1 2	James J. Lee, Esq. (Nevada Bar No. 1909) james@leelitigate.com				
3	LEGAL OFFICES OF JAMES J. LEE 2620 Regatta Drive #102 Las Vegas, NV 89128				
4	Telephone: 702.521.4377 (cell) Telephone: 702.664.6545 (office)				
5	Facsimile: 702.946.1115				
6	Wendy R. Fleishman (NY Bar No. WF 3017) (Admission pro hac vice anticipated)				
7	wfleishman@lchb.com LIEFF CABRASER HEIMANN & BERNSTEIN, LLP				
8	250 Hudson Street, 8th Floor New York, NY 10013-1413 Telephone: 212.355.9500				
9	Facsimile: 212.355.9592				
10	Fabrice N. Vincent (CA Bar No. 160780) (Admission pro hac vice anticipated)				
11	fvincent@lchb.com Lexi J. Hazam (CA Bar No. 224457)				
12	(Admission pro hac vice anticipated) lhazam@lchb.com				
13	LIEFF CABRASER HEIMANN & BERNSTEIN, LLP 275 Battery Street, 29th Floor				
1415	San Francisco, CA 94111-3339 Telephone: 415.956.1000 Facsimile: 415.956.1008				
16	Attorneys for Plaintiffs				
17	UNITED STATES DISTRICT COURT				
18	FOR THE DISTRICT OF NEVADA				
19					
20	DARIUS MEDLEY and CHAKOYA	Case No			
21	ROBINSON, individually and on behalf of their minor child KM as his natural and				
22	legal guardians,	CIVIL COMPLAINT FOR DAMAGES			
23	Plaintiffs,				
24	V.	JURY TRIAL DEMANDED			
25	ABBOTT LABORATORIES, INC.,				
26	Defendant.				
27					
28					

Plaintiffs Darius Medley and ChaKoya Robinson bring this action on behalf of their minor son KM and complain of Defendant Abbott Laboratories, Inc., as follows, based upon information and belief, their counsels' investigation, and personal knowledge.

I. INTRODUCTION

- 1. This is an action to redress the serious and grievous injuries suffered by infant KM, who has spent the majority of his almost four years of life fighting a horrific disease caused by Defendant's cow-based infant formula and fortifier Similac Neosure ("NeoSure"). Necrotising enterocolitis (NEC) is a potentially fatal disease that largely affects low birth weight babies who are fed cow-based formula. KM, a prematurely born, low birth weight baby, was fed NeoSure and developed NEC shortly thereafter.
- 2. Plaintiffs Darius Medley and ChaKoya Robinson bring claims against Defendant Abbott Laboratories, Inc., arising from Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of NeoSure.

II. THE PARTIES

- 3. KM ("Baby KM") was born prematurely at 23 weeks and 5 days on July 6, 2018, at Sunrise Hospital and Medical Center in Las Vegas, Nevada. He weighed 1 pound, 1 ounce at birth and was therefore by definition a low birth weight infant. Baby KM developed NEC within days of being fed NeoSure while he was in the neonatal intensive care unit (NICU) at Sunrise Hospital.
- 4. Plaintiffs Darius Medley and ChaKoya Robinson are the natural parents and guardians of Baby KM, and they are all residents of Nevada.
- 5. Defendant Abbott Laboratories, Inc., ("Abbott") is a corporation incorporated under the laws of Illinois with its principal place of business in Abbott Park, Illinois.
- 6. Defendant Abbott manufactures, designs, formulates, prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce, and sells NeoSure in all fifty states, including Nevada, and is a "product seller" under Nevada law.

III. <u>JURISDICTION AND VENUE</u>

- 7. This Court has jurisdiction under 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiffs, each citizens of Nevada, and Defendant Abbott, a citizen of Illinois, and the matter in controversy, exclusive of interest and costs, exceeds \$75,000.
- 8. This Court has personal jurisdiction over Defendant Abbott because Abbott markets, promotes, distributes, and sells NeoSure in Nevada, and Plaintiffs' claims arise out of Abbott's contacts with Nevada.
- 9. Venue is proper in this district under 28 U.S.C. § 1391(b) because Plaintiffs reside in this district, Baby KM consumed NeoSure in this district, and therefore a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this district.

