**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**

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| **NICOLE SCHNEIDER,** *individually and on behalf of the minor child*, **K.M.,**<br>*Plaintiffs*,<br>v.<br>**MEAD JOHNSON & COMPANY, LLC**<br>**&**<br>**MEAD JOHNSON NUTRITION COMPANY**<br>*Defendants* | **MDL No. 3026**<br><br>**Case No. 1:26-cv-7292** |
| **Complaint with Jury Demand** | |

## NATURE OF ACTION

1. This action arises from the injury of a premature infant, who was afflicted with a disease caused by cow's milk-based infant formula 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. On information and belief, K.M., a preterm newborn baby, was fed Enfamil® Premature 20 Cal/fl oz® and developed NEC as a result. Plaintiff files 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 product known as Enfamil® Premature 20 Cal/fl oz®, referred to as "the Product".

## THE PARTIES

3. **K.M.** was born at Intermountain Health Saint Joseph Hospital in Denver, CO on June 26, 2009. She developed NEC after being fed on information and belief, the Product**. K.M.** was a resident of Colorado.

4. Nicole Schneider is the mother of **K.M.** She brings this action individually and as guardian of **K.M.**, a minor child. She is a resident of Colorado and is domiciled in Colorado.

5. 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.

6. 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.

7. 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

8. 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.

9. This Court has personal jurisdiction over Defendants and venue is proper here under 28 U.S.C. §§ 1391(b)(2).

## FACTUAL BACKGROUND

### The Science, The Product, The Marketing, and The Baby

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

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

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

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

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

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

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

16. Despite having knowledge of these medical and scientific studies and advances, 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.

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

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

19. As early as 1990, a prospective multicenter study on 926 preterm infants found that NEC was six-to-ten times more common in exclusively formula-fed babies than in babies fed breast milk alone, and three times more common than in those who received formula plus breast milk. 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).

20. Premature infants have immature gastrointestinal systems, especially as compared to full term infants. The specific physiology of the preterm gastrointestinal system makes premature babies vulnerable to NEC: "The preterm gut is characterized by reduced peristalsis, a thin mucous layer, reduced tight junctions, increased enterocyte apoptosis, and impaired enterocyte regeneration. Decreased

structural integrity and functionality of the gut result in poor digestion and absorption of energy, protein, and other nutrients necessary for growth, the development of organs, and immunoprotection." Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv. Nutr. 80–91 (2017).

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

22. Before **K.M.** 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.

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

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

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

26. The use of a 100% human milk-based diet was known to be cost-effective before **K.M.** 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.

27. 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.

28. Medical recommendations and scientific studies conducted, after **K.M.** was born, would continue to support what the scientific community knew in 2018.

29. In 2018, 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).

30. 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 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.

31. 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).

32. 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).

33. 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).

34. 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.*

35. 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).

36. 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).

37. 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).

38. 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).

39. 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).

40. 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).

41. In summary, medical studies (including studies published (before and after K.M. 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 Product:
## Defendants' cow's milk-based infant formula

42. Mead's Enfamil® Premature 20 Cal/fl oz® (whether in the form of a powder or a concentrated liquid) is a cow's milk- based product.

43. 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.

44. Defendants' cow's milk-based 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.

45. 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 Product.

46. 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.

47. Before K.M. 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.

48. Before **K.M.** 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 and 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.

49. 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.

50. 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"**

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

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

53. 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."

54. 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.

55. 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 they leave the hospital, at great expense to the parents and great risk to premature infants.

56. 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.

57. 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).

58. Mead has 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,andpromotion." https://hcp.meadjohnson.com/s/terms-of-use

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

60. Notwithstanding the Code, Mead aggressively markets to both new parents and medical providers that cow's milk-based formulas and fortifiers (like the Product) will benefit their newborns and give them the best chance of survival. The pervasive marketing involved, ostensibly prohibited by the Code, has impacted public and

medical perceptions of synthetic non-human-milk-derived substitutes, such as 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.

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

62. 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. 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*.

63. 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).

64. 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.*

65. 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.*

66. 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.

67. One study reports, "since 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.*

68. 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.

69. 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.

**Mead's misleading marketing of Enfamil**

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

71. 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.

72. 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.

