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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

LATRICE RICHARDSON, as
Parent, Guardian Ad Litem, and as
Next Friend of NEPOLEON
RICHARDSON, a minor,

Plaintiff,

v.

ABBOTT LABORATORIES, INC.;
MEAD JOHNSON & COMPANY,
LLC and/or MEAD JOHNSON
NUTRITION COMPANY,

Defendants.

Case No: 2:21-cv-9932

COMPLAINT

1 **PARTIES, JURISDICTION, AND VENUE**

2 1. Plaintiff, Latrice Richardson, the mother of baby Napoleon Richardson
3 (hereinafter “Baby Richardson”), brings this cause of action against Abbott
4 Laboratories, Inc., (“Abbott” or “Defendant”) and Mead Johnson & Company, LLC
5 and/or Mead Johnson Nutrition Company (“Mead” or “Defendant”) to recover for
6 Baby Richardson’s injuries, which are the direct and proximate result of
7 consumption of Defendants’ unreasonably dangerous cow’s milk based products.

8 2. On January 18, 2020, Baby Richardson was born at Kaiser
9 Permanente’s Los Angeles Medical Center in Los Angeles, California.

10 3. Defendant Mead manufactures, designs formulates, prepares, tests,
11 provides instructions, markets, labels, packages, places into the stream of commerce
12 in all fifty states, including California, and sells premature infant formula products
13 including Enfamil Human Milk Fortifier and Enfacare Powder.

14 4. Defendant Abbott manufactures, designs, formulates prepares, tests,
15 provides instructions, markets, labels, packages, places into the stream of commerce
16 in all fifty states, including California, and sells premature infant formula including
17 Similac Special Care.

18 5. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a)
19 because complete diversity exists between Plaintiff and Defendants, and the matter
20 in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000.

21 6. This Court has personal jurisdiction over Defendants because
22 Defendants are authorized to conduct and do conduct business in the State of
23 California and Defendants have sufficient minimum contacts with this State and/or
24 sufficiently avails itself of the markets in this State through its promotion, sales,
25 distribution and marketing within this State to render the exercise of jurisdiction by
26 this Court permissible.

27 7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b)
28 because a substantial part of the events or omissions giving rise to Plaintiff’s claims

1 occurred in this judicial district.

2 **GENERAL ALLEGATION**

3 8. On January 18, 2020, Baby Richardson, was born prematurely.

4 9. Following the birth, Baby Richardson, was placed in the Neonatal
5 Intensive Care Unit (NICU) at Community Hospital of San Bernardino.

6 10. Baby Richardson was intravenously fed Similac and Enfamil, while in
7 the NICU.

8 11. After being fed Similac and Enfamil, on January 19, 2020, Baby
9 Richardson was diagnosed with Necrotizing Enterocolitis (“NEC”) while in the
10 NICU. He developed the following symptoms: abdomen obstruction with partially
11 digested formula, blood in the stool, difficulty breathing, and acute neurological
12 deterioration.

13 12. Baby Richardson underwent surgery to remove one-third of both his
14 small and large intestines. At the time Baby Richardson was diagnosed with and
15 treated for NEC, Plaintiff was unaware of the fact that the Defendant’s cow’s milk
16 based products fed to their baby caused or substantially contributed to the
17 development of NEC and resulting injuries.

18 **THE SCIENCE**

19 13. According to the World Health Organization (“WHO”), babies born
20 prematurely, or “preterm,” are defined as being born alive before 37 weeks of
21 pregnancy are completed, like Baby Richardson. The WHO estimates that
22 approximately 15 million babies are born preterm every year and that number is
23 rising.

24 14. Nutrition for preterm babies, like Baby Richardson, is significantly
25 important. Since the United States ranks in the top ten countries in the world with
26 the greatest number of preterm births, the market of infant formula and fortifiers is
27 particularly vibrant.

28 15. Originally, cow’s milk-based products were believed to be good for the

1 growth of premature, low birth weight babies; however, science and research have
2 advanced for decades confirming the significant dangers of the Defendants' cow's
3 milk-based products in causing Necrotizing Enterocolitis ("NEC") and/or
4 substantially contributing to death in preterm and severely preterm, low-weight
5 infants, along with many other health complications and long-term risks to babies,
6 yet, the Defendants did nothing to change their product, packaging, guidelines,
7 instructions, and/or warnings. Additionally, advances in science have created
8 alternative formulas and fortifiers that are derived from human milk and non-bovine
9 based products; however, the Defendants continue to promote and sell their defunct
10 cow's milk-based products.

11 16. As early as 1990, a prospective, multicenter study on 926 preterm
12 infants found that NEC was six to ten times more common in exclusively formula-
13 fed babies than in those fed breast milk alone and three times more common than in
14 those who received formula plus breast milk. Babies born at more than 30 weeks
15 gestation confirmed that NEC was rare in those whose diet included breast milk, but
16 it was 20 times more common in those fed formula only. A. Lucas, T. Cole, *Breast*
17 *Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

18 17. In a study published in 2007 it was reported: "The use of an
19 exclusive HUM [Human] diet is associated with significant benefits for
20 extremely premature infants <1259 g BW. The benefits include decreased NEC
21 rates, mortality, late-onset sepsis, PDA, BPD, ventilator days, and ROP.
22 Importantly, while evaluating the benefits of using an exclusive HUM-based
23 protocol, it appears that there were no feeding-related adverse outcomes. This
24 study demonstrates that an exclusive HUM diet provides important benefits
25 beyond NEC." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention:*
26 *Improving Outcomes with an Exclusive Human Milk-Based Diet.* (Breastfeeding
27 Medicine. 2016, Nov 2., 11(2):70-75.)

28 ///

1 18. A study published in 2010 established that when premature babies were
2 fed an exclusive diet of mother's milk, donor milk, and human milk fortifier, these
3 babies were 90% less likely to develop surgical NEC. Sullivan, S., et al., *An*
4 *Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising*
5 *Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products.*
6 (Journal of Pediatrics 2010; 156:562-7.)

7 19. In 2011, the U.S. Surgeon General published a report titled, "The
8 Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon
9 General warned that "for vulnerable premature infants, formula feeding is associated
10 with higher rates of [NEC]." U.S. Dep't. of Health & Human Serv., Off. of Surgeon
11 Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p. 1, (2011).
12 This same report stated that premature infants who are not breast fed are 138% more
13 likely to develop NEC. Id., Table 1, p. 2.

