

JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

ANIKA HUNTE, AS ADMINISTRATOR OF THE ESTATE OF ARIES PETERSON

(b) County of Residence of First Listed Plaintiff New Haven
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Levin, Rojas, Camassar & Reck, LLC
40 Russ Street
Hartford, CT 06106

DEFENDANTS

ABBOTT LABORATORIES, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
 2 U.S. Government Defendant
 3 Federal Question (U.S. Government Not a Party)
 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
 2 Removed from State Court
 3 Remanded from Appellate Court
 4 Reinstated or Reopened
 5 Transferred from Another District (specify)
 6 Multidistrict Litigation - Transfer
 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 USC 1332

Brief description of cause:
Product Liability / Wrongful Death - Diversity

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND \$**

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Hon. Stefan Underhill

DOCKET NUMBER 3:20-cv-00099-SRU

DATE

10/28/2020

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

**UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT**

ANIKA HUNTE, AS ADMINISTRATOR
OF THE ESTATE OF ARIES PETERSON,

Civil Action No.:

Plaintiff,

Vs.

ABBOTT LABORATORIES, INC.

Defendants.

COMPLAINT

INTRODUCTION

1. This action arises out of the death of a three month old baby, who spent the majority of those three months fighting a horrific and deadly disease caused by cow-based infant formula and/or fortifier. Necrotising Enterocolitis (“NEC”), is a deadly disease that largely affects low birth weight babies who are fed cow-based formula or products. Aries Peterson, a premature born, low birth weight baby, was fed *Similac Neosure*, *Similac Human Milk Fortifier* and *Similac Special Care*, and developed NEC shortly thereafter. Plaintiff Anika Hunte brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendant’s negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the product known as *Similac Neosure*, *Similac Human Milk Fortifier* and *Similac Special Care* (hereinafter collectively referred to as “Products”).

THE PARTIES

2. Aries Peterson (the baby) (“Baby Aries”) was born at Yale New Haven Hospital in New Haven, Connecticut on January 30, 2018. He died on April 18, 2018 at Yale New Haven Hospital after developing Necrotising Enterocolitis. Baby Aries developed NEC within days of being fed Similac Human Fortifier, a cow-based product, and within a day of being started on Similac Special Care.

3. Anika Hunte is the mother of Baby Aries. Mrs. Hunte was duly appointed administrator of the Estate of Aries Hunte on September 10, 2020. She brings this action as Administrator of the Estate of Aries Peterson.

4. The defendant, Abbott Laboratories, Inc. manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including Connecticut, and sells premature infant formula including Similac Neosure, Similac Human Milk Fortifier, and Similac Special Care, and is a "product seller" in accordance with the Connecticut Products Liability Act (CPLA), Conn. Gen. Stat. Section 52-572m, et seq.

JURISDICTION

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

6. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct and does conduct business in the State of Connecticut. Defendant has marketed, promoted, distributed, and sold the Products in the state of Connecticut and Defendant has sufficient minimum contacts with this State and/or sufficiently avails itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

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

BACKGROUND: (The Science, The Marketing and The Baby)

A. The Science

8. Science and research have advanced in recent years confirming strong links between cow-based products and NEC and death in premature infants.

9. In 1990, a prospective multicentre study on 926 preterm infants found that necrotising enterocolitis was 6-10 times more common in exclusively formula-fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. Babies born at more than 30 weeks gestation confirmed that necrotising enterocolitis was rare in those whose diet included breast milk; it was 20 times more common in those fed

formula only. Lucas A, Cole T. *Breast milk and neonatal necrotising enterocolitis*. Lancet 1990; 336: 1519–1523.

10. A study published in 2010 established that when premature babies were fed an exclusive diet of mother’s milk, donor milk, and human milk fortifier, these babies were **90% less likely to develop surgical NEC**. Sullivan, S., et al, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*. (*Journal of Pediatrics* 2010; 156:562-7)

11. In 2011, the Surgeon General published a report titled The Surgeon General’s Call to Action to Support Breastfeeding, warning that **“For vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC).”** U.S. Department of Health and Human Services. The Surgeon General’s Call to Action to Support Breastfeeding. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011, p. 1. This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id.*, Table 1, P.2.

12. 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-based formula. 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.” *Pediatrics* 2012; 129:e827-

e841, *Breastfeeding and the Use of Human Milk*.

13. 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 HC gain (weight and head circumference). 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.” Hair, A, et al, BMC Research Notes 2013, 6-459, *Human milk feed supports adequate growth in infants \leq 1250 grams birthweight*. Thus, inadequate growth was proven to be a poor excuse for feeding cow-based formula.

14. In another study published in 2013 it was reported: “This is the first randomized trial in EP [Extremely Premature] infants of exclusive HM [Human Milk] vs. PF [Preterm Formula]. The significantly shorter duration of TPN and lower rate of surgical NEC support major changes in the strategy to nourish EP infants in the NICU.” Cristofalo, E.A., et al, *Exclusive Human Milk vs Preterm formula: Randomized Trial in Extremely Preterm Infants*. (J Pediatr 2013 Dec; 163(6): 1592-1595.)

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

and After the Development of Necrotizing Enterocolitis. (Expert Rev Clin Immunol. 2014 July; 10 (7): 875-884.) In that same study it was reported: “Necrotizing enterocolitis (NEC) is the most frequent and lethal gastrointestinal disorder affecting preterm infants [1,2], and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies [1-3]. 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 [3,4].” “A wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing necrotizing enterocolitis. There have been several meta-analysis reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC [11–13]. By determining the specific ingredients in breast milk that are protective against NEC, it is our hope that this devastating disease will one day be preventable.”

16. In yet another study published in 2014 it was reported: “An exclusive human milk diet, devoid of CM [Cow Milk] -containing products was associated with lower mortality and morbidity in EP [Extremely Premature] infants without compromising growth and should be

considered as an approach to nutritional care of these infants.” Abrams, Steven, et al. *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*. (Breastfeeding Medicine. 2014, Nov. 4, 9(6):281-286.)

