UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

JENNIFER RAMSEY and JOHN PAUL RAMSEY, both individually and on behalf of their minor child, M.R..	DOCKET NO. 3:23-cv-217
VERSUS	DISTRICT JUDGE
ABBOTT LABORATORIES, INC.	MAGISTRATE JUDGE

INITIAL COMPLAINT

NOW INTO COURT, through undersigned counsel, come Plaintiffs, Jennifer Ramsey and John Paul Ramsey, in both of their respective individual capacities and also on behalf of their minor child, M. R., and who now both respectfully represent as follows:

Parties

1.

Plaintiff, Jennifer Ramsey, is a competent individual of the age of majority domiciled in the Parish of Union in the State of Louisiana at all times material hereto. She gave birth to her minor child, M. R., on February 2, 2021.

2.

Plaintiff, John Paul Ramsey, a competent individual of the age of majority domiciled in the Parish of Union in the State of Louisiana at all times material hereto. He is the father of the minor child, M. R., who was born on February 2, 2021.

3.

Defendant, Abbott Laboratories, Inc., (hereinafter "Abbott") is Delaware

corporation with its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

Jurisdiction and Venue

4.

This Court has jurisdiction over this matter pursuant to 28 USC § 1332 because (1) the parties are completely diverse; and (2) the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

5.

Venue is proper in the Western District of Louisiana under 28 USC § 1391(2) as a substantial part of the events giving rise to these claims occurred in the Western District of Louisiana.

6.

This Court has specific personal jurisdiction over Abbott because Abbott has purposefully availed itself of the privileges and benefits of doing business within the State of Louisiana.

7.

Abbott subjected itself to the jurisdiction of the State of Louisiana by doing business in Louisiana by causing its products to be sold in Louisiana, and by committing torts where one or more elements of the tort, or one or more of the tortious acts occurred in Louisiana.

8.

The claims against Abbott are linked to its conduct, key elements of the episode-in-suit occurred in Louisiana, and Abbott participated in placing the

infant formula at issue into the stream of commerce in Louisiana. Abbott's contacts with Louisiana relate to the sale of infant formula, and all of the conduct associated with such products at issue in the potential claims is related to and connected with such contacts.

9.

Abbott markets and sells its products across the United States, including the State of Louisiana. Abbott manufactured and sold the products involved in the incident made the basis of this lawsuit, and the incident made the basis of this lawsuit occurred in the State of Louisiana. Abbott has purposefully availed itself of the privilege of conducting activities in the State of Louisiana. Abbott cultivated a market for its products in the State of Louisiana and the defective product was purchased and consumed in the State of Louisiana. Abbott advertised its products in the State of Louisiana. Abbott engages in wide-ranging promotional activities, including television, print, online, and direct mail advertisements in the State of Louisiana. Abbott has ongoing connections with its products and the products' owners in the State of Louisiana. Abbott systematically served a market in the State of Louisiana for the very products that Plaintiff alleges were contaminated and severely injured them in this State. As such, there is a strong relationship among Defendant Abbott, the State of Louisiana, and the subject litigation. Abbott contracts with Louisiana residents, including Louisiana entities and individuals, as part of its business operations. Abbott has recruited and continues to recruit Louisiana residents for employment inside and outside the State of Louisiana. Abbott conducts

substantial business in the State of Louisiana and has continuous, systematic and specific contacts in the State of Louisiana. At all relevant times, Abbott was and is regularly doing business in the State of Louisiana. At all relevant times, Abbott has been engaged in the business of manufacturing, testing, inspecting, labeling, packaging, marketing, distributing, and selling products, including the products involved in the incident made the basis of this suit, through a worldwide chain of distribution that has targeted and benefited from the Louisiana market.

Nature of the Action

10.

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

11.

M.R., the minor child of the Plaintiffs, was born alive at 36 weeks gestation to Jennifer Ramsey and John Paul Ramsey on February 2, 2021.