14 20. In 2012, the American Academy of Pediatrics issued a policy statement
15 that all premature infants should be fed an exclusive human milk diet because of the
16 risk of NEC associated with the consumption of cow's milk-based products. The
17 Academy stated that "[t]he potent benefits of human milk are such that all pre-term
18 infants should receive human milk ... If the mother's own milk is
19 unavailable...pasteurized donor milk should be used." Breastfeeding and the Use
20 of Human Milk, PEDIATRICS, 129:e827-e841 (2012).

21 21. A study published in 2013 showed that, out of 104 the premature infants
22 participating in the study receiving an exclusive human-milk based diet, all 104
23 exceeded targeted growth standards, as well as length, weight, and head
24 circumference gain. The authors concluded that "this study provides data showing
25 that infants can achieve and mostly exceed targeted growth standards when receiving
26 an exclusive human milk-based diet." A. Hair, et al., *Human Milk Feed Supports*
27 *Adequate Growth in Infants \leq 1250 Grams Birthweight*, BMC RESEARCH NOTES,
28 6- 459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding

1 cow's milk-based products, but the practice continued largely due to extensive and
2 aggressive marketing campaigns conducted by infant formula companies.

3 22. In another study published in 2013 it was reported: "This is the first
4 randomized trial in EP [Extremely Premature] infants of exclusive HM [Human
5 Milk] vs. PF [Preterm Formula]. The significantly shorter duration of TPN and
6 lower rate of surgical NEC support major changes in the strategy to nourish EP
7 infants in the NICU." Cristofalo, E.A., et al., *Exclusive Human Milk vs. Preterm*
8 *Formula: Randomized Trial in Extremely Preterm Infants*. (J Pediatr 2013 Dec;
9 163(6): 1592-1595.)

10 23. In a study published in 2014, it was reported: "Necrotizing enterocolitis
11 (NEC) is a devastating disease of premature infants and is associated with significant
12 morbidity and mortality. While the pathogenesis of NEC remains incompletely
13 understood, it is well established that the risk is increased by the administration of
14 infant formula and decreased by the administration of breast milk." Good, Misty, et
15 al., *Evidence Based Feeding Strategies Before and After the Development of*
16 *Necrotizing Enterocolitis*. (Expert Rev Clin Immunol. 2014 July; 10 (7): 875-884.)

17 24. In that same article it was reported: "Necrotizing enterocolitis (NEC) is
18 the most frequent and lethal gastrointestinal disorder affecting preterm infants, and
19 is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-
20 system organ failure and death. NEC affects 7-12% of preterm infants weighing less
21 than 1500 grams, and the frequency of disease appears to be either stable or rising
22 in several studies. The typical patient who develops NEC is a premature infant who
23 displays a rapid progression from mild feeding intolerance to systemic sepsis, and
24 up to 30% of infants will die from this disease."

25 25. In that same article it was reported: "A wide variety of feeding practices
26 exist on how to feed the premature infant in the hopes of preventing necrotizing
27 enterocolitis. There have been several meta-analysis reviewing the timing of
28 administration and rate of advancement of enteral feedings in the premature infant

1 as reviewed above, but there is no consensus on the precise feeding strategy to
2 prevent this disease. The exclusive use of human breast milk is recommended for
3 all premature infants and is associated with a significant decrease in the incidence of
4 NEC. By determining the specific ingredients in breast milk that are protective
5 against NEC, it is our hope that this devastating disease will one day be preventable.”

6 26. In a study published in 2016 it was reported: “Extremely premature
7 infants who received an exclusive HUM diet had a significantly lower incidence
8 of NEC and mortality. The HUM group also had a reduction in late-onset sepsis,
9 BPD, and ROP. This multicenter study further emphasizes the many benefits of
10 an exclusive HUM diet, and demonstrates multiple improved outcomes after
11 implementation of such a feeding protocol.” Hair, Amy, et al. *Beyond*
12 *Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive*
13 *Human Milk-Based Diet*. (Breastfeeding Medicine. 2016, Nov. 2, 11(2):70-75.)

14 27. In a study published in 2017, it was reported: “Human milk is the
15 preferred diet for preterm infants as it protects against a multitude of NICU
16 challenges, specifically necrotizing enterocolitis. Infants who receive greater
17 than 50% of mother’s own milk (MOM) in the 2 weeks after birth have a
18 significantly decreased risk of NEC. An additional factor in the recent declining
19 rates of NEC is the increased utilization of donor human milk (DHM). This
20 creates a bridge until MOM is readily available, thus decreasing the exposure to
21 cow milk protein. Preterm infants are susceptible to NEC due to the immaturity
22 of their gastrointestinal and immune systems. An exclusive human milk diet
23 compensates for these immature systems in many ways such as lowering gastric
24 pH, enhancing intestinal motility, decreasing epithelial permeability, and
25 altering the composition of bacterial flora. Ideally, preterm infants should be fed
26 human milk and avoid bovine protein. A diet consisting of human milk-based
27 human milk fortifier is one way to provide the additional nutritional supplements
28 necessary for adequate growth while receiving the protective benefits of a human

1 milk diet.” Maffei, Diana, Schanler, Richard J., *Human milk is the feeding*
2 *strategy to prevent necrotizing enterocolitis!* (Semin Perinatol. 2017 Feb;
3 41(1):36-40.).

4 28. In another study published in 2017, it was reported: “In summary,
5 HM [Human Milk] has been acknowledged as the best source of nutrition for
6 preterm infants and those at risk for NEC. Two RCTs [Randomized Clinical
7 Trials] on preterm infants weighing between 500 and 1250 g at birth compared
8 the effect of bovine milk-based preterm infant formula to MOM or DHM on the
9 incidence of NEC. Both trials found that an exclusive HM diet results in a lower
10 incidence of NEC. A Cochrane systematic review that evaluated the effect of
11 DHM or bovine milk-based formula on health outcomes for preterm infants also
12 determined that formula significantly increases the risk of NEC.” Shulhan,
13 Jocelyn, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm*
14 *Infants and the Impact of Different Types of Enteral Nutrition Products.* (ASN.
15 ADV Nutr 2017; 8:8-0.91.)

16 29. Yet another study that analyzed the data from a 12-center randomized
17 trial concluded that fortification of breast milk with a cow’s milk-based fortifier
18 resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical
19 NEC or death, compared to fortification with a breast milk-based fortifier.