17. A 2016 study supported previous findings that an exclusive human milk diet in extreme premature 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 with multiple years of follow-up using an exclusive human milk diet, and as a result was a very large study. The authors concluded that “the use of an exclusive HUM [human milk] diet is associated with significant benefits for extremely premature infants” and “while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes.” Hair, et al, *Breastfeeding Medicine 2016, 11-2, Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*.

18. In a study published in 2017, it was reported: “In summary, HM has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs on preterm infants weighing between 500 and 1250 g at birth compared the effect of bovine milk-based preterm infant formula to MOM or DHM on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence of NEC.”

19. A Cochrane systematic review that evaluated the effect of DHM or bovine milk-

based formula on health outcomes for preterm infants also determined that formula significantly increases the risk of NEC (75).” Shulhan, Jocelyn, et al *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*.

(ASN. ADV Nutr 2017; 8:8—0-91.)

B. The Marketing

20. Notwithstanding strong medical evidence establishing the extreme dangers that cow-based products pose for premature infants, Abbott has marketed its cow-based products as an equally safe alternative to breast milk, and indeed has promoted its products as necessary for additional nutrition and growth. The Defendant has specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants*, when indeed its products pose a known and substantial risk to these babies.

21. Abbott has attempted to “hook” moms on formula, by offering free formula and other goodies in baskets given to moms in hospital and medical clinics. The impetus behind such efforts is to create brand loyalty, and create the appearance of “medical blessing” so that moms continue to use formula to feed their babies after they leave the NICU, at great expense to the parents, and substantial profit to Abbott.

22. Abbott’s practice of trying to get moms to choose formula over breast milk goes back decades. The company has for decades promoted its product as more healthy, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Their advertising has at

times attempted to portray breast feeding as an inferior, less sophisticated choice.

23. 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 the international marketing of breast-milk substitutes. The World Health 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."** (Baumslag & Michels, 1995, p. 161). 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. The International Code of Marketing of Breast-milk Substitutes specifically prohibited advertising in Article 5 Section 1: "There should be no advertising or other form of promotion to the general public..." The International Code of Marketing of Breast-milk Substitutes. Geneva:World Health Organization, p.16 - 20 (1981).

24. Abbott has acknowledged the Code: "We support, educate and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast- feeding up to and beyond two years of age. . . We acknowledge the importance of the World Health Organization's 1981 International Code of

Marketing of Breast-Milk Substitutes (the “WHO Code”) and subsequent World Health Assembly (WHA) resolutions. We respect the aim and principles of the WHO Code to contribute to the provision of safe and adequate nutrition for infants, by: a) the protection and promotion of breast-feeding; and b) ensuring the proper use of Breast-milk Substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.”

Abbott Policy on the Marketing of Instant Formula.

25. Despite this assurance and warranty contained in its Policy, Abbott has systematically violated the Code’s most important provision: “There should be no advertising or other form of promotion to the general public...”

26. Notwithstanding the Code and Abbott’s own policy claiming to recognize the Code, advertising of infant formula has remained pervasive and widespread in the United States. In short, Abbott has paid lip service to the Code, but in actuality has systematically violated its central provision.

27. Similac was deceptive from its very inception. Similac’s very name (*i.e. similar to lactation*) is deceptive. Beginning with its brand name, Abbott has continued to perpetuate the deception that its product is on par with or similar to human milk.

28. “Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breastmilk.” *Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP. Marketing infant formula through hospitals: the impact of commercial hospital*

discharge packs on breastfeeding. Am J Public Health. 2008;98(2):290-295.

29. For example, one author found an advertisement for Similac on the back cover of American Baby Magazine, April 2004 issue which made repeated references and comparisons to breast milk, and indeed the short ad uses the phrases **“like breastmilk” six times**. Broussard Hyderkhan, A, *Mammary malfunction: a comparison of breastfeeding and bottle feeding product ads with magazine article content*, 2005:



The advertisement is set within a yellow and white striped border. At the top center is a small circular logo with a teddy bear. Below it, the text reads: "Similac® Advance® can help develop both your baby's immune system and brain like breast milk. (Kisses, hugs, and silly songs are up to you.)". A large photograph shows a smiling woman in profile kissing a baby on the forehead; the baby is wearing a yellow hat and a pink shirt. Below the photo, a line of text states: "Breastfeeding is recommended for its many benefits. If you choose to feed formula, ask your doctor about Similac Advance." To the left is an image of a Similac Advance can. To the right, the text says: "Only Similac Advance with DHA and ARA has both*:" followed by two bullet points. The first bullet point describes a patented blend of special breast milk nutrients called nucleotides, which has been clinically shown to help support the development of a baby's immune system like breast milk. It includes a sub-note: "The clinical study showed immune cell development like breast milk. Whether this development provides immune protection like breast milk has not been shown. Breast milk also contains antibodies not found in infant formulas that are important for a baby's immune protection." The second bullet point mentions published long-term clinical research showing brain development like breast milk. At the bottom, the text reads: "So much like breast milk in so many ways." A small footnote at the very bottom states: "*Among formulas with DHA and ARA; infants studied at 12 and 39 months of age. ©2004 Abbott Laboratories. www.SimilacAdvance.com"

30. In addition to perpetuating the myth that Similac is “*like breastmilk*”, Abbott has also deceived the public into believing that Physicians believe Similac is an ideal choice for babies.

31. Beginning in 1989, Abbott began using claims in its advertising that Similac was “first choice of more physicians.”

32. Although the claim did not specifically compare itself to breast milk, a plain interpretation of this claim is that physicians believe Similac is the “1st choice”, naturally implying that it is superior even to breastfeeding.

33. Beginning in 1995, Abbott began a heavy marketing campaign which featured “1st choice of Doctors” on all its infant formula product labels.

34. A marketing report commissioned by Abbott in March, 1998 summarized consumer reactions to several informational advertising pamphlets on Similac. The one stressing the “1st Choice of Doctors” claim scored highest in terms of consumers’ likelihood of purchase. The report concluded: “Doctor recommendations and the ‘science’ behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested,” and use of similar pieces emphasizing the claim was “highly recommended.”

