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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Marina Seiken, surviving mother of deceased minor K.S., individually and on behalf of all wrongful death statutory beneficiaries; Shen Seiken, individually, Plaintiffs, vs. Abbott Laboratories, an Illinois corporation; Abbott Laboratories, Inc., a Delaware corporation, Defendants.	Case No. _____ Jury Trial Demanded

PLAINTIFFS' COMPLAINT

Plaintiffs Marina Seiken, surviving mother of deceased minor child K.S., individually, and on behalf of all wrongful death statutory beneficiaries, and Shen Seiken, surviving father of deceased minor child K.S., individually, hereby bring this Complaint against Defendants Abbott Laboratories and Abbott Laboratories, Inc., alleging as follows:

GENERAL ALLEGATIONS

1. At all times material hereto, Plaintiffs Marina Seiken and Shen Seiken were Arizona citizens domiciled in Arizona and comprising a marital community therein. They were the mother and father, respectively, of K.S.

2. K.S. was an infant born prematurely at Banner Thunderbird Medical Center in 2023.

3. K.S. developed Necrotizing Enterocolitis ("NEC") after being fed cow's milk-based products, including but not necessarily limited to Similac Special Care.

4. On February 25, 2023, K.S. died as a direct and proximate result from the NEC caused by being fed cow's milk-based products, including but not necessarily limited to Similac Special Care.

5. Defendant Abbott Laboratories was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Illinois with its principal place of business and headquarters in the State of Illinois.

6. Defendant Abbott Laboratories, Inc. was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Delaware with its principal place of business and headquarters in the State of Illinois.

7. Defendant Abbott Laboratories, Inc. is a wholly owned subsidiary of its parent company Defendant Abbott Laboratories.

8. Upon information and belief, and for all purposes relevant to this Complaint, Defendants Abbott Laboratories and Abbott Laboratories, Inc., functioned as one entity

[collectively referred to hereafter as "Abbott"].

9. Defendants Abbott manufacture, design, formulate, prepare, test, provide instructions for, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Arizona and Illinois, premature infant formula including but not limited to Similac Human Milk Fortifier, Similac Special Care, Similac NeoSure, and Liquid Protein Fortifier.

10. At all times material hereto, Defendants Abbott solely or jointly designed, developed, formulated, prepared, manufactured, provided instructions for, packaged, labeled, promoted, marketed, distributed, and/or sold Similac products specifically targeting medical providers and parents of preterm infants, including but not limited to Liquid Protein Fortifier, Similac Neosure, Similac Human Milk Fortifier, and "Similac Special Care Formulas" such as Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30 [collectively referred to hereinafter as "Cow's Milk Products" and/or "Cow's Milk-Based Products].

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

JURISDICTION AND VENUE

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

13. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiffs and Defendants, and the matter in controversy,

exclusive of interest and costs, exceeds the sum or value of $75,000.00.

14. This Court has personal jurisdiction over Defendants Abbott because Defendants are authorized to conduct business and do conduct business in the State of Arizona, purposefully direct and/or directed their actions toward and/or within Arizona, and consented to being sued in Arizona by registering an agent for service of process in Arizona. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within the State of Arizona, the damages were sustained by Plaintiffs within Arizona, and the damages sustained by Plaintiffs were a result of Defendants' actions and/or inactions, described herein, that were purposefully directed at and/or within Arizona. Further, Defendants Abbott have marketed, promoted, distributed, and/or sold their products described herein in the State of Arizona. Defendants Abbott have sufficient minimum contacts with this state and/or sufficiently avail themselves of the markets in the state through their promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

15. Venue of this action is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district.

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

16. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy

are completed, like K.S. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

17. Nutrition for preterm babies is significantly important. Because the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

18. Historically, there are three types of nutrition for preterm babies: parenteral nutrition for feed intolerance such as a feeding tube, human milk whether it is the mother's own milk or donor milk, and cow's milk-based formulas and fortifiers. Cow's Milk Products were once believed to be good for the growth of premature, low birth weight babies. While the Cow's Milk Products were good for bulking up these babies quickly, science and research have advanced in recent years confirming strong links between cow-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-bovine based products. Despite knowledge of a causal connection between Cow's Milk Products and NEC, the manufacturers of the Cow's Milk Products, including Defendants Abbott, did nothing to change their product, packaging, guidelines, instructions, and/or warnings and continue to promote and sell the Cow's Milk Product versions.

19. NEC is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier, which often becomes fatal when it advances to necrosis and

perforation of the gut.

20. With normal absorption in the small intestine, the cells lining the lumen of the intestines have microvilli that magnify the surface area available for uptake. Nutrients are absorbed by these cells, then transported through the cells, and released where they are then transported to the rest of the body through the bloodstream and lymphatic system. The cells keep out the bacteria and toxins that are present in the intestines which would be harmful if absorbed into the other tissues of the body. The tight junctions between each cell play a major role in preventing the bacteria and toxins from entering the body.

21. If these tight junctions are broken down, harmful bacteria and toxins are able to enter the baby's bloodstream and lymphatics, which induces an inflammatory response in the baby's intestinal walls. These toxins further breakdown and weaken the tight, intercellular junctions, and as a result, bacteria, toxins, and plasma escape into the surrounding interstitial spaces resulting in a condition known as "third-spacing" and sepsis. This process begins with the administration of Cow's Milk Products and can lead to sepsis, multi-system organ failure, and death.

