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

Heidi Paul as the natural guardian and personal representative of the Estate of C.P., and Heidi Paul, individually, Plaintiffs, v. Mead Johnson & Company, LLC, Defendant.	Case No.: Judge: **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs, Heidi Paul as the natural guardian and personal representative of the Estate of C.P., and Heidi Paul, individually, (collectively "Plaintiffs"), bring this action against Defendant Mead Johnson & Company, LLC, ("Defendant" or "Mead"), asserting claims arising from the catastrophic injury and often deadly disease known as Necrotizing Enterocolitis ("NEC") that largely affects premature and/or low birth weight newborn/babies as a direct and proximate result of the ingestion of bovine-based infant formula or products. C.P., a premature infant born with a low birth weight, was fed Enfamil Premature, including Enfamil A+, Enfamil NeuroPro, Enfamil Liquid Human Milk Fortified, Enfamil Liquid HMF, Enfamil Enspire, and EnfaCare Powder, and subsequently developed NEC shortly thereafter. Plaintiffs bring this action against Defendants for claims arising from the direct and proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of bovine-based formulas and/or fortifiers ("bovine formula") to premature infants known as Enfamil and/or Enfamil Premature (hereinafter collectively referred to as "Products").

INTRODUCTION

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

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

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

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

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

PARTIES

Plaintiff

6. Heidi Pail, residing in Pawling, New York, is the mother of C.P., the a deceased minor.

7. C.P. was born on [redacted], at Westchester Medical Center in Valhalla, New York, at 27 weeks gestation and weighing two pound and one ounces.

8. Given the premature birthweight, C.P. was transferred to the Neonatal Intensive Care Unit ("NICU").

9. While in the NICU, C.P. was provided nutrients through an enteral feeding tube specifically given Enfamil and/or Enfamil Premature ("formula" and/or "product"), a formula and/or fortifier which is a formula which is bovine based. Shortly after receiving the formula enterally, C.P. began suffering from gastrointestinal issues, including intestinal perforation, and was diagnosed with NEC. This injury led C.P. to develop bowel problems, abscess, sepsis, blood transfusion, and hematochezia.

10. C.P. tragically died on September 29, 2007, due to NEC.

Defendant

11. Defendant manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, sells and places its Products, specifically infant formula Enfamil and/or Enfamil Premature, into the stream of commerce in all fifty states, including Kentucky.

12. Mead was at all times material hereto and is now a limited liability company duly organized and existing under the laws of the State of Delaware with its principal place of business

and headquarters in the State of Illinois. Mead's sole member is Mead Johnson Nutrition Company and is thus a resident, citizen, and domicile in Delaware and Illinois.

13. At all times relevant to this action, Mead conducted, and continues to conduct, a substantial amount of business activity and has engaged in tortious conduct, in whole or in part, in this District. Defendant is headquartered in Chicago, Illinois and engaged in interstate commerce in all fifty states when it advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce Enfamil and/or Enfamil Premature, an infant formula and/or fortifier, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this District.

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

A. Necrotizing Enterocolitis

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

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

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

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

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

22. The NEC diagnosis is commonly determined with the use of Modified Bell's Staging Criteria, ranging from Stage IA (suspected NEC) to the most severe at Stage IIIB

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

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

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

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

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

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

(advanced, severely ill, perforated bowel).[7] The Modified Bell's Staging Criteria incorporate systemic, intestinal, and radiological signs to adequately diagnose, stage, and treat NEC.

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

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

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

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

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

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

[10] *Id.*

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

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

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

B. Bovine Formula Increases NEC Risk

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

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

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

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

29. Bovine formula and/or fortifiers are often given to infants enterally and NEC only occurs after infants have been enterally fed.[15] Several challenges exist for preterm nutritional support. Many preterm infants, especially those born <1500 g and/or <34 weeks gestation, are not

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

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

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

able to breastfeed.[16] The suck-swallow-breathe rhythm of oral feeding may not be possible for preterm infants because of coordination issues and/or low body stores of energy.[17]

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

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

[16] Jocelyn Shulhan, *et al.*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv Nutr. 80–91 (2017).