12.

Nutrition for preterm babies, like M.R., is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

13.

At all times material hereto, M R. was prescribed and ingesting Similac Alimentum brand formula manufactured by Abbott. The lot number of this particular can of Similac formula is covered in the recall initiated by Abbott in February of 2022.

14.

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

15.

As early as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula- fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. Babies born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast

milk, but it was 20 times more common in those fed formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

16.

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

17.

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

18.

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

19.

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

20.

A study published in 2013 showed that, out of 104 the premature infants participating in the study receiving an exclusive human-milk-based diet, all 104 exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, et al., *Human Milk*

Feed Supports Adequate Growth in Infants ≤1250 Grams Birthweight, BMC RESEARCH NOTES, 6- 459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding cow's milk-based products, but the practice continued largely due to extensive and aggressive marketing campaigns conducted by infant formula companies.

21.

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

22.

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

23.

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

24.

In that same article it was reported: "A wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing necrotizing enterocolitis. There have been several meta-analyses reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC. By determining the specific ingredients in breast milk that are protective against NEC, it is our hope that this devastating disease will one day be preventable."

25.

In a study published in 2016, it was reported: "Extremely premature infants who received an exclusive HUM diet had a significantly lower incidence

of NEC and mortality. The HUM group also had a reduction in late-onset sepsis, BPD, and ROP. This multicenter study further emphasizes the many benefits of an exclusive HUM diet, and demonstrates multiple improved outcomes after implementation of such a feeding protocol." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet.* (Breastfeeding Medicine. 2016, Nov. 2, 11(2):70-75.)

26.

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

strategy to prevent necrotizing enterocolitis! (Semin Perinatol. 2017 Feb; 41(1):36-40.).

27.

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

28.

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

29.

Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-

based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

30.

Further, when Defendant recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier." Similar to the "Human Milk" formula, these names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that 91.2 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning breast milk-based product.

31.

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

32.

Abbott has designed powerful, misleading marketing campaigns to deceive

parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider Defendants' cow's milk-based products a first choice. This marketing scheme is employed despite Abbott knowing of and failing to warn of the extreme risk of NEC and injury that cow's milk-based products pose to preterm infants like M. R..

33.

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

34.

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

35.

Abbott deceived the public, parents, physicians, other medical

professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

36.

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

37.

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

Abbott's Failure to Provide Adequate Warnings, Instructions or Guidelines

38.

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

39.

Abbott's Similac product contained only the following packaging information guidelines, instructions and warnings:

"Similac Special Care 20 – 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 24 – 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 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."

40.

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."

41.

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 Fortifer 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

Liquid Protein Fortifier: Precaution

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

42.

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.

43.

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.

44.

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.

45.

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 significant injury, and deliberately failed to provide any detailed instructions or guidance on how to avoid NEC or injury when feeding Similac.

46.

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.

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 and suffer injury.

48.

Abbott Laboratories, Inc., failed to properly warn that its product, Similac, can significantly increase the risk that the premature infant will develop NEC and suffer injuries as occurred to M. R..

49.

Based on information and belief, Abbott Laboratories, Inc.'s cow's milk-based product, Similac Alimentum, did cause M. R. to develop NEC or other intestinal disease due to contamination.

50.

The Defendant, Abbott Laboratories, Inc. was aware, or should have been aware, that its product was not safe for use, as it was used, in the premature

infant, M. R., yet they took no steps to prevent its use in such a situation.

51.

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

52.

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

53.

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

54.

The Defendant, Abbott Laboratories, Inc, has marketed its products as safe and beneficial for premature infants like M. R..

55.

Because Abbott Laboratories, Inc.'s product is specially designed as food for vulnerable premature infants and contains no warning that it causes death or NEC, it is viewed as safe by physicians and parents of premature infants.

56.

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

57.

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

58.

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

59.

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

60.

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

61.

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

62.

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

63.

