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

SAMANTHA PARKER and BLAKE PARKER, individually and as Co-Administrators of the ESTATE OF C.P., deceased,

Plaintiff,

vs.

ABBOTT LABORATORIES, and ABBOTT LABORATORIES, INC.,

Defendants,

_____/

Case No.: 1:24-cv-03365

COMPLAINT AND DEMAND FOR JURY TRIAL

SAMANTHA PARKER and BLAKE PARKER, individually and as Co-Administrators of the ESTATE OF C.P, deceased (collectively, "Plaintiffs"), by and through undersigned counsel, Parker Waichman LLP, bring this Complaint and Demand for Jury Trial against ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. (collectively "Defendants") and allege as follows upon information and belief:

INTRODUCTION

1. This action arises out of the injuries suffered by premature infant C.P. who was given Defendants' cow's milk-based infant nutrition products. Defendants' products caused C.P. to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based nutrition products. As a result, C.P. was catastrophically injured, and succumbed to his injuries shortly thereafter, resulting in harm to Plaintiffs.

2. NEC is the most lethal gastrointestinal disorder affecting preterm infants, and is characterized by disruption of the intestinal barrier leading to intestinal necrosis, multi-system organ failure and death. The current treatment regimen for infants with NEC includes cardiorespiratory

support, nasogastric decompression, broad-spectrum antibiotics, cessation of enteral feedings, and surgical intervention involving the removal of necrotic intestine or peritoneal drainage, which is indicated when NEC causes a bowel perforation or fails to improve with medical management.

3. Years before C.P. was exposed to Defendants' cow's milk-based infant nutrition products and developed NEC, Defendants were aware, or should have been aware, of the overwhelming body of reliable scientific evidence and research confirming that cow's milk-based nutrition products cause or substantially increase the risk of NEC in preterm infants. Although Defendants knew, or should have known, about the unreasonable and substantial adverse risks their cow's milk-based products posed to preterm infants, they negligently, recklessly, or intentionally failed to make these products safer or adequately warn consumers or the health care community of their products' true risks.

4. Instead, Defendants undermined the science connecting cow's milk-based nutrition products to NEC and unduly influenced the perception of the public and medical community through aggressive and misleading marketing campaigns promoting their cow's milk-based infant nutrition products (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively "Cow's Milk-Based Products") as safe and equivalent or superior alternatives to human milk for *all* infants, which they knew was false.

5. Accordingly, and as a direct and proximate result of Defendants' wrongful conduct in researching, developing, designing, manufacturing, marketing, distributing, and selling Cow's Milk-Based Products, and their failure to warn consumers such as Plaintiffs or C.P.'s physicians and health care providers regarding the known or foreseeable risks of Cow's Milk-Based Products, C.P. was catastrophically injured, and succumbed to his injuries shortly thereafter, resulting in harm to Plaintiffs.

JURISDICTION AND VENUE

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

7. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiffs and the Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

8. This Court has personal jurisdiction over Defendants Abbott Laboratories and Abbott Laboratories, Inc. (collectively "Abbott Defendants") because Abbott Defendants reside in this District, and are incorporated under the laws of Illinois and are authorized to conduct business and do conduct business in the State of Illinois. Abbott Defendants have marketed, promoted, distributed, and/or sold its Cow's Milk-Based Products in the States of Illinois and Kentucky, and Abbott Defendants have sufficient minimum contacts with this state and/or sufficiently avails themselves of the markets in the state through its promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

3. Venue is proper in this Court, under 28 U.S.C. §1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Abbott Defendants are headquartered in this District and transact substantial business in this District.

PLAINTIFF

9. C.P. was born prematurely at Norton Hospital in Louisville, Kentucky in April 2023. C.P. developed NEC shortly after ingesting Defendants' Cow's Milk-Based Products while in the Newborn Intensive Care Unit ("NICU"). At all times material hereto, C.P. was domiciled in and a citizen of the State of Kentucky.

10. C.P. ultimately succumbed to his injuries sustained as a result of ingesting Defendants' Cow's Milk-Based Products on May 1, 2023.

11. Plaintiff, Samantha Parker, the mother of C.P., (hereinafter "C.P.'s Mother"), is domiciled in and a citizen of State of Kentucky, and resides in Trigg County, Kentucky. C.P.'s Mother brings this action individually and to recover for C.P.'s injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous Cow's Milk-Based Products.

12. Plaintiff, Blake Parker, the father of C.P., (hereinafter "C.P.'s Father"), is domiciled in and a citizen of State of Kentucky, and resides in Trigg County, Kentucky. C.P.'s Father brings this action individually and to recover for C.P.'s injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous Cow's Milk-Based Products.

DEFENDANTS

13. Abbott Laboratories, Inc. and/or Abbott Laboratories manufactures, designs, formulates, pre- pares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including New York, and sells premature infant formula including Similac Neosure, Similac Human Milk Fortifier, and Similac Special Care.

14. Abbott Laboratories and Abbott Laboratories, Inc. were at all times material hereto and are now a corporation duly organized, incorporated, and existing under the laws of the State of Illinois with their principal place of business and headquarters in the State of Illinois and is thus residents, citizens and domiciliaries of Illinois. Abbott Laboratories and/or Abbott Laboratories, Inc. manufacture, design, formulate, prepare, test, provide instructions for, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Illinois and Kentucky, premature infant formula and premature infant milk fortifier under the Similac brand name.

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

15. 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 C.P. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

16. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 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.

17. 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.

18. 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).

19. 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).

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 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*.

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 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).

22. 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.

23. 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).

24. 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.*

25. 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).

26. 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).

27. 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).

28. 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).

29. 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). 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.

30. 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).

31. Recognizing a shift in the medical community towards an exclusive human-based diet for preterm infants, 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.

32. The Defendants 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 Defendants market 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.

33. Thus, despite the existence of alternative and safe human milk-based fortifiers, the Defendants continue 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 C.P.

The Inadequate Warnings

34. 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.

35. 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, Defendants did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendants 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.

36. In fact, Defendants did not provide any warning in its labeling, websites, or marketing that warns that its Cow's Milk-Based Products exponentially increase the risk of NEC 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.P. and the Dangerous, Defective Products

37. C.P. was born prematurely in April 2023.

38. C.P. was fed Defendants' Cow's Milk-Based Products while in the NICU.

39. After being fed Defendants' Cow's Milk-Based Products, C.P. was diagnosed with NEC.

40. C.P. died on May 1, 2023 due to NEC.

41. At the time of his death, C.P.'s parents were unaware of the fact that the Defendants' Cow's Milk-Based Products C.P. was fed caused or substantially contributed to his development of NEC and ultimately to C.P.'s death.

COUNT I: STRICT LIABILITY
DESIGN DEFECT (ALL DEFENDANTS)

42. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

43. At all times material to this action, Defendants were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers, including C.P.

44. Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

45. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed and/or sold by Defendants, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

46. Defendants specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like C.P.

47. Defendants' Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

48. Prior to C.P.'s birth, Defendants were aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet took no steps to prevent the use of these products in such situations.

49. Defendants knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

50. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for preterm infants like C.P.

51. Despite the foregoing, the Defendants continue to sell and market their defective and/or unreasonably dangerous products to preterm infants.

52. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as C.P., to risks of serious bodily injury;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers which were available for use here;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;

f. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants failed to inspect or test its products with sufficient care.

53. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable dangerous condition, C.P. suffered serious bodily injury and died.

54. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT II: NEGLIGENCE (ALL DEFENDANTS)

55. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

56. Defendants, as the manufacturers and/or sellers of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

57. Defendants, as manufacturers, has a duty to hold the knowledge and skill of an expert, and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

58. Defendants, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

59. Defendants breached the duty owed to Plaintiffs and acted negligently in its actions, including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data to determine if its products were safe for preterm infants;

d. Failing to collect data to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC;

h. Failing to stop or deter its products from being fed to extremely preterm infants like C.P.;

i. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;

j. Failing to continuously and vigorously study its Cow's Milk-Based products in order to avoid NEC in premature infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

l. Failing to adopt an adequate or sufficient quality control program;

m. Failing to inspect or test its products with sufficient care; and/or

n. Failing to properly and adequately warn of the risks of NEC with use of its products.

60. Defendants knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, like C.P.

61. Defendants knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

62. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for premature infants like C.P.

63. As a direct and proximate result of the negligence of Defendants, C.P. suffered serious bodily injury and died.

64. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: STRICT LIABILITY FAILURE TO WARN (ALL DEFENDANTS)

65. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

66. Defendants, as the manufactures and/or sellers of Cow's Milk-Based Products, 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 Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

67. Defendants, as the manufacturers and/or sellers of Cow's Milk Product, were 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 Cow's Milk-Based Products, as the magnitude of the risk involved is using Defendant's Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury.

68. Defendants, as the manufacturers and/or sellers of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers of its Cow's Milk-Based Products.

69. Defendants owed a duty to provide warnings and instructions on its Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a NICU, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

70. Rather than provide adequate warnings, Defendants developed relationships which included incentives and financial gain to health care providers and facilities for using its Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

71. In addition, and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not used such a dangerous product.

72. Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

73. Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infants.

74. Defendants, through their knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC.

75. Defendants breached the foregoing duties and failed to provide proper warnings and/or instructions of its Cow's Milk-Based Products, including but not limited to the following acts:

a. Providing **no warnings** regarding the risk of NEC;

b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;

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 Product;

e. Failed to provide instructions to consumers and health care providers that the Defendants' products carried a significant risk that its Cow's Milk-Based Products exponentially increased their baby's risk of developing NEC;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do

not warn that the use of Cow's Milk-Based Products significantly increasing the risk of NEC, and they fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk-Based Products are known to significantly increase the risk of NEC when compared to Human Milk in preterm infants;

h. Failed to provide well researched and well-established studies that linked its Cow's Milk-Based Products to NEC in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;

j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

k. Failed to send out "Dear Dr." letters warning of the risks of NEC and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

76. As a direct and proximate result of Defendants' failure to warn, C.P. suffered serious bodily injury and died.

77. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants'

unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT IV: NEGLIGENT MISREPRESENTATION (ALL DEFENDANTS)

78. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

79. Defendant, as the manufacturer, designer, producer, seller, and distributor of the subject products, had a duty to the consuming public, including Plaintiffs, to provide truthful and accurate information about the risks of its bovine-based ingredients when the products are used in their intended manner and for their intended purpose.

80. At all relevant times, C.P. was administered the products at issue in their intended manner and for their intended purpose.

81. Defendant breached its duty to the consuming public, including Plaintiffs, by:

a. misrepresenting that its Cow's Milk-Based Products were safe for premature infants when it knew or should have known that its Cow's Milk-Based Products were unreasonably dangerous and caused NEC and death in premature infants;

b. misrepresenting that its Cow's Milk-Based Products have no serious side effects, when it knew or should have known the opposite to be true;

c. misrepresenting to consumers, including but not limited to, Plaintiffs here, as well as other parents and/or guardians, physicians and healthcare providers, that its Cow's Milk-Based Products were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth and other safer alternatives are available;

d. misrepresenting that its Cow's Milk-Based Products are safe for premature infants;

e. misrepresenting Cow's Milk-Based Products are necessary for optimum growth;

f. misrepresenting that Cow's Milk-Based Products are similar or equivalent and/or a safe alternative to human milk;

g. misrepresenting that the efficacy of Cow's Milk-Based Products were based on well-established studies and/or science; and

h. omitting and/or concealing that the subject products significantly increase the risk of NEC in premature infants, which can cause severe injury and death.

82. As a direct result of Defendants' conduct, as described herein, C.P. was exposed to dangerous Cow's Milk-Based Products, causing him to contract NEC and suffer severe injury and death.

83. As a direct result of Defendants' conduct, as described herein, its unreasonably dangerous products were enterally administered to C.P. causing him to develop NEC and suffer severe injury and death.

84. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiffs suffered significant damages as their lives have been significantly affected by the injuries to and death of their baby.

85. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT V: INTENTIONAL MISREPRESENTATION (ALL DEFENDANTS)

86. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

87. At all times relevant to this action, C.P. (and C.P.'s caretakers) used the products at issue in their intended manner and for their intended purpose.

88. Defendants, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

89. Defendants breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

90. Specifically, upon information and belief, Defendants made the following false statements of material fact on an ongoing and repeated basis and prior to the time C.P. was fed their products:

a. That their 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 cause NEC, serious injury, and death in premature infants; and/or

b. 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

c. That their Cow's Milk-Based Products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That Cow's Milk-Based Products were safe for premature infants; and/or

e. That Cow's Milk-Based Products were necessary for optimum growth; and/or

f. That Cow's Milk-Based Products were similar or equivalent to breast milk; and/or

g. That their Cow's Milk-Based Products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

91. Defendants knew or reasonably should have known those misrepresentations to be false.

92. Defendants' misrepresentations were intended to, and in fact did, induce hospitals and healthcare providers, including C.P.'s hospital and healthcare providers, to provide their infant products to babies, including to C.P.

93. Plaintiffs were not aware that these misrepresentations were false and justifiably relied on them. Defendants' misrepresentations induced C.P. to be fed Cow's Milk-Based Products, in reliance on all the messaging received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Defendants not committed these intentional misrepresentations, C.P. would not have been exposed to their unreasonably dangerous Cow's Milk-Based Products.

94. As a direct and proximate result, Defendants' Cow's Milk-Based Products were fed to C.P. causing him NEC and the subsequent health impacts and death.

95. As a further direct result, Plaintiffs has incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Plaintiffs' lives have been significantly affected by C.P.'s injuries and death.

96. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VI – VIOLATION OF THE KENTUCKY CONSUMER FRAUD PROTECTION ACT KRS § 367, *et seq.*

97. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

98. The Kentucky Consumer Protection Act, KRS § 367.170, states that, "[u]nfair, false, misleading, or deceptive acts or practices . . . are hereby declared unlawful."

99. By the conduct described in detail above and incorporated herein, Defendants engaged in unfair or deceptive acts in violation of the Kentucky Consumer Protection Act.

100. Defendants' unfair and deceptive practices include:

a. developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents and healthcare providers believe that Cow's Milk-Based Products were as safe, or even safer, than human milk; including that it was safe for premature infants;

b. engaging in advertising, promotion and marketing inducing parents and healthcare providers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level;

c. concealing and omitting the risks of NEC associated with the use of Cow's Milk-Based products by premature infants;

d. knowingly and falsely representing that Defendants' formulas and/or fortifiers were fit to be used for the purpose for which it was intended; and

e. representing that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

101. Defendants' false and misleading representations and omissions concerning Cow's Milk-Based Products are material facts that a reasonable person would have considered when deciding whether or not to purchase or use Cow's Milk-Based Products.

102. Defendants' misleading omissions and representations concerning the risks of Cow's Milk-Based Products, and Defendants' scheme to promote Cow's Milk-Based Products as no less safe than human milk: (a) were against public policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

103. Defendants intended for parents and healthcare providers, including the parents and healthcare providers of C.P., to rely on its misleading representations and omissions regarding Cow's Milk-Based Products.

104. Defendants' unfair scheme to promote Cow's Milk-Based Products, and its deceptive representations and omissions concerning Cow's Milk-Based Products, occurred in the course of conduct involving trade or commerce.

105. C.P.'s healthcare providers relied upon Defendants' misrepresentations and omissions in determining which product to administer to him, and C.P.'s parents were deceived into not objecting to Defendants' products by virtue of Defendants' misrepresentations and omissions and deceptive marketing campaigns.

106. As a direct and proximate result of Defendants' deceptive and unfair conduct, described above, C.P. was administered Cow's Milk-Based Products and sustained injuries and damages as described herein.

107. As a direct and proximate result of Defendants' deceptive and unfair conduct, described above, Plaintiffs suffered damages, as described herein, as their lives have been significantly affected by the death of their baby, C.P.

108. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and others. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in the future.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VII - VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACT 815 ILCS 505/1, et seq. (ALL DEFENDANTS)

109. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

110. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2, states that, "[u]nfair methods of competition and unfair or deceptive acts or practices . . . are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby."

111. By the conduct described in detail above and incorporated herein, Defendants engaged in unfair or deceptive acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act.

112. Defendants' unfair and deceptive practices include:

a. developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents and healthcare providers believe Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and other bovine products were as safe, or even safer, than human milk; including that it was safe for premature infants;

b. engaging in advertising, promotion and marketing inducing parents and healthcare providers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level;

c. concealing and omitting the risks of NEC associated with the use of Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and bovine milk by premature infants;

d. knowingly and falsely representing that Defendants' formulas and/or fortifiers were fit to be used for the purpose for which it was intended; and

e. representing that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

113. Defendant's false and misleading representations and omissions concerning Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and bovine milk are material facts that a reasonable person would have considered when deciding whether or not to purchase or use Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care.

114. Defendant's misleading omissions and representations concerning the risks of Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care, and Defendants' scheme to promote Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and other bovine milk products as no less safe than human milk: (a) were against public policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

115. Defendants intended for parents and healthcare providers, including the parents and healthcare providers of C.P., to rely on its misleading representations and omissions regarding Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and other bovine milk products.

116. Defendants' unfair scheme to promote Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and bovine milk products, and its deceptive representations and omissions concerning Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and other bovine milk products, occurred in the course of conduct involving trade or commerce.

117. C.P.'s healthcare providers relied upon Defendants' misrepresentations and omissions in determining which product to administer to him, and C.P.'s parents were deceived into not objecting to Defendants' products by virtue of Defendants' misrepresentations and omissions and deceptive marketing campaigns.

118. As a direct and proximate result of Defendants' deceptive and unfair conduct, described above, C.P. was administered Cow's Milk-Based Products, including but not limited to, Similac and/or Similac Special Care and sustained injuries and damages as described herein.

119. As a direct and proximate result of Defendants' deceptive and unfair conduct, described above, Plaintiffs Samantha Parker and Blake Parker suffered significant damages, including severe emotional distress, loss of income, and other damages as their lives have been significantly affected by the death of their baby, C.P.

COUNT VIII - PARENTAL CLAIM FOR LOSS OF FILIAL CONSORTIUM, LOSS OF SERVICES, AND LOSS OF MEDICAL EXPENSES (ALL DEFENDANTS)

120. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

121. At all relevant times, Plaintiffs Samantha Parker and Blake Parker were the Parents and Legal Guardians of C.P., a minor.

122. As a proximate result of one or more of the aforesaid wrongful acts and/or omissions of the Defendants, Plaintiffs Samantha Parker and Blake Parker, as the Parents and Next Friends of C.P., a minor, have incurred certain necessary medical expenses and costs for medical care and treatment rendered to C.P., a minor, as a result of his injuries.

123. As a result of Defendants' tortious conduct, Plaintiffs Samantha Parker and Blake Parker suffered a loss of affection, companionship, society, and consortium of their child.

124. As a result of Defendants' negligence, Plaintiffs Samantha Parker and Blake Parker were deprived of the society, love, affection, companionship, and services of their minor son, C.P., and are entitled to recover pursuant to KRS 411.135 and their rights at common law.

125. Plaintiffs Samantha Parker and Blake Parker bring this loss of filial consortium as a derivative claim of each of the claims and allegations above.

WHEREFORE, Plaintiffs, Samantha Parker and Blake Parker, individually and as the Parents and Next Friends of C.P., seek recovery for all damages permitted by law against the Defendants, and for whatever further relief this Court deems appropriate.

COUNT IX – SURVIVAL ACTION (ALL DEFENDANTS)

126. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

127. Plaintiffs Samantha Parker and Blake Parker, individually and as the Parents and Next Friends of C.P., are entitled to damages for the harms inflicted upon the decedent, as provided under applicable state law.

128. Plaintiffs Samantha Parker and Blake Parker bring this claim as a derivative claim of each of the claims and allegations above.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable survival action damages, costs of this action, post-judgment interest, and trial by jury.

COUNT X – WRONGFUL DEATH ACTION (ALL DEFENDANTS)

129. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

130. Plaintiffs Samantha Parker and Blake Parker, individually and as the Parents and

Next Friends of C.P., are entitled to damages for the harms inflicted upon the decedent, as provided under KRS 411.130 and other applicable state law.

131. Plaintiffs Samantha Parker and Blake Parker bring this claim as a derivative claim of each of the claims and allegations above.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendants for all applicable wrongful death action damages, costs of this action, post-judgment interest, and trial by jury.

COUNT XI – PUNITIVE DAMAGES (ALL DEFENDANTS)

132. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

133. The failures, acts, and/or omissions of Defendants constitute a reckless disregard for the life and safety of C.P, and therefore, the Plaintiffs are entitled to recover punitive damages from the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment as follows:

1. For compensatory damages in an amount to be proven at trial;

2. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Defendants' conduct;

3. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment, which have or may be recommended;

4. For exemplary and punitive damages against Defendants in an amount to be

proven at trial, and sufficient to punish or deter Defendants and others from repeating the injurious conduct alleged herein;

5. For interest as permitted by law;

6. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby request a trial by jury on all issues triable by jury.

Dated: April 25, 2024

Respectfully submitted,

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