UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

KAYLA O'MALLEY, for herself and as personal representative of the estate of her beloved son, L.B., Deceased, Plaintiff, v. ABBOTT LABORATORIES, INC., Defendant.	CIVIL ACTION DEMAND FOR JURY TRIAL Case No.:

COMPLAINT

Plaintiff, Kayla O'Malley, individually and as personal representative of the estate of her beloved son L.B., deceased, by and through her attorneys, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP complaining of Defendant, ABBOTT LABORATORIES, INC., states as follows based on her personal knowledge and on information and belief:

I. INTRODUCTION

1. This is an action to redress the injuries and wrongful death suffered by Plaintiff parent Kayla O'Malley and her beloved son L.B., who developed Necrotizing Enterocolitis ("NEC") and died as a result of being fed bovine-milk based (or "cows' milk-based") infant formula manufactured, marketed, and sold by Defendant.

2. Plaintiff brings these claims, individually and as personal representative of the Estate of L.B., pursuant to the Ohio Product Liability Act, O.R.C. §§ 2307.75–2307.77 (including design defect, inadequate warning, and failure to conform to representation), and Ohio's Wrongful Death Act, O.R.C. § 2125.02.

3. NEC is an often fatal disease that largely affects premature and low birth-weight babies fed cows' milk-based formulas. There is a significantly increased rate of NEC among that population of infants who are fed cows' milk-based formula. L.B., who was premature and low-weight at birth, was fed Defendant's cows' milk-based formula, developed NEC, and suffered related significant injuries and death.

4. Plaintiff brings claims against Defendant arising from Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, and labeling of its cows' milk-based formulas.

II. JURISDICTION AND VENUE

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

6. This Court has subject matter 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.

7. The Court maintains personal jurisdiction over Defendant as it purposely engaged in the business of designing, developing, selecting, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, its cow's milk-based infant formula and fortifier products, including Similac within the State of Ohio and specifically the District, with a reasonable expectation that the products would be used within this District.

8. Venue of this action is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district.

9. Plaintiff anticipates that this action will be treated as a tag-along and transferred by the Judicial Panel on Multidistrict Litigation to MDL No. 3026, *In re Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation*, for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

III. THE PARTIES

10. Plaintiff Kayla O'Malley resides in Cincinnati, Ohio.

11. L.B., Plaintiff's son, was born in a hospital in Cincinnati, Ohio, was transferred to another hospital within Cincinnati, and passed away at the second hospital.

12. 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.

IV. BACKGROUND

A. The Science

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

14. 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 formula 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).

15. 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 Diet of Human Milk and Bovine Milk-Based Products*, 156 J. OF PEDIATR. 562-67 (2010).

16. 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).

17. 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).

18. 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. 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 formula.

19. 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).

20. 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).

21. 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.*

22. 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).

23. 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).

24. 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).

25. 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 its 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

26. Notwithstanding strong scientific and medical evidence establishing the serious danger that cows' milk-based formula poses for premature infants, Defendant has long marketed its cows' milk-based products as an equally safe alternative to breast milk, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Its advertising has at times attempted to portray breastfeeding as an inferior, less sophisticated choice.

27. Further, Defendant has specifically marketed its cows' milk-based formulas as necessary to the growth and development of premature infants, when in fact, Defendant's products pose a known and substantial risk to these babies.

28. Defendant's practice of trying to get parents to choose its cows' milk-based formulas 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).

29. 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).

30. 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).

31. 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 formula has remained pervasive in the United States until today, including Defendant'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.)

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

33. 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 they leave the hospital, at great expense to the parents, and substantial profit to Defendant.

34. 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).

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

38. One author found an advertisement for Defendant'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 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).

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

40. Beginning in 1989, Defendant 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.

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

42. 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."

43. 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 its own promotional purposes. *See e.g.*, *Similac Commercial The Mother 'Hood*, YOUTUBE, www.youtube.com/watch?v=JUbGHeZCxe4 (last visited May 8, 2026).

44. 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.

45. 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." 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 May 8, 2026).

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

47. 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."

48. 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."

49. 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."

50. 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.

51. Defendant disseminated online advertisements for Similac products, with the heading "For Babies Born Prematurely." For example, one ad stated, "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.

52. At all relevant times, Defendant maintained a website, "similac.com," that encouraged parents to choose formula products. The website states, "We promise to offer products that give your child a strong start. Let's find the right option for your little one!" *See Formula Finder—Learn About Formula Options for Your Child?*, SIMILAC, https://www.similac.com/baby-tools-resources/best-milk-formula.html (last visited May 8, 2026). The website includes the prompt, "Was your child born prematurely?" *Id*. If the parent clicks "Yes," the website directs the parent to a page promoting Similac products. *Id*.

53. There is no mention of the risk of NEC on Defendant's similac.com website. 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.

