UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

KENNETH AND ERICA FIRLIT, *individually and as natural parents and guardians for the minor child* **ALEXIS FIRLIT,** *Plaintiffs,* v. **ABBOTT LABORATORIES,** **ABBOTT LABORATORIES, INC.,** **MEAD JOHNSON NUTRITION COMPANY,** **AND** **MEAD JOHNSON & COMPANY, LLC** *Defendants.*	
Complaint with Jury Demand	

NATURE OF ACTION

1. This action arises out of the injury of a premature infant, who was afflicted with a disease caused by cow's-milk-based infant fortifier manufactured and sold by Defendants.

2. Necrotizing enterocolitis ("NEC") is a deadly disease that largely affects low-birth-weight babies who are fed cow's-milk-based formula or fortifier. Alexis Firlit, a premature baby, was fed Similac® and/or Enfamil® "human milk fortifier" and developed NEC as a result. Plaintiffs file this complaint against Defendants for negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, and distribution, labeling,

and/or sale of the products known as Similac® Human Milk Fortifier and Enfamil® Human Milk Fortifier (referred to as "the Products").

THE PARTIES

3. Alexis Firlit ("Alexis") was born at Advocate Christ Medical Center in Oak Lawn, Illinois on August 17, 2011. She developed NEC after being fed the Products. Alexis was and remains a resident of Illinois.

4. Kenneth Firlit and Erica Meeks Firlit are the father and mother of Alexis. They bring this action individually and as guardians of Alexis, a minor child. The Firlits are residents of Illinois.

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 "Abbott."

8. Defendant Mead Johnson Nutrition Company is a corporation organized under the laws of the state of Delaware. Its principal place of business is in Indiana.

9. Defendant Mead Johnson & Company, LLC is a limited liability company organized under the laws of the state of Delaware. Its citizenship is that of its sole

member: Mead Johnson Nutrition Company. Its principal place of business is in Indiana.

10. On information and belief, for all purposes relevant to this Complaint, Mead Johnson Nutrition Company and Mead Johnson & Company, LLC as one entity, so this Complaint will refer to both collectively as "Mead."

JURISDICTION

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

12. This Court has personal jurisdiction over Defendants and venue is proper here under 28 U.S.C. §§ 1391(b)(3).

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

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

14. Optimal nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), like Alexis (born at 790 grams), is important for the babies' survival.

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

16. 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 Products) can cause NEC—which may require surgery or cause death—in preterm, low-birth-weight infants, as well as other health complications and long-term risks.

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

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

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

20. 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. Defendants, however, continue to promote and sell cow's-milk-based products for feeding to premature infants.

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

22. 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. Among babies born at more than 30 weeks' gestation, confirmed NEC was rare in those whose diet included breast milk; it was 20 times more common in those fed formula only. Lucas T. Cole, *Breast Milk and Neonatal Necrotising Enterocolitis,* 336 Lancet 1519–23 (1990).

23. Premature 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).

24. 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*.

25. Before Alexis was born, rapidly increasing the use of bovine-based fortifier as an infant gained tolerance for enteral feedings was causally linked to the 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.

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

27. Other scientific studies published before Alexis was born on August 17, 2011 further established that administering an exclusive human-milk diet to extremely

premature infants significantly reduced the risk of NEC—and was cost-effective for NICUs.

28. 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.

29. 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.

30. The use of a 100% human-milk-based diet was known to be cost-effective before Alexis was born. Ganapathy, et al. concluded that "[t]he NICU cost burden of NEC among EP infants is huge. Provision of an exclusively human milk diet composed of mother's own milk, or donor human milk when mother's milk is not adequately available, and fortified by donor HMF can result in saving net NICU resources and produce societal value by preventing infant mortality." Ganapathy V, Hay JW, Kim JH. *Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-*

based products in feeding extremely premature infants. Breastfeed Med. 2012 Feb;7(1):29–37. Epub 2011 Jun 30.

31. 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: "[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 are 138% more likely to develop NEC than premature infants who are breast fed. *Id*., Table 1, p. 2.

32. Medical recommendations and scientific studies conducted after Alexis was born on August 17, 2011 would continue to support what the scientific community knew in 2011.

33. 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).

34. Ghandehari, et al. found in a 2012 study that feeding extremely premature infants a 100% human-milk-based diet (using human-milk-based fortifiers) significantly reduced the need for infants to return to total parenteral nutrition after beginning enteral feedings—a desired outcome, for both infants' health and NICU costs. Ghandehari H, Lee ML, Rechtman DJ; H2MF Study Group. *An exclusive human milk-based diet in extremely premature infants reduces the probability of remaining on total parenteral nutrition: a reanalysis of the data*. BMC Res Notes. 2012 Apr 25;5:188.

35. A study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk-based diet exceeded targeted growth standards for length, weight, and head circumference. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." Amy B. Hair et al., *Human Milk Feeding Supports Adequate Growth in Infants ≤ 1250 Grams Birth Weight*, 6 BMC Research Notes 459 (2013).

36. Another study published in 2013 reported: "This is the first randomized trial in EP [extremely premature] infants of exclusive HM [human milk] vs. PR [preterm formula]. The significantly shorter duration of TPN [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish EP infants in the NICU [neonatal intensive care unit]." E.A. Cristofalo et al., *Randomized trial of Exclusive Human Milk versus Preterm formula*, 163 J. Pediatrics 1592–95 (2013).

37. In another study published in 2014, it was reported: "Necrotizing enterocolitis (NEC) is a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good et al., *Evidence-Based Feeding Strategies Before and After Development of Necrotizing Enterocolitis*, 10 Expert Rev. Clin. Immunol. 875–84 (2014).

38. That same study reported: "Necrotizing enterocolitis (NEC) is the most frequent and lethal gastrointestinal disorder affecting preterm infants, and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. NEC affects 7–12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease." "A wide variety of feeding practices exist on how to feed premature infants in the hopes of preventing necrotizing enterocolitis. There have been several meta-analysis [*sic*] reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC." *Id*.

39. In yet another study published in 2014, scientists reported: "An exclusive human milk diet, devoid of CM [cow's-milk]-containing products was associated with lower mortality and morbidity in EP [extremely premature] infants without compromising growth and should be considered as an approach to nutritional care of these infants." Steven Abrams et al., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, 9 Breastfeeding Medicine 281–85 (2014).

40. A 2016 study supported previous findings that an exclusive human-milk diet in extremely premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first large-scale study to compare rates of NEC after implementing a feeding protocol using an exclusive human-milk diet at multiple institutions with years of follow-up. The authors concluded that "the use of an exclusive HUM [human-milk] diet is associated with significant benefits for extremely premature infants" and "while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes." Amy B. Hair et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, 11 Breastfeeding Medicine 70–74 (2016).

41. An article published in 2017 reported: "In summary, HM 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).

42. 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).

43. 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).

44. 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).

45. In summary, medical studies (including studies published before Alexis 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 increase 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 Products:
Defendants' cow's-milk-based "human milk fortifiers"

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

47. Mead's Enfamil® Human Milk Fortifier (whether in the form of a powder or a concentrated liquid) is a cow's-milk-based product.

48. 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.