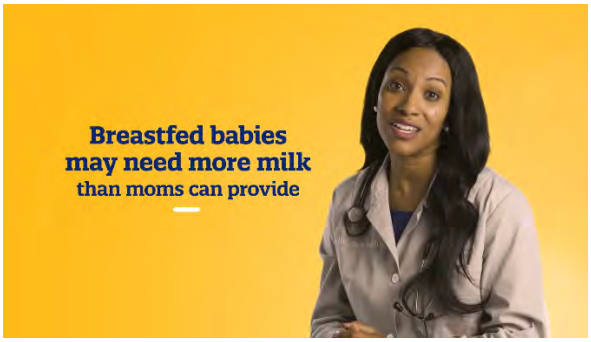
73. Mead promotes a range of products specifically for "premature and low weight" babies on its website.

74. 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."

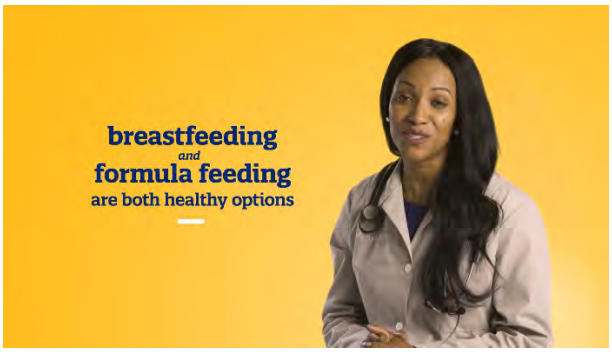
75. These representations that Enfamil is backed by science and equivalent to breast milk mislead parents by intentionally omitting the established fact that cow's milk-based products have been proven to significantly increase the risk of NEC, injury, surgery, and death in premature infants.

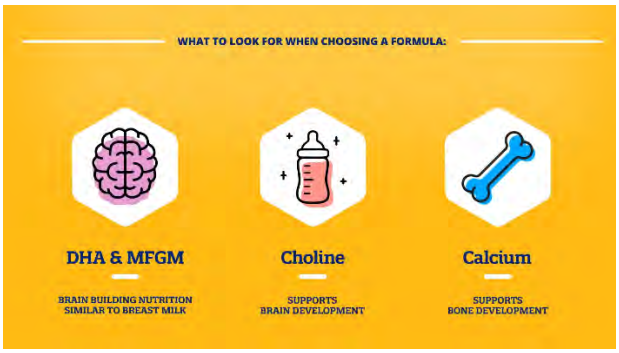
76. When comparing cow's milk-based breast milk substitutes and breast milk, Mead does not recognize the potent benefits of breast milk or acknowledge the risk of feeding cow's milk-based products to premature infants. Nor does Mead acknowledge that breastfeeding or an exclusive human milk-based diet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

77. 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. Screen shots from the video appear below.






78. 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.

79. 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.

80. 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/ .

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

82. 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.

83. 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.

84. 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.

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

86. 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/.

87. 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*.

88. "From Enfamil NeuroPro to 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").

89. "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/ .

90. 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.

91. Mead represents that "Enfamil gives every baby the DHA amount found in average breast milk." See https://www.enfamil.com/why-enfamil/.

92. 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's 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.

93. 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.

94. 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/.

95. 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/.

96. 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.

97. 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.

98. 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/.

99. 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 equivalence 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.

100. 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.

101. 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**

102. Through long-term exposure to Defendants' advertising, **K.M.**'s mother had been conditioned to believe that cow's milk-based infant feeding products like the Product are suitable alternatives to breast milk and necessary supplements for premature and low birth-weight infants.

103. The scope of Defendants' marketing efforts is vast. One study estimated 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).

104. Moreover, the data indicates 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).

105. 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).

106. 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).

107. 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]

108. The 2010 Stang study also found that 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**

109. 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 Product, for feeding to premature infants.

110. 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 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.

**Mead Defendants' inadequate warnings**

111. 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

[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).

significantly increase the risk of a premature infant developing NEC, requiring surgery, or death.

112. 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.

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

114. 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.

115. 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 preterm infants.

**Defendants failed to warn the public and K.M.'s mother**

116. Despite knowing that cow's milk-based products significantly increase an infant's 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.

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

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

119. 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 infants.

120. Despite knowing that cow's milk-based products were being fed to 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 infants.

121. Despite knowing that cow's milk-based products, including the Products, were being fed to 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 infants.

122. 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.

123. To this day, Defendants have never warned the public about the extreme danger its cow's milk-based products pose for preterm infants like K.M.

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

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

126. Neither the hospital nor the physicians provided a choice to the parents about whether to feed K.M. their infant cow's milk-based formula. While in NICU, K.M. was fed by the hospital's NICU staff. Her mother had to rely on the hospital staff members to feed her child. The NICU staff members, in turn, had to rely on Defendants to manufacture safe products with appropriate warnings.