22. The classic signs and symptoms of NEC experienced by vulnerable preterm babies after ingesting the Cow's Milk Products include, but are not limited to: irritability, crying, pain, abdominal distention, hyperthermia, tachycardia, decreased bowel sounds, lethargy, reduced urine output, shock, free air in the abdomen, elevated white blood count, tenderness, portal venous gas, greenish discoloration, worsening or persistent thrombocytopenia, completely gasless abdomen, repeated feeding intolerance, intestinal

strictures, passage of meconium through patent processus vaginalitis, and fixed and dilated loop on serial abdominal radiographs.

23. Science and research have advanced in recent years confirming strong links between cow's milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products; however, the manufacturers of the Cow's Milk-Based Products continue to promote and sell the Cow's Milk-Based versions.

24. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula-fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk but was 20 times more common in those fed cow's milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

25. A study published in 2010 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were 90% less likely to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, et al., *An*

Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products, JOURNAL OF PEDIATRICS, 156: 562-7 (2010).

26. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011). This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id*.

27. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used." Breastfeeding and the Use of Human Milk, PEDIATRICS, 129:e827-e84l (2012).

28. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and weight and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A.

Hair, et al., *Human Milk Feeding Supports Adequate Growth in Infants* ≤ 1250 Grams Birthweight, BMC RESEARCH NOTES,6:459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula companies such as the Defendant.

29. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a significantly higher rate of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU (Newborn Intensive Care Unit). E.A. Cristofalo, et al., *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013).

30. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, et al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July). The same study found that NEC "is the most frequent and lethal gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure

and death. *Id*. The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id*. The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease." *Id*. Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id*.

31. In another study published in 2014, it was reported that an exclusive human milk diet, devoid of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, et al., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

32. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants significantly decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with "significant benefits" for extremely preterm infants and while evaluating the benefits of using an exclusive human milk- based protocol, "it appears that there were no feeding-

related adverse outcomes." Hair, et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016).

33. A publication by the American Society for Nutrition, in 2017, noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow's milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an exclusive human milk diet resulted in a much lower incidence of NEC. While the study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the cow's milk-based products significantly increase the risk of NEC and death. The study also noted the "exponential" health care costs associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and nearly doubles to $313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017).

34. Defendant Abbott's Cow's Milk Products do not require a prescription from a healthcare provider; rather, they are readily available to the average consumer. As such, they are not regulated in the same manner by the FDA as prescribed drugs.

35. When it comes to drugs requiring prescription, the FDA requires manufacturers to study their medications and perform trials and collect data to determine the safety and efficacy of their drugs and to determine the likelihood of side effects and to continuously study the drug's use to review adverse outcomes and create proper warnings and instructions; however, because baby products, such as Defendants Abbott's Cow's Milk Products, are not "drugs," Defendants Abbott have not performed such trials and have not collected data on when and how the products should be fed. Despite knowing for decades that their Cow's Milk Products are associated with and are significantly increasing NEC and death in premature infants, and are far more dangerous than most prescription drugs, Defendants Abbott have done nothing to stop or lessen NEC or death.

36. If Defendants Abbott had performed the pharmacovigilance required by the FDA vis-à-vis drug manufacturers for their premature infant formulas and fortifiers, which a reasonably prudent manufacturer of baby products intended for preterm infants like the Cow's Milk Products at issue would have done, Defendants' Cow's Milk Products would not have been fed to K.S., she would not have developed NEC, and she would not have died.

37. There are human milk-based formulas and fortifier products which are safer feasible alternatives to Defendants' Cow's Milk Products.

Defendants Abbott's Marketing

38. Notwithstanding strong and overwhelming medical evidence establishing the extreme dangers that Cow's Milk Products pose for preterm infants, Defendants Abbott

have marketed their Cow's Milk Products as an equally safe alternative to breast milk and have promoted these products as necessary for additional nutrition and growth. Defendants have specifically marketed their formulas and fortifiers as necessary to the growth and development of preterm infants, when instead, these products pose a known and substantial risk to these babies.

39. Defendants Abbott have also engaged in tactics reminiscent of tobacco manufacturers by trying to "hook" moms when they are most vulnerable. They often offer free formula and other freebies and coupons in "gift baskets" given to mothers in hospitals, medical clinics, and even left at residential charities where out-of-town families have to stay when their babies are being treated for a substantial amount of time in the neonatal intensive care units of hospitals. By doing this, Defendants are able to create brand loyalty under the guise of a "medical blessing" so that these vulnerable parents continue to use formula to feed their babies after they leave the hospital, resulting in great expense to parents, significant risk to the babies, and substantial profit to Defendants.

40. Defendants are also able to hook a customer base for other products they manufacture as the customer base ages. For example, Defendants Abbott's Similac website also advertises its products Ensure and Zone Perfect as "healthy living" and markets its "therapeutics," such as Glucerna, Alliance, Mi Glucerna, and Nepro, which are products largely marketed to aging and geriatric populations.

41. Defendants Abbott's self-serving and nefarious tactics go back decades, as it and its competitors continue to fight for their respective market share by scaring mothers

with newborn infants, especially those who are higher risk because they are born preterm. Defendants Abbott falsely advertises that their products are healthier or even necessary for adequate nutrition and that formula is the only appropriate choice for modern mothers. In fact, these tactics are purposefully designed to encourage parents to buy into the myth that formula is best, which further discourages mothers from breastfeeding at all and which further reduces the supply of available breast milk and ensures that more of their formula will be purchased.

42. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000).

43. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "There should be no advertising or other form of promotion to the general

public [of breast milk substitutes].” In Article 5.2, the Code states that “manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.” In addition, the Code expressly prohibits, “point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…” See Int’l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

44. The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to US $44.8 billion and "is expected to rise to US $70.6 billion by 2019." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21.

