UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

JAYONA JONES, *individually and on behalf of the Estate of her deceased minor child* **K.J.** *Plaintiff*, v. **ABBOTT LABORATORIES** and **ABBOTT LABORATORIES, INC.** *Defendants*.	**MDL No. 3026** **Master Docket No. 1:22-cv-00071** **Case No. _____** **Hon. Rebecca R. Pallmeyer**
Complaint with Jury Demand	

NATURE OF ACTION

1. This action arises out of the injury of a premature infant ("Baby K.J."), who was afflicted with a disease caused by cow's-milk-based infant formula and fortifier manufactured and sold by Defendant Abbott Laboratories, Inc ("Defendant").

2. Necrotizing enterocolitis ("NEC") is a deadly disease that largely affects low-birth-weight babies who are fed cow's-milk-based formula or products. Baby K.J., a very prematurely born, low-birth-weight baby, was fed Similac® formula and developed NEC as a result. Plaintiff Jayona Jones ("Plaintiff") files this complaint against Defendant for negligent, willful, and wrongful conduct in connection with the design, development, manufacturing, testing, packaging, promoting, marketing, and distribution, labeling, and/or sale of the product known as Similac® Special Care® 24 ("the Product").

THE PARTIES

3. Plaintiff's premature infant, Baby K.J., was born at Indiana University Health Ball Memorial Hospital ("IUH") in Muncie, Indiana on July 28, 2013. He developed NEC and died after being fed the Product. Baby K.J. was a resident of Indiana.

4. Jayona Jones is the mother of Baby K.J. She brings this action individually and on behalf of the Estate of Baby K.J. Ms. Jones was a resident of Indiana at all times relevant.

5. Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business in this jurisdiction. It is the parent company of its wholly owned subsidiary, Defendant Abbott Laboratories, Inc.

6. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in this jurisdiction. Defendant Abbott Laboratories, Inc. is a wholly owned subsidiary of its parent company, Abbott Laboratories.

7. On information and belief, for all purposes relevant to this Complaint, Abbott Laboratories and Abbott Laboratories, Inc. functioned as one entity, so this Complaint will refer to both collectively as "Defendant" or "Abbott."

JURISDICTION

8. This Court has original jurisdiction under 28 U.S.C. § 1332(a) because Plaintiffs and Defendant are citizens of different states and the matter in controversy, exclusive of interest and costs, exceeds $75,000.

9. This Court has personal jurisdiction over Defendant and venue is proper here because Defendant is a citizen of this State with its principal place of business in this

jurisdiction. 28 U.S.C. §§ 1391(b).

FACTUAL BACKGROUND

The Science, The Products, The Marketing, and The Baby

The Science: Cow's-milk-based products significantly increase the risk of NEC in premature infants

10. According to the World Health Organization ("WHO"), babies born alive before 37 weeks of pregnancy are completed, like Baby K.J., are defined as "premature" or "preterm." The WHO estimates that approximately 15 million babies are born preterm every year, and that number is rising.

11. Optimal nutrition for preterm babies, especially those who have a low birth weight (under 2500 grams), like Baby K.J. (born at 1750 grams), is important for the babies' survival.

12. The United States ranks tenth or higher in the list of countries with the highest number of preterm births.

13. The medical and scientific community traditionally believed that infant formulas based on cow's milk were beneficial for the growth of premature, low-birth-weight babies. But for decades, medical and scientific research have established that feeding premature infants cow's-milk-based formulas or fortifiers (like the Product) can cause NEC—which may require surgery or cause death—in preterm, low-birth-weight infants, and many other health complications and long-term risks.

14. Scientific advances have made alternatives to cow's-milk-based formulas and fortifiers available.

15. As of 2006, human milk-based fortifiers were available to supplement human milk given to premature infants.

16. Despite having knowledge of these medical and scientific studies and advances, Defendant did nothing to change the design or formulation of its cow's-milk-based formulas and fortifiers. Likewise, Defendant did nothing to change its cow's-milk-based products' packaging, guidelines, instructions, and/or warnings.

17. Feasible alternatives to cow's-milk-based products that do not substantially increase the risk of NEC for premature infants exist, including formulas and fortifiers derived from human milk and amino acids. Defendant, however, continues to promote and sell cow's-milk-based products for feeding to premature infants.

18. Medical science and research establish the strong causal relationship between cow's-milk-based products and NEC and death in premature infants.

19. As early as 1990, a prospective multicenter study on 926 preterm infants found that NEC was six-to-ten times more common in exclusively formula-fed babies than in babies fed breast milk alone, and three times more common than in those who received formula plus breast milk. Lucas T. Cole, *Breast Milk and Neonatal Necrotising Enterocolitis,* 336 Lancet 1519–23 (1990).

20. Preterm infants have immature gastrointestinal systems, especially as compared to the gastrointestinal systems of term infants. The specific physiology of the preterm gastrointestinal system makes premature babies vulnerable to NEC: "The preterm gut is characterized by reduced peristalsis, a thin mucous layer, reduced tight junctions, increased enterocyte apoptosis, and impaired enterocyte regeneration. Decreased structural integrity and functionality of the gut result in poor digestion and absorption of energy, protein, and other nutrients necessary for growth, the development of organs, and immunoprotection." Jocelyn Shulhan et al.,

Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products, 8 Adv. Nutr. 80–91 (2017).

21. Preterm infants' immune systems are also significantly different than those of term infants, which compounds their susceptibility to NEC when fed unsafe products: "[T]here are distinct differences between term and preterm infants in regard to the expression of immune cells and signaling pathways. A preterm immune system cannot readily detect pathogens and protect against infections due to multiple associated factors such as 1) the decreased production of IgA, IgM, IgG, and defensins; 2) changes in the expression of toll-like receptors (TLRs), especially TLR4 and TLR9, which are involved in pathogen recognition and the activation of the innate immune system; and 3) upregulation of proinflammatory TLRs and/or proinflammatory cytokines…. The culmination of these factors increases a preterm infant's vulnerability to infections and disease, particularly NEC." *Id*.

22. Before Baby K.J. was born, rapidly increasing use of bovine-based fortifier as an infant gained tolerance for enteral feedings was causally linked to fulminant development of NEC. Lambert DK, Christensen RD, Baer VL, Henry E, Gordon PV, Besner GE, Wilkes J, Wiedmeier SE, Gerday E. *Fulminant necrotizing enterocolitis in a multihospital healthcare system*. J Perinatol. 2012 Mar;32(3):194–98.

23. A study published in 2010, before Baby K.J. was born, established that when premature babies were fed an exclusive human-milk diet (of mother's own milk and/or pasteurized donor milk, and human-milk fortifier), these babies were 90% less likely to develop surgical NEC compared to infants who received the usual feeding protocol with human milk supplemented with bovine-based fortifier and cow's-milk- based formula if

mother's own milk was insufficient. S. Sullivan et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J. Pediatrics 562– 67 (2010).

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

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

26. In 2011, the Surgeon General published a report titled The Surgeon General's Call to Action to Support Breastfeeding, which further emphasized the danger of cow's-milk-based products to premature infants. The report warned that, "[f]or vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." U.S. Dept. of Health & Human Services, *The Surgeon General's Call to Action to Support Breastfeeding*, Washington, D.C., Office of the Surgeon General; 2011, p.1. This same report stated that formula-fed premature infants who are not breastfed are 138% more likely to develop NEC than

premature infants who are breastfed. *Id*., Table 1, p. 2.

27. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human-milk diet because of the risk of NEC associated with the consumption of cow's-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).

28. An article published in 2017 reported: "In summary, HM [human-milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs [randomized control trials] on preterm infants weighing between 500 and 1250g at birth compared the effect of bovine[-]milk-based preterm infant formula to MOM [mother's own milk] or DHM [donor human milk] on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence of NEC." Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv. Nutr. 80–91 (2017).

29. Another study published in 2017 reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis … Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering

the composition of bacterial flora. Ideally, preterm infants should be fed human milk and avoid bovine protein. A diet consisting of human milk-based human milk fortifier is one way to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a human milk diet." Diana Maffei et al., *Human Milk is the Feeding Strategy to Prevent Necrotizing Enterocolitis!* 41 Semin Perinatal. 36–40 (2017).

30. A 2020 review explained: "Due to the lack of effective treatments for NEC, research focus has shifted to testing strategies for the prevention of NEC, specifically early exposure to colostrum and mother's own milk …. Colostrum, the first milk produced by mothers in the days after birth, has been shown to contain high concentrations of beneficial immune mediators that provide bacterial and anti-inflammatory protection, and stimulate the development of the GI tract… Human breast milk contains many factors thought to help prevent NEC including nitrate/nitrite antioxidant factors, L-arginine, human milk oligosaccharides and prebiotics, secretory IgA, platelet-activating factor acetylhydrolase, lactoferrin, and growth factors." Alissa L. Meister et al., *Necrotizing Enterocolitis: It's Not All in the Gut*, 245 Experimental Biology and Medicine 85–95 (2020).

