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

P.W. by and through his natural mother and guardian, Vanessa Yates, and Vanessa Yates, individually, Plaintiffs, v. Abbott Laboratories, Inc., Defendant.	Case No.: Judge: **JURY TRIAL DEMANDEDP**

COMPLAINT

Plaintiffs, P.W. and Vanessa Yates, (collectively, "Plaintiffs"), bring this action against Defendant Abbott Laboratories, Inc., ("Defendant" or "Abbott"), asserting claims arising from the catastrophic injury and often deadly disease known as Necrotizing Enterocolitis ("NEC") that largely affects premature and/or low birth weight newborn/babies as a direct and proximate result of the ingestion of bovine-based infant formula or products. P.W., a premature born, low birth weight baby was fed *Similac Special Care*, and developed NEC shortly thereafter. Plaintiffs brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of bovine-based formulas and/or fortifiers ("bovine formula") to premature infants known as *Similac Special Care*, (hereinafter collectively referred to as "Products").

INTRODUCTION

1. Defendant knowingly advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce its baby formula, Similac and/or Similac Special Care, which is unsafe and unreasonably dangerous for its intended use and purpose.

2. Similac and/or Similac Special Care causes a significant increase in incidences of necrotizing enterocolitis when administered enterally to premature infants.

3. Despite well-known, reliable scientific studies and data establishing the increased risk of necrotizing enterocolitis when Similac and/or Similac Special Care is administered to premature infants, Defendant knowingly withheld this information from the consuming public, including Plaintiffs.

4. In its quest to maximize profits, Defendant placed its own economic interests over its customers' lives and safety, by deceptively marketing, promoting, and advertising Similac and/or Similac Special Care as being a safe, alternative to human milk-based formulas and fortifiers, when it knew or should have known that Similac and/or Similac Special Care was unsafe and unreasonably dangerous for administration to premature infants—including P.W., due to the increased risk of necrotizing enterocolitis and associated medical conditions that Similac and/or Similac Special Care causes in premature infants.

5. As a direct and proximate result of Defendant's conduct, as described herein, P.W. was diagnosed with necrotizing enterocolitis, sustaining severe injuries as a cause thereof.

PARTIES

Plaintiffs

6. Vanessa Yates is a resident of Chester, New York. She is the mother of P.W., who is a minor.

7. P.W. was born on [redacted], at Grady Memorial Hospital in Atlanta, Georgia, at 26 weeks gestation and weighing two pounds and two ounces.

8. Given his premature birthweight, P.W. was transferred to the Neonatal Intensive Care Unit ("NICU") for care.

9. While in the NICU, P.W. was provided nutrients through an enteral feeding tube. For that process, P.W. was specifically given Similac and/or Similac Special Care ("formula" and/or "product"), a formula and/or fortifier which is a formula which is bovine based, and which does not contain human milk. Shortly after receiving the formula enterally, P.W. began to suffer from gastrointestinal issues, including intestinal rupturing and was diagnosed with NEC. This injury led P.W. to develop bowel problems and infection.

10. P.W. continues to suffer from severe injury as a result of his NEC diagnosis caused by Defendant's Similac and/or Similac Special Care product.

Defendant

11. The defendant, Abbott Laboratories, Inc. manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including New York, and sells premature infant formula Similac Special Care.

12. At all times relevant to this action, Abbott Laboratories, Inc., conducted, and continues to conduct, a substantial amount of business activity and has engaged in tortious

conduct, in whole or in part, in this District. Defendant is headquartered in Chicago, Illinois and engaged in interstate commerce in all fifty states when it advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce Similac and/or Similac Special Care, an infant formula and/or fortifier, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this District.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendant is a citizen of a state other than the state in which Plaintiffs are citizens.

14. Venue in this District is proper under 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this District.

15. This Court has personal jurisdiction over Defendant because Defendant is headquartered in Chicago, Illinois and Defendant has sufficient minimum contacts with this State and/or sufficiently avails itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court appropriate.

FACTUAL ALLEGATIONS

A. Necrotizing Enterocolitis

16. Necrotizing Enterocolitis ("NEC") is a severe gastrointestinal disease in premature (preterm) infants ("infants").

17. The Centers for Disease Control and Prevention ("CDC") defines preterm birth as when a baby is born before the 37 weeks of full-term pregnancy have been completed.[1] In 2020 alone, preterm birth affected one out of every ten infants born in the United States.[2]

18. NEC is the most common, and frequently dangerous, gastrointestinal emergency in premature infants in the NICU. It is also the most common cause of gastrointestinal-related death among the smallest, most premature infants in the NICU.[3]

19. NEC occurs when tissue in the large intestine, also known as the colon, becomes inflamed.[4] This inflammation damages and kills tissue in the infant's colon.

20. Signs and symptoms of NEC often include abdominal distension, hemorrhage and necrosis of tissue within the intestine, peritonitis,[5] intestinal perforation, discomfort, and death.[6]

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[1] Center for Disease Control and Prevention, *Preterm Birth*, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm (last modified Nov. 1, 2021).

[2] *Id.* For context, in 2020, 3,605,201 babies were born in the United States, meaning that more than 360,000 of those babies were born prematurely—*close to 1,000 every day*. https://www.cdc.gov/nchs/data/vsrr/vsrr012-508.pdf

[3] Sheila M. Gephart, RN, BSN, *et al.*, *Necrotizing Enterocolitis Risk: State of Science*, 12 Advances in Neonatal Care 77-89 (2012).

[4] Stanford Children's Health, *Necrotizing Enterocolitis in the Newborn*, https://www.stanfordchildrens.org/en/topic/default?id=necrotizing-enterocolitis-90-P02388 (last visited Feb. 22, 2022).

[5] Peritonitis is defined as redness, swelling, and inflammation of the tissue that lines the abdomen.

[6] Anand RJ, *et al.*, *The Role of the Intestinal Barrier in the Pathogenesis of Necrotizing Enterocolitis*, 27 Shock 124–33 (2007).

21. The NEC diagnosis is commonly determined with the use of Modified Bell's Staging Criteria, ranging from Stage IA (suspected NEC) to the most severe at Stage IIIB (advanced, severely ill, perforated bowel).[7] The Modified Bell's Staging Criteria incorporate systemic, intestinal, and radiological signs to adequately diagnose, stage, and treat NEC.

22. In some infants, NEC is mild. In others, however, symptoms are severe and life-threatening. Mild cases of NEC may be effectively treated by withholding enteral feeds,[8] decompressing the stomach with a nasogastric tube, and/or starting broad-spectrum antibiotics.[9]

23. In advanced cases, however, NEC may lead to surgery, extensive intestinal necrosis, and death.[10] The mortality rate for NEC patients ranges from 10% to 50% and approaches 100% for patients with the most severe form of the disease.[11]

24. If the infant survives the disease, the long-term outcomes present a multitude of health issues. Surgical NEC survivors are much more likely to have feeding difficulties and gastrointestinal ostomies from ages six months to 36 months than those without an NEC diagnosis.[12] NEC infants treated with non-surgical intervention are more likely to have a higher

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[7] Josef Neu, MD, *Necrotizing Enterocolitis, The Search for a Unifying Pathogenic Theory Leading to Prevention*, 43 Pediatr. Clin. North. Am. 409–432 (1996), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7127724/.

[8] Enteral feeding refers to intake of food through the gastrointestinal (GI) tract. The GI tract is composed of the mouth, esophagus, stomach, and intestines. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine.

