UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ANDREW COULOMBE and KENSIE SHEEHAN, individually and on behalf of their minor child AUTUMN COULOMBE, Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	CIVIL ACTION NO.: **COMPLAINT AND PLAINTIFFS' DEMAND FOR A TRIAL BY JURY**

NATURE OF THE CASE

1. This case arises out of serious and preventable injuries suffered by a newborn infant, Autumn Coulombe, due to a horrific and potentially deadly disease caused and/or substantially contributed to by cow's-milk-based infant formula and/or fortifier. The Plaintiffs in this action, Andrew Coulombe and Kensie Sheehan, bring this suit on their own behalves as parents, and on behalf of their minor infant daughter, Autumn Coulombe. In bringing this case, they seek recovery for damages as a result of Baby Autumn developing Necrotizing Enterocolitis (hereinafter "NEC"), which was directly and proximately caused by the Defendant's Cow's Milk-Based Products, specifically, Similac NeoSure Premature Infant Formula. NEC is a dangerous, potentially deadly, and life-altering intestinal disease that largely affects premature babies who are given cow's-milk-based feeding products. NEC is characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. 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, including the Defendant here, Abbott Laboratories, 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 potentially deadly products as something similar to or even superior to human breast milk. As a result, Baby Autumn was seriously injured, resulting in long-term health effects and harm to her and her parents.

PARTIES

2. Plaintiff, Andrew Coulombe, is a natural person and a resident of the Commonwealth of Massachusetts. Mr. Coulombe is Autumn Coulombe's father. Mr. Coulombe brings this suit in his personal capacity and on behalf of his minor child, Autumn Coulombe ("Baby Autumn").

3. Plaintiff, Kensie Sheehan, is a natural person and a resident of the Commonwealth of Massachusetts. Ms. Sheehan is Autumn Coulombe's mother. Ms. Sheehan brings this suit in her personal capacity and on behalf of her minor child, Autumn Coulombe ("Baby Autumn").

4. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name. Abbott Laboratories is listed as a Massachusetts Secretary of State Entity No. 364184946, in "active" status. Abbott Laboratories has conducted business and has derived substantial revenue from the Commonwealth of Massachusetts.

JURISDICTION AND VENUE

5. This Court has personal jurisdiction over Abbott under 28 U.S.C. § 1391(c) because Abbott transacts business in the Commonwealth of Massachusetts and is a corporation doing business within the Commonwealth of Massachusetts. Abbott knows that its Similac products are

and were sold throughout Massachusetts, and more specifically, caused Similac to be fed to Baby Autumn in Massachusetts. In addition, Abbott maintains sufficient contacts with the Commonwealth of Massachusetts such that this Court's exercise of personal jurisdiction over it does not offend traditional notions of fair play and substantial justice.

6. Abbott advertises and sells food, specifically Similac premature infant formula, throughout Massachusetts. It derives substantial revenue from goods and products used in Massachusetts. It expected its acts to have consequences within Massachusetts and derived substantial revenue from interstate commerce. Specific to this case, Abbott engaged in the business of developing, manufacturing, testing, packaging, marketing, distributing, labeling and selling Similac NeoSure Premature Infant Formula. Abbott purposefully availed itself of the privilege of conducting activities within Massachusetts, thus invoking the benefits and protections of its laws.

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between the Plaintiffs and the Defendant. Abbott is a citizen of Illinois. Plaintiffs are citizens of Massachusetts, and the amount in controversy exceeds $75,000 exclusive of interest and costs.

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

TAG-ALONG ACTION

9. This is a potential tag-along action and in accordance with 28 U.S.C. § 1407, it should be transferred to the United States District Court for the Northern District of Illinois for inclusion in the *In Re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation*

MDL # 3026 (Hon. Rebecca R. Pallmeyer).

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

10. Nutrition for preterm babies, like Baby Autumn, is significantly important. Preterm and low birth weight infants are especially susceptible to NEC because of their underdeveloped digestive systems.

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

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-e84l (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 manufacturers 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. 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 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).

20. 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).

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

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

The Defendant's 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, Abbott did not warn parents or medical providers of the significantly increased risk of NEC associated with its products in preterm infants, or the magnitude of this increased risk. 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. Moreover, despite knowing that its product significantly increases the risk of NEC and death in premature infants, Abbott deliberately chose to omit a specific warning of NEC or death and deliberately failed to provide any detailed instructions or guidance on how to avoid NEC or death when feeding Similac.

