

**MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT
CITY OF ST. LOUIS**

**MARGO GILL, ON BEHALF OF
HERSELF AND HER MINOR CHILD,
R.D.,**

Plaintiff,

v.

ABBOTT LABORATORIES, et al.,

Defendants.

Cause No.: 2322-CC01251

Div 22

FIRST AMENDED PETITION

Plaintiff Margo Gill, on behalf of herself and her minor child R.D., brings this First Amended Petition against Abbott Laboratories Inc. as well as Susie Mondello, Matthew McClure, and Tara Todd (together with Abbott, “Defendants”). Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters:

NATURE OF THE ACTION

1. This action arises out of injuries suffered by R.D. when, as a premature infant, she was given Defendants’ cow’s milk-based infant feeding products. Defendants’ products caused her to develop necrotizing enterocolitis (“NEC”), a life- altering and deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, R.D. was seriously injured, resulting in accompanying harm to her mother, Margo Gill.

2. Plaintiff brings this cause of action against Defendants to recover for injuries that are the direct and proximate result of R.D.’s consumption of Defendants’ unreasonably dangerous cow’s milk-based infant feeding products.

PARTIES

3. Plaintiff, Margo Gill, is a natural person and a resident of Illinois. She is the mother of R.D., a minor. Margo Gill and R.D. intend to remain in Illinois indefinitely, are domiciled in Illinois, and are citizens of Illinois.

4. Defendant Abbott Laboratories Inc. (“Abbott”) is a corporation, incorporated under the laws of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

5. Defendant Matthew McClure was, and is, a sales representative for Abbott. He has served in that position since at least 1997. Mr. McClure is a natural person and resident of Missouri. He is domiciled in Missouri and is a citizen of Missouri.

6. Defendant Tara Todd was a sales representative for Abbott. She served in that position from March 2018 to November 2021. Ms. Todd is a natural person and resident of Missouri. She is domiciled in Missouri and is a citizen of Missouri.

JURISDICTION AND VENUE

7. At all relevant times, Defendants had, and continue to have, regular and systematic contact with and conduct business in and from Missouri, such that they have purposefully availed themselves of the laws of Missouri and expect to both sue and be sued in Missouri. Defendants’ presence in Missouri satisfies the due process requirements for Missouri courts to exercise jurisdiction over them. Defendants have consented to the exercise of jurisdiction over them by Missouri courts by registering and conducting business from Missouri. This Court may exercise specific personal jurisdiction over all Defendants because the cause of action arises out of or is related to Defendants’ activities in Missouri and Defendants purposefully availed themselves of the privilege of conducting activities within Missouri. This Court may exercise

general personal jurisdiction over Matthew McClure and Tara Todd because they are domiciled in and reside in Missouri.

8. Missouri's general venue statute, Mo. Rev. Stat. § 508.010.4, provides as follows:

Notwithstanding any other provision of law, in all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the acts or conduct alleged in the action.

9. Venue is proper in the Twenty-Second Judicial Circuit pursuant to Mo. Rev. Stat. § 508.010.4 because R.D. developed NEC after first being exposed to Defendants' products while receiving care at Cardinal Glennon Children's Hospital in the City of St Louis, Missouri.

FACTUAL ALLEGATIONS

R.D.'s NEC Diagnosis

10. R.D. was born prematurely at SSM St. Mary's Hospital in St. Louis, Missouri on August 26, 2021.

11. Shortly after her birth, R.D. was transferred to Cardinal Glennon Children's Hospital in the City of St. Louis, Missouri, where she was fed Similac and/or Enfamil cow's milk-based products for the first time.

12. After she ingested Defendants' products, R.D. developed NEC.

13. R.D. was forced to undergo extensive surgery as a result of her NEC diagnosis and has continued to suffer long-term health consequences throughout her life.

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

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the

intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was **six to ten** times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and **three times** more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was **20 times more common** in those only fed cow's milk formula than in those fed breast milk.

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

18. 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.

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

breastfed are **138% more likely** to develop NEC.

20. The American Academy of Pediatrics, “an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults,” has advised that *all* premature infants should be fed either their mother’s milk or, if their mother’s milk is unavailable, pasteurized human donor milk. This recommendation is based on the “potent benefits of human milk,” including “lower rates of ... NEC.”

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

22. 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.