[9] PK, Rasiah SV, Ewer AK, *Necrotizing Enterocolitis: Current Perspectives*, 4 Res. Rep. Neonatal 31-42 (2014).

[10] *Id.*

[11] Holman RC, *et al*., *Necrotizing Enterocolitis Hospitalizations Among Neonates in the United States*, 20 Paediatr Perinat Epidemiol, 498–506 (2006).

[12] Ganapathy V. Hay, *et al.*, *Long-term Healthcare Costs of Infants Who Survived Neonatal Necrotizing Enterocolitis*: *A Retrospective Longitudinal Study Among Infants Enrolled in Texas Medicaid*, 13 BMC Pediatrics 127 (2013).

risk of failure to thrive, feeding difficulties, neurodevelopmental delay, and open gastrointestinal ostomies when they are between six and twelve months of age.[13]

B. Bovine Formula Increases NEC Risk

25. Bovine milk is used to supplement infant formula. It contains oligosaccharides, some of which are structurally identical, or similar to, those found in human milk.[14]

26. Bovine formula and/or fortifiers are non-prescription. Thus, it does not require a physician's recommendation and is sold with packaging and labels designed to inform the average consumer.

27. The Food and Drug Administration ("FDA") has issued guidance specifically for the labeling of infant formulas, stating, in pertinent part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.

28. Bovine formula and/or fortifiers are often given to infants enterally and NEC only occurs after infants have been enterally fed.[15] Several challenges exist for preterm nutritional support. Many preterm infants, especially those born <1500 g and/or <34 weeks gestation, are not able to breastfeed.[16] The suck-swallow-breathe rhythm of oral feeding may not

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[13] *Id.*; Rees CM, *et al.*, *Neurodevelopmental Outcomes of Neonates with Medically and Surgically Treated Necrotizing Enterocolitis*, 92 Arch. Dis. Child Fetal Neonatal Ed. 193–8 (2007).

[14] Fernando Meli, *et al.*, *Growth and safety evaluation of infant formulae containing oligosaccharides derived from bovine milk: a randomized, double-blind, noninferiority trial*, 14 BMC PEDIATRICS 306 (2014).

[15] Siggers RH, *et al.*, *Nutritional Modulation of the Gut Microbiota and Immune System in Preterm Neonates Susceptible to Necrotizing Enterocolitis*, 22 J Nutr. Biochem 511-21 (2011).

[16] 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. 80–91 (2017).

be possible for preterm infants because of coordination issues and/or low body stores of energy.[17]

29. Several studies establish that bovine formulas and/or fortifiers lead to a higher incidence of NEC in preterm infants than human milk does.[18] An exclusively human milk-based diet is associated with a lower rate of NEC than a diet of human milk and bovine-based products.

30. In 1990, a landmark study was published linking bovine formula to NEC.[19] The authors conducted two parallel dietary studies, involving 926 very low birth weight infants. In Study A, infants were randomly assigned to pasteurized banked donated breast milk or nutrient-enriched preterm formula. Randomization was stratified according to whether the mother provided breast milk for her own infant. Thus, donor milk and preterm formula could be compared as sole diets in infants whose mothers did not provide their own milk or as a supplement to breast milk. Study B compared standard term formula or the preterm formula as sole diets or as supplements to the mother's milk. All infants with NEC had received enteral feeds. NEC developed in 51 of the 926 preterm infants (5.5%). Of those confirmed cases, 35% needed surgery and 26% died. Of the 86 infants exclusively fed donor breast milk, there were three cases (4%) of NEC, and among the 76 infants fed exclusively preterm formula, there were six cases (8%) of NEC. NEC was determined to be *six to ten times* more common in those fed

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[17] *Id.*

[18] *See* Chowning R., *et al*., *A Retrospective Analysis of the Effect of Human Milk on Prevention of Necrotizing Enterocolitis and Postnatal Growth* 36 J Perinatol 221-4 (2016); Johnson TJ, et al., *Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants*, 107 Neonatology 271–6 (2015); Sullivan, S., *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 Pediatr 562–7 (2010); Cristofalo EA, *et al., Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants,* 163 J Pediatr1592-5 (2013).

[19] Lucas A., Cole TJ, *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 Lancet 1519-1523 (1990).

bovine-based formula, and *three times* more common than in those who received the formula plus breast milk.

31. The effects of human milk versus formula feeding were evaluated in another study, published in 1999.[20] That study specifically compared outcomes of 62 infants fed fortified human milk, which was defined as the mother's own milk plus Similac and/or Similac Special Care. 46 infants were fed exclusively the preterm formula Similac and/or Similac Special Care 20 and/or Similac Special Care 22 and/or Similac Special Care 24. The study found that infants fed with any amount of human milk were discharged earlier than infants fed preterm formula, despite significantly slower rates of weight gain and size. In addition, there was lower incidence of NEC and late onset of sepsis in infants fed fortified human milk as compared to those fed preterm formula. The study concluded that the unique properties of human milk promote an improved host defense and gastrointestinal function compared with the feeding of formula.

32. Another study was published in 2010, evaluating the benefits of an exclusively human milk-based diet compared with a diet of both human milk and bovine milk-based products in extremely premature infants.[21] Infants fed their own mothers' milk were separated into three different study groups: (1) HM100: pasteurized donor human milk-based human milk fortifier with an enteral intake of 100 mL/kg/d; (2) HM40: pasteurized donor human milk-based human milk fortifier with an enteral intake of 40 mL/kg/d; and (3) BOV: bovine milk-based human milk fortifier with an enteral intake of 100 mL/kg/d. The groups receiving an exclusively human milk diet had significantly lower rates of NEC and NEC requiring surgical intervention, as depicted in Figure 2, below.

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[20] Schanler RJ, *et al.*, *Feeding Strategies for Premature Infants: Beneficial Outcomes of Feeding Fortified Human Milk vs Preterm Formula*, 103 Pediatrics 1150-57 (1999).

[21] Sullivan, *supra* note 18.

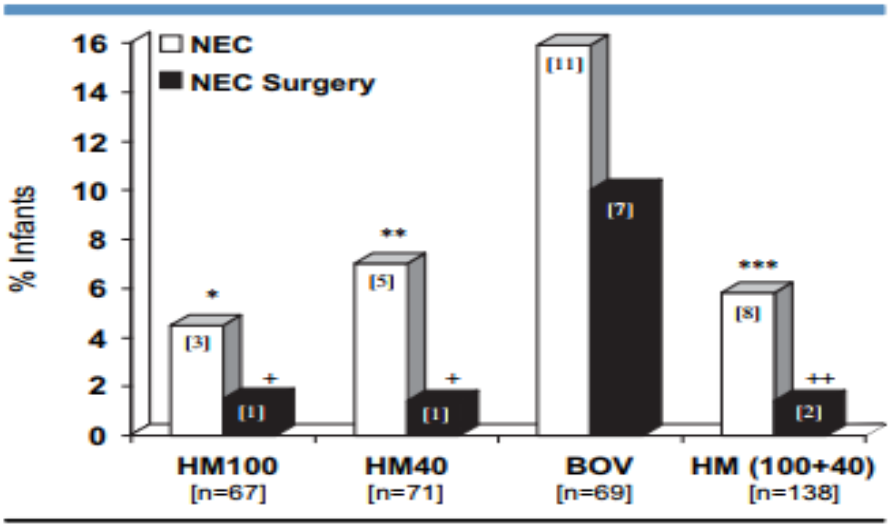


Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $^{*}P = .04$ vs BOV, $^{**}P = .09$ vs BOV, $^{***}P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P = .03$ vs BOV, $^{\dagger\dagger}P = .007$ vs BOV. [ ] refers to number of infants.

