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

Lakisha Best, individually and as Administratrix of the Estate of her minor child B.H., Plaintiff, v. Abbott Laboratories, Inc., Defendant.	CIVIL ACTION DEMAND FOR JURY TRIAL Case No.: 1:24-cv-7329 Direct Filing to MDL No. 3026, Case No. 1:22-cv-00071

COMPLAINT

Plaintiff Lakisha Best individually and as Administratrix of her deceased daughter, B.H. complains of Defendant Abbott Laboratories, Inc. (or "Abbott") as follows, based on her personal knowledge, investigation and on information and belief:

I. INTRODUCTION

1. This is an action to redress the injuries and damages suffered by Plaintiff Lakisha Best and her deceased minor child B.H. B.H. developed Necrotizing Enterocolitis ("NEC") as a result of being fed bovine-milk based (or "cows' milk-based") fortifier manufactured, marketed, and sold by Abbott.

2. 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 infants who are fed cows' milk-based formulas and fortifiers. B.H., who was premature and low-weight at birth, was fed Abbott's cows' milk-based fortifier, developed NEC, suffered significant and horribly painful injuries, and died as a result.

3. Plaintiff Lakisha Best, as Administratrix of the Estate of B.H, brings this cause of action against Abbott for claims arising from the direct and proximate result of Abbott's negligent, willful, and wrongful misconduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, failure to warn, and/or the sale and or delivery of Abbott's cow's milk-based formulas and fortifiers, which were fed to baby B.H.

II. JURISDICTION AND VENUE

4. This is an action for damages which exceed the sum of $75,000, exclusive of interest and costs.

5. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Abbott, and the matter in controversy, exclusive of interest and costs, exceeds $75,000.

6. This Court has personal jurisdiction over Abbott. Abbott is incorporated under the laws of Illinois and has its headquarters in Abbott Park, Lake County, Illinois. Abbott is authorized to conduct business and does conduct business in the States of Illinois, Missouri and North Carolina. Abbott has marketed, promoted, distributed, and/or sold its cows' milk-based products in the States of Illinois, Missouri and North Carolina. Abbott has sufficient minimum contacts with this state through its operations within this state to render exercise of jurisdiction by this Court permissible.

7. Venue of this action is proper in this Court as to Abbott 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.

8. Plaintiff hereby states the U.S. District Court, outside of the Northern District of Illinois, to which this case shall be remanded at the conclusion of pretrial proceedings is the

Eastern District of Missouri because that is the location where the preterm infant allegedly developed necrotizing enterocolitis after ingesting cow's milk-based preterm fortifier.

III. THE PARTIES

9. Plaintiff currently resides in Greensboro, North Carolina.

10. B.H. was born prematurely at SSM Health St. Mary's Hospital in Richmond Heights, Missouri, on August 21, 2022.

11. B.H. was subsequently transferred to Cardinal Glennon Children's Hospital in St. Louis, Missouri, on August 22, 2022, where she was diagnosed with NEC Totalis.

12. B.H. died at Cardinal Glennon Children's Hospital in St. Louis, Missouri on September 14, 2022, after developing NEC and as a result of the NEC Totalis.

13. Plaintiff brings this action for the wrongful death of baby B.H.

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

15. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including Similac NeoSure, Similac Advance, Similac Alimentum, Similac Organic, and Similac Human Milk Fortifier, premature infant formula and premature infant milk fortifier under the Similac brand name.

IV. BACKGROUND

A. The Science

16. Scientific research has demonstrated strong links between cows' milk-based infant formula and NEC in premature infants.

17. 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 babies exclusively fed cows'

milk-based formulas and fortifiers than in babies 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).

18. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and/or human milk fortifier, they were 90 percent less likely to develop surgical NEC. Sandra Sullivan, et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products*, 156 J. OF PEDIATR. 562-67 (2010).

19. In 2011, the U.S. Surgeon General published a report titled "The Surgeon General's Call to Action to Support Breastfeeding," warning that, "[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).