45. While Defendants Abbott have publicly acknowledged the Code since its adoption and claim to support the effort to educate mothers to breastfeed, they insidiously undermine breastfeeding efforts and flout the Code. *See* "Don't Push It: Why the Formula Milk Industry Must Clean up its Act," SAVE THE CHILDREN, 2018. In the decades since adoption of the Code, Defendants Abbott continue to aggressively market and exploit the

vulnerabilities of these families by advertising directly to the new parents' darkest fears - that by not buying and using these products, they will somehow hurt their newborns by not giving them the very best chance of survival. In fact, in the WHO's 2018 Status Report on this issue, it was noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to $44.8 billion and "is expected to rise to US $70.6 billion by 2019." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p. 21.

46. Yet, Defendants Abbott continue to aggressively market because it works, especially since they consistently employ unfair and deceptive tactics from the inception of the Cow's Milk Products. For example, the name "Similac," as in, it is "similar to lactation," is deceptively designed to perpetuate a false sense that its product is similar to human breast milk.

47. Moreover, Defendants Abbott's advertisement for Similac on the back cover of the April 2004 issue of American Baby Magazine makes repeated references and comparisons to breast milk for brain and visual development, along with greater calcium absorption and greater bone density. *See* Angela B. Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottlefeeding Product Ads with*

Magazine Article Content, (2005) LSU MASTER'S THESES, 667, https://digitalcommons.lsu.edu/gradschool_theses/667/.

48. In addition to deliberately disseminating or perpetuating the myth that these Cow's Milk Products are similar to breast milk, Defendants Abbott have also intentionally deceived the public into believing that healthcare providers believe these products are superior to breast milk or even ideal and that physicians and institutions endorse the Cow's Milk Products.

49. A marketing report commissioned by Defendants Abbott in March 1998 summarized consumer reactions to several informational advertising pamphlets on Similac. Defendants Abbott found that the advertisements that scored highest in terms of whether consumers would actually buy the product included the claims about being the "1st Choice of Doctors." Defendants Abbott found that using doctor recommendations and the supposed "science" behind the formula further drove consumer interest and sales.

50. Another study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would select those brands to feed to infants. R.S. Parker, *Ethical Considerations in the Use of Direct-to-Consumer Advertising and Pharmaceutical Promotions: The Impact on Pharmaceutical Sales and Physicians*, J. OF BUS. ETHICS, 48, 279-290 (2003). Thus, by Defendants Abbott's marketing in advance to the public that a product is recommended by physicians, the public buys more of the product, and then the physicians are actually more likely to recommend the product in the future, further perpetuating and fueling a deceptive vicious cycle or

harmful self-fulfilling prophesy.

51. Defendants Abbott have also long attempted to market its products specifically to preterm infants, whom are in fact at highest risk from the dangers of the product. In 1978, Defendants Abbott began marketing "Similac 24 LBW" specifically for premature infants, claiming that the product was introduced to meet the special needs of premature infants. In 1980, Defendants 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." In 1988, Defendants Abbott introduced and marketed Similac Special Care with Iron, claiming it was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US. Indeed, Defendants Abbott has marketed and sold a variety of 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, and Similac Special Care 30.

52. In recent years, recognizing a shift in the medical community towards an exclusive human milk-based diet for preterm infants, Defendants Abbott began heavily promoting its products as "human milk fortifiers," a name which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk.

53. Defendants Abbott have thereby designed a systematic, powerful, and misleading marketing campaign to persuade physicians and parents alike to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are

equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk-Based Products a first choice. Similarly, Defendants Abbott market their products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk-Based Products and failing to warn of the deadly disease of NEC and risk of death.

54. Defendants Abbott have also engaged in other tactics reminiscent of the tobacco companies by "maneuvering to hijack the political and legislative process, exaggerating economic importance of the industry, manipulating public opinion to gain appearance and respectability, fabricating support through front groups, discrediting proven science, and intimidating governments with litigation" all over the United States and across the world. Sabrina Ionata Granheim, *et al, Interference in Public Health Policy: Examples of How the Baby Food Industry Uses Tobacco Industry Tactics*, WORLD NUTRITION, 8(2): 290-298 (2017). To this end, Defendants Abbott also attempt to manipulate hospitals and medical professionals by donating large amounts of money to coffers disguised as charity for supposed research and advances in science, and Defendants have even created alleged "Pediatric Nutrition Institutes" worldwide. All the while, their Cow's Milk Products pose the greatest health survival risks to these vulnerable babies.

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

weight infants.

The Inadequate Warnings

56. Defendants Abbott promoted the use of their preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

57. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC and death, Defendants Abbott did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendants provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC or death.

58. In fact, Defendants Abbott did not provide any warning whatsoever in its labeling, websites, or marketing that discusses the risk of NEC and death with use of its Cow's Milk-Based Products with preterm infants.

59. The warnings on Defendants Abbott's Similac preterm Cow's Milk Products, specifically and deceptively characterized as "Human Milk Fortifier," state:

/ / /

/ / /

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.

* *American Dietetic Association and Centers for Disease Control and Prevention*

[1] *Klein CJ. J Nutr 2002;132(6):1395S-1577S.*

[2] *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.*

[3] *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.*

[4] *Data on file, 2010. Abbott Nutrition Market Research, Abbott Laboratories, Columbus, Ohio.*

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

K.S. and the Dangerous, Defective Products

61. K.S. was an infant born prematurely by c-section delivery – one of two twins – at Banner Thunderbird Medical Center [“Banner”] in 2023 at a gestational age of 32

weeks 6 days and underweight.

62. K.S. was admitted into the NICU immediately following delivery where the indications for such admission included "prematurity."