[22]

33. In another 2020 publication, the twelve-center randomized trial published in 2010,[23] that compared bovine milk derived fortifier to human milk derived fortifier, was reviewed and analyzed.[24] The new study noted that it was common practice to feed preterm infants a base diet comprising of only human milk, usually fortified with a bovine derived fortifier.[25] The study took the old data[26] and focused on the infants who had a diet comprised 100% of their mothers' own milk (*i.e.*, they had no donor milk or preterm formula). This allowed for an isolated comparison of the bovine derived fortifier and the human derived fortifier. The study found that the bovine derived fortifier was associated with a higher risk of

[22] *Id.*

[23] Sullivan, *supra* note 18.

[24] Lucas, *et al.*, *Preterm Infants Fed Cow's Milk-Derived Fortifier had Adverse Outcomes Despite a Base Diet of Only Mother's Own Milk*, 15 Breastfeeding Medicine 297-303 (2020).

[25] *Id.*

[26] Lucas, *supra* note 24.

NEC, NEC requiring surgery, reduced head circumference gain, and death.[27] Despite the high intake of the mother's own milk, the bovine derived fortifier was still associated with a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of NEC surgery or death. Thus, those fed a human derived fortifier were significantly advantaged in terms of a reduced incidence of morbidity. The authors concluded that the available evidence points to an increase in adverse outcomes with bovine derived fortifier, including NEC (Modified Bell's Staging Criteria Stage 2 or greater), NEC surgery or death, and surgical NEC.[28]

Parameter	*HMDF (n=82)*	*CMDF (n=32)*
NEC (Bell Stage 2 or greater)	3/82 (3.7%)	5/32 (15.6%)
NEC surgery or death[b]	3/82 (3.7%)	6/32 (18.8%)
Surgical NEC[b]	1/82 (1.2%)	3/32 (9.4%)
Death[b]	3/82 (3.7%)	4/32 (12.5%)
BPD	24/82 (29.3%)	11/32 (34.4%)
Ventilator days	Median 9.5 IQR=0.75, 41.25	Median 15.5 IQR=1, 50.25
ROP (grade 3 or 4)	6/82 (7.3%)	2/32 (6.3%)

[29]

[a]Chi-square/Fisher's exact test for categorical variables; for ventilator days, Wilcoxon's test.
[b]Note that for the index "NEC surgery or death" there are three versus six cases in the HMDF and CMDF groups; this is one less in each group than the sum of NEC surgery and death when shown individually. This is because in each diet group, one case had *both* NEC surgery and death (not counted twice in the index).
BPD, bronchopulmonary dysplasia; CMDF, cow's milk-derived fortifier; HMDF, human milk-derived fortifier; ROP, retinopathy of prematurity.

C. Defendant Knew of the Risks Associated with Bovine Formula

34. When sufficient maternal breast milk is not available, it has been widely recognized that alternative sources of enteral nutrition for preterm or low birth weight infants include donor breast milk or artificial formula.

35. There are several clinical trials comparing the effects of feeding preterm infants with human milk, human donor milk, and bovine milk-based products.

[27] Lucas, *supra* note 24.

[28] *Id.*

[29] *Id.*

36. A Cochrane Library meta-analysis, last updated in 2018, analyzed data from eight trials including 1,605 participants who were either preterm or low birth weight infants in a neonatal unit.[30] The combined data showed a higher risk of NEC in the formula-fed group. The studies compared the use of formula and donor breast milk. The meta-analysis showed that the overall risk of the infant developing NEC with donor breast milk was 3.7% and the overall risk with formula was 7% (4.5-10.7%). The analysis documented that there is a higher risk of NEC in the formula-fed group. Below is a summary of the studies that were examined as part of the meta-analysis:

a. **Term Formula versus Unfortified Donor Breast Milk:** the study evaluated the outcomes of preterm infants fed human milk compared to modified infant formula.[31] This study reported on 67 preterm infants from 1980 to 1982, comparing infants fed with unfortified donor milk and term formula. The results showed that three out of 26 infants on the formula milk developed NEC, whereas only one out of 41 infants receiving donor breast milk developed NEC—*a 300% difference*.

b. **Preterm Formula versus Fortified Donor Breast Milk:** the study evaluated growth, metabolic response, and development in very-low-birth-weight infants fed donor milk or enriched formula.[32] This study reported on 76 healthy infants of very low birth weights, comparing banked human milk and Similac Special Care protein-mineral–

[30] Quigley, *et al.*, *Formula versus Donor Breast Mild for Feeding Preterm or Low Birth Weight Infants*, 6 Cochrane Database of Systematic Reviews (2018), https://pubmed.ncbi.nlm.nih.gov/29926476/.

[31] Gross SJ, *Growth and Biochemical Response of Preterm Infants Fed Human Milk or Modified Infant Formula*, 308 New England Journal of Medicine 237-41 (1983); Duke University Department of Pediatrics; Funded by Mead Johnson Nutrition.

[32] Tyson JE, *et al.*, *Growth, Metabolic Response, and Development in Very-Low-Birth-Weight Infants Fed Banked Human Milk or Enriched Formula. I. Neonatal Findings*, 103 Journal of Pediatrics 95-104 (1983).

calorie-enriched formula. Two of the infants on the formula developed NEC while none of the infants on the donor milk developed NEC.

c. **Preterm Formula versus Fortified Donor Breast Milk**: this study evaluated the clinical impact of infants fed bovine fortified breast milk.[33] Published in 1996, this trial involved 276 preterm infants who were fed a base diet of a mother's own milk, and if insufficient breast milk was available, bovine based preterm formula was added. The number of infants with NEC was 5.8% in the fortified group compared to 2.2% in the control group. The trial showed that the addition of bovine derived fortifiers to breast milk, as the sole intervention, more than doubled the combined incidence of confirmed NEC or sepsis.

d. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial of extremely premature infants on donor human milk versus preterm formula was conducted.[34] This study, published in 2005, compared the differences in 243 infants fed with their mothers' milk, pasteurized donor milk plus Similac and/or Similac Special Care or Similac Human Milk Fortifier, and preterm formula (Similac and/or Similac Neosure Premature Formula). The results of this trial showed that infants who received their own mothers' milk had a 50% less chance of NEC and/or late-onset sepsis compared with infants fed either donor human milk or preterm formula.

e. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial examining the use of exclusive human milk versus preterm formula diets in extremely

[33] Lucas A., *et al.*, *Randomized Outcome Trial of Human Milk Fortification and Developmental Outcome in Preterm Infants*, 64 Am J Clin Nutr 142-51 (1996); Supported by Mead Johnson (Evansville, IN) which also supplied the fortifier.