IV. <u>BACKGROUND</u>

A. The Science

- 10. Scientific research has demonstrated strong links between cow-based infant formula like NeoSure and NEC in premature infants.
- 11. More than thirty years ago, in 1990, a prospective multi-center study on 926 preterm infants found that NEC was 6 to 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. Lucas A, Cole T. Breast milk and neonatal necrotising enterocolitis. Lancet 1990; 336: 1519–1523.
- 12. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and/or human milk fortifier, they were 90 percent 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 Death of Human Milk and Bovine Milk-Based Products. Journal of Pediatrics 2010; 156:562-7.
- 13. In 2011, the U.S. Surgeon General published a report titled "The Surgeon General's Call to Action to Support Breastfeeding," warning that, "[f]or vulnerable premature infants, formula feeding is associated with higher rates of [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.

- 14. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed exclusively a human milk diet because of the risk of NEC associated with the consumption of cow-based formula like NeoSure. 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 2012; 129:e827-e841.
- 15. A study published in 2013 showed that all 104 premature infants participating in the study receiving exclusively a human-milk based diet exceeded targeted growth standards in height and weight (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., Human milk supports adequate growth in infants ≤1250 grams birthweight. BMC Research Notes 2013, 6-459. Thus, inadequate growth was shown to be no reason for feeding cow-based formula.
- 16. Another study published in 2013 reported, "This is the first randomized trial in [extremely premature] infants of exclusive [human Milk] vs. [preterm formula]. The significantly shorter duration of [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish [extremely premature] 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.
- 17. "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. The same study noted, "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. 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." (Internal citations omitted.) Further, "[a] wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing [NEC]. ...

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." (Internal citations omitted.)

- 18. Yet another study published in 2014 reported, "An exclusive human milk diet, devoid of [cow milk]-containing products was associated with lower mortality and morbidity in [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.
- 19. A 2016 study supported previous findings that an exclusive human milk diet in extremely 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 was a very large study. The authors concluded, "[T]he use of an exclusive [human milk] diet is associated with significant benefits for extremely premature 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 2016, 11-2.
- 20. A study published in 2017 reported, "[Human milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two [randomized clinical trials] on preterm infants weighing between 500 and 1250 g at birth compared the effect of bovine milk-based preterm infant formula to [mother or donor milk] on the incidence of NEC. Both trials found that an exclusive [human milk] diet results in a lower incidence of NEC."
- 21. A systematic review that evaluated the effect of cow milk-based formula like NeoSure on health outcomes for preterm infants also determined that cow milk-based formula significantly increases the risk of NEC. 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

- 22. Notwithstanding strong scientific and medical evidence establishing the serious danger that cow-based formula like NeoSure poses for premature infants like Baby KM,

 Defendant 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.

 Abbott has specifically marketed NeoSure as necessary to the growth and development of premature infants, when in fact its products pose a known and substantial risk to these babies.
- 23. Defendant Abbott has attempted to "hook" parents on formula by offering free samples and other blandishments in baskets given to parents in hospitals and medical clinics. The goal is to create brand loyalty and the appearance of "medical blessing" so that parents continue to use NeoSure to feed their babies after they leave the NICU, at great expense to the parents, and substantial profit to Abbott.
- 24. Defendant Abbott's practice of trying to get parents to choose formula over breast milk goes back decades. The company has for decades promoted its product as healthier, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Their advertising has at times attempted to portray breastfeeding as an inferior, less sophisticated choice.
- 25. 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) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and prohibited any advertising or promotion of breast milk

substitutes to the general public. The Code 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). Defendant Abbott has acknowledged and pretended to endorse 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 breastfeeding 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 ... 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 Infant Formula. https://dam.abbott.com/en-us/documents/pdfs/transparency/Abbott_Policy_on_the_Marketing_of_Infant_Formula.pdf

- 26. Despite this assurance and warranty contained in its Policy, Defendant Abbott has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public."
- 27. Notwithstanding the Code and Defendant Abbott's own Policy claiming to recognize the Code, advertising of cow-based infant formula like NeoSure has remained pervasive in the United States until today. Abbott has paid lip service to the Code, but in actuality has systematically violated its central provision.
- 28. The very name "Similar NeoSure" is deceptive, suggesting that NeoSure is *similar* to *lactation*. Beginning with its brand name, Defendant Abbott has perpetuated the deception that its product is on par with or similar to human milk.
- 29. "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.

30. For example, one author found an advertisement for a Similac product like NeoSure on the back cover of the April 2004 issue of American Baby Magazine, reproduced below, that made repeated comparisons of cow-based formula to breast milk; the ad used the phrase "like breastmilk" six times. Broussard Hyderkhan, A, Mammary malfunction: a comparison of breastfeeding and bottle feeding product ads with magazine article content, 2005.



