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

Tess Wallace, individually and on behalf of her minor child, M.C., Plaintiff, v. Abbott Laboratories Inc., Defendant.	CIVIL ACTION DEMAND FOR JURY TRIAL Case No.: 1:23-cv-3396 Direct Filing to MDL No. 3026, Case No. 1:22-cv-00071

COMPLAINT

Plaintiff complains of Defendants Abbott Laboratories Inc., ("Defendant" and/or "Abbott") as follows, based on her personal knowledge and on information and belief:

I. INTRODUCTION

1. This is an action to redress the injuries suffered by Plaintiff Tess Wallace and her minor daughter M.C., who has spent the majority of her young life fighting against the harm caused by cows' milk-based "human milk fortifier" manufactured, marketed, and sold by Defendant Abbott Laboratories Inc.. M.C. suffered from necrotizing enterocolitis as a result of being fed Abbott's cows' milk-based fortifier. Necrotising enterocolitis ("NEC") is a potentially fatal disease that largely affects premature and low birth-weight babies. There is a significantly increased rate of NEC among that population of premature infants who are fed cows' milk-based formula or fortifier. M.C., a prematurely born, low birth-weight baby, was fed Abbott's cows' milk-based fortifier Similac, and developed NEC as a result.

2. Plaintiff brings claims against Defendant Abbott arising as a result of Defendant's negligent, willful, and wrongful misconduct in connection with the design, development,

manufacture, testing, packaging, promotion, marketing, distribution, and labeling of its cows' milk-based human milk fortifier, Similac.

II. JURISDICTION AND VENUE

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

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

5. This Court has personal jurisdiction over Defendant. Defendant is incorporated under the laws of Illinois and is authorized to conduct business and does conduct business in the States of Illinois and California. Defendant has marketed, promoted, distributed, and/or sold its cows' milk-based fortifier in the States of Illinois and California, and Defendant has sufficient minimum contacts with this state and/or sufficiently avails itself of the markets in the state through its promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

6. 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 Defendant transacts substantial business in this District.

III. THE PARTIES

7. Plaintiff resides in New York, New York.

8. M.C., Plaintiff's daughter, was born in New York, New York in 2021.

9. Defendant Abbott is a corporation incorporated under the laws of Illinois with its principal place of business in Abbott Park, Illinois.

IV. BACKGROUND

A. The Science

10. Abbott's Similac Human Milk Fortifier (whether in the form of a powder or a concentrated liquid) is a cows' milk-based product.

11. Scientific research has demonstrated that feeding premature infants cows' milk-based formulas or fortifiers can cause NEC.

12. More than thirty years ago, in 1990, a prospective multi-center study on 926 preterm infants found that NEC was 6 to 10 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. Antoine Lucas, et al., *Breast Milk and Neonatal Necrotising Enterocolitis*, 336 LANCET 1519–23 (1990).

13. A study published in 2010 established that when premature babies were fed an exclusive human-milk diet (containing mother's own milk and/or pasteurized donor milk, with the addition of human-milk-based fortifier), these babies were 90% less likely to develop surgical NEC compared to infants who received the usual feeding protocol with human milk supplemented with bovine-based fortifier and cows' milk-based formula if mother's own milk was insufficient. Sandra Sullivan, 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*, 156 J. OF PEDIATR. 562-67 (2010).

14. Other scientific studies further established that administering an exclusive human-milk diet to extremely premature infants significantly reduced the risk of NEC—and was cost-effective for NICUs.

15. As Ziegler, et al. concluded: "A fortifier based on human milk protein has recently been shown to provide, if used in conjunction with banked donor milk, better protection against NEC than a fortifier based on bovine milk protein used in conjunction with formula." Ziegler EE. *Meeting the nutritional needs of the low-birth-weight infant*. ANN NUTR METAB. 2011; 58 Suppl. 1:8–18.

16. Czank, et al. advised that while it is necessary to fortify human milk to achieve optimal growth in the preterm infant, the addition of non-human-milk components is suboptimal because it increases the risk of feeding intolerance and necrotizing enterocolitis. The study concluded that human milk-based fortifier can be designed to appropriately meet the protein and energy requirements of the preterm infant. Czank C, Simmer K, Hartmann PE. *Design and characterization of a human milk product for the preterm infant.* BREASTFEED MED. 2010 Apr; 5(2):59–66.