[34] Schanler RJ, *et al.*, *Randomized Trial of Donor Human Milk versus Preterm Formula as Substitutes For Mothers' Own Milk in the Feeding of Extremely Premature Infants*, 116 Pediatrics 400-6 (2005).

premature infants was conducted.[35] This study, published in 2013, examined 53 extremely premature infants fed exclusive diets of either bovine milk–based preterm formula, or donor human milk with human milk-based fortifier. The incidence of NEC in the bovine formula group was 21% (five cases) versus 3% in the human milk group (one case). Surgical NEC was significantly higher in the bovine formula group (four cases) than human milk group (no cases). It was concluded that in extremely preterm infants, given exclusive diets of preterm formula versus human milk, there was a significantly higher rate of surgical NEC in infants receiving preterm formula. The researchers concluded that this trial supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU.

f. **Preterm Formula versus Fortified Donor Breast Milk**: this study examined the effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low birth-weight infants at eighteen months.[36] This trial evaluated 363 very low birth weight infants whose mother's breast milk became insufficient in four neonatal units in Ontario, California. The infant mother's milk was supplemented with either preterm formula (Similac Special Care or Similac and/or Similac Neosure Premature), or pasteurized donor breast milk supplemented with a fortifier (Similac Human Milk Fortifier or Similac and/or Similac Neosure Human Milk Fortifier), and a protein module (Beneprotein-Nestlé). The study showed that the nutrient

[35] Cristofalo EA, *et al.*, *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants*, 163 Journal of Pediatrics 1592-95 (2013).

[36] O'Connor DL, *et al.*, *Effect of Supplemental Donor Human Milk Compared with Preterm Formula on Neurodevelopment of Very Low Birth-weight Infants at 18 months: A Randomized Clinical Trial,* 316 JAMA 1897-1905 (2016). This study was funded by the Canadian Institutes of Health Research and the Ontario Ministry of Health and Long-Term Care.

enriched donor milk was associated with a lower risk of NEC (1.7%) compared with feeding preterm formula (6.6%).

37. As demonstrated by these studies, although Defendant misleadingly markets and promotes Similac and/or Similac Special Care to make parents and healthcare providers believe that it is safe and necessary for growth of a premature infant, the product is in fact extremely dangerous for premature infants. Similac and/or Similac Special Care substantially increase the chance of a premature infant developing NEC, resulting in severe injury and death.

38. Despite the aforementioned science confirming the dangers of Defendant's bovine product in causing NEC and death in premature infants, Defendant took no action to change its product, packaging, guidelines, instructions, and warnings.

39. Defendant continues to sell its bovine formulas and/or fortifiers commercially at retail locations and online.

40. Despite knowing NEC's risks arising from the use of its bovine-based products, including its Similac and/or Similac Special Care product, Defendant failed to properly warn the consuming public, including parents of premature infants and medical and healthcare providers, that its bovine formulas and/or fortifiers, including Similac and/or Similac Special Care, significantly increase the risk that premature infants will develop NEC and/or death.

41. Despite knowing NEC's risks arising from the use of its bovine-based products, including its Similac and/or Similac Special Care product, Defendant failed to design its bovine-based products to make them safe and deceived the consuming public, including parents and healthcare providers of premature infants, into believing that the products were safe and necessary alternatives, supplements, and/or substitutes to human milk.

42. As a direct result of Defendant's failure to take action to make its bovine-based products safe and warn the consuming public of NEC's risks arising from the use of those products, Defendant's bovine formulas and/or fortifiers caused P.W. to develop NEC, which resulted in his significant injuries. Prior to the administering of the formula to P.W., Defendant knew or should have known that its bovine formula and/or fortifier was not safe for use by premature infants, including P.W., yet it took no action to prevent the use of its product by premature infants.

43. Defendant knew or should have known that its bovine formula and/or fortifier would be used to feed premature infants, such as P.W., and knew or should have known that such use would significantly increase the risk of NEC in premature infants, including P.W., yet it took no action to prevent such use.

44. Defendant's formula is not safe to be used by premature infants, such as P.W., and Defendant knew or should have known it was unsafe, yet it failed to properly instruct or warn the FDA, NICUs, hospitals, doctors, and parents that its product was unsafe.

45. Despite Defendant's knowledge that its product was not safe for use by premature infants, including P.W., it also failed to provide detailed instructions or guidelines on when and how its product would be safe to use in premature infants, like P.W..

46. Notwithstanding substantial medical evidence establishing the extreme dangers that bovine formulas pose for premature infants, Defendant markets its bovine formulas and/or fortifiers as equally safe alternatives to breast milk and promotes its products as necessary for additional nutrition and growth. Defendant has specifically marketed its bovine formulas and/or fortifiers as necessary to the growth and development of premature infants, despite knowing its product poses a well-established and substantial risk to premature infants.

47. Despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to misleadingly market and sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, including premature infants, and despite knowing the significant health risk posed to infants by ingesting these products, especially to preterm, low weight infants, like P.W..

48. Defendant knows that its bovine formulas and/or fortifiers are causing NEC, devastating injuries, and death in premature infants, yet Defendant has taken no action to change its product, packaging, guidelines, instructions, and warnings to make them safe.

49. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby to develop NEC and other severe resulting injuries.

50. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby any harm, including the development of NEC and other severe resulting injuries.

51. Defendant never informed Plaintiffs that its formula and/or fortifier was made with bovine based ingredients.

52. Despite Defendant's knowledge of the numerous studies establishing that its products increase the risk of NEC in premature infants, Defendant never informed Plaintiffs of the studies establishing that bovine formula and/or fortifier were extremely dangerous to their baby.

53. Had Plaintiffs been informed of the facts, data, and science that linked the Defendant's product to its potential for causing NEC in their baby, they would not have allowed their baby to be fed Similac and/or Similac Special Care.

54. Due to Defendant's conduct, in not publicizing and/or distributing and/or warning of the dangers of using its bovine formulas and/or fortifiers in preterm, low weight infants,

Plaintiffs, nor any reasonably person, would have been able to have discovered the dangerous nature of Defendant's product or how it injured their child until shortly before the filing of this lawsuit.

CLAIMS ALLEGED

FIRST CAUSE OF ACTION
FAILURE TO WARN

55. Plaintiffs repeat and reallege the allegations in Paragraphs 1-54, above, as if fully set forth herein.

56. Defendant, as the manufacturer and/or seller of the infant formulas and/or fortifiers at issue in this litigation, owed a duty to the consuming public and Plaintiffs, to properly warn and provide adequate warnings, instructions, labeling, and/or packaging about the dangers and risks associated with the use of their products by preterm infants, specifically including, but not limited to, the risk of NEC.

57. Given the bovine formula and/or fortifier at issue is non-prescription, does not require a physician's recommendation, and is sold with packaging and labels meant to inform the average consumer. Thus, the learned intermediary doctrine does not apply.

58. The FDA has issued guidance specifically for the labeling of infant formulas, stating in part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.[37]

[37] U.S. Food and Drug Administration, *FDA Issues Guidance for the Labeling of Infant Formula*, September 16, 2016, https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidance-labeling-infant-formula.

59. Defendant, as the manufacturer and/or seller of the subject products, had a non-delegable duty to design reasonably safe products; and thus, it cannot rely upon any intermediary, including physicians, other healthcare providers, or healthcare staff, to fully warn the end user of the hidden dangers and risks in its infant formula products that contain bovine-based ingredients, specifically as it relates to the serious injuries that may result in preterm infants due to the increased risk of NEC.

60. Defendant had a duty to manufacture and distribute infant formula products that were reasonably safe for their foreseeable uses. It was Defendant's duty to adequately warn of the unreasonable risk of harm posed by bovine-based ingredients in its formulas and/or fortifiers, specifically the increased risk of NEC, bodily injury, and even death, that may result with the use of its formulas by pre-term infants, like P.W..

61. Defendant knew or should have known, as a leader in the industry, that the formulas and/or fortifiers manufactured and/or distributed by Defendant were unreasonably dangerous because of Defendant's failure to warn of the adverse side effects, including NEC and/or death in preterm infants.

62. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, to warn of the foreseeable risks of the formulas and/or fortifiers at issue by:

a. failing to properly warn consumers, including, but not limited to, physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that their bovine formulas and/or fortifier products significantly increase the risk of NEC and death in preterm infants;

b. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

c. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption by premature infants, including P.W.;

d. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

e. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature infants in order to decrease the risk of NEC and/or avoid other significant complications including death;

f. failing to insert warnings and/or instructions in its packaging of other alternatives to bovine formulas including human milk which poses a decreased risk of NEC;

g. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, and did not warn that bovine based ingredients significantly increase the risk of NEC;

h. failing to provide a label and/or instructions that reflect prominent studies regarding the risks and benefits of bovine formulas and/or fortifiers;

i. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the extreme risk associated with feeding premature infants bovine formula and/or fortifiers;

j. failing to provide detailed instructions to physicians and/or hospitals, and other healthcare providers on when to stop feeding the subject product to preterm infants;

k. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

l. failing to warn and/or concealed that there is a significant risk of NEC in premature infants fed bovine based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine based formula;

m. failing to place a prominent warning and instructions that would have prevented the feeding of the subject products to preterm infants, including P.W.;

n. failing to establish an appropriate standard for safe use;

o. failing to provide statistical evidence of adverse effects regarding the feeding of its products to preterm infants;

p. failing to guide, instruct, and/or advise on when preterm infants should be administered the formula, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using this formula and/or fortifier; and

q. failing to develop a protocol for hospitals and physicians with the elements to assure safe use.

63. Had physicians, hospitals, and other healthcare providers known of the extreme risk associated with feeding premature infants Defendant's bovine formula and/or fortifier, they would not have administered Defendant's unsafe product to P.W..

64. Had Plaintiffs known of the extreme risks associated with feeding premature infants bovine formula and/or fortifier, they would not have allowed Defendant's unsafe product to be administered to P.W..

65. As a direct and proximate result of Defendant's conduct, as described herein, P.W. was administered and/or enterally fed the subject product causing him to develop NEC, and ultimately caused serious injuries.

66. As a direct and proximate result of Defendant's conduct, as described herein, Plaintiffs suffered significant damages and their lives have been significantly affected by the injuries of their baby.

SECOND CAUSE OF ACTION
STRICT LIABILITY FOR DEFECTIVE PRODUCT

67. Plaintiffs repeat and reallege the allegations in Paragraphs 1-66, above, as if fully set forth herein.

68. Defendant, as the manufacturer and/or seller of the infant formula and/or fortifier at issue, owed a duty to the consuming public, including Plaintiffs, to manufacture, sell, and distribute the formula and/or fortifier in a manner that was not unreasonably dangerous for its intended use.

69. Defendant knew or should have known that its formula and/or fortifier was intended for use on premature infants, like P.W., and that such use was unreasonably dangerous due to bovine formula and/or fortifier significantly increasing the risk of NEC and/or death.

70. Reliable scientific studies and data establish that bovine formulas and/or fortifiers, including those manufactured and distributed by Defendant, carry unreasonable risks of NEC and death, yet Defendant continued to market and sell its defective products for premature infants, like P.W..

71. Despite Defendant's knowledge of these significant risks, Defendant continued to market, sell, and distribute their defective products to premature infants.

72. Defendant's formula and/or fortifier, which was administered and/or enterally fed to P.W., was unreasonably dangerous.

73. Defendant failed to develop a human-based milk product which was safer for premature infants, despite knowing of the dangers of bovine formulas.

74. Defendant also failed to reformulate and/or redesign its formulas and/or fortifiers to make them safe, including by reducing the risks of NEC, even though it knew of safer, more effective alternatives.

75. As a direct result of Defendant's conduct, as described herein, Defendant's unreasonably dangerous products were administered to P.W., causing him to develop NEC and sustain serious injuries.

76. As a direct and proximate result of Defendant's conduct, including developing, manufacturing, selling, and distributing its unreasonably dangerous bovine formulas and/or fortifiers, Plaintiffs suffered damages as their lives have been significantly affected by the injuries of their baby.

THIRD CAUSE OF ACTION
NEGLIGENCE

77. Plaintiffs repeat and reallege the allegations in Paragraphs 1-76, above, as if fully set forth herein.

78. Defendant, as the manufacturer, designer, seller, and distributor of the bovine formulas and/or fortifiers at issue, had a duty to the consuming public, including Plaintiffs, to exercise reasonable care to design, test, manufacture, inspect, and distribute a safe product that did not present an unreasonable risk of harm to consumers when used in its intended manner and for its intended purpose.

79. At all relevant times, P.W. was administered the formula and/or fortifier at issue in its intended manner and for its intended purpose.

80. Defendant negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the bovine products at issue and thereby breached its duty to the consuming public, including Plaintiffs.

81. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, by:

a. failing to properly warn consumers, including but not limited to physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that its bovine products significantly increase the risk of NEC and death in preterm infants;

b. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

c. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption of premature infants including P.W.;

d. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

e. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature infants in order to decrease the risk of NEC and/or avoid other significant complications, including death;

f. failing to insert warnings and/or instructions in its packaging, notifying the consuming public of safe alternatives to bovine formulas and/or fortifiers, including human milk which decreases the risk of NEC;

g. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, and did not warn that bovine-based ingredients significantly increase the risk of NEC;

h. failing to establish a label and/or instructions that notify the consuming public of reliable scientific studies and data establishing the risks of bovine formulas and/or formulas;

i. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the significant risk associated with administering premature infants' bovine formulas and/or fortifiers;

j. failing to provide detailed instructions to physicians, hospitals, and healthcare providers regarding when to stop administering the subject product to preterm infants;

k. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

l. failing to warn and/or concealed that there is a significant risk of NEC in premature infants fed bovine based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine based formula;

m. failing to place a prominent warning and instructions that would have prevented the administering of the subject products to P.W.;

n. failing to establish an appropriate standard for safe use;

o. failing to provide statistical evidence of adverse effects regarding the administration of its products to preterm infants;

p. failing to guide, instruct, and/or advise the consuming public regarding when preterm infants should be administered the subject product, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using its formula and/or fortifier; and

q. failing to develop a protocol for hospitals, physicians, and healthcare providers to ensure safe use of its products.

82. As a direct result of Defendant's conduct, as described herein, P.W. was exposed to Defendant's unreasonably dangerous infant formula and suffered from NEC and suffered severe injury.

83. As a direct result of Defendant's conduct, as described herein, Defendant's unreasonably dangerous formulas and/or fortifiers were administered to P.W. causing him to develop NEC and suffer severe injury.

84. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs suffered damages as their lives have been significantly affected by the injuries to their baby, to P.W..

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

85. Plaintiffs repeat and reallege the allegations in Paragraphs 1-84, above, as if fully set forth herein.

86. Defendant, as the manufacturer, designer, producer, seller, and distributor of the subject products, had a duty to the consuming public, including Plaintiffs, to provide truthful and accurate information about the risks of its bovine-based ingredients when the products are used in their intended manner and for their intended purpose.

87. At all relevant times, P.W. was administered the products at issue in their intended manner and for their intended purpose.