31. In fact, Defendant 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 and death in preterm infants, or that human breast milk, donor breast milk, and human breast milk- based formulas and fortifiers are much safer for preterm babies than its Cow's Milk-Based Products.

32. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

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

34. The Defendant, Abbott Laboratories, failed to properly warn that its product, Similac, can significantly increase the risk that a premature infant will develop NEC and suffer serious life-altering injuries as occurred to Baby Autumn.

35. Based on information and belief, Abbott's Cow's Milk-Based Product, Similac NeoSure, did cause Baby Autumn to develop NEC, which caused her severe and personal injuries, physical pain and suffering, emotional pain and mental anguish to her parents, medical expenses, and other economic and non-economic damages.

Safer Alternative Designs

36. Abbott's Cow's Milk-Based Products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant could have used pasteurized breast milk instead of cow's milk in its products, which would have produced a safer product.

37. Prolacta Bioscience manufactures and sells breast milk-based feeding products specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that Cow's Milk-Based Products provide, without the same unreasonably dangerous and deadly effects.

38. On information and belief, Abbott was aware of the significantly increased risk of NEC and death associated with its Cow's Milk-Based Products and instead of warning of the dangers, or removing them altogether, Abbott has continued to use cow's milk as the foundation of its products.

Abbott's False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

39. Abbott has aggressively marketed its Cow's Milk-Based Products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to Baby Autumn's birth.

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

41. Abbott's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that Defendant's Cow's Milk-Based Products are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mother from breastfeeding, which reduces the mother's supply of breast milk. *None* of the Defendant's marketing materials, including its promotional websites, reference the science showing how significantly their products increase the risk of NEC.

42. Abbott markets and sells multiple products specifically targeting preterm and low birth weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help her support her development." Yet, no mention was made of the accompanying significant risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

43. Formula manufacturers such as Abbott have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-of-town families stay while their babies receive long-term treatment in the NICU.

44. Through this early targeting, the Defendant creates brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the

hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant. Defendant's gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their health care professionals, and they have been shown to negatively impact breastfeeding rates.

45. Further, when the Defendant recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier." This name is misleading in that it suggests that the product is derived from breast milk, when, in fact, it is a Cow's Milk-Based Product. The packaging appears as:

46. The Defendant has designed powerful misleading marketing campaigns to deceive parents into believing that: (1) Cow's Milk-Based Products are safe, including for preterm

infants; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breast milk; (3) Cow's Milk-Based Products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant's Cow's Milk-Based Products a first choice. This marketing scheme is employed depute the Defendant knowing of and failing to warn of the extreme risk of NEC that its Cow's Milk-Based Products pose to preterm infant like Baby Autumn.

Baby Autumn and the Dangerous, Defective Products

47. Baby Autumn was born at Beverly Hospital in Beverly, Massachusetts on July 15, 2022.

48. Baby Autumn was born prematurely, at 37 weeks gestation. She was born with a low birth weight of 4 pounds 5.8 ounces. She was also born in respiratory distress and had an intrauterine growth restriction.

49. Following her birth, Baby Autumn was placed in the Special Care Nursery at Beverly Hospital.

50. Baby Autumn's mother, Kensie Sheehan, was advised by physicians not to breastfeed due to Ms. Sheehan's own condition of epilepsy and medication that she takes to treat that condition.

51. Starting on July 16, 2022, one day after her birth, Baby Autumn was fed Similac NeoSure premature infant formula, which is a Cow's Milk-Based Product, through a nasogastric, or NG tube.

52. For the next few days, Similac NeoSure formula made up most of Baby Autumn's diet.

53. On July 20, 2022, Baby Autumn was noted to be "ill appearing, jaundiced, mottled, decreased tone (cries with painful stim)...." Her abdomen was tender to the touch, and she had "very loose stools with Bright Red bloody streaks." The evaluating nurse noted her condition to

be "consistent with NEC."

54. Following X-rays and a blood culture, Baby Autumn was diagnosed with Necrotizing Enterocolitis (NEC) while in the Special Care Nursery at Beverly Hospital, at only five (5) days old, just a few days after she first ingested the Defendant's products.

55. On that same day, July 20, 2022, Baby Autumn was transferred from Beverly Hospital to Beth Israel Deaconess Medical Center in Boston, Massachusetts for treatment of her NEC. She remained at Beth Israel Deaconess Medical Center until August 19, 2022.