17. The use of a 100% human-milk-based diet for premature infants has long been known to be cost-effective. Ganapathy, et al. concluded that "[t]he NICU cost burden of NEC among [extremely premature] infants is huge. Provision of an exclusively human milk diet composed of mother's own milk, or donor human milk when mother's milk is not adequately available, and fortified by donor HMF can result in saving net NICU resources and produce societal value by preventing infant mortality." Ganapathy V, Hay JW, Kim JH. *Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants*. BREASTFEED MED. 2012 Feb; 7(1):29–37. Epub 2011 Jun 30.

18. In 2011, the U.S. Surgeon General published a report titled "The Surgeon General's Call to Action to Support Breastfeeding" that further emphasized the danger of cows'

milk-based products to premature infants. The report warned: "[f]or vulnerable premature infants, formula feeding is associated with higher rates of [NEC]." Arthur I. Eidelman, et al. *Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS e827-41 (2012).

19. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed exclusively a human milk diet because of the risk of NEC associated with the consumption of cows' milk-based formula. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk. … If the mother's own milk is unavailable … pasteurized donor milk should be used." Margreete Johnston et al., *Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS 827–41 (2012).

20. A study published in 2013 showed that all 104 premature infants participating in the study receiving exclusively a human-milk based diet exceeded targeted growth standards in height and weight (weight and head circumference). 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." Amy B. Hair, et al., *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birth Weight*, 129 BMC RESEARCH NOTES 6-459 (2013). Thus, inadequate growth was shown to be no reason for feeding cows' milk-based formulas or fortifiers to premature infants.

21. Another study published in 2013 reported, "This is the first randomized trial in [extremely premature] infants of exclusive [human milk] vs. [preterm formula]. The significantly shorter duration of TPN [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish [extremely premature] infants in the NICU." Elizabeth A. Cristofalo, et al., *Exclusive Human Milk vs. Preterm Formula: Randomized Trial in Extremely Preterm Infants*, 163 J. PEDIATR. 1592-95 (2013).

22. Another study published in 2014 reported: "It is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, et al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, 10 EXPERT REV. CLIN. IMMUNOL. 875-84 (2014).

23. The same study noted: "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, multisystem 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." Further, "[a] wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing [NEC]. … 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." *Id.*

24. In yet another study published in 2014, scientists reported, "An exclusive human milk diet, devoid of [cow milk]-containing products was associated with lower mortality and morbidity in [extremely premature] infants without compromising growth and should be considered as an approach to nutritional care of these infants." Steven Abrams, et al. *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, 9 BREASTFEEDING MEDICINE 281-86 (2014).

25. A 2016 study supported previous findings that an exclusive human milk diet in extremely premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation

at multiple institutions with multiple years of follow-up using an exclusive human milk diet, and was a very large study. The authors concluded, "[T]he use of an exclusive [human milk] diet is associated with significant benefits for extremely premature infants" and, "while evaluating the benefits of using an exclusive [human milk]-based protocol, it appears that there were no feeding-related adverse outcomes." Amy B. Hair, et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, 11 BREASTFEEDING MEDICINE, 70-74 (2016).

26. A study published in 2017 reported, "[Human milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two [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 [mother or donor milk] on the incidence of NEC. Both trials found that an exclusive [human milk] diet results in a lower incidence of NEC." Jocelyn Shulhan, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, 8 ADV. NUTR. 0-91 (2017).

27. Another study published in 2017 reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis … 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."

Diana Maffei et al., *Human Milk is the Feeding Strategy to Prevent Necrotizing Enterocolitis!* 41 SEMIN PERINATAL. 36–40 (2017).

B. The Marketing

28. Notwithstanding strong scientific and medical evidence establishing the serious dangers that cows' milk-based formulas and fortifiers pose for premature infants, Defendant Abbott has marketed its cows' milk-based products as an equally safe alternative to breast milk, and indeed has promoted its products as *necessary* for additional nutrition and growth. Defendant has specifically marketed its cows' milk-based formulas and fortifiers as necessary to the growth and development of premature infants, when in fact, Abbott's products pose a known and substantial risk to these babies.