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

64.

Abbott Laboratories, Inc. knew or should have known that its product would be used in the way it was used on this premature infant, M. R.

65.

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

66.

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

67.

Plaintiffs, Jennifer Ramsey and John Paul Ramsey, were never told that the Similac Alimentum product could cause their baby to develop NEC or other intestinal disease.

68.

Plaintiffs, Jennifer Ramsey and John Paul Ramsey, were never told that the Similac Alimentum product could cause their baby any harm.

69.

Plaintiffs, Jennifer Ramsey and John Paul Ramsey, were never told that

the Similac Alimentum product was made from cow's milk.

70.

Plaintiffs, Jennifer Ramsey and John Paul Ramsey, were never told of the studies showing cow's milk-based product was extremely dangerous to their baby.

71.

Had the plaintiffs, Jennifer Ramsey and John Paul Ramsey, been made aware of the facts, data, and science that linked Similac to NEC, they would not have allowed their son to be fed Similac Alimentum.

72.

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.

73.

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 M. R. and he would not have developed NEC and he would not have suffered the devastating effects of NEC.

74.

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

DAMAGES SUFFERED BY PLAINTIFFS

75.

As a result of his exposure to Abbott's cow's milk-based products, M. R. suffered severe intestinal discomfort and disease and was unable to gain weight and absorb nutrition sufficiently. Because of this, he was required to undergo additional medical care and treatment.

76.

Plaintiffs, Jennifer Ramsey and John Paul Ramsey, suffered emotional harm and distress due to their son's injuries caused by the exposure to the tainted Similac Alimentum formula and resulting delay in his development and maturation.

COUNT I: FAILURE TO WARN

77.

Plaintiffs reallege all paragraphs prior to this paragraph as if fully set forth herein.

78.

Defendant, as the manufacturers and/or sellers of the product at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in

particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of such product with preterm infants, specifically including but not limited to the risk of NEC and serious bodily injury.

79.

Defendant, as the manufacturer and/or seller of the product at issue in this litigation, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in their products that contained cow's milk-based ingredients, as the magnitude of the risk involved in using said products with preterm infants is significant and involves the real danger of serious bodily injury and potentially death.

80.

Defendant's duty to warn is part of their general duty to design, manufacture, and sell their products that are reasonably safe for their foreseeable uses and by designing Similac with cow's milk-based ingredients, Defendant undertook a duty to adequately warn of the unreasonable risk of harm posed by such ingredients and specifically the increased risk of NEC, bodily injury, and even death of use of such products by pre-term infants like Plaintiffs' child. The failure to warn creates a defect and makes the Similac Alimentum product at issue in this litigation unreasonably dangerous.

81.

Specifically, Defendant breached its duty to warn of the foreseeable risks

of the Similac Alimentum product at issue in this litigation because the Defendant knew or should have known that its cow's milk-based products (or its instructions/label):

a. Would be used, as it was, on premature infants like M. R. yet it failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that their cow's milk-based product significantly increases the risk of NEC and death in these babies; and/or
b. Was unsafe and/or contra-indicated for premature infants like M. R.; and/or
c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed their products to premature infants in order to decrease the risk of NEC and/or death; and/or
d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's cow's milk-based product; and/or
e. Failed to provide instructions that parents needed to know that the Defendant's product carried a significant risk that its cow's milk-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 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
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
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, M. R. 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 Defendant's failure 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 to M. R.; 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.

82.

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 M. R. Had M. R.'s parents known of the extreme risks associated with feeding premature infants cow's milk-based product, they would have not allowed such a product to be given to

their son.

83.

As a result of this failure to warn,, M. R. was fed Abbott's Similac Alimentum cow's milk-based product causing him to develop NEC or other intestinal disease.

84.

As a direct and proximate result of Defendant's failure to warn as explained herein, Plaintiffs Jennifer Ramsey and John Paul Ramsey suffered significant emotional distress and other harms as their life has been significantly affected as a direct and proximate result of Defendant's conduct described herein.