20 30. Another study conducted a randomized comparison of extremely
21 preterm infants who were given either (a) a diet of breast milk fortified with a breast
22 milk-based fortifier or (b) a diet containing variable amounts of cow’s milk-based
23 products. The babies given exclusively breast milk products suffered NEC 5% of the
24 time. The babies given cow’s milk products suffered NEC 17% of the time.

25 31. Further, when Defendants recognized a shift in the medical community
26 towards an exclusive breast milk-based diet for premature infants, Abbott developed
27 a product called “Similac Human Milk Fortifier.” Similar to the “Human Milk”
28 formula, these names are misleading in that they suggest that the products are

1 derived from breast milk, when, in fact, they are cow’s milk-based products. One
2 study, for example, found that 91.2 percent of parents surveyed in the NICU
3 interpreted “human milk fortifier” as potentially meaning breast milk-based product.

4 32. Abbott’s packaging directs users to: “Add only to human milk—do not
5 add water.” This direction is convoluted by Abbott’s misleading use of the term
6 human milk. The fortifier can be added to Abbott’s “Human Milk” formula, as well
7 as breast milk. There is no indication that the fortifier is only meant to be added to
8 breast milk, and even if this was the intended direction, the widespread
9 misapplication of the fortifier to Abbott’s “Human Milk” formula would be its own
10 doing by deliberately conflating and misdirecting the delineation of “human milk.”

11 The packaging appears as:



22 33. Defendants have designed powerful misleading marketing campaigns
23 to deceive parents into believing that: (1) cow’s milk-based products are safe,
24 including for preterm infants; (2) cow’s milk-based products are equal, or even
25 superior, substitutes to breast milk; (3) cow’s milk-based products are necessary for
26 proper growth and development of preterm infants; and (4) physicians consider
27 Defendants’ cow’s milk-based products a first choice. This marketing scheme is
28 employed despite Defendants knowing of and failing to warn of the extreme risk of

1 NEC and death that cow’s milk-based products pose to preterm infants like baby
2 Richardson.

3 34. The products Abbott markets specifically for premature infants are
4 available at retail locations and online. No prescription is necessary. As seen above,
5 Abbott’s packaging failed to give any precaution to use the product under the
6 direction of a physician, however, newer packaging includes such a caution: “To be
7 used only under the supervision of a doctor.” The packaging seems to be changed
8 recently to include this warning and products with the older packaging are still
9 widely available to buy online.

10 35. Despite knowing of the risk of NEC, Abbott did not warn of the
11 significantly increased risk of NEC (and resulting medical conditions, and/or death)
12 associated with its products, or of the magnitude of this increased risk. Abbott
13 likewise did not provide instructions or guidance for how to avoid NEC.

14 36. Abbott deceived the public, parents, physicians, other medical
15 professionals, and medical staff into believing that its products were a safe and
16 necessary alternative, supplement and/or substitute to breast milk.

17 37. Despite knowing that its products were being fed to premature infants,
18 often without the parents’ informed consent, Abbott failed to require or recommend
19 that medical professionals or hospitals inform parents of the significant risk of NEC
20 or to require that parental consent be obtained prior to the products being fed to their
21 babies.

22 38. On information and belief, Abbott was aware of the significantly
23 increased risk of NEC and death associated with their cow’s milk-based products,
24 and instead of warning of the dangers, or removing them altogether, Abbott has
25 continued to use cow’s milk as the foundation of their products. Abbott fails to
26 mention “cow’s milk” anywhere on its packaging, and surreptitiously refers to cow’s
27 milk under its ingredients as “Nonfat Milk.” The words “cow’s milk” or “cow” are
28 nowhere to be found on any of the packaging or marketing for its product.

1 ***Abbott’s Failure to Provide Adequate Warnings, Instructions or Guidelines***

2 39. Defendant Abbott Laboratories, Inc. manufactures, designs,
3 formulates, prepares, tests, provides instructions, markets, labels, packages, places
4 into the stream of commerce in all fifty states, including California, and sells
5 premature infant formula and fortifier.

6 40. Abbott’s Similac product contained only the following packaging
7 information guidelines, instructions and warnings:

8 “Similac Special Care 20 – Precautions:

- 9 • Very low-birth-weight infants are particularly susceptible to
10 gastrointestinal complications; therefore, feeding should be initiated
11 cautiously
12 • Tolerance to enteral feedings should be confirmed by initially offering
13 small volumes of formula followed by cautious progression to higher
14 caloric feedings
15 • Spitting up, abdominal distention, abnormal stools or stool patterns,
16 excessive gastric residuals, or other signs of intestinal dysfunction have
17 been associated with enteral feeding before the intestinal tract is ready
18 to accommodate the regimen. At the first sign of these problems, enteral
19 feeding should be slowed or discontinued
20 • Not intended for feeding low-birth-weight infants after they reach a
21 weight of 3600 g (approximately 8 lb) or as directed by a physician”

22 “Similac Special Care 24 – Precautions:

- 23 • Very low-birth weight infants are particularly susceptible to
24 gastrointestinal complications; therefore, feeding should be initiated
25 cautiously
26 • Tolerance to enteral feedings should be confirmed by initially offering
27 small volumes of formula followed by cautious progression to higher
28 caloric feedings
• Spitting up, abdominal distention, abnormal stools or stool patterns,
excessive gastric residuals, or other signs of intestinal dysfunction have
been associated with enteral feeding before the intestinal tract is ready
to accommodate the regimen. At the first sign of these problems, enteral
feeding should be slowed or discontinued
• Not intended for feeding low-birth-weight infants after they reach a
weight of 3600 g (approximately 8 lb) or as directed by a physician”

“Similac Special Care 24 High Protein – Precautions:

- 1 • Very low-birth-weight infants are particularly susceptible to
2 gastrointestinal complications; therefore, feeding should be initiated
3 cautiously
- 4 • Tolerance to enteral feedings should be confirmed by initially offering
5 small volumes of formula followed by cautious progression to higher
6 caloric feedings
- 7 • Spitting up, abdominal distention, abnormal stools or stool patterns,
8 excessive gastric residuals, or other signs of intestinal dysfunction have
9 been associated with enteral feeding before the intestinal tract is ready
10 to accommodate the regimen. At the first sign of these problems, enteral
11 feeding should be
12 slowed or discontinued.
- 13 • Not intended for feeding low-birth-weight infants after they reach a
14 weight of 3600 g (approximately 8 lb) or as directed by a physician

11 “Similac Special Care 30 – Precautions:

- 12 • Very low-birth-weight infants are particularly susceptible to
13 gastrointestinal complications; therefore, feeding should be initiated
14 cautiously
- 15 • Use this product only after feedings of lower caloric density are well-
16 established. For improved tolerance, it is best to increase caloric density
17 slowly, by 2- to 4-Cal/fl oz increments
- 18 • Hydration status should be monitored
- 19 • Spitting up, abdominal distention, abnormal stools or stool patterns,
20 excessive gastric residuals, or other signs of intestinal dysfunction have
21 been associated with enteral feeding before the intestinal tract is ready
22 to accommodate the regimen. At the first sign of these problems, enteral
23 feeding should be slowed or discontinued
- 24 • Not intended for feeding low-birth-weight infants after they reach a
25 weight of 3600 g (approximately 8 lb) or as directed by a physician”

22 “Similac Special Care Premature 20 calorie and 24 calorie and High Protein
23 Precaution:

- 24 • If signs of intolerance develop, slow feeding or discontinue.
- 25 • Not intended for low-birth-weight infants after they reach a weight of
26 3600 grams (approx.. 8 lb) or as directed by a doctor.”

26 “Similac Special Care Premature 30 calorie – Precaution:

- 27 • Use once feeding tolerance is established
- 28 • If signs of intolerance develop, slow feeding or discontinue.
- Hydration status should be monitored

- 1 • Not intended for low-birth-weight infants after they reach a weight of
2 3600 grams (approx.. 8 lb) or as directed by a doctor.”

3 41. Defendant Abbott’s product, Similac Alimentum and Similac
4 Alimentum Expert Care, contain only the following packaging information warnings
5 and instructions:

6 Safety Precautions: Never use a microwave oven to warm
7 mixture. Serious burns can result.

8 Warning: Powdered infant formulas are not sterile and should
9 not be fed to premature infants or infants who might have
10 immune problems unless directed and supervised by your baby’s
11 doctor.

12 42. Defendant Abbott’s range of Human Milk Fortifiers contain only the
13 following packaging information warnings and instructions:

14 Similac Human Milk Fortifier Concentrated Liquid: Precautions

- 15 • Add only to human milk—do not add water
- 16 • This product is nutritionally incomplete by itself and is designed
17 to be added to human breast milk

18 Similac Human Milk Fortifer Hydrolyzed Protein Concentrated Liquid:
19 Precautions

- 20 • Add only to human milk—do not add water
- 21 • This product is nutritionally incomplete by itself and is designed
22 to be added to human breast milk
- 23 • Additional iron may be necessary
- 24 • Tolerance to enteral feedings should be confirmed by offering
25 small volumes of unfortified human milk
- 26 • Once enteral feeding is well established, Similac Human Milk
27 Fortifier Hydrolyzed Protein Concentrated Liquid can be added
28 to human milk
- Not intended for feeding low-birth-weight infants after they
reach a weight of 3600 g (approximately 8 lb) or as directed by
a physician

Similac Human Milk Fortifier Powder: Precautions

- Add only to human milk—do not add water

- 1 • Tolerance to enteral feedings should be confirmed by offering
 - 2 small volumes of unfortified human milk
 - 3 • Once enteral feeding is well established, Similac Human Milk
 - 4 Fortifier Power can be added to human milk (see Preparation,
 - 5 page 29)
 - 6 • Not intended for feeding low-birth-weight infants after they
 - 7 reach a weight of 3600 g (approximately 8 lb) or as directed by
 - 8 a physician
- 9 1. Barrett-Reis B, et al. Pediatrics. 2000;106:581-588.
 - 10 2. Chan GM. J Perinatol. 2003;23:620-623.
 - 11 3. *Escherichia coli, Staphylococcus, Group B Streptococcus, and
 - 12 Enterobacter sakazakii (now Cronobacter sakazakii).

13 Liquid Protein Fortifier: Precaution

- 14 • If signs of intolerance develop, slow feeding or discontinue.

15 43. Science and research have advanced in recent years confirming the

16 dangers of the defendant's cow's milk-based product in causing NEC and death in

17 premature infants, yet the Defendant did nothing to change its product, packaging,

18 guidelines, instructions and warnings.

19 44. The warnings and instructions are overly broad and vague, and do not

20 ever mention that the product significantly increases the risk of NEC and death, nor

21 provide any detailed instructions or evidence on when and how to feed the infants

22 and how to avoid NEC and death when feeding its products.

23 45. None of this medical literature properly warns the user that its product

24 causes NEC and death nor does it provide guidance on how to avoid NEC or death

25 while using its product.

26 46. Despite knowing that its product significantly increases the risk of NEC

27 and death, Abbott Laboratories, Inc. deliberately chose to omit a specific warning of

28 NEC or death, and deliberately failed to provide any detailed instructions or

guidance on how to avoid NEC or death when feeding Similac.

47. The cow's milk-based product, Similac, is dangerous to premature

infants in that it significantly increases the risk that the baby will develop NEC.

1 48. The cow's milk-based product, Similac, is dangerous to premature
2 infants in that it significantly increases the risk that the baby will develop NEC and
3 die.

4 49. The Defendant, Abbott Laboratories, Inc., failed to properly warn that
5 its product, Similac, can significantly increase the risk that the premature infant will
6 develop NEC and suffer catastrophic injuries as occurred to Baby Richardson.

7 50. Based on information and belief, Abbott Laboratories, Inc.'s cow's
8 milk-based product, Similac, did cause Baby Richardson to develop NEC.

9 51. Prior to February 2019, the Defendant, Abbott Laboratories, Inc. was
10 aware, or should have been aware, that its product was not safe for use, as it was
11 used, in the premature infant, Nepoleon Richardson, yet they took no steps to prevent
12 its use in such a situation.

13 52. The Defendant, Abbott Laboratories, Inc. did foresee, or should have
14 foreseen, that its product would be used as it was in the case of Nepoleon Richardson
15 and knew or should have known, that such use would significantly increase the risk
16 of NEC in Nepoleon Richardson, yet it took no steps to prevent such use.

17 53. The product, Similac, was not safe to be used as it was in the case of
18 Nepoleon Richardson, and the Defendant knew, or should have known, it was
19 unsafe, yet it failed to properly instruct, or warn the FDA, NICUs, hospitals, doctors
20 and parents that its product was not safe.