35. One study estimates that formula manufacturers spent \$4.48 billion on marketing and promotion in 2014. *Baker, P, et al, Global trends and patterns of commercial milk-based*

formula sales: is an unprecedented infant and young child feeding transition underway? Public Health Nutrition, 2016.

36. The contradictory messages women receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is unnecessary and difficult if not impossible to achieve" Hausman, B. L. (2000, Summer). *Rational management: Medical authority and ideological conflict in Ruth Lawrence's Breastfeeding: A guide for the medical profession*. *Technical Communication Quarterly*, 9(3), 271-289.

37. One study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. Parker, R. S., & Pettijohn, C. E. (2003). *Ethical considerations in the use of direct-to-consumer advertising and pharmaceutical promotions: The impact on pharmaceutical sales and physicians*. *Journal of Business Ethics*, 48, 279-290.

38. One study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB. *Exposure to infant feeding information in the media during pregnancy is associated with feeding decisions postpartum*. Paper presented at American Public Health Association 138th Annual Meeting & Exposition; November 2010; Washington, DC.

39. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that

when the frequency of infant formula advertisements increased, the percentage change in breast-feeding rates reported the next year generally tended to decrease. *Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.*

40. The Stang study also found that Infant formula company websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing a product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance. *Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.*

41. Abbott has developed an advertisement campaign which attempts to create a perception of “mommy wars”. One advertisement, which received significant attention, *The Mother Hood* tries to depict a “mom war”, where all the competing sides come together to save a baby at the end. The ad is effective in so much as it is manipulative. The advertisement, at one point depicts three “bottle feeding moms”, and one of them proclaims: “*Oh look, the breast police have arrived*”. The ad then depicts the “breastfeeding moms” with arrogant and superior appearing faces, and even disdainful mannerisms, with one of the moms proclaiming in a condescending voice, “100% breast fed - straight from the source”, and a second mom grasping her breast in a profane manner. The negative portrayal of breastfeeding moms is subtle, but power-

ful, and casts the breastfeeding moms as judgmental and nasty, while portraying the bottle-feeding moms as nurturing victims.

www.youtube.com/watch?list=RDJUbgHeZCxe4&v=JUbgHeZCxe4&feature=emb_rel_end

42. Another advertisement titled “The Judgment Stops Here”, a documentary-styled ad, is powerful and moving in that it shows moms coming together, putting aside judgment of each others choices. However, the ad is manipulative, deceptive and violative of the Code and Abbott’s own marketing Policy, in that it puts breast milk and formula on an even playing field, and attempts to chastise any judgment that might be cast in favor or what is clear scientific judgment. In other words, the ad attempts to insulate Similac from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint. <https://www.facebook.com/Similac/videos/1126104447462943>

43. In an Abbott advertisement for a Similac product, the ad states “when you are ready to turn to infant formula, but you don’t want to compromise, look to Pure Bliss by Similac. *It’s modeled after breast milk . . .*” www.youtube.com/watch?v=kRaHiTMyYXs

44. Moreover, Abbott has also attempted to market its products specifically to *prema-ture infants*, who are the infants at highest risk from the dangers of the product.

45. In 1978, Abbott began marketing “Similac 24 LBW”, specifically for premature infants, claiming that the product was “introduced to meet the special needs of premature infants.”

46. In 1980, Abbott began marketing “Similac Special Care” claiming it was the first low-birth-weight, premature infant formula with a composition designed to meet fetal accretion rates.”

47. In 1988, Abbott introduced and marketing Similac Special Care With Iron, claiming it “was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US.”

48. As of 2016, Abbott marketed and sold seven products specifically targeting “Premature/Low birth-Weight Infants”:

- Liquid Protein Fortifier.....
- Similac® NeoSure®.....
- Similac® Human Milk Fortifiers.....
- Similac® Special Care® 20.....
- Similac® Special Care® 24.....
- Similac® Special Care® 24 High Protein.....
- Similac® Special Care® 30.....

49. Upon information and belief, Abbott specifically targets parents of premature infants in their marketing. For example, a Google search “feeding preemies formula”, reveals a paid advertisement on the first page for Similac NeoSure, with the heading “For Babies Born Prematurely”. The web-based advertisement states “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 support her development.” The advertisement further claims that it is “pediatrician recommend-

ed” and “#1 brand fed in Hospitals” and “backed by science”. The advertisement makes no reference to specialized need pre-term infants have for human breast milk, and makes no mention of the risk of developing Necrotising Enterocolitis. Although it is unclear when the promotional effort began, it appears that it was at least as far back as July 24, 2015, which is the date of the first “customer review” on the website.

50. At all relevant times, Abbott has a website “similac.com” where the mothers can choose the formula the Corporation recommends. The website has a tab that indicates “Need help choosing the right formula for your baby? Our Formula Finder can walk you through it”. The website prompts the question: “was your child born prematurely?”. If the mother clicks “yes”, the website directs the mother a page located at <https://similac.com/formula-finder/baby-formula/similac-expert-care-neosure-premature>. Through this website, Abbott directs mothers of premature babies to use Similac NeoSure - a cow-based formula. The page further indicates that the product is “For babies who were born prematurely. Similac NeoSure supports excellent growth in premature babies' gains in weight, length, and head circumference when compared to these gains in preterm babies fed term formulas.”

51. In this promotional website, there is no mention of the risk of necrotising enterocolitis. The promotional web page expressly and implicitly represents that its cow-based product are safe for use with premature infants. This is false and misleading.

52. A consumer searching the following phrases on Google: (1) “Is formula healthy

for premature infants”; or (2) “Is formula safe for premature infants” are shown paid advertisements by Abbott, specifically for their product Similac NeoSure.

https://similac.com/baby-formula/similac-expert-care-neosure-premature?gclid=Cj0KCQjw-uH6BRDQARIsAI3I-UeYjPowMASPff9f0R0P7xM5BNJD-E-6FxOrZtsxgCYhJ75Atli-M8CwaAklEALw_wcB&gclsrc=aw.ds.

