UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DEANDREA CLARK, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF A. K., DECEASED,	)	Civil Action No.: 1:23-cv-3722
Plaintiffs,	)	**COMPLAINT and JURY TRIAL DEMAND**
v.	)	
ABBOTT LABORATORIES, INC.,	)	
Defendant		

COMPLAINT

This action arises out of the catastrophic and preventable death of a newborn baby who died due to a horrific and deadly disease caused and/or substantially contributed to by cow's-milk-based infant formula and/or fortifier. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC may lead to surgery and to death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow-based formula or fortifier products. The companies who manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, Baby A.K., who was premature at birth, was fed these cow-based products, she developed NEC and passed away on August 6, 2021.

Plaintiffs, DeAndrea Clark, Individually and as Administrator of the Estate of A. K., Deceased, bring this cause of action against Defendant for claims arising from the direct and

proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendant's cow-based products (hereinafter "Cow Formula," "Cow Fortifier," or collectively "Cow's Milk Products").

GENERAL ALLEGATIONS

Plaintiffs, DeAndrea Clark, Individually and as Administrator of the Estate of A. K., Deceased, (hereinafter "Plaintiffs"), by and through the undersigned counsel, brings this Complaint against Defendant, Abbott Laboratories, Inc. and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

JURISDICTION AND VENUE

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

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

3. This Court has personal jurisdiction over Defendant as Defendant Abbott is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant formula products and markets many of its products under the "Similac" brand name.

4. Abbott is the manufacturer of the infant formula products, Similac Special Care 20, Similac Special Care 24, and Similac Special Care 24 High Protein with Iron, in addition to others.

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

PLAINTIFFS

6. Baby A.K. was born prematurely at The Ohio State University Wexner Medical Center in Ohio on August 1, 2021.

7. Baby A.K. developed NEC after being fed Defendant's Cow's Milk Products and died on August 6, 2021.

8. Plaintiff, Plaintiffs, DeAndrea Clark, the mother of Baby A.K., then domiciled in and a citizen of Ohio, brings this action as Parent and as Administrator of the Estate of A. K., for the serious bodily injuries and the wrongful death suffered by Baby A.K.

DEFENDANT

9. Defendant, Abbott Laboratories, Inc. ("Abbott") 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 and is thus a resident, citizen and domiciliary of Delaware and Illinois. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including New Jersey, premature infant formula including Similac Human Milk Fortifier and Similac Special Care.

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

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

11. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Baby A.K. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

12. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams) like Baby A.K., is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant here in the United States.

13. Before the 1970s, babies born preterm with very low or extremely low birth weights did not tend to survive and thus, human breast milk did not evolve to meet the nutritional needs of preterm babies. In utero, babies receive the majority of their nutritional needs from the placenta and swallowing amniotic fluids, but these conditions are not possible to mimic outside of the womb in neonatal care settings. Caring for preterm, low-weight babies is challenging because they typically have metabolic immaturity, poor gut function, cannot coordinate sucking with breathing so it is not safe to feed them by mouth, and they have special nutrient needs. Whereas a full-term infant takes about four to five months to double its birth weight, a preterm baby with very low birth weight typically doubles its weight in seven weeks, and that excess growth rate needs to be fueled nutritionally.

14. 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. Up until the 1960s, preterm

babies were most often fed on human milk from either the baby's mother or a donor, but it did not meet the unique nutritional needs of preterm babies. Thereafter, cow's milk-based formula products became more popular, but still did not meet the nutritional needs. In the early 1980s, cow's milk-based products began to be specially designed for preterm babies. Following the concerns that emerged later in the decade with HIV and the AIDS epidemic, the practice of using human donor breast milk largely ceased, and instead, cow's milk was increasingly used in formulas and in new fortifiers that were created as an additive to mother's breast milk. When the supply of a mother's breast milk was insufficient, a preterm formula based on cow's milk was used instead.

15. This system allowed preterm babies to get their specialized nutritional needs, especially in terms of rapid brain growth, which is a key to their survival. However, 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, however, the manufacturers of the Cow's Milk Products continue to promote and sell the Cow's Milk Product versions.