20. 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 formulas and fortifiers. 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).

21. 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 and fortifiers.

22. 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 [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).

23. 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).

24. The same study noted, "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.*

25. In yet another study published in 2014, scientists reported, "An exclusive human milk diet, devoid of [cows' 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).

26. 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).

27. 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).

28. 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. <u>The Marketing</u>

29. Notwithstanding strong scientific and medical evidence establishing the serious danger that cows' milk-based formulas and fortifiers poses for premature infants, Abbott has long marketed their cows' milk-based products as an equally safe alternative to breast milk, 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.

30. Further, Abbott has specifically marketed their 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, such as baby B.H.

31. Abbott's practice of trying to get parents to choose their cows' milk-based formulas and fortifiers over breast milk goes back decades. "Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breastmilk." 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).

32. 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).

33. 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).

34. Abbott has both acknowledged and pretended to endorse the Code. Nonetheless, Abbott 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 formula has remained pervasive in the United States until today, including Abbott's advertising. 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.)

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

36. Abbott's across-the-board marketing of their cows' milk-based products to parents of all infants begins early. Abbott sends marketing materials and formula samples to expectant mothers. Abbott routinely offers free cows' milk-based formulas and fortifiers and other goodies in baskets given to mothers of both term and preterm infants after they give birth in hospitals and medical clinics. Abbott 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 Abbott.

37. One study found that such 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).

38. 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).

39. 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).

40. 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 product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance. *Id.*

41. One author found an advertisement for Abbott's 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 formulas and fortifiers 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).

42. In addition to perpetuating the myth that its cows' milk-based products are "like breast milk," Abbott has also deceived the public into believing that physicians believe Similac products are an ideal choice for babies.

43. Beginning in 1989, Abbott began using claims in its advertising that Similac products were the "first choice of more physicians." A plain interpretation of this claim is that physicians believe Similac products are the "first choice" even in preference to breast milk.

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

45. A marketing report commissioned by Abbott 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."

46. Abbott 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 Abbott for their own promotional purposes. *See e.g.*, *Similac Commercial The Mother 'Hood*, YOUTUBE, www.youtube.com/watch?v=JUbGHeZCxe4 (last visited Nov. 22, 2023).

47. Another advertisement by Abbott, 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.

48. Another ad by Abbott 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." This ad implies that being "ready" to "turn to" formula, instead of continuing to breastfeed, is inevitable. *See e.g.*, Similac US, *90 Years Crafting*, YOUTUBE, www.youtube.com/watch?v=kRaHiTMyYXs (last visited Nov. 22, 2023).

49. Moreover, Abbott has also attempted to market their cows' milk-based products specifically to premature infants—the very children at highest risk from their use.

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

51. In 1980, Abbott 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."

52. In 1988, Abbott 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."

53. As of 2016, Abbott 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.

54. A Google search for "feeding preemies formula" reveals among first-page results a paid advertisement by Abbott 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.

55. At all relevant times, Abbott 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.

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

57. Another advertisement by Abbott states, "whether you choose to formula feed or to supplement breast feeding with formula, you can be confident in the nourishment of Similac." The representation to parents that they can be "confident" is directly contradicted by studies that indicate the cows' milk-based formulas and fortifiers is dangerous to premature infants. The ad is false and misleading. *See Why Similac?*, SIMILIAC, https://www.similac.com/why-similac.html (last visited Nov. 22, 2023).

58. Abbott'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 Abbott to present a misleading picture of unanimous endorsement of its products.

59. CBS News reported that Abbott paid so-called "mommy bloggers" for positive reviews of Similac products. Jim Edwards, *Abbott Pays Bloggers For Positive Reviews of Its Similac App*, CBS NEWS, https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app.

60. Despite knowing of the risk of NEC, Abbott did not warn parents of the risk of NEC associated with their cows' milk-based formulas and fortifiers and fortifiers.