31. Another 2020 review stated: "Human milk is the only modifiable risk factor that has been consistently shown to protect against the development of NEC." Jocelyn Ou et al., *Nutrition in Necrotizing Enterocolitis and Following Intestinal Resection*, 12 Nutrients 520 (2020). "The specific mechanisms by which breast milk is protective continue to be studied. However, several non-nutrient components have been found to contribute to the immune functions of the gastrointestinal tract and augment

mucosal integrity. These include secretory IgA, growth hormones (epidermal growth factor, insulin, and insulin-like growth factor), polyunsaturated fatty acids, and oligosaccharides. A 2019 study found that not only is an infant's IgA largely derived from maternal milk in the first month of life, but also that infants with NEC have larger proportions of IgA-unbound bacteria compared to age-matched controls." *Id*. Scientific studies also establish that necrotizing enterocolitis carries significant risks for long-term complications among surviving infants. NEC requiring surgical treatment is causally associated with increased rates of neurodevelopmental delays, failure to thrive, intestinal failure, short-bowel syndrome, feeding difficulties, intestinal strictures, and intestinal adhesions with small-bowel obstruction. Catalina Bazacliu et al., *Necrotizing Enterocolitis: Long Term Complications*, 15 Current Pediatric Reviews 115–24 (2019).

32. In summary, medical studies (including studies published before Baby K.J. was born) clearly established that: (1) NEC causes serious short-term and long-term medical problems for infants who develop the disease; (2) cow's-milk-based infant formula and fortifier substantially increases the risk of low-birth weight/premature infants developing NEC, and (3) growth and nutritional benchmarks can be reached or exceeded in premature, low-birth-weight infants who are fed an exclusive diet of human milk (mother's milk, donor milk, and/or a human-milk-derived formula or fortifier such as Prolacta).

The Product:
Defendant's cow's-milk-based formulas and fortifiers

33. Defendant's Similac® Special Care® 24 is a cow's-milk-based product.

34. Feeding cow's-milk-based products to a premature infant significantly

increases the risk that the infant will develop NEC, sustain devastating injuries, require surgery, and/or die.

35. Defendant's cow's-milk-based Similac® and Abbott Nutrition products are dangerous to premature infants because the products significantly increase the risk that these infants will develop NEC, sustain devastating injuries, require surgery, and/or die.

36. Despite knowing that cow's-milk-based products significantly increase the risk of NEC, devastating injuries, surgical intervention, and/or death for premature infants, Defendant deliberately choose not to provide a specific warning of these risks.

37. Defendant failed to properly warn consumers that its cow's-milk-based products significantly increase the risk that a preterm infant will develop NEC, sustain devastating injuries, require surgery, and/or die.

38. Before Baby K.J. developed NEC, Defendant knew or should have known that its cow's-milk-based products were not safe to feed to premature infants. Yet Defendant took no steps to prevent such use among this vulnerable infant population.

39. Before Baby K.J. developed NEC, Defendant did foresee or should have foreseen that its products would be used as they were in this case—for feeding premature infants and/or adding to human milk to be fed to premature infants—and knew or should have known that such use would significantly increase the risk of premature infants developing NEC. Yet Defendant took no steps to prevent such use among this vulnerable infant population.

40. Defendant's cow's-milk-based products were not safe to be used as they were used in this case, and Defendant knew or should have known they were unsafe, yet

Defendant failed to properly instruct and/or warn the FDA, NICUs, hospitals, doctors, and parents that these products were unsafe.

41. Defendant's cow's-milk-based products were not safe to be used as they were used in this case, and Defendant knew or should have known they were unsafe. Yet Defendant failed to provide detailed instructions or guidelines on when, whether, and how its products would be safe to use.

The Marketing:
Defendant's misleading marketing of cow's-milk-based Similac® formulas and "human milk fortifiers"

42. Notwithstanding strong medical evidence establishing the extreme dangers that cow's-milk-based products pose for premature infants, Defendant has marketed its cow's-milk-based products as an equally safe or superior alternative to exclusive breast milk for premature infants.

43. Defendant has promoted its products as not only safe but ***necessary*** for the growth and development of premature infants, when, in fact, its products pose a known and substantial risk to these babies and are not necessary for their growth and development.

44. Defendant's practice of trying to get mothers of both preterm and term infants to choose its cow's-milk-based fortifiers or formulas—without accounting for the different physiological needs and NEC risks between these preterm and term infant populations—goes back decades. Defendant has promoted its cow's-milk-based products as healthier, necessary for adequate nutrition, supported by "science," and the choice for the modern, sophisticated mother. Indeed, Defendant's advertising has attempted to portray breastfeeding as inferior to and less sophisticated than formula

feeding or "supplementing."

45. Defendant's marketing for cow's-milk-based Similac® products (which are available for purchase by the public) and Abbott Nutrition products (which are sold exclusively to medical providers) failed to warn consumers about the crucial physiological differences between term and preterm infants, including preterm infants' far greater risk of developing NEC as a result of being fed cow's-milk-based formulas.

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

47. For years, the international health community has recognized the abuse and dangers of infant-formula marketing. The WHO and the 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 WHO 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." Baumslag & Michels, *Milk, Money, and Madness: the Culture and Politics of Breastfeeding* (1995), p. 161.

48. In 1981, the World Health Assembly (WHO's decision-making body) developed an International Code of Marketing of Breast-milk Substitutes ("the Code"), which recommended that companies be required to acknowledge the superiority of breast milk and condemned any advertising or promotion of breast-milk substitutes to the public. More than 40 years ago, the Code specifically condemned such advertising: "There should be no advertising or other form of promotion to the general public …" International Code of Marketing of Breast Milk Substitutes. WHO, Geneva, Art. 5, § 1, 16–20 (1981).

49. Defendant 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-[m]ilk 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. We acknowledge that, independently of any other measures taken by governments to implement the WHO Code, we are responsible for monitoring our marketing practices according to the principles and aims of the Code, and for taking steps to ensure that our conduct at every level in this regard conforms to this Infant Formula Marketing Policy and local law in the countries where we operate." Abbott

Laboratories, Inc., *Abbott Policy on the Marketing of Infant Formula, Version 2,* WWW.ABBOTT.COM, p. 3–4, https://dam.abbott.com/en-us/documents/pdfs/transparency/Abbott_Policy_on_the_Marketing_of_Infant_Formula.pdf (last visited Apr. 14, 2022).

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

51. Notwithstanding the Code, Defendant aggressively markets to both new parents and medical providers that cow's-milk-based formulas and fortifiers (like the Product) will benefit their newborns and give them the best chance of survival. The pervasive marketing involved, ostensibly prohibited by the Code, has impacted public and medical perceptions of synthetic non-human-milk-derived substitutes, such as a formula and fortifier, in such a way that it lessens the likelihood that a parent of a baby receiving this food in the NICU will ask questions, request alternatives, or object to their baby receiving cow's-milk-based products. In short, Defendant has systematically violated the Code's central provision.

52. Defendant's pervasive marketing, ostensibly prohibited by the Code, has affected the perceptions of synthetic non-human-milk-derived substitutes, such as cow's-milk-based formula and fortifier, to make parents believe it is safe for all infants.

53. As the WHO and UNICEF reported in February 2022, 40 years after the Code was promulgated: "formula milk marketing still represents one of the most underappreciated risks to infants' and children's health." World Health Organization,

How the Marketing of Formula Milk Influences Our Decisions on Infant Feeding (2022), available at https://www.who.int/publications/i/item/9789240044609 (last visited July 9, 2023). This "distortion of objective information and the misuse of science negatively impacts on access to accurate and impartial information—an essential human right as stated in the Convention on the Rights of the Child." *Id.*

54. A 2020 review concluded that, notwithstanding the Code, which "aims to shield parents from unfair commercial pressures," formula marketing "remains widespread because some countries (e.g., the USA) have not adopted the Code, and elsewhere industry has developed follow-on and specialist milks by which they promote formula by proxy." Gerard Hastings et al., *Selling Second Best: How Infant Formula Marketing Works*, 16 Globalization and Health 77–88 (2020).

55. The marketing techniques deployed by Defendant and other formula companies have become more pervasive and insidious in the age of social media: "The campaigns use emotional appeals to reach out to and build relationships with parents and especially mothers…The advent of social media has made it easier to pose as the friend and supporter of parents; it is also providing companies a rich stream of personal data with which they hone and target their campaigns." *Id.*

56. Defendant's and other formula companies' efforts to portray themselves as benevolent sources of emotional support for new parents seek to conceal their profit motives: "The formula industry is dominated by a small number of extremely powerful multinational corporations with the resources to buy the best global marketing expertise. Like all corporations[,] they are governed by the fiduciary imperative which puts the pursuit of profits ahead of all other concerns. The mix of

fiscal power, sophisticated marketing, and single-mindedness is causing great harm to public health." *Id*.

57. Defendant's marketing makes it less likely that the parents of a premature infant receiving cow's-milk-based formula or fortifier in the NICU will ask questions about the products' safety, ask for a non-cow's-milk-based alternative (like human donor milk or human-milk-based formula or fortifier), or object to their babies ingesting such products. In short, Defendant has systematically violated the Code's central provision.

58. One study reports that "[s]ince the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breast milk." Kenneth 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). The same study has also found that manufacturers have repeatedly used their relationships with hospitals and the discharge process to encourage mothers of both term and preterm infants to substitute formula for breast milk even after they leave the hospital. *Id*.

59. This kind of marketing practice undermines the doctor-patient relationship and reduces a parent's capacity to make informed decisions regarding an infant's care.