56. As a result of developing NEC, Baby Autumn was forced to undergo fourteen (14) days of antibiotic therapy, which included no food or liquid for that time, with solely intravenous nutrition, an extended hospitalization at the time of her birth, and she suffered long-term health effects.

57. Upon her discharge from Beth Israel Deaconess Medical Center, Baby Autumn was transferred back to the Special Care Nursery at Beverly Hospital where she stayed until August 31, 2022 when she was finally able to go home with her parents for the first time.

58. At the time of her diagnosis and hospitalization, Baby Autumn's parents were unaware of the fact that the Defendant's Cow's Milk-Based Products that Autumn was fed caused or substantially contributed to her development of NEC.

COUNT I
NEGLIGENCE

59. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

60. Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and the 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.

61. Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert, and is obligated to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

62. At all times relevant to this action, Baby Autumn's health care providers used the products at issue in their intended manner and for their intended purpose.

63. 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.

64. Specifically, although Abbott knew or reasonably should have known that its Cow's Milk-Based Products significantly increased the risk of NEC, serious injury, and even death, in premature infants, Abbott failed to act in a reasonably prudent manner and breached its duty owed to the Plaintiffs by:

a. Designing 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. Allowing the products to contain hidden and dangerous design defects and not be 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 Autumn;

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; and/or

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

65. Abbott knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, like Baby Autumn.

66. 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 potentially deadly NEC.

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

68. As a direct result of Abbott's failure to act in a reasonably prudent manner and its breach of duty, Baby Autumn was fed Cow's Milk-Based Products, which caused her to develop NEC.

69. Had Abbott satisfied its duties to the consuming public in general, Baby Autumn would not have been exposed to Abbott's unreasonably dangerous Cow's Milk-Based Products.

70. As a direct and proximate result of the negligence of the Defendant Abbott Laboratories, Baby Autumn suffered serious bodily injury, and significant pain and suffering. Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Their lives have been significantly affected by their daughter's injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT II
DESIGN DEFECT

71. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

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

73. Despite knowing that its product would be used on premature infants, like Baby Autumn, and despite knowing (or should have known) that such use was unreasonably dangerous to premature infants in that its Cow's Milk-Based Product was significantly increasing the risk of NEC, a dangerous and potentially deadly disease, the Defendant continued to sell its defective product to premature infants.

74. Over the last several years, scientific data and well researched studies have concluded

that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the product's benefits, yet the Defendant continued to market and sell its defective products for premature infants like Baby Autumn.

75. The Defendant's Cow's Milk-Based Product, Similac NeoSure, fed to Baby Autumn was unreasonably dangerous.

76. The risks of feeding the Defendant's cow's milk-based product, Similac NeoSure, to Baby Autumn outweighed its benefits.

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

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

79. As a direct result, Abbott's unreasonably dangerous product was fed to Baby Autumn, causing her to develop NEC.

80. As a direct and proximate result of Abbott's developing, manufacturing, selling, and distributing its unreasonably dangerous cow's milk-based infant formulas, Plaintiff Baby Autumn suffered serious bodily injury, and significant pain and suffering. Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Their lives have been significantly affected by their daughter's injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment

against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT III
FAILURE TO WARN

81. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

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

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

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

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

a. Would be used, as it was, on premature infants like Baby Autumn yet it failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that its cow's milk-based product significantly increases the risk of NEC and death in these babies; and/or

b. Was unsafe and/or contra-indicated for premature infants like Autumn; and/or

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

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's cow's milk-based product; and/or

e. Failed to provide instructions that parents needed to know that the Defendant's product carried a significant risk that its cow's milk-based product could cause their baby to develop NEC and potentially die; and/or

f. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn on cow's milk-based formula significantly involving the risk of NEC and death or providing any details on how to avoid such harm; and/or

g. Failed to have a large and prominent "black box" type warning that its cow's milk-based products are known to significantly increase the risk of NEC and death when compared to Human Milk in premature infants; and/or

h. Failed to provide well researched and well-established studies that linked its cow's milk-based products to NEC and death in premature infants; and/or