[17] *Id.*

[18] *See* Chowning R., *et al*., *A Retrospective Analysis of the Effect of Human Milk on Prevention of Necrotizing Enterocolitis and Postnatal Growth* 36 J Perinatol 221-4 (2016); Johnson TJ, et al., *Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants*, 107 Neonatology 271–6 (2015); Sullivan, S., *et al.*, *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J Pediatr 562–7 (2010); Cristofalo EA, *et al*., *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants*, 163 J Pediatr1592-5 (2013).

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

determined to be *six to ten times* more common in those fed bovine-based formula, and *three times* more common than in those who received the formula plus breast milk.

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

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

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

[21] Sullivan, *supra* note 18.

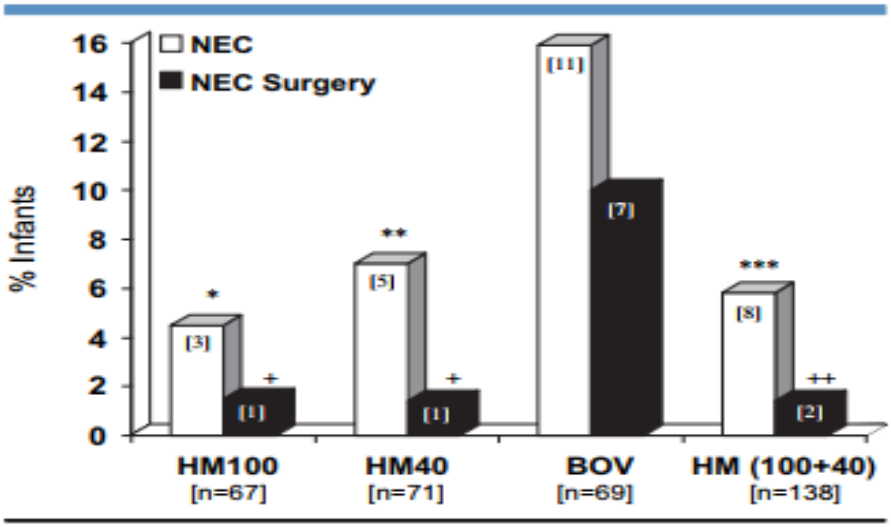

Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $^{*}P = .04$ vs BOV, $^{**}P = .09$ vs BOV, $^{***}P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P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

[22]

34. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a significantly higher rate of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU.[23]

35. In another study published in 2014, it was reported that 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."[24]

[22] *Id.*

[23] Cristofalo, et. al., *Randomized Trial in Extremely Preterm Infants,* Pediatr., 163(6): 1592-1595 (2013).

[24] Good, et. al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, Expert Rev. Clin. Immunol., 10(7): 875-884 (2014).

36. In another 2020 publication, the twelve-center randomized trial published in 2010,[25] that compared bovine milk derived fortifier to human milk derived fortifier, was reviewed and analyzed.[26] The new study noted that it was common practice to feed preterm infants a base diet comprising of only human milk, usually fortified with a bovine derived fortifier.[27] The study took the old data[28] and focused on the infants who had a diet comprised 100% of their mothers' own milk (*i.e.*, they had no donor milk or preterm formula). This allowed for an isolated comparison of the bovine derived fortifier and the human derived fortifier. The study found that the bovine derived fortifier was associated with a higher risk of NEC, NEC requiring surgery, reduced head circumference gain, and death.[29] Despite the high intake of the mother's own milk, the bovine derived fortifier was still associated with a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of NEC surgery or death. Thus, those fed a human derived fortifier were significantly advantaged in terms of a reduced incidence of morbidity. The authors concluded that the available evidence points to an increase in adverse outcomes with bovine derived fortifier, including NEC (Modified Bell's Staging Criteria Stage 2 or greater), NEC surgery or death, and surgical NEC.[30]

[25] Sullivan, *supra* note 18.

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

[27] *Id.*

[28] Lucas, *supra* note 24.

[29] Lucas, *supra* note 24.