60. Indeed, most hospitals in the U.S. distribute "commercial discharge bags packaged as smart diaper bags containing various coupons, advertisements, baby products, and infant formula samples." Yeon Bai et al., *Alternative Hospital Gift Bags and Breastfeeding Exclusivity*, 2013 ISRN Nutrition, article ID 560810 1–7 (2013). These commercial gift bags send confusing signals to breastfeeding mothers about

the feasibility of continued breastfeeding and have been shown to negatively impact breastfeeding rates. *Id*. at 5. But the practice continues because it is a very effective way to solicit customers, including the parents of preterm infants, who are encompassed within the company's across-the-board marketing strategy.

Abbott's misleading marketing of Similac®

61. Similac® was deceptive from its very inception. Similac®'s name (i.e., *simi*lar to *lac*tation) is deceptive. Beginning with the selection of its brand name, Defendant has continued to perpetuate the deception that its products are on par with or similar to human milk. This marketing has altered the perceptions of parents and directly contradicts the medicine and the science.

62. Defendant routinely compares its Similac® products with human breast milk and attempts to create an equivalency. For example, an advertisement for Similac® Advance published on the back cover of American Baby Magazine in April 2004 made repeated references and comparisons to breast milk, and indeed the one-page ad uses the phrases "like breastmilk" six times:

See also Angela Broussard Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottle Feeding Product Ads with Magazine Article Content*, LSU Master's Thesis (2005).

63. The pervasive exposure of parents to media, advertising, and promotion equating cow's-milk-based formulas and fortifiers to human breast milk has the generalized impact of: (a) reducing lactation; (b) causing parents to believe that

formula is comparable to breast milk; (c) causing parents to believe that cow's-milk-based fortifiers are necessary to supplement mother's own milk; and (d) reducing parents' capacity to engage in informed consent and informed decision-making about their child's nutrition. Through long-term exposure to Abbott's advertising, Baby K.J.'s parents had been conditioned and were caused to believe that Similac® products (and, by extension, Abbott Nutrition products sold only to hospitals like Liquid Protein Fortifiers) are suitable alternatives to breastmilk and necessary supplements for low-birth-weight infants.

64. In addition to perpetuating the myth that Similac® is "like breast milk," Abbott has also deceived the public into believing that physicians believe Similac® is an ideal choice for babies.

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

66. Although the claim did not expressly compare itself to breast milk, a plain interpretation of this claim that Similac® is physicians' "first choice" implies that it is superior to breastfeeding or an exclusive human-milk diet.

67. Beginning in 1995, Defendant began a heavy marketing campaign that featured "first choice of doctors" on all its infant formula product labels.

68. A marketing report issued by Defendant in March 1998 summarized consumer reactions to several informational advertising pamphlets on Similac®. The one stressing the "first 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."

69. Defendant's efforts to expose parents of both term and preterm infants to media, advertising, and promotion within hospitals and doctors' offices has the generalized impact of:

a. causing parents to believe that cow's-milk-based formula is equally as safe for preterm infants as it is for term infants;

b. causing parents to believe that cow's-milk-based formula is equivalent to breast milk in terms of nutrition, digestibility, and health risks;

c. causing parents to believe that cow's-milk-based fortifiers are necessary supplements to mother's own milk or donor milk, despite the availability of human-milk-based fortifier;

d. reducing mothers' lactation efforts and lactation, thereby reducing the best available source of nutrition for premature infants; and;

e. reducing infants' parents' capacity for informed consent and informed decision-making.

70. Defendant has developed an advertisement campaign that attempts to create and capitalize upon a perception of "mommy wars." One advertisement that received significant attention—titled *The Mother 'Hood*—depicts a "war" where breastfeeding and formula-feeding moms are about to fight one another on a playground, but come together in the end to save a baby whose stroller rolls down a hill while the parents are preparing to rumble. The ad is effective because it is manipulative. In the ad, a formula-feeding mom proclaims: "Oh look, the breast police have arrived" as three breastfeeding moms arrive. The breastfeeding moms are portrayed as arrogant and disdainful of the bottlefeeders. One breastfeeding mom proclaims condescendingly, "100% breast fed — straight from the source," another grasps her breast in a profane

manner, and a third exclaims, "looks like some moms are too lazy to breastfeed." The negative portrayal of the breastfeeding moms casts them as mean, judgmental, and nasty while portraying the bottle-feeding moms as nurturing victims. https://www.youtube.com/watch?v=JUbGHeZCxe4 (last visited Apr. 14, 2022).

71. Another advertisement in Abbott's #EndMommyWars campaign—titled *The Judgment Stops Here*—is a powerful and moving documentary-styled ad showing mothers coming together, putting aside judgment of each other's choices. But the ad is manipulative, deceptive, and violative of the Code and Abbott's own marking policy in that it puts breast milk and formula on equal footing and attempts to chastise any judgment that might be cast in favor of what is clear scientific truth. In other words, the ad attempts to insulate Similac® from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint because breast milk is, in fact, superior to formula. https://www.facebook.com/Similac/videos/1126104447462943/ (last visited Apr. 14, 2022).

72. In an advertisement for a Similac® product, Defendant's 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 . . . it's thoughtfully crafted nutrition." https://www.youtube.com/watch?v=kRaHiTMyYXs (last visited Apr. 14, 2022).

73. In an advertisement for a Similac® product, the ad states that the formula contains "2'-FL human milk oligosaccharide, a nourishing prebiotic like that found in breast milk." The ad further states that "Similac® supports babies' developing immune system in the gut" and uses the following image to illustrate the claim:

While the image includes the fine print "*not from human milk" that caveat is not included in the ad's audio, so anyone listening to—rather than reading—the ad would not be aware that this "Human Milk Oligosaccharide" is not, in fact, from human milk. *See* https://www.youtube.com/watch?v=OWuqDb1PoG0 (last visited Apr. 14, 2022).

74. Moreover, Defendant has also attempted to market its products specifically to premature infants, who are the infants at highest risk from the dangers of its products.

75. 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."

76. 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."

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

78. 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.

79. On information and belief, Abbott specifically targets parents of premature infants in its marketing. For example, a Google search "feeding preemies formula" revealed a paid advertisement on the first page for Similac® NeoSure®, with the heading "For Babies Born Prematurely." *See* https://prod7-similac-2015-com.abbottnutrition.com/baby-formula/similac-expert-care-NeoSure-premature (last visited Apr. 14, 2022). The web-based advertisement 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 claimed that it is "pediatrician recommended" and "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to preterm infants' specialized needs for human breast milk, and does not mention that infants may develop NEC because of ingesting cow's-milk-based products.

80. Through Defendant's website "similac.com", Abbott directs mothers of premature babies to use Similac® NeoSure®—a cow's-milk-based formula—as the "Best Feeding Option," specifically stating it is "enriched nutrition" for premature

infants. By clicking on "Learn More," the user is taken to the "Product Description" that describes the product as "complete nutrition for babies born prematurely." *See* https://www.similac.com/products/preemie-formula/NeoSure-powder/22-8oz-can-4pack.html (last visited Apr. 14, 2022). The "Product Description" further states: "This special blend has protein, calories, vitamins, and minerals, including calcium, to help your baby grow. Similac® NeoSure® is from the #1 infant formula brand for premature babies."

81. In the promotional website described in the preceding paragraph, there is no mention of the risk of necrotizing enterocolitis. There is no mention of breast milk or human-milk-derived products as the "Best Feeding Option." This promotional web page expressly and implicitly represents that its cow's-milk-based products are safe for use with premature infants and a better option than breast milk. This is false and misleading.

82. Another advertisement by Defendant states that "whether you choose to formula feed or to supplement breast feeding with formula, you can be confident in the nourishment of Similac®." *See* https://www.similac.com/why-similac.html (last visited Apr. 14, 2022). The representation to parents that they can be "confident" in what they "choose" contradicts the studies that indicate that cow's-milk-based breast milk substitutes like the Product are dangerous to premature infants. Accordingly, it is false and misleading.

83. Defendant's website also tells moms that "human milk fortifier" "enhances mom's milk with extra protein, vitamins, and minerals to support a preemie's high nutrition needs for growth and development," without acknowledging that cow's-

milk-based fortifiers also carry risks, such as potentially causing NEC. *See* Bringing Your Preemie Home: Make a preterm infant nutrition plan, https://www.similac.com/baby- feeding/premature-development/bringing-preemie-home.html (last visited Dec. 19, 2022).