- 31. In addition to perpetuating the myth that Similac products like NeoSure are "like breastmilk," Defendant Abbott has also deceived the public into believing that physicians believe Similac products are an ideal choice for babies.
- 32. Beginning in 1989, Abbott began using claims in its advertising that Similac products like NeoSure were the "first choice of more physicians."
- 33. A plain interpretation of this claim is that physicians believe Similac products like NeoSure are the "first choice" even in preference to breastmilk.
- 34. Beginning in 1995, Defendant Abbott began a heavy marketing campaign featuring the claim "1st choice of Doctors" on all its infant formula product labels, including NeoSure.
- 35. A marketing report commissioned by Defendant Abbott in March 1998 summarized consumer reactions to several advertising pamphlets for Similac products. 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." Use of similar pieces emphasizing the same claim was "highly recommended."
- 36. One study estimated 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.
- 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 advertising has a negative effect on breastfeeding initiation. Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB. Exposure to infant feeding advertising during pregnancy is associated with feeding decisions

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27 28 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 breastfeeding 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. Defendant Abbott released an ad called "The Mother 'Hood" that frames the choice between breastmilk and Similac products like NeoSure as a matter of personal preference, a debate which, while heated, is ultimately conducted by parents who simply wish the best for all children. The advertising conceals the fact that the "debate" is a false one, manufactured by companies like Abbott for their own promotional purposes. www.youtube.com/watch?v=JUbGHeZCxe4.
- 42. Another advertisement by Defendant Abbott, titled "The Judgment Stops Here," a documentary-style ad, likewise shows parents coming together, putting aside judgment of each other's choices. The ad is deceptive, however, and violative of the Code and Abbott's own marketing Policy, because it puts breast milk and formula on an even playing field, and attempts to chastise any opinion that the question is *not* merely one of personal choice and but clear scientific evidence. In other words, the ad attempts to insulate Similac products like NeoSure from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint.

babies who were born prematurely, and help support her development." The advertisement further claims that NeoSure is "pediatrician recommended," "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to the specialized need pre-term infants have for human breast milk, and makes no mention of the risk of developing NEC.

- 50. At all relevant times, Defendant Abbott maintained "similac.com," website directed at parents choosing formula products. The website states, "Need help choosing the right formula for your baby? Our Formula Finder can walk you through it." The website includes the prompt, "Was your child born prematurely?" If the parent clicks "yes," the website directs the parent to a page promoting NeoSure, https://similac.com/formula-finder/baby- formula/similac-expert-care-neosure-premature. Through this website, Abbott directs parents of premature babies to use NeoSure. The page further claims that NeoSure is "[f]or 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. There is no mention of the risk of NEC. The website expressly and implicitly represents that NeoSure is safe for use with premature infants. This promotion is false and misleading.
- 52. A search for the following on Google returns paid advertisements by Defendant Abbott for NeoSure: (1) "Is formula healthy for premature infants?"; and (2) "Is formula safe for premature infants?" produces paid advertisements by Abbott for NeoSure.
- 53. Another advertisement by Defendant Abbott states "whether you choose to formula feed or, to supplement breast feeding with formula, you can be confident in the nourishment of Similac." www.similac.com/why-similac.html. The representation to parents that they can be "confident" is directly contradicted by studies that indicate the cow-based formula like NeoSure is dangerous to premature infants. The ad is false and misleading.
- 54. Defendant Abbott's website also features reviews from parents whose premature infants were in the NICU, discussing how wonderful and safe the products are. There are no

reviews discussing NEC. It is therefore likely that these reviews are curated by Abbott to present a misleading picture of unanimous endorsement of NeoSure.

- 55. CBS News reported that Defendant Abbott paid so-called "mommy bloggers" for positive reviews of Similac products like NeoSure. https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app/
- 56. Defendant Abbott has designed and implemented a systematic, powerful, and misleading marketing campaign to deceive parents into believing that: (1) cow-milk formula and fortifiers like NeoSure are safe; (2) cow-milk products like NeoSure are equivalent or even superior substitutes for breastmilk; (3) physicians consider cow-based products like NeoSure a first choice; (4) the decision to breastfeed or to use Similac products like Neosure is a matter of personal preference merely, with no objective scientific criteria; and (5) Similac products like NeoSure are necessary for the growth of and are perfectly safe for premature infants.