21 54. The product, Similac, was not safe to be used as it was in the case of
22 Nepoleon Richardson and the Defendant knew or should have known it was unsafe,
23 yet it failed to provide detailed instructions or guidelines on when and how its
24 product would be safe to use in a premature infant like Nepoleon Richardson.

25 55. The Defendant, Abbott Laboratories, Inc, has marketed its products as
26 safe and beneficial for premature infants like Nepoleon Richardson.

27 56. Because the Defendant Abbott Laboratories, Inc.'s product is specially
28 designed as food for vulnerable premature infants and contains no warning that it

1 causes death or NEC, it is viewed as safe by physicians and parents of premature
2 infants.

3 57. Because the Defendant Abbott Laboratories, Inc.’s product is specially
4 designed as food for vulnerable premature infants and requires that no warning of
5 NEC or death be given to parents or an informed consent be provided by hospitals
6 or doctors, it is viewed as safe by physicians and parents of premature infants.

7 58. The Defendant, Abbott Laboratories, Inc. has promoted its product for
8 premature infants and claim its product increases the baby’s weight and caloric
9 intake and its product is more beneficial than harmful.

10 59. Notwithstanding strong medical evidence establishing the extreme
11 dangers that cow’s milk-based products pose for premature infants, Abbott
12 Laboratories, Inc. has marketed its cow’s milk-based products as an equally safe
13 alternative to breast milk, and has promoted its products as necessary for additional
14 nutrition and growth. The Defendant has specifically marketed its formula and
15 fortifier as necessary to the growth and development of *premature infants*, when
16 indeed its product poses a known and substantial risk to these babies.

17 60. Moreover, Abbott Laboratories, Inc. has also attempted to market its
18 products specifically to *premature infants*, who are the infants at highest risk from
19 the dangers of the product.

20 61. As of 2016, Abbott Laboratories, Inc. marketed and sold seven products
21 specifically targeting “Premature/Low birth-Weight Infants”: Liquid Protein
22 Fortifier, Similac® NeoSure®, Similac® Human Milk Fortifiers, Similac® Special
23 Care® 20, Similac® Special Care® 24, Similac® Special Care® 24 High Protein,
24 and Similac® Special Care® 30.

25 62. With the proliferation of the internet, the Defendant, Abbott
26 Laboratories, Inc., has updated its tactics to advertise heavily online and through its
27 own website.

28

1 63. In this promotional website, there is no mention of the risk of
2 necrotizing enterocolitis. The promotional web page expressly and implicitly
3 represents that its cow's milk-based products are safe for use with premature infants.
4 This is false and misleading. Abbott Laboratories, Inc. advertisements claim to give
5 proper nourishments but fails to disclose the risk.

6 64. Thus, despite the existence of alternative and safe human milk-based
7 formulas and fortifiers, Defendant Abbott continues to market and/or sell its cow's
8 milk-based products under the guise of being safe for newborns and despite knowing
9 the significant health risk posed by ingesting these products, especially to preterm,
10 low weight infants, like Napoleon Richardson.

11 65. Abbott Laboratories, Inc. knew or should have known that its product
12 would be used in the way it was used on this premature infant, Napoleon Richardson.

13 66. The way in which the Defendant Abbott Laboratories, Inc. product was
14 fed to Baby Richardson was extremely dangerous and caused an unreasonably high
15 risk that he would develop NEC, yet the defendant, Abbott Laboratories, Inc.,
16 provided no detailed instructions or warnings to prevent or alter the way this product
17 was used.

18 67. The Defendant, Abbott Laboratories, Inc. has learned that its cow's
19 milk-based product was causing NEC, devastating injuries, and death in premature
20 infants, yet Defendant Abbott did nothing to change its product, packaging,
21 guidelines, instructions and warnings.

22 68. The mother, Latrice Richardson, was never told that the Similac
23 product could cause her baby to develop NEC.

24 69. The mother, Latrice Richardson, was never told that the Similac
25 product could cause her baby any harm.

26 70. The mother, Latrice Richardson, was never told that the Similac was
27 made from cow's milk.

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1 77. Defendant Mead’s product, Enfamil Human Milk Fortifier, contained
2 only the following packaging information guidelines, instructions and warnings:

3 Warning: Your baby’s health depends on carefully following the
4 instructions below. Use only as directed by a medical professional.
5 Improper hygiene, preparation, dilution, use or storage may result in
6 severe harm. Although this powder is formulated for premature infants,
7 nutritional powders are not sterile and should not be fed to premature
8 infants or infants who might have immune problems unless directed and
9 supervised by your baby’s doctor.

10 Caution: Nutritionally Incomplete: To be used only under the
11 supervision of a physician.

12 Caution: Regarding use in extremely low-birth-weight infants (ELBW
13 -1 kg or less): Hypercalcemia has been reported in some of these infants
14 on full enteral feeds of human milk supplemented with human milk
15 fortifiers.

16 78. The product, Enfacare Powder, contained only the following packaging
17 information guidelines, instructions and warnings:

18 “Warning: Your baby’s health depends on carefully following the
19 instructions below. Use only as directed by a medical professional.
20 Improper hygiene, preparation, dilution, use or storage may result in
21 severe harm. Although this powder is formulated for infants born
22 prematurely, powdered infant formulas are not sterile and should not be
23 fed to premature infants or infants who might have immune problems
24 unless directed and supervised by your baby’s doctor. Ask your baby’s
25 doctor which formula is appropriate for your baby.”

26 79. Defendant Mead cited no medical literature or research to guide the user
27 for its product, Enfacare Powder, nor that its product causes or significantly
28 increases the risk of NEC or death.

80. As previously discussed, science and research have advanced in recent
years confirming the dangers of the Defendant Mead’s cow’s milk-based product in
causing NEC and death in premature infants, yet Defendant Mead did nothing to
change its product, packaging, guidelines, instructions and warnings.

1 81. The warnings and instructions are overly broad and vague, and do not
2 ever mention that the product significantly increases the risk of NEC and death, nor
3 provide any detailed instructions or evidence on when and how to feed the infants
4 and how to avoid NEC and death when feeding its products.

5 82. Despite knowing that its product significantly increases the risk of NEC
6 and death, Defendant Mead deliberately chose to omit a specific warning of NEC or
7 death, and deliberately failed to provide any detailed instructions or guidance on
8 how to avoid NEC or death when feeding Enfamil.

9 83. Enfamil contains bovine or cow's milk-based formula.

10 84. The cow's milk-based formula product, Enfamil, is dangerous to
11 premature infants in that it significantly increases the risk that the baby will develop
12 NEC.