127. The Product was not safe to be fed to premature infants like K.M. without warning of the risks of NEC.

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

129. Defendants knew or should have known that the Product would be used as they were used on K.M.

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

131. 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.

132. 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.

133. 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 Product's packaging, guidelines, instructions, and warnings.

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

135. On information and belief, K.M.'s mother, physicians, and medical staff were never told that the Product would cause K.M. to develop NEC.

136. On information and belief, K.M.'s mother, 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.

137. On information and belief, K.M.'s mother, physicians, and medical staff were never told that safer alternatives to cow's milk-based formulas existed.

138. On information and belief, K.M.'s mother, 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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 Product to be fed to their children.

144. 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.

145. If K.M.'s mother had known that cow's milk-based formulas, like the Product. increased the risk of NEC, she would not have allowed the Product to be fed to her and she would not have suffered NEC.

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

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

148. 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.

149. 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.

150. 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.

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

**The Baby: K.M. and her exposure to the Product**

152. K.M. was born on June 20, 2009, at Intermountain Health Saint Joseph's Hospital in Denver, CO at 34 weeks and 0 days gestation with a birthweight of 1.93 kg.

153. Shortly after her birth, K.M. was placed in the neonatal intensive care unit, where she was initially started on total parenteral nutrition.

154. On June 20, 2009, K.M. began receiving small trophic feedings with Enfamil® Premature® formula via nasogastric tube.

155. From June 20, 2009, until June 26, 2009, K.M. received Enfamil® Premature 20 Cal/fl oz® formula while in the NICU.

156. On June 26, 2009, K.M. was diagnosed with NEC Stage 2 and made NPO (nothing by mouth) for 7 days.

157. K.M. was treated for NEC Stage 2 with antibiotics from June 26, 2009 until July 3, 2009.

158. K.M.'s mother had no knowledge that cow's milk-based infant formula would increase. K.M.'s risk of developing NEC.

159. K.M.'s mother had been exposed to Defendants' advertisements for years.

160. Based on Defendants' marketing of its formulas and fortifiers, including Defendants' marketing of the Product as specifically intended to address premature infants' needs, K.M.'s mother believed the Product was safe for K.M. to consume and necessary for her growth and nutrition as a premature infant.

161. Although Defendants aggressively market their products, including the Product, 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.

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

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

164. Despite knowing the Product 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 Product when fed to premature infants.

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

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

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

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

**Safer Alternative Designs**

169. Infant formulas and fortifiers made or derived from cow's milk ingredients, including the Product fed to K.M., 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 K.M.'s birth.

170. The Product is not unavoidably unsafe. For decades, before K.M. was fed the Product, 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.

171. 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.

172. 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 January 30, 2025).

173. 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 January 30, 2025).

174. 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 Product.

175. 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.

176. 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 Product, which are marketed to and labeled for feeding to premature infants.

## COUNT 1: STRICT PRODUCTS LIABILITY—DEFECTIVE DESIGN

177. Plaintiffs incorporate all prior allegations.

178. Defendants are strictly liable to Plaintiffs under state law because the Product's design caused them to have an unreasonably dangerous condition, which existed at the time the Product left the Defendants' control, and the Product's unreasonably dangerous condition proximately caused injury to K.M.

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

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

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

182. 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.

183. 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.

184. 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.

185. Defendants have failed to take corrective action to re-design the Product after learning about how their cow's milk-based formula and fortifier products, including the Product, 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.

186. 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 premature infants.

**COUNT 2: NEGLIGENT PRODUCTS LIABILITY—DEFECTIVE DESIGN**

187. Plaintiffs incorporate all prior allegations.

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

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

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

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

192. 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 premature infants because the formulas were defective in design.

193. 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.

194. Defendants have failed to take corrective action to re-design the Product after learning about how their cow's milk-based formula and fortifier products, including the Product, 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.

195. 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 premature infants.

**COUNT 3: STRICT PRODUCTS LIABILITY—FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS**

196. Plaintiffs incorporate all prior allegations.

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

198. The Product was unreasonably dangerous. The Product's design, which included cow's milk ingredients, caused it to have an unreasonably dangerous condition. This condition existed at the time the Product left the Defendants' control, and the Product's unreasonably dangerous condition proximately caused injury to K.M.

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

200. Defendants failed to instruct Plaintiff, K.M.'s medical providers, or the public about how to safely use the Product with preterm infants.

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

202. Defendants sold the Product to hospitals and directly to consumers.

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

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

205. 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.

206. Defendants further failed to provide an adequate warning or instruction that considered the characteristics of, and ordinary knowledge common to, the person 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.