63. At or around the time of delivery and/or initial NICU presentation, prior to receiving Cow's Milk-Based Products, K.S. was documented to have a "Soft and nondistended abdomen."

64. Banner medical records reflected the following nutrition plan: "Will plan to begin gavage feedings of EBM [expressed breast milk] or SSC [Similac Special Care] 24kcal by 24 hours of life."

65. Within that same latter note, under the subheading "FLUID INTAKE," was the following: "FEEDS: Similac Special Care 24 24kcal/oz".

66. Banner medical record flowsheets indicate that K.S.' feedings in the NICU with "Similac Special Care" regularly occurred thereafter.

67. Banner medical records indicate that, while feedings in the NICU with expressed breast milk were sometimes documented as well, they were in addition to, or in combination with, feedings with "Similac Special Care."

68. Banner medical records indicate that the final feeding that included Similac Special Care was on February 24, 2023 at or about 5:00 p.m. (1700).

69. In a "Neonatal Progress note" with a Service Date/Time of February 24, 2023 at 9:27 p.m. (2127), it was documented: "Called by bedside RN for increased abdominal girth and emesis. Infant at half volume feeds. Receiving mostly SSC 24 kCal, some EBM…

Infant pale, tachypneic, grunting and mild subcostal retractions. Infant had just had emesis… +BS with distended abdomen. Formed green/brown stool noted. 26 ml of partially digested pink tinged residual aspirated from stomach… KUB with gaseous distention but no pneumatosis or focal concerns. Will place NPO, will give glycerin suppository."

70. On February 24, 2023, at or about 9:39 p.m. (2139), K.S. underwent an abdominal x-ray that revealed "Moderate gaseous distension of bowel diffusely. No pneumatosis or portal venous gas."

71. On February 25, 2023, at or about 5:06 a.m. (0506), K.S. underwent an abdominal x-ray for "follow up gaseous distention" that revealed "No evidence of free air… Moderate gaseous distention of bowel loops throughout the abdomen, maintaining normal polyhedral appearance, with gas extending to the region of the rectum."

72. On February 25, 2023, at or about 10:15 a.m. (1015), K.S. underwent an abdominal x-rays to "eval for free air," for which the Findings included: "Air-filled distended loops of bowel with bubbly appearance in the right abdomen suspicious for pneumatosis" and the Impression included "Free intraperitoneal air. Suspected pneumatosis. Consider necrotizing enterocolitis in the differential diagnosis."

73. In a "Consultation Report" dated February 25, 2023 at 11:02 a.m. (1102), it was documented that the reason for the consultation was for "Pneumoperitoneum. Request for mini laparotomy, drain placement," with a history including: "started to clinically decline last night with signs of NEC."

74. In the same latter "Consultation Report" dated February 25, 2023 at 11:02 a.m. (1102), it was documented under "Assessment/Plan": "Necrotizing enterocolitis with necrosis and perforation... My plan is for immediate mini laparotomy and intraperitoneal drain placement."

75. In a "Operative Report" dated February 25, 2023 at 1:02 p.m. (1302), the pre and post-operative diagnosis was "NECROTIZING ENTEROCOLITIS WITH PERFORATION," whereas the post-operative diagnosis also included: "concern for total bowel necrosis. Necrotizing Enterocolitis Totalis."

76. In that same latter "Operative Report" dated February 25, 2023 at 1:02 p.m. (1302), it was documented: "On entering the peritoneum there was flow of a small volume of air and very dark and foul-smelling fluid consistent with necrotic bowel… Gentle palpation on the abdomen on all of the quadrants expelled some additional foul-smelling air and more of the dark peritoneal fluid consistent with necrosis… I spoke with the parents explaining to them the significance of our findings clearly confirming that there was some bowel necrosis given the appearance and smell of the fluid. We also explained that based on the baby's clinical course at this point and the radiographic findings that we had concern that the baby had necrosis of all of the intestine which would result in a fatal outcome."

77. In a "Neonatal Progress note" with a Service Date/Time of February 25, 2023 at 5:03 p.m. (1703), it was documented: "ABDOMEN: Round, tender to touch, taunt hypoactive bowel sounds"… "COMMENTS: Due to increased events and concerning KUB [kidney, ureter, and bladder X-ray], sepsis work up completed. CBC on 2/24

unremarkable for infection. Blood culture pending. Infant started on empiric antibiotics along with flagyl due to concerns of NEC."

78. In the same "Neonatal Progress note" with a Service Date/Time of February 25, 2023 at 5:03 p.m. (1703), it was documented: "COMMENTS: Infant was receiving advanced feedings of EBM 24kcal or SSC 24kcal. Due to increased abdominal distension overnight, infant made NPO."

79. In the same "Neonatal Progress note" with a Service Date/Time of February 25, 2023 at 5:03 p.m. (1703), under the diagnosis subheading of "NECROTIZING ENTEROCOLITIS," comments included: "Infant with concerns for pneumatosis based on x-ray and clinical status. With placement of penrose drain, Dr. Lacey noticed very dark and foul-smelling fluid consistent with necrotic bowel. Infant is already NPO and on antibiotics with Replogle to LIWS."

80. In a "Neonatal Progress note" with a Service Date/Time of February 25, 2023 at 8:54 p.m. (2054), it was documented: "Acidosis continued to worsen throughout the day despite inotropes, increased ventilation, and penrose drain for SIP. Multiple discussions with parents regarding quality of life, chances of survival, and chances of improving clinically. After max inotropes and max ventilator settings with continued worsening acidosis, pH less than 7.0 x2, and discussion with that parents [sic], decision was made to withdrawal support [sic]… At 2102, infant did not have a heart rate. Parents held briefly and placed infant back in isolette."