16. 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. Babies born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast milk, but it was **20 times more common** in those fed formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990)

(emphasis added).

17. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and bovine 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 bovine milk-based products. S. Sullivan, *et al*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

18. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, **formula feeding is associated with higher rates** of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added). This same report stated that premature infants who are not breast-fed are **138% more likely** to develop NEC. *Id.*, Table 1, p.2.

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

exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendant.

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

21. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant morbidity and mortality**. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up**

to 30% of infants will die from this disease." *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

22. In yet another study published in 2014 it was reported that an exclusive human milk diet, devoid of Cow's Milk 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).

23. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an **exclusive human milk diet is associated with "significant benefits"** for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were **no feeding-related adverse outcomes**." Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

24. 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 bovine

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 bovine milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **bovine-based products significantly increase the risk of NEC and death**. The study also noted the **"exponential" health care costs** associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and nearly doubles to $313,000 per infant for surgically-treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

The Marketing

25. Notwithstanding strong and overwhelming medical evidence establishing the extreme dangers that Cow's Milk Products pose for preterm infants, Defendant has 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. The Defendant has 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.

26. The Defendant has 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, the Defendant is 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 the Defendant.

27. The Defendant is also able to hook a customer base for other products they manufacture as the customer base ages.

28. The Defendant's self-serving and nefarious tactics go back decades, as these companies 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. The Defendant 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 breast feeding at all, and which further reduces the supply of available breast milk and ensures that more of their formula will be purchased.

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

30. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly (WHA--the decision-making body of the world's Member States) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or

promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "**There should be no advertising or other form of promotion to the general public** [of breast milk substitutes]." (emphasis added). In Article 5.2, the Code states that "manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales,…" *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

31. While the Defendant has 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, the Defendant 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 World Health Organization'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 **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*.

32. In addition to perpetuating the myth that these Cow's Milk Products are similar to breast milk, Defendant has also intentionally deceived the public into believing that health care providers believe these products are superior to breast milk or even ideal, and that physicians and institutions endorse the Cow's Milk Products.

33. A study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. 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 a company 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 cycle.

34. Manufacturers have also repeatedly used their relationships with hospitals and the discharge process to encourage mothers to substitute Cow's Milk Products for human breastmilk even after they leave the hospital. K.D. Rosenberg, C.A. Eastham, *et al, Marketing Infant Formula Through Hospitals: The Impact of Commercial Hospital Discharge Packs on Breastfeeding*, AM J PUBLIC HEALTH, 98(2):290-295 (2008).

35. Indeed, most hospitals in the U.S. distribute "commercial discharge bags packaged as smart diaper bags containing various coupons, advertisements, baby products, and infant formula samples." Yeon Bai, *et al*, *Alternative Hospital Gift Bags and Breastfeeding Exclusivity*, ISRN NUTR., article ID 560810: 2 (2013). Providing commercial gift bags to breastfeeding mothers sends confusing signals and has been shown to negatively impact breastfeeding rates. *Id.* at 5. However, the practice continues since it is a very effective way to exploit potential formula customers.

36. With the proliferation of the internet, the Defendant has updated their tactics to advertise heavily on the internet and through their websites. For example, Defendant Abbott uses its website to boast that their line of Similac products provide "complete nutrition for immune support and brain and eye development."

37. Defendant Abbott also offers new mothers "Similac StrongMoms Rewards" on their website, advertising up to "$400 in great offers" and even though the fine print says that "offers may vary," they advertise providing "formula samples, information about your baby's milestones, and a free Shutterfly photobook," and note "It's fast and FREE" to join.

38. One study estimates that formula manufacturers spent $4.48 billion on marketing and promotion in 2014 alone. P. Baker, *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).

39. The contradictory messages mothers receive from images, articles, and advertising in doctors' offices, hospitals, popular magazines, websites, and now social media campaigns are often most successful when employing medical authorities to suggest that breastfeeding is unnecessary and difficult, if not impossible, to achieve. *See, generally*, B.L. Hausman, *Rational Management: Medical Authority and Ideological Conflict in Ruth Lawrence's Breastfeeding: A Guide for the Medical Profession,* TECH. COMM. QUARTERLY, 9(3), 271-289 (2000).