49. Defendants' cow's-milk-based Similac® and Enfamil® 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.

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

51. Defendants 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.

52. Before Alexis developed NEC, Defendants knew or should have known that their cow's-milk-based products were not safe to feed to premature infants. Yet Defendants took no steps to prevent such use among this vulnerable infant population.

53. Before Alexis developed NEC, Defendants did foresee or should have foreseen that their products would be used as they were in this case—for 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 Defendants took no steps to prevent such use among this vulnerable infant population.

54. Defendants' cow's-milk-based products were not safe to be used as they were used in this case, and Defendants knew or should have known they were unsafe, yet Defendants failed to properly instruct and/or warn the FDA, NICUs, hospitals, doctors, and parents that these products were unsafe.

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

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

56. Notwithstanding strong medical evidence establishing the extreme dangers that cow's-milk-based products pose for premature infants, both Abbott and Mead have marketed their cow's-milk-based products as an equally safe or superior alternative to exclusive breast milk for premature infants.

57. Defendants have promoted their fortifiers as not only safe but ***necessary*** for the growth and development of premature infants, when, in fact, the Products pose a known and substantial risk to these babies and are not necessary for their growth and development.

58. Defendants' practice of trying to get mothers of both preterm and term infants to choose their 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. Defendants have promoted their cow's-milk-based products as healthier, necessary for adequate nutrition, supported by "science," and the choice for the modern, sophisticated mother. Indeed, Defendants' advertising has attempted to portray breastfeeding as inferior to and less sophisticated than formula feeding or "supplementing."

59. Defendants' marketing for cow's-milk-based products (including those that are available for purchase by the public and those that 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.

60. Defendants' across-the-board marketing to parents of all infants begins early. Defendants send marketing materials and formula samples to expectant mothers. Defendants routinely offer 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. Defendants promote their 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.

61. 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.

62. 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 general 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).

63. Abbott has acknowledged the Code. "We support, educate[,] and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast-feeding up to and beyond two years of age. . . We acknowledge the importance of the World Health Organization's 1981 International Code of Marketing of Breast-[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 Dec. 19, 2022).

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

65. Mead has also acknowledged the Code. Recognizing that some countries have adopted the Code as law, a page of Mead's website entitled "Terms of Use" states: "Information for Non-U.S. Internet Users … Mead Johnson Nutrition endorses the aim of the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes in developing countries, including standards for product integrity, labeling, distribution, and promotion." https://hcp.meadjohnson.com/s/terms-of-use (last visited Dec. 19, 2022).

66. Mead quotes from the Code that "breastfeeding is best for infants," but then contradicts the WHO by stating that "[f]ormula, when used properly, provides a sound nutritious substitute or supplement to breast milk, but is more expensive." *Id.*

67. Notwithstanding the Code, both Abbott and Mead aggressively market to both new parents and medical providers that cow's-milk-based formulas and fortifiers (like the Products) 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 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, Defendants have systematically violated the Code's central provision.

68. Defendants' 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.

69. 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 Apr. 12, 2022). 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.*

70. 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).

71. The marketing techniques deployed by Defendants 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.*

72. Defendants' 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.*

73. Defendants' 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, Defendants have systematically violated the Code's central provision.

74. 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.*

75. 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.

76. 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®

77. 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, Abbott has

continued to perpetuate the deception that its products are on par with or necessary to supplement human milk. This marketing has altered the perceptions of parents and directly contradicts the medicine and the science.

78. Abbott routinely compares Similac® products with human breast milk and attempt 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:

Similac® Advance® can help develop both your baby's immune system and brain like breast milk.

(Kisses, hugs, and silly songs are up to you.)

Breastfeeding is recommended for its many benefits. If you choose to feed formula, ask your doctor about Similac Advance.

Only Similac Advance with DHA and ARA has both*:

- A patented blend of special breast milk nutrients called nucleotides, which has been clinically shown to help support the development of a baby's immune system like breast milk.

  The clinical study showed immune cell development like breast milk. Whether this development provides immune protection like breast milk has not been shown. Breast milk also contains antibodies not found in infant formulas that are important for a baby's immune protection.

- Published long-term clinical research showing brain development like breast milk.*

So much like breast milk in so many ways.

*Among formulas with DHA and ARA; infants studied at 12 and 39 months of age. ©2004 Abbott Laboratories.
www.SimilacAdvance.com

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).

79. The pervasive exposure of parents to media, advertising, and promotion equating cow's-milk-based formulas and fortifiers 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 decision-making about their child's nutrition. Through long-term exposure to Abbott's advertising, Alexis's parents had been conditioned and was 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.

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

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

82. 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.

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

84. A marketing report issued by Abbott 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."

85. Abbott'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.

86. Abbott 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 and capitalizes upon maternal guilt and insecurity. 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 Dec. 19, 2022).

87. 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 others' choices. But the ad is manipulative, deceptive, and violative of the Code and Abbott's own marketing policy in that it puts breast milk and formula on 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 cow's-milk-based breast-milk substitutes like the Products.

https://www.facebook.com/Similac/videos/1126104447462943/ (last visited Dec. 19, 2022).

88. In an advertisement for a Similac® product, Abbott'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 Dec. 19, 2022). This ad implies that being "ready" to "turn to" formula, instead of continuing to breastfeed, is inevitable.

89. 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 Dec. 19, 2022).

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

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

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

93. In 1988, Abbott 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."

94. As of 2016, Abbott marketed and sold seven products specifically targeting premature, low-birth-weight infants: Liquid Protein Fortifier, Similac®, NeoSure®, Similac® Human Milk Fortifiers, Similac® Special Care® 20, Similac® Special Care® 24, Similac® Special Care® 24 High Protein, and Similac® Special Care® 30.

95. 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 milk and does not mention that infants may develop NEC because of ingesting cow's-milk-based products.

96. At all relevant times, Abbott has had a website "similac.com" where mothers can choose the formula the corporation recommends using its "Formula Finder." By clicking on "Resources & Tools," the user is directed to a page where the following appears in large print: "Formula Finder — Find the Best Feeding Option for Your Child." *See* https://www.similac.com/baby-tools-resources/best-milk-formula.html (last visited Dec. 19, 2022).

97. In smaller type, Abbott states: "We promise to offer products that give your child a strong start. Let's find the right option for your little one." The first question

in the Formula Finder asks "How old is your child?" with response options of "Newborn to 12 months" and "Older than 12 months." *Id.*

98. If the mother selects the first option, she is prompted to answer the question: "Was your child born prematurely?" If the mother clicks "yes," the website directs her to a page located at https://www.similac.com/baby-tools-resources/best-milk-formula/similac-neoSure.html. (last visited Dec. 19, 2022).

99. Through this website, 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 Dec. 19, 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."

100. 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.

101. Another advertisement by Abbott 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 Dec. 19, 2022). The representation to parents that they can be "confident" in what they "choose" is in direct contradiction of the studies that indicate that cow's-milk-based breast-milk substitutes like the Products are dangerous to premature infants. Accordingly, it is false and misleading.

