamil, is dangerous to premature infants in that it significantly increases the risk that the baby will develop NEC.

85. The cow's milk-based formula product, Enfamil, is dangerous to premature infants in that it significantly increases the risk that the baby will die.

86. The Defendant, Mead, failed to properly warn that its product, Enfamil, can significantly increase the risk that the premature infant will develop NEC and suffer catastrophic injuries as occurred to K.D.

87. The Defendant, Mead's cow's milk-based formula product, Enfamil, did cause K.D. to develop NEC.

88. The Defendant, Mead, was aware, or should have been aware, that its product was not safe for use, as it was used, in the premature infant, K.D., yet it took no steps to prevent its use in such a situation.

89. The Defendant, Mead did foresee, or should have foreseen, that its product would be used as it was in the case of K.D., and knew or should have known, that such use would significantly increase the risk of NEC in K.D., yet it took no steps to prevent such use.

90. The product, Enfamil, was not safe to be used as it was in the case of K.D., and the Defendant Mead knew, or should have known, it was unsafe, yet it failed to property instruct or warn the FDA, NICUs, hospitals, doctors and parents that its product was not safe.

91. The product, Enfamil, was not safe to be used as it was in the case of K.D. and the Defendant, Mead, knew, or should have known, it was unsafe, yet it failed to provide detailed instructions or guidelines on when and how its product would be safe to use in a premature infant like K.D.

92. The Defendant, Mead, has marketed its products as safe and beneficial for premature infants like K.D.

93. Because the Mead product is specially designed as food for vulnerable premature infants and contains no warning that it causes death or NEC, it is viewed as safe by physicians and parents of premature infants.

94. The Defendant, Mead, has marketed and sold its products as safe and beneficial for premature infants like K.D.

95. The Defendant, Mead, has promoted its products for extremely premature infants and claim its products increases the babies' weight and caloric intake and its product is more beneficial than harmful.

96. The studies show the Mead products should not be sold for use in extremely premature infants, yet Defendant Mead continued to market and sell its product knowing it would be used on infants like K.D. and knowing its product would significantly increase the risk of NEC and death in extremely premature infants like K.D.

97. Defendant Mead promotes a range of products specifically for "premature and low weight" babies on their website: Enfamil Human Milk Fortifier Liquid High Protein, Enfamil Milk Fortifier Liquid Standard Protein, Enfamil NeuroPro Enfacare, Enfamil Premature 20 Cal, Enfamil Premature 24 Cal, Enfamil Premature 24 Cal/fl oz HP, Enfamil Premature 30 Cal, Enfamil Human Milk Fortifier Acidified Liquid, Enfamil Human Milk Fortifier Powder, Enfamil 24 and DHA & ARA Supplement.

98. Notwithstanding strong medical evidence establishing the extreme dangers that cow's milk-based products pose for premature infants, Defendant Mead have marketed their cow's milk-based products as equally safe alternatives to breast milk, and have promoted their products as necessary for additional nutrition and growth. Defendant Mead has specifically marketed its formula and fortifiers as necessary to the growth and development of premature infants, when indeed the products pose a known and substantial risk to these babies.

99. Mead knew or should have known that its product would be used in the way it was used on this premature infant, K.D.

100. The way in which the Mead product was fed to K.D. was extremely dangerous and caused an unreasonably high risk that he would develop NEC, yet the defendant, Mead, provided no detailed instructions or warnings to prevent or alter the way this product was used.

101. The Defendant, Mead, has learned that its cow's milk-based product was causing NEC, devastating injuries, and death in premature infants, yet Defendant did nothing to change its product, packaging, guidelines, instructions and warnings.

102. The mother, Karrie Devine, was never told that the Enfamil formula could cause her baby to develop NEC.

103. The mother, Karrie Devine, was never told that the Enfamil formula could cause her baby any harm.

104. If the mother had known of the significant risks of feeding Enfamil to her premature infant, she would not have allowed the product to be fed to her baby.

105. Mead has known for many years that their Enfamil premature infant products are causing premature infants to develop NEC, devastating injuries, and die and know that hospitals and physicians around the United States are not informing the parents of this risk and Defendant Mead Johnson promotes this silence to protect its brands and profits.

106. The FDA requires manufacturers of prescription medications to study their medications and perform drug trials and collect data to determine the safety and efficacy of their drugs and to determine the likelihood of side effects and to continuously study the drug's use to review adverse outcomes and create proper warnings and instructions; however, because baby formulas, such as Enfamil, are not drugs, the manufacturer, Mead does not perform such trials and does not collect data on when and how the formula should be fed. Despite knowing for decades that the products are significantly increasing NEC and death in premature infants, and are far more dangerous than most prescription drugs, Mead is doing nothing to stop or lessen NEC or death.

107. If Mead had performed the pharmacovigilance required by drug manufacturers for their premature infant formulas and fortifiers, these products would not have been fed to K.D. and he would not have developed NEC and he would not have suffered the devastating effects of NEC.

