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

MARY KATE MILLER, individually and on behalf of HELEN MILLER ***Plaintiffs*** **v.** **ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC.** ***Defendants***	**COMPLAINT AND JURY DEMAND**

COMPLAINT AND JURY DEMAND

1. This action arises out of the catastrophic and preventable death of a newborn baby girl who died due to a horrific and deadly disease caused and/or substantially contributed to by cow's-milk-based infant formula and/or fortifier. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC may lead to surgery and to death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow's milk-based formula or fortifier products. ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. (collectively referred to as 'ABBOTT' and/or the 'ABBOTT DEFENDANTS'), manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, Helen Miller, who was born premature and with low birth weight, was fed these cow's milk-based products, developed NEC, and died shortly thereafter.

2. Plaintiff, Mary Kate Miller, is the natural parent of Helen Miller. Mary Kate Miller individually and on behalf of Helen Miller, brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendant's Cow's Milk-Based Products (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively "Cow's Milk-Based Products").

PARTIES

3. Plaintiff Mary Kate Miller is a citizen and resident of Fairhope, Baldwin County, in the State of Alabama, located in the United States District Court for the Southern District of Alabama- Southern Division. Plaintiff brings this action to recover for Helen Miller's injuries as well as her own damages due to Helen Miller's injuries, which are the direct and proximate causes of Defendants' unreasonably dangerous Cow's Milk-Based Products.

4. Helen Miller was born on February 16, 2009, and died on February 26, 2009, at the Sacred Heart Hospital located in Pensacola, Escambia County, in the State of Florida located in the United States District Court for the Northern District of Florida. Helen Miller developed NEC after being fed Defendants' Cow's Milk-Based Product while in the Newborn Intensive Care Unit ("NICU").

5. Defendant ABBOTT LABORATORIES is a corporation organized and existing under the laws of the State of Illinois with its principal place of business, the "nerve center" of its operations, in Abbott Park, Illinois.

6. Defendant ABBOTT LABORATORIES, INC. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business, the "nerve

center" of its operations, in Abbott Park, Illinois. (ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC are collectively referred to as "ABBOTT" and/or the "ABBOTT DEFENDANTS".) The ABBOTT DEFENDANTS, at all times relevant hereto, advertised, promoted, labeled, marketed, sold, and distributed their Cow's Milk-Based Products, and continues to do so, in the States of Illinois, Alabama, and Florida.

JURISDICTION & VENUE

7. This is an action for damages which exceed the sum of $75,000.00, exclusive of costs, interest, and attorneys' fees.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a)(3), as complete diversity exists between Plaintiff and Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

9. Plaintiff resides and is domiciled in Fairhope, Alabama.

10. This Court has personal jurisdiction over the ABBOTT DEFENDANTS because the ABBOTT DEFENDANTS are Illinois corporations and/ or have a principal place of business in Illinois, who transact business in the States of Illinois, Alabama, and Florida.

11. Venue is proper in the United States District Court for the Southern District of Alabama- Southern Division, the Northern District of Illinois, and the Northern District of Florida, under 28 U.S.C. §1391. Plaintiff Mary Kate Miller resides and is domiciled in the Southern District of Alabama. Helen Miller was born and died in the Northern District of Florida. The ABBOTT DEFENDANTS at all time relevant hereto, are located in Illinois and conducted and continue to conduct business in the Northern District of Illinois.

12. This Complaint is filed in the Northern District of Illinois because the Defendants are located in Illinois and therefore have sufficient minimum contacts with the State of Illinois

and/or sufficiently avail themselves to the markets in the State of Illinois through its promotion, sales, distribution, and marketing within the State of Illinois to render exercise of jurisdiction by this Court permissible.

FACTUAL ALLEGATIONS

A. The Science and Scope of the Problem

13. 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 Helen Miller, born at 30 weeks. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

14. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams) like Helen Miller (1015 grams), 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.

15. Science and research have advanced in recent years confirming strong links between cow's milk-based products and NEC causing 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 these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products; however, the manufacturers of the Cow's Milk-Based Products continue to promote and sell the Cow's Milk-Based Product versions.

16. As far back 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. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk but was **20 times more common** in those fed cow's milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990) (emphasis added).

17. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were **90% less likely** to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, *et al*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

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 necrotizing enterocolitis (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) (emphasis added). This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id.*

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 preterm 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-e84l (2012).

20. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and 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 Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendants.

21. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a **significantly higher rate** of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU. E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

22. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant morbidity and mortality**. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al.*, *Evidence Based Feeding Strategies Before and After the Development*

of Necrotizing Enterocolitis, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that **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. *Id*. The study noted that "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. *Id.* 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**." *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

23. In yet another study published in 2014 it was reported that an exclusive human milk diet, devoid of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

24. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an **exclusive human milk diet is associated with "significant benefits"** for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-

based protocol, "it appears that there were **no feeding-related adverse outcomes**." Hair, *et al.*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

25. A publication by the American Society for Nutrition, in 2017, noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow's milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an **exclusive human milk diet resulted in a much lower incidence of NEC**. While the study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **cow's milk-based products significantly increase the risk of NEC and death**. The study also noted the **"exponential" health care costs** associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and nearly doubles to $313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al.*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

26. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, "**In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement**." Jules Law, *The Politics of*

Breastfeeding: Assessing Risk, Dividing Labor, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

27. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "**There should be no advertising or other form of promotion to the general public** [of breast milk substitutes]." (Emphasis added.)

28. In Article 5.2, the Code states that "manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…" *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

29. The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "**a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes**," noting that in 2014, the global sales of breast-milk substitutes amounted to **US $44.8 billion** and "is expected to rise to **US $70.6 billion** by

2019." *Marketing of Breast-milk Substitutes*: *Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added).

30. Recognizing a shift in the medical community towards an exclusive human based diet for preterm infants, the Defendants began heavily promoting "human milk fortifiers," a name which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk.

31. The Defendant has designed competing, systematic, powerful, and misleading marketing campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk-Based Products a first choice. Similarly, the Defendant markets its products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk-Based Products and failing to warn of the deadly disease of NEC and risk of death.

32. Thus, despite the existence of alternative and safe human milk-based fortifiers, the Defendant continues to market and/or sell the Cow's Milk-Based Products under the guise of being a safe product for newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants like Helen Miller.

B. The Inadequate Warnings

33. Defendants promote the use of its preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

34. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC and death,

Defendants did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendant provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC or death.

35. In fact, Defendants did not provide any warning in their labeling, websites, or marketing that warns that its Cow's Milk-Based Products exponentially increase the risk of NEC and death in preterm infants, or that human breast milk, donor breast milk, and human breast milk- based formulas and fortifiers are much safer for preterm babies than its Cow's Milk-Based Products.

C. Helen Miller and the Dangerous, Defective Products

36. On February 16, 2009, Helen Miller was born at 30 weeks gestation in Pensacola, Florida, weighing only 1015 grams.

37. Immediately after birth, Helen Miller was sent to the Neonatal Intensive Care Unit where Helen Miller was fed and ingested Similac Special Care Formula (an ABBOTT Product).

38. Subsequently, Helen Miller developed, was diagnosed with, and died from NEC caused by ingesting Defendants' Cow's Milk-Based Products.

CAUSES OF ACTION

COUNT I. NEGLIGENCE

39. Plaintiff repeats, reiterates, and re-alleges every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

40. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of

their Cow's Milk-Based Products into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects and/or death.

41. Defendants failed to exercise ordinary care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, quality assurance, quality control, and/or distribution of their Cow's Milk-Based Products into interstate commerce in that Defendants knew or should have known that using these Cow's Milk-Based Products created a high risk of unreasonable, dangerous side effects, including, but not limited to, the development of NEC, and Death.

42. The negligence by the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing producing, promoting, formulating, creating, and/or designing their Cow's Milk-Based Products without thoroughly testing them;

b. Failing to test their Cow's Milk-Based Products and/of failing to adequately, sufficiently, and properly test their Cow's Milk-Based Products;

c. Not conducting sufficient testing programs to determine whether or not Cow's Milk-Based Products were safe for use; in that Defendants herein knew or should have known that their Cow's Milk-Based Products were unsafe and unfit for use by reason of the dangers to the infants to whom their products were fed;

d. Failing to adequately and correctly warn the Plaintiff, the public, the medical professions, and government regulators and regulatory agencies of

the dangers of premature and/or low-birth weight baby's ingesting Cow's Milk-Based Products;

e. Negligently marketing, advertising, and recommending the use of Cow's Milk-Based Products without sufficient knowledge as to their dangerous propensities;

f. Negligently representing that Defendants' Cow's Milk-Based Products had equivalent safety and efficacy as Human Milk-Based Products;

g. Negligently designing their Cow's Milk-Based Products in a manner, which was dangerous to their users;

h. Negligently manufacturing their Cow's Milk-Based Products in a manner, which was dangerous to their users;

i. Negligently producing their Cow's Milk-Based Products in a manner, which was dangerous to their users;

j. Negligently formulating their Cow's Milk-Based Products in a manner, which was dangerous to their users;

k. Concealing information from the Plaintiff while knowing that Cow's Milk-Based Products were unsafe and dangerous;

l. Improperly concealing and/or misrepresenting information from the Plaintiff, scientific and medical professionals, and/or the regulatory agencies, including the FDA, concerning the severity of risks and dangers of Cow's Milk-Based Products compared to Human Milk-Based Products; and,

m. Negligently selling their Cow's Milk-Based Products with false and misleading labels.

43. Defendants under-reported, underestimated, and downplayed the serious dangers of their Cow's Milk-Based Products.

44. Defendants negligently and deceptively compared the safety risks and/or dangers of their Cow's Milk-Based Products with Human Milk-Based Products.

45. Even though Defendants knew or should have known that Cow's Milk-Based Products caused, or could cause, unreasonably dangerous side effects, including NEC and death, Defendants continued and continue to market, manufacture, distribute, and/or sell their Cow's Milk-Based Products to medical facilities, hospitals, and consumers, including to Plaintiff and Helen Miller.

46. Defendants knew or should have known that consumers such as Helen Miller would foreseeably suffer serious injuries and die due to Defendants' failure to exercise ordinary care, as set forth above.

47. As a result of the foregoing negligent acts and omissions, Helen Miller developed and was diagnosed with Necrotizing Enterocolitis (NEC) and other life-threatening side-effects and medical conditions associated with and/or caused by NEC, including Helen Miller's subsequent death, caused by ingesting Defendants' Cow's Milk-Based Formula and/or Fortifier.

48. As a result of the foregoing negligent acts and omissions, Plaintiff Mary Kate Miller suffered personal injuries including mental and emotional anguish, which are severe and long-lasting in nature, diminished enjoyment of life, and incurred financial expenses for the NICU medical care and burial costs of Helen Miller, among others.

COUNT II. MANUFACTURING & DESIGN DEFECT

49. Plaintiff repeats, reiterates, incorporates, and realleges every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

50. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of their Cow's Milk-Based Products, including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

51. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of their Cow's Milk-Based Products because Defendants knew, or should have known, that feeding their Cow's Milk-Based Products to premature and/or low-birth weight infants was linked to and causes NEC, and therefore not safe for consumption by premature and/or low birth weight infants, such as Helen Miller.

52. Defendants continued to manufacture and market their Cow's Milk-Based Products despite the knowledge, whether direct or ascertained with reasonable care, that Cow's Milk-Based Products posed a serious risk of bodily harm to their intended consumers.

53. Defendants knew, or should have known, that consumers such as Helen Miller, would foreseeably suffer severe injury and could possibly die because of Defendants' failure to exercise ordinary care.

54. The characteristic of the Cow's Milk-Based Products that renders them unreasonably dangerous existed at the time the product left the control of Defendants.

55. Defendants' Cow's Milk-Based Products were expected to, and did, reach the intended consumers, medical institutions and facilities, and medical professionals with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

56. Defendants' Cow's Milk-Based Products were manufactured, designed, marketed, labeled and sold in a defective condition, for use by premature and/or low-birth weight infants, like Helen Miller, making the product unreasonably dangerous.

57. Cow's Milk-Based Products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and formulation in that when they left the hands of the manufacturers, suppliers, and distributors, the foreseeable risks of harm caused by these products exceeded the claimed benefits of the product.

58. Cow's Milk-Based Products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and formulation because when it left the hands of Defendants, the products were unreasonably dangerous and were also far more dangerous than expected by the ordinary consumer.

59. At all times relevant to this action, Defendants knew and had reason to know that Cow's Milk-Based Products were inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Defendants, and when used and ingested in the form manufactured and distributed by Defendants, and in the manner instructed by Defendants to be used by Helen Miller and other consumers.

60. Helen Miller was fed and ingested Defendants' Cow's Milk-Based Products for the purpose intended by Defendants, and in a manner normally intended to be used. Defendants had a duty to design, create, and manufacture products that were reasonably safe and not unreasonably

dangerous for their normal, common, and intended use. Defendants' products were not reasonably fit, suitable, or safe for their anticipated use, and safer, reasonable alternative designs existed and could have been utilized at the time the product left Defendants' control.

61. In light of then-existing reasonably available scientific and technological knowledge, Defendants could have known of the design characteristic that caused the damage or the danger of such characteristic.

62. Reasonably prudent manufacturers would not have placed the Cow's Milk-Based Products in the stream of commerce with knowledge of these design flaws.

63. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being, and of death to Helen Miller and other consumers.

64. Defendants are therefore liable for Helen Miller's injuries and death, sustained and proximately caused by ingesting Defendants' Cow's Milk-Based Products, as Defendants' products were and are unreasonably dangerous, and all damages and the death of Helen Miller arose from the reasonably anticipated use of the product by the Plaintiff.

65. Defendants are therefore liable for Plaintiff Mary Kate Miller's injuries and damages, sustained and proximately caused by the injuries to and death of her child, Helen Miller, from ingesting Defendants' Cow's Milk-Based Products, as Defendants' products were and are unreasonably dangerous, and all damages suffered by Plaintiff Mary Kate Miller as a result of the injuries and death of Helen Miller arose from the reasonably anticipated use of the product, *to wit*, feeding the Cow's Milk-Based Products to Helen Miller.

66. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of Defendants' products and/or perceive its defective dangers prior to its use.

67. Cow's Milk-Based Products were a substantial, proximate, and contributing factor in causing Helen Miller's injuries and death, and Plaintiff Mary Kate Miller's injuries.

68. As a proximate result of Defendants' acts and omissions and Plaintiff's use of Defendants' defective products, Helen Miller suffered serious physical injuries, pain, and died, and Plaintiff Mary Kate Miller incurred substantial medical costs and expenses to treat and care for Helen Miller, and suffered and continues to suffer from emotional distress and mental anguish caused by the death of Helen Miller from NEC caused by ingesting Defendants' Cow's Milk-Based Products.

COUNT III. INADEQUATE WARNING

69. Plaintiff repeats, reiterates, incorporates, and realleges every allegation contained in this Complaint with the same force and effect as if fully set forth herein

70. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed Cow's Milk-Based Products.

71. Defendants' Cow's Milk-Based Formula and/or Fortifier products were unreasonably dangerous because an adequate warning about the product had not been provided at the time the product left its manufacturer's control, despite the product possessing a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

72. Defendants' Cow's Milk-Based Products were expected to, and did, reach the intended consumers, medical facilities, institutions and hospitals all with no substantial change in

the condition in which the products were designed, produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

73. Defendants' Cow's Milk-Based Products was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff and all other consumers of the product, making the product unreasonably dangerous.

74. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Cow's Milk-Based Products and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its products.

75. Defendants' Cow's Milk-Based Products, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants, were defective due to the product's inadequate warnings and instructions. Defendants knew, or should have known, and adequately warned that its products created a risk of serious and dangerous side effects, including but not limited to, Necrotizing Enterocolitis, and death.

76. These products were under the exclusive control of Defendants and was unaccompanied by appropriate and inadequate warnings regarding the risk of severe and permanent injuries and death associated with its use, including, but not limited to, the risk of developing Necrotizing Enterocolitis, and of death. The warnings given did not accurately reflect these risks, incidences, symptoms, scope or severity of such injuries to the consumer.

77. Notwithstanding Defendants' knowledge of the defective condition of its product, Defendants failed to adequately warn the medical community and consumers of the product,

including Plaintiff and her healthcare providers, of the dangers and risk of harm associated with the use of Cow's Milk-Based Products.

78. Defendants downplayed and/ or hid the serious, dangerous, and deadly side effects of its products to encourage sales of the product; consequently, Defendants placed profits above its customers' safety.

79. The Cow's Milk-Based Product was defective when it left the possession of Defendants in that it contained insufficient warnings to alert Plaintiff and other consumers to the dangerous risks associated with it, including the risk of developing NEC and of death.

80. Even though Defendants knew or should have known of the risks and reactions associated with their product, Defendants still failed and continue to fail to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

81. Helen Miller used, was fed, and ingested Defendants' Cow's Milk-Based Products as Defendants intended or in a reasonably foreseeable manner.

82. Each Defendant, individually, as a manufacturer of agricultural products, is held to the level of knowledge of an expert in the field and further, each Defendant had knowledge of the dangerous risks and side effects of its product.

83. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiff or any other consumers.

84. Each Defendant had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with its products, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, each Defendant breached its duty.

85. Although each Defendant knew, or should have known, of the defective nature of Cow's Milk-Based Products, Defendants continued and continue to design, manufacture, market, and sell their products without providing adequate warnings and instructions concerning the use of the products so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused to premature, low-birth weight infants and their families caused by Cow's Milk-Based Products.

86. As a direct and proximate result of Defendants' failure to adequately warn or other acts and omissions of Defendants described herein, Helen Miller suffered severe injuries, pain, and died, and Plaintiff Mary Kate Miller suffered and continues to suffer from economic damages and emotional distress and mental anguish, including diminished enjoyment of life.

87. Defendants' failure to warn extended beyond the product's label and into other media available to Defendants, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

88. Cow's Milk-Based Products, upon information and belief, as manufactured by Defendants, were further defective due to inadequate post-market warnings or instructions because after Defendants knew, or should have known, of the risk of serious bodily harm from the use of Cow's Milk-Based Products, Defendants failed to provide adequate warnings to consumers about the product, knowing the product could cause serious injury and death.

89. Cow's Milk-Based Products, upon information and belief, as manufactured and supplied by Defendants, were unreasonably dangerous because an adequate warning about the product was not provided if, as at the time the product left Defendants' control, the product possessed the aforementioned characteristics that may cause damages, injuries, and death to users - premature, low-birth weight infants such as Helen Miller, and Defendants failed to use

reasonable care to provide an adequate warning of such characteristic and its danger to consumers and users of these products.

90. After Defendants had started shipping product that had left its control, Defendants acquired knowledge of characteristics of the product that might cause damage and the danger of such characteristic, and is liable for damages and deaths caused by a subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to consumers and users of these products since that knowledge of the characteristics and its danger to users was acquired.

91. A reasonably prudent manufacturer would have warned of these characteristics and the danger to users, and Defendants' failure to do so renders it liable for all damages, injuries, and death caused by its subsequent failure to use reasonable care to provide adequate warning of the danger to Plaintiff and other users of the product.

92. As a proximate result of Defendants' acts and omissions and Plaintiff's use of Defendants' defective Cow's Milk-Based Products, Helen Miller suffered serious physical injuries and died, and Plaintiff Mary Kate Miller incurred substantial medical and other costs and expenses, and suffered and continues to suffer from mental anguish and emotional distress as a result of the death of her child.

COUNT IV: NON-CONFORMITY TO EXPRESS WARRANTY

93. Plaintiff repeats, reiterates, incorporates, and realleges every allegation contained in this Complaint with the same force and effect as if fully set forth herein, Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

94. At all times relevant to this claim, Defendants, Defendants' corporate predecessors, and others with whom they acted in concert were engaged in the business of

designing, manufacturing, distributing, and selling Cow's Milk-Based Products and held themselves out as having knowledge or skill regarding Cow's Milk-Based Products.

95. At all times relevant to this claim, Defendants, Defendants' corporate predecessors, and others with whom they acted in concert designed, manufactured, distributed, and sold Cow's Milk-Based Products intending or expecting that it would be sold and used in the States of Illinois, Alabama, and Florida.

96. At the time of each sale of Cow's Milk-Based Products which Plaintiff was fed and ingested, Defendants, Defendants' corporate predecessors, and others with whom they acted in concert impliedly warranted that it was of merchantable quality, including that it was fit for the ordinary purposes for which such goods were used, when it was not of merchantable quality.

97. Defendants, through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that Cow's Milk-Based Products was safe and effective and fit for consumption by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, NEC or death, was adequately tested and fit for its intended use.

98. Cow's Milk-Based Products, as manufactured and sold by Defendants, did not conform to these representations because they caused serious injury, including NEC, and can cause death to consumers such as Helen Miller, when used as directed by the product label.

99. Defendants breached their express warranties because their products were and are defective for their intended purpose.

100. Plaintiff did rely on Defendants' express warranties regarding the safety and efficacy of their product in using the product, and such warnings induced Plaintiff to use the

product, and Plaintiff's damages were proximately caused by the untruthfulness of the express warranty.

101. As a foreseeable, direct, and proximate result of the breach of the express warranties, Helen Miller suffered severe personal injuries, and died, causing Plaintiff Mary Kate Miller to suffer and continue to suffer from emotional distress, mental anguish, and economic loss.

PRAYER FOR RELIEF

WHEREFORE, regarding each cause of action set forth above, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and causes of action and as follows:

a. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other noneconomic damages in an amount to be determined at trial of this action;

b. Awarding compensatory damages to Plaintiff for the injuries to and death of Helen Miller, including Helen Miller's pain and suffering, and for severe personal injuries sustained by Helen Miller;

c. Awarding compensatory damages to Plaintiff for the health care costs, funeral costs, and economic loss;

d. Awarding Punitive damages for defendants' conduct;

e. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, and other economic damages in an amount to be determined at trial of this action; and

f. Awarding Pre-judgment interest;

g. Awarding Post-judgment interest;

h. Awarding Plaintiff's reasonable attorneys' fees;

i. Awarding Plaintiff the costs of these proceedings; and,

j. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues so triable.

Dated: January 9, 2026

Respectfully submitted,

/s/ Mackenzi L. Saucier
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