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

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

63. Abbott failed to properly warn parents and healthcare providers that their cows' milk-based formulas and fortifiers 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.

64. Despite knowing that their cows' milk-based formulas and fortifiers were being fed to premature infants without parents' informed consent, Abbott 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 cows' milk-based formulas and fortifiers to preterm infants.

V. Baby B.H.'s Use of Abbott's Cows' Milk-Based Products

65. Baby B.H., was born in Richmond Heights, Missouri at 24 weeks, 1 day gestation, weighing only 770 grams, or roughly 1.67 pounds on August 21, 2022.

66. As a patient in the Neonatal Intensive Care Unit, Cardinal Glennon Children's Hospital, Baby B.H. was fed breast milk together with Abbott's cows' milk-based fortifier manufactured, marketed, and sold by Abbott.

67. Baby B.H. was diagnosed with NEC Totalis as a result of being fed Abbott's cows' milk-based fortifier.

68. B.H.'s NEC required serious medical intervention and she ultimately died in her mother's arms as a result of the NEC Totalis only three weeks after she was born.

First Cause of Action: Strict Products Liability—Defective Design

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

70. At all times material to this action, Abbott was engaged in the sale of and sold their cows' milk-based products, including the cows' milk-based product fed to B.H., in the course of their business.

71. Abbott, as a manufacturer and seller of cows' milk-based products, owed a duty to consumers, including Plaintiff and B.H., 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.

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

73. Abbott knew or should have known that their cows' milk-based products would be used as nutrition and nutritional supplements with preterm infants, like B.H.

74. Prior to the use of Abbott cows' milk-based product by Baby B.H., Abbott knew or should have known that their cows' milk-based premature baby products were unreasonably dangerous for use in preterm infants.

75. Scientific research has unequivocally established the dangers of cows' milk-based products in causing NEC in premature infants, a fact of which Abbott was aware at all times relevant to this lawsuit.

76. Abbott's cows' milk-based formulas and fortifiers and fortifiers were defectively designed and unreasonably dangerous when put to the reasonably anticipated use by ordinary consumers.

77. Abbott's cows' milk-based formulas and fortifiers and fortifiers' risk of causing NEC is extreme, and substantially deviates from consumers' reasonable expectations.

78. 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.

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

80. The risk of using Abbott's cows' milk-based formulas and fortifiers and fortifiers for premature infants far outweighs any benefits of the products.

81. 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.

82. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cows' 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.

83. As a direct and proximate result of Abbott's negligence in the design of their cows' milk-based premature infant formulas and fortifiers, Baby B.H. suffered severe medical injuries, causing Plaintiff to expended significant sums for B.H.'s care and treatment. B.H.'s injuries that ultimately led to Baby B.H.'s death within three weeks of her birth.

Second Cause of Action: Failure To Warn

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

85. Abbott, as a manufacturer and seller of cows' milk-based formulas and fortifiers and fortifiers, had a duty to warn hospitals, NICUs, doctors, parents, and consumers that their cows' milk-based formulas and fortifiers 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 B.H.

86. Abbott breached their duty to warn by failing to:

a. warn hospitals, NICUs, doctors, parents, or consumers that their 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 B.H.;

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.

87. Neither Plaintiff nor B.H.'s physicians and other healthcare providers were told that cows' milk-based formulas and fortifiers could substantially increase the risk that B.H. would be caused to suffer NEC.

88. Neither Plaintiff nor B.H.'s physicians and other healthcare providers were informed that cows' milk-based formulas and fortifiers could cause B.H. to develop NEC.

89. Neither Plaintiff nor B.H.'s physicians and other healthcare providers were told that cows' milk-based formulas and fortifiers could and would cause B.H. to suffer long term, devastating maladies, as B.H. has.

90. Neither Plaintiff nor B.H.'s physicians and other healthcare providers were told of the studies showing that cows' milk-based formulas and fortifiers was extremely dangerous if fed to B.H. as a premature infant.