88. Defendant breached its duty to the consuming public, including Plaintiffs, by:

a. misrepresenting that its bovine formulas and/or fortifiers were safe for premature infants when it knew or should have known that its bovine formulas and/or fortifiers were unreasonably dangerous and caused NEC and death in premature infants;

b. misrepresenting that its bovine formulas and/or fortifiers have no serious side effects, when it knew or should have known the opposite to be true;

c. misrepresenting to consumers, including but not limited to, Plaintiffs here, as well as other parents and/or guardians, physicians and healthcare providers, that its bovine formulas and/or fortifiers were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth and other safer alternatives are available;

d. misrepresenting that its bovine formulas and/or fortifiers are safe for premature infants;

e. misrepresenting those bovine formulas and/or fortifiers are necessary for optimum growth;

f. misrepresenting those bovine formulas and/or fortifiers are similar or equivalent and/or a safe alternative to human milk;

g. misrepresenting that the efficacy of bovine formulas and/or fortifiers were based on well-established studies and/or science; and

h. omitting and/or concealing that the subject products significantly increase the risk of NEC in premature infants, which can cause severe injury and death.

89. As a direct result of Defendant's conduct, as described herein, P.W. was exposed to dangerous bovine formulas and/or fortifiers, causing him to contract NEC and suffer severe injury.

90. As a direct result of Defendant's conduct, as described herein, its unreasonably dangerous products were enterally administered to P.W. causing him to develop NEC and suffer severe injury.

91. As a direct and proximate result of Defendant's conduct, as described herein, Plaintiffs suffered significant damages as their lives have been significantly affected by the injuries to their baby.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

92. Plaintiffs repeat and reallege the allegations in Paragraphs 1-91, above, as if fully set forth herein.

93. At all relevant times, P.W.'s parents and/or guardians, physicians, and/or other healthcare providers enterally administered the bovine formulas and/or fortifiers to P.W. in their intended manner and for their intended purpose.

94. Defendant warranted, through marketing, advertisements, labels, packaging, and instructions that its products were safe and effective for their reasonably anticipated uses, including the enteral administration to premature infants.

95. Defendant warrants and markets on its "For Healthcare Professionals" webpage, that: Similac and/or Similac Special Care 24: "a 24 Cal/fl oz iron-fortified feeding for growing, low-birth-weight infants and premature infants, and Similac Special Care 20 " a 20 Cal/fl oz iron-fortified formula for growing, low-birth-weight infants and premature infants." .. Designed to be used as a preterm post-discharge formula. OptiGRO® is our exclusive blend of DHA, lutein and vitamin E: these important ingredients are found in breast milk. Supports better gains in weight, length, and head circumference when compared to term infant formula. ."[38]

96. Notwithstanding strong medical evidence establishing the extreme dangers that cow-based products pose for premature infants, Abbott has marketed its cow-based products as

[38] Abbott Nutrition, https://www.abbottnutrition.com/our-products/similac-special-care-24 (last visited September 15,2023).

an equally safe alternative to breast milk, and indeed has promoted its products as necessary for additional nutrition and growth. The Defendant has specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants*, when indeed its products pose a known and substantial risk to these babies.

97. Abbott has attempted to "hook" moms on formula, by offering free formula and other goodies in baskets given to moms in hospital and medical clinics. The impetus behind such efforts is to create brand loyalty, and create the appearance of "medical blessing" so that moms continue to use formula to feed their babies after they leave the NICU, at great expense to the parents, and substantial profit to Abbott.

98. Abbott's practice of trying to get moms to choose formula over breast milk goes back decades. The company has for decades promoted its product as more healthy, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Their advertising has at times attempted to portray breast feeding as an inferior, less sophisticated choice.

99. 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." advertisement."** (Baumslag & Michels, 1995, p. 161). Recognizing the abuse and dangers of the marketing of Infant formula, in 1981, the World Health Assembly (WHA; the decision-making body of the world's Member States) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and outlawed any advertising or promotion of breast milk

substitutes to the general public. The International Code of Marketing of Breast-milk Substitutes specifically prohibited advertising in Article 5 Section 1: "There should be no advertising or other form of promotion to the general public..." The International Code of Marketing of Breast-milk Substitutes. Geneva: World Health Organization, p.16 - 20 (1981).

100. Abbott has acknowledged the Code: "We support, educate and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast- feeding up to and beyond two years of age. . . We acknowledge the importance of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes (the "WHO Code") and subsequent World Health Assembly (WHA) resolutions. We respect the aim and principles of the WHO Code to contribute to the provision of safe and adequate nutrition for infants, by: a) the protection and promotion of breast-feeding; and b) ensuring the proper use of Breast-milk Substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution." *Abbott Policy on the Marketing of Instant Formula.*

101. Despite this assurance and warranty contained in its Policy, Abbott has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public..."

102. Notwithstanding the Code and Abbott's own policy claiming to recognize the Code, advertising of infant formula has remained pervasive and widespread in the United States. In short, Abbott has paid lip service to the Code, but in actuality has systematically violated its central provision."

103. Similac was deceptive from its very inception. Similac's very name (*i.e. similar to lactation*) is deceptive. Beginning with its brand name, Abbott has continued to perpetuate the deception that its product is on par with or similar to human milk.

104. "Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breastmilk." *Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP. Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding. Am J Public Health. 2008;98(2):290-295*.

105. For example, one author found an advertisement for Similac on the back cover of American Baby Magazine, April 2004 issue which made repeated references and comparisons to breast milk, and indeed the short ad uses the phrases **"like breastmilk" six times.** Broussard Hyderkhan, A, *Mammary malfunction: a comparison of breastfeeding and bottle feeding product ads with magazine article content*, 2005:

106. In addition to perpetuating the myth that Similac is *"like breastmilk"*, Abbott has also deceived the public into believing that Physicians believe Similac is an ideal choice for babies.

107. Beginning in 1989, Abbott began using claims in its advertising that Similac was "first choice of more physicians."

108. Although the claim did not specifically compare itself to breast milk, a plain interpretation of this claim is that physicians believe Similac is the "1st choice", naturally implying that it is superior even to breastfeeding.

109. Beginning in 1995, Abbott began a heavy marketing campaign which featured "1st choice of Doctors" on all its infant formula product labels.

110. A marketing report commissioned by Abbott in March, 1998 summarized consumer reactions to several informational advertising pamphlets on Similac. The one stressing 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," and use of similar pieces emphasizing the claim was "highly recommended."

111. One study estimates that formula manufacturers spent $4.48 billion on marketing and promotion in 2014. *Baker, P, et al, Global trends and patterns of commercial milk-based* formula sales: is an unprecedented infant and young child feeding transition underway? Public Health Nutrition, 2016.

112. The contradictory messages women receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is unnecessary and difficult if not impossible to achieve" Hausman, B. L. (2000, Summer). *Rational management:*

Medical authority and ideological conflict in Ruth Lawrence's Breastfeeding: A guide for the medical profession. Technical Communication Quarterly, 9(3), 271-289.

113. One study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. Parker, R. S., & Pettijohn, C. E. (2003). *Ethical considerations in the use of direct-to- consumer advertising and pharmaceutical promotions: The impact on pharmaceutical sales and physicians. Journal of Business Ethics*, 48, 279-290.

114. One study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. *Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB. Exposure to infant feeding information in the media during pregnancy is associated with feeding decisions postpartum. Paper presented at American Public Health Association 138th Annual Meeting & Exposition; November 2010; Washington, DC.*

115. 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 breast-feeding rates reported the next year generally tended to decrease. *Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.*

116. 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. *Stang J, Hoss K, Story M. Health*

statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.