C. Baby KM and Similac NeoSure

- 57. Baby KM was born extremely prematurely at 23 weeks gestation on July 6, 2018, with a low birth weight of one pound, one ounce.
- 58. Baby KM was admitted to the NICU at Sunrise Hospital and Medical Center in Las Vegas, Nevada.
 - 59. Following the birth, Baby KM was immediately fed NeoSure.
- 60. Baby KM then contracted life-threatening NEC that required three immediate surgeries. NEC has caused him to suffer failure to thrive, severe and ongoing developmental delays, difficult bowel movements, constipation, and significant suffering to this day.
- 61. Baby KM's parents had no knowledge that NeoSure would increase the risk of their baby developing NEC.
- 62. As described above, Defendant Abbott promotes NeoSure on its website and in other media as a safe product, and one specifically needed by premature infants for adequate growth. https://similac.com/baby-formula/ similac-expert-care-neosure-premature. A link on this page claims that premature infants need NeoSure for "catchup growth". https://similac.com/baby-

development/preemie/nutrition- premature-babies. A screenshot of both is captured on the following two pages.

63. This same webpage contains a video promoting NeoSure as a means to achieve adequate growth in premature infants.



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.

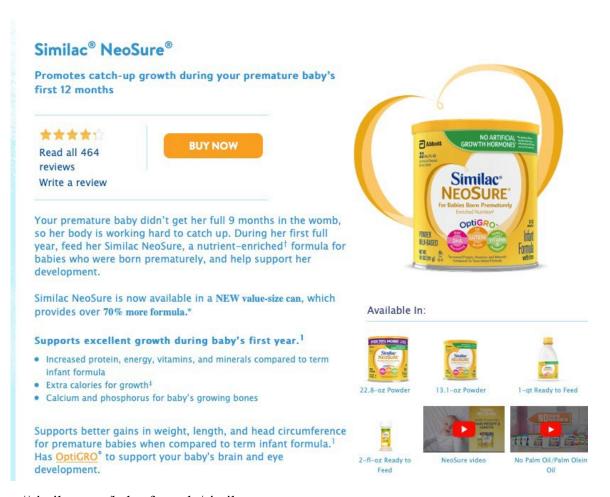
Whether you choose to breastfeed or use baby formula, after leaving the hospital, most preemies will benefit from nutritional supplementation or a specialized formula with nutrients that support brain, muscle, bone, and organ growth, and development of a strong immune system.

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.

<u>Similac NeoSure</u> 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.

- 64. This marketing is designed to instill confidence in Defendant Abbott's NeoSure, and to plant the seed in parents' minds that such formula is safe and necessary to the growth of a premature infant.
- 65. Prior to Baby KM being fed NeoSure, Plaintiffs were exposed to marketing from Defendant Abbott that NeoSure was safe and necessary to the growth and nutrition of their premature infant.
- 66. Although Defendant Abbott engages in 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 highly dangerous to premature infants. NeoSure substantially increases the risk of NEC, as explained above.
- 67. NeoSure is commercially available at retail locations throughout Nevada and online for delivery to Nevada.

- 68. Despite knowing of the risk of NEC, Defendant Abbott did not warn parents of the risk of NEC associated with NeoSure.
- 69. Despite knowing of the risk of NEC, Defendant Abbott did not warn doctors, hospitals, or other healthcare providers of the risk of NEC associated with NeoSure.
 - 70. The only warnings NeoSure contains are the following:

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.

- 71. Despite knowing that NeoSure increases the risk of NEC, Defendant Abbott did not provide any instructions or guidance on how to avoid NEC.
- 72. Defendant Abbott failed to properly warn parents and healthcare providers that NeoSure can significantly increase the risk that a premature infant will develop NEC, failed to design said product such as to make it safe, and deceived the public, parents, physicians, and other healthcare providers into believing that NeoSure is a safe and necessary alternative to, supplement to, or substitute for human milk.
- 73. Despite knowing that NeoSure was being fed to premature infants without parents' informed consent, Defendant Abbott failed to require or recommend that hospitals inform parents of the significant risk of NEC, or to require that parents' informed consent be obtained prior to feeding it to preterm infants.
- 74. Defendant Abbott's cow-based formula NeoSure caused Baby KM to develop NEC, triggering severe intestinal disease and long-term adverse effects.

^{*} 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.