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

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

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated

risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

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

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

27. At the times R.D. was fed Defendants' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

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

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

29. Abbott has aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to R.D.'s birth.

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

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

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

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their

families.

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

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

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

website until at least December 2020.

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

38. Mr. McClure was responsible for convincing hospital personnel, including personnel at the hospital where R.D. was treated and developed NEC, to give Abbott's products to infants and/or to convince parents like Ms. Gill to allow her child to be fed those products.

39. In connection with his job duties, Mr. McClure provided information about Abbott's products to hospital personnel, including personnel at the hospitals where R.D. was treated and developed NEC. Abbott sales representatives routinely misrepresented the risks and benefits of their products versus human milk and human milk products, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

40. Ms. Todd was responsible for convincing hospital personnel, including personnel at the hospital where R.D. was treated and developed NEC, to give Abbott's products to infants and/or to convince parents like Ms. Gill to allow her child to be fed those products.

41. In connection with her job duties, Ms. Todd provided information about Abbott's products to hospital personnel, including personnel at the hospitals where R.D. was treated and developed NEC. Abbott sales representatives routinely misrepresented the risks and benefits of their products versus human milk and human milk products, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

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

43. Further, when Abbott 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." This name is misleading in that it suggests that the product is derived from breast milk, when, in fact, it is a cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



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

Defendants' Inadequate Warnings and Other Misconduct

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

46. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

47. 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.

48. 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.

49. 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.

50. At all relevant times, Abbott knew its pre-term infant formula was the primary controllable risk factor for NEC.

51. Although Abbott knew that ingestion of infant formula was the primary controllable risk factor for NEC, Abbott concealed this fact from parents.

52. Although Abbott knew that ingestion of infant formula was the primary risk factor for NEC, Abbott concealed this fact from healthcare providers.

53. Although Abbott knew that ingestion of infant formula was the primary controllable risk factor for NEC, Abbott concealed this fact from the FDA.

54. Abbott also concealed from the FDA all deaths related to its infant formula in violation of federal regulations that required Abbott to report those deaths.

55. Abbott engaged in efforts to impede competitors from conducting research as to whether human milk oligosaccharides (HMOs) in its formula products could decrease the deadly disease called NEC.

56. Abbott manipulated scientific findings to avoid admitting there was evidence that infant formula causes NEC.

Safer Alternative Designs

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

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

59. 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 and Mead have continued to use cow's milk as the foundation of their products.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott)

60. Plaintiff incorporates by reference the preceding paragraphs of this Petition.

61. Abbott, 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 manufacture, sell, and distribute its products in a manner that was not unreasonably dangerous.

62. Abbott also owed a duty to the consuming public in general, and Plaintiff in particular, to manufacture, sell, and distribute its products in a manner that was merchantable and reasonably suited for their intended use.

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

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

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

66. Abbott's Mead's products contained cow's milk at the time they left the manufacturing facility.

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

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

68. Abbott's products were fed to R.D., which directly and proximately caused her NEC and injuries.

69. As a further direct result, Ms. Gill suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by R.D.'s injuries.

70. Abbott's acts, omissions and/or representations showed a deliberate and flagrant disregard for the safety of others, and therefore, Plaintiff is entitled to punitive damages to punish and to deter Abbott and others from like conduct.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott)

71. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Petition.

72. Abbott, as the manufacturer and/or seller of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of its products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

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

issue in this litigation unreasonably dangerous.

74. Specifically, Abbott breached its duty to warn of the foreseeable risks of the infant products at issue in this litigation because Abbott knew or should have known that its cow's milk-based premature infant products would be fed to premature infants like R.D. and that its products might cause those infants to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, Abbott:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like R.D.; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants' products, notwithstanding their

substantial risks; and/or

- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

75. Abbott's products contained cow's milk at the time they left the manufacturing facility.

76. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Abbott's products, R.D. was fed cow's milk-based products, which caused her to develop NEC.

77. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed R.D. those products. Had Ms. Gill known of the significant risks of feeding R.D. cow's milk-based formula, she would not have allowed such products to be fed to her child.

78. As a further direct result, Ms. Gill suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by R.D.'s injuries.

79. Abbot's acts, omissions and/or representations showed a deliberate and flagrant disregard for the safety of others, and therefore, Plaintiff is entitled to punitive damages to punish and to deter Abbott and others from like conduct.

COUNT III: NEGLIGENCE
(Against All Defendants)

80. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Petition.