102. Abbott'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).

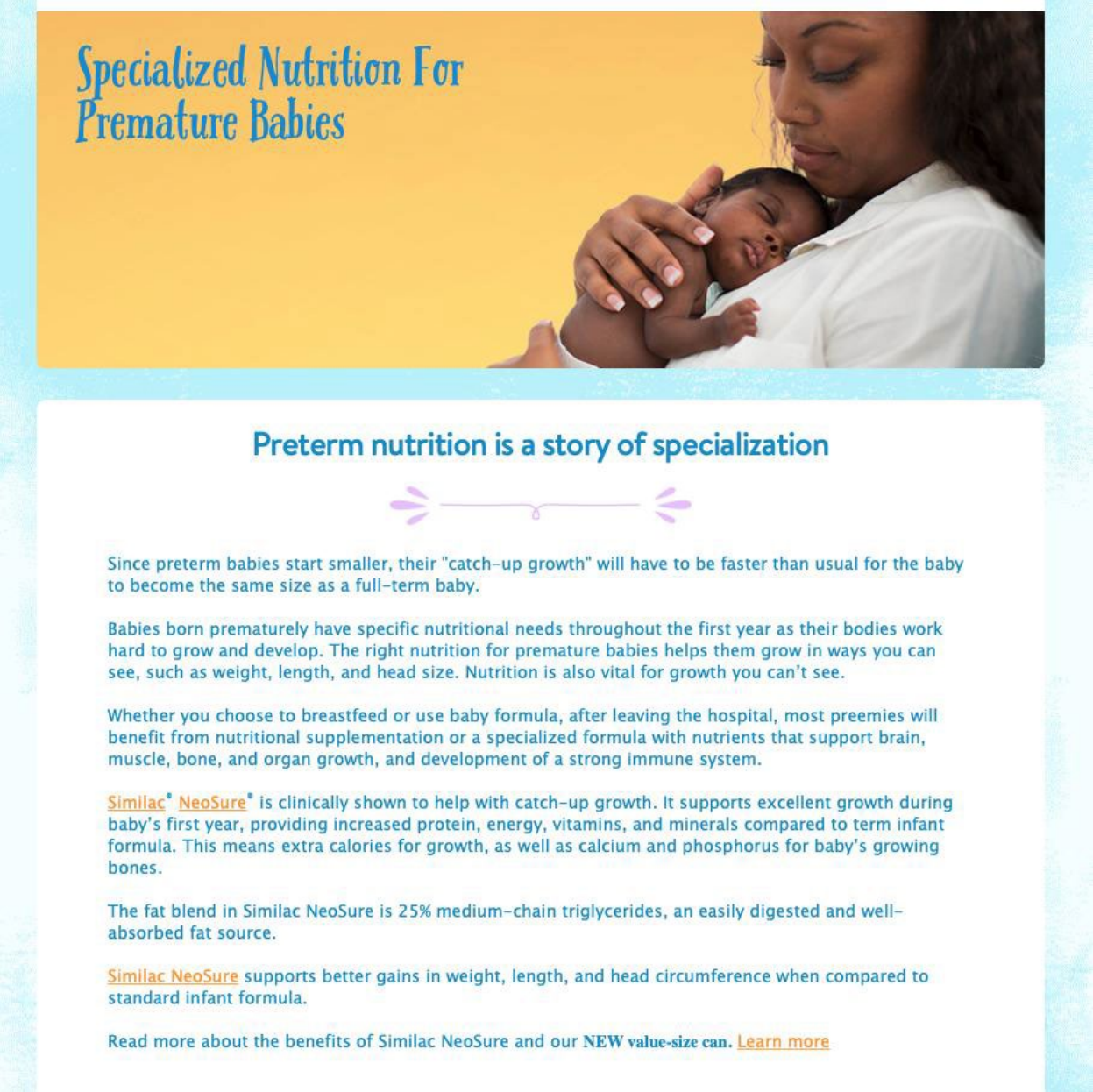
103. The Similac® website also has reviews from mothers whose premature infants were in the NICU, and they discuss how wonderful and safe the products are. There are no mother reviews discussing NEC and death. This is a false and misleading narrative, and Abbott actively perpetuates it. Abbott has designed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

104. In 2011, CBS News reported that Abbott paid mom bloggers to give positive reviews of the Similac® app. *See* https://www.cbsnews.com/news/abbott-pays-

bloggers-for-positive-reviews-of-its-similac-app/ (last visited Dec. 19, 2022). Abbott's Similac® app is a tool it uses to create and maintain brand loyalty and collect data on mothers and their babies.

105. Abbott promotes NeoSure® on its website and other media 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 Dec. 19, 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 cow's-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 NEC compared to Abbott's products.

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



107. This same web page contains a video, promoting the necessity of formula as a means 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).

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

109. 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.

110. 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.

111. Alexis's parents 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.

112. Nor did Alexis's parents know that human-milk-based fortifier was available.

113. Abbott'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. Abbott'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 as a result of consuming cow's-milk-based products.

114. Abbott'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.

115. Abbott 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; (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.

Mead's misleading marketing of Enfamil

116. Mead has marketed Enfamil® in a deliberately deceptive manner, including by using a product name intended to convey that it is an "infant meal."

117. Mead has promoted Enfamil products for extremely premature infants, claiming that Enfamil increases the babies' weight and caloric intake, and representing to the public that its products are beneficial and not harmful.

118. The studies show that Mead's products should not be sold for use in extremely premature infants, yet Mead continued to market and sell its products knowing they would be used on premature babies and knowing its products would significantly increase the risk of NEC, injury, surgery, and death in premature infants.

119. Mead promotes a range of products specifically for "premature and low weight" babies on its website.

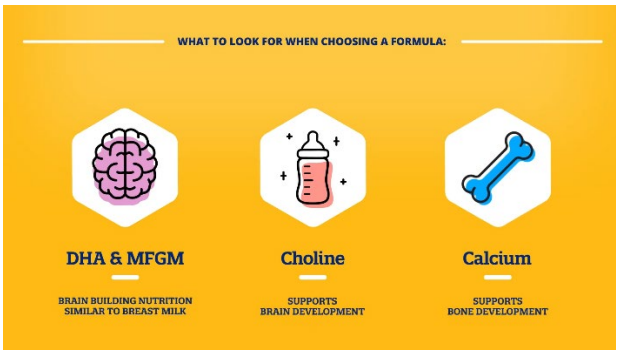
120. Mead falsely boasts its commitment to science on its website and claims that "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date."

121. These representations that Enfamil is backed by science and equivalent to breast milk mislead parents by intentionally omitting the established fact that cow's-milk-based products have been proven to significantly increase the risk of NEC, injury, surgery, and death in premature infants.

122. When comparing cow's-milk-based breast-milk substitutes and breast milk, Mead does not recognize the potent benefits of breast milk or acknowledge the risk of feeding cow's-milk-based products to premature infants. Nor does Mead acknowledge that breastfeeding or an exclusive human-milk-based diet is nutritionally superior to an infant diet that includes cow's-milk-based products.

123. In a video on Enfamil's YouTube channel entitled "Ask Us Anything: Formula Feeding," Mead features a pediatrician-mom who tells parents "9 out of 10 moms use formula during the first year" and that "breastfeeding and formula feeding are valid healthy choices for your baby," emphasizing "the decision is purely personal." This advertisement normalizes the use of breast-milk substitutes by telling parents that their babies "may need more milk than moms can provide" and proclaiming "Formula to the Rescue" and "breast feeding and formula feeding are both healthy options." This video is available on Enfamil's YouTube channel at

https://www.youtube.com/watch?v=qSfdX9Yse4U (last visited Dec. 19, 2022). Screen shots from the video appear below.