108. The products made from cow's milk, specifically for premature infants by Enfamil, are unsafe to premature infants and are avoidable for use in that there is human donor milk available and/or human milk derived fortifier products available made from human milk instead of cow's milk.

109. Despite knowing that its cow's milk-based product was causing NEC, devastating injuries, and death in premature infants, Mead did not recommend to the FDA, hospitals, NICUs or physicians that they should discuss the risks of NEC or death with the parents.

110. There are human milk-based formulas and fortifier products which are feasible alternatives to the premature infant formula and fortifier products offered by Mead Johnson.

## DAMAGES SUFFERED BY PLAINTIFFS

111. As a result of her exposure to Abbott and/or Mead's cow's milk-based products, K.D. was required to undergo medical care and costs. K.D. was diagnosed with NEC and suffered further complications including failure to thrive and cerebral palsy.

112. Also, her mother, Karrie Devine, suffered extensive financial loss and costs and emotional harm and distress related to her daughter's injuries.

## COUNT I FAILURE TO WARN

**(As to All Defendants)**

113. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

114. Defendants, as the manufacturer and/or seller of the product at issue in this litigation, 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 such products with preterm infants, specifically including but not limited to the risk of NEC and serious bodily injury.

115. Defendants, as the manufacturer and/or seller of the product at issue in this litigation, 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 Similac products that contained cow's milk-based ingredients, as the magnitude of the risk involved is using Abbott's Similac with preterm infants is significant and involves the real danger of serious bodily injury and potentially death.

116. Defendants' duty to warn is part of its general duty to design, manufacture, and sell its products that are reasonably safe for their foreseeable uses and by designing Similac and/or Enfamil with cow's milk-based ingredients, Defendants undertook a duty to adequately warn of the unreasonable risk of harm posed by such ingredients and specifically the increased risk of NEC, bodily injury, and even death of use of the such products by pre-term infants like Plaintiff.

The failure to warn creates a defect and makes the Similac and Enfamil products at issue in this litigation unreasonably dangerous.

117. Specifically, Defendants breached their duty to warn of the foreseeable risks of the Similac and Enfamil products at issue in this litigation because Defendants knew or should have known that its cow's milk-based product (or its instructions/label):

a. Would be used, as it was, on premature infants like K.D. yet it failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that their cow's milk-based product significantly increases the risk of NEC and death in these babies; and/or
b. Was unsafe and/or contra-indicated for premature infants like K.D.; and/or
c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed their products to premature infants in order to decrease the risk of NEC and/or death; and/or
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-based product; and/or
e. Failed to provide instructions that parents needed to know that the Defendant's product carried a significant risk that its cow's milk- based product could cause their baby to develop NEC and die; and/or
f. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn on cow's milk-based products significantly involving the risk of NEC and death or providing any details on how to avoid such harm; and/or
g. Failed to have 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 premature infants; and/or
h. Failed to provide well researched and well-established studies that linked their cow's milk-based products to NEC and death in premature infants; and/or
i. Failed to cite to or utilize current up to date medical data on the proper and safe use of their products; and/or
j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow's milk- based product; and/or
k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or
l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or
m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, K.D. was fed cow's milk-based products which caused him to develop NEC; and/or
n. Science and data have established that the only consistent observations made in infants who develop NEC are the presence of: 1) prematurity 2) cow's milk-based products, yet Defendants fail to warn of this significant scientific conclusion and instead tries to

hide this conclusion; and/or

o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to K.D.; and/or
p. Failed to establish a standard for safe use; and/or
q. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or
r. Failed to provide statistical evidence of adverse effects regarding the feeding of their products; and/or
s. Failed to guide or instruct on when to start, how much to start, how to increase, volume and timing of feeds, when not to feed, and/or when to stop feeding their products to premature infants; and/or
t. Failed to provide periodic or yearly safety reports; and/or
u. Failed to provide periodic or yearly risk-benefit analysis for use of their products; and/or
v. Failed to provide or produce yearly safety update reports; and/or
w. Failed to develop a protocol for hospitals and physicians with the elements to assure safe use; and/or
x. Failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of their products specifically designed for premature infants.

118. Moreover, had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based products, they would have not used such a dangerous product on K.D. Had Makai Sander's mother known of the extreme risks associated with feeding premature infants cow's milk-based product, she would have not allowed such a product to be given to her daughter.

119. As a result and proximate cause, K.D. was fed Defendant Abbott's Similac and Defendant Mead's Enfamil cow's milk-based product causing her to develop NEC.

120. As a direct and proximate result of Defendants' failure to warn as explained herein Plaintiff Karrie Devine suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected as a direct and proximate result of Defendants' conduct described herein.