54. Another advertisement by Defendant states, "[f]or 100 years, we've been committed to nourishing your baby and supporting you along the way, because babies deserve to be fed, happy, and healthy." The representation to parents that their babies fed Similac will be "fed, happy, and healthy" is directly contradicted by studies that indicate the cows' milk-based formula is dangerous to premature infants. The ad is false and misleading. *See Why Similac?*, SIMILAC, https://www.similac.com/why-similac.html (last visited May 8, 2026).

55. Defendant's website also features reviews from parents whose premature infants were in the NICU, discussing how wonderful and safe the products are. *See e.g., Similac NeoSure Premature Post-Discharge Infant Formula Powder*, SIMILAC,

https://www.similac.com/products/preemie-formula/neosure-powder/22-8oz-can-4pack.html (last visited May 8, 2026) ("The NICU started my baby on this formula. I wanted to switch to a cheaper competitor, but two pediatricians advised to stick with Similac Neosure because my baby was doing so well on it and doubled his weight!"). 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.

56. CBS News reported that Defendant 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 (MAR. 11, 2021), https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app.

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

58. 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.

59. 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.

60. Defendant failed to properly warn parents and healthcare providers that its cows' milk-based formulas 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.

61. Despite knowing that its cows' milk-based formulas 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 cows' milk-based formula to preterm infants.

V. L.B.'s Use of Defendant's Cows' Milk-Based Products

62. Plaintiff's child, L.B., was born in Cincinnati, Ohio.

63. After birth, L.B. was fed cows' milk-based formula manufactured, marketed, and sold by Defendant, Similac Special Care 30 kcal.

64. L.B. was diagnosed with NEC as a result of being fed Defendant's cows' milk-based formula.

65. L.B.'s NEC required serious medical interventions.

FIRST CAUSE OF ACTION: STRICT LIABILITY – DEFECTIVE DESIGN UNDER OHIO REV. CODE ANN. 2307.75

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

67. Under Ohio law, Defendant may be liable for a strict liability defective design violation when a product leaves Defendant's control, and the foreseeable risks associated with its design and/or formulation exceeded its benefits, and practical, technically feasible safer alternative designs/formulations were available.

68. At all times material to this action, Defendant was engaged in the sale of and sold its cows' milk-based products, including the cows' milk-based formula fed to L.B. in the course of its business.

69. Defendant, as a manufacturer and seller of cows' milk-based formulas, owed a duty to consumers, including Plaintiff and L.B., 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.

70. Defendant, as a manufacturer and seller of cows' milk-based formulas, had a duty to hold the knowledge and skill of an expert and was obliged to keep abreast of any scientific discoveries and is presumed to know the result of all such advances.

71. Defendant knew or should have known that its cows' milk-based products would be used as nutrition and nutritional supplements with preterm infants, like L.B.

72. Prior to the use of Defendant cows' milk-based formulas by L.B., Defendant knew or should have known that its cows' milk-based formulas were unreasonably dangerous for use in preterm infants.

73. Scientific research has unequivocally established the dangers of cows' milk-based products in causing NEC in premature infants, a fact of which Defendant was aware.

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

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

76. The unreasonable danger of Defendant'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.

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

78. The risk of using Defendant's cows' milk-based formulas for premature infants far outweighs any benefits of the products.

79. Defendant could have used pasteurized breast milk instead of cows' milk in its products, which would have produced an equally effective, but safer product, or other alternative designs and/or formulations.

80. 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.

81. As a direct and proximate result of Defendant's defective design of its cows' milk-based formulas, L.B. suffered severe and fatal medical injuries.

82. As a direct and proximate cause of Defendant's misconduct, L.B. suffered severe medical injuries, pain and suffering and wrongful death, and Plaintiff Kayla O'Malley suffered related damages and emotional distress, in amounts to be determined.

SECOND CAUSE OF ACTION:
STRICT LIABILITY - FAILURE TO WARN UNDER OHIO REV. CODE ANN. 2307.76

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

84. Under Ohio law, Defendant, as a manufacturer and seller of cows' milk-based formulas, had a duty to warn hospitals, NICUs, doctors, parents, and consumers that its cows' milk-based formulas 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 L.B.

85. Defendant 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 L.B.;

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.

86. Plaintiff was never told that cows' milk-based formula could substantially increase the risk that L.B. would be caused to suffer NEC and die.

87. Plaintiff was never informed that cows' milk-based formula could cause L.B. to develop NEC.

88. Plaintiff was never told that cows' milk-based formula could and would cause L.B. to suffer long term, devastating maladies, as L.B. has.

89. Plaintiff was never told of the studies showing that cows' milk-based formula was extremely dangerous if fed to L.B. as a premature infant.

90. Plaintiff was never told of the studies showing that human donor milk was safer for L.B. than cows' milk-based products.

91. Plaintiff was never told of the studies showing that an exclusive human milk diet is sufficient to meet all growth and nutritional goals of premature infants.