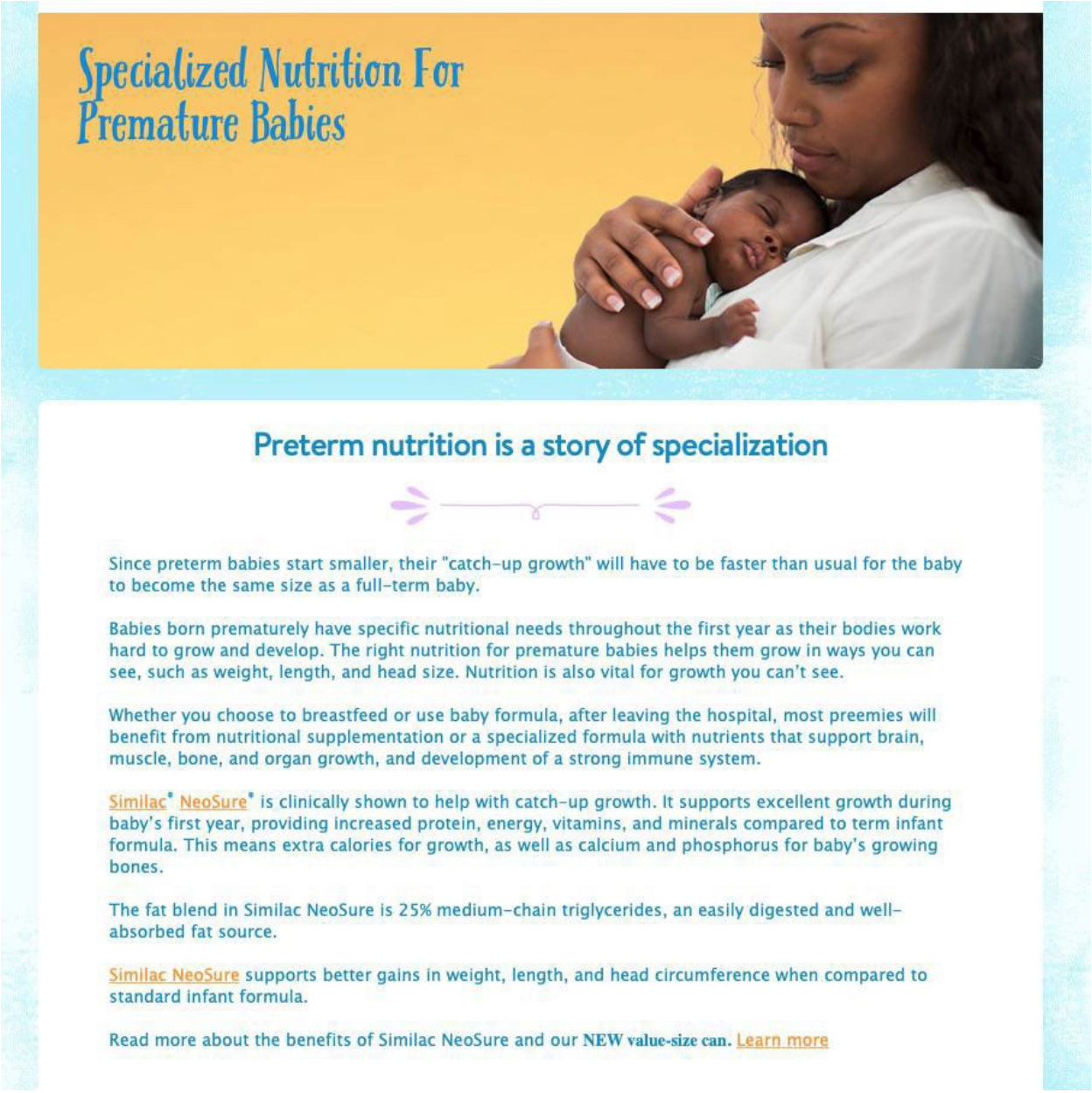
84. The Similac® website also has reviews from mothers whose premature infants were in the NICU, and they discuss how wonderful and safe the products are. There are no mother reviews discussing NEC and death. This is a false and misleading narrative, and Defendant actively perpetuates it. Abbott has designed a plan to induce parents to continue to purchase its products after leaving the NICU, at great expense and risk.

85. In 2011, CBS News reported that Defendant paid mom bloggers to give positive reviews of its Similac® app. *See* https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app/ (last visited Apr. 14, 2022). Abbott's Similac® app is a tool it uses to create and maintain brand loyalty and collect data on mothers and their babies.

86. Defendant promotes NeoSure® on its website and other mediums as a safe product, and one specifically needed by preemies for adequate growth. https://www.similac.com/baby-feeding/premature-development/preemie-catchup-growth.html (last visited March 7, 2022). Under the heading "Specialized Nutrition for Your Preemie," Abbott advises parents that preemies have "higher nutrient needs than full-term newborns" and "need tailored nutrition." Abbott advises mothers that a "preterm baby's nutrient needs are greater than what breast milk alone can

provide." This is misleading because it implies that Abbott's cows'-milk-based fortifiers are necessary, despite the availability of human-milk-based fortifiers that offer sufficient nutritional supplementation but with a significantly reduced risk of ENC compared to Abbott's products.

87. The following is a true and accurate image of an Abbott ad targeting parents of premature infants:



88. This same web page contains a video, promoting the necessity of formula to achieve adequate growth in premature infants ("to help her catch up on the inside and the outside"). The page further claims that Similac® NeoSure is the "MOST EXTENSIVELY STUDIED PRETERM FORMULA" and "has been shown to promote growth and developmental outcomes of preemies when fed for the first full year." The video concludes by inviting parents to "count on the promise of Similac®." *See* https://similac.com/baby-formula/similac-expert-care-NeoSure-premature (last visited Apr. 14, 2022).

89. Recognizing a shift in the medical community towards an exclusive human-milk-based diet for premature infants, Defendant began developing a product called "Similac® Human Milk Fortifier." The name itself is misleading in that it suggests that the product is derived from human milk.

90. Although Prolacta has manufactured and sold a human milk fortifier made from human milk since 2006, Abbott's Similac® Human Milk Fortifier is a cow's-milk-based product that contains no human milk.

91. Many parents find the term "human milk fortifier" confusing because it implies that it contains human milk. Canvasser, et al., *Parent and Provider Perspectives on the Imprecise Label of "Human Milk Fortifier" in the NICU*, Nutrients 2020, 12, 720. Plaintiffs did not know that Similac® Human Milk Fortifier was derived from cow's milk. The product's name is misleading and causes consumers to believe it is a human-milk-derived product.

92. Nor did Plaintiff know that human-milk-based fortifier was available.

93. Defendant's statements as set forth above ignore the Code, the American

Academy of Pediatrics, and the numerous studies demonstrating the nutritional and immunological superiority of breast milk. Defendant's efforts to create a false equivalency between its products and breast milk are particularly dangerous for premature infants, who are most at risk for developing NEC because of consuming cow's-milk-based products.

94. Defendant's successful efforts to reduce breastfeeding rates in favor of cow's-milk-based formula feeding—thereby increasing its "share of stomach"—encompass mothers of premature infants, causing these babies to have an increased chance of NEC.

95. Defendant has designed and implemented a systemic, powerful, and misleading marketing campaign to deceive parents to believe that: (1) cow's-milk-based formula and fortifiers are safe for all babies and do not cause disease in premature infants; (2) cow's-milk-based products are equal or superior to breastmilk for all infant populations; and (3) cow's-milk-based fortifiers are necessary for premature infants and carry no risks; and (4) physicians consider cow's-milk-based products the best choice for every baby.

The effects of Defendant's marketing

96. Through long-term exposure to Defendant's advertising, Baby K.J.'s parent was conditioned to believe that cow's-milk-based infant feeding products like the Product are suitable alternatives to breastmilk and necessary supplements for premature and low-birth-weight infants.

97. The scope of Defendant's and other formula companies' marketing efforts is vast. One study estimates that formula manufacturers spent $4.48 billion on

marketing and promotion in 2014. Philip Baker et al., *Global Trends and Patterns of Commercial Milk-based Formula Sales: Is an Unprecedented Infant and Young Child Feeding Transition Underway*? 19 Public Health Nutrition 2540–50 (2016).

98. Moreover, the data indicate that these marketing efforts are successful at achieving brand-name recognition among consumers. One study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. R. Stephen Parker et al., *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 279–90 (2003).

99. Despite knowing that feeding premature infants cow's-milk-based formulas significantly increases the risk of NEC and that breastfeeding significantly reduces the risk of NEC, Defendant persists with marketing that is part of a broader industry-wide campaign to convince parents that breastfeeding (instead of or in addition to formula feeding) is not feasible. The contradictory messages parents receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is unnecessary and difficult, if not impossible. *See* Bernice L. Hausman, *Rational Management: Medical Authority and Ideological Conflict in Ruth Lawrence's Breastfeeding: A Guide for the Medical Profession*. 9 Technical Communication Quarterly 271–89 (2000).

100. One study found that exposure to this advertising has a negative effect on breastfeeding initiation. Merewood et al., *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, Washington, D.C. (Nov. 2010).

101. 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).[1]

102. The 2010 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 for all infant populations. This may induce reliance on a biased source for infant-feeding guidance. *Id*.

Defendant's specific marketing to premature babies' caregivers

103. In addition to including parents of premature infants within its general marketing claims regarding the safety of cow's-milk-based formula products as detailed above, Defendant has also specifically marketed cow's-milk-based formulas, including the Product, for feeding to premature infants.

104. Although Defendant knows and has known that cow's-milk-based formulas and fortifiers cause a significantly increased risk of NEC in premature infants, and

[1] *See also* Angela Broussard Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottle Feeding Product Ads with Magazine Article Content*, LSU Master's Thesis (2005).

although Defendant knows that human-milk-based formulas and fortifiers are technologically feasible and commercially available, Defendant has continued to market and sell cow's-milk-based formulas for premature babies.