53. This webpage makes numerous representations specific to premature infants. For example, Similac “Promotes catch-up growth during your premature baby’s first 12 months” and states that “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 support her development.” There is no reference on this page to the risks associated with Abbott’s product in terms of causing NEC. The promotional website misleads parents of premature infants to believe that Abbott’s product is optimal for premature infants. This is false and misleading.

54. An Abbott advertisement states that “whether you choose to formula feed or, to supplement breast feeding with formula, you can be confident in the nourishment of Similac.” The representation to parents that they can be “confident” is in direct contradiction of the studies that indicate the cow-based formula is dangerous to premature infants. Accordingly, it is false and misleading.

55. The website of Abbott also has reviews from mothers whose premature infants were in the NICU, and they discuss how wonderful and safe the products are. There are no

mother reviews discussing N.E.C. or death. This is false and misleading, and is perpetuated by Abbott. Abbott has designed a plan to induce mother's to continue to purchase the product after leaving the NICU, at great expense.

56. CBS news reported that Abbott paid mom bloggers to give positive reviews of Abbott products.

57. Recognizing a shift in the medical community towards an exclusive human based diet for premature infants, Abbott began developing a product called "Similac Human Milk Fortifier". The name in itself is misleading in that it suggests that the product is derived from human milk. In fact, it is a cow-based product.

58. Abbott has designed a systematic, powerful and misleading marketing campaign to deceive mothers to believe that: (1) cow milk formula and fortifier is safe; (2) cow-milk products are equal, or even superior, substitutes, to breastmilk; and (3) Physicians consider their cow-based products a first choice. Similarly, Abbott has marketed its products for premature infants as necessary for growth, and perfectly safe for premature infants, despite knowing of the extreme risks posed by cow-based products relative to the deadly disease of NEC with regard to premature infants and cow products.

C. **Baby Aries and the Product**

59. Baby Aries was born extremely prematurely with a low birth weight of just over one pound (620 grams), at 27 weeks gestation.

60. The baby was placed in the Neonatal Intensive Care Unit (N.I.C.U.) at Yale New Haven Hospital.

61. Following the birth of Baby Aries, Anika Hunte (mother) successfully pumped her own breast milk, and produced a significant supply sufficient for her baby's nutrition.

62. Early morning of February 16, 2018, Baby Aries was fed a combination of Breast-milk and *Similac Neosure*. *Similac Neosure* is a cow-based formula.

63. By the evening of February 16, 2018, Baby Aries was noted to have a bloody stool.

64. Baby Aries' mother and father had no knowledge that Neosure would increase the risk of their baby developing Necrotising Enterocolitis.

65. Similac promotes Neosure on their website and other mediums as a safe product, and one specifically needed by preemies for adequate growth. See <https://similac.com/baby-formula/similac-expert-care-neosure-premature>. A link on this page specifically promotes the claim that preemies need Neosure for "catchup growth". <https://similac.com/baby-development/preemie/nutrition-premature-babies>. A screenshot is of both is captured on the following two pages.

66. This same webpage contains a video, promoting the necessity of formula as a means to achieve adequate growth in premature infants.

Similac® NeoSure®

Promotes catch-up growth during your premature baby's first 12 months



Read all 464 reviews

Write a review

BUY NOW

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 support her development.

Similac NeoSure is now available in a **NEW value-size can**, which provides over **70% more formula.***

Supports excellent growth during baby's first year.¹

- Increased protein, energy, vitamins, and minerals compared to term infant formula
- Extra calories for growth‡
- Calcium and phosphorus for baby's growing bones

Supports better gains in weight, length, and head circumference for premature babies when compared to term infant formula.¹ Has **OptiGRO®** to support your baby's brain and eye development.



Available In:



22.8-oz Powder



13.1-oz Powder



1-qt Ready to Feed



2-fl-oz Ready to Feed



NeoSure video



No Palm Oil/Palm Olein Oil

Specialized Nutrition For Premature Babies



Preterm nutrition is a story of specialization



Since preterm babies start smaller, their "catch-up growth" will have to be faster than usual for the baby to become the same size as a full-term baby.

Babies born prematurely have specific nutritional needs throughout the first year as their bodies work hard to grow and develop. The right nutrition for premature babies helps them grow in ways you can see, such as weight, length, and head size. Nutrition is also vital for growth you can't see.

Whether you choose to breastfeed or use baby formula, after leaving the hospital, most preemies will benefit from nutritional supplementation or a specialized formula with nutrients that support brain, muscle, bone, and organ growth, and development of a strong immune system.

Similac® NeoSure® is clinically shown to help with catch-up growth. It supports excellent growth during baby's first year, providing increased protein, energy, vitamins, and minerals compared to term infant formula. This means extra calories for growth, as well as calcium and phosphorus for baby's growing bones.

The fat blend in Similac NeoSure is 25% medium-chain triglycerides, an easily digested and well-absorbed fat source.

Similac NeoSure supports better gains in weight, length, and head circumference when compared to standard infant formula.

Read more about the benefits of Similac NeoSure and our NEW value-size can. [Learn more](#)

<https://similac.com/baby-formula/similac-expert-care-neosure-premature>.

67. All this marketing and promotion is designed to instill confidence in Abbott's product lines, and indeed to plant a subtle seed in a parent's mind that formula is safe and necessary to the growth of a premature infant.

68. Prior to baby Aries being fed Similac Neosure, Anika Hunte was exposed to marketing from Abbott that Abbott products were safe and necessary to the growth and nutrition of her premature infant.

69. Although Abbott promotes an aggressive marketing campaign designed to make parents believe that Neosure is safe and necessary for growth of a premature infant, the product is in fact extremely dangerous for premature infants. Neosure substantially increases the chances of a premature infant getting NEC and of dying.

70. Neosure is commercially available at retail locations and online.

71. Despite knowing of the risk of NEC, Abbott did not warn parents of the risk of NEC or dying associated with Neosure.

72. Despite knowing of the risk of NEC, Abbott did not warn doctors, hospital, nurses and medical staff of the risk of NEC or dying associated with Neosure.