81. In a "Spiritual Care Assessment" dated February 25, 2023 at 8:42 p.m.

(2042), it was noted: "[Plaintiff Shen Seiken's] dad died in New York and he was unable to attend his dad's funeral so he could be home when his twin girls were born, dad is heavily mourning and grieving."

82. Banner's "NICU death summary" read, in pertinent part: "Baby had abdominal distention overnight, sepsis workup done and antibiotics (amp/gent/Flagyl) initiated, serial abdominal X-Rays obtain and by early morning it showed pneumatosis intestinalis and later pneumoperitoneum was noted on X-Ray. Penrose drain placed… Acidosis continued to worsen throughout the day despite pressor support, optimization of ventilation, and remains anuric… Death was pronounced at 2102. Fulminant NEC with gram negative sepsis are preliminary cause of death."

83. The State of Arizona Certificate of Death for K.S. identifies her cause of death as "Cardiorespiratory Failure" due to or as a consequence of "Necrotizing Enterocolitis and Sepsis."

COUNT I: STRICT LIABLITY – DESIGN DEFECT

84. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

85. At all times relevant hereto, Defendants Abbott were actively engaged in the business of designing, manufacturing, marketing, warranting, distributing, and selling of Cow's Milk Products, including but not limited to Similac Special Care, which was fed to and ingested by K.S., in the course of their business.

86. Defendants Abbott is/was a "Seller" and/or "Manufacturer" as defined in

A.R.S. § 12-681 and was engaged in the business of designing, manufacturing, and/or selling Cow's Milk Products, including but not limited to Similac Special Care, within the state of Arizona.

87. Defendants Abbott, as the Seller and/or Manufacturer of the Cow's Milk Products, owed a duty to the consuming public in general, including Plaintiffs, to design, manufacture, distribute, and sell their respective Cow's Milk Products in a manner that was not unreasonably dangerous and are liable despite any care exercised to design a safe product.

88. At the time Defendants Abbott placed in the stream of commerce the Cow's Milk Products that were ultimately fed to and ingested by K.S., they were defective and unreasonably dangerous when put to reasonably anticipated use for preterm infants.

89. As such, Plaintiffs sustained damages as a direct and proximate result of the defective condition of Defendants Abbott's Cow's Milk Products that existed when placed in the stream of commerce, sold, and/or used in a reasonably anticipated manner.

90. Defendants Abbott's Cow's Milk Products were expected to and did reach the user without substantial change affecting their defective and/or unreasonably dangerous condition.

91. Defendants Abbott was actually aware or should have been aware that their Cow's Milk Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these Products in such situations.

92. Defendants Abbott knew or should have known that the use of their Cow's Milk Products with preterm infants were unreasonably dangerous in that its Cow's Milk Products significantly increased the risk of NEC and death.

93. Furthermore, scientific data and well-researched studies have concluded that Defendants Abbott's Cow's Milk Products carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants like K.S.

94. Despite the foregoing, Defendants Abbott continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

95. Defendants Abbott's Cow's Milk Products were defectively designed and/or unreasonably dangerous, including, but not limited to, the following:

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

B. Defendants Abbott's products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as K.S., to risks of serious bodily injury and death;

C. Defendants Abbott's products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an

intended or reasonably foreseeable manner;

D. Defendants Abbott failed to utilize economically, practically, and technically available safer design alternatives for preterm infant formula and fortifiers, including formulas and fortifiers based on or derived from human milk or amino acids;

E. Defendants Abbott's products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product or allow it to be fed to their preterm infant;

F. Defendants Abbott failed to adopt an adequate or sufficient quality control program;

G. Defendants Abbott failed to inspect or test their products with sufficient care;

H. Defendants' Abbott's design for their premature infant formulas and fortifiers was defective because it included ingredients known to cause NEC in premature infants, specifically Cow's Milk ingredients, which are not necessary components of infant formula or fortifier; therefore, they are not an unavoidably unsafe aspect of the products.

96. Defendants Abbott are therefore strictly liable under applicable product liability law in the state of Arizona.

97. As a direct and proximate result of the defective and unreasonably dangerous

condition of Defendants Abbott's Cow's Milk Products, thereby comprising strict liability under applicable product liability law in Arizona, K.S. sustained fatal injuries.

98. As a direct and proximate result of the defective and unreasonably dangerous condition of Defendants Abbott's Cow's Milk Products, thereby comprising strict liability under applicable product liability law in Arizona, Plaintiffs Marina Seiken and Shen Seiken sustained damages available under Arizona's wrongful death statute including but not limited to: loss of love, affection, companionship, care, protection, guidance and support the K.S. would have given to her family for the rest of her natural life, but for her untimely death; past and future pain, grief, sorrow, anguish, stress, shock, and mental suffering, and economic losses/loss of income/medical/funeral expenses in an amount provable at trial.

COUNT II: NEGLIGENCE

99. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

100. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk Products, owed a duty to the consuming public in general, including to Plaintiffs, to exercise reasonable care in designing, testing, manufacturing, inspecting, labeling, marketing, promoting, distributing, selling, and warning regarding their Cow's Milk Products and to exercise reasonable care to ensure that their Cow's Milk Products were free of unreasonable risk of harm to users and patients, including K.S., when said product is used in its intended manner.

101. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk

Products, owed a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

102. Defendants Abbott negligently and defectively designed, tested, manufactured, inspected, labeled, marketed, promoted, distributed, sold, and warned regarding the subject Cow's Milk Products, including but not limited to Similac Special Care.