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

92. Neither Plaintiff nor B.H.'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.

93. Abbott's massive marketing campaigns targeted at parents as well as health care providers as detailed in previous paragraphs 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.

94. As a direct and proximate result of Abbott's negligent failure to warn parents, physicians, and other healthcare providers of the unreasonable danger of their cows' milk-based formulas and fortifiers, B.H. suffered severe medical injuries, causing Plaintiff to expended significant sums for B.H.'s care and treatment. B.H.'s injuries ultimately led to her death.

Third Cause of Action: Negligent Misrepresentation

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

96. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians, and other healthcare providers through their advertising and promotional materials. These representations were made by Abbott on an ongoing and repeated basis.

97. Abbott misrepresented that their cows' milk-based products are safe and beneficial for premature infants like B.H., when they knew or should have known that their products are unreasonably dangerous and cause NEC in premature infants and low birth-weight infants like B.H.

98. 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 they knew or should have known that they are not necessary to achieve adequate growth.

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

100. Abbott negligently misrepresented that cows' milk-based products are safe for premature infants like B.H.

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

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

103. Plaintiff justifiably relied on Abbott's misrepresentations in allowing Abbott's formula to be fed to B.H.

104. Abbott's misrepresentations proximately caused B.H.'s NEC and its sequelae, and ultimately led to her death.

Fourth Cause of Action: Negligence

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

106. Despite knowing that cows' milk-based formulas and fortifiers significantly increases the risk of NEC in premature infants, Abbott was careless and negligent because they failed to:

a. Collect data to determine if their products were safe for premature infants;

b. Collect data to determine when and how their products could be used safely;

c. Use the significant peer reviewed research to develop instructions and/or warnings on how and when their cows' milk-based formulas and fortifiers should be used in order to protect babies from NEC and its medical sequelae;

d. Develop evidence-based guidelines or instructions to decrease the risk of their cows' milk-based formulas and fortifiers causing NEC;

e. Provide evidence-based guidelines or instructions to decrease the risk of their cows' milk-based formulas and fortifiers causing NEC;

f. Stop or deter their cows' milk-based formulas and fortifiers from being fed to extremely premature infants like B.H.;

g. Provide evidence-based guidelines or instructions on when or how an extremely premature infant like B.H. should be transitioned to their cows' milk-based formulas and fortifiers;

h. Continuously and vigorously study their cows' milk-based formulas and fortifiers to avoid NEC in premature infants;

i. Send out letters with warnings to hospitals, NICUs, and doctors that their cows' milk-based formulas and fortifiers was significantly increasing the risk of NEC in premature infants like B.H.;

j. Send out letters with instructions to hospitals, NICUs, and doctors on when and how their cows' milk-based formulas and fortifiers should be used to avoid NEC;

k. Market and/or sell their products in a way which would protect infants like B.H. from NEC;

l. Provide proper training or information to health care providers for safe use of their cows' milk-based formulas and fortifiers;

m. Take reasonable precautions to prevent premature infants like B.H. from developing NEC;

n. Develop a human-milk-based premature infant formula;

o. Properly or promptly notify the FDA that their cows' milk-based formulas and fortifiers significantly increases the risk of NEC in infants like B.H.;

p. Require or recommend that hospitals warn of the risk of causing NEC created by their cows' milk-based formulas and fortifiers, despite knowing that NICUs and physicians were not warning of such.

107. As a direct and proximate cause of Abbott's misconduct, Baby B.H. suffered severe and horribly painful medical injuries, causing Plaintiff to have expended significant sums for B.H.'s care and treatment. B.H.'s injuries ultimately led to her untimely death

Prayer for Relief

108. Plaintiff Mother and Administratrix of the Estate of Baby girl B.H. seeks a judgment awarding Plaintiff:

a. All applicable wrongful death damages;

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

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

d. Attorneys' fees and costs of suit; and

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

Demand for Jury Trial

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

Dated: August 15, 2024

Respectfully submitted,

/s/ *Wendy R. Fleishman*
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