Safety Precautions

- **Never use a microwave oven to warm formula.** Serious burns can result.
- Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

* Increased protein, vitamins, and minerals compared to term infant formula.

† Compared to infants fed a formula without DHA and ARA in a clinical trial with Similac Special Care and Similac NeoSure infant formulas with iron; prior to the addition of lutein.

‡ Visual acuity measured at 4 and 6 months corrected age and assessed by VEP (visual evoked potential).

§ Based on a subset of infants in a post-hoc analysis.

¶ No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.

¹ Carver JD, et al. *Pediatrics* 2001;107:638-689.

² Groh-Wargo S, et al. *Pediatr Res* 2005;57:712-718.

³ O'Connor DL, et al. *Pediatrics* 2001;108:359-371.

⁴ Canfield LM, et al. *Eur J Nutr* 2003;42:133-141.

⁵ Schweigert FJ, et al. *Eur J Nutr* 2004;43:39-44.

⁶ Patton S, et al. *Lipids* 1990;25:159-165.

⁷ Rubin LP, et al. *J Perinatol* 2012;32:418-424.

73. The only warnings contained are the following:

74. On or about February 22, 2018, the product, *Similac Human Milk Fortifier*, was introduced to the baby and feeding of this product continued thereafter.

75. Notwithstanding its name, *Similac Human Milk Fortifier* is not derived from human milk. Rather, it is a bovine-derived product.

76. *Similac Human Milk Fortifier* substantially increases the chances of a premature infant developing NEC.

77. Baby Aries was fed *Similac Human Milk Fortifier* from February 22, 2018 through February 26, 2018.

78. Baby Aries' parents were told by hospital staff that their baby would receive *Similac Human Milk Fortifier* as a supplement to mom's own breastmilk.

79. Baby Aries' parents did not know that *Similac Human Milk Fortifier* was derived from cow milk.

80. Baby Aries's parents did not know *Similac Human Milk Fortifier* put their baby at increased risk of NEC and death.

81. The product, *Similac Human Milk Fortifier*, contained only the following packaging information guidelines, instructions and warnings:


Similac® Human Milk Fortifier Concentrated Liquid

- Intended for premature and low-birth-weight infants as a nutritional supplement to add to human milk.
- Use under medical supervision.
- Small, convenient packet is designed for easy mixing.
- When added to human milk, meets the nutrient recommendations for the premature infant.¹
- Commercially sterile and meets the ADA and CDC recommendation to use liquid for NICU feedings.^{2,3,*}
- Packet is simple to open and mixes easier with human milk than powder.⁴
- Low iron level provides flexibility to add iron as needed.
- Halal.
- Kosher.

Safety Precautions

- Add only to human milk - do not add water.
- This product is nutritionally incomplete by itself and is designed to be added to human breast milk.
- Additional iron may be necessary.
- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.
- Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk.
- Never use a microwave oven to warm feedings.** Serious burns can result.

¹ American Dietetic Association and Centers for Disease Control and Prevention
² Klein CJ. *J Nutr* 2002;132(6):1395S-1577S.
³ Centers for Disease Control and Prevention. *Enterobacter sakazakii* infections associated with the use of powdered infant formula—Tennessee, 2001. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5114a1.htm>. Accessed March 10, 2016.
⁴ Pediatric Nutrition Practice Group, Robbins ST, Myers R. *Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities*. ed 2. Chicago: American Dietetic Association, 2011.
⁵ Data on file, 2010. Abbott Nutrition Market Research, Abbott Laboratories, Columbus, Ohio.



82. Despite knowing that *Similac Human Milk Fortifier* increases the risk of NEC and death, Abbott did not warn the parents or the medical providers of NEC or death, nor did it provide any instructions or guidance on how to avoid NEC or death.

83. On February 25, 2018, Baby Aries was first fed *Similac Special Care*.

84. *Similac Special Care* is a cow-based formula.

85. Abbott promotes *Similac Special Care* to parents, physicians, hospitals and medical staff as a safe product, and one specifically needed by preemies for adequate growth.

86. Upon information and belief, *Similac Special Care* is available for purchase directly by the consumer at the retail level.

87. Despite knowing that *Similac Special Care* increases the risk of NEC and death, Abbott did not warn the parents or the medical providers of NEC or death, nor did it provide any instructions or guidance on how to avoid NEC or death.

88. Abbott does not warn the user, the parents, or the physicians that its products (*Similac Neosure*, *Similac Human Milk Fortifier* and/or or *Similac Special Care*) cause NEC or death, nor provides guidance on how to avoid NEC or death while using its products.

89. The cow-based formula products, *Similac Neosure*, *Similac Human Milk Fortifier* and/or or *Similac Special Care* are dangerous to premature infants in that it significantly increases the risk that the baby will develop NEC.

90. The cow-based formula product, *Similac Neosure*, *Similac Human Milk Fortifier* and/or or *Similac Special Care*, are dangerous to premature infants in that it significantly in-

creases the risk that the baby will die.

91. The defendant, Abbott failed to properly warn parents and medical providers that its products, Similac Neosure, Similac Human Milk Fortifier and/or or Similac Special Care, can significantly increase the risk that the premature infant will develop N.E.C. and/or death, failed to design said products such as to make them safe, and deceived the public, parents, physicians and medical staff into believing that the product was a safe and necessary alternative, supplement and/or and substitute to human milk.

92. Despite knowing that its products were being fed to premature infants without the parents' informed consent, Abbott failed to require or recommend that Hospitals inform the parents of the significant risks, and to require that the consent of the parent be obtained prior to feeding it to babies.

93. The defendant, Abbott Laboratories, Inc.'s cow-based formula products did cause Baby Aries to develop NEC, which triggered severe intestinal disease and death to Baby Aries.

COUNT ONE: (PRODUCTS LIABILITY AS TO ABBOTT LABORATORIES, INC.)