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

j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow's milk-based formula; and/or

k. Failed to provide detailed instructions to NICUs and physicians on when to stop feeding Similac; and/or

l. Despite knowing that parents were not being warned of the risk of NEC by their physician, failing to take adequate measures to warn the parents directly; and/or

m. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, Baby Autumn was fed Cow's Milk-Based Products which caused her to develop NEC; and/or

n. Science and data have established that the only consistent observations made in infants who develop NEC are the presence of: 1) prematurity 2) cow's milk formula, yet Abbott fails to warn of this significant scientific conclusion and instead tries to hide this conclusion; and/or

o. Failed to place a prominent warning and instructions that would have prevented the feeding of Similac to Baby Autumn; and/or

p. Failed to establish a standard for safe use; and/or

q. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or

r. Failed to provide statistical evidence of adverse effects regarding the feeding of its products; and/or

s. Failed to guide or instruct on when to start, how much to start, how to increase, volume and timing of feeds, when not to feed, and/or when to stop feeding its products to premature infants; and/or

t. Failed to provide periodic or yearly safety reports; and/or

u. Failed to provide periodic or yearly risk-benefit analysis for use of its products; and/or

v. Failed to provide or produce yearly safety update reports; and/or

w. Failed to develop a protocol for hospitals and physicians with the elements to assure safe use; and/or

x. Failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of its products specifically designed for premature infants.

86. Moreover, had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would have not used such a dangerous product when feeding Baby Autumn. Had the Plaintiffs known of the extreme risks

associated with feeding premature infants cow's milk-based formula, they would have not allowed such a product to be given to their daughter.

87. As a result and proximate cause, Baby Autumn was fed Abbott's Similac NeoSure Cow's Milk-Based Product causing her to develop NEC and suffer serious bodily injuries.

88. As a direct and proximate result of Abbott's failure to warn as explained herein, Baby Autumn suffered serious bodily injuries and significant pain and suffering. Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms as lives have been significantly affected by their daughter's injuries as a direct and proximate result of Abbott's conduct described herein.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY
M.G.H. Chapter 106, Section 2-313

89. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

90. The Defendant Abbott Laboratories manufactured, marketed, promoted, distributed and/or sold its Similac NeoSure cow's milk-based formula as safe for use by premature infant babies. Abbott knew the use for which the formula was intended and expressly warranted the products to be merchantable quality, safe and fit for use.

91. The Defendant further expressly warranted that its product was the "#1 Formula Brand, Backed by Science" and that it had "over 90 years of innovations" in infant formula.

92. In its advertising, Abbott expressly warranted that its product had the ability to assist underdeveloped babies in reaching their growth targets. Moreover, on its since-edited webpage, Abbott expressly warranted that Similac NeoSure was a nutrient-enriched formula that would support the development of premature infants.

93. The Defendant's Cow's Milk-Based Products do not conform to these express warranties and representations because they are not the #1 formula brand, backed by science when they have the potential to cause the dangerous and deadly disease of NEC.

94. Abbott's Cow's Milk-Based Products, namely Similac NeoSure, does not conform to these express representations in violation of Massachusetts General Laws Chapter 106 §2-313(1), and Massachusetts common law because the formulas are not safe or effective, nor are they safer or more effective than other breast-milk based formulas available, and they may produce serious side effects, including among other things, NEC and potentially death.

95. As a direct and proximate result of Abbott's breach of express warranty, Plaintiff Baby Autumn developed NEC, suffered severe physical injuries and significant pain and suffering. Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms as lives have been significantly affected by their daughter's injuries as a direct and proximate result of Abbott's conduct described herein.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT V
BREACH OF IMPLIED WARRANTY
M.G.H. Chapter 106, Sections 2-314, 2-315

96. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

97. The Defendant, Abbott Laboratories, is a merchant with respect to goods like Similac NeoSure cow's milk-based formula.

98. The Defendant marketed, manufactured, promoted, distributed and/or sold Similac NeoSure cow's milk-based formula as safe for use by premature infants, including the Plaintiff Baby Autumn, who was fed the formula by the hospital where she was born prematurely.

99. The Defendant knew or in the exercise of reasonable care should have known the use for which Similac NeoSure cow's milk-based formula was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

100. Abbott's Similac NeoSure cow's milk-based formula does not conform to these implied warranties in violation of Massachusetts General Laws Chapter 106 §§ 2-314 and 2-315, and Massachusetts common law, as it is defective in design and manufacture and is therefore not fit for its intended uses and was not designed, manufactured, or sold in accordance with good design, manufacturing, or industry standards. Similac NeoSure cow's milk-based formula is not fit for its common, ordinary and intended uses because of the increased risk of NEC in premature infants. Therefore, the Defendant Abbott Laboratories has breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose. Such breaches by the Defendant was a proximate cause of the injuries and damages sustained by the Plaintiffs.