103. Defendants Abbott breached the duty owed to Plaintiffs and K.S. and acted negligently in their actions, including, but not limited to, the following:

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

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

C. Defendants Abbott either failed to collect data, study, and test to determine if its products were safe for preterm infants, or did possess such data and nonetheless did not change its practices with regard to its Products' manufacture, design, marketing, and/or sale;

D. Defendants Abbott either failed to collect data, study, and test to determine when and how its products could be used safely, or did possess such data and did not change its practices with regard to its Products' manufacture, design, marketing, and/or sale;

E. Defendants Abbott failed to utilize the significant peer reviewed research to develop instructions and warn of all known risks and complications associated with the Cow's Milk Products;

F. Defendants Abbott failed to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

G. Defendants Abbott failed to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

H. Defendants Abbott failed to take reasonable efforts to stop or deter its products from being fed to preterm infants like K.S., but instead encouraged and/or marketed its products specifically for such use;

I. Defendants Abbott failed to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;

J. Defendants Abbott failed to continuously and vigorously study their own Cow's Milk Products in order to avoid NEC and death in

premature infants;

K. Defendants Abbott failed to utilize economically, practically, and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

L. Defendants Abbott failed to adopt an adequate or sufficient quality control program;

M. Defendants Abbott failed to warn consumers, including Plaintiffs, healthcare providers, the FDA, and the general public of all known risks and complications associated with their Cow's Milk Products;

N. Defendants Abbott marketed and promoted their Cow's Milk Products in a misleading, inadequate, and deceptive manner;

O. Defendants Abbott failed to provide periodic or yearly safety reports and risk-benefit analyses of their Cow's Milk Products;

P. Defendants Abbott failed to develop and provide a protocol and/or guidelines to hospitals, physicians, and parents regarding the proper and safe use their Cow's Milk Products;

Q. Defendants Abbott failed to perform the necessary scientific process of collection, detection, assessment, monitoring, and prevention of the adverse effects of feeding its Cow's Milk Products to premature infants like K.S.; and/o

R. Defendants Abbott failed to inspect or test their products with

sufficient care.

104. Defendants Abbott knew or should have known that their Cow's Milk Products were to be used as nutrition and nutritional supplements with preterm infants, like K.S.

105. Defendants Abbott knew or should have known that the use of their Cow's Milk Products with preterm infants was unreasonably dangerous in that their Cow's Milk Products significantly increased the risk of NEC and death.

106. Furthermore, scientific data and well researched studies have concluded that Defendants Abbott's Cow's Milk Products carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely premature infants like K.S.

107. Had Defendants Abbott not committed negligence, as set forth herein, K.S. would not have been exposed to Defendants' unreasonably dangerous Cow's Milk Products and would not have developed NEC with resulting death.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

108. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

109. Defendants Abbott failed to adequately warn consumers, including Plaintiffs, healthcare providers, the FDA, and the general public of all known risks and complications associated with their Cow's Milk Products, including the risk of NEC and resulting medical conditions, complications, and injuries, including death.

110. Plaintiffs were damaged as a direct result of Defendants' Abbott placing into the stream of commerce its Cow's Milk Products without an adequate warning.

111. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk Products, owed a duty to the consuming public in general, including Plaintiffs, as well as healthcare providers, to properly warn and provide adequate warnings and instructions about the dangers, risks, and complications associated with the use of Cow's Milk Products with preterm infants, specifically including but not limited to the risk of NEC and death.

112. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk Product, were unreasonable in relying upon physicians and/or other healthcare providers and/or healthcare staff, to reasonably or fully warn the end user of the hidden risks and dangers associated with their Cow's Milk Products, as the magnitude of the risk involved is using Defendants' Cow's Milk Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

113. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk Product, failed to reasonably or fully warn and instruct physicians and/or other healthcare providers and/or healthcare staff of the significant risks and dangers in their Cow's Milk Products.

114. Defendants Abbott failed to provide warnings and instructions on its Cow's Milk Products marketed and/or sold for use with preterm infants that adequately communicated information on the risks, dangers and safe use of the product to healthcare providers and staff using these products in a Newborn Intensive Care Unit ("NICU"),

taking into account the characteristics of, and the ordinary knowledge common to, such treating healthcare providers and administering healthcare staff and to specifically warn of the risks and dangers associated with the use of Cow's Milk Products with preterm infants, specifically including, but not limited to, the risk of NEC and death.

115. Rather than provide adequate warnings, Defendants Abbott developed relationships that included incentives and financial gain to healthcare providers and facilities for using their Cow's Milk Products within the NICU, such that healthcare providers and facilities were actively incentivized to withhold any instructions and/or warnings from parents of preterm infants whom were to be fed such Products.

116. In addition and/or in the alternative, if healthcare providers and healthcare staff had been properly instructed and warned of the risks associated with the use of Defendants Abbott's Cow's Milk Products with preterm infants, they would have not used such a dangerous product on such patients, including but not limited to K.S.

117. Defendants Abbott, as the Manufacturer and/or Seller of their Cow's Milk Product, owed a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and were presumed to know the result of all such advances.

