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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

ALICIA RESTAD, individually and on behalf of THE ESTATE OF DANIEL RENTERIA-HERNANDEZ, and DANIEL RENTERIA-HERNANDEZ,

Plaintiff,

v.

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

Defendants.

Case No:

COMPLAINT

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Alicia Restad, individually and on behalf of the Estate of Daniel Renteria-Hernandez, is an adult and resident of Multnomah County, Oregon. She is the mother of Daniel Renteria-Hernandez, who was a minor and is now deceased, and sues as his successor-in-interest for causes of action that survive Daniel's death.

2. Plaintiff Daniel Renteria-Hernandez, individually, is an adult and resident of Multnomah County, Oregon. He is the father of Daniel Renteria-Hernandez, who was a minor and is now deceased.

3. On April 29, 2019, Daniel Renteria-Hernandez ("the baby" or "Daniel") was born at Dignity Hospital in Merced, California.

4. The baby, Daniel, was the son of Alicia Restad ("the mother") and Daniel Renteria-Hernandez ("the father," together with the mother, the "Plaintiffs").

5. On May 15, 2019, the baby, Daniel died at Valley Children's Hospital in Madera, California.

6. The Defendant, Mead Johnson & Company, LLC and/or Mead Johnson Nutrition Company ("Mead") 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 products including Enfamil Human Milk Fortifier and Enfacare Powder.

7. The Defendant, Abbott Laboratories, Inc. ("Abbott," together with Mead, the "Defendants") 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 Similac Special Care.

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

9. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct and do conduct business in the State of California and Defendants have

sufficient minimum contacts with this State and/or sufficiently avails itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

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

GENERAL ALLEGATION

11. The baby, Daniel, was born prematurely with a low birth weight of 2 pound 2 ounces and was the product of a 31-week pregnancy.

12. The baby, Daniel, was placed in the Neonatal Intensive Care Unit (NICU) at Valley Children's Hospital.

13. The baby, Daniel, developed Necrotizing enterocolitis while in the NICU and passed away on May 15, 2019 at only 16 days old.

THE SCIENCE

14. 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, like Daniel. The WHO estimates that approximately 15 million babies are born preterm every year and that number is rising.

15. Nutrition for preterm babies, like Daniel, 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.

16. 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 Defendants' 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 Defendants continue to promote and sell their defunct cow's milk-based products.

17. 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).

18. 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.)

19. 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.)

20. 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.

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21. 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).

22. 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 formula, but the practice continued largely due to extensive and aggressive marketing campaigns conducted by infant formula companies.

23. 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.)

24. 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.)

25. 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."

26. 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-analysis 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."

27. 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.)

28. 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.).

29. 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.)

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

30. The 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 California, and sells premature infant formula.

31. 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."

32. 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.

33. 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 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

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.

34. 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.

35. 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.

36. 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.

37. 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.

38. The cow's milk-based formula product, Similac, is dangerous to premature infants in that it significantly increases the risk that the baby will develop NEC.

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

40. The Defendant, 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 catastrophic injuries as occurred to Daniel.

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41. Based on information and belief, Abbott Laboratories, Inc.'s cow's milk-based formula product, Similac, did cause the baby, Daniel, to develop NEC, which caused his unfortunate and untimely death.

42. Prior to April 2019, 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, Daniel, yet they took no steps to prevent its use in such a situation.

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

44. The product, Similac, was not safe to be used as it was in the case of Daniel, 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.

45. The product, Similac, was not safe to be used as it was in the case of Daniel 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 Daniel.

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

47. Because the Defendant 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.

48. Because the Defendant 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.

49. 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.

50. 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.

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

52. 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.

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

54. 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.

55. 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 Daniel.

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

57. The way in which the Defendant Abbott Laboratories, Inc. product was fed to Daniel was extremely dangerous and caused an unreasonably high risk that he would develop NEC

and die, yet the defendant, Abbott Laboratories, Inc., provided no detailed instructions or warnings to prevent or alter the way this product was used.

58. 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.

59. The Plaintiffs were never told that the Similac formula could cause their baby to develop NEC and death.

60. The Plaintiffs were never told that the Similac formula could cause their baby any harm.

61. The Plaintiffs were never told that the Similac was made from cow's milk.

62. The Plaintiffs were never told of the studies showing cow's milk-based formula was extremely dangerous to their baby.