124. In another marketing video, Enfamil asserts that its "#1 pediatrician-recommended formula" has "an MFGM and a DHA blend of brain-building benefits similar to those of breast milk." https://www.youtube.com/watch?v=cXJTPvYTxiw (last visited Dec. 19, 2022).

125. These statements ignore the Code, the American Academy of Pediatrics, and the numerous studies demonstrating the superiority of breast milk by creating a false equivalency between cow's-milk-based breast-milk substitutes and breast milk.

126. Mead uses bright colors and drop-down menus for its website, while making seemingly innocuous statements such as, "When it comes to making important choices about your baby's nutrition, there is nothing like a recommendation from a trusted source. Whether it comes from your pediatrician, the hospital where your baby was born or another mom, using Enfamil gives you the confidence you've made the best choice for your baby." *See* https://www.enfamil.com/why-enfamil/ (last visited Dec. 19, 2022).

127. Mead's website does not disclose the dangers posed by its products to premature infants.

128. Mead also pays for ads on Google and other search engines specifically targeted to searches involving preterm infants and designed to net the company more profit share of this lucrative market.

129. Mead has a YouTube channel for Enfamil on which it posts marketing content, including specifically directed towards parents of premature babies. In a Super Bowl-themed ad featuring Jets offensive tackle Mekhi Becton (who is identified as having been born five weeks early) it promises to "go the extra yard to give these babies the best start in life." *See* https://youtu.be/aVVZ1R6MS-k (last visited Dec. 19, 2022).

130. Mead markets its Enfamil brand as being wholly dedicated to providing safe and effective nutrition for children across the globe, and expressly makes the

following "Commitment to Parents:" "We understand the significance of the trust placed in us by parents, and we offer them ongoing reassurance about the uncompromising and rigorous quality standards to which we hold each and every facility, production line, employee, and product." *See* https://www.meadjohnson.com/research-and-innovation/journal/research-and-innovation (last visited Dec. 19, 2022).

131. Mead also targets the parents of premature infants by emphasizing the need for catch-up growth.

132. On the section of its Enfamil webpage devoted to "Preemie Formulas," Mead represents that its "premature baby formula is specially formulated for your preemie's unique needs," "specially designed to promote their continued catch-up growth and development throughout their first nine months," and "easy on the tummy." *See* https://www.enfamil.com/products/preemie-formula/ (last visited Dec. 19, 2022).

133. Mead further asserts that "Enfamil has a variety of powder and ready-to-use milk-based premature baby formula choices, as well as human milk fortifiers, that have important nutrients for preemies and low-birth-weight babies, such as: … "DHA blended with arachidonic acid (ARA) so your baby can get some of the same benefits as they do from nursing" and "protein and calories to help babies with catch-up growth." *Id*.

134. "From Enfamil NeuroPro EnfaCare, clinically shown to promote catch-up growth similar to full-term breastfed infants, to our other premature formula options,

Enfamil has formulas to support the special nutritional needs of your perfect baby." *Id*. (containing a footnote reference to the Journal of Pediatrics").

135. "For a very low birth weight baby to grow at the optimum rate, the amount of protein that premature babies should receive is a level well above the values in your premature breast milk, and these levels will reduce over time." *See* https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/ (last visited Dec. 19, 2022).

136. In another Mead-posted YouTube video, titled "WAVE Discharge Program Parent Educator," Amy Gates, PHD, RD, CSP, LD, identified as the Medical Scientific Liaison for Mead Johnson Nutrition, talks about what parents of premature infants should know as they are being discharged from the NICU. Dr. Gates tells parents, "I've been taking care of premature babies for more than 20 years. I specialize in nutrition for preterm babies. My job is to help babies like yours grow and thrive." In discussing "the special nutrition" premature babies "need," Dr. Gates talks about avoiding "dehydration" or "not gaining enough weight" but does not mention NEC. *See* https://www.youtube.com/watch?v=o_nx6_AwRak (last visited Dec. 19, 2022).

137. Mead represents that "Enfamil gives every baby the DHA amount found in average breast milk." See https://www.enfamil.com/why-enfamil/ (last visited Dec. 19, 2022).

138. The above-quoted statements and others on Defendant's websites mislead parents into believing that Mead's products are safe and based on the latest science, when in fact, science has proven Mead's cow'-milk-based products significantly

increase the risk of NEC, injury, surgery, and death in premature infants. Such statements also mislead parents into believing that Mead's products are a necessary aspect of nutrition for premature infants and just as good as or better than breast milk.

139. On its webpage titled "Special Feeding Concerns for Preemies," Mead advises parents that "[i]f you are having trouble feeding your premature baby, there is also a possibility they have developed necrotizing enterocolitis." *Id*. But nowhere does Mead disclose that *its products* may cause NEC. Nor does Mead disclose the early warning signs of NEC beyond "trouble feeding" or explain the havoc NEC wreaks on infants' digestive tracts.

140. Enfamil encourages parents to download a form "Letter of Medical Necessity" from its website for signature of their child's pediatrician so that insurance will cover the cost of its products. *See* https://www.enfamil.com/reimbursement-support/ (last visited Dec. 19, 2022).

141. Enfamil also represents that it is the "#1 infant formula brand recommended by pediatricians" and that "80% of birthing hospitals use Enfamil." See https://www.enfamil.com/why-enfamil/ (last visited Dec. 19, 2022).

142. 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.

143. Similarly, Mead has marketed its products for premature infants as necessary for "catch-up growth" and perfectly safe for premature infants, despite knowing of the

extreme risks posed by cow's-milk-based products relative to the deadly disease of NEC to premature infants.

144. When visiting the Enfamil® website, a pop-up screen appears encouraging visitors to "Join Enfamil Family Beginning for up to $400 in free gifts." See https://www.enfamil.com/why-enfamil/ (last visited Dec. 19, 2022).

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

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

147. 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.

148. Alexis's parents did not know that Enfamil® 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.

149. Nor did Alexis's parents know that human-milk-based fortifier was available.

150. Mead'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. Mead'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 as a result of consuming cow's-milk-based products.

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

152. Mead 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; (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 Defendants' marketing

153. Through long-term exposure to Defendants' advertising, Alexis's parents had been conditioned to believe that cow's-milk-based infant feeding products like the Products are suitable alternatives to breast milk and necessary supplements for premature and low-birth-weight infants.

154. The scope of Defendants' marketing efforts is vast. One study estimates that major 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).

155. 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).

156. Despite knowing that feeding premature infants cow's-milk-based products significantly increases the risk of NEC and that breastfeeding significantly reduces the risk of NEC, Defendants persist 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).

157. 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).

158. 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]

159. 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.*

Defendants' specific marketing to premature babies' caregivers

160. In addition to including parents of premature infants within its general marketing claims regarding the safety of cow's-milk-based products as detailed above, Defendants have also specifically marketed cow's-milk-based formulas and fortifiers, including the Products, for feeding to premature infants.

161. Although Defendants know and have 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 Defendants know that human-milk-based formulas and fortifiers are technologically feasible and commercially available, Defendants have continued to market and sell cow's-milk-based formulas and fortifiers for premature babies.

