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12	UNITED STATES DISTRICT COURT	
13	CENTRAL DISTRICT OF CALIFORNIA	
	EASTERN DIVISION	
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	MARY KELTON, as Parent,	Case No: 5:21-cv-2145
15 16 17		
15 16	MARY KELTON, as Parent, Guardian Ad Litem, and as Next	Case No: 5:21-cv-2145
15 16 17	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a	Case No: 5:21-cv-2145
15 16 17 18	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor,	Case No: 5:21-cv-2145
15 16 17 18	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v.	Case No: 5:21-cv-2145
15 16 17 18 19 20	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v. ABBOTT LABORATORIES, INC.,	Case No: 5:21-cv-2145
15 16 17 18 19 20 21 22	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v.	Case No: 5:21-cv-2145
15 16 17 18 19 20 21 22 22 23	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v. ABBOTT LABORATORIES, INC.,	Case No: 5:21-cv-2145
15 16 17 18 19 20 21	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v. ABBOTT LABORATORIES, INC.,	Case No: 5:21-cv-2145
15 16 17 18 19 20 21 22 23 24	MARY KELTON, as Parent, Guardian Ad Litem, and as Next Friend of SOPHIE BOWDEN, a minor, Plaintiff, v. ABBOTT LABORATORIES, INC.,	Case No: 5:21-cv-2145



PARTIES, JURISDICTION, AND VENUE

- 1. Plaintiff, Mary Kelton, the mother of baby Sophie Bowden (hereinafter "Baby Sophie"), brings this cause of action against Abbott Laboratories, Inc. ("Abbott" or "Defendant") to recover for Baby Sophie's injuries, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous cow's milk based products.
- 2. On October 17, 2019, Sophie Bowden was born prematurely at Riverside Community Hospital in Riverside, California.
- 3. The Defendant, Abbott Laboratories, Inc. manufactures, designs, formulates prepares, tests, provides instructions, markets, labels, packages, places into the stream of commerce in all fifty states, including California, and sells premature infant formula including Similac Special Care.
- 4. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a) because complete diversity exists between Plaintiff and Defendant, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000.
- 5. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct and do conduct business in the State of California and Defendant has sufficient minimum contacts with this State and/or sufficiently avails itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.
- 6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district.

GENERAL ALLEGATION

7. On October 17, 2019, Baby Sophie was born prematurely with a low birth weight of 2 pounds and 12 ounces.



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- 8. Following the birth, Baby Sophie was placed in the Neonatal Intensive Care Unit (NICU) at Riverside Community Hospital.
- Baby Sophie was intravenously fed Similac Special Care, while in the 9. NICU.
- 10. After being fed Similac Special Care, on October 24, 2019, Baby Sophie was diagnosed with Necrotizing Enterocolitis ("NEC") while in the NICU. She developed the following symptoms: vomiting, blood in her stool, difficulty breathing, and an elevated white blood cell count.
- At the time Baby Sophie was diagnosed with and treated for NEC, 11. Plaintiff was unaware of the fact that the Defendant's cow's milk based products fed to their baby caused or substantially contributed to the development of NEC and resulting injuries.

THE SCIENCE

- According to the World Health Organization ("WHO"), babies born 12. prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Sophie Bowden. The WHO estimates that approximately 15 million babies are born preterm every year and that number is rising.
- 13. Nutrition for preterm babies, like Sophie Bowden, 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.
- Originally, cow's milk-based products were believed to be good for the growth of premature, low birth weight babies; however, science and research have advanced for decades confirming the significant dangers of the Defendant's cow's milk-based products in causing Necrotizing Enterocolitis ("NEC") 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 babies,



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yet, the Defendant did nothing to change their product, packaging, guidelines, instructions, and/or warnings. Additionally, advances in science have created alternative formulas and fortifiers that are derived from human milk and non-bovine based products; however, the Defendant continues to promote and sell their defunct cow's milk-based products.

15. As early 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).

- 16. In a study published in 2007 it was reported: "The use of an exclusive HUM [Human] diet is associated with significant benefits for extremely premature infants <1259 g BW. The benefits include decreased NEC rates, mortality, late-onset sepsis, PDA, BPD, ventilator days, and ROP. Importantly, while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes. This study demonstrates that an exclusive HUM diet provides important benefits beyond NEC." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet.* (Breastfeeding Medicine. 2016, Nov 2., 11(2):70-75.)
- 17. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and human milk fortifier, these babies were 90% less likely to develop surgical NEC. Sullivan, S., et al., <u>An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products</u>. (Journal of Pediatrics 2010; 156:562-7.)



- 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 [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., 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-based products. The Academy stated that "[t]he potent benefits of human milk are such that all pre-term 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-e841 (2012).
- 20. A study published in 2013 showed that, out of 104 the premature infants participating in the study receiving an exclusive human-milk based diet, all 104 exceeded targeted growth standards, as well as length, 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 Feed 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 products, but the practice continued largely due to extensive and aggressive marketing campaigns conducted by infant formula companies.
- 21. In another study published in 2013 it was reported: "This is the first randomized trial in EP [Extremely Premature] infants of exclusive HM [Human Milk] vs. PF [Preterm Formula]. The significantly shorter duration of TPN and lower rate of surgical NEC support major changes in the strategy to nourish EP

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