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

95. Prior to January 30, 2018, the defendant, Abbott Laboratories, Inc. was aware, or should have been aware, that its products were not safe for use, as they were used,

in the premature infant, Baby Aries, yet it took no steps to prevent its use in such a situation.

96. The defendant, Abbott Laboratories, Inc. did foresee, or should have foreseen, that its products would be used, as they were in the case of baby Aries, and knew or should have known, that such use would significantly increase the risk of NEC and death in Baby Aries, yet it took no steps to prevent such use.

97. The products, Similac Neosure, Similac Human Milk Fortifier, and Similac Special Care were not safe to be used as they were in the case of Baby Aries and the defendant knew or should have known they was unsafe, yet it failed to provide any instructions or guidelines on when and how its product would be safe to use in a premature infant like Baby Aries.

98. The defendant, Abbott Laboratories, Inc, has marketed their products as safe and beneficial for premature infants like Baby Aries.

99. The defendant, Abbott Laboratories, Inc. has promoted their product for extremely premature infants and claim its product increases the babies weight and caloric intake and its product is more beneficial than harmful.

100. The Defendant Abbott Laboratories, Inc. has advanced the false premise to parents, physicians and medical staff that human milk is not sufficient to meet the nutritional needs of premature infants, and the equally false premise that their products are necessary as either substitutes and/or supplements to human milk.

101. Science and research have unequivocally established the dangers of the defen-

dant, Abbott's, cow-based product in causing NEC and death in premature infants, yet the defendant did nothing to change its product, packaging, guidelines, instructions and warnings.

102. Scientific studies show the Abbott products should not be sold for use in extremely premature infants, yet Abbott continued to market and sell its product knowing it would be used on infants like Baby Aries and knowing its product would significantly increase the risk of NEC and death in extremely premature infants like Baby Aries.

103. Abbott knew or should have known that its products would be used in the way it was used on this baby.

104. The way in which the Abbott products were fed to the baby was extremely dangerous and caused an unreasonably high risk that the baby would develop NEC and die, yet Abbott provided no detailed instructions or warnings to prevent or alter the way this product was used.

105. Despite learning that its products were linked to NEC and death, Abbott failed to properly collect data from doctors and hospitals in order to develop evidence based strategies, instructions, and warnings to reduce or prevent its product from causing NEC and death.

106. Despite knowing its products were leading to NEC and death, Abbott took no steps to determine how or why its products were causing NEC or death.

107. The defendant, Abbott Laboratories, Inc. has learned that its cow-based

products were causing NEC and death in premature infants, yet the defendants did nothing to change its products, packaging, guidelines, instructions and warnings.

108. Despite knowing that its cow-based products were causing NEC and death in premature infants, the defendant, Abbott Laboratories, Inc. did not conduct any testing, data analysis, or research to determine when its product should not be used or when and how its product was safe for use.

109. Despite knowing that its products were causing NEC and death in premature infants, the defendant, Abbott Laboratories, Inc. did not contact the FDA to inform them its product was linked to causing NEC and death.

110. Baby Aries' parents, physicians and medical staff were never told that the formula could cause their baby to develop N.E.C. and death.

111. Baby Aries' parents, physicians and medical staff were never told that the formula could cause their baby to die.

112. Baby Aries' parents, physicians and medical staff were never told of the studies showing cow-based formula was extremely dangerous to their baby.

113. Baby Aries' parents, physicians and medical staff were never told of the studies showing human donor milk was safer for their baby.

114. Baby Aries' parents, physicians and medical staff were never told of the studies showing that an exclusive human milk diet is sufficient to meet all growth and nutritional goals.

115. Despite knowing that its cow-based products were causing NEC and death in premature infants, Abbott Laboratories, Inc. did not recommend or require hospitals, NICUs or physicians that they should discuss the risks of NEC or death with the parents.

116. Despite knowing that its products were causing NEC and death in premature infants, the defendant, Abbott Laboratories, Inc. did not contact the FDA, NICUs, hospitals, and physicians to inform them its cow-based product was linked to causing NEC and death.

117. The defendant, Abbott Laboratories, Inc., is liable to the plaintiff under the Connecticut Product Liability Act, Conn. Gen. Stat. Section 52-572m, et seq. in one or more of the following ways:

A. Failure to Warn and/or Instruct

- a. The defendant knew or should have known that its cow-based premature infant products would be used, as it was, on extremely premature infants like Baby Aries, yet it failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that its cow-based product significantly increases the risk of NEC and death in these babies; and/or
- b. Was unsafe and/or contra-indicated for extremely premature infants and low birth weight babies like Baby Aries; and/or
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its 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 based product; and/or
- e. Failed to provide instructions that parents and physicians that the defendant's products carried a significant risk that its cow-based product could cause their

- baby to develop NEC and die; and/or
- f. The warnings and instructions 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-based formula significantly increasing 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-based products are known to significantly increase the risk of NEC and death when compared to Human Milk in premature infants;
 - h. Failed to provide well researched and well-established studies that linked its cow-based product to NEC and death in premature infants;
 - i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its product;
 - j. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding premature infants cow-based formula;
 - k. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow-based formula, they would have not used such a dangerous product;
 - l. 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 the hospitals and physicians to better care for the extremely premature infants.
 - m. Failed to advise physicians and healthcare providers that cow-based products are not necessary to achieve growth and nutritional targets for premature infants;
 - n. Failed to advise physicians and healthcare providers that human milk is superior to cow-based products with regard to the overall health of a premature infant;
 - o. Failed to advise physicians and healthcare providers that Prolacta is a better alternative to cow-based fortification.
 - p. 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;
 - q. Defendant’s massive marketing campaign as detailed in previous paragraphs has had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a healthcare provider to give formula; (2) diminished mom’s desire and sense of import to breastfeed; (3) diminished the relationship between physician and patient relative nutritional decision-making; (4) made it more difficult for a physician to persuade a mother to breastfeed; (5) made it easier and more economically viable for hospitals to feed preemies

formula over donor milk or human milk-derived fortifiers;

- r. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of their products, Baby Aries was fed cow-based products which caused him to develop NEC and ultimately die.