Abbott's inadequate warnings

162. Abbott's aggressive marketing campaign is designed to make parents believe that Abbott'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.

163. Abbott provides the following warnings for its Human Milk Fortifier (powder form):

> Safety Precautions
>
> Add only to human milk - do not add water.
>
> Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.
>
> Once enteral feeding is well established, Similac Human Milk Fortifier Powder can be added to human milk.
>
> Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.
>
> **Never use a microwave oven to warm feedings**. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Powder, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Powder.pdf (last visited Dec. 19, 2022).

164. Abbott provides the following warnings for its Human Milk Fortifier (concentrated-liquid form):

Safety Precautions

Add only to human milk - do not add water.

This product is nutritionally incomplete by itself and is designed to be added to human breast milk.

Additional iron may be necessary.

Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.

Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk.

Never use a microwave oven to warm feedings. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Concentrated Liquid, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Concentrated-Liquid.pdf (last visited Dec. 19, 2022).

165. Abbott provides the following warnings for its product Liquid Protein Fortifier:

Safety Precautions

If signs of intolerance develop, slow feeding or discontinue.

This product is nutritionally incomplete.

Must be mixed with human milk, fortified human milk, or formula before feeding.

Enteral use only; not for IV use.

Abbott Laboratories, Inc., Product Information: Liquid Protein Fortifier, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-

prod/abbottnutrition-2016.com/img/Liquid-Protein-Fortifier.pdf (last visited Dec. 19, 2022).

166. None of the "Safety Precautions" Abbott provided with the Products warned of the risk of NEC.

Mead Defendants' inadequate warnings

167. Mead's aggressive marketing campaign is designed to make parents believe that its 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 of a premature infant developing NEC, requiring surgery, or death.

168. Mead provides the following warnings for its Enfamil® Human Milk Fortifier (powder form):

> A baby's health depends on carefully following the instructions below. Use only as directed by a medical professional.
>
> Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although Enfamil Human Milk Fortifier Powder is formulated for premature infants, nutritional powders are not sterile and should NOT be fed to premature infants or infants who might have immune problems unless directed and supervised by a doctor.
>
> - Follow hospital rules or the baby's doctor's instructions for the safe handling of human milk.
> - To aid mixing, agitate the human milk well. Pour the desired amount into a sterile container and warm to feeding temperature.
> - The baby's doctor will provide instructions for the desired amount of calories to add.

Additional Calories Desired	Human Milk	Enfamil Human Milk Fortifier

2 Calories/fl oz	50 mL	1 packet (0.71 g)
4 Calories/fl oz	25 mL	1 packet (0.71 g)

- Add the powder to the human milk according to the following chart:

Failure to follow these instructions could result in severe harm. Once prepared, fortified breast milk can spoil quickly. Either feed fortified human milk immediately or cover and store in refrigerator at 35–40°F (2–4°C) for no longer than 24 hours. Agitate before each use.

For bottle feeding: Pour only the amount of fortified human milk to be fed into a feeding container and feed immediately. Do not use fortified human milk if it is unrefrigerated for more than a total of 2 hours. After feeding begins, use fortified human milk within 1 hour or discard.

For tube feeding: Once fortified human milk is prepared, it can remain at room temperature for no longer than a total of 4 hours.

WARNING: Do not use a microwave oven to warm the fortified human milk. Serious burns may result.

CAUTION: Nutritionally incomplete. To be used only under the supervision of a physician.

CAUTION: Regarding use in extremely low birth weight infants (ELBW–1 kg or less): Hypercalcemia has been reported in some of these infants on full enteral feeds of mothers' milk supplemented with human milk fortifiers.

Packet Storage: Store packets at room temperature. Avoid freezing and excessive heat. Use by date on carton and packet label.

Mead Johnson Nutrition, Enfamil® Human Milk Fortifier Powder, WWW.HCP.MEADJOHNSON.COM, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQiUAK/enfamil-human-milk-fortifier-powder (last visited Dec. 19, 2022).

169. Mead provides the following warnings for its Enfamil® Human Milk Fortifier High Protein:

Use as directed by the baby's doctor. Shake gently before using. Do not shake vigorously to minimize product foaming. Foaming is normal with this product. Remove protective seal around cap, remove cap and foil seal. This product is commercially sterile as produced. Only use in a formulary or centralized milk preparation room where there is little risk of contamination, using proper aseptic technique.[1]

A variety of aseptic preparation methods are available including the use of sterile containers, or sterile transfer lids and sterile, single-use, enteral syringes. When using sterile containers, after opening bottle pour into disposable, sterile container and draw up needed volume into a sterile, single-use, enteral syringe. Dispense into measured breast milk and swirl. For directions using sterile transfer lids and sterile, single-use, enteral syringes, see carton.

Failure to follow these instructions could result in severe harm. Opened bottles and fortified breast milk can spoil quickly. Either use immediately or replace fortifier bottle cap and store in refrigerator at 35-40°F (2-4°C) for no longer than 48 hours. Gently agitate product before each use. After feeding begins, use fortified breast milk within one hour or discard. After 48 hours of opening, discard any unused product. Do not freeze.

Add fortifier to breast milk according to the following chart for mixing:

Additional Calories Desired (per fl oz concentration)	Breast Milk	Enfamil Liquid Human Milk Fortifier High Protein	Total Concentration (Breast Milk + LHMF)
2 Calories/fl oz	50 mL	5 mL	22 Cal/fl oz concentration
4 Calories/fl oz	25 mL	5 mL	24 Cal/fl oz concentration

The baby's doctor will provide instructions for the desired amount of calories to add.

WARNING: Do not use product that has unusual characteristics.

WARNING: Do not use a microwave oven to warm the fortified breast milk. Serious burns may result.

WARNING: Not for parenteral (I.V.) use. Do not administer directly—must add to breast milk.

Mead Johnson Nutrition, Enfamil® Human Milk Fortifier Powder, WWW.HCP.MEADJOHNSON.COM, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQRUA0/enfamil-liquid-human-milk-fortifier-high-protein (last visited Dec. 19, 2022).

170. Mead provides the following warnings for its Enfamil® Human Milk Fortifier Standard Protein:

> Use as directed by the baby's doctor. Shake gently before using. Do not shake vigorously to minimize product foaming. Foaming is normal with this product. Remove protective seal around cap, remove cap and foil seal. This product is commercially sterile as produced. Only use in a formulary or centralized milk preparation room where there is little risk of contamination, using proper aseptic technique.[1]
>
> A variety of aseptic preparation methods are available including the use of sterile containers, or sterile transfer lids and sterile, single-use, enteral syringes. When using sterile containers, after opening bottle pour into disposable, sterile container and draw up needed volume into a sterile, single-use, enteral syringe. Dispense into measured breast milk and swirl. For directions using sterile transfer lids and sterile, single-use, enteral syringes, see carton.
>
> Failure to follow these instructions could result in severe harm. Opened bottles and fortified breast milk can spoil quickly. Either use immediately or replace fortifier bottle cap and store in refrigerator at 35-40°F (2-4°C) for no longer than 48 hours. Gently agitate product before each use. After feeding begins, use fortified breast milk within one hour or discard. After 48 hours of opening, discard any unused product. Do not freeze.
>
> Add fortifier to breast milk according to the following chart for mixing:

Additional Calories Desired (per fl oz concentration)	Breast Milk	Enfamil Liquid Human Milk Fortifier Standard Protein	Total Concentration (Breast Milk + LHMF)
2 Calories/fl oz	50 mL	5 mL	22 Cal/ fl oz Concentration
4 Calories/fl oz	25 mL	5 mL	24 Cal/ fl oz Concentration

> The baby's doctor will provide instructions for the desired amount of calories to add.
>
> WARNING: Do not use product that has unusual characteristics.
>
> WARNING: Do not use a microwave oven to warm the fortified breast milk. Serious burns may result.
>
> WARNING: Not for parenteral (I.V.) use. Do not administer directly—must add to breast milk

Mead Johnson Nutrition, Enfamil® Human Milk Fortifier Powder, WWW.HCP.MEADJOHNSON.COM, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQmUAK/enfamil-liquid-human-milk-fortifier-standard-protein (last visited Dec. 19, 2022).