FIRST CAUSE OF ACTION

(NEGLIGENT PRODUCTS LIABILITY)

- 75. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 76. Prior to July 6, 2018, Defendant Abbott was aware, or should have been aware, that NeoSure was not safe for use in the premature infant, Baby KM, yet it took no steps to prevent its use in such a situation.
- 77. Defendant foresaw or should have foreseen that NeoSure would be used as it was in the case of Baby KM, and knew or should have known that such use would significantly increase the risk of NEC in Baby KM, yet it took no steps to prevent such use.
- 78. NeoSure was not safe to be used in the case of Baby KM and Defendant Abbott knew or should have known that NeoSure was unsafe to be fed to a preterm, low birth weight infant, yet it failed to provide any instructions or guidelines on when and how NeoSure would be safe to use in a premature infant like Baby KM.
- 79. Defendant Abbott has marketed NeoSure as safe and beneficial for premature infants like Baby KM.
- 80. Defendant Abbott has promoted NeoSure for extremely premature infants and claims NeoSure increases the baby's weight and caloric intake, and that NeoSure is more beneficial than harmful.
- 81. Defendant Abbott has advanced the false premises to parents, physicians, and other healthcare providers that human milk is not sufficient to meet the nutritional needs of premature infants, and that NeoSure is necessary as a substitute for or supplement to human milk.
- 82. Scientific research has unequivocally established the dangers of Defendant Abbott's cow-based product NeoSure in causing NEC in premature infants, yet Abbott did nothing to change its product, packaging, guidelines, instructions, or warnings.
- 83. Scientific studies show Defendant Abbott's NeoSure should not be sold for use in extremely premature infants, yet Abbott continued to market and sell NeoSure knowing it would

be used by infants like Baby KM and knowing NeoSure would significantly increase the risk of NEC in extremely premature infants like Baby KM.

- 84. Defendant Abbott knew or should have known that NeoSure would be used in the way it was used with Baby KM.
- 85. NeoSure's use was extremely dangerous and caused an unreasonably high risk that Baby KM would develop NEC, yet Defendant Abbott provided no detailed instructions or warnings to prevent or alter the way NeoSure was used.
- 86. Despite learning that NeoSure was linked to NEC, Defendant Abbott failed to properly collect data from doctors and hospitals in order to develop evidence based strategies, instructions, and warnings to reduce or prevent NeoSure from causing NEC.
- 87. Despite learning that NeoSure was linked to NEC, Defendant Abbott took no steps to determine whether and how that link was causal.
- 88. In the alternative, Defendant Abbott learned that NeoSure causes NEC in premature infants, yet did nothing to change its product, packaging, guidelines, instructions or warnings.
- 89. Despite knowing that NeoSure causes NEC in premature infants, Defendant Abbott did not conduct any testing, undertake to have others conduct testing and studies, or do any data analysis or research to determine when NeoSure should not be used or when and how NeoSure is safe for use.
- 90. Despite knowing that NeoSure causes NEC in premature infants, Defendant Abbott did not contact the FDA to inform the agency of this fact.
- 91. Baby KM's parents, physicians, and other healthcare providers were never told that NeoSure could cause Baby KM to develop NEC.
- 92. Baby KM's parents, physicians, and other healthcare providers were never told that NeoSure could and would cause Baby KM to suffer long term, devastating maladies, as Baby KM has and will.
- 93. Baby KM's parents, physicians, and other healthcare providers were not told of the studies showing cow-based formula like NeoSure was extremely dangerous to Baby KM.

- 94. Baby KM's parents, physicians, and other healthcare providers were not told of the studies showing that human donor milk was safer for Baby KM than cow-cased products like NeoSure.
- 95. Baby KM's parents, physicians, and other healthcare providers were not told of the studies showing that an exclusive human milk diet is sufficient to meet all growth and nutritional goals of premature infants.
- 96. Despite knowing that NeoSure causes NEC and long term adverse effects in premature infants, Defendant Abbott did not recommend or require discussion by hospitals, NICUs, or physicians of the risks of NEC and long term maladies with parents.
- 97. Despite knowing that NeoSure causes NEC, as well as serious and devastating long term illnesses and adverse effects on growth and development, as it has in Baby KM, Defendant Abbott did not contact the FDA, NICUs, hospitals, or physicians to inform them that NeoSure is linked to or causes NEC and these long term consequences
- 98. Defendant Abbott knew or should have known that its cow-based premature infant product NeoSure would be used, as it was, on extremely premature infants like Baby KM, yet it failed to properly warn hospitals, NICUs, doctors, parents, or consumers that NeoSure significantly increases the risk of NEC and long term adverse medical and developmental consequences in these babies; and is unsafe or contraindicated for extremely premature infants and low birth weight babies like Baby KM.
- 99. Defendant Abbott's warnings and instructions for NeoSure 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 that cow-based formula like NeoSure significantly increases the risk of NEC and its sequelae, nor provide any details on how to avoid such harm.
 - 100. Defendant Abbott failed to:
- a. provide a warning or instruction that parents need to be provided an informed choice between the safety of human milk versus the dangers of NeoSure;