63. Had the Plaintiffs 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.

64. 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 formulas, such as Similac, are not drugs, the manufacturer, Abbott does not perform such trials and does not collect data on when and how the formula 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.

65. 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 Daniel and he would not have developed NEC and he would not have suffered the devastating effects of NEC.

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66. 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

67. 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.

68. Defendant Mead's product, Enfamil Human Milk Fortifier, contained only the following packaging information guidelines, instructions and warnings:

> Warning: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although this powder if formulated for premature infants, nutritional powders 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.
>
> Caution: Nutritionally Incomplete: To be used only under the supervision of a physician.
>
> Caution: Regarding use in extremely low-birth-weight infants (ELBW -1 kg or less): Hypercalcemia has been reported in some of these infants on full enteral feeds of human milk supplemented with human milk fortifiers.

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

> "Warning: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilation, use or storage may result in severe harm. Although this powder is formulated for infants born prematurely, 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. Ask your baby's doctor which formula is appropriate for your baby."

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

71. As previously discussed, science and research have advanced in recent years

confirming the dangers of the Defendant Mead's cow's milk-based product in causing NEC and death in premature infants, yet Defendant Mead did nothing to change its product, packaging, guidelines, instructions and warnings.

72. 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.

73. Despite knowing that its product significantly increases the risk of NEC and death, Defendant Mead 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 Enfamil.

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

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

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

77. The Defendant, Mead, failed to properly warn that its product, Enfamil, can significantly increase the risk that the premature infant will develop NEC and suffer catastrophic injuries as occurred to Daniel.

78. The Defendant, Mead's cow's milk-based formula product, Enfamil, did cause the baby, Daniel, to develop NEC, and ultimately caused his death.

79. Prior to April 2019, the Defendant, Mead, was aware, or should have been aware, that its product was not safe for use, as it was used, in the premature infant, Daniel, yet it took no steps to prevent its use in such a situation.

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

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81. The product, Enfamil, was not safe to be used as it was in the case of Daniel, and the Defendant Mead knew, or should have known, it was unsafe, yet it failed to property instruct or warn the FDA, NICUs, hospitals, doctors and parents that its product was not safe.

82. The product, Enfamil, was not safe to be used as it was in the case of Daniel and the Defendant, Mead, 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 Daniel.

83. The Defendant, Mead, has marketed its products as safe and beneficial for premature infants like Daniel.

84. Because the Mead 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.

85. The Defendant, Mead, has marketed and sold its products as safe and beneficial for premature infants like Daniel.

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

87. The studies show the Mead products should not be sold for use in extremely premature infants, yet Defendant Mead continued to market and sell its product knowing it would be used on infants like Daniel and knowing its product would significantly increase the risk of NEC and death in extremely premature infants like Daniel.

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

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

90. Mead knew or should have known that its product would be used in the way it was used on this premature infant, Daniel.

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

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

93. The Plaintiffs were never told that the Enfamil formula could cause their baby to develop NEC and death.

94. The Plaintiffs were never told that the Enfamil formula could cause their baby any harm.

95. If the Plaintiffs had known of the significant risks of feeding Enfamil to their premature infant, they would not have allowed the product to be fed to their baby.

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

97. 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

formulas, such as Enfamil, are not drugs, the manufacturer, Mead does not perform such trials and does not collect data on when and how the formula 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, Mead is doing nothing to stop or lessen NEC or death.

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

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

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

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

DAMAGES SUFFERED BY PLAINTIFFS

102. As a result of his exposure to Abbott's and/or Mead's cow's milk based infant formula products, the baby, Daniel, was required to undergo medical care and costs. The baby, Daniel, was diagnosed with NEC and ultimately died at 16 days.

103. Also, his mother, Alicia Restad, and his father, Daniel Renteria-Hernandez, suffered extensive financial loss and costs and emotional harm and distress related to their son's injuries and death.

COUNT I
FAILURE TO WARN
(As to All Defendants)

104. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

105. Defendants Abbott and Mead, as the manufacturer and/or seller of the infant formula at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of such products with preterm infants, specifically including but not limited to the risk of NEC and serious bodily injury.