171. Mead provides the following warnings for its Enfamil® Human Milk Fortifier Acidified Liquid:

> A baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm.
>
> - Follow hospital rules or the baby's doctor's instructions for the safe handling of human milk.
> - To aid mixing, agitate the human milk well. Pour the desired amount into a sterile container and warm to feeding temperature.
> - Add fortifier to breast milk according to the following chart:

Additional Calories Desired	Human Milk	Enfamil Human Milk Fortifier
2 Calories/fl oz	50 mL	1 vial
4 Calories/fl oz	25 mL	1 vial

> Each vial of Enfamil Human Milk Fortifier Acidified Liquid is designed to deliver 5 mL when opened and poured.
>
> - The baby's doctor will provide instructions for the desired amount of calories to add
> - Remove vials from foil pouch and separate number of vials needed

- Store remaining vials in foil pouch at room temperature. Once pouch has been opened, vials must be used within 24 hours
- Shake vial vigorously to mix contents. Firmly hold vial UPRIGHT by bottom tab and slowly twist top off completely. Add fortifier to human milk

Some liquid may remain in cap and vial; disregard this liquid. Discard opened vial and cap promptly. Do not use product that has unusual characteristics

Failure to follow these instructions could result in severe harm. Once prepared, fortified breast milk can spoil quickly. Either feed fortified human milk immediately or cover and store in refrigerator at 35–40°F (2–4°C) for no longer than 24 hours. Agitate before each use.

For bottle feeding: Pour only the amount of fortified human milk to be fed into a feeding container and feed immediately. Do not use fortified human milk if it is unrefrigerated for more than a total of 2 hours. After feeding begins, use fortified human milk within 1 hour or discard.

For tube feeding: Once fortified human milk is prepared, it can remain at room temperature for no longer than a total of 4 hours.

WARNING: Do not use a microwave oven to warm the fortified human milk. Serious burns may result.

WARNING: Not for parenteral (I.V.) use. Fortifier is designed to be mixed with breast milk; do not administer directly.

CAUTION: Regarding use in extremely low birth weight infants (ELBW—1 kg or less): Hypercalcemia has been reported in some of these infants on full enteral feeds of mother's milk supplemented with human milk fortifiers.

CAUTION: Nutritionally incomplete: To be used only under the supervision of a physician.

Mead Johnson Nutrition, Enfamil® Human Milk Fortifier Powder, WWW.HCP.MEADJOHNSON.COM, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpR7UAK/enfamil-human-milk-fortifier-acidified-liquid (last visited Dec. 19, 2022).

172. Despite knowing of the increased risk of NEC, surgery, or death, Mead did not warn of these risks associated with its Enfamil products, nor the magnitude of these increased risks.

173. Mead likewise did not provide instructions or guidance for how to feed these products in order to avoid these risks.

174. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil is a safe and necessary alternative, supplement, or substitute to breast milk.

175. Despite knowing that its products were being fed to preterm infants as marketed, often without the parents' informed consent, Mead failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC, surgery, or death.

176. Despite knowing that its products were being fed to preterm infants as marketed, often without the parents' informed consent, Mead failed to require or recommend that parental consent be obtained prior to the products being fed to infants.

Defendants failed to warn the public and Alexis's parents

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

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

179. Although Defendants' products are sometimes given to infants at medical facilities, many of Defendants' cow's-milk-based products for premature infants are marketed to the public and available to consumers without a doctor's prescription.

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

181. Despite knowing that cow's-milk-based products were being fed to preterm infants as marketed, often without the parents' informed consent, Defendants failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC, injury, surgery, or death associated with feeding cow's-milk-based products to premature infants.

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

183. 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.

184. To this day, Defendants have never warned the public about the extreme danger its cow's-milk-based products pose for premature infants like Alexis.

185. Members of the medical community, physicians, and hospitals, as well as the parents, relied upon the representations and advertising of Defendants, 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 Products being fed to Alexis.

186. On information and belief, the product label(s) for the fortifier(s) given to Alexis did not warn consumers or medical professionals about the risk of NEC from giving premature infants cow's-milk-based products.

187. Neither the hospital nor the physicians involved in Alexis's care informed her parents that Defendants cow's-milk-based products would significantly increase the risk of NEC.

188. Neither the hospital nor the physicians provided a choice to the parents about whether to feed their premature infant cow's-milk-based fortifier. Alexis spent months in the NICU, where she was fed by NICU staff. Her parents had to rely on these hospital staff members to feed their child. The NICU staff members, in turn, had to rely on Defendants to manufacture safe products with appropriate warnings.

189. The Products were not safe to be fed to premature infants like Alexis without warning of the risks of NEC.

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

191. Defendants knew or should have known that the Products would be used as they were used on Alexis.

192. The way the Products were fed to Alexis was extremely dangerous and caused an unreasonably high risk that Alexis would develop NEC, yet Defendants provided no detailed instructions or warnings to prevent or alter the way the Product was used.

193. Despite learning that its products were linked to NEC and death, Defendants failed to properly collect data from patients, parents, doctors, and hospitals to develop evidence-based strategies, instructions, and warnings to reduce or prevent its products from causing NEC and death.

194. On information and belief, despite knowing that its products were leading to NEC and death, Defendants took no steps to determine how or why the products were causing NEC or death.

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

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

197. On information and belief, Alexis's parents, physicians, and medical staff were never told that the Products would cause Alexis to develop NEC.

198. On information and belief, Alexis's parents, 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.

199. On information and belief, Alexis's parents, physicians, and medical staff were never told that safer alternatives to cow's-milk-based fortifiers existed, including fortifiers derived from human milk.

200. On information and belief, Alexis's parents, 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.

201. On information and belief, despite knowing that their cow's-milk-based products were causing NEC and death in premature infants, Defendants 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.

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

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

204. Defendants have known for many years that their 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.

205. Defendants know that if they required or even requested that medical providers 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 Products to be fed to their children.

206. Defendants know that if their product labels advised that the products should not be fed to premature infants until the parents are informed the products significantly increase the risk of NEC, the use of Defendants' products would plummet. Parents would not allow the products to be fed to their premature infants, Defendants' corporate images would be damaged, and Defendants would lose profits.

207. If Alexis's parents had known that cow's-milk-based fortifiers like the Products increased the risk of NEC, they would not have allowed the Products to be fed to her, and she would not have suffered NEC and sustained long-term medical and physical impairments and disability.