advice of a healthcare provider to give formula; (2) diminishing parents' desire and understanding of the importance of breastfeeding; (3) diminishing the relationship between physicians and patients relative to nutritional decision-making; (4) making it more difficult for a physician to persuade parents to breastfeed; and (5) making it easier and more economically viable for hospitals to feed premature infants instead of donor milk or human milk-derived fortifiers.

- 102. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of cow-based formula like NeoSure, Baby KM was fed NeoSure, which caused him to develop NEC and ultimately suffer significant long-term medical problems and developmental delays.
- 103. Defendant Abbott owed a duty of care to the children to whom NeoSure was targeted.
- 104. As a direct and proximate result of Defendant's Abbott's breach of duty in the design, development, manufacturing, labeling, advertising, and sale of NeoSure, Baby KM suffered severe medical injuries and long term damages that are yet to be determined. Baby KM's parents have expended and continue to expend significant sums for Baby KM's care and treatment.
- 105. NeoSure's defective design proximately caused Baby KM's NEC, and proximately caused Baby KM's long term medical and developmental problems.

SECOND CAUSE OF ACTION (STRICT PRODUCTS LIABILITY)

- 106. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 107. Prior to July 6, 2018, Defendant Abbott was aware, or should have been aware, that NeoSure is not safe for use in premature infants like Baby KM, yet it took no steps to prevent its use in such a situation.
 - 108. NeoSure was defectively designed as alleged above.
 - 109. NeoSure is unreasonably dangerous as alleged above.

- 110. Over the last several years, scientific data and well researched studies have concluded that cow-based products like NeoSure carry unreasonable risks of NEC, which far outweigh the products' benefits.
- 111. NeoSure's risk of causing NEC is extreme, and substantially deviates from consumers' and Plaintiffs' expectations.
- 112. Defendant Abbott failed to develop a human-based milk product that was safer for extremely premature infants and low birth weight infants like Baby KM.
- 113. As a result of NeoSure's defective design, Baby KM developed NEC and has continued to suffer long term problems and has needed multiple surgeries, treatments, and interventions, and will need them far into the future.
- 114. NeoSure's defective design proximately caused Baby KM's NEC, and proximately caused Baby KM's long term medical and developmental problems.

THIRD CAUSE OF ACTION (NEGLIGENCE)

- 115. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 116. Despite knowing that NeoSure significantly increases the risk of NEC in premature infants, Defendant Abbot was careless and negligent because it failed to:
 - a. Collect data to determine if its products were safe for premature infants;
 - b. Collect data to determine when and how its products could be used safely;
- c. Use the significant peer reviewed research to develop instructions and/or warnings on how and when NeoSure should be used in order to protect babies from NEC and its medical sequellae;
- d. Develop evidence-based guidelines or instructions to decrease the risk of NeoSure causing NEC;
- e. Provide evidence-based guidelines or instructions to decrease the risk of NeoSure causing NEC;

1		f.	Stop or deter NeoSure from being fed to extremely premature infants like
2	Baby KM;		
3		g.	Provide evidence-based guidelines or instructions on when or how an
4	extremely premature infant like Baby KM should be transitioned to NeoSure;		
5		h.	Continuously and vigorously study NeoSure to avoid NEC in premature
6	infants;		
7		i.	Send out letters with warnings to hospitals, NICUs, and doctors that
8	NeoSure was significantly increasing the risk of NEC in premature infants like Baby KM;		
9		j.	Send out letters with instructions to hospitals, NICUs, and doctors on when
10	and how NeoSure should be used to avoid NEC;		
11		k.	Market and/or sell its products in a way which would protect premature
12	infants like Baby KM from NEC;		
13		1.	Provide proper training or information to health care providers for safe use
14	of NeoSure;		
15		m.	Take reasonable precautions to prevent premature infants like Baby KM
16	from developing NEC;		
17		n.	Develop a human-milk-based premature infant formula;
18		0.	Properly or promptly notify the FDA that NeoSure significantly increases
19	the risk of NEC in premature infants like Baby KM; and/or		
20		p.	Require or recommend that hospitals warn of NeoSure's risk of causing
21	NEC, despite	knowin	ng that NICUs and physicians were not warning of such.
22	117.	Defen	dant Abbot's negligence proximately caused Baby KM's NEC, and
23	proximately caused Baby KM's long-term medical problems and developmental delays.		
24			FOURTH CAUSE OF ACTION
25			(NEGLIGENT MISREPRESENTATION)
26	118.	Plaint	iffs incorporate by reference each of the preceding paragraphs as if fully set
27	forth herein.		
28			