40. Another study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. A. Merewood, *et al, Exposure to Infant Feeding Information in the Media During Pregnancy is Associated with Feeding Decisions Postpartum*, Am. Public Health Ass'n 138th Ann. Meeting (2010).

41. 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 breastfeeding rates decreased after the frequency of infant formula advertisements increased. J. Stang, *et al*, *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, INFANT CHILD ADOLESC NUTR., 2(1):16-25 (2010). In addition, the authors found that infant formula company websites, along with their printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into believing that they are purchasing a product equivalent or superior to human milk, which further induces reliance on information from a biased source. *Id.*

42. The Defendant has become adept at developing psychological advertising campaigns which attempt to create a perception of "mommy wars." One advertisement from Defendant Abbott, which received significant attention and won advertising awards to combat the threat to formula sales by rising breastfeeding rates, was called "The Mother Hood." (https://www.youtube.com/watch?list=RDJUbGHeZCxe4&v=JUbGHeZCxe4&feature=emb%20rel%20end.) In this ad, Abbott depicts a gang war between mostly mothers and a few fathers arguing about the best way to take care of their babies. The ad is effective in so much as it is manipulative. The advertisement, at one point depicts three "bottle feeding moms," and one of them proclaims: "Oh look, the breast police have arrived." The ad then depicts the "breastfeeding moms" with arrogant and superior appearing faces, and even disdainful mannerisms, with one of the moms proclaiming in a condescending voice, "100% breast fed - straight from the source," and a second mom grasping her breast in a profane manner. The negative portrayal of breastfeeding moms is subtle, but powerful, and casts the breastfeeding moms as judgmental and nasty, while portraying the bottle-feeding moms as nurturing victims. At the end, they all come together to rescue a baby in an errant stroller rolling down a hill, and the ad says, "Welcome to the sisterhood of

motherhood" before closing with their product name and new hashtag, and reinforcing the idea that formula is good. *See also* G. Hastings, *et al*, *Selling Second Best: How Infant Formula Marketing Works*, GLOBALIZATION AND HEALTH (2020) 16:77.

43. Another advertisement titled "The Judgment Stops Here," is a documentary-styled ad, which purports to encourage mothers to come together and put aside judgment of one another's choices. However, the ad is manipulative, deceptive, and violative of the Code in that it puts breast milk and formula on an even playing field and attempts to chastise any judgment that might be cast in favor or what is clear scientific judgment. In other words, the ad attempts to insulate the formula maker from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint, under the guise of reducing judgment for moms who primarily use infant formula.

44. In an Abbott advertisement for another Similac product, the ad says "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac. It's ***modeled after*** breast milk." Abbott uses a scene of a mother bottle-feeding her baby with a window that opens to a field and in small, light-colored lettering, writes, "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows. Ingredients not genetically engineered." Abbott claims mothers should trust its "thoughtfully crafted" product which comes after "90 years of crafting" infant formula. (https://www.youtube.com/watch?v=kRaHiTMyYXs).

45. Moreover, Abbott has also attempted to market its products specifically to preterm infants, who are in fact at highest risk from the dangers of the product. In 1978, Abbott began marketing "Similac 24 LBW," specifically for premature infants, claiming that the product was introduced to meet the special needs of premature infants. In 1980, Abbott began marketing "Similac Special Care" claiming it was the first low birth weight, premature infant formula with a

composition designed to meet fetal accretion rates." In 1988, 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. Abbott markets and sells multiple 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.

46. Defendant also pays for ads on Google and other search engines specifically targeted to searches involving preterm infants and designed to net them more profit share of this lucrative market.

47. Recognizing a shift in the medical community towards an exclusive human-based diet for preterm infants, the Defendant began heavily promoting "human milk fortifiers," which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk Products.