13 85. The cow's milk-based formula product, Enfamil, is dangerous to
14 premature infants in that it significantly increases the risk that the baby will die.

15 86. The Defendant, Mead, failed to properly warn that its product, Enfamil,
16 can significantly increase the risk that the premature infant will develop NEC and
17 suffer catastrophic injuries as occurred to Napoleon Richardson.

18 87. The Defendant, Mead's cow's milk-based formula product, Enfamil,
19 did cause Baby Richardson to develop NEC.

20 88. Prior to February 2019, the Defendant, Mead, was aware, or should
21 have been aware, that its product was not safe for use, as it was used, in the premature
22 infant, Napoleon Richardson, yet it took no steps to prevent its use in such a
23 situation.

24 89. The Defendant, Mead did foresee, or should have foreseen, that its
25 product would be used as it was in the case of Napoleon Richardson, and knew or
26 should have known, that such use would significantly increase the risk of NEC in
27 Napoleon Richardson, yet it took no steps to prevent such use.

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1 90. The product, Enfamil, was not safe to be used as it was in the case of
2 Napoleon Richardson, and the Defendant Mead knew, or should have known, it was
3 unsafe, yet it failed to properly instruct or warn the FDA, NICUs, hospitals, doctors
4 and parents that its product was not safe.

5 91. The product, Enfamil, was not safe to be used as it was in the case of
6 Napoleon Richardson and the Defendant, Mead, knew, or should have known, it was
7 unsafe, yet it failed to provide detailed instructions or guidelines on when and how
8 its product would be safe to use in a premature infant like Napoleon Richardson.

9 92. The Defendant, Mead, has marketed its products as safe and beneficial
10 for premature infants like Napoleon Richardson.

11 93. Because the Mead product is specially designed as food for vulnerable
12 premature infants and contains no warning that it causes death or NEC, it is viewed
13 as safe by physicians and parents of premature infants.

14 94. The Defendant, Mead, has marketed and sold its products as safe and
15 beneficial for premature infants like Napoleon Richardson.

16 95. The Defendant, Mead, has promoted its products for extremely
17 premature infants and claim its products increases the babies' weight and caloric
18 intake and its product is more beneficial than harmful.

19 96. The studies show the Mead products should not be sold for use in
20 extremely premature infants, yet Defendant Mead continued to market and sell its
21 product knowing it would be used on infants like Napoleon Richardson and knowing
22 its product would significantly increase the risk of NEC and death in extremely
23 premature infants like Napoleon Richardson.

24 97. Defendant Mead promotes a range of products specifically for
25 "premature and low weight" babies on their website: Enfamil Human Milk Fortifier
26 Liquid High Protein, Enfamil Milk Fortifier Liquid Standard Protein, Enfamil
27 NeuroPro Enficare, Enfamil Premature 20 Cal, Enfamil Premature 24 Cal, Enfamil
28 Premature 24 Cal/fl oz HP, Enfamil Premature 30 Cal, Enfamil Human Milk

1 Fortifier Acidified Liquid, Enfamil Human Milk Fortifier Powder, Enfamil 24 and
2 DHA & ARA Supplement.

3 98. Notwithstanding strong medical evidence establishing the extreme
4 dangers that cow's milk-based products pose for premature infants, Defendant Mead
5 have marketed their cow's milk-based products as equally safe alternatives to breast
6 milk, and have promoted their products as necessary for additional nutrition and
7 growth. Defendant Mead has specifically marketed its formula and fortifiers as
8 necessary to the growth and development of premature infants, when indeed the
9 products pose a known and substantial risk to these babies.

10 99. Mead knew or should have known that its product would be used in the
11 way it was used on this premature infant, Nepoleon Richardson.

12 100. The way in which the Mead product was fed to Nepoleon Richardson
13 was extremely dangerous and caused an unreasonably high risk that he would
14 develop NEC, yet the defendant, Mead, provided no detailed instructions or
15 warnings to prevent or alter the way this product was used.

16 101. The Defendant, Mead, has learned that its cow's milk-based product
17 was causing NEC, devastating injuries, and death in premature infants, yet
18 Defendant did nothing to change its product, packaging, guidelines, instructions and
19 warnings.

20 102. The mother, Latrice Richardson, was never told that the Enfamil
21 formula could cause her baby to develop NEC.

22 103. The mother, Latrice Richardson, was never told that the Enfamil
23 formula could cause her baby any harm.

24 104. If the mother had known of the significant risks of feeding Enfamil to
25 her premature infant, she would not have allowed the product to be fed to her baby.

26 105. Mead has known for many years that their Enfamil premature infant
27 products are causing premature infants to develop NEC, devastating injuries, and die
28 and know that hospitals and physicians around the United States are not informing

1 the parents of this risk and Defendant Mead Johnson promotes this silence to protect
2 its brands and profits.

3 106. The FDA requires manufacturers of prescription medications to study
4 their medications and perform drug trials and collect data to determine the safety and
5 efficacy of their drugs and to determine the likelihood of side effects and to
6 continuously study the drug's use to review adverse outcomes and create proper
7 warnings and instructions; however, because baby formulas, such as Enfamil, are
8 not drugs, the manufacturer, Mead does not perform such trials and does not collect
9 data on when and how the formula should be fed. Despite knowing for decades that
10 the products are significantly increasing NEC and death in premature infants, and
11 are far more dangerous than most prescription drugs, Mead is doing nothing to stop
12 or lessen NEC or death.

13 107. If Mead had performed the pharmacovigilance required by drug
14 manufacturers for their premature infant formulas and fortifiers, these products
15 would not have been fed to Napoleon Richardson and he would not have developed
16 NEC and he would not have suffered the devastating effects of NEC.

17 108. The products made from cow's milk, specifically for premature infants
18 by Enfamil, are unsafe to premature infants and are avoidable for use in that there is
19 human donor milk available and/or human milk derived fortifier products available
20 made from human milk instead of cow's milk.

21 109. Despite knowing that its cow's milk-based product was causing NEC,
22 devastating injuries, and death in premature infants, Mead did not recommend to the
23 FDA, hospitals, NICUs or physicians that they should discuss the risks of NEC or
24 death with the parents.

25 110. There are human milk based formulas and fortifier products which are
26 feasible alternatives to the premature infant formula and fortifier products offered
27 by Mead Johnson.