29. Defendant's across-the-board marketing of its cows' milk-based products to parents of all infants begins early. Defendant sends marketing materials and formula samples to expectant mothers. Defendant routinely offers free cows' milk-based formula and other goodies in baskets given to mothers of both term and preterm infants after they give birth in hospitals and medical clinics. Defendant promotes its products to parents of newborns in medical facilities to create brand loyalty and the appearance of "medical blessing" so that mothers continue to feed their babies formula after the leave the hospital, at great expense to the parents, and substantial profit to Defendant.

30. Defendant's practice of trying to get parents to choose cows' milk-based products over breast milk goes back decades. The company has for decades promoted its product as healthier, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Their advertising has at times attempted to portray breastfeeding as an inferior, less sophisticated choice.

31. The World Health Organization (WHO) and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address the international marketing of breast-milk substitutes. The World Health Director concluded the meeting with the following statement: "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Naomi Baumslag & Dia L. Michels, *Milk, Money, and Madness: The Culture and Politics of Breastfeeding* 161 (Bergin & Harvey, eds. 1995).

32. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly (WHO's decision-making body) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and prohibited any advertising or promotion of breast milk substitutes to the general public. The Code specifically prohibited advertising in Article 5, Section 1: "There should be no advertising or other form of promotion to the general public." World Health Organization, The International Code of Marketing of Breast-milk Substitutes: Frequently Asked Questions 16-20 (1981, updated 2017).

33. Defendant has acknowledged and pretended to endorse the Code. Nonetheless, Defendant has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public." Advertising of cows' milk-based infant formulas and fortifiers has remained pervasive in the United States until today, including Defendant's advertising. "Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breast milk." Kenneth D. Rosenberg et al. *Marketing Infant Formula Through Hospitals: The Impact of Commercial Hospital Discharge Packs on Breastfeeding*, 98 AM J PUBLIC HEALTH, 290-95 (2008). One study estimated that

formula manufacturers spent $4.48 billion on marketing and promotion in 2014. Phillip Baker, et al, *Global Trends and Patterns of Commercial Milk-Based Formula Sales: Is an Unprecedented Infant and Young Child Feeding Transition Underway?*, 1 PUBLIC HEALTH NUTRITION (2016.)

34. Another study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. R. Stephen Parker & Charles E. Pettijohn, *Ethical Considerations in the Use of Direct-to-Consumer Advertising and Pharmaceutical Promotions: The Impact on Pharmaceutical Sales and Physicians*, 48 J. OF BUSINESS ETHICS 279-290 (2003).

35. Another study found that exposure to infant feeding advertising has a negative effect on breastfeeding initiation. Xena Grossman, et al., *Exposure to Infant Feeding Advertising During Pregnancy is Associated with Feeding Decisions Postpartum*. Paper presented at American Public Health Association 138th Annual Meeting & Exposition, Washington, DC (Nov. 2010).

36. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that when the frequency of infant formula advertisements increased, the percentage change in breastfeeding rates reported the next year generally tended to decrease. Jamie Stang, et al., *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, 2 INFANT CHILD ADOLESC. NUTR. 16-25 (2010).

37. The Stang study also found that infant formula company websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing a cows' milk-based product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance. *Id.*

38. Defendant has designed and implemented a systematic, powerful, and misleading marketing campaign to deceive parents into believing that: (1) cows' milk-based formulas and fortifiers are safe; (2) cows' milk-based products are superior substitutes for breast milk; (3) physicians consider cows' milk-based products a first choice; (4) the decision to breastfeed or to use cows' milk-based products is a matter of personal preference merely, with no objective scientific criteria; (5) cows' milk-based products are necessary for the growth of and are perfectly safe for premature infants; and (6) cows' milk-based products are better than breast milk to feed the babies to catch up on their growth.

39. For example, one author found an advertisement for a Similac product on the back cover of the April 2004 issue of American Baby Magazine, reproduced below, that made repeated comparisons of cows' milk-based formula to breast milk; the ad used the phrase "like breast milk" six times. Angela B. Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottle Feeding Product Ads With Magazine Article Content*, LSU Master's Thesis 667 (2005).

40. In addition to perpetuating the myth that Similac products are "like breast milk," Defendant has also deceived the public into believing that physicians believe Similac products are an ideal choice for babies.

41. Beginning in 1989, Defendant began using claims in its advertising that Similac products were the "first choice of more physicians."

42. A plain interpretation of this claim is that physicians believe Similac products are the "first choice" even in preference to breast milk.

43. Beginning in 1995, Defendant began a heavy marketing campaign featuring the claim "1st choice of Doctors" on all its infant formula product labels.