208. Defendants provides free or discounted products to hospitals, encouraging the products to be overused with no warnings, instructions, or consents.

209. Alexis's parents, like most parents whose children suffered from NEC after being fed cow's-milk-based fortifiers or formulas, were never informed that Defendants' Products caused Alexis to develop NEC. Despite many years of premature infants developing NEC or dying after being fed Defendants' products,

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 Defendants' products to NEC and/or death.

210. In no uncertain terms, Defendants' 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.

211. 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.

212. Defendants should be barred from arguing that the statute of limitations has run on unknowing parents whose children were severely injured or died, until such time as Defendants finally warn, inform, and instruct the public and parents that

these products significantly increase the risk of NEC and death when fed to premature infants.

213. To this day, Defendants have never warned the public about the extreme danger of its products.

The Baby: Alexis and her exposure to the Products

214. Alexis was born extremely prematurely on August 17, 2011 with a low birth weight of 790 grams (1 lb. 12 oz.), at 26-weeks' gestation.

215. Shortly after her birth, Alexis was placed in the neonatal intensive care unit.

216. Alexis's mother diligently pumped breastmilk and provided it to be fed to Alexis.

217. Upon her admission to the NICU, Alexis, like most extremely premature infants, was initially fed via total parenteral nutrition. She received total parental nutrition from August 17, 2011 to August 22, 2011.

218. From August 22, 2011 to August 27, 2011, Alexis was fed parenteral nutrition supplemented by trophic or "gut stimulation" feeds of small amounts of unfortified breast milk.

219. From August 27, 2011 to September 7, 2011, Alexis was fed gradually increasing amounts of fortified breast milk.

220. After Alexis had a bloody stool consistent with NEC on September 7, 2011, NICU staff eliminated the enteral feeds of fortified breast milk and began feeding Alexis via total parenteral nutrition again.

221. On September 13, 2011, Alexis required surgery. Her physician performed a bedside exploratory laparotomy and bowel resection.

222. On October 18, 2011, Alexis required a second surgery: a subtotal colectomy and ileocolostomy.

223. On November 13, 2011, Alexis required a third surgery: a small bowel resection, lysis of adhesions, and ileostomy and sigmoid colon mucous fistula surgery.

224. On December 23, 2011, Alexis required a fourth surgery: a suction rectal biopsy.

225. Alexis was required to stay in the NICU for more than six months.

226. Since infancy, Alexis has suffered from short gut syndrome.

227. Alexis's parents had no knowledge that cow's-milk-based formulas and fortifiers would increase Alexis's risk of developing NEC.

228. Alexis's parents had been exposed to Defendants' advertisements for years.

229. Based on Defendants' marketing of its formulas and fortifiers, including Defendants' marketing of the Products as specifically intended to address premature infants' needs, Alexis's parents believed the Products were not only safe for Alexis to consume but necessary for her growth and nutrition as a premature infant.

230. Although Defendants aggressively market their products, including the Products, to make parents believe Defendants' products are safe and necessary for growth of a premature infant, their products are extremely dangerous for premature infants. Defendants' cow's-milk-based products, including the Products, substantially increase the chances of a premature infant getting NEC.

231. Defendants' cow's-milk-based products are commercially available at retail locations and online. No prescription is necessary.

232. Despite knowing the Products significantly increased the risk of NEC, Defendants did not warn parents of the risk of NEC or death associated with the Products when fed to premature infants.

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

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

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

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

237. Defendants failed to properly warn parents and medical providers that cow's-milk-based formula and fortifier products, including the Products, 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.

238. Despite knowing that cow's-milk-based formula and fortifier products, including the Products, were being fed to premature infants without the parents' informed consent, Defendants failed to require or recommend that hospitals inform the parents of the significant risks, and to require parental consent before feeding Defendants' cow's-milk-based products to babies.

239. Defendants' cow's-milk-based formula and fortifier products—specifically, the Products—caused Alexis to develop NEC, which triggered severe intestinal disease, the need for serious surgeries, excruciating pain, and ultimately long-term impairments to Alexis's activities of daily living.

Safer Alternative Designs

240. Infant formulas and fortifiers made or derived from cow's-milk ingredients, including the Products fed to Alexis, 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 Alexis's birth.

241. The Products are not unavoidably unsafe. For decades before Alexis was fed the Products, Defendants 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, which had the necessary utility, safety, or effectiveness Defendants were attempting to achieve with cow's-milk-based products.

242. Since 2006, Prolacta Bioscience has manufactured and sold fortifiers for premature infants that contain no cow's-milk products. 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.

243. 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.

244. In fact, Abbott has manufactured and sold elemental amino-acid-based formulas that do not contain cow's-milk protein under the brand name EleCare® since 1998. https://elecare.com/?psproductGroup=US%20Elecare&sku=US_55251 (last accessed Dec. 19, 2022).

245. Mead has manufactured and sold PurAmino® Hypoallergenic Infant Formula, which the PurAmino® website touts as "a hypoallergenic, iron fortified, amino acid-based infant formula used for infants and toddlers with severe cow's milk protein allergy, and other food allergies" since 2013. PurAmino® is an elemental amino-acid-based formula. https://www.enfamil.com/products/puramino-formula/ (last accessed Dec. 19, 2022).

246. Mead also began manufacturing and selling Nutramigen, a cow's-milk-free elemental formula marketed as "the first infant formula for the nutritional management of cow's milk allergy" in ***1942***. https://www.nutramigen.co.uk/why-nutramigen/history-of-mead-johnson-nutrition/ (last accessed Dec. 19, 2022)

247. At a minimum, Defendants 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. Defendants then should have provided appropriate guidance regarding the use of such products, including the Products.

248. 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 or fortifier products.

249. On information and belief, Defendants were aware of the increased risk of NEC and death associated with their cow's-milk-based products and instead of warning of (or removing) the dangers, Defendants have stubbornly insisted on continuing to use cow's milk as the foundation of the Products, which are marketed to and labeled for feeding to premature infants.

COUNT 1: STRICT PRODUCTS LIABILITY—DEFECTIVE DESIGN

250. Plaintiffs incorporate all prior allegations.

251. Defendants are strictly liable to Plaintiffs under state law because the Products' design caused them to have an unreasonably dangerous condition, which existed at the time the Products left the Defendants' control, and the Products' unreasonably dangerous condition proximately caused injury to Alexis and Plaintiffs.

252. The Products were unreasonably dangerous because they were unsafe when used in a manner that was reasonably foreseeable to Defendants considering the Products' nature and function. The Products failed to meet consumers' expectations for safety.

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

254. The Products were further unreasonably dangerous because their risks outweighed their 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 Products—including the expectations consumers had from Defendants' 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.

255. 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.

256. Defendants are thus strictly liable to Plaintiffs 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.

257. Given the reprehensibility of Defendants' 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 Defendants with punitive damages under state law.

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

259. Punitive damages are necessary to punish Defendants and deter Defendants 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

260. Plaintiffs incorporate all prior allegations.

261. Defendants were negligent in the defective design of the Products because they knew or should have known, in the exercise of ordinary care, that the Products were unreasonably dangerous because they were made from cow's-milk ingredients, and Defendants failed to warn of this dangerous propensity.