101. When Abbott's Similac NeoSure cow's milk-based formula was distributed into the stream of commerce and sold by the Defendant, it was unsafe for its intended use, and not of merchantable quality as warranted by the Defendant, as its use causes NEC in premature infants.

102. As a direct and proximate result of Defendant's breach of implied warranty, Baby Autumn developed NEC, suffered severe physical injuries and significant pain and suffering. Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms as lives have been significantly affected by their daughter's injuries as a direct and proximate result of Abbott's conduct described herein.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT VI
INTENTIONAL MISREPRESENTATION

103. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

104. At all times relevant to this action, Baby Autumn (and her physicians and caretakers) used the products at issue in their intended manner and for their intended purpose.

105. Abbott, as the manufacturer and/or seller of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using its products when used in the intended manner and for the intended purpose.

106. Abbott breached its duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous

paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

107. Specifically, upon information and belief, Abbott made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Autumn was fed its products:

a. That Abbott's Cow's Milk-Based Products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. 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/or

c. That its 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 optimal growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That its products were safe and more like breast milk that other infant products and that it had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or

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

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

108. Abbott knew or reasonably should have known those misrepresentations to be false.

109. The Defendant's misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including Baby Autumn's hospital and health care providers, to

provide their infant products to babies, including to Baby Autumn.

110. Baby Autumn's parents were not aware that these misrepresentations were false and justifiably relied on them. The Defendant's misrepresentations induced her parents to allow their daughter to be fed Abbott's infant products, in reliance on all the messaging they received about formula feeding, including directly or indirectly, the Defendant's messaging. Had Abbott not committed these intentional misrepresentations, Baby Autumn would not have been exposed to the Defendant's unreasonably dangerous Cow's Milk-Based Products.

111. As a direct result, Abbott's products were fed to Baby Autumn, causing her to develop NEC and the subsequent health impacts.

112. As a further direct result, Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms as lives have been significantly affected by their daughter's injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT VII
NEGLIGENT MISREPRESENATION

113. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

114. At all times relevant to this action, the Plaintiffs used the products at issue in their intended manner and firm their intended purpose.

115. Abbott, as the manufacturer and/or seller of the products at issue in this litigation, owed a duty to the consuming public in general and to the Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using its products when used in the

intended manner and for the intended purpose.

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

117. Specifically, upon information and belief, Abbott made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Autumn was fed its products:

a. That Abbott's Cow's Milk-Based Products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. 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/or

c. That its 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 optimal growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That its products were safe and more like breast milk that other infant products and that it had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or

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

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

118. Abbott was negligent or careless in not determining those representations to be false.

119. The Defendant's misrepresentations were intended to and did in fact induce hospitals and health care providers including Baby Autumn's hospital and health care providers, to provide their infant products to babies, including to Baby Autumn.

120. The Defendant's misrepresentations induced, and were intended to induce, Baby Autumn's parents to allow their daughter to be fed Abbott's infant products, in reliance on all the messaging they received about formula feeding, including directly or indirectly, the Defendant's messaging. Had Abbott not committed these negligent misrepresentations, Baby Autumn would not have been exposed to the Defendant's unreasonably dangerous Cow's Milk-Based Products.

121. As a direct result, Abbott's products were fed to Baby Autumn, causing her to develop NEC and the subsequent health impacts.

122. As a further direct result, Baby Autumn's parents have incurred significant expenses for medical care and treatment and suffered significant emotional distress, loss of income, loss of consortium, and other harms as lives have been significantly affected by their daughter's injuries.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

COUNT VIII
LOSS OF CONSORTIUM

123. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

124. Loss of filial consortium is a derivative claim. It is derivative of each of the claims and allegations above.

125. At all relevant times, Plaintiffs Andrew Coulombe and Kensie Sheehan were Baby

Autumn's lawful parents.

126. As a direct result of Abbott's tortious conduct as outlined above, Plaintiffs Andrew Coulombe and Kensie Sheehan suffered a loss of affection, companionship, society and consortium of their child, Baby Autumn.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant Abbott Laboratories for compensatory damages, costs of this action, attorney's fees, post-judgment interest, and all relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

127. The Plaintiffs hereby demand a trial by jury on each claim asserted or hereafter asserted by the Plaintiffs and on each defense asserted or hereafter asserted by the defendant.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray for judgment as follows:

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

129. 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 the Defendant's conduct;

130. 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;

131. For interest as permitted by law;

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

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

Respectfully submitted,
The Plaintiffs,
By their attorneys,

/s/ Julie E. Lamkin

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