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

LASHANAE LITTLES, individually  
and on behalf of THE ESTATE OF  
MAKAI SANDERS,

Plaintiff,

v.

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

Defendants.

Case No: 5:21-cv-2146

**COMPLAINT**

**PARTIES, JURISDICTION, AND VENUE**

1  
2 1. Plaintiff LaShanae Littles, individually and on behalf of the Estate of  
3 Makai Sanders, is an adult and resident of San Bernardino County, California. She  
4 is the mother of Makai Sanders, who was a minor and is now deceased, and sues as  
5 his successor-in-interest for causes of action that survive her baby's death.

6 2. On December 25, 2020, Makai Sanders ("Baby Sanders") was born at  
7 Community Hospital of San Bernardino in San Bernardino, California.

8 3. Baby Sanders, is the son of LaShanae Littles ("Plaintiff" or "the  
9 mother").

10 4. The Defendant, Mead Johnson & Company, LLC and/or Mead Johnson  
11 Nutrition Company ("Mead") manufactures, designs formulates, prepares, tests,  
12 provides instructions, markets, labels, packages, places into the stream of commerce  
13 in all fifty states, including California, and sells premature infant formula products  
14 including Enfamil Human Milk Fortifier and Enfacare Powder.

15 5. The Defendant, Abbott Laboratories, Inc. ("Abbott," together with  
16 Mead, the "Defendants") manufactures, designs, formulates prepares, tests, provides  
17 instructions, markets, labels, packages, places into the stream of commerce in all  
18 fifty states, including California, and sells premature infant formula including  
19 Similac Special Care.

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

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

1           8.     Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b)  
2 because a substantial part of the events or omissions giving rise to Plaintiff's claims  
3 occurred in this judicial district.

4                                   **GENERAL ALLEGATION**

5           9.     On December 25, 2020, Baby Sanders was born prematurely with a low  
6 birth weight of 4 pounds and 2 ounces.

7           10.    Following the birth, Makai Sanders, was placed in the Neonatal  
8 Intensive Care Unit (NICU) at Community Hospital of San Bernardino.

9           11.    Baby Sanders, was intravenously fed Similac Special Case 20Fe,  
10 Enfamil HMF High Protein, Enfamil Premature, and Enfamil Premium, while in the  
11 NICU.

12          12.    On January 25, 2021, after being fed Defendants products, Baby  
13 Sanders developed Necrotizing Enterocolitis ("NEC").

14          13.    On January 27, 2021, at only 34 days old, Baby Sanders passed away  
15 from medical complications after developing NEC, which are the direct and  
16 proximate result of consumption of Defendants unreasonably dangerous cow's milk-  
17 based products.

18                                   **THE SCIENCE**

19          14.    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 Makai Sanders. The WHO estimates that  
22 approximately 15 million babies are born preterm every year and that number is  
23 rising.

24          15.    Nutrition for preterm babies, like Makai Sanders, 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    ///

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

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

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

1           19. 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 Diet of Human Milk and Bovine Milk-Based Products.  
6 (Journal of Pediatrics 2010; 156:562-7.)

7           20. 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           21. 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           22. 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 23. 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 24. 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 25. 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 26. 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 27. 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 28. 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 29. 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 30. 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 31. 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 32. 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 33. 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 34. 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 Sanders.

3 35. 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 36. 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 37. 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 38. 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 39. 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           40. 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           41. 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:

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal 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 30 – Precautions:

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Use this product only after feedings of lower caloric density are well-established. For improved tolerance, it is best to increase caloric density slowly, by 2- to 4-Cal/fl oz increments
- Hydration status should be monitored
- 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 Premature 20 calorie and 24 calorie and High Protein Precaution:

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

“Similac Special Care Premature 30 calorie – Precaution:

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

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

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

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

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

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

Similac Human Milk Fortifier Concentrated Liquid: Precautions

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

Similac Human Milk Fortifier Hydrolyzed Protein Concentrated Liquid: Precautions

- Add only to human milk—do not add water
- This product is nutritionally incomplete by itself and is designed to be added to human breast milk
- Additional iron may be necessary
- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk
- Once enteral feeding is well established, Similac Human Milk Fortifier Hydrolyzed Protein Concentrated Liquid can be added 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

- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk
  - Once enteral feeding is well established, Similac Human Milk Fortifier Power can be added to human milk (see Preparation, page 29)
  - 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
1. Barrett-Reis B, et al. Pediatrics. 2000;106:581-588.
  2. Chan GM. J Perinatol. 2003;23:620-623.
  3. \*Escherichia coli, Staphylococcus, Group B Streptococcus, and Enterobacter sakazakii (now Cronobacter sakazakii).

#### Liquid Protein Fortifier: Precaution

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

44. Science and research have advanced in recent years confirming the dangers of the defendant's cow's milk-based product in causing NEC and death in premature infants, yet the Defendant did nothing to change its product, packaging, guidelines, instructions and warnings.

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

46. None of this medical literature properly warns the user that its product causes NEC and death nor does it provide guidance on how to avoid NEC or death while using its product.

47. Despite knowing that its product significantly increases the risk of NEC and death, Abbott Laboratories, Inc. deliberately chose to omit a specific warning of NEC or death, and deliberately failed to provide any detailed instructions or guidance on how to avoid NEC or death when feeding Similac.

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

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

6           51. Based on information and belief, Abbott Laboratories, Inc.'s cow's  
7 milk-based product, Similac, did cause Baby Sanders, to develop NEC, which  
8 caused his unfortunate and untimely death.

9           52. 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, Makai Sanders, yet they took no steps to prevent its  
12 use in such a situation.

13           53. 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 Makai Sanders and  
15 knew or should have known, that such use would significantly increase the risk of  
16 NEC in Makai Sanders, yet it took no steps to prevent such use.

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

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

25           56. The Defendant, Abbott Laboratories, Inc., has marketed its products as  
26 safe and beneficial for premature infants like Makai Sanders.

27           57. 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 58. 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 59. 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 60. 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 61. 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 62. 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 63. 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       64. 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       65. 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 Baby Sanders.

11       66. 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, Baby Sanders.

13       67. The way in which the Defendant Abbott Laboratories, Inc. product was  
14 fed to Baby Sanders was extremely dangerous and caused an unreasonably high risk  
15 that she would develop NEC and die, 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       68. 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       69. The mother, LaShanae Littles, was never told that the Similac product  
23 could cause her baby to develop NEC and death.

24       70. The mother, LaShanae Littles, was never told that the Similac product  
25 could cause her baby any harm.

26       71. The mother, LaShanae, was never told that the Similac was made from  
27 cow's milk.

28 ///

72. The mother, LaShanae Littles, was never told of the studies showing cow's milk-based product was extremely dangerous to her baby.

73. Had the mother, LaShanae Littles, been made aware of the facts, data, and science that linked Similac to NEC, she would not have allowed her son to be fed Similac.

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

75. If Abbott had performed the pharmacovigilance required by drug manufacturers for their premature infant formulas and fortifiers, these products would not have been fed to Baby Sanders and he would not have developed NEC and he would not have suffered the devastating effects of NEC.

76. There are human milk based formulas and fortifier products which are feasible alternatives to the premature infant formula and fortifier products.

### *Mead Johnson's Failure to Provide Adequate Warnings, Instructions, or Guidelines*

77. The Defendant, Mead Johnson & Company, LLC and/or Mead Johnson Nutrition Company manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula including Enfamil Human Milk Fortifier and Enfacare Powder.

1       78. 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       79. 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, dilation, 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       80. 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.

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

33       82. The warnings and instructions are overly broad and vague, and do not

1 ever mention that the product significantly increases the risk of NEC and death, nor  
2 provide any detailed instructions or evidence on when and how to feed the infants  
3 and how to avoid NEC and death when feeding its products.