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

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

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

265. Defendants are thus liable to Plaintiffs under state law for negligently manufacturing, aggressively marketing, and selling cow's-milk-based formulas and fortifiers for feeding to premature infants because the formulas were defective in design.

266. Given the reprehensibility of Defendants' 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 Defendants with punitive damages under state law.

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

268. Punitive damages are necessary to punish Defendants and deter Defendants 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

269. Plaintiff incorporates all prior allegations.

270. Defendants are strictly liable to Plaintiffs under state law for failing to warn of the Products' unreasonably dangerous conditions or instruct on its proper use.

271. The Products were unreasonably dangerous. The Products' design, which included cow's-milk ingredients, caused them to have an unreasonably dangerous condition. This condition existed at the time the Products left the Defendants' control, and the Products' unreasonably dangerous condition proximately caused injury to Alexis and Plaintiffs.

272. Defendants failed to warn Plaintiffs, Alexis's medical providers, or the public that the Products could cause NEC and significantly increased the risk that a preterm infant would suffer NEC.

273. Defendants failed to instruct Plaintiffs, Alexis's medical providers, or the public about how to safely use the Products with preterm infants.

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

275. Defendants sold the Products to hospitals and directly to consumers.

276. At the time the Products left Defendant's control, Defendants knew or, in light of 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 Products' dangerous condition.

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

278. Despite Defendants' knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendants 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.

279. Defendants 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 product is intended to be used. It was not, and is not, common knowledge among ordinary parents or medical providers of premature newborns that Defendants' cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

280. Defendants' products, including the Products, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so Defendants are not entitled to a rebuttable presumption that its warning label was adequate.

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

282. Defendants are thus liable to Plaintiffs under state law for failing to warn in all of the following specific ways:

a. Defendants failed to provide any warning or instruction to consumers that their cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Alexis;

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

c. Defendants 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 Defendants' cow's-milk-based products;

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

e. Defendants failed to provide any warning or instruction to medical professionals (including nurses, physicians, and other healthcare providers) and hospital administrators that their cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Alexis;

f. Defendants 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. Defendants 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. Defendants 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. Defendants 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. Defendants 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, Defendants failed to directly warn the parents of the risk that their cow's-milk-based formulas would cause NEC; and/or

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

m. Defendants failed to require or recommend that hospitals and/or physicians inform parents before feeding Defendants' 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. Defendants 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. Defendants failed to develop a protocol for hospitals and physicians to ensure safe use of cow's-milk-based formulas;

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

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

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

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

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

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

v. Defendants 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. Defendants 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 Products;

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

y. Defendants' warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that Defendants warn and instruct 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 provide no information on how to avoid such harm;

283. Defendants' failure to warn was deliberate because Defendants knew that if they 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.

284. Defendants' 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 Defendants' 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 product rather than donor milk or human-milk-derived products.

285. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendants' products, Alexis was fed the Products in the NICU, which caused her to develop NEC, require surgery, and suffer long-term disabilities.

286. As a result of Defendants' failures to warn in violation of state law as detailed above, Alexis was fed the Products in the NICU, which caused her to develop NEC, require surgery, and suffer long-term disabilities.

287. Given the reprehensibility of Defendants' 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 Defendants' acts and omissions, the Court should assess Defendants with punitive damages under state law.

288. Defendants have failed to take corrective action after learning about how their cow's-milk-based formula and fortifier products, including the Products, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendants

have actively concealed information about how these products cause NEC from the public and profited substantially from these actions.

289. Punitive damages are necessary to punish Defendants and deter Defendants 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

290. Plaintiff incorporates all prior allegations.

291. Defendants are liable to Plaintiffs under state law for negligently failing to warn of the Products' unreasonably dangerous conditions or instruct on proper use.

292. The Products were unreasonably dangerous. The Products' design, which included cow's-milk ingredients, caused them to have an unreasonably dangerous condition. This condition existed at the time the Products left the Defendants' control, and the Products' unreasonably dangerous condition proximately caused injury to Alexis and Plaintiffs.

293. Defendants knew or should have known of the dangers posed by the Products.

294. Defendants failed to warn Plaintiffs, Alexis's medical providers, or the public that the Products could cause NEC and significantly increased the risk that a preterm infant would suffer NEC.

295. Defendants failed to instruct Plaintiffs, Alexis's medical providers, or the public about how to safely use the Products with preterm infants.

296. Defendants' cow's-milk-based formula and fortifier products, including the Products, are not prescription drugs or medical devices.

297. Defendants sold the Products to hospitals.

298. At the time the Products left Defendant's control, Defendants knew or, in light of 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 Products' dangerous condition.

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

300. Despite Defendants' knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendants 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.

301. Defendants 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 product is intended to be used. It was not, and is not, common knowledge among ordinary parents or medical providers of premature newborns that Defendants' cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

302. Defendants' products, including the Products, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so

Defendants are not entitled to a rebuttable presumption that its warning label was adequate.

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

304. Defendants are thus liable to Plaintiffs under state law for failing to warn in all of the following specific ways:

a. Defendants failed to provide any warning or instruction to consumers that their cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Alexis;

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

c. Defendants 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 Defendants' cow's-milk-based products;

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

e. Defendants failed to provide any warning or instruction to medical professionals (including nurses, physicians, and other healthcare providers) and hospital administrators that their cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Alexis;

f. Defendants 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. Defendants 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. Defendants 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. Defendants 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. Defendants 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, Defendants failed to directly warn the parents of the risk that their cow's-milk-based products would cause NEC; and/or

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

m. Defendants failed to require or recommend that hospitals and/or physicians inform parents before feeding Defendants' 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. Defendants 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. Defendants failed to develop a protocol for hospitals and physicians to ensure safe use of cow's-milk-based products;

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

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

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

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

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

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

v. Defendants 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. Defendants 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 Products;

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

y. Defendants' warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that Defendants warn and instruct 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 provide no information on how to avoid such harm;

305. Defendants' failure to warn was deliberate because Defendants 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.

306. Defendants' 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 product rather than donor milk or human-milk-derived products.

307. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendants' products, Alexis was fed Defendant's cow's-milk-based formula and fortifier products (the Products), which caused her to develop NEC, require surgery, and die.

308. As a result of Defendants' failures to warn in violation of state law as detailed above, Alexis was fed the Products in the NICU, which caused her to develop NEC, require surgery, and suffer long-term disabilities.

309. Given the reprehensibility of Defendants' 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 Defendants' acts and omissions, the Court should assess Defendants with punitive damages under state law.

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

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

PRAYER FOR RELIEF

Plaintiffs respectfully demand:

1. Entry of judgment in Plaintiffs' 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.

Plaintiff also respectfully requests trial by jury on all claims.

Respectfully submitted,

/s/ Ashlie Case Sletvold

Ashlie Case Sletvold
Jessica S. Savoie
Marilyn K. Eble
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
1422 Euclid Avenue, Suite 1610
Cleveland, Ohio 44115
Phone: (216) 589-9280
Fax: (216) 258-0161
asletvold@peifferwolf.com
jsavoie@peifferwolf.com
meble@peifferwolf.com

Brandon M. Wise
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
818 Layfayette Avenue, Floor 2
St. Louis, Missouri 63104
Phone: (314) 833-4825
Fax: (217) 666-7776
bwise@peifferwolf.com