81. Abbott, 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 exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

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

83. Abbott, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and Plaintiff. Mr. McClure and Ms. Todd directly or indirectly, negligently marketed, sold, and/or distributed Mead's and Abbott's cow's milk-based infant products at issue in this litigation, including to R.D.'s caregivers, and thereby breached their duty to the general public and Plaintiff.

84. Specifically, although Abbott knew or reasonably should have known at the time of production that its cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by:

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

contraindicated for premature infants like R.D.; and/or

- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants’ products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

85. Mr. McClure and Ms. Todd knew or reasonably should have known at the time of marketing, sale, and/or distribution of cow’s milk- based infant products significantly increased the risk of NEC, serious injury, and death; they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like R.D.; and/or
- c. Failing to provide the hospitals for which she was Mead's sales representative, including R.D.'s treating hospitals, with the well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- d. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- e. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- f. Misrepresenting that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

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

87. As a direct and proximate result of Defendants' failure to act in a reasonably prudent manner and their breach of duty, R.D. was fed cow's milk-based products, which

caused her to develop NEC.

88. Had Defendants satisfied their duties to the consuming public in general, R.D. would not have been exposed to their unreasonably dangerous cow's milk-based products.

89. As a further direct result, Ms. Gill suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by R.D.'s injuries.

90. Abbott's acts, omissions and/or representations showed a deliberate and flagrant disregard for the safety of others, and therefore, Plaintiff is entitled to punitive damages to punish and to deter Abbott and others from like conduct.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against All Defendants)

91. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Petition.

92. At all times relevant to this action, R.D. (and her caretakers) used the products at issue in their intended manner and for their intended purpose.

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

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

95. Specifically, Defendants made the following false statements of material fact on an ongoing and repeated basis and prior to the time R.D. was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.
- j. That premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

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

97. Defendants' misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including R.D.'s hospital and health care providers, to provide their infant products to babies, including R.D.

98. Ms. Gill was not aware that these misrepresentations were false and justifiably relied on them. Defendants' misrepresentations induced Ms. Gill to allow her child to be fed Abbott's infant products, in reliance on all the messaging she received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Defendants not committed these intentional misrepresentations, R.D. would not have been exposed to the Defendants' unreasonably dangerous cow's milk-based products.

99. As a direct and proximate result, Abbott's products were fed to R.D., causing her NEC and subsequent injuries.

100. As a further direct result, Ms. Gill has suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by R.D.'s injuries.

101. Abbott's acts, omissions and/or representations showed a deliberate and flagrant disregard for the safety of others, and therefore, Plaintiff is entitled to punitive damages to punish and to deter Abbott and others from like conduct.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against All Defendants)

102. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Petition

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

104. Defendants, as the manufacturers and/or sellers of the products at issue in this

litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

105. In the course of their business, Defendants breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials and interactions, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

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

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

107. Upon information and belief, Mr. McClure and Ms. Todd made the same false statements of material fact on an ongoing and repeated basis including to individuals at R.D.'s treating hospital and prior to the time R.D. was fed their products. Upon information and belief, Mr. McClure and Ms. Todd also represented that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

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

109. Defendants' misrepresentations were intended to and did in fact induce hospitals and health care providers, including R.D.'s hospital and health care providers, to provide their products to babies, including R.D.

110. Defendants' misrepresentations induced, and were intended to induce, parents to allow their children to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Defendants not committed these negligent misrepresentations, R.D. would not have been exposed to their unreasonably dangerous cow's milk-based

products.

111. As a direct and proximate result, Abbott's and Mead's products were fed to R.D., causing her NEC and subsequent injuries.

112. As a further direct result, Ms. Gill suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by R.D.'s injuries.

113. Abbott's acts, omissions and/or representations showed a deliberate and flagrant disregard for the safety of others, and therefore, Plaintiff is entitled to punitive damages to punish and to deter Abbott and others from like conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

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

115. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Defendants' conduct;

116. 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;

117. For interest as permitted by law;

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

119. For punitive damages; and

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

DEMAND FOR JURY TRIAL

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

Dated: May 30, 2024.

Respectfully submitted,

/s/John F. Garvey

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing First Amended Petition has been filed by using the Court's electronic case filing system, thereby serving all counsel of record, on this 30th day of May, 2024.

/s/John F. Garvey