- 119. The allegations contained in previous paragraphs set forth specific representations Defendant Abbott has made to consumers, physicians, and other healthcare providers through its advertising and promotional materials (some of which are reproduced above). These representations were made by Abbott on an ongoing and repeated basis, and, as specifically relevant here, at various points between January 1, 2018, and July 2, 2018.
- 120. Defendant Abbott misrepresented that NeoSure was safe and beneficial for premature infants like Baby KM when it knew or should have known that NeoSure is unreasonably dangerous and causes NEC in premature infants and low birth weight infants like Baby KM.
- 121. Defendant Abbott misrepresented to parents, physicians, and other healthcare providers that cow-based products like NeoSure are necessary to the growth and nutrition of premature infants, when it knew or should have known that NeoSure is not necessary to achieve adequate growth.
- 122. Defendant Abbott misrepresented that NeoSure has no serious side effects, when it knew or should have known that it does.
- 123. Defendant Abbott negligently misrepresented that cow-based products like NeoSure are safe for premature infants like Baby KM.
- 124. Defendant Abbot negligently misrepresented that cow-based products like NeoSure are necessary for optimum infant growth.
- 125. Defendant negligently misrepresented that cow-based products like NeoSure are similar or equivalent to human milk.
- 126. Defendant Abbott's misrepresentations proximately caused Baby KM's NEC, and proximately caused Baby KM's long-term medical problems and developmental delays.

FIFTH CAUSE OF ACTION

(DECEPTIVE TRADE PRACTICES)

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

- 128. The allegations contained in previous paragraphs set forth specific representations Defendant Abbott has made to consumers, physicians, and other healthcare providers through its advertising and promotional materials (some of which are reproduced above). These representations were made by Abbott on an ongoing and repeated basis, and, as specifically relevant here, at various points between January 1, 2018, and July 2, 2018.
- 129. Defendant Abbott willfully ignored or avoided the recent scientific data and studies concluding that NeoSure causes NEC so that it could continue to profit from the sale of NeoSure.
- 130. Defendant Abbott willfully failed to take protective measures it knew would save premature infants like Baby KM from developing NEC, and suffering long-term medical and developmental problems as a result.
- 131. The acts, omissions, and practices of Defendant Abbott alleged herein constitute deceptive trade practices within the meaning of Nev. Rev. Stat. §§ 598.0915 and 598.0925. Plaintiffs have standing to bring these claims because they have suffered and lost money as a result of Abbott's deceptive trade practices.
- 132. Defendant Abbott has engaged in deceptive trade practices by making misrepresentations as alleged above.
 - 133. Defendant Abbott engaged in deceptive trade practices by and through:
- a. Developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents believe that cow-based products like NeoSure are as safe, or even safer, than human milk, specifically as to premature infants like Baby KM;
- b. Purporting to support the Code while actually undermining and disobeying its key provisions;
- c. Advertising, promotion, and marketing that induced parents of premature infants not to breastfeed by disparaging breastfeeding, placing its cow-based products like NeoSure on an equivalent level, and marketing "personal choice" as a substitute for sound medical judgment;

1 d. Concealing the risks of NEC associated with the use of NeoSure by 2 premature infants like Baby KM; 3 Representing that NeoSure has characteristics, ingredients, uses, or benefits it does not have; 4 f. 5 Engaging in fraudulent or deceptive conduct that creates a likelihood of 6 confusion or misunderstanding; 7 Expending enormous amounts of money on political lobbying, political g. 8 involvement, "donations" to hospitals, and medical associations—all designed to protect 9 Defendant Abbott's financial interests, motivated by profit, and in direct conflict with societal 10 interests—ensuring that regulators do not publicize the dangers of formula like NeoSure versus breastmilk, ensuring that direct advertising of infant formula is not prohibited in the United 11 12 States, and preventing federal regulation of formula; 13 h. Intentionally marketing breastfeeding parents as unappealing, in order to disparage breastfeeding and promote NeoSure; 14 15 i. Paying online reviewers, especially so-called "mommy bloggers," to give positive reviews of NeoSure, when Defendant Abbott knew this would induce parents to buy 16 17 NeoSure; 18 į. Making monetary contributions to endear itself to the medical profession and win its favor; and/or 19 k. 20 Marketing campaigns that created an environment where parents would 21 resist medical advice to breastfeed. 22 Defendant Abbott intended for parents and healthcare providers to rely on its 23 representations and advertisements regarding NeoSure so that Abbott would profit from its sale. 24 Abbott has spent millions of dollars in promotion, advertising, lobbying, gifts, and "charitable 25 donations"—all designed to maintain an image that NeoSure is safe and effective, despite 26 knowing the opposite to be true, and to secure profits in an incredibly lucrative industry. 27