106. Defendants Abbott and Mead, as the manufacturer and/or seller of the infant formula 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 its Similac and Enfamil products that contained cow's milk based ingredients, as the magnitude of the risk involved is using Abbott's Similac and/or Mead's Enfamil infant formulas with preterm infants is significant and involves the real danger of serious bodily injury and potentially death.

107. Defendants Abbott and Mead's duty to warn is part of its general duty to design, manufacture, and sell its infant formula products that are reasonably safe for their foreseeable uses and by designing its Similac and Enfamil infant formula with cow's milk-based ingredients, Abbott and Mead 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 the such products by pre-term infants like the baby, Daniel. The failure to warn creates a defect and makes the Similac products at issue in this litigation unreasonably dangerous.

108. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the Similac and Enfamil products at issue in this litigation because Abbott and Mead knew or should have known that its cow's milk based premature infant formula (or its instructions/label):

a. Would be used, as it was, on premature infants like Daniel 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 Daniel; 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 Defendants' cow's milk-based product; and/or
e. Failed to provide instructions that parents needed to know that the Defendants' 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 formula 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 formula; and/or
k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or
l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or
m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, the baby, Daniel, 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 formula, yet Abbott and Mead fail to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or
o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to the baby, Daniel; 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.

109. Moreover, had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would have not used such a dangerous product on the baby, Daniel. Had the Plaintiffs known of the extreme risks associated with feeding premature infants cow's milk-based formula, they would have not allowed such a product to be given to their son.

110. As a result and proximate cause, the baby, Daniel, was fed Defendants Abbott and Mead's Similac and/or Enfamil cow's milk-based product causing him to develop NEC, and ultimately caused his death.

111. As a direct and proximate result of Abbott and Mead's failure to warn as explained herein Plaintiffs suffered significant emotional distress, loss of income, and other harms as their life has been significantly affected by the death of their son as a direct and proximate result of Abbott and Mead's conduct described herein.

COUNT II
STRICT LIABILITY FOR DEFECTIVE PRODUCT
(Against All Defendants)

112. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

113. Abbott and Mead as the manufacturers and/or sellers of the infant formulas at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute its Similac and Enfamil infant products in a manner that was not unreasonably dangerous and is liable despite any care exercised to design a safe product.

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

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

116. The Defendants' cow's milk-based products, Similac and Enfamil, fed to the baby, Daniel, were unreasonably dangerous.

117. The risks of feeding the Defendants' cow's milk-based products, Similac and Enfamil, to the baby, Daniel, outweighed its benefits.

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

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

120. As a direct result Abbott and Mead's unreasonably dangerous products were fed to the baby, Daniel, causing him to develop NEC, and ultimately his death.

121. As a direct and proximate result of Abbott and Mead's developing, manufacturing, selling, and distributing their unreasonably dangerous cow's milk based infant formulas, Plaintiffs suffered significant emotional distress, loss of income, and other harms as their life has been significantly affected by the death of their son as a direct and proximate result of Abbott and Mead's conduct described herein.

COUNT III
NEGLIGENCE
(As to All Defendants)

122. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

123. Abbott and Mead as the designers, manufacturers, sellers, and distributors of the cow's milk infant formulas that are the subject of this action had a duty to the general public and

to the Plaintiffs 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.

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

125. Abbott and Mead, directly or indirectly, negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk based infant formula products and thereby breached its duty to the general public and the Plaintiffs.

126. Specifically, Abbott and Mead Johnson breached its duty by:

a. Would be used, as it was, on premature infants like the baby, Daniel, 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 the baby, Daniel; 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 Defendants' cow's milk-based product; and/or
e. Failed to provide instructions that parents needed to know that the Defendants' 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 formula 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 formula; and/or

k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac and/or Enfamil; and/or
l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or
m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, the baby, Daniel, 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 formula, yet Abbott and Mead fail to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or
o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac and/or Enfamil to the baby, Daniel; 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.

127. 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.

128. Had Abbott and Mead not committed negligence, the baby, Daniel, would not have been exposed to Abbott and Mead's unreasonably dangerous infant formula and would still be alive today.

129. As a direct result Abbott and Mead's negligence as described herein, Abbott and Mead's unreasonably dangerous products were fed to, the baby, Daniel, causing him to develop NEC, and ultimately causing his death.

130. As a direct and proximate result of Abbott and Mead's negligent conduct, Plaintiffs suffered significant emotional distress, loss of income, and other harms as their life has been significantly affected by the death of their son as a direct and proximate result of Abbott and Mead's conduct described herein.

COUNT IV
NEGLIGENT MISREPRESENTATION
(As to All Defendants)

131. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

132. Abbott and Mead as the designers, manufacturers, sellers, and distributors of the cow's milk infant formulas that are the subject of this action had a duty to the general public and to Plaintiffs to provide truthful, accurate, fulsome information about the risks and benefits of using their products when said products are used in their intended manner and for their intended purpose.

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

134. Abbott and Mead breached this duty in the following ways:

a. The allegations contained in previous paragraphs set forth specific representations Abbott and Mead has made to consumers, physicians and medical staff through their advertising and promotional materials. The allegations contained in those paragraphs are incorporated herein. Upon information and belief said representations were made by Abbott and Mead on an ongoing and repeated basis and prior to the time of feeding Similac and/or Enfamil to the baby, Daniel.
b. The Defendants misrepresented that its cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and caused NEC and death in premature infants; and/or
c. The Defendants misrepresented to parents, physicians and healthcare providers that their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
d. Defendants misrepresented that their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
e. Defendants negligently misrepresented that cow's milk-based products are safe for premature infants; and/or
f. Defendants negligently misrepresented that cow's milk-based products are necessary for optimum growth; and/or

g. Defendants negligently misrepresented that cow's milk-based products are similar or equivalent to human milk; and/or
h. Defendants Abbott and Mead negligently misrepresented that their Similac and Enfamil products were safe and more like human milk and that they had removed the harmful ingredients of cow's milk, and for babies who had trouble digesting cow's milk when, in fact, their products were made from cow's milk; and/or
i. Defendants negligently misrepresented that Similac and Enfamil were based on current up-to-date science, which made them safe for premature infants; and/or
j. Defendants negligently omitted the material fact that their products, Similac and Enfamil significantly increases the risk of NEC in premature infants.

135. Had Abbott and Mead not committed negligence, the baby, Daniel, would not have been exposed to Abbott and Mead's unreasonably dangerous infant formulas and the baby, Daniel, would not have passed away.

136. As a direct result Abbott and Mead's negligence as described herein, Abbott and Mead's unreasonably dangerous products were fed to, the baby, Daniel, causing him to develop NEC and ultimately causing his death.

137. As a direct and proximate result of Abbott and Mead's negligent conduct, Plaintiffs suffered significant emotional distress, loss of income, and other harms as their life has been significantly affected by the death of their son as a direct and proximate result of Abbott and Mead's conduct described herein.

COUNT V
BREACH OF IMPLIED WARRANTIES
(As to All Defendants)

138. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as if fully set forth herein.

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

140. The allegations contained in previous paragraphs set forth specific representations Abbott and Mead have made to consumers, physicians, and medical staff through their advertising and promotional materials. The allegations contained in those paragraphs are incorporated herein.

141. The Defendants implicitly warranted, through direct-to-consumer marketing, advertisements, and labels, that their products were safe and effective for reasonably anticipated

uses, including use by premature infants.

142. The Defendants implicitly warranted that their products were similar or equivalent to human milk.

143. The Defendants implicitly warranted that their products were necessary for growth.

144. The Defendants implicitly warranted that their products were safe based upon current data and science.

145. The Products did not conform to these implied representations because they cause serious injury when used to feed premature infants.

146. As a direct result Abbott and Mead's breach of their implied warranties as described herein, Abbott and Mead's unreasonably dangerous products were fed to, the baby, Daniel, causing him to develop NEC, which ultimately caused his death.

147. As a direct and proximate result of Abbott and Mead's breach of their implied warranties, Plaintiffs have suffered significant emotional distress, loss of income and other harms as their life has been significantly affected by the death of their son as a direct and proximate result of Abbott and Mead's conduct described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

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

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

150. For interest as permitted by law;

151. For costs of suit; and

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims for triable.

Dated: March 18, 2021

By: */s/ John H. Gomez*
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