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1 **DAMAGES SUFFERED BY PLAINTIFFS**

2 111. As a result of his exposure to Abbott and/or Mead’s cow’s milk based
3 products, Napoleon Richardson was required to undergo medical care and costs.
4 Napoleon Richardson was diagnosed with and required surgery to remove one-third
5 of his small and large intestines.

6 112. Also, his mother, Latrice Richardson, suffered extensive financial loss
7 and costs and emotional harm and distress related to her son’s injuries.

8 **COUNT I**
9 **FAILURE TO WARN**
10 **(As to All Defendants)**

11 113. Plaintiff realleges all paragraphs previous and subsequent to this
12 paragraph as if fully set forth herein.

13 114. Defendants, as the manufacturer and/or seller of the product at issue in
14 this litigation, owed a duty to the consuming public in general, and Plaintiff in
15 particular, to properly warn and provide adequate warnings or instructions about the
16 dangers and risks associated with the use of such products with preterm infants,
17 specifically including but not limited to the risk of NEC and serious bodily injury.

18 115. Defendants, as the manufacturer and/or seller of the product at issue in
19 this litigation, was unreasonable in relying upon any intermediary, including
20 physicians, other health care providers or health care staff, to fully warn the end user
21 of the hidden dangers and risks in its Similac products that contained cow’s milk
22 based ingredients, as the magnitude of the risk involved is using Abbott’s Similac
23 with preterm infants is significant and involves the real danger of serious bodily
24 injury and potentially death.

25 116. Defendants’ duty to warn is part of its general duty to design,
26 manufacture, and sell its products that are reasonably safe for their foreseeable uses
27 and by designing Similac and/or Enfamil with cow’s milk-based ingredients,
28 Defendants undertook a duty to adequately warn of the unreasonable risk of harm

1 posed by such ingredients and specifically the increased risk of NEC, bodily injury,
2 and even death of use of the such products by pre-term infants like Plaintiff. The
3 failure to warn creates a defect and makes the Similac and Enfamil products at issue
4 in this litigation unreasonably dangerous.

5 117. Specifically, Defendants breached their duty to warn of the foreseeable
6 risks of the Similac and Enfamil products at issue in this litigation because
7 Defendants knew or should have known that its cow's milk based product (or its
8 instructions/label):

- 9 a. Would be used, as it was, on premature infants like Napoleon
10 Richardson yet it failed to properly warn hospitals, NICUs, doctors,
11 parents and/or consumers that their cow's milk-based product
12 significantly increases the risk of NEC and death in these babies;
13 and/or
- 14 b. Was unsafe and/or contra-indicated for premature infants like
15 Napoleon Richardson; and/or
- 16 c. Failed to provide proper instructions or guidelines or studies, or data
17 on when and how to feed their products to premature infants in order
18 to decrease the risk of NEC and/or death; and/or
- 19 d. Failed to insert a warning or instruction that parents needed to be
20 provided an informed choice between the safety of human milk
21 versus the dangers of the Defendant's cow's milk-based product;
22 and/or
- 23 e. Failed to provide instructions that parents needed to know that the
24 Defendant's product carried a significant risk that its cow's milk-
25 based product could cause their baby to develop NEC and die;
26 and/or
- 27 f. Carried warnings and instructions that are severely inadequate,
28 vague, confusing, and provide a false sense of security in that they
warn and instruct specifically on certain conditions, but do not warn
on cow's milk-based products significantly involving the risk of
NEC and death or providing any details on how to avoid such harm;
and/or
- g. Failed to have a large and prominent "black box" type warning that
their cow's milk-based products are known to significantly increase
the risk of NEC and death when compared to Human Milk in
premature infants; and/or

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- h. Failed to provide well researched and well-established studies that linked their cow’s milk-based products to NEC and death in premature infants; and/or
- i. Failed to cite to or utilize current up to date medical data on the proper and safe use of their products; and/or
- j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow’s milk-based product; and/or
- k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or
- l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or
- m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, Nepoleon Richardson was fed cow’s milk-based products which caused him to develop NEC; and/or
- n. Science and data have established that the only consistent observations made in infants who develop NEC are the presence of: 1) prematurity 2) cow’s milk based products, yet Defendants fail to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or
- o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to Nepoleon Richardson; and/or
- p. Failed to establish a standard for safe use; and/or
- q. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or
- r. Failed to provide statistical evidence of adverse effects regarding the feeding of their products; and/or
- s. Failed to guide or instruct on when to start, how much to start, how to increase, volume and timing of feeds, when not to feed, and/or when to stop feeding their products to premature infants; and/or
- t. Failed to provide periodic or yearly safety reports; and/or
- u. Failed to provide periodic or yearly risk-benefit analysis for use of their products; and/or
- v. Failed to provide or produce yearly safety update reports; and/or
- w. Failed to develop a protocol for hospitals and physicians with the elements to assure safe use; and/or
- x. Failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of their products specifically designed for premature infants.

1 118. Moreover, had physicians and healthcare providers known of the
2 extreme risk associated with feeding premature infants cow's milk-based products,
3 they would have not used such a dangerous product on Napoleon Richardson. Had
4 Makai Sander's mother known of the extreme risks associated with feeding
5 premature infants cow's milk-based product, she would have not allowed such a
6 product to be given to her son.

7 119. As a result and proximate cause, Baby Richardson was fed Defendant
8 Abbott's Similac and Defendant Mead's Enfamil cow's milk-based product causing
9 him to develop NEC.

10 120. As a direct and proximate result of Defendants' failure to warn as
11 explained herein Plaintiff Latrice Richardson suffered significant emotional distress,
12 loss of income, and other harms as her life has been significantly affected as a direct
13 and proximate result of Defendants' conduct described herein.

14 **COUNT II**
15 **STRICT LIABILITY FOR DEFECTIVE PRODUCT**
16 **(Against All Defendants)**

17 121. Plaintiff realleges all paragraphs previous and subsequent to this
18 paragraph as if fully set forth herein.

19 122. Defendants as the manufacturer and/or seller of the products at issue in
20 this litigation, owed a duty to the consuming public in general, and Plaintiff in
21 particular, to manufacture, sell, and distribute its Similac and Enfamil infant
22 products in a manner that was not unreasonably dangerous and is liable despite any
23 care exercised to design a safe product.

24 123. Despite knowing that its product would be used on premature infants,
25 like Napoleon Richardson, and despite knowing (or should have known) that such
26 use was unreasonably dangerous to premature infants in that its cow's milk-based
27 product was significantly increasing the risk of NEC and death, the Defendants
28 continued to sell and market their defective products to premature infants.