48. The Defendant has separately designed competing, systematic, powerful, and misleading marketing campaigns to deceive mothers to believe that: (1) Cow's Milk formula and fortifiers are safe; (2) Cow's Milk Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk Products a first choice. Similarly, the Defendant 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 Products and failing to warn of the deadly disease of NEC and risk of death.

49. The Defendant has 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, the Defendant also attempts to manipulate hospitals and medical professionals by donating large amounts of money to coffers disgusted as charity for supposed research and advances in science, and Defendant has 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.

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

The Inadequate Warnings

51. Defendant promotes the use of their preterm infant Cow's Milk Products to parents, physicians, hospitals and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

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

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

preterm infants.

54. For example, the warning on Neosure, an Abbott Cow's Milk Product specifically marketed for use with preterm infants states:

> Safety Precautions
> • Never use a microwave oven to warm formula. Serious burns can result.
> • Powdered infant formulas are not sterile and should not be fed to premature infants or
> infants who might have immune problems unless directed and supervised by your baby's doctor.
> *Increased protein, vitamins, and minerals compared to term infant formula.*

55. Likewise, Similac preterm Cow's Milk Products contains similar labeling.

56. Thus, Defendant does not warn the users, the parents, or the medical providers and staff that these Cow's Milk Products can cause NEC and serious injury or death, nor do they provide any guidance on how to avoid or reduce the risks of NEC and serious injury while using their products. Unfortunately, this means that vulnerable consumers continue to use and buy these products, resulting in greater health care costs and in more preventable injuries and deaths.

Baby A.K. and the Dangerous, Defective Products

57. Baby A.K. was born prematurely at The Ohio State Wexner Medical Center on August 1, 2021. Baby A.K. was preterm at 33 weeks and 1 day, with a low birth weight of 1940 grams and a length of 43.5 cm.

58. Baby A.K. was fed Similac Special Care 24, and Similac Neosure.

59. On August 5, 2021, Baby A.K. was suspected to suffer from necrotizing enterocolitis, which required an exploratory laparotomy.

60. Ultimately, a diagnosis of necrotizing enterocolitis was confirmed.

61. Unfortunately, Baby A.K.'s condition continued to deteriorate and she was pronounced dead on August 6, 2021.

COUNT I: STRICT LIABLITY

61. Plaintiffs incorporate by reference each of the proceeding paragraphs as though fully set forth herein.

62. At all times material to this action, Defendant was engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk Products, which are defectively designed and/or unreasonably dangerous to consumers, including Baby A.K.

63. Defendant, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

64. At all times material to this action, the Cow's Milk Products manufactured, distributed and/or sold by Defendant, was in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

65. Defendant specifically marketed and created their Cow's Milk Products for use as nutrition and nutritional supplements for preterm infants, like Baby A.K.

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

67. Prior to September 2018, Defendant were 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.

68. Defendant knew or should have known that the use of their Cow's Milk Products with preterm infants were unreasonably dangerous in that their Cow's Milk Products significantly

increased the risk of NEC, serious injury, and death.

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

70. Despite the foregoing, the Defendant continued to sell and market their defective and/or unreasonably dangerous products to extremely preterm infants.

71. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

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

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Baby A.K., to risks of serious bodily injury and death;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of the products when used in an intended or reasonably foreseeable manner;

d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the products;

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

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

72. As a direct and proximate result of the Cow's Milk Products' unreasonable dangerous condition, Baby A.K. suffered serious bodily injury, which resulted in permanent continuing injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demands judgment against Defendant, for all applicable wrongful death damages, survival damages, costs of this action, post-judgment interest, and trial by jury, and for all other further relief this Court deems appropriate.

COUNT II: NEGLIGENCE

73. Plaintiffs incorporate by reference each of the proceeding paragraphs as though fully set forth herein.

74. Defendant, as the manufacturers and/or sellers of Cow's Milk Product, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and/or to distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

75. Defendant, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

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

77. Defendant breached the duty owed to Plaintiffs and acted negligently in their actions, including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in foreseeable and intended manner;
b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;
c. Failing to collect data to determine if its products were safe for preterm infants;
d. Failing to collect data to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions;
f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
h. Failing to stop or deter its products from being fed to extremely preterm infants like Baby A.K.;
i. Failing to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;
j. Failing to continuously and vigorously study its Cow's Milk Products in order to avoid NEC and death in preterm infants;
k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
l. Failing to adopt an adequate or sufficient quality control program; and/or
m. Failing to inspect or test their products with sufficient care.