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

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

208. Defendants knew or should have known that its cow's milk-based formula and fortifier products, including the Product, would be fed to premature, low-birth-weight infants, like K.M. 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.

209. Defendants are thus liable to the Plaintiff 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 Product, increased the risk of NEC for premature infants and low-birth-weight babies.

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 Product, 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 Product, increased the risk of NEC for premature infants and low-birth-weight babies.

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 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 Product;

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 Product;

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 do not warn that cow's milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and provide no information on how to avoid such harm;

210. 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 premature infants in hospitals, including neonatal intensive care units.

211. 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.

212. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendants' products, K.M. was fed the Product in the NICU, which caused her to develop NEC, remain in the NICU for an extended time, and be treated with intravenous antibiotics.

213. 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.

214. Defendants have failed to take corrective action after learning about how their cow's milk-based formula and fortifier products, including the Product, 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.

215. 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 premature infants.

**COUNT 4: PRODUCTS LIABILITY—NEGLIGENT FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS**

216. Plaintiffs incorporate all prior allegations.

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

218. The Product was unreasonably dangerous. The Product's design, which included cow's milk ingredients, caused them to have an unreasonably dangerous condition. This condition existed at the time the Product left the Defendants' control, and the Product's unreasonably dangerous condition proximately caused injury to K.M.

219. Defendants knew or should have known of the dangers posed by the Product.

220. Defendants failed to warn Plaintiff, K.M.'s medical providers, or the public that the Product could cause NEC and significantly increase the risk that a preterm infant would suffer NEC.

221. Defendants failed to instruct Plaintiffs, K.M.'s medical providers, or the public about how to safely use the Product with preterm infants.

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

223. Defendants sold the Product to hospitals.

224. At the time the Product 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 Product (caregivers for premature newborns) would not realize the Product's dangerous condition.

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

226. 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.

227. Defendants further failed to provide an adequate warning or instruction that considered 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.

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

229. Defendants knew or should have known that its cow's-milk-based formula and fortifier products, including the Product, would be fed to premature, low-birth-weight infants, 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.

230. 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 Product, increased the risk of NEC for extremely premature infants and low-birth-weight babies.

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 Product, 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 Product, increased the risk of NEC for extremely premature infants and low-birth-weight babies.

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 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 alternatives 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 Product;

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 Product;

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;

231. 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 premature infants in hospitals, including neonatal intensive care units.

232. 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.

233. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendants' products, K.M. was fed Defendants' cow's milk-based formula, which caused her to develop NEC and require intravenous antibiotics for treatment.

234. 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.

235. Defendants have failed to take corrective action after learning about how their cow's milk-based formula and fortifier products, including the Product, 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.

236. 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 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.

Plaintiffs also respectfully request trial by jury on all claims.

Respectfully submitted,

*/s/ Ashlie Case Sletvold*

Ashlie Case Sletvold
**PEIFFER WOLF CARR KANE CONWAY & WISE, LLP**
6370 SOM Center Road, Suite 108
Cleveland, OH 44139
(216) 589-9280
asletvold@peifferwolf.com

JS 44 (Rev. 10/20)

# CIVIL COVER SHEET

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

## I. (a) PLAINTIFFS

NICOLE SCHNEIDER, individually and on behalf of her minor child, K.M.

**(b)** County of Residence of First Listed Plaintiff Logan County, CO

*(EXCEPT IN U.S. PLAINTIFF CASES)*

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

Ashlie Case Sletvold/ Peiffer Wolf Carr Kane Conway & Wise
6370 SOM Center Rd., #108,Cleveland, OH 44139
504-387-7067

## DEFENDANTS

MEAD JOHNSON & COMPANY, LLC & MEAD JOHNSON NUTRITION CO.

County of Residence of First Listed Defendant Vanderberg, IN

*(IN U.S. PLAINTIFF CASES ONLY)*

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

Attorneys *(If Known)*

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

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

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

*(For Diversity Cases Only)*

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

**TORTS**

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

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

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

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

**PRISONER PETITIONS**

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

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

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

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

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

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

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

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

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

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

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

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

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Sec. 1332; Product Liability

Brief description of cause:
Pharmaceutical Personal Injury

## VII. REQUESTED IN COMPLAINT:

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

**DEMAND $**

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

*(See instructions):*

JUDGE Hon. Rebecca Pallmeyer DOCKET NUMBER MDL No.3026

DATE
June 22, 2026

SIGNATURE OF ATTORNEY OF RECORD
/s/ Ashlie Case Sletvold

**FOR OFFICE USE ONLY**

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE