**IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS CHICAGO DIVISION**

[redacted]

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Case No.

**PLAINTIFF'S COMPLAINT AND JURY DEMAND: PRODUCTS LIABILITY**

**INTRODUCTION**

This action arises out of the injuries suffered by Plaintiff's premature infant, who was fed Defendant's cow's-milk-based infant formula and/or fortifier. Defendant's products caused the injured infant to develop Necrotizing Enterocolitis (hereinafter "NEC"), a life-threatening and potentially 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 often lead to surgery and even 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. The companies who 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, baby [redacted] (hereinafter "[redacted]"), who was premature at birth, was fed these cow's milk-based products, developed NEC, and suffered significant injuries as a result.

Plaintiff, [redacted], as Parent, Natural Parent, and Next Friend of [redacted], brings this cause of action against Defendant 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").

## GENERAL ALLEGATIONS

Plaintiff, [redacted], as Parent, Natural Parent, and Next Friend of [redacted], (hereinafter "Plaintiff"), by and through the undersigned counsel, brings this Complaint against Defendant, Abbott Laboratories; and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

## JURISDICTION AND VENUE

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

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

3. This Court has personal jurisdiction over Defendant because Defendant resides in this District and is incorporated under the laws of Illinois and is authorized to conduct business and does conduct business in the State of Illinois. Defendant has marketed, promoted, distributed, and/or sold its Cow's Milk-Based Products in the States of Illinois and Texas, and Defendant has sufficient minimum contacts with this state and/or sufficiently avails itself 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.

4. Venue of this action is proper in this Court pursuant to 28 U.S.C. §§1391 (a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Defendant transacts substantial business in this District.

**PLAINTIFF**

5. [redacted] was born prematurely at Methodist Dallas Medical Center in Dallas, Texas on April 19, 2015. Upon information and belief, [redacted] developed NEC after being fed Abbott's Similac Cow's Milk-Based Products while in the NICU at Methodist Dallas Medical Center in Dallas, Texas. At all times material hereto, [redacted] was domiciled in and was a citizen of State of Texas.

6. Plaintiff, DaNitra Rhodes, the mother of [redacted], (hereinafter "[redacted]'s Mother"), domiciled in and is a citizen of State of Texas, and resides in Desoto in Dallas County, Texas. [redacted]'s Mother brings this action against Defendant to recover for [redacted]'s injuries, which are the direct and proximate result of consumption of Defendant's unreasonably dangerous cow's milk-based products.

**DEFENDANT**

7. Defendant, Abbott Laboratories ("Abbott") was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Illinois with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen and domiciliary of Illinois. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of

commerce in all fifty states premature infant formula and premature infant milk fortifier under the Similac brand name, including Similac Human Milk Fortifier and Similac NeoSure.

8. Defendant Abbott advertises that it provides the "#1 Formula Brand, Backed by Science" and claims to have "over 90 years of innovations" in infant formula.

## FACTUAL ALLEGATIONS

### The Science and Scope of the Problem

9. 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 Baby Kingston. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

10. 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 Baby Kingston, 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.

11. 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 versions.

12. 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).

13. 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).

14. 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.*

15. 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-e841 (2012).

16. 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 companies such as the Defendant.

17. 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 (Newborn Intensive Care Unit). E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

18. 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.*

19. In 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).

20. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants significantly 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).

21. 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).

22. 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).

23. 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.

24. 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).

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

26. The Defendant has designed a systematic, powerful, and misleading marketing campaign 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, 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.

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

**The Inadequate Warnings**

28. Defendant promotes 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.

29. 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, Defendant 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.

30. In fact, the Defendant does not provide any warning in its labeling, websites, or marketing that discusses the risk of NEC and death with use of its Cow's Milk-Based Products

with preterm infants.

31. Thus, Defendant does not warn the users, the parents, or the medical providers and staff that these Cow's Milk-Based Products can cause NEC or death, nor do they provide any guidance on how to avoid or reduce the risks of NEC or death while using its products.

**Baby Kingston and the Dangerous, Defective Products**

32. [redacted] was born prematurely at Methodist Dallas Medical Center in Dallas, Texas on April 19, 2015. [redacted] was born preterm at 26 weeks and 3 days gestation age with a low birth weight of 701 grams, and a length of 33 centimeters.

33. After he was born, [redacted] was sent to the Neonatal Intensive Care Unit (NICU) at Methodist Dallas Medical Center.

34. Following his birth, his mother successfully pumped her own breast milk for her baby's nutrition.

35. [redacted] was fed his mother's own milk or donor breast milk from day of life one until May 14, 2015, when a **Human Milk Fortifier** was added to his feeds of breast milk to increase the calories to 22 calories per ounce.

36. The next day, on May 15, 2020 his feeds were increased to 24 calories per ounce by adding additional Human Milk Fortifier to his feeds of human milk.

37. On May 22, 2015, [redacted] was first fed **Similac NeoSure** preterm formula, a cow's milk-based product.

38. On May 28, 2015 at 1:00 AM, [redacted]'s feeds were stopped due to recurrent episodes of vomiting and a significant increase in his abdominal girth.

39. [redacted] was diagnosed with NEC on May 28, 2015 and was forced to undergo an exploratory laparotomy, resulting in the resection of half of his small intestine and the

placement of an ostomy.

40. [redacted] underwent a second abdominal surgery for anastomosis of his intestinal tract on July 7, 2015.

41. Shortly after his discharge from Methodist Dallas Medical Center, Baby Kingston was admitted to Children's Medical Center Dallas where he was forced to undergo an additional operation for complications from his first two NEC surgeries.

42. Today, [redacted] suffers from short bowel syndrome because of his extensive surgical history. He is underweight, suffers from incontinence, and will require gastrointestinal follow-up care for the rest of his life.

43. At the time he was diagnosed with and treated for NEC, [redacted]'s parents were unaware of the fact that the Defendant's Cow's Milk-Based Products he was fed caused or substantially contributed to his development of NEC and resulting injuries.

**COUNT I: STRICT LIABILITY AS TO DEFENDANT ABBOTT'S DESIGN**

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

45. At all times material to this action, Defendant Abbott was 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 Baby Kingston.

46. Defendant Abbott, as a manufacturer, 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.

47. At all times material to this action, the Cow's Milk-Based Products manufactured,

distributed and/or sold by Defendant Abbott, 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.

48. Defendant Abbott specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like [redacted].

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

50. Prior to [redacted]'s birth, Defendant Abbott was aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, as nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

51. Defendant Abbott 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.

52. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants like [redacted].

53. Despite the foregoing, the Defendant continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

54. 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 [redacted], 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. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

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

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

55. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable dangerous condition, [redacted] suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

**COUNT II: NEGLIGENCE AS TO DEFENDANT ABBOTT**

56. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

57. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

58. Defendant Abbott, as a manufacturer, 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.

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

60. Defendant breached the duty owed to Plaintiff 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 and death 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 and death;

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

h. Failing to stop or deter its products from being fed to preterm infants like Baby Mason;

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 update its warnings and/or instructions based upon currently available data, research, and studies;

k. Failing to take reasonable steps to prevent preterm infants from developing NEC and/or death

l. Failing to take reasonable precautions to prevent preterm infants from developing NEC and/or death

m. Improperly creating agreements with hospitals whereby its products would be over utilized to the detriment of the preterm infants; and/or

n. Improperly promoting continued use of its product in hospitals despite knowing of the great harm it was causing; and/or

o. Failing to develop comprehensive mitigation strategies to reduce the risk of NEC and/or death in its products; and/or

p. Intentionally promoting a culture of silence whereby the harmful effects of its products were never being communicated to the parents or the public; and/or

q. Failing to insert a warning or instruction to healthcare professionals in the NICU

that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed cow's milk-based products; and/or

r. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC and death in premature infants;

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

t. Failing to adopt an adequate or sufficient quality control program; and/or

u. Failing to inspect or test their products with sufficient care.

61. Defendant Abbott knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, like [redacted].

62. Defendant Abbott 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.

63. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely premature infants like [redacted].

64. As a direct and proximate result of the negligence of Defendant Abbott, [redacted] suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

**COUNT III: FAILURE TO WARN AS TO DEFENDANT ABBOTT**

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set

forth herein.

66. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

67. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its 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 and death.

68. Defendant Abbott, as the manufacturer and/or seller 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 in its Cow's Milk-Based Products.

69. Defendant 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 Newborn Intensive Care Unit ("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, Defendant Abbott 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. Defendant Abbott, as a manufacturer, 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.

73. Defendant Abbott, 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. Defendant Abbott, through its 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 and death.

75. Defendant Abbott 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 defendant's Cow's Milk Product;

e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that its Cow's Milk-Based Products could cause their baby to develop 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 on the use of Cow's Milk-Based Products significantly increasing the risk of NEC and 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 death 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 Defendant Abbott's failure to warn, [redacted] suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff 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 Defendant's 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 interest as permitted by law;

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

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

**DEMAND FOR JURY TRIAL**

Plaintiff hereby requests a trial by jury on all issues triable by jury.

Respectfully submitted,