124. Over the last several years, scientific data and well researched studies

1 have concluded that the cow's milk-based products of the Defendants carried
2 unreasonable risks of NEC and death, which far outweighed the product's benefits,
3 yet the Defendants continued to market and sell their defective products for
4 premature infants like Napoleon Richardson.

5 125. The Defendants' cow's milk-based products, Similac and Enfamil, fed
6 to Napoleon Richardson was unreasonably dangerous.

7 126. The risks of feeding the Defendants; cow's milk-based products,
8 Similac and Enfamil, to Napoleon Richardson outweighed its benefits.

9 127. Defendants failed to develop a human-based milk product which was
10 safer for premature infants although they knew of this development and were aware
11 of its superiority to the products that it offered.

12 128. Defendants also failed to properly reformulate their products to reduce
13 the risks of NEC, devastating injuries, and/or death even though they knew of safer,
14 more effective alternative reformulations that would have made their products safer
15 to use and not carry the added and significant risk of NEC.

16 129. As a direct result Defendants' unreasonably dangerous products were
17 fed to Baby Richardson causing him to develop NEC, and required surgery to
18 remove one-third of his small and large intestines.

19 130. As a direct and proximate result of Defendants' developing,
20 manufacturing, selling, and distributing their unreasonably dangerous cow's milk
21 based products, Plaintiff Latrice Richardson suffered significant emotional distress,
22 loss of income, and other harms as her life has been significantly affected as a direct
23 and proximate result of Defendants' conduct described herein.

24 **COUNT III**
25 **NEGLIGENCE**
26 **(As to All Defendants)**

27 131. Plaintiff realleges all paragraphs previous and subsequent to this
28 paragraph as if fully set forth herein.

132. Defendants as the designer, manufacturer, seller, and distributor of the

1 cow's milk products that are the subject of this action had a duty to the general public
2 and to the Plaintiff to exercise reasonable care to design, test, manufacture, inspect,
3 and distribute a product free of unreasonable risk of harm to users, when said
4 products are used in their intended manner and for their intended purpose.

5 133. At all relevant times to this action Napoleon Richardson used the
6 products at issue in their intended manner and for their intended purpose.

7 134. Defendants, directly or indirectly, negligently and/or defectively made,
8 created, manufactured, designed, assembled, tested, marketed, sold, and/or
9 distributed the cow's milk based products and thereby breached their duty to the
10 general public and Plaintiff.

11 135. Specifically, Defendants breached their duty by:

- 12 a. Would be used, as it was, on premature infants like Napoleon
13 Richardson yet they failed to properly warn hospitals, NICUs,
14 doctors, parents and/or consumers that their cow's milk-based
15 products significantly increases the risk of NEC and death in these
16 babies; and/or
- 17 b. Was unsafe and/or contra-indicated for premature infants like
18 Napoleon Richardson; and/or
- 19 c. Failed to provide proper instructions or guidelines or studies, or data
20 on when and how to feed their products to premature infants in order
21 to decrease the risk of NEC and/or death; and/or
- 22 d. Failed to insert a warning or instruction that parents needed to be
23 provided an informed choice between the safety of human milk
24 versus the dangers of the Defendants' cow's milk-based product;
25 and/or
- 26 e. Failed to provide instructions that parents needed to know that the
27 Defendants' products carried a significant risk that its cow's milk-
28 based product could cause their baby to develop NEC and die;
and/or
- f. Carried warnings and instructions that are severely inadequate,
vague, confusing, and provide a false sense of security in that they
warn and instruct specifically on certain conditions, but do not warn
on cow's milk-based product significantly involving the risk of NEC
and death or providing any details on how to avoid such harm;
and/or

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- g. Failed to have a large and prominent “black box” type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to Human Milk in premature infants; and/or
- h. Failed to provide well researched and well-established studies that linked their cow’s milk-based products to NEC and death in premature infants; and/or
- i. Failed to cite to or utilize current up to date medical data on the proper and safe use of their products; and/or
- j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow’s milk-based product; and/or
- k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or
- l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or
- m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, Napoleon Richardson was fed cow’s milk-based products which caused him to develop NEC; and/or
- n. Science and data have established that the only consistent observations made in infants who develop NEC are the presence of: 1) prematurity 2) cow’s milk based product, yet Defendants failed to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or
- o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to Napoleon Richardson; and/or
- p. Failed to establish a standard for safe use; and/or
- q. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or
- r. Failed to provide statistical evidence of adverse effects regarding the feeding of their products; and/or
- s. Failed to guide or instruct on when to start, how much to start, how to increase, volume and timing of feeds, when not to feed, and/or when to stop feeding their products to premature infants; and/or
- t. Failed to provide periodic or yearly safety reports; and/or
- u. Failed to provide periodic or yearly risk-benefit analysis for use of their products; and/or
- v. Failed to provide or produce yearly safety update reports; and/or

- 1 w. Failed to develop a protocol for hospitals and physicians with the
- 2 elements to assure safe use; and/or
- 3 x. Failed to provide detailed and adequate instructions on proper use,
- 4 administration, application, and limitations of their products
- 5 specifically designed for premature infants.

6 136. Additionally, despite knowing for many years that the most vulnerable

7 humans were suffering extreme harm related to the feeding of its products, failed to

8 perform the necessary scientific process of collection, detection, assessment,

9 monitoring, and prevention of these adverse effects of feeding its products.

10 137. Had Defendants not committed negligence, Nepoleon Richardson

11 would not have been exposed to Defendants' unreasonably dangerous products and

12 would still be alive today.

13 138. As a direct result Defendants' negligence as described herein,

14 Defendant's unreasonably dangerous products were fed to Baby Richardson, causing

15 him to develop NEC, and required surgery to remove one-third of his small and large

16 intestines.

17 139. As a direct and proximate result of Defendants' negligent conduct,

18 Plaintiff Latrice Richardson suffered significant emotional distress, loss of income,

19 and other harms as her life has been significantly affected son as a direct and

20 proximate result of Defendants' conduct described herein.

21 **PRAYER FOR RELIEF**

22 WHEREFORE, Plaintiff prays for judgment as follows:

23 140. For general damages in an amount to be proven at trial;

24 141. For special damages in an amount to be proven at trial;

25 142. For interest as permitted by law;

26 143. For costs of suit; and

27 144. For such other and further relief as the Court deems proper.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial for all claims for triable.

[REDACTED]