78. Defendant knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Baby A.K.

79. Defendant 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.

80. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely preterm infants like Baby A.K.

81. As a direct and proximate result of the negligence of Defendant, Baby A.K. suffered serious bodily injury, which resulted in permanent, continuous injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant, for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury, and for all other further relief this Court deems appropriate.

COUNT III: FAILURE TO WARN

82. Plaintiffs incorporate by reference each of the proceeding paragraphs as though fully set forth herein.

83. Defendant, as the manufacturers and/or sellers of Cow's Milk Products, owed a duty to the consuming public in general, and Plaintiffs in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk Products with preterm infants, specifically including but not limited to the risk of NEC and death.

84. Defendant, as the manufacturers and/or sellers of Cow's Milk Product, were unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's Milk Products, as the magnitude of the risk involved is using Defendant's Cow's Milk Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

85. Defendant, as the manufacturers and/or sellers of Cow's Milk Product, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers in its Cow's Milk Products.

86. Defendant owed a duty to provide warnings and instructions on their Cow's Milk Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk Products with preterm infants, specifically including but not limited to the risk

of NEC and death.

87. Rather than provide adequate warnings, Defendant developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's Milk Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

88. In addition and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk Products with preterm infants, they would have not used such a dangerous product.

89. Defendant, as manufacturers, have a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

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

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

92. Defendant breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's Milk Products, including but not limited to the following acts:

a. Providing **no warnings** regarding the risk of NEC and death;
b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk Products and preterm infants, including but not limited to NEC;

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

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's Cow's Milk Products;

e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that it's Cow's Milk Products could cause their baby to develop NEC and die;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk Products significantly increasing the risk of NEC and death and fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk Products are known to significantly increase the risk of NEC and death when compared to Human Milk in preterm infants;

h. Failed to provide well researched and well-established studies that linked its Cow's Milk Products to NEC and death in preterm infants;

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

j. Failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk Products;

k. Failed to send out "Dear Dr." letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

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

m. Failed to contain sufficient instructions and warnings on the Cow's Milk Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk Products and preterm infants.

93. As a direct and proximate result of Defendant's failure to warn, Baby A.K. suffered serious bodily injury, in his which resulted in permanent, continuing injury.

WHEREFORE, Plaintiffs, by and through undersigned counsel, demand judgment against Defendant, for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury, and for all other further relief this Court deems appropriate.

COUNT IV: PARENTAL CLAIM FOR LOSS OF FILIAL CONSORTIUM, LOSS OF SERVICES, AND LOSS OF MEDICAL EXPENSES

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

95. At all relevant times, DeAndrea Clark was the Parent and Legal Guardian of Baby A.K., a minor.

96. As a proximate result of one or more of the aforesaid negligent acts and/or omissions of the above named Defendant, DeAndrea Clark, Individually and as Administrator of the Estate of A. K., Deceased, have incurred certain necessary medical expenses and costs for medical care and treatment rendered to Baby A.K., a minor, as a result of her injuries.

97. As a result of Defendant's tortious conduct, Plaintiff, DeAndrea Clark, suffered a loss of affection, companionship, society, and consortium of her child.

98. Plaintiff, DeAndrea Clark, brings this loss of filial consortium as a derivative claim of each of the claims and allegations above.

WHEREFORE, DeAndrea Clark, Individually and as Administrator of the Estate of A. K., Deceased, seeks recovery for all applicable wrongful death damages, survival damages, filial damages, costs of this action, post-judgment interest and trial by jury and any other damages permitted by law against the Defendant, and for all other further relief this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs hereby request a trial by jury on all issues triable by jury.

Date: June 13, 2023

Respectfully submitted,

/s/ Marjorie Levine

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