44. A marketing report commissioned by Defendant in March 1998 summarized consumer reactions to several advertising pamphlets for Similac products. The "1st Choice of Doctors" claim scored highest in terms of consumers' likelihood of purchase. The report concluded, "Doctor recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested." Use of similar pieces emphasizing the same claim was "highly recommended."

45. Defendant released an ad called "The Mother 'Hood" that frames the choice between breast milk and Similac products as a matter of personal preference, a debate which, while heated, is ultimately conducted by parents who simply wish the best for all children. The advertising conceals the fact that the "debate" is a false one, manufactured by companies like Defendant for their own promotional purposes. www.youtube.com/watch?v=JUbGHeZCxe4.

46. Another advertisement by Defendant, titled "The Judgment Stops Here," a documentary-style ad, likewise shows parents coming together, putting aside judgment of each other's choices. The ad is deceptive, however, and violative of the Code, because it puts breast milk and cows' milk-based products on an even playing field, and attempts to chastise any opinion that the question is not merely one of personal choice but of clear scientific evidence. In other words, the ad attempts to insulate Similac products from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint.

47. Another ad by Defendant for a Similac product states, "[W]hen you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac. It's modeled after breast milk." www.youtube.com/watch?v=kRaHiTMyYXs. This ad implies that being "ready" to "turn to" formula, instead of continuing to breastfeed, is inevitable.

48. Moreover, Defendant has also attempted to market its Similac products specifically to premature infants—the very children at highest risk from their use.

49. In 1978, Defendant began marketing "Similac 24 LBW" specifically for premature infants, claiming that the product was "introduced to meet the special needs of premature infants."

50. In 1980, Defendant began marketing "Similac Special Care," claiming it was "the first low-birth-weight, premature infant formula with a composition designed to meet fetal accretion rates."

51. In 1988, Defendant began marketing "Similac Special Care With Iron," claiming it "was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US."

52. As of 2016, Defendant 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.

53. Defendant specifically targets parents of premature infants in its marketing. For example, a Google search for "feeding preemies formula" reveals among first-page results a paid advertisement for Similac products, with the heading "For Babies Born Prematurely." The ad states, "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." The advertisement further claims that the product is "pediatrician recommended," "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to the specialized need pre-term infants have for human breast milk, and makes no mention of the risk of developing NEC because of ingesting cows' milk-based products.

54. At all relevant times, Defendant maintained a website, "similac.com," that encouraged parents to choose formula products. The website states, "Need help choosing the right formula for your baby? Our Formula Finder can walk you through it." The website includes the prompt, "Was your child born prematurely?" If the parent clicks "yes," the website directs the parent to a page promoting Similac products.

55. There is no mention of the risk of NEC. The website expressly and implicitly represents that Defendant's cows' milk-based products are safe for use with premature infants. This promotion is false and misleading.

56. Another advertisement by Defendant states "whether you choose to formula feed or to supplement breast feeding with formula, you can be confident in the nourishment of Similac." *See Why Similac?,* https://www.similac.com/why-similac.html (last visited August 18, 2022). The representation to parents that they can be "confident" is directly contradicted by studies that indicate the cows' milk-based formula is dangerous to premature infants. The ad is false and misleading.

57. Defendant's website also features reviews from parents whose premature infants were in the NICU, discussing how wonderful and safe the products are. There are no reviews

discussing NEC. It is therefore likely that these reviews are curated by Defendant to present a misleading picture of unanimous endorsement of its products.

58. CBS News reported that Defendant paid so-called "mommy bloggers" for positive reviews of Similac products. https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app.

59. Defendant engages in an aggressive marketing campaign designed to make parents believe that its cows' milk-based formulas and fortifiers are safe and necessary for growth of a premature infant, they are in fact highly dangerous to premature infants. Cows' milk-based products substantially increase the risk of NEC, as explained above.

60. Defendant's Similac products are commercially available at retail locations throughout New York and online for delivery to New York.

61. Despite knowing of the risk of NEC, Defendant did not warn parents of the risk of NEC associated with its cows' milk-based formulas and fortifiers.

62. Despite knowing of the risk of NEC, Defendant did not warn doctors, hospitals, or other healthcare providers of the risk of NEC associated with its cows' milk-based formulas and fortifiers.