92. Defendant'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.

93. As a direct and proximate result of Defendant's negligent failure to warn parents, physicians, and other healthcare providers of the unreasonable danger of its cows' milk-based formulas for premature infants, L.B. suffered severe and fatal medical injuries.

94. As a direct and proximate cause of Defendant's misconduct, L.B. suffered severe medical injuries, pain and suffering and wrongful death, and Plaintiff Kayla O'Malley suffered related damages and emotional distress, in amounts to be determined.

THIRD CAUSE OF ACTION: PRODUCT NONCONFORMING WITH MANUFACTURER'S REPRESENTATIONS UNDER OHIO CODE REV. ANN. § 2307.77

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

96. Under Ohio law, a product is defective if it did not conform, when it left the control of Defendant, to a representation made by Defendant. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

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

98. Defendant misrepresented that its cows' milk-based products are safe and beneficial for premature infants like L.B. when it knew or should have known that its products

are unreasonably dangerous and cause NEC in premature infants and low birth-weight infants like L.B.

99. Defendant 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 its products are not necessary to achieve adequate growth.

100. Defendant misrepresented that cows' milk-based products have no serious side effects, when it knew or should have known that its products do.

101. Defendant negligently misrepresented that cows' milk-based products are safe for premature infants like L.B.

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

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

104. Plaintiff justifiably relied on Defendant's misrepresentations in allowing Defendant's formula to be fed to L.B.

105. Defendant's misrepresentations proximately caused L.B.'s NEC and its sequelae, including wrongful death.

106. As a direct and proximate cause of Defendant's misconduct, L.B. suffered severe medical injuries, pain and suffering and wrongful death, and Plaintiff Kayla O'Malley suffered related damages and emotional distress, in amounts to be determined.

FOURTH CAUSE OF ACTION: WRONGFUL DEATH UNDER OHIO CODE REV. ANN. § 2125.02

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

108. Plaintiff brings this wrongful death claim in her capacity as the personal representative of the Estate of L.B., deceased.

109. The wrongful death of L.B. entitles the beneficiaries to recover the full measure of damages permitted by O.R.C. § 2125.02, including, but not limited to:

a. The mental anguish incurred by the surviving spouse, dependent children, parents, or next of kin of the decedent'

b. Loss of the society of the decedent, including loss of companionship, consortium, care, assistance, attention, protection, advice, guidance, counsel, instruction, training, and education, suffered by the surviving spouse, dependent children, parents, or next of kin of the decedent;

c. Loss of support from the reasonably expected earning capacity of the decedent.

110. As a direct and proximate cause of Defendant's misconduct, L.B. suffered severe medical injuries, pain and suffering and wrongful death, and Plaintiff Kayla O'Malley suffered related damages and emotional distress, in amounts to be determined.

FIFTH CAUSE OF ACTION: NEGLIGENCE

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

112. Despite knowing that cows' milk-based formula significantly increases the risk of NEC in premature infants, Defendant was careless and negligent because it failed to:

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

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

c. Use the significant peer-reviewed research to develop instructions and/or warnings on how and when its cows' milk-based formula 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 its cows' milk-based formula causing NEC;

e. Provide evidence-based guidelines or instructions to decrease the risk of its cows' milk-based formula causing NEC;

f. Stop or deter its cows' milk-based formula from being fed to extremely premature infants like L.B.;

g. Provide evidence-based guidelines or instructions on when or how an extremely premature infant like L.B. should be transitioned to its cows' milk-based formula;

h. Continuously and vigorously study its cows' milk-based formula to avoid NEC in premature infants;

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

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

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

l. Provide proper training or information to health care providers for safe use of its cows' milk-based formula;

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

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

o. Properly or promptly notify the FDA that its cows' milk-based formula significantly increases the risk of NEC in infants like L.B.;

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

113. As a direct and proximate cause of Defendant's misconduct, L.B. suffered severe medical injuries, pain and suffering and wrongful death, and Plaintiff Kayla O'Malley suffered related damages and emotional distress, in amounts to be determined.

Prayer for Relief

114. 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

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

Dated: May 14, 2026

Respectfully submitted,

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Attorneys for Plaintiff

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Kayla O'Malley, for herself and as personal representative of the estate of her beloved son, L.B., Deceased

(b) County of Residence of First Listed Plaintiff Hamilton County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Daniel Karon, Karon LLC, 631 W. St. Clair Ave., Cleveland, OH 44113, (216) 622-1851

DEFENDANTS

Abbott Laboratories, Inc.

County of Residence of First Listed Defendant Lake County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
O.R.C. §§ 2307.75–2307.77 & O.R.C. § 2125.02

Brief description of cause:
Wrongful death suffered by Pltf & her son who developed Necrotizing Enterocolitis from drinking Deft's product.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ $10,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Rebecca R. Pallmeyer DOCKET NUMBER MDL No. 3026 (N.D. Ill.)

DATE

SIGNATURE OF ATTORNEY OF RECORD
/s/ Daniel R. Karon (0069304)

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.