- 135. Despite publicly expressing a commitment to breastfeeding, Defendant Abbott designed and executed promotional campaigns that discourage breastfeeding, allowing Abbott to capture greater market share and earn greater profits.
- 136. As a result of the deceptive trade practices engaged in by Defendant Abbott, Baby KM's parents paid and will have to pay large sums of money to care for and treat Baby KM. The cumulative effect of Abbott's conduct directed at parents and healthcare providers has been to create demand for and sell NeoSure. Each aspect of Abbott's conduct combined to artificially create sales of NeoSure, and to deceive the public at large and Baby KM's parents in particular.
- 137. Defendant Abbott is under a duty to refrain from deceptive acts or practices in the design, labeling, development, manufacture, promotion, and sale of NeoSure.
- 138. Had Defendant Abbott not engaged in the deceptive conduct described above, Baby KM would not have been fed the dangerous product, and would not have incurred related injuries and damages.
- 139. Defendant Abbott's intentional, deceptive, unconscionable, immoral, and fraudulent representations and material omissions to Baby KM's parents, physicians, and consumers constitute deceptive trade practices.
- 140. Defendant Abbott violated Nevada law intended to protect consumers against deceptive trade and business practices and false advertising, by knowingly and falsely representing that NeoSure is fit to be used for the purpose for which it is intended, when in fact it is defective and dangerous. These representations were made in marketing and promotional materials.
- 141. Defendant Abbott had actual knowledge of the defective and dangerous condition of NeoSure and failed to take any action to cure such defective and dangerous conditions.
- 142. Baby KM's physicians and healthcare providers relied upon Defendant Abbott's misrepresentations and omissions in deciding to use NeoSure.
- 143. Baby KM's parents were misled into not objecting to the use of NeoSure as a result of Defendant Abbott's misrepresentations, omissions, and deceptive marketing campaigns.

1	PRAYER FOR RELIEF			
2	144. Plaintiffs seek a judgment awarding:			
3	a. Compensatory damages in an amount to be determined at trial;			
4	b. Punitive damages in an amount to be determined at trial;			
5	c. Attorneys' fees and costs of suit; and			
6	d. All other relief the Court finds just and proper.			
7	DEMAND FOR JURY TRIAL			
8	145. Plaintiffs demand a jury trial on all issues so triable.			
9	Dated: February 12, 2022 Respectfully submitted,			
10	LEGAL OFFICES OF JAMES J. LEE			
11				
12	By: /s/ James J. Lee			
13	James J. Lee, Esq. (Nevada Bar No. 1909)			
14	james@leelitigate.com 2620 Regatta Drive #102			
15	Las Vegas, NV 89128 Telephone: 702.521.4377 (cell)			
16	Telephone: 702.664.6545 (office) Facsimile: 702.946.1115			
17	Wendy R. Fleishman (NY Bar No. WF 3017)			
18	(pro hac vice anticipated) wfleishman@lchb.com			
19	LIEFF CABRASER HEIMANN & BERNSTEIN, LLP 250 Hudson Street, 8th Floor			
20	New York, NY 10013-1413 Telephone: 212.355.9500			
21	Facsimile: 212.355.9592			
22	Fabrice N. Vincent (CA Bar No. 160780) <u>fvincent@lchb.com</u>			
23	(pro hac vice anticipated) Lexi J. Hazam (CA Bar No. 224457)			
24	lhazam@lchb.com (pro hac vice anticipated)			
25	LIEFF CABRASER HEIMANN & BERNSTEIN, LLP 275 Battery Street, 29th Floor			
26	San Francisco, CA 94111-3339 Telephone: 415.956.1000			
27	Facsimile: 415.956.1008			
, ,	Attorneys for Plaintiffs			