COUNT II: STRICT LIABILITY FOR DEFECTIVE PRODUCT

85.

Plaintiffs reallege all paragraphs prior to this paragraph as if fully set forth herein.

86.

Defendant, as the manufacturer and/or seller of the product at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their Similac Alimentum infant formula products in a manner that was not unreasonably dangerous and is liable despite any care exercised to design a safe product.

87.

Despite knowing that their products would be used on premature infants,

like M. R., and despite knowing (or should have known) that such use was unreasonably dangerous to premature infants in that their cow's milk-based products were significantly increasing the risk of NEC and death, the Defendant continued to sell and market its defective products to premature infants.

88.

Over the last several years, scientific data and well researched studies have concluded that the cow's milk-based products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits, yet the Defendant continued to market and sell their defective products for premature infants like M. R.

89.

The Defendant's cow's milk-based products, Similac fed to M. R. were unreasonably dangerous.

90.

The risks of feeding the Defendant's cow's milk-based products, like Similac Alimentum, to M. R. outweighed its benefits.

91.

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

92.

Defendant also failed to properly reformulate its products to reduce the risks of NEC, devastating injuries, and/or death even though it knew of safer,

more effective alternative reformulations that would have made its products safer to use and not carry the added and significant risk of NEC.

93.

As a direct result, Defendant's unreasonably dangerous products were fed to M. R. causing him to develop NEC or other intestinal disease resulting in severe injuries and a failure to properly develop and mature.

94.

As a direct and proximate result of Defendant's developing, manufacturing, selling, and distributing their unreasonably dangerous cow's milk-based products, Plaintiffs Jennifer Ramsey and John Paul Ramsey suffered significant emotional distress and other harms as their life has been significantly affected as a direct and proximate result of Defendant's conduct described herein.

COUNT III: NEGLIGENCE

95.

Plaintiffs reallege all paragraphs prior to this paragraph as if fully set forth herein.

96.

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

intended purpose.

97.

At all relevant times to this action, M. R. used the products at issue in their intended manner and for their intended purpose.

98.

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

99.

Specifically, Defendants breached their duty by selling the Similac Alimentum product at issue in this litigation because the Defendant knew or should have known that its cow's milk-based products (or its instructions/label)::

a. Would be used, as it was, on premature infants like M. R. yet they failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that its cow's milk-based products significantly increases the risk of NEC and death in these babies; and/or
b. Was unsafe and/or contra-indicated for premature infants like M. R.; and/or
c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed their products to premature infants in order to decrease the risk of NEC and/or death; and/or
d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's cow's milk-based product; and/or
e. Failed to provide instructions that parents needed to know that the Defendant's products carried a significant risk that its cow's milk-based product could cause their baby to develop NEC; 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

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

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, M. R. 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 Defendant 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 to M. R.; 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.

100.

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

101.

Had Defendants not committed negligence, M. R. would not have been exposed to Defendants' unreasonably dangerous products and thereafter suffered injuries as stated herein.

102.

As a direct result Defendants' negligence as described herein, Defendants' unreasonably dangerous products were fed to M. R., causing him to develop NEC or other intestinal disease, resulting in severe injuries that have led to stunted development.

103.

As a direct and proximate result of Defendants' negligent conduct, Plaintiffs Jennifer Ramsey and John Paul Ramsey have suffered significant

emotional distress, and other harms as their lives has been significantly affected as a direct and proximate result of Defendants' conduct described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment as follows:

1. For general damages in an amount to be proven at trial;
2. For special damages in an amount to be proven at trial;
3. For interest as permitted by law;
4. For costs of suit; and
5. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Respectfully Submitted:

ANDERSON BLANDA & SALTZMAN

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been uploaded to the CM/ECF Filing System for the Western District of Louisiana on this 17th day of February 2023.

JASON A. WEAVER