B. Strictly Liable for Defective Product

- a. Defendants products were defectively designed as aforementioned;
- b. Defendants products were unreasonably dangerous as aforementioned;
- c. Over the last several years, scientific data and well researched studies have concluded that the cow-based products of the defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits;
- d. The product risk of causing Necrotising Enterocolitis was extreme, and substantially deviated from consumer expectation;
- e. Failed to develop a human-based milk product which was safer for extremely premature infants.
- f. As a result of the defective design of the product, Baby Aries developed NEC and died.
- g. The defective design was the proximate cause of Baby Aries suffering NEC, and the proximate cause of his death.

C. Negligence

Despite knowing that its products significantly increased the risk of NEC in premature infants, the defendant was careless and negligent in one or more of the following ways:

- a. Failing to collect data to determine if its products were safe for premature infants; and/or
- b. Failing to collect data to determine when and how its products could be used safely; and/or
- c. Failing to utilize the significant peer reviewed research to develop instructions and/or warnings on how and when its products should be used in order to protect babies from NEC and death; and/or
- d. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death; and/or
- e. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death; and/or
- f. Failing to stop or deter its products from being fed to extremely premature

- infants like Baby Aries; and/or
- g. Failing to provide evidence based instructions or guidance on when or how an extremely premature infant should be transitioned to the defendant's product; and/or
 - h. Failing to continuously and vigorously study its cow-based products in order to avoid NEC and death in premature infants; and/or
 - i. Failing to send out letters with warnings to hospitals, NICUs and doctors that its products were significantly increasing the risk of NEC and death in premature infants; and/or
 - j. Failing to send out letters with instructions to hospitals, NICUs and doctors on when and how its products should be used to avoid NEC and death; and/or
 - k. Failing to market and/or sell its products in a way which would protect the premature infants from NEC and death; and/or
 - l. Failing to provide proper training or information to health care providers for safe use of its products; and/or
 - m. Failing to take reasonable precautions to prevent premature infants from developing NEC or dying; and/or
 - n. Failing to develop a human based premature infant formula/fortifier; and/or
 - o. Failing to properly or promptly notify the FDA that its cow-based product was significantly increasing NEC and death in premature infants; and/or
 - p. Despite knowing that NICU's and physicians were not warning of the risk of NEC, failed to require or recommend that hospital warn of such.
 - q. The above stated negligence was the proximate cause of Baby Aries getting NEC, and the proximate cause of his death.

D. Negligent Misrepresentation

- a. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians and medical staff through its advertising and promotional materials (some of which are actually inserted above). The allegations contained in those paragraphs are incorporated herein. Upon information and belief said representations were made by Abbott on an ongoing and repeated basis, and specifically relevant here, at various points between January 1, 2018 and February 22, 2018.
- b. The defendant misrepresented that its cow-based products were safe and beneficial for premature infants when it knew or should have known that its product were unreasonably dangerous and caused NEC and death in premature infants.

- c. The defendant misrepresented to parents, physicians and healthcare providers that its cow-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.
- d. Defendant misrepresented that its Products have no serious side effects, when it knew or should have known the contrary to be true.
- e. Defendant negligently misrepresented that cow-based products are safe for premature infants;
- f. Defendant negligently misrepresented that cow-based products are necessary for optimum growth; and
- g. Defendant negligently misrepresented that cow-based products are similar or equivalent to human milk.
- h. Defendant negligently used the brand “Human Milk Fortifier”, which suggests to average consumers that the product is derived from human milk.
- i. The aforementioned misrepresentations were the proximate cause of Baby Aries getting NEC, and the proximate cause of his death.

E. Intentional Misrepresentation

- a. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians and medical staff through its advertising and promotional materials (some of which are actually inserted above). The allegations contained in those paragraphs are incorporated herein. Upon information and belief said representations were made by Abbott on an ongoing and repeated basis, and specifically relevant here, at various points between January 1, 2018 and February 22, 2018.
- b. The defendant knew that its representations claiming its products were safe were false.
- c. The defendant knew that its product placed premature infants at significant risk of developing necrotising enterocolitis, yet nevertheless marketed its product as safe and effective for premature infants.
- d. Defendant intentionally misrepresented that cow-based products are safe for premature infants.
- e. Defendant intentionally misrepresented that cow-based products are necessary for optimum growth.
- f. Defendant intentionally misrepresented that cow-based products are similar or equivalent to human milk.

- g. Defendant intentionally used the brand “Human Milk Fortifier”, which suggests to average consumers that the product was derived from human milk.
- h. Defendant intentionally advertised in a massive fashion in order to create a stigma around breastfeeding.
- i. Defendant intentionally made it difficult for physicians to urge the use of breastmilk by creating a false sense that non-breastfeeding moms were being judged and stigmatized.
- j. The aforementioned misrepresentations were the proximate cause of Baby Aries getting NEC, and the proximate cause of his death.

F. Breach of Express Warranties

- a. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians and medical staff through its advertising and promotional materials (some of which are actually inserted above). The allegations contained in those paragraphs are incorporated herein. Upon information and belief said representations were made by Abbott on an ongoing and repeated basis, and specifically relevant here, at various points between January 1, 2018 and February 22, 2018.
- b. Defendant expressly warranted, through direct- to-consumer marketing, advertisements, and labels, that the Products were safe and effective for reasonably anticipated uses, including use by premature infants.
- c. Defendant expressly warranted that its product was similar or equivalent to human milk.
- d. Defendant expressly warranted that its product was necessary for growth.
- e. The Product did not conform to these express representations because they cause serious injury when used to feed premature infants.
- f. The aforementioned breached warranties were the proximate cause of Baby Aries getting NEC, and the proximate cause of his death.

G. Reckless Disregard – Punitive Damages

- a. The allegations contained in previous paragraphs set forth specific representations Abbott has made to consumers, physicians and medical staff through its advertising and promotional materials (some of which are actually inserted above). The allegations contained in those paragraphs are incorporated herein. Upon information and belief said representations were made by Abbott on

an ongoing and repeated basis, and specifically relevant here, at various points between January 1, 2018 and February 22, 2018.