63. Despite knowing that its cows' milk-based products increase the risk of NEC, Defendant did not provide any instructions or guidance on how to recognize and avoid NEC.

64. Defendant failed to properly warn parents and healthcare providers that its cows' milk-based formulas and fortifiers can significantly increase the risk that a premature infant will develop NEC; failed to design said products such as to make them safe; and deceived the public, parents, physicians, and other healthcare providers into believing that cows' milk-based products are safe and necessary alternatives to, supplements to, or substitutes for human milk.

65. Despite knowing that its cows' milk-based formulas and fortifiers were being fed to premature infants without parents' informed consent, Defendant failed to require or recommend that hospitals inform parents of the significant risk of NEC, or to require that parents' informed consent be obtained prior to feeding it to preterm infants.

C. Plaintiff's Use of Defendant's Similac Product

66. M.C. was born in New York, New York, on August 28, 2021, at 24 weeks and 1 day gestation, weighing 560 grams.

67. Approximately 20 days after she was born, M.C. was fed Defendant's Similac product.

68. Approximately 29 days later, M.C. was diagnosed with NEC as a result of being fed Defendant's Similac product.

69. M.C.'s NEC required serious medical interventions.

First Cause of Action: Strict Liability – Design Defect

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

71. At all times material to this action, Abbott was engaged in the sale of and sold its cows' milk-based products, including the cows' milk-based fortifier fed to M.C., in the course of its business.

72. Abbott knew or should have known that its cows' milk-based fortifier would be used in the way it was used with M.C.

73. Abbott's cows' milk-based fortifier was defectively designed and unreasonably dangerous when put to the reasonably anticipated use by ordinary consumers, including Plaintiff.

74. Scientific research has unequivocally established that Abbott's cows' milk-based formulas and fortifiers are not safe for use by premature infants like M.C.

75. Abbott's cows' milk-based fortifier's risk of causing NEC is extreme, and substantially deviates from consumers' and Plaintiff's reasonable expectations.

76. The risk of using Abbott's cows' milk-based formulas and fortifiers by premature infants like M.C. far outweighs any benefits of the product.

77. Abbott could have used pasteurized breast milk instead of cow's milk in their products, which would have produced an equally effective but safer product, or other alternative designs and/or formulations.

78. 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 cows' milk-based products provide, without the same unreasonably dangerous and deadly effects.

79. Abbott's cows' milk-based fortifier was defectively designed and unreasonably dangerous when it was placed in the stream of commerce for nutritional use by preterm infants like M.C.

80. Abbott's cows' milk-based fortifier was expected to and did reach consumers without substantial change affecting its defective and unreasonably dangerous condition.

81. As a result of Abbott's cows' milk-based fortifiers' defective design, M.C. developed NEC and has continued to suffer long term problems and has needed multiple surgeries, treatments, and interventions, and will need them far into the future.

82. Abbott's cows' milk-based fortifiers' defective design proximately caused M.C.'s NEC, and proximately caused M.C.'s long term medical and developmental problems.

Second Cause of Action: Strict Liability - Failure to Warn

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

84. Abbott knew or should have known that its cows' milk-based fortifier would be used in the way it was used with M.C.

85. Abbott's cows' milk-based fortifier was defectively designed and unreasonably dangerous when put to the reasonably anticipated use by ordinary consumers, including Plaintiff.

86. Abbott, as the manufacturer and seller of its cows' milk-based fortifier, had a duty of warn hospitals, NICUs, doctors, parents, and consumers that its cows' milk-based fortifier significantly increases the risk of NEC and long-term adverse medical and developmental consequences and are unsafe or contraindicated for extremely premature infants and low birth-weight babies like M.C.

87. Abbott breached its duty to warn by failing to:

a. warn hospitals, NICUs, doctors, parents, or consumers that its cows' milk-based products significantly increase the risk of NEC and long term adverse medical and developmental consequences in these babies; and are unsafe or contraindicated for extremely premature infants and low birth-weight babies like M.C.;

b. provide a warning or instruction that parents need to be provided an informed choice between the safety of human milk versus the dangers of cows' milk-based products;

c. provide proper instructions, guidelines, studies, or data on when and how to feed cows' milk-based products to premature infants in order to decrease the risk of NEC;

d. provide instructions to parents and physicians that cows' milk-based products carry a significant risk of NEC and its long term sequelae;