Defendant's inadequate warnings

105. Defendant's aggressive marketing campaign is designed to make parents believe that Defendant's products are safe and necessary for the growth of premature infants, despite decades of research that establish the fact that cow's-milk-based products significantly increase the risk that a premature infant will develop NEC, require surgery, or die.

106. Defendant provides the following warnings for its product Similac® Special Care® 24 formula:

> Safety Precautions
>
> Very-low-birthweight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously.
>
> Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings.
>
> Spitting up, abdominal distension, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At first signs of these problems, enteral feeding should be slowed or discontinued.
>
> Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb) or as directed by a physician.
>
> **Never use a microwave oven to warm formula**. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Special Care® 24, WWW.ABBOTTNUTRITION.COM, https://www.abbottnutrition.com/our-products/similac-special-care-24 (last visited July 10, 2023).

107. None of the "Safety Precautions" Defendant provided with the Product warned of the risk of NEC.

Defendant failed to warn the public and Baby K.J.'s parent

108. Despite knowing that cow's-milk-based products significantly increase premature infants' risk of NEC, surgery, and/or death, Defendant did not warn consumers of these risks or the magnitude by which cow's-milk-based products increased these risks.

109. Defendant likewise did not provide instructions or guidance for how to feed these products to attempt to avoid or mitigate these risks.

110. Although Defendant's products are sometimes given to infants at medical facilities, the Product is marketed to the public and available for consumers to purchase without a doctor's prescription. The Liquid Protein Fortifier is sold directly to medical facilities, but like the direct-to-consumer Products, it lacks any warning about NEC. Indeed, Defendant's products, including the Product, are often donated to medical facilities so that parents will develop brand loyalty and purchase the same brand of products post-discharge.

111. Defendant deceived the public, parents, physicians, other medical professionals, and medical staff into believing that cow's-milk-based products, including formulas and fortifiers, are a safe and necessary alternative, supplement, or substitute to breast milk for premature infants.

112. Despite knowing that cow's-milk-based products were being fed to preterm infants as marketed, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals or hospitals inform parents of the

significant risk of NEC, surgery, or death associated with feeding cow's-milk-based products to premature infants.

113. Despite knowing that its cow's-milk-based products, including the Product, were being fed to preterm infants as marketed and labeled, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals obtain the parents' informed consent before feeding these cow's-milk-based products to premature infants.

114. No parent would reasonably expect that an infant formula or fortifier could be extremely dangerous to their baby unless properly warned and informed of the extreme dangers and risk of NEC, serious injury, surgery, or death.

115. To this day, Defendant has never warned the public about the extreme danger its cow's-milk-based products pose for premature infants like Baby K.J.

116. Members of the medical community, physicians, and hospitals, as well as the parents, relied upon the representations and advertising of Defendant, which categorically omit that cow's-milk-based products significantly increase the risk of NEC, surgery, and death in premature infants, which contributed to the Product being fed to Baby K.J.

117. On information and belief, the product label for the Product fed to Baby K.J. did not warn consumers or medical professionals about the risk of NEC from giving premature infants cow's-milk-based formulas.

118. Neither the hospital nor the physicians involved in Baby K.J.'s care informed her parents that Defendant's cow's-milk-based products would significantly increase the risk of NEC.

119. Neither the hospital nor the physicians provided a choice to the parents about whether to feed their premature infant cow's-milk-based fortifier or formula. Baby K.J. spent his entire short life in the NICU, where he was fed by NICU staff. His parent had to rely on these hospital staff members to feed her child. The NICU staff, in turn, had to rely on Defendant to manufacture safe products with appropriate warnings.

120. The Product was not safe to be fed to premature infants like Baby K.J. without warning of the risks of NEC.

121. Science and research have unequivocally established the dangers of Defendant's cow's-milk-based products in causing NEC and death in premature infants, yet Defendant did nothing to change its products, packaging, guidelines, instructions, and warnings.

122. Defendant knew or should have known that the Product would be used as it was used on Baby K.J.

123. The way the Product was fed to Baby K.J. was extremely dangerous and caused an unreasonably high risk that the baby would develop NEC and die, yet Defendant provided no detailed instructions or warnings to prevent or alter the way this product was used.

124. Despite learning that the Product was linked to NEC and death, Defendant failed to properly collect data from patients, parents, doctors, and hospitals to develop evidence-based strategies, instructions, and warnings to reduce or prevent the Product from causing NEC and death.

125. On information and belief, despite knowing that its products were leading to

NEC and death, Defendant took no steps to determine how or why the products were causing NEC or death.

126. On information and belief, Defendant has learned that its cow's-milk-based products were causing NEC and death in premature infants, yet did nothing to change its products, packaging, guidelines, instructions, and warnings.

127. On information and belief, despite knowing that its products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and/or inform them that its products were linked to causing NEC and death.

128. On information and belief, Baby K.J.'s parent, physicians, and medical staff were never told that the Product would cause the baby to develop NEC.

129. On information and belief, Baby K.J.'s parent, physicians, and medical staff were never told of the studies showing that cow's-milk-based formulas and fortifiers were extremely dangerous for premature infants.

130. On information and belief, Baby K.J.'s parent, physicians, and medical staff were never told of the studies showing that safer alternatives to cow's-milk-based formulas existed, including fortifiers derived from human milk and elemental formulas.

131. On information and belief, Baby K.J.'s parent, physicians, and medical staff were never told that an exclusive human-milk diet (including mother's own milk, donor milk, and/or human-milk-based fortifiers) is sufficient to meet all growth and nutritional goals.

132. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not recommend or

require hospitals, NICUs, or physicians to discuss the risks of NEC or death with the parents before cow's-milk-based products were fed to premature babies.

133. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and physicians to inform them that Defendant's cow's-milk-based formula was linked to causing NEC and death.

134. Defendant knew that it was standard practice throughout the U.S., including in Illinois and Indiana, for NICU staff not to disclose the risks of cow's-milk-based formulas and fortifiers to premature infants' parents.

135. Defendant has known for many years that cow's-milk-based products significantly increase the risk of premature infants developing NEC and dying and that medical providers generally do not inform parents of these risks.

136. Defendant knows that if it required or even requested that hospitals and doctors obtain informed consent regarding the risks of feeding cow's-milk-based products to premature infants, most—if not all—parents would not allow the Product to be fed to their children.

137. Defendant knows that if its product labels advised that the products should not be fed to premature infants until the parents are warned and informed that feeding the products would significantly increase the risk of NEC or death, then the use of Defendant's products would immediately plummet. Parents would not allow the products to be fed to their premature infants, Defendant's corporate image would be damaged, and Defendant would lose profits.

138. If Baby K.J.'s parent had known that cow's-milk-based formulas like the

Product increased the risk of NEC, she would not have allowed the Product to be fed to him, and he would not have suffered NEC and died.

139. Defendant provides free or discounted products to hospitals, which encourages the products to be overused with no warnings, instructions, or consents.

140. Despite many years of premature infants developing NEC or dying after being fed Defendant's products, many parents remain completely in the dark as to the cause of their child's injury or loss and are not told of the abundance of data linking Defendant's products to NEC and/or death.

141. In no uncertain terms, Defendant's products should state this warning or similar:

> **WARNING: THIS PRODUCT CONTAINS OR IS DERIVED FROM COW'S MILK, WHICH SIGNIFICANTLY INCREASES THE RISK OF NECROTIZING ENTEROCOLITIS (NEC), LIFE-THREATENING INJURIES, AND/OR DEATH IN PREMATURE INFANTS WHEN COMPARED TO HUMAN MILK.**
>
> Before feeding this product to a premature infant, parent(s)/guardian(s) must be counseled regarding the potential risks and benefits of cow's-milk-based breast-milk substitutes, including the increased risk of necrotizing enterocolitis (NEC), life-threatening injury, and/or death in premature infants, when compared to a human-milk-based diet. NEC may result in bowel necrosis, requiring surgical removal of the necrotic tissue. NEC is associated with high infant mortality. Parent(s)/guardian(s) should be informed that mother's milk (including human donor milk) or human-milk-based formulas and fortifiers are associated with a significant reduction in the risk of NEC, life-threatening injury, and death. Before feeding this product, parent(s)/guardian(s) must be presented the option for human-milk-based feedings. All attempts should be made to obtain consent from parent(s)/guardian(s) before using this product.

142. No parent could reasonably expect that a food product could be extremely dangerous to their baby unless properly warned and informed of the extreme dangers and risk of NEC, serious injury, surgery, or death.

143. To this day, Defendant has never warned the public about the extreme danger of its products.

The Baby: Baby K.J. and his exposure to the Product

144. Baby K.J. was born very prematurely with a low birth weight of 1750 grams (3 lb. 13.73 oz.), at 31 weeks and 6 days' gestation.

145. Baby K.J. was placed in the NICU at the Indiana University Health Ball Memorial Hospital in Muncie, Indiana.

146. Baby K.J.'s mother, Jayona Jones, diligently pumped breastmilk and provided it to be fed to Baby K.J.

147. Upon his admission to the NICU, Baby K.J., like many very premature infants, was initially fed via total parenteral nutrition. The NICU staff began initiating enteral feeds on his first day of life.