117. Abbott has developed an advertisement campaign which attempts to create a perception of "mommy wars". One advertisement, which received significant attention, *The Mother 'Hood* tries to depict a "mom war", where all the competing sides come together to save a baby at the end. The ad is effective in so much as it is manipulative. The advertisement, at one point depicts three "bottle feeding moms", and one of them proclaims: "*Oh look, the breast police have arrived".* The ad then depicts the "breastfeeding moms" with arrogant and superior appearing faces, and even disdainful mannerisms, with one of the moms proclaiming in a condescending voice, "100% breast fed - straight from the source", and a second mom grasping her breast in a profane manner. The negative portrayal of breastfeeding moms is subtle, but powerful, and casts the breastfeeding moms as judgmental and nasty, while portraying the bottle-feeding moms as nurturing victims.

www.youtube.com/watch?list=RDJUbGHeZCxe4&v=JUbGHeZCxe4&feature=emb_rel_end

118. Another advertisement titled "The Judgment Stops Here", a documentary-styled ad, is powerful and moving in that it shows moms coming together, putting aside judgment of each other's choices. However, the ad is manipulative, deceptive and violative of the Code and Abbott's own marketing Policy, in that it puts breast milk and formula on an even playing field, and attempts to chastise any judgment that might be cast in favor or what is clear scientific judgment. In other words, the ad attempts to insulate Similac from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint.

https://www.facebook.com/Similac/videos/1126104447462943

119. In an Abbott advertisement for a Similac product, the ad states "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac. *It's modeled after breast milk…*" *www.youtube.com/watch?v=kRaHiTMyYXs*

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

121. 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."

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

123. In 1988, Abbott introduced and 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."

124. 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.....
Similac® Special Care® 30……

125. At all relevant times, Abbott has a website "similac.com" where the mothers can choose the formula the Corporation recommends based on different categories such as: Preemie, baby, toddler 12-36 months, prenatal and postnatal.

126. In this promotional website, there is no mention of the risk of necrotizing enterocolitis. The promotional web page expressly and implicitly represents that its cow-based products are safe for use with premature infants. This is false and misleading.

127. Defendant Abbott implicitly warrants that "Similac Human Milk Fortifier Hydrolyzed Protein Concentrated Liquid": is "[i]ntended for premature and low-birth-weight infants as a nutritional supplement to add to human milk" [39]; "[clinical study shows improved growth for your littlest babies"; "meets expert recommendations for protein and other nutrients for the preterm infant"; and is "[w]ell tolerated" (pictured below).[40]

FEATURES

- Clinical study shows improved growth for your littlest babies.[1]
- Extensively hydrolyzed protein for easy digestion and absorption.
- Non-acidified.
- Lutein and DHA for developing eyes and brain.
- When added to human milk, meets expert recommendations for protein[2,3,*] and other nutrients for the preterm infant.[2]
- Well tolerated.
- Small, convenient packet is designed for easy mixing.
- Commercially sterile and meets the AND and CDC recommendation to use liquid for NICU feedings.[4,5,†]
- Low iron level provides flexibility to add iron as needed.
- Gluten-free.

128. Abbott warrants and markets on its own website that its "Similac Human Milk Fortifier Concentrated Liquid" is: intended "for premature and low-birth-weight infants"[41]; "meets the nutrient recommendations for the premature infant"[42]; and "[c]ommercially sterile

[39] Abbott Nutrition, *https://abbottnutrition.com/similac-human-milk-fortifier-hydrolyzed-protein-concentrated-liquid (*last visited Sep. 15, 2023).
[40] *Id.*
[41] Abbott Nutrition, https://abbottnutrition.com/similac-human-milk-fortifier-concentrated-liquid (last visited Sep. 15, 2023).
[42] *Id.*

and meets the AND and CDC recommendation to use liquid for NICU feedings"[43] (pictured below).

FEATURES

- Small, convenient packet is designed for easy mixing.
- When added to human milk, meets the nutrient recommendations for the premature infant.[1]
- Commercially sterile and meets the AND and CDC recommendation to use liquid for NICU feedings.[2,3,*]
- Packet is simple to open and mixes easier with human milk than powder.[4]
- Low iron level provides flexibility to add iron as needed.
- Halal.
- Kosher.

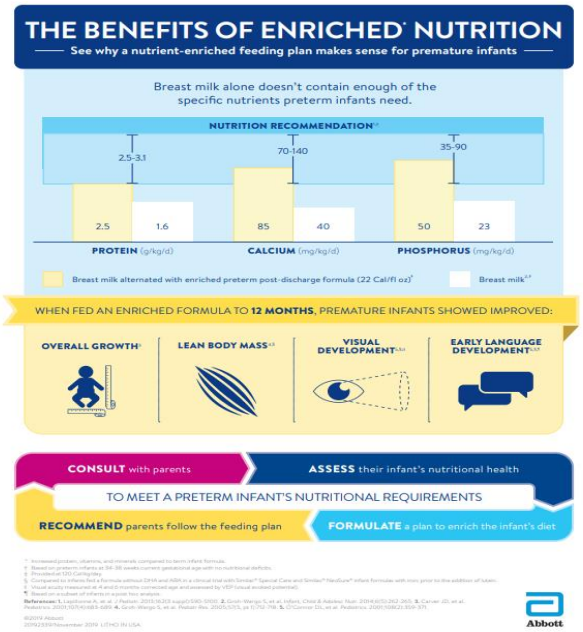
129. Abbott warrants and markets that its Similac Special Care 24 formula: is "iron-fortified feeding for growing, low-birth-weight infants and premature infants"; and its packaging features the word "PREMATURE" on the front directly under the product's name.

130. Defendant Abbott also warrants and markets that: "[b]reast milk alone doesn't contain enough of the specific nutrients preterm infants need"[44]; and "[w]hen fed an enriched formula to 12 months, premature infants showed improved" overall growth, lean body mass, visual development, and early language development"[45] (see chart below);

[43] Abbott Nutrition, *Preterm Infants Need Increased Nutrients to Catch Up,* https://static.abbottnutrition.com/cmsprod/abbottnutrition2016.com/img/NeoSure%20Infographic_tcm1226-135785.pdf (last visited Feb. 22, 2022).

[44] Abbott *supra* note 57; *see also* Abbott, *Commitment to Responsible Marketing of Infant Formula and Breast Milk Substitutes* (June 2020) https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Infant-Formula-Marketing-Commitment-OnePager-FINAL-061820.pdf.

[45] *Id.*



131. Defendant Abbott warrants that its premature infant formulas, specifically Similac Special Care 24: "clinically shown to improve early language development, early visual development, and body composition"; "nucleotides for immune support"[46].

Description

Similac NeoSure Infant Formula is a nutrient-enriched baby formula that promotes excellent catch-up growth during your premature baby's first 12 months including better gains in weight, length and head circumference when compared to premature babies fed term infant formulas*. Help support her development in the first full year with specialized nutrition from the #1 brand of premature formula** Also available in ready-to-feed bottles. *Compared to infants fed a formula without DHA and ARA in a clinical trial with Similac Special Care and Similac Expert Care NeoSure Infant formulas with iron **Total US Premature infant formula all outlets as of 12/31/16, Nielsen data) †

132. Defendant Abbott warrants on its Similac retail website that Similac Special Care 24 and Similac Special Care 20 provides: "Supports Brain & Eye Development: Has our unique blend of DHA, lutein, & vitamin E to support brain and eye development"[47]

[46] Abbott, https://www.abbottnutrition.com/our-products/similac-special-care-24 (last visited Sep. 15,2023).

[47] Similac, https://www.abbottnutrition.com/our-products/similac-special-care-24 (last visited Sep. 15,2023).