- b. In violation of Conn. Gen. Stat. Section 52-240b the defendant was reckless in that it continued to market and sell its cow-based products to premature infants when it knew its product was causing death and NEC in these babies; and/or
- c. Intentionally ignored or avoided the more recent scientific data and studies concluding that its product was causing NEC and death so that it could continue to profit from the sale of its product; and/or
- d. Intentionally failed to take protective measures it knew would save premature infants from developing NEC and/or dying; and/or
- e. Intentionally allowed NICUs, hospitals, and doctors to utilize different feeding strategies instead of developing an evidence based nationwide safety plan to prevent its product from causing NEC and death in premature infants; and/or
- f. Continued to claim its product was beneficial to the growth of extremely premature infants when it knew its cow-based product was unnecessarily causing NEC and death in these babies; and/or
- g. Deliberately withheld important data to the FDA that its product was causing NEC and death in premature infants; and/or
- h. Failed to promote human based milk and instead continued to promote its dangerous cow-based product for premature infants because it did not have a human based product it could sell.
- i. Designed an intentional and reckless marketing campaign designed to deceive parents and healthcare providers regarding the safety and necessity of their products.

COUNT TWO – VIOLATION OF CONNECTICUT UNFAIR TRADE PRACTICES ACT

1-117. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

118. Defendants engaged in unfair methods of competition and deceptive acts or practices that were proscribed by law, including the following:

- a. By developing a systematic, pervasive, effective and manipulative marketing scheme designed to make moms believe the formula and other cow-based products were as safe, or even safer, than human milk, and more particularly that it was safe for premature infants;
- b. By purporting to support the Code while actually undermining and disobeying its key provisions;
- c. Through advertising, promotion and marketing, inducing mothers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level - i.e. marketing “personal choice” at the expense of sound medical choice;
- d. Concealing the risks of NEC associated with the use of cow milk by premature infants;
- e. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding;
- g. Expending enormous amounts of money on political lobbying, political involvement, “donations” to hospitals, and medical associations all designed to protect their financial interests: ensuring that the Government does not suffi-

ciently promote the dangers of Formula versus breastmilk; that direct advertising of infant formula is not prohibited in the United States; and preventing aggressive federal regulation of formula. These expenditures were made from a profit motive, and in direct conflict with the interests of society, and babies in particular;

- h. Intentionally marketed breastfeeding moms as having unappealing characteristics, in order to cause mother to not breastfeed;
- i. Paid “mommy bloggers” to give positive reviews of their product, when they knew this would have the effect of causing moms to buy their product;
- j. Through money contributions, endeared itself to the medical profession in order to win favor over the medical profession;
- k. Through its marketing campaigns, created an environment where moms would resist any advice from medical professionals to breastfeed.

119. Defendant intended for parents and medical staff to rely on its representations and advertisements regarding the Products in order to achieve monetary gain from sale of their Products. Abbott has spent millions and millions of dollars in promotion, advertising, lobbying, gifts, “charitable donations” all designed to maintain an image that its product is safe and effective, despite knowing the opposite to be true, and all for the purpose of securing profits in an incredibly lucrative industry.

120. Despite publicly expressing a commitment to breastfeeding, Defendant designed and executed promotional campaigns which discourage breastfeeding, thus allowing Abbott to capture greater market share and deliver greater profits to their stockholders.

121. As a result of the unfair trade practices engaged in by the Defendant Abbott, Baby Aries was injured and killed by the cumulative nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at parents and other consumers was to create demand for and sell the Products. Each aspect of Defendant's conduct combined to artificially create sales of the product, to deceive the public at large, and Baby Aries parents in particular.

122. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Products.

123. Had Defendant not engaged in the deceptive conduct described above, Baby Aries would not have been fed the dangerous product, and would not have incurred related injuries and damages.

124. Defendant's intentional, deceptive, unconscionable, immoral, and fraudulent representations and material omissions to Baby Aries' parents, physicians, and consumers, constituted unfair and deceptive acts and trade practices in violation of the Connecticut Unfair Trade Practices Act.

125. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, immoral, unscrupulous, deceptive or fraudulent acts, or trade practices in

violation of the Connecticut Unfair Trade Practices Act.

126. Defendant has engaged in unfair competition or unfair or deceptive acts or trade practices, or have made false representations in violation of the Connecticut Unfair Trade Practices Act.

127. Defendant violated the statutes that were enacted in Connecticut to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Defendant's Products were fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

128. Defendant had actual knowledge of the defective and dangerous condition of Defendants' product and failed to take any action to cure such defective and dangerous conditions.

129. Baby Aries' Physicians and medical staff relied upon Defendants' misrepresentations and omissions in determining which product to use.

130. Baby Aries' parents were deceived into not objecting to Defendant's products by virtue of Defendant's misrepresentations and omissions and deceptive marketing campaigns.

131. By reason of the unlawful acts engaged in by the Defendant, and as a direct and proximate result thereof, Baby Aries and his estate, suffered ascertainable losses and damages in the form of: (a) lost wages; (b) funeral and burial expenses; (d) medical bills and costs.

132. Additionally, Baby Aries suffered Noneconomic losses including physical and mental pain and suffering, emotional distress, while living; and Death.

133. Plaintiff is entitled to punitive damages pursuant to Conn. Gen. Stat. §42-110g(a) because defendant's conduct was reckless as set forth in the preceding paragraphs.

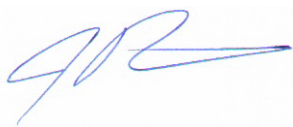
WHEREFORE, Plaintiff demands:

- a) Fair, just and adequate money damages;
- b) As to the reckless allegations, punitive damages up to twice the damages pursuant to 52-240b;
- c) Attorneys fees;
- d) Punitive Damages pursuant to Conn. Gen. Stat. §42-110g(a);
- e) Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues and causes of action.

Dated: October 28, 2020

By:  _____

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