148. On July 29-30 and August 2, 2013, NICU staff fed Baby K.J. Similac® Special Care® 24.

149. On August 3, 2013, Baby K.J. began passing bloody stools and developed a feeding intolerance, abdominal distention, and lethargic and apneic events. An abdominal x-ray revealed bubbly lucencies over the bowel and right upper abdomen, which were diagnosed as pneumatosis intestinalis with portal venous gas. Baby K.J-B was transferred to Riley Hospital for Children at IUH later that same day.

150. Upon his arrival at Riley Hospital, Baby K.J. underwent intubation and blood transfusions due to respiratory failure and anemia of prematurity before being started on triple antibiotics. Additional scans and imaging were conducted and showed pneumatosis intestinalis with free air, leading doctors to perform the first of

two exploratory laparotomies on August 4, 2013.

151. During this first surgery, doctors found perforation and necrosis of Baby K.J.'s intestines, which prompted the removal of a total of 8 cm of necrotic bowel and the creation of an ileostomy.

152. On August 5, 2013, doctors performed the second exploratory laparotomy and diagnosed Baby K.J. with NEC totalis, meaning the entire bowel was nonviable. Due to the nonsurvivable reality of this diagnosis, Baby K.J. was designated DNR before being electively extubated and dying that same day.

153. Baby K.J.'s caregivers, including Plaintiff, had no knowledge that cow's- milk-based formula would increase Baby K.J.'s risk of developing NEC.

154. Plaintiff had been exposed to Defendant's advertisements for years.

155. Based on Defendant's marketing of its formulas and fortifiers, including Defendant's marketing of the Product as specifically intended to address premature infants' needs, Baby K.J.'s parent believed the Product were not only safe for Baby K.J. to consume but necessary for his growth and nutrition as a premature infant.

156. Although Defendant aggressively markets its products, including the Product, to make parents believe Defendant's products are safe and necessary for growth of a premature infant, the products are in fact extremely dangerous for premature infants. Defendant's cow's-milk-based products, including the Product, substantially increase the chances of a premature infant getting NEC and dying.

157. The Product is commercially available at retail locations and online. No prescription is necessary.

158. Despite knowing the Product significantly increased the risk of NEC,

Defendant did not warn parents of the risk of NEC or death associated with the Product when fed to premature infants.

159. Despite knowing the Product significantly increased the risk of NEC, Defendant did not warn doctors, hospitals, nurses, or other medical staff of the risk of NEC or death associated with the Product when fed to premature infants.

160. Defendant's cow's-milk-based formula and fortifier products, including the Product, are dangerous to premature infants in that they significantly increase the risk that a baby will develop NEC.

161. Defendant's cow's-milk-based formula and fortifier products, including the Product, are dangerous to premature infants in that they significantly increase the risk that a baby will require surgery.

162. Defendant's cow's-milk-based formula and fortifier products, including the Product, are dangerous to premature infants in that they significantly increase the risk that a baby will die.

163. Defendant failed to properly warn parents and medical providers that cow's-milk-based formula and fortifier products, including the Product, can significantly increase the risk that the premature infant will develop NEC, require surgery, and/or die, failed to design products to make them safe, and deceived the public, parents, physicians, and medical staff into believing that the products were a safe and necessary alternative and/or supplement to and/or substitute for human milk.

164. Despite knowing that cow's-milk-based formula and fortifier products, including the Product, were being fed to premature infants without the parents'

informed consent, Defendant failed to require or recommend that hospitals inform the parents of the significant risks, and to require parental consent before feeding Defendant's cow's-milk-based products to babies.

165. Defendant's cow's-milk-based formula and fortifier products—specifically, the Product—caused Baby K.J. to develop NEC, which triggered severe intestinal disease, the need for serious surgeries, excruciating pain, and ultimately caused Baby K.J.'s death.

Safer Alternative Designs

166. Infant formulas and fortifiers made or derived from cow's-milk ingredients, including the Product fed to Baby K.J., are unsafe for premature infants and are avoidable because safe alternatives—including human donor milk and human- milk-derived formula and fortifier—are available and were available before Baby K.J.'s birth.

167. The Product is not unavoidably unsafe. For decades before Baby K.J. was fed the Product, Defendant and the formula industry knew that infant formulas and fortifiers designed and formulated without cow's-milk were not only scientifically possible but practically feasible. These alternative designs include products derived exclusively from human milk or amino acids without diminishing the product's utility, safety, or effectiveness Defendant was attempting to achieve with cow's-milk-based products.

168. Since 2006, Prolacta Bioscience has manufactured and sold fortifiers and formulas for premature infants that contain no cow's-milk. These products are an example of a feasible alternative design. These alternative designs provide all the

necessary nutrition and growth that bovine formula provides, without the deadly effects of NEC.

169. Elemental formulas present another feasible alternative design. Elemental, or amino-acid-based formulas, are widely available and are fed to infants after NEC surgery to re-establish enteral feeding because they are more easily digested than traditional formulas.

170. In fact, Defendant has manufactured and sold elemental amino-acid-based formulas that do not contain cow's-milk ingredients under the brand name EleCare® since 1998. https://elecare.com/?psproductGroup=US%20Elecare&sku=US_55251 (last accessed Mar. 28, 2022).

171. At a minimum, Defendant should have conducted research and investigation into whether elemental formulas, alone or in combination with human milk sources or parenteral feeding, could have been used to establish enteral feeding in premature infants before introducing or reintroducing a cow's-milk-based fortifier or formula. Defendant then should have provided appropriate guidance regarding the use of such products, including the Product.

172. The use of elemental formulas to re-establish enteral feeding in infants who have had their intestines resected during NEC surgery indicates that elemental formulas would, at a minimum, be safe for premature infants to consume to establish enteral feeding initially before introducing other formula products or fortifier products.

173. On information and belief, Defendant was aware of the increased risk of NEC and death associated with its cow's-milk-based products and instead of warning of (or

removing) the dangers, Defendant has stubbornly insisted on continuing to use cow's milk as the foundation of the Product, which is marketed to and labeled for feeding to premature infants.

COUNT 1: STRICT PRODUCTS LIABILITY—DEFECTIVE DESIGN (UNDER ILLINOIS LAW)

174. Plaintiff incorporates all prior allegations.

175. Defendant is strictly liable to Plaintiff under state law because the Product's design caused them to have an unreasonably dangerous condition, which existed at the time the Product left the Defendant's control, and the Product's unreasonably dangerous condition proximately caused injury to Baby K.J. and Plaintiff.

176. The Product was unreasonably dangerous because it was unsafe when used in a manner that was reasonably foreseeable to Defendant considering the Product's nature and function. The Product failed to meet consumers' expectations for safety.

177. Cow's-milk ingredients are not necessary components of infant formula or fortifier, so they are not an unavoidably unsafe aspect of the product.

178. The Product was further unreasonably dangerous because its risks outweighed its utility for premature infants, when considering the magnitude and probability of the foreseeable risks of harm, the lack of appropriate warnings and instructions, and the nature and strength of consumer expectations regarding the Product—including the expectations consumers had from Defendant's marketing. The cost of implementing alternative designs, including but not limited to using human milk instead of cow's milk, were feasible and proportionate to the needs of the premature-infant population.

179. Cow's-milk ingredients can be eliminated from infant formulas and fortifiers without substantially compromising the products' usefulness or desirability. To the contrary: human-milk-based or amino-acid-based formulas and fortifiers would be more useful and desirable to consumers.

180. Defendant is thus strictly liable to Plaintiff under state law for manufacturing, aggressively marketing, and selling cow's-milk-based formulas and fortifiers for feeding to premature infants because the formulas were defective in design.

181. Given the reprehensibility of Defendant's conduct, which was undertaken willfully, with actual malice, and/or such gross negligence as to indicate a wanton disregard for the rights of others, including the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

182. Defendant has failed to take corrective action to re-design the Product after learning about how its cow's-milk-based formula and fortifier products, including the Product, have caused infants to suffer NEC, surgical treatment, and death. Instead, Defendant has actively concealed information about how these products cause NEC from the public and profited substantially from these actions.

183. Punitive damages are necessary to punish Defendant and deter Defendant and other infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas and fortifiers for feeding to premature infants.

COUNT 2: NEGLIGENT PRODUCTS LIABILITY—DEFECTIVE DESIGN (UNDER ILLINOIS LAW)

184. Plaintiff incorporates all prior allegations.

185. Defendant was negligent in the defective design of the Product because it knew

or should have known, in the exercise of ordinary care, that the Product was unreasonably dangerous because they were made from cow's-milk ingredients, and Defendant failed to warn of this dangerous propensity.

186. Other manufacturers in Defendant's industry designed infant formulas and fortifiers that did not include the dangerous cow's-milk ingredients.

187. Defendant's design for its premature-infant formulas and fortifiers, including the Product, was defective because it included ingredients known to cause NEC in premature infants.

188. Cow's-milk ingredients are not necessary components of infant formula or fortifier, so they are not an unavoidably unsafe aspect of the product.

189. Defendant is thus liable to Plaintiff under state law for negligently manufacturing, aggressively marketing, and selling cow's-milk-based formulas and fortifiers for feeding to premature infants because the products were defective in design.

190. Given the reprehensibility of Defendant's conduct, which was undertaken willfully, with actual malice, and/or such gross negligence as to indicate a wanton disregard for the rights of others, including the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

191. Defendant has failed to take corrective action to re-design the Product after learning about how its cow's-milk-based formula and fortifier products, including the Product, have caused infants to NEC, surgical treatment, and death. Instead, Defendant has actively concealed information about how its products cause NEC from

the public and profited substantially from these actions.