133. On Abbott's promotional website, there is no mention of the risk of NEC. The promotional web page expressly and implicitly represents that its bovine products are safe for use with premature infants. This is false and misleading. Defendant's advertisements claims to give proper nourishments but fails to disclose the risk of NEC.

134. Despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to market and/or sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like the baby.

135. The bovine formulas and/or fortifiers did not conform to these implied representations because Defendant manufactured, sold, and advertised the formula, which was not similar or equivalent to human milk, was not necessary for growth, and which was not based upon current data and science establishing problematic health risks of bovine-based formula to pre-term infants that caused significant harm and/ or death to premature infants.

136. As a direct result of Defendant's conduct, as described herein, unreasonably dangerous bovine formulas and/or fortifiers were administered to the baby, causing the baby to develop NEC, which ultimately caused the baby's serious injuries, including but not limited to intestinal rupturing which led to various surgeries, including but not limited to interventions for the removal of portions of his large and small intestines, had an ileostomy reversal, a drain and an ostomy bag. Due to his injuries, P.W. developed bowel problems, infection, sepsis and hematochezia.

137. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiffs have suffered catastrophic damages and injuries such as developmental delays,

emotional distress, loss of income, etc., and other damages as their lives have been significantly affected by the injuries of their baby, P.W..

SIXTH CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT
UNDER NEW YORK LAW

138. Plaintiffs repeat and reallege the allegations in Paragraphs 1-137, above, as if fully set forth herein.

139. Defendant's bovine formulas and/or fortifiers, which were consumed by P.W. and which caused his injuries, were defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purpose and/or the foreseeable risks exceed the benefits associated with their design and formulation. The products were unreasonably dangerous in design.

140. At all relevant times, Defendant's bovine formulas and/or fortifiers expected to reach, and did reach, consumers in the State of New York and across the United States, including Plaintiffs, without substantial change in the condition in which they were sold.

141. At all relevant times, Defendant's bovine formulas and/or fortifiers were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective or unreasonably dangerous condition at the time placed in the stream of commerce in ways, which include, but are not limited to, one or more of the following:

a. when placed in the stream of commerce, the bovine formulas and/or fortifiers contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting P.W. to risks that exceeded the benefits of the subject product, including personal injury and death;

b. when placed in the stream of commerce, Defendant's formulas and/or fortifiers were defective in design and formulation, making the use of Defendant's products more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with non-bovine formulas and/or fortifiers;

c. the design defects with Defendant's formulas and/or fortifiers existed before they left the control of Defendant;

d. the harmful side effects of Defendant's formulas and/or fortifiers outweighed any potential utility;

e. Defendant's formulas and/or fortifiers were not accompanied by adequate instructions and/or adequate warnings to fully apprise consumers, including Plaintiffs, of the full nature and extent of the risks and side effects associated with their use; and

f. at the time Defendant's formulas and/or fortifier's left Defendant's control, there existed one or more safe, alternative designs for said products, with such alternative design(s) capable of preventing Plaintiffs damages, and the danger of the damage from Defendant's bovine formulas and/or fortifiers outweighed the burden on Defendant of adopting the alternative design(s).

142. Defendant knew or should have known that its respective products would be administered to premature infants, including P.W., and that such use would significantly increase the risk of NEC and significant injury to him.

143. Defendant took no actions to prevent the administration of its bovine formulas and/or fortifiers to premature infants, including P.W..

144. The formulas and/or fortifiers were designed, manufactured, and distributed by Defendant.

145. Defendant's bovine formulas and/or fortifiers were not safe to be administered to premature infants, including P.W., and Defendant knew or should have known they were unsafe.

146. Despite Defendant's knowledge that its products were unreasonably dangerous when administered to premature infants, it failed to provide any instructions or guidelines on when and how its products would be safe to administer to or with a premature infant, like P.W. Defendant misleadingly marketed its respective products as safe and beneficial for premature infants, like P.W..

147. As a direct and proximate result of the foregoing acts and omissions, Defendant's formulas and/or fortifiers were a substantial factor in causing P.W.'s NEC and his serious injuries arising therefrom.

148. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs suffered damages as their life has been significantly affected by the injuries to their baby, P.W..

SEVENTH CAUSE OF ACTION
VIOLATION OF THE ILLINOIS CONSUMER FRAUD
AND DECEPTIVE TRADE PRACTICES ACT 815 ILCS 505/1, *et seq.*

149. Plaintiffs repeat and reallege the allegations in Paragraphs 1-148 above, as if fully set forth herein.

150. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2, states that, "[u]nfair methods of competition and unfair or deceptive acts or practices… are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby."

151. By the conduct described in detail above and incorporated herein, Defendant engaged in unfair or deceptive acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act.

152. Defendant's unfair and deceptive practices include:

a. developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents and healthcare providers believe Similac and/or Similac Special Care and other bovine products were as safe, or even safer, than human milk; including that it was safe for premature infants;

b. engaging in advertising, promotion and marketing inducing parents and healthcare providers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level;

c. concealing and omitting the risks of NEC associated with the use of Similac and/or Similac Special Care and bovine milk by premature infants;

d. knowingly and falsely representing that Defendant's formulas and/or fortifiers were fit to be used for the purpose for which it was intended; and

e. representing that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

153. Defendant's false and misleading representations and omissions concerning Similac and/or Similac Special Care and bovine milk are material facts that a reasonable person would have considered when deciding whether or not to purchase or use Similac and/or Similac Special Care.

154. Defendant's misleading omissions and representations concerning the risks of Similac and/or Similac Special Care, and Defendant's scheme to promote Similac and/or Similac Special Care and other bovine milk products as no less safe than human milk: (a) were against public policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

155. Defendant intended for parents and healthcare providers, including the parents and healthcare providers of P.W., to rely on its misleading representations and omissions regarding Similac and/or Similac Special Care and other bovine milk products.

156. Defendant's unfair scheme to promote Similac and/or Similac Special Care and bovine milk products, and its deceptive representations and omissions concerning Similac and/or Similac Special Care and other bovine milk products, occurred in the course of conduct involving trade or commerce.

157. P.W.'s healthcare providers relied upon Defendant's misrepresentations and omissions in determining which product to administer to him, and P.W.'s parents were deceived into not objecting to Defendant's products by virtue of Defendant's misrepresentations and omissions and deceptive marketing campaigns.

158. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, P.W. was administered Similac and/or Similac Special Care and sustained injuries and damages as described herein.

159. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, P.W. suffered damages, as described herein, as his life has been significantly affected by the injuries to P.W..

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendant on each of the above-stated Claims as follows:

A. For general damages in a sum in excess of this Court's jurisdictional minimum;

B. For medical, incidental, and hospital expenses, according to proof;

C. For pre-judgment and post-judgment interest, as provided by law;

D. For consequential damages in excess of this Court's jurisdictional minimum;

E. For compensatory damages in excess of this Court's jurisdictional minimum;

F. For punitive damages;

G. For treble damages as defined by various statutes herein;

H. For attorneys' fees, expenses, and costs of this action; and

I. For all other and further relief that this Court deems appropriate.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all claims so triable.

Dated: January 9, 2025

Respectfully submitted,

/s/ Christopher R. LoPalo
Christopher R. LoPalo, Esq.
NS PR LAW SERVICES LLC
1302 Ave. Ponce de León
Santurce, PR 00907
T: (212)-397-1000
F: (646) 927-1676
CLoPalo@nsprlaw.com

Counsel for Plaintiffs