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

8 84. Enfamil and Enfacare contain bovine or cow's milk-based formula.

9 85. The cow's milk-based formula products are dangerous to premature  
10 infants in that it significantly increases the risk that the baby will develop NEC.

11 86. The cow's milk-based formula products are dangerous to premature  
12 infants in that it significantly increases the risk that the baby will die.

13 87. The Defendant, Mead, failed to properly warn that its product can  
14 significantly increase the risk that the premature infant will develop NEC and suffer  
15 catastrophic injuries as occurred to Makai Sanders.

16 88. The Defendant, Mead's cow's milk-based formula products did cause  
17 Baby Sanders to develop NEC, and ultimately caused his death.

18 89. Prior to February 2019, the Defendant, Mead, was aware, or should  
19 have been aware, that its product was not safe for use, as it was used, in the premature  
20 infant, Makai Sanders, yet it took no steps to prevent its use in such a situation.

21 90. The Defendant, Mead did foresee, or should have foreseen, that its  
22 product would be used as it was in the case of Baby Sanders, and knew or should  
23 have known, that such use would significantly increase the risk of NEC in Baby  
24 Sanders, yet it took no steps to prevent such use.

25 91. The products were not safe to be used, as it was in the case of Baby  
26 Sanders, and the Defendant Mead knew, or should have known, it was unsafe, yet it  
27 failed to properly instruct or warn the FDA, NICUs, hospitals, doctors and parents  
28 that its product was not safe.

1           92. The products were not safe to be used as it was in the case of Baby  
2 Sanders and the Defendant, Mead, knew, or should have known, it was unsafe, yet  
3 it failed to provide detailed instructions or guidelines on when and how its product  
4 would be safe to use in a premature infant like Makai Sanders.

5           93. The Defendant, Mead, has marketed its products as safe and beneficial  
6 for premature infants like Makai Sanders.

7           94. Because the Mead product is specially designed as food for vulnerable  
8 premature infants and contains no warning that it causes death or NEC, it is viewed  
9 as safe by physicians and parents of premature infants.

10          95. The Defendant, Mead, has marketed and sold its products as safe and  
11 beneficial for premature infants like Makai Sanders.

12          96. The Defendant, Mead, has promoted its products for extremely  
13 premature infants and claim its products increases the babies' weight and caloric  
14 intake and its product is more beneficial than harmful.

15          97. The studies show the Mead products should not be sold for use in  
16 extremely premature infants, yet Defendant Mead continued to market and sell its  
17 product knowing it would be used on infants like Makai Sanders and knowing its  
18 product would significantly increase the risk of NEC and death in extremely  
19 premature infants like Makai Sanders.

20          98. Defendant Mead promotes a range of products specifically for  
21 "premature and low weight" babies on their website: Enfamil Human Milk Fortifier  
22 Liquid High Protein, Enfamil Milk Fortifier Liquid Standard Protein, Enfamil  
23 NeuroPro Enficare, Enfamil Premature 20 Cal, Enfamil Premature 24 Cal, Enfamil  
24 Premature 24 Cal/fl oz HP, Enfamil Premature 30 Cal, Enfamil Human Milk  
25 Fortifier Acidified Liquid, Enfamil Human Milk Fortifier Powder, Enfamil 24 and  
26 DHA & ARA Supplement.

27          99. Notwithstanding strong medical evidence establishing the extreme  
28 dangers that cow's milk-based products pose for premature infants, Defendant Mead

1 have marketed their cow's milk-based products as equally safe alternatives to breast  
2 milk, and have promoted their products as necessary for additional nutrition and  
3 growth. Defendant Mead has specifically marketed its formula and fortifiers as  
4 necessary to the growth and development of premature infants, when indeed the  
5 products pose a known and substantial risk to these babies.

6 100. Mead knew or should have known that its product would be used in the  
7 way it was used on this premature infant, Makai Sanders.