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

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

120. Defendants Abbott nonetheless failed to provide proper warnings and/or instructions regarding their Cow's Milk Products, including but not limited to as follows:

A. Defendants Abbott provided no warnings regarding the risk of NEC and death;

B. Defendants Abbott provided inadequate labeling that failed to warn of the risks of use of Cow's Milk Products with preterm infants, including but not limited to NEC and death;

C. Defendants Abbott failed to provide proper instructions, guidelines, studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC and/or death;

D. Defendants Abbott failed to insert a warning or instruction that parents needed to be provided an informed choice by healthcare providers between the safety of human milk versus the dangers of Defendants' Cow's Milk Products;

E. Defendants Abbott failed to provide warnings or notices to consumers and healthcare providers that Defendants' products carried a significant risk that their Cow's Milk Products could cause babies to

develop NEC and die;

F. Any warnings or notices that Defendants Abbott did provide were inadequate, vague, confusing, and/or provided a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk Products significantly increasing the risk of NEC and death and fail to provide any details on how to avoid such harm;

G. Defendants Abbott failed to contain a large and prominent "black box" type warning on its Cow's Milk Products stating that they are known to significantly increase the risk of NEC and death when compared to human milk in preterm infants;

H. Defendants Abbott failed to provide, cite, or otherwise reference or incorporate the findings of well-researched and well-established studies that linked the Cow's Milk Products to NEC and death in preterm infants;

I. Defendants Abbott failed to cite to or utilize current up-to-date medical data on the proper and safe use of its Cow's Milk Products;

J. Defendants Abbott failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk Products;

K. Defendants Abbott failed to send out "Dear Doctor" letters warning

of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for preterm infants;

L. Defendants Abbott failed to advise physicians and healthcare providers that Cow's Milk Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

M. Defendants Abbott failed to contain sufficient instructions and warnings on the Cow's Milk Products such that healthcare providers and healthcare staff were not properly warned of the dangers of NEC with use of Cow's Milk Products and preterm infants.

121. If Defendants Abbott had fully warned and instructed physicians, other healthcare providers, and/or health care staff who provided care and treatment to and/or fed Defendants' Cow's Milk Products to K.S., of the significant risks and dangers in the Cow's Milk Products, including NEC, they would not have fed Defendants' Cow's Milk Products to K.S.

122. If Defendants Abbott had fully warned and instructed physicians, other healthcare providers, and/or health care staff who provided care and treatment to and/or fed Defendants' Cow's Milk Products to K.S., of the significant risks and dangers in the Cow's Milk Products, including NEC, and if such healthcare providers had then communicated such risks to Plaintiffs Marina Seiken and Shen Seiken, Plaintiffs would have objected to the feeding of Defendants' Abbott's Cow's Milk Products to K.S. and

insisted on safer preterm feeding alternatives.

COUNT IV: NEGLIGENT MISREPRESENTATION

123. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

124. Defendants Abbott provided materially misleading and false information and/or omitted material information in labeling, marketing, distributing, selling, and warning regarding their Cow's Milk Products.

125. Defendants Abbott provided such materially misleading and false information, and/or omitted such material information, while knowing or reasonably expecting healthcare providers and/or parents to materially rely on the same, to the detriment of healthcare providers, preterm patients, and the patients' parents.

126. Defendants Abbott , as the designer, manufacturer, seller, and distributor of their Cow's Milk Products, had a duty to the general public to provide truthful, accurate, and complete information about the risks and benefits of using their Products.

127. Defendants Abbott failed to exercise reasonable care by failing to provide or disclose truthful, accurate, and complete information about the risks and benefits of using their Cow's Milk Products.

128. Because of Defendants Abbott's failure to exercise reasonable care, the information provided to healthcare providers and the public regarding their respective Cow's Milk Products was misleading and/or false, including, but not limited to, the following:

A. Defendants Abbott negligently misrepresented that their Cow's Milk Products were safe and beneficial for premature infants when they knew or should have known that the Products were unreasonably dangerous, caused NEC, and could thereby be expected to result in devastating injuries and/or death in premature infants;

B. Defendants Abbott negligently misrepresented to parents, physicians, and healthcare providers that their respective Cow's Milk 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; were safe and beneficial for premature infants when they knew or should have known that the Products were unreasonably dangerous and caused NEC, and could thereby be expected to result in devastating injuries and/or death in premature infants;

C. Defendants Abbott negligently misrepresented that their Cow's Milk Products have no serious side effects, when they knew or should have known the contrary to be true;

D. Defendants Abbott negligently misrepresented that their Cow's Milk Products are similar or equivalent to human milk;

E. Defendants Abbott negligently misrepresented that their Cow's Milk Products were based on current up-to-date science, which made it safe

for premature infants;

F. Defendants Abbott negligently omitted the material fact that their Cow's Milk Products significantly increase the risk of NEC in premature infants; and

G. Defendants' Abbott negligently misrepresented that their Cow's Milk Products contain fats that are good for the baby's brain and similar to breast milk.

129. Defendants Abbott intended that the general public, the medical community, including K.S.' healthcare providers, rely on this information and provided this information to induce such reliance.

130. This materially false and/or materially incomplete information was provided by Defendants Abbott to K.S.' healthcare providers in the sale of their Cow's Milk Products, who justifiably or reasonably relied on that information, and by which Plaintiffs have consequently sustained damages set forth herein.

COUNT V: GROSS NEGLIGENCE

131. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

132. In committing the acts and omissions set forth herein, Defendants Abbott acted knowing or with reason to know their actions created an unreasonable risk of bodily harm with a high probability that such harm would result to the general public and patients, including K.S.

133. In committing the acts and omissions set forth herein, Defendants Abbott acted and failed to act when they knew or had reason to know facts which would lead a reasonable company to realize that its conduct not only created an unreasonable risk of bodily harm to others, including Plaintiff K.S., but also involved a high probability that substantial harm would result.

134. As a direct and proximate cause of Defendants' Abbott's gross negligence, described herein, Plaintiffs suffered the wrongful death of their preterm daughter, K.S., with associated damages asserted pursuant to Arizona's wrongful death statute, elsewhere set forth herein, and/or otherwise available by law.