192. Punitive damages are necessary to punish Defendant and deter Defendant and other infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas and fortifiers for feeding to premature infants.

COUNT 3: STRICT PRODUCTS LIABILITY—FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS (UNDER ILLINOIS LAW)

193. Plaintiff incorporates all prior allegations.

194. Defendant is strictly liable to Plaintiff under state law for failing to warn of the Product's unreasonably dangerous conditions or instruct on their proper use.

195. The Product was unreasonably dangerous. The Product's design, which included cow's-milk ingredients, caused it to have an unreasonably dangerous condition. This condition existed at the time the Product left the Defendant's control, and the Product's unreasonably dangerous condition proximately caused injury to Baby K.J. and Plaintiff.

196. Defendant failed to warn Plaintiff, Baby K.J.'s medical providers, or the public that the Product could cause NEC and significantly increased the risk that a preterm infant would suffer NEC.

197. Defendant failed to instruct Plaintiff, Baby K.J.'s medical providers, or the public about how to safely use the Product with preterm infants.

198. Defendant's cow's-milk-based formula and fortifier products, including the Product, are not prescription drugs, medical devices, or other products intended to be used only under the supervision of a physician or other medical professional.

199. Defendant sold the Product to hospitals and directly to consumers.

200. At the time the Product left Defendant's control, Defendant knew or, considering reasonably available knowledge should have known, that cow's-milk-based formulas and fortifiers caused NEC in premature infants and that the ordinary consumers of these products (caregivers for premature newborns) would not realize the Product's dangerous condition.

201. The significantly increased risk of NEC was not an open and obvious danger of the Product, which was labeled for feeding to premature infants.

202. Despite Defendant's knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendant failed to provide an adequate product warning or instruction that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger. A reasonably prudent person would consider NEC to be a serious risk and warn that the Product could cause NEC in premature infants.

203. Defendant further failed to provide an adequate warning or instruction that took into account the characteristics of, and ordinary knowledge common to, the persons by whom the products are intended to be used. It was not, and is not, common knowledge among ordinary parents or medical providers of premature newborns that Defendant's cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

204. Defendant's products, including the Product, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so Defendant is not entitled to a rebuttable presumption that the warning label was adequate.

205. Defendant knew or should have known that its cow's-milk-based formula and fortifier products, including the Product, would be fed to very premature and low-birth-weight infants like Baby K.J., but Defendant failed to properly warn hospitals, NICUs, doctors, parents, and/or consumers that Defendant's cow's-milk-based products significantly increase the risk of NEC and death in those babies.

206. Defendant is thus liable to Plaintiff under state law for failing to warn in all the following specific ways:

a. Defendant failed to provide any warning or instruction to consumers that its cow's-milk-based formula and fortifier products, including the Product, increased the risk of NEC for very premature infants and low-birth-weight babies like Baby K.J.;

b. Defendant failed to have a large and prominent black-box-type warning that its cow's-milk-based formula and fortifier products, including the Product, are known to significantly increase the risk of NEC, surgery, and/or death for premature infants when compared to human milk;

c. Defendant failed to provide instructions that parents, physicians, NICU staff, and hospital administrators needed to make an informed choice between the safety of human milk versus the dangers of Defendant's cow's-milk-based products;

d. Defendant failed to provide proper instructions, guidelines, studies, or data on when and how to feed Defendant's products to premature infants to decrease the risk of NEC;

e. Defendant failed to provide any warning or instruction to medical professionals (including nurses, physicians, and other healthcare providers) and hospital administrators that its cow's-milk-based formula and fortifier products, including the Product, increased the risk of NEC for very premature infants and low-birth-weight babies like Baby K.J.;

f. Defendant failed to send "Dear Dr." letters warning of the risks of NEC, the need for surgery, and/or death based on the current scientific research and data to better guide hospitals and physicians caring for premature infants;

g. Defendant failed to advise physicians and healthcare providers that

cow's-milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

h. Defendant failed to advise physicians and healthcare providers that human milk is superior to cow's-milk-based products to support the nutrition and health of a premature infant;

i. Defendant failed to instruct or warn that an exclusive human-milk-based diet significantly decreases the risk of NEC when compared to a diet that includes cow's-milk-based products;

j. Defendant failed to advise physicians and healthcare providers that human-milk-based products and amino-acid-based formulas were viable alternative to cow's-milk-based products to significantly reduce the risk of premature infants developing NEC;

k. Despite knowing that parents were not being warned of the risk of NEC by their children's physicians, Defendant failed to directly warn the parents of the risk that its cow's-milk-based formulas would cause NEC;

l. Defendant failed to instruct physicians on whether, when, or how to safely transition to cow's-milk-based products;

m. Defendant failed to require or recommend that hospitals and/or physicians inform parents before feeding Defendant's products to their premature babies that cow's-milk-based products significantly increase the risk of NEC, the need for surgery, and/or death;

n. Defendant failed to provide a thorough and detailed risk-benefit analysis on the decision to feed cow's-milk-based formulas to premature infants for hospitals, doctors, and parents;

o. Defendant failed to develop a protocol for hospitals and physicians to ensure safe use of cow's-milk-based formulas;

p. Defendant failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of its products specifically designed for premature infants;

q. Defendant failed to provide periodic or yearly safety reports;

r. Defendant failed to provide periodic or yearly risk-benefit analyses for use of its products;

s. Defendant failed to develop comprehensive mitigation strategies to reduce the risk of NEC, surgery, and death from its products specifically designed and marketed for premature infants;

t. Defendant failed to publish a label or instruction that would correspond to the current science regarding the serious risks associated with using the Product;

u. Defendant failed to provide consumers with statistical evidence of adverse effects regarding the feeding of its products;

v. Defendant failed to guide or instruct medical professionals and infant caregivers regarding when to start feeding an infant cow's-milk-based formulas, how much cow's-milk-based formula to feed premature infants, how to increase volume and timing of feeds, when not to feed premature infants cow's-milk-based formulas, and/or when to stop feeding these products to premature infants;

w. Defendant failed to guide or instruct on how to properly monitor a preterm infant who is fed cow's-milk-based formula and fortifier products, including the Product;

x. Defendant failed to condition the sale or delivery of its products to the hospital with the assurance that hospitals would issue proper warnings about the risk of NEC to the parents; and/or

y. Defendant's warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that Defendant warn and instruct about other specific product uses (including warnings not to microwave formula before feeding it to infants), but do not warn that cow's-milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and provide no information on how to avoid such harm.

207. Defendant's failure to warn was deliberate because Defendant knew that if it advised physicians and healthcare providers of the extreme risks associated with feeding premature infants cow's-milk-based products, they would not have purchased such dangerous products for feeding to premature infants in hospitals, including neonatal intensive care units.

208. Defendant's massive marketing campaigns as detailed above have had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a healthcare provider to feed cow's-milk-based products; (2) diminishing mothers'

desire to breastfeed by framing it as a personal decision without health ramifications for infants, especially premature infants; (3) diminishing mothers' confidence in the capability of their bodies to provide sufficient and adequate nutrition for their premature infants without help from Defendant's products; (4) interfering with and supplanting the physician-patient relationship with respect to nutritional decision-making for newborns; (5) making it more difficult for a physician or other medical provider to persuade a mother to breastfeed; and (6) making it easier and more economically viable for hospitals to feed preemies cow's-milk-based products rather than donor milk or human-milk-derived products.

209. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendant's products, Baby K.J. was fed the Product in the NICU, which caused him to develop NEC, require surgery, and die.

210. As a result of Defendant's failures to warn in violation of state law as detailed above, Baby K.J. was fed the Product in the NICU, which caused him to develop NEC, require surgery, and die.

211. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

212. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Product, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how these products cause NEC from the public

and profited substantially from these actions.

213. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based products for feeding to premature infants.

COUNT 4: PRODUCTS LIABILITY—NEGLIGENT FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS (UNDER ILLINOIS LAW)

214. Plaintiff incorporates all prior allegations.

215. Defendant is liable to Plaintiff under state law for negligently failing to warn of the Product's unreasonably dangerous conditions or instruct on proper use.

216. The Product was unreasonably dangerous. The Product's design, which included cow's-milk ingredients, caused it to have an unreasonably dangerous condition. This condition existed at the time the Product left the Defendant's control, and the Product's unreasonably dangerous condition proximately caused injury to Baby K.J. and Plaintiff.

217. Defendant knew or should have known of the dangers posed by the Product.

218. Defendant failed to warn Plaintiff, Baby K.J.'s medical providers, or the public that the Product could cause NEC and significantly increased the risk that a preterm infant would suffer NEC.

219. Defendant failed to instruct Plaintiff, Baby K.J.'s medical providers, or the public about how to safely use the Product with preterm infants.

220. Defendant's cow's-milk-based formula and fortifier products, including the Product, are not prescription drugs or medical devices.

221. Defendant sold the Product to hospitals.

222. At the time the Product left Defendant's control, Defendant knew or, considering reasonably available knowledge should have known, that cow's-milk-based formulas and fortifiers caused NEC in premature infants and that the ordinary consumers of the Product (caregivers for premature newborns) would not realize the Product's dangerous condition.