e. provide a prominent "black box"-type warning that cows' milk-based products are known to significantly increase the risk of NEC and its sequelae when compared to human milk in premature infants and in low birth weight infants;

f. provide well researched and well established studies linking cows' milk-based products to NEC and its long term sequelae in premature infants and low birth-weight infants;

g. cite to or use up-to-date medical data on the proper and safe use of cows' milk-based products;

h. send out "Dear Doctor" letters warning of the risks of NEC, and provide current scientific research and data to better guide hospitals and physicians to better care for the extremely premature infants;

i. advise physicians and other healthcare providers that cows' milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

j. advise physicians and other healthcare providers that human milk is superior to cows' milk-based products with regard to the overall health of a premature infant; and/or,

k. take adequate measures to warn despite knowing that parents were not being warned of the risk of NEC by their physicians.

88. Abbott's warnings and instructions for its cows' milk-based fortifier 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 that cows' milk-based fortifier significantly increases the risk of NEC and its sequelae, nor provide any details on how to avoid such harm.

89. As a result of Abbott's failure to warn against the reasonably foreseeable risks of its cows' milk-based fortifier, M.C. developed NEC and has continued to suffer long term problems and has needed multiple surgeries, treatments, and interventions, and will need them far into the future.

90. Abbott's failure to warn against the reasonably foreseeable risks of its cows' milk-based fortifier proximately caused M.C.'s NEC, and proximately caused M.C.'s long term medical and developmental problems.

Third Cause of Action: Negligent Design

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

92. Abbott, as the manufacturer and seller of its cows' milk-based fortifier, owed a duty to consumers, including Plaintiff and M.C., to exercise reasonable care to design, test, manufacture, inspect, and to distribute a product free of the unreasonable risk of harm when put to its reasonably anticipated use.

93. Abbott, as the manufacturer and seller of its cows' milk-based fortifier, had a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

94. Abbott knew or should have known that its cows' milk-based products would be used as nutrition and nutritional supplements with preterm infants, like M.C.

95. Prior to its use by Plaintiff and M.C., Abbott knew or should have known that its cows' milk-based fortifier was unreasonably dangerous for use in preterm infants, like M.C.

96. Scientific research has unequivocally established the dangers of Abbott's cows' milk-based products in causing NEC in premature infants.

97. The unreasonable danger of Abbott's cows' milk-based products for premature infants was latent and not obvious to consumers and patients using the product in a foreseeable and intended manner

98. Nevertheless, Abbott has promoted its cows' milk-based products for extremely premature infants and has claimed the products significantly increase infants' weight and caloric intake, and that the products are more beneficial than harmful.

99. As a direct and proximate result of Abbott's negligence in the design of its cows' milk-based fortifier, M.C. suffered severe medical injuries and long term damages that are yet to be determined. Plaintiff has expended and continue to expend significant sums for M.C.'s care and treatment.

Fourth Cause of Action: Negligent Failure to Warn

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

101. Abbott knew or should have known that its cows' milk-based fortifier would be used in the way it was used with M.C.

102. Abbott's knew or should have known that its cows' milk-based fortifier was defectively designed and unreasonably dangerous when put to the reasonably anticipated use by ordinary consumers, including Plaintiff.

103. Abbott, as the manufacturer and seller of its cows' milk-based fortifier, had a duty of warn hospitals, NICUs, doctors, parents, and consumers that its cows' milk-based products significantly increase the risk of NEC and long-term adverse medical and developmental consequences and are unsafe or contraindicated for extremely premature infants and low birth-weight babies like M.C.

104. Abbott's warnings and instructions for its cows' milk-based fortifiers 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 that cows' milk-based products significantly increase the risk of NEC and its sequelae, nor provide any details on how to avoid such harm.

105. Abbott breached the duty to warn consumers, including Plaintiff, that its cows' milk-based products significantly increase the risk of NEC by, among other things:

a. failing to warn hospitals, NICUs, doctors, parents, or consumers, including Plaintiff, that its cows' milk-based products significantly increase the risk of NEC and long term adverse medical and developmental consequences in premature infants and low birth-weight babies like L.N; and are unsafe or contraindicated for these babies;

b. failing to provide a warning or instruction that parents need to be provided an informed choice between the safety of human milk versus the dangers of cows' milk-based products;

c. failing to provide proper instructions, guidelines, studies, or data on when and how to feed cows' milk-based products to premature infants in order to decrease the risk of NEC;