COUNT VI: BREACH OF WARRANTIES

135. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

136. At all times material hereto, Defendants Abbott's Cow's Milk Products were widely sold, distributed, marketed, promoted, and advertised by Defendants as products to feed premature babies, including K.S.

137. Defendants Abbott marketed, promoted, advertised, sold, and distributed their Cow's Milk Products in the State of Arizona and into the stream of commerce knowing that they would enter the State of Arizona and be used therein, including at hospitals such as Banner.

138. When Defendants Abbott placed their Cow's Milk Products into the stream of commerce in Arizona, they knew of the use for which the Products were intended and

expressly and impliedly warranted such Products to be of merchantable quality and to be safe and effective and fit for such use.

139. Defendants Abbott made numerous representations about the quality, safety, and effectiveness of the Cow's Milk Products Products, which formed warranties, to K.S.' healthcare providers and to Plaintiffs.

140. At the time of making the warranties, Defendants Abbott knew or should have known that, in fact, said representation and warranties were false, misleading, incomplete, and/or untrue in that the Products were not safe and fit for their intended use and, in fact, produced serious injuries to the user, including K.S.

141. K.S.' healthcare providers and Plaintiffs reasonably relied upon the expertise, skill, judgment, and knowledge of Defendants Abbott and on the express and/or implied warranties that the Products were of merchantable quality and fit for use.

142. The Cow's Milk Products did not conform to Defendant Abbott's representations and were not of merchantable quality and not safe or fit for their intended use because the Products were, and are, unreasonably dangerous and unfit for the ordinary and expected purposes for which they were used in that they caused fatal injury to K.S. and others far beyond any acceptable or warned of risk or complication.

143. As a direct and proximate result of Defendant Abbott's breach of th express and implied warranties described herein, Plaintiffs suffered the wrongful death of their preterm daughter, K.S., with associated damages asserted pursuant to Arizona's wrongful death statute, elsewhere set forth herein, and/or otherwise available by law.

COUNT VII: PUNITIVE DAMAGES

144. Plaintiffs incorporate the allegations contained in the foregoing and subsequent paragraphs as though fully set forth herein.

145. Arizona law authorizes an award of punitive damages in this case; A.R.S. § 46-455(H)(4) provides that the "court or jury may order the payment of punitive damages under common law principles that are generally applicable to the award of punitive damages in other civil actions."

146. Defendants Abbott continued to accept, benefit, and/or profit from the sale of its Cow's Milk Products, while knowing or having reason to know that such Products' known dangers were not meaningfully or materially disclosed, while materially and falsely overstating the benefits of such Products.

147. Defendants Abbott thereby continued to accept, benefit, and/or profit from the sale of its Cow's Milk Products while exhibiting a conscious disregard knowing or having reason to know that it could cause preterm infants like K.S. to suffer serious harm or death.

148. Defendants Abbott engaged in such actions for their own benefit, while having reason to know and consciously disregarding the substantial risk and harms posed to preterm infants like K.S. and, by extension, their parents.

149. At all times material to this action, Defendants Abbott acted with a proverbial evil hand guided by an evil mind.

150. At all times material to this action, Defendants Abbott acted with an intentional, fraudulent, malicious, reckless, willful, wanton, and/or grossly culpable mental state, rendering its actions outrageous and shocking to the conscience.

151. Under Arizona law, such conscious disregard, reckless indifference, and/or intentional fraudulent acts warrant the imposition of punitive damages, both to punish defendants for their own specific wrongdoing, and to serve as deterrence to those similarly situated from committing similar wrongs in the future.

JURY DEMAND AND PRAYER FOR RELIEF

152. Plaintiffs demand a trial by jury on all claims in this action.

WHEREFORE, Plaintiffs seek judgment against Defendants Abbott as follows:

1. For reasonable actual, general, and compensatory damages, in an amount to be determined at trial;
2. For punitive damages;
3. For disgorgement of corporate profits;
4. For reasonable special damages in an amount to be determined at trial;
5. For pre-judgment and post-judgment interest as provided by law;
6. For costs of suit incurred herein and accruing; and
7. For such other and further relief as the Court deems just and proper.

/ / /

DATED this 21st day of February, 2025

KNAPP & ROBERTS, P.C.

/s/ Craig Knapp

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UNITED STATES DISTRICT COURT DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **Marina Seiken, surviving mother of deceased minor K.S., individually and on behalf of all wrongful death statutory beneficiaries , ; Shen Seiken, individually , ;**	**Defendant**(s): **Abbott Laboratories , ; Abbott Laboratories, Inc. , ;**
County of Residence: Maricopa	County of Residence: Outside the State of Arizona
County Where Claim For Relief Arose: Maricopa	
Plaintiff's Atty(s):	Defendant's Atty(s):
Craig A. Knapp , Knapp & Roberts, P.C. 8777 N. Gainey Center Dr., Ste. 165 Scottsdale, Arizona 85258 480-991-7677	,

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IFP REQUESTED

REMOVAL FROM COUNTY, CASE #

II. Basis of Jurisdiction:	**4. Diversity (complete item III)**
III. Citizenship of Principal Parties **(Diversity Cases Only)**	
Plaintiff:-	**1 Citizen of This State**
Defendant:-	**5 Non AZ corp and Principal place of Business outside AZ**
IV. Origin :	**1. Original Proceeding**
V. Nature of Suit:	**365 Personal Injury - Product Liability**
VI.Cause of Action:	**28 U.S.C. Sec. 1332**
VII. Requested in Complaint	
Class Action:	**No**
Dollar Demand:	
Jury Demand:	**Yes**

VIII. This case **is not related** to another case.

Signature: Craig A. Knapp

Date: 02/21/2025

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014