223. The significantly increased risk of NEC was not an open and obvious danger of the Product, which was labeled for feeding to premature infants.

224. Despite Defendant's knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendant failed to provide an adequate product warning or instruction that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger. A reasonably prudent person would consider NEC to be a serious risk and warn that the Product could cause NEC in premature infants.

225. Defendant further failed to provide an adequate warning or instruction that took into account the characteristics of, and ordinary knowledge common to, the persons by whom the products are intended to be used. It was not, and is not, common knowledge among ordinary parents or medical providers of premature newborns that Defendant's cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

226. Defendant's products, including the Product, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so Defendant is not entitled to a rebuttable presumption that the warning label was adequate.

227. Defendant knew or should have known that its cow's-milk-based formula and fortifier products, including the Product, would be fed to very premature and low-birth-weight infants like Baby K.J., but Defendant failed to properly warn hospitals, NICUs, doctors, parents, and/or consumers that Defendant's cow's-milk-based products significantly increase the risk of NEC and death in those babies.

228. Defendant is thus liable to Plaintiff under state law for failing to warn in all the following specific ways:

a. Defendant failed to provide any warning or instructions to consumers that its cow's-milk-based formula and fortifier products, including the Product, increased the risk of NEC for very premature infants and low-birth-weight babies like Baby K.J.

b. Defendant failed to have a large and prominent black-box-type warning that its cow's-milk-based formula and fortifier products, including the Product, are known to significantly increase the risk of NEC, surgery, and/or death for premature infants when compared to human milk;

c. Defendant failed to provide instructions that parents, physicians, NICU staff, and hospital administrators needed to make an informed choice between the safety of human milk versus the dangers of Defendant's cow's-milk-based products;

d. Defendant failed to provide proper instructions, guidelines, studies, or data on when and how to feed Defendant's products to premature infants to decrease the risk of NEC;

e. Defendant failed to provide any warning or instruction to medical professionals (including nurses, physicians, and other healthcare providers) and hospital administrators that its cow's-milk-based formula and fortifier products, including the Product, increased the risk of NEC for very premature infants and low-birth-weight babies like Baby K.J.;

f. Defendant failed to send "Dear Dr." letters warning of the risks of NEC, the need for surgery, and/or death based on the current scientific research and data to better guide hospitals and physicians caring for premature infants;

g. Defendant failed to advise physicians and healthcare providers that cow's-milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

h. Defendant failed to advise physicians and healthcare providers that human milk is superior to cow's-milk-based products to support the nutrition and health of a premature infant;

i. Defendant failed to instruct or warn that an exclusive human-milk-based diet significantly decreases the risk of NEC when compared to a diet that includes cow's-milk-based products;

j. Defendant failed to advise physicians and healthcare providers that human-milk-based products and amino-acid-based formulas were viable alternative to cow's-milk-based products to significantly reduce the risk of premature infants developing NEC;

k. Despite knowing that parents were not being warned of the risk of NEC by their children's physicians, Defendant failed to directly warn the parents of the risk that its cow's-milk-based products would cause NEC; and/or

l. Defendant failed to instruct physicians on whether, when, or how to safely transition to cow's-milk-based products;

m. Defendant failed to require or recommend that hospitals and/or physicians inform parents before feeding Defendant's products to their premature babies that cow's-milk-based products significantly increase the risk of NEC, the need for surgery, and/or death;

n. Defendant failed to provide a thorough and detailed risk-benefit analysis on the decision to feed cow's-milk-based products to premature infants for hospitals, doctors, and parents;

o. Defendant failed to develop a protocol for hospitals and physicians to ensure safe use of cow's-milk-based products;

p. Defendant failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of its products specifically designed for premature infants;

q. Defendant failed to provide periodic or yearly safety reports;

r. Defendant failed to provide periodic or yearly risk-benefit analyses for use of its products;

s. Defendant failed to develop comprehensive mitigation strategies to

reduce the risk of NEC, surgery, and death from its products specifically designed and marketed for premature infants;

t. Defendant failed to publish a label or instruction that would correspond to the current science regarding the serious risks associated with using the Product;

u. Defendant failed to provide consumers with statistical evidence of adverse effects regarding the feeding of its products;

v. Defendant failed to guide or instruct medical professionals and infant caregivers regarding when to start feeding an infant cow's-milk-based products, how much cow's-milk-based products to feed premature infants, how to increase volume and timing of feeds, when not to feed premature infants cow's-milk-based products, and/or when to stop feeding these products to premature infants;

w. Defendant failed to guide or instruct on how to properly monitor a preterm infant who is fed cow's-milk-based formula and fortifier products, including the Product;

x. Defendant failed to condition the sale or delivery of its products to the hospital with the assurance that hospitals would issue proper warnings about the risk of NEC to the parents;

y. Defendant's warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that Defendant warns and instructs about other specific product uses (including warnings not to microwave formula before feeding it to infants), but does not warn that cow's-milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and does not provide any information on how to avoid such harm;

229. Defendant's failure to warn was deliberate because Defendant knew that if it advised physicians and healthcare providers of the extreme risks associated with feeding premature infants cow's-milk-based products, they would not have purchased such dangerous products for feeding to premature infants in hospitals, including neonatal intensive care units.

230. Defendant's massive marketing campaigns as detailed above have had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a

healthcare provider to feed cow's-milk-based products; (2) diminishing mothers' desire to breastfeed by framing it as a personal decision without health ramifications for infants, especially premature infants; (3) diminishing mothers' confidence in the capability of their bodies to provide sufficient and adequate nutrition for their premature infants without help from Defendant's products; (4) interfering with and supplanting the physician-patient relationship with respect to nutritional decision-making for newborns; (5) making it more difficult for a physician or other medical provider to persuade a mother to breastfeed; and (6) making it easier and more economically viable for hospitals to feed preemies cow's-milk-based products rather than donor milk or human-milk-derived products.

231. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendant's products, Baby K.J. was fed Defendant's cow's-milk-based formula and fortifier products (including the Product), which caused him to develop NEC, require surgery, and die.

232. As a result of Defendant's failures to warn in violation of state law as detailed above, Baby K.J. was fed the Product in the NICU, which caused him to develop NEC, require surgery, and die.

233. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under state law.

234. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Product, have caused

infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

235. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based products for feeding to premature infants.

COUNT 5: WRONGFUL DEATH
(UNDER THE ILLINOIS WRONGFUL DEATH ACT)

236. Plaintiff incorporates all prior allegations.

237. Defendant is liable to Plaintiff under the Illinois Wrongful Death Act, 740 Ill. Comp. Stat. 180/1, et seq., because Defendant's wrongful acts caused Baby K.J. to develop NEC, require surgery, and die.

238. Baby K.J. experienced unimaginable pre-death pain and suffering.

239. Plaintiff incurred medical expenses for Baby K.J.'s medical treatment.

240. Plaintiff has suffered and will continue to suffer pecuniary loss from the loss of Baby K.J.'s society and companionship for the remainder of Plaintiff's life, including lost financial support, advice, counsel, companionship, and other services that a child would customarily provide to a parent.

241. Under the Illinois Wrongful Death Act, Plaintiff, as Baby K.J.'s administrator, should be awarded damages for her economic losses, including for medical expenses and loss of society, companionship, and support.

COUNT 6: SURVIVAL
(UNDER THE ILLINOIS SURVIVAL ACT)

242. Plaintiff incorporates all prior allegations.

243. Defendant is liable to Plaintiff under the Illinois Survival Act, 740 Ill. Comp.

Stat. 5/27-6, et seq., because Defendant's wrongful acts caused Baby K.J. to develop NEC, require surgery, and die.

244. Baby K.J. experienced unimaginable pre-death pain and suffering because of Defendant's actions and omissions and would have had causes of action against Defendant if he had lived.

245. Baby K.J.'s death required Plaintiff to incur funeral and burial expenses.

246. Under the Illinois Survival Act, Plaintiff, as Baby K.J.'s parent, should be awarded damages for his pre-death pain and suffering and funeral and burial expenses.

247. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages pursuant to 735 Ill. Comp. Stat. 5/2-604.1.

248. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Product, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

249. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas for feeding to premature infants.

PRAYER FOR RELIEF

Plaintiff respectfully demands:

1. Entry of judgment in Plaintiff's favor on all claims for relief;
2. Economic and non-economic damages to compensate for the losses suffered;
3. Attorneys' fees and costs of suit;
4. Punitive damages; and
5. Such other relief as the Court deems just and proper.

JURY DEMAND

Plaintiff respectfully demands a jury trial in this matter.

Dated: July 27, 2023

Respectfully submitted,

/s/Ellen A. Presby
Ellen A. Presby
FERRER, POIROT, FELLER, DANIEL
2603 Oak Lawn, Suite 300
Dallas, Texas 75219
Tel: (214) 521-4412
Fax: (866) 513-0115
epresby@lawyerworks.com

/s/Yvette Ferrer
Yvette Ferrer
FERRER, POIROT, FELLER, DANIEL
2603 Oak Lawn, Suite 300
Dallas, Texas 75219
Tel: (214) 521-4412
Fax: (866) 513-0115
yferrer@lawyerworks.com