8 101. The way in which the Mead product was fed to Makai Sanders was  
9 extremely dangerous and caused an unreasonably high risk that he would develop  
10 NEC and die, yet the defendant, Mead, provided no detailed instructions or warnings  
11 to prevent or alter the way this product was used.

12 102. The Defendant, Mead, has learned that its cow's milk-based product  
13 was causing NEC, devastating injuries, and death in premature infants, yet  
14 Defendant did nothing to change its product, packaging, guidelines, instructions and  
15 warnings.

16 103. The mother, LaShanae Littles, was never told that Enfamil and  
17 Enfacare could cause her baby to develop NEC and death.

18 104. The mother, LaShanae Littles, was never told that Enfamil and  
19 Enfacare could cause her baby any harm.

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

22 106. Mead has known for many years that their premature infant products  
23 are causing premature infants to develop NEC, devastating injuries, and die and  
24 know that hospitals and physicians around the United States are not informing the  
25 parents of this risk and Defendant Mead Johnson promotes this silence to protect its  
26 brands and profits.

27 107. The FDA requires manufacturers of prescription medications to study  
28 their medications and perform drug trials and collect data to determine the safety and



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

9       108. If Mead had performed the pharmacovigilance required by drug  
10 manufacturers for their premature infant formulas and fortifiers, these products  
11 would not have been fed to Makai Sanders and he would not have developed NEC  
12 and he would not have suffered the devastating effects of NEC.

13       109. The products made from cow's milk specifically for premature infants,  
14 are unsafe to premature infants and are avoidable for use in that there is human donor  
15 milk available and/or human milk derived fortifier products available made from  
16 human milk instead of cow's milk.

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

21       111. There are human milk based formulas and fortifier products which are  
22 feasible alternatives to the premature infant formula and fortifier products offered  
23 by Mead Johnson.

#### 24                   **DAMAGES SUFFERED BY PLAINTIFFS**

25       112. As a result of his exposure to Abbott and/or Mead's cow's milk based  
26 products, Makai Sanders was required to undergo medical care and costs. Makai  
27 Sanders was diagnosed with NEC and ultimately died at 34 days.

28       ///

1 113. Also, his mother, LaShanae Littles, suffered extensive financial loss  
2 and costs and emotional harm and distress related to her son's injuries and death.

3 **COUNT I**  
4 **FAILURE TO WARN**  
5 **(As to All Defendants)**

6 114. Plaintiff realleges all paragraphs previous and subsequent to this  
7 paragraph as if fully set forth herein.

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

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

20 117. Defendants' duty to warn is part of its general duty to design,  
21 manufacture, and sell its products that are reasonably safe for their foreseeable uses  
22 and by designing Similac and/or Enfamil and Enfacare with cow's milk-based  
23 ingredients, Defendants undertook a duty to adequately warn of the unreasonable  
24 risk of harm posed by such ingredients and specifically the increased risk of NEC,  
25 bodily injury, and even death of use of the such products by pre-term infants like  
26 Plaintiff. The failure to warn creates a defect and makes the Similac and Enfamil  
27 and Enfacare products at issue in this litigation unreasonably dangerous.

28 118. Specifically, Defendants breached their duty to warn of the foreseeable

1 risks of the Similac and Enfamil and Enfacare products at issue in this litigation  
 2 because Defendants knew or should have known that its cow's milk based product  
 3 (or its instructions/label):