d. failing to provide a prominent "black box"-type warning that cows' milk-based products are known to significantly increase the risk of NEC and its sequelae when compared to human milk in premature infants and in low birth weight infants;

e. failing to contact the FDA, NICUs, hospitals, or physicians to inform them that cows' milk-based products are linked to or cause NEC and these long term consequences;

f. failing to provide well-researched and well-established studies linking cows' milk-based products to NEC and its long term sequelae in premature infants and low birth-weight infants;

g. failing to cite to or use up-to-date medical data on the proper and safe use of cows' milk-based products;

h. failing to send out "Dear Doctor" letters warning of the risks of NEC and to provide current scientific research and data to better guide hospitals and physicians to better care for the extremely premature infants;

i. failing to advise physicians and other healthcare providers that cows' milk-based products are not necessary to achieve growth and nutritional targets for premature infants; and,

j. failing to advise physicians and other healthcare providers that human milk is superior to cows' milk-based products with regard to the overall health of a premature infant.

106. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were told that cows' milk-based fortifier could substantially increase the risk that M.C. would be caused to suffer NEC.

107. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were informed that cows' milk-based fortifier could cause M.C. to develop NEC.

108. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were told that cows' milk-based fortifier could and would cause M.C. to suffer long term, devastating maladies, as M.C. has and will.

109. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were told of the studies showing that cows' milk-based fortifier was extremely dangerous if fed to M.C. as a premature infant.

110. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were told of the studies showing that human donor milk was safer for M.C. than cows' milk-based products.

111. Neither Plaintiff nor M.C.'s physicians and other healthcare providers were told of the studies showing that an exclusive human milk diet is sufficient to meet all growth and nutritional goals of premature infants.

112. Abbott's massive marketing campaign targeted at parents as well as health care providers as detailed in previous paragraphs has had the effect of: (1) diminishing the ability of parents to intelligently resist the advice of a healthcare provider to give cows' milk-based products; (2) diminishing parents' desire and understanding of the importance of breastfeeding; (3) diminishing the relationship between physicians and patients relative to nutritional decision-making; (4) making it more difficult for a physician to persuade parents to breastfeed; and (5) making it easier and more economically viable for hospitals to feed premature infants cows' milk-based products instead of donor milk or human milk-derived fortifiers.

113. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of cows' milk-based fortifier, M.C. was fed Similac fortifier, which caused her to develop NEC and ultimately suffer significant long-term medical problems and developmental delays.

114. As a direct and proximate result of Abbott's negligent failure to warn parents, physicians, and other healthcare providers, including Plaintiff, of the unreasonable danger of its

cows' milk-based fortifier for premature infants, M.C. suffered severe medical injuries and long term damages that are yet to be determined. Plaintiff has expended and continue to expend significant sums for M.C.'s care and treatment.

Fifth Cause of Action: Negligent Misrepresentation

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

116. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians, and other healthcare providers through its advertising and promotional materials (some of which are reproduced above). These representations were made by Abbott on an ongoing and repeated basis.

117. Abbott misrepresented that its cows' milk-based products are safe and beneficial for premature infants like M.C. when it knew or should have known that they are unreasonably dangerous and causes NEC in premature infants and low birth-weight infants like M.C.

118. Abbott misrepresented to parents, physicians, and other healthcare providers that cows' milk-based products are necessary to the growth and nutrition of premature infants, when it knew or should have known that they are not necessary to achieve adequate growth.

119. Abbott misrepresented that cows' milk-based products have no serious side effects, when it knew or should have known that they do.

120. Abbott negligently misrepresented that cows' milk-based products are safe for premature infants like M.C.

121. Abbott negligently misrepresented that cows' milk-based products are necessary for optimum infant growth.

122. Abbott negligently misrepresented that cows' milk-based products are similar or equivalent to human milk.

123. Abbott's misrepresentations proximately caused M.C.'s NEC, and proximately caused M.C.'s long-term medical problems and developmental delays.

Prayer for Relief

124. Plaintiff seeks a judgment awarding:

a. Compensatory damages in an amount to be determined at trial;

b. Punitive damages in an amount to be determined at trial;

c. Attorneys' fees and costs of suit; and

d. All other relief the Court finds just and proper.

Demand for Jury Trial

125. Plaintiff demands a jury trial on all issues so triable.

Dated: May 30, 2023

Respectfully submitted,

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