## COUNT II

## STRICT LIABILITY FOR DEFECTIVE PRODUCT

**(Against All Defendants)**

121. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

122. Defendants as the manufacturer and/or seller of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to manufacture, sell, and distribute its Similac and Enfamil infant products in a manner that was not unreasonably dangerous and is liable despite any care exercised to design a safe product.

123. Despite knowing that its product would be used on premature infants, like K.D., and despite knowing (or should have known) that such use was unreasonably dangerous to premature infants in that its cow's milk-based product was significantly increasing the risk of NEC and death, the Defendants continued to sell and market their defective products to premature infants.

124. Over the last several years, 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 product's benefits, yet the Defendants continued to market and sell their defective products for premature infants like K.D.

125. The Defendants' cow's milk-based products, Similac and Enfamil, fed to K.D. was unreasonably dangerous.

126. The risks of feeding the Defendants; cow's milk-based products, Similac and Enfamil, to K.D. outweighed its benefits.

127. Defendants failed to develop a human-based milk product which was safer for premature infants although they knew of this development and were aware of its superiority to the products that it offered.

128. Defendants also failed to properly reformulate their products to reduce the risks of NEC, devastating injuries, and/or death even though they knew of safer, more effective alternative

reformulations that would have made their products safer to use and not carry the added and significant risk of NEC.

129. As a direct result Defendants' unreasonably dangerous products were fed to K.D. causing her to develop NEC, which led to further injuries including failure to thrive and cerebral palsy.

130. As a direct and proximate result of Defendants' developing, manufacturing, selling, and distributing their unreasonably dangerous cow's milk-based products, Plaintiff Karrie Devine suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected as a direct and proximate result of Defendants' conduct described herein.

## COUNT III NEGLIGENCE

**(As to All Defendants)**

131. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

132. Defendants as the designer, manufacturer, seller, and distributor of the cow's milk products that are the subject of this action had a duty to the general public and to the Plaintiff to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when said products are used in their intended manner and for their intended purpose.

133. At all relevant times to this action K.D. used the products at issue in their intended manner and for their intended purpose.

134. Defendants, directly or indirectly, negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based products and thereby breached their duty to the general public and Plaintiff.

135. Specifically, Defendants breached their duty by:

a. Would be used, as it was, on premature infants like K.D. yet they failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that their cow's milk-based products significantly increases the risk of NEC and death in these babies; and/or
b. Was unsafe and/or contra-indicated for premature infants like K.D.; and/or

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

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 product; and/or

e. Failed to provide instructions that parents needed to know that the Defendants' products carried a significant risk that its cow's milk- based product could cause their baby to develop NEC and die; and/or

f. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn on cow's milk-based product significantly involving the risk of NEC and death or providing any details on how to avoid such harm; and/or

g. Failed to have 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 premature infants; and/or

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

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

j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow's milk- based product; and/or

k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or

l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or

m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, K.D. was fed cow's milk-based products which caused him to develop NEC; and/or

l) Science and data have established that the only consistent observations made in infants who develop NEC are the presence of: 1) prematurity 2) cow's milk-based product, yet Defendants failed to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or

n. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to K.D.; and/or

o. Failed to establish a standard for safe use; and/or

p. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or

q. Failed to provide statistical evidence of adverse effects regarding the feeding of their products; and/or

r. Failed to guide or instruct on when to start, how much to start, how to increase, volume and timing of feeds, when not to feed, and/or when to stop feeding their products to premature infants; and/or

s. Failed to provide periodic or yearly safety reports; and/or

t. Failed to provide periodic or yearly risk-benefit analysis for use of their products; and/or
u. Failed to provide or produce yearly safety update reports; and/or
v. Failed to develop a protocol for hospitals and physicians with the elements to assure safe use; and/or
w. Failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of their products specifically designed for premature infants.

136. Additionally, despite knowing for many years that the most vulnerable humans were suffering extreme harm related to the feeding of its products, failed to perform the necessary scientific process of collection, detection, assessment, monitoring, and prevention of these adverse effects of feeding its products.

137. Had Defendants not committed negligence, K.D. would not have been exposed to Defendants' unreasonably dangerous products and thereafter suffered injuries as stated herein.

138. As a direct result Defendants' negligence as described herein, Defendant's unreasonably dangerous products were fed to K.D., causing her to develop NEC, which led to further injuries including failure to thrive and cerebral palsy.

139. As a direct and proximate result of Defendants' negligent conduct, Plaintiff Karrie Devine suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected as a direct and proximate result of Defendants' conduct described herein.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

1. For general damages in an amount to be proven at trial;
2. For special damages in an amount to be proven at trial;
3. For interest as permitted by law;
4. For costs of suit; and
5. For such other and further relief as the Court deems proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a jury trial for all claims for triable.

Respectfully Submitted,

DATED: March 7, 2022

***Counsel for Plaintiffs KARRIE DEVINE, as Parent, Guardian Ad Litem, and as Next Friend of K.D., a minor,***