[30] *Id.*

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

31

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

C. Defendant Knew of the Risks Associated with Bovine Formula

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

38. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. 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."[32]

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

40. A Cochrane Library meta-analysis, last updated in 2018, analyzed data from eight trials including 1,605 participants who were either preterm or low birth weight infants in a neonatal unit.[33] The combined data showed a higher risk of NEC in the formula-fed group. The studies

[31] *Id.*

[32] Eidelman, et. al., *Breastfeeding and the Use of Human Milk*, Pediatrics, 129: e827-e841 (2012).
[33] Quigley, *et al.*, *Formula versus Donor Breast Mild for Feeding Preterm or Low Birth Weight Infants*, 6 Cochrane Database of Systematic Reviews (2018), https://pubmed.ncbi.nlm.nih.gov/29926476/.

compared the use of formula and donor breast milk. The meta-analysis showed that the overall risk of the infant developing NEC with donor breast milk was 3.7% and the overall risk with formula was 7% (4.5-10.7%). The analysis documented that there is a higher risk of NEC in the formula-fed group. Below is a summary of the studies that were examined as part of the meta-analysis:

a. **Term Formula versus Unfortified Donor Breast Milk:** the study evaluated the outcomes of preterm infants fed human milk compared to modified infant formula.[34] This study reported on 67 preterm infants from 1980 to 1982, comparing infants fed with unfortified donor milk and term formula. The results showed that three out of 26 infants on the formula milk developed NEC, whereas only one out of 41 infants receiving donor breast milk developed NEC—*a 300% difference*.

b. **Preterm Formula versus Fortified Donor Breast Milk:** the study evaluated growth, metabolic response, and development in very-low-birth-weight infants fed donor milk or enriched formula.[35] This study reported on 76 healthy infants of very low birth weights, comparing banked human milk and Similac Special Care protein-mineral–calorie-enriched formula. Two of the infants on the formula developed NEC while none of the infants on the donor milk developed NEC.

c. **Preterm Formula versus Fortified Donor Breast Milk**: this study evaluated the clinical impact of infants fed bovine fortified breast milk.[36] Published in 1996, this trial

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

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

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

involved 276 preterm infants who were fed a base diet of a mother's own milk, and if insufficient breast milk was available, bovine based preterm formula was added. The number of infants with NEC was 5.8% in the fortified group compared to 2.2% in the control group. The trial showed that the addition of bovine derived fortifiers to breast milk, as the sole intervention, more than doubled the combined incidence of confirmed NEC or sepsis.

d. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial of extremely premature infants on donor human milk versus preterm formula was conducted.[37] This study, published in 2005, compared the differences in 243 infants fed with their mothers' milk, pasteurized donor milk plus preterm formula (Enfamil and/or Enfamil Premature). The results of this trial showed that infants who received their own mothers' milk had a 50% less chance of NEC and/or late-onset sepsis compared with infants fed either donor human milk or preterm formula.

e. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial examining the use of exclusive human milk versus preterm formula diets in extremely premature infants was conducted.[38] This study, published in 2013, examined 53 extremely premature infants fed exclusive diets of either bovine milk–based preterm formula, or donor human milk with human milk-based fortifier. The incidence of NEC in the bovine formula group was 21% (five cases) versus 3% in the human milk group (one case). Surgical NEC was significantly higher in the bovine formula group (four cases) than human

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

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

milk group (no cases). It was concluded that in extremely preterm infants, given exclusive diets of preterm formula versus human milk, there was a significantly higher rate of surgical NEC in infants receiving preterm formula. The researchers concluded that this trial supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU.

f. **Preterm Formula versus Fortified Donor Breast Milk**: this study examined the effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low birth-weight infants at eighteen months.[39] This trial evaluated 363 very low birth weight infants whose mother's breast milk became insufficient in four neonatal units in Ontario, California. The infant mother's milk was supplemented with either preterm formula, or pasteurized donor breast milk supplemented with a fortifier. The study showed that the nutrient enriched donor milk was associated with a lower risk of NEC (1.7%) compared with feeding preterm formula (6.6%).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

58. Due to Defendant's conduct, in not publicizing and/or distributing and/or warning of the dangers of using its bovine formulas and/or fortifiers in preterm, low weight infants, Plaintiffs, nor any reasonably person, would have been able to have discovered the dangerous nature of Defendant's product or how it injured their child until shortly before the filing of this lawsuit.