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

- 1 l. Despite knowing that parents were not being warned of the risk of  
2 NEC by their physician, failing to take adequate measures to warn  
3 the parents directly; and/or
- 4 m. As a result of the inadequacy of the warnings and the pervasive  
5 marketing suggesting the safety and necessity of their products,  
6 Makai Sanders was fed cow's milk-based products which caused  
7 him to develop NEC; and/or
- 8 n. Science and data have established that the only consistent  
9 observations made in infants who develop NEC are the presence of:  
10 1) prematurity 2) cow's milk based products, yet Defendants fail to  
11 warn of this significant scientific conclusion and instead tries to hide  
12 this conclusion; and/or
- 13 o. Failed to place a prominent warning and instructions that would  
14 have prevented the feeding of Similac and/or Enfamil and Enfacare  
15 to Makai Sanders; and/or
- 16 p. Failed to establish a standard for safe use; and/or
- 17 q. Failed to establish a label or instruction that would correspond to the  
18 current science regarding the positive risk-benefit profile; and/or
- 19 r. Failed to provide statistical evidence of adverse effects regarding the  
20 feeding of their products; and/or
- 21 s. Failed to guide or instruct on when to start, how much to start, how  
22 to increase, volume and timing of feeds, when not to feed, and/or  
23 when to stop feeding their products to premature infants; and/or
- 24 t. Failed to provide periodic or yearly safety reports; and/or
- 25 u. Failed to provide periodic or yearly risk-benefit analysis for use of  
26 their products; and/or
- 27 v. Failed to provide or produce yearly safety update reports; and/or
- 28 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.

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



1           126. The Defendants' cow's milk-based products, Similac and Enfamil and  
2 Enficare, fed to Makai Sanders was unreasonably dangerous.

3           127. The risks of feeding the Defendants; cow's milk-based products,  
4 Similac and Enfamil and Enficare, to Makai Sanders outweighed its benefits.

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

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

12           130. As a direct result Defendants' unreasonably dangerous products were  
13 fed to Baby Sanders, causing him to develop NEC, and ultimately his death.

14           131. As a direct and proximate result of Defendants' developing,  
15 manufacturing, selling, and distributing their unreasonably dangerous cow's milk  
16 based products, Plaintiff LaShanae Littles suffered significant emotional distress,  
17 loss of income, and other harms as her life has been significantly affected by the  
18 death of her son as a direct and proximate result of Defendants' conduct described  
19 herein.

20                           **COUNT III**  
21                           **NEGLIGENCE**  
                              **(As to All Defendants)**

22           132. Plaintiff realleges all paragraphs previous and subsequent to this  
23 paragraph as if fully set forth herein.

24           133. Defendants as the designer, manufacturer, seller, and distributor of the  
25 cow's milk products that are the subject of this action had a duty to the general public  
26 and to the Plaintiff to exercise reasonable care to design, test, manufacture, inspect,  
27 and distribute a product free of unreasonable risk of harm to users, when said  
28 products are used in their intended manner and for their intended purpose.

1           134. At all relevant times to this action Makai Sanders used the products at  
2 issue in their intended manner and for their intended purpose.

3           135. Defendants, directly or indirectly, negligently and/or defectively made,  
4 created, manufactured, designed, assembled, tested, marketed, sold, and/or  
5 distributed the cow's milk based products and thereby breached their duty to the  
6 general public and Plaintiff.

7           136. Specifically, Defendants breached their duty by:

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

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137. Additionally, despite knowing for many years that the most vulnerable humans were suffering extreme harm related to the feeding of its products, failed to perform the necessary scientific process of collection, detection, assessment, monitoring, and prevention of these adverse effects of feeding its products.

138. Had Defendants not committed negligence, Makai Sanders would not have been exposed to Defendants' unreasonably dangerous products and would still be alive today.

139. As a direct result Defendants' negligence as described herein, Defendant's unreasonably dangerous products were fed to Baby Sanders, causing him to develop NEC, and ultimately causing his death.

140. As a direct and proximate result of Defendants' negligent conduct, Plaintiff LaShanae Littles suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son as a direct and proximate result of Defendants' conduct described herein.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment as follows:

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

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

143. For interest as permitted by law;

144. For costs of suit; and

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

### **DEMAND FOR JURY TRIAL**

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

Dated: December 27, 2021

By: /s/ Deborah S. Dixon

Deborah S. Dixon

Tarina Mand

**DIXON DIAB & CHAMBERS LLP**

John H. Gomez  
**GOMEZ TRIAL ATTORNEYS**

*Attorneys for Plaintiff*

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