CLAIMS ALLEGED

FIRST CAUSE OF ACTION
FAILURE TO WARN

59. Plaintiffs repeat and reallege the allegations in Paragraphs 1-59, above, as if fully set forth herein.

60. Defendant, as the manufacturer and/or seller of the infant formulas and/or fortifiers at issue in this litigation, owed a duty to the consuming public and Plaintiffs, to properly warn and provide adequate warnings, instructions, labeling, and/or packaging about the dangers and risks

associated with the use of their products by preterm infants, specifically including, but not limited to, the risk of NEC.

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

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

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.[40]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECOND CAUSE OF ACTION
STRICT LIABILITY FOR DEFECTIVE PRODUCT

71. Plaintiffs repeat and reallege the allegations in Paragraphs 1-71, above, as if fully set forth herein.

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

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

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

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

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

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

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

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

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

THIRD CAUSE OF ACTION
NEGLIGENCE

81. Plaintiffs repeat and reallege the allegations in Paragraphs 1-81, above, as if fully set forth herein.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

p. failing to guide, instruct, and/or advise the consuming public regarding when preterm infants should be administered the subject product, the amount of formula and/or fortifier that should be administered, when the amount of

formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using its formula and/or fortifier; and

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

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

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

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

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

89. Plaintiffs repeat and reallege the allegations in Paragraphs 1-89, above, as if fully set forth herein.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

96. Plaintiffs repeat and reallege the allegations in Paragraphs 1-96, above, as if fully set forth herein.

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

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

99. Defendant warrants and markets on its "trust brand of pediatricians and parents" webpage, that: Enfamil and/or Enfamil Premature 20: "a 20 Cal/fl oz iron, feeding for brain building, immune support, and specially designed formula to help low-birthweight or premature babies who can't breastfeed. growing, low-birth-weight infants and premature infants". Designed

to be used as a preterm post-discharge formula. It has a blend of two nutrients also found in human milk—DHA & ARA—so the baby can get some of the same benefits as they do from nursing. Amounts of calcium, phosphorus, and vitamin D to help support bone mineralization & growth. DHA helps support brain & eye development, as well as blood DHA concentration."[41]

100. Notwithstanding strong medical evidence establishing the extreme dangers that cow-based products pose for premature infants, Mead has marketed its cow-based products as an equally safe alternative to breast milk, and indeed has promoted its products as necessary for additional nutrition and growth. The Defendant has specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants*, when indeed its products pose a known and substantial risk to these babies.

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

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

103. The World Health Organization (WHO) and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address the

[41] Mead Johnson Nutrition - https://www.enfamil.com/products/premature-ready-to-use-20-iron/liquid-2-fl-oz-2-fl-oz-6-bottles/ (last visited November 13, 2023).

international marketing of breast-milk substitutes. The World Health Director concluded the meeting with the following statement: **"In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement."** (Baumslag & Michels, 1995, p. 161). Recognizing the abuse and dangers of the marketing of Infant formula, in 1981, the World Health Assembly (WHA; the decision-making body of the world's Member States) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and outlawed any advertising or promotion of breast milk substitutes to the general public. The International Code of Marketing of Breast-milk Substitutes specifically prohibited advertising in Article 5 Section 1: "There should be no advertising or other form of promotion to the general public..." The International Code of Marketing of Breast-milk Substitutes. Geneva: World Health Organization, p.16 - 20 (1981).

104. Mead has acknowledged the Code. They include on their website the handbook on "Infant Food Manufacturers' Commitment and Rules for Responsible Conduct" prepared by the International Association of Infant Food Manufacturers (IFM). The rules of responsible conduct in the handbook, as a preamble, they say that:

> "1.3 IFM and its members acknowledge the importance and respect the aim and principles of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes (the "WHO Code"), the stated aim of which is "to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."

> 1.4 The WHO Code also recognizes that, when mothers do not breast-feed, or only do so partially, there is a legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding."[42]

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

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

107. In May 2006 WHO celebrated the 25th anniversary of the International Code of Marketing of Breastmilk Substitutes. As the breast milk versus infant formula controversy continued, Mead Johnson and its peers in the industry found themselves waging a global battle of sorts to market their products.

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

[42] https://www.meadjohnson.com/sites/corp/files/IFM_Rules-of-Responsible-Conduct.pdf (last visited October 31, 2023)

109. Over the years, Mead Johnson has produced an impressive array of formulas for infants and specialty nutritional innovations including Enfamil, our leading products today. Enfamil, introduced in 1959, has undergone several significant formulations — each one designed to optimize nutrition.

110. Despite being aware of the significantly increased risk of NEC, devastating injuries, and/or death associated with use of its cow's milk-based products-especially in preterm and low birth weight infants, Defendant, engaged in a deceptive marketing campaign in which they misled parents of preterm and low birth weight infants into believing its products were safe and necessary for the growth of those infants.

111. Notwithstanding strong medical evidence establishing the extreme dangers that cow's milk-based products posed for preterm and low birth weight infants, Defendant, marketed its cow's milk-based products as equally safe and nutritionally equivalent alternatives to human milk and have promoted its products as necessary for extra nutrition and growth.

112. Enfamil was deceptive from its very inception. Enfamil's very name (*i.e. infant meal*) is deceptive. Beginning with its brand name, Mead has continued to perpetuate the deception that its product is with the same or similar to human milk as infant food.

113. We are seeing more ads for baby formulas than ever before. The closure of Abbott Laboratories' formula plant in Michigan, after complaints of bacterial infections in infants, eroded the Similac maker's market share. Other brands, like Enfamil, had a chance to step in due to relaxed government rules, frantic parents looking for formula and retailers seeking alternatives. Formula makers are attracted to the United States because birth rates are higher than Europe, China and Japan and many U.S. moms return to work outside the home. Since the United States ranks in the

top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

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

115. The WHO asks that governments and companies ban advertising of baby formula to guard against predatory marketing practices and encourage breastfeeding, which it recommends as the healthier choice. The United States never enacted legislation enforcing the WHO advertising ban. The last significant U.S. TV advertising campaign for formula was in 2017, when Enfamil ran commercials for its formula for toddlers over 1 year old, according to ISpotTV.[43] In 2018, The WHO Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes."[44]

116. The contradictory messages women receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is unnecessary and difficult if not impossible to achieve" Hausman, B. L. (2000, Summer). *Rational management: Medical authority and ideological conflict in Ruth Lawrence's Breastfeeding: A guide for the medical profession*. Technical Communication Quarterly, 9(3), 271-289.

[43] https://www.reuters.com/world/us/us-baby-formula-shortage-leads-boom-advertisements-2022-12-22/ (last visited November 3, 2023)

[44] *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*, Genova: World Health Org., 2018, p.21

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

118. One study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. *Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB. Exposure to infant feeding information in the media during pregnancy is associated with feeding decisions postpartum. Paper presented at American Public Health Association 138th Annual Meeting & Exposition; November 2010; Washington, DC.* In a study on infant feeding advertisements in 87 issues of Parents magazine, apopular parenting magazine, from the years 1971 through 1999, content analysis showed that when the frequency of infant formula advertisements increased, the percentage change in breast- feeding rates reported the next year generally tended to decrease. *Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.*

119. The Stang study also found that Infant formula company websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing a product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance. *Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.*

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

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

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

123. As a direct result of Defendant's conduct, as described herein, unreasonably dangerous bovine formulas and/or fortifiers were administered to the baby, causing the baby to develop NEC, which ultimately caused the baby's serious injuries, including but not limited to intestinal rupturing which led to various surgeries, including but not limited to interventions for the removal of portions of the large and small intestines, had an ileostomy reversal, a drain and an ostomy bag. Due to injuries, C.P. developmental delays, and on-going gastrointestinal issues.

124. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiffs have suffered catastrophic damages and injuries such as intestinal rupturing which led to various surgeries, hematochezia, sepsis, blood transfusion, emotional distress, loss of income, etc., and other damages as their lives have been significantly affected by the injuries of their baby, C.P.

SIXTH CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT
UNDER KENTUCKY LAW

125. Plaintiffs repeat and reallege the allegations in Paragraphs 1-125, above, as if fully set forth herein.

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

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

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

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

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

dangerous than other risks associated with non-bovine formulas and/or fortifiers;

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

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

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

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

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

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

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

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

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

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

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

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

136. Plaintiffs repeat and reallege the allegations in Paragraphs 1-136 above, as if fully set forth herein.

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

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

139. Defendant's unfair and deceptive practices include:

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

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

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

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

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

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

141. Defendant's misleading omissions and representations concerning the risks of Enfamil and/or Enfamil Premature, and Defendant's scheme to promote Enfamil and/or Enfamil Premature and other bovine milk products as no less safe than human milk: (a) were against public

policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

142. Defendant intended for parents and healthcare providers, including the parents and healthcare providers of C.P., to rely on its misleading representations and omissions regarding Enfamil and/or Enfamil Premature and other bovine milk products.

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

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

145. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, C.P. was administered Enfamil and/or Enfamil Premature and sustained injuries and damages as described herein.

146. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, C.P. suffered damages, as described herein.

EIGHTH CAUSE OF ACTION
WRONGFUL DEATH CAUSE OF ACTION

147. Plaintiffs repeat and reallege the allegations in Paragraphs 1-147 above, as if fully set forth herein.

148. Defendant's bovine formulas and/or fortifiers, consumed by C.P. and caused C.P.'s death, were unreasonably dangerous to preterm babies.

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

150. The Consolidated Laws of New York, Chapter 17-B (Estates, Powers & Trusts), include the §5-4.1 "Action by Personal Representative for Wrongful Act, Neglect or Default Causing Death of Decedent":

> (1) The personal representative, duly appointed in this state or any other jurisdiction, of a decedent who is survived by distributes may maintain an action to recover damages for a wrongful act, neglect or default which caused the decedent's death against a person who would have been liable to the decedent by reason of such wrongful conduct if death had not ensued.

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

152. Defendant had a duty to the consuming public, including Plaintiffs, to manufacture, sell, and distribute the formula and/or fortifier in a manner that was not unreasonably dangerous for its intended use.

153. Defendant had a duty to the consuming public, including Plaintiffs, to exercise reasonable care to design, test, manufacture, inspect, and distribute a safe product that did not present an unreasonable risk of harm to consumers when used in its intended manner and for its intended purpose.

154. Defendant had a duty to the consuming public, including Plaintiffs, to provide truthful and accurate information about the risks of its bovine-based ingredients when the products are used in their intended manner and for their intended purpose.

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

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

157. The failure of the Defendant to fulfill its duty to the consuming public, including Plaintiffs, as a direct and immediate result of the foregoing acts and omissions, baby C.P. sustained significant damage and injuries resulting in her death.

REQUEST FOR RELIEF

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

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

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

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

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

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

F. For punitive damages;

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

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

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

JURY DEMAND

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

Dated: December 6, 2023

Respectfully submitted,

/s/ Christopher R. LoPalo
Christopher R. LoPalo, Esq.
NS PR LAW SERVICES LLC
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Santurce, PR 00907
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Counsel for Plaintiffs

JS 44 (Rev. 04/21)

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

Heidi Paul as the natural guardian and personal representative of the Estate of C.P., and Heidi Paul,

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
NS PR Law Service PLLC
1302 Avenida Ponce De Leon, Santurce, PR 00907
212-397-1000

DEFENDANTS

Mead Johnson & Company, LLC

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

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

Attorneys *(If Known)*

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

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

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

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

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

Click here for: Nature of Suit Code Descriptions.

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

TORTS

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

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

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

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

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

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

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

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

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

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

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

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

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

PRISONER PETITIONS

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability, Negligence, Violations of Consumer Protection Acts, Wrongful Death

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 Rebecca R. Pallmeyer DOCKET NUMBER Master Docket No. 22-cv-71 MDL 3

DATE
Dec 6, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Christopher R. LoPalo

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

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

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

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

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

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