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11
12 **UNITED STATES DISTRICT COURT**
13 **CENTRAL DISTRICT OF CALIFORNIA**
14 **EASTERN DIVISION**

15
16 MARY KELTON, as Parent,
Guardian Ad Litem, and as Next
17 Friend of SOPHIE BOWDEN, a
18 minor,

19 Plaintiff,

20 v.

21 ABBOTT LABORATORIES, INC.,
22 Defendants.
23

Case No: 5:21-cv-2145

COMPLAINT

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1 **PARTIES, JURISDICTION, AND VENUE**

2 1. Plaintiff, Mary Kelton, the mother of baby Sophie Bowden (hereinafter
3 “Baby Sophie”), brings this cause of action against Abbott Laboratories, Inc.
4 (“Abbott” or “Defendant”) to recover for Baby Sophie’s injuries, which are the
5 direct and proximate result of consumption of Defendants’ unreasonably dangerous
6 cow’s milk based products.

7 2. On October 17, 2019, Sophie Bowden was born prematurely at
8 Riverside Community Hospital in Riverside, California.

9 3. The Defendant, Abbott Laboratories, Inc. manufactures, designs,
10 formulates prepares, tests, provides instructions, markets, labels, packages, places
11 into the stream of commerce in all fifty states, including California, and sells
12 premature infant formula including Similac Special Care.

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

16 5. This Court has personal jurisdiction over Defendant because Defendant
17 is authorized to conduct and do conduct business in the State of California and
18 Defendant has sufficient minimum contacts with this State and/or sufficiently avails
19 itself of the markets in this State through its promotion, sales, distribution and
20 marketing within this State to render the exercise of jurisdiction by this Court
21 permissible.

22 6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b)
23 because a substantial part of the events or omissions giving rise to Plaintiff’s claims
24 occurred in this judicial district.

25 **GENERAL ALLEGATION**

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

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1 8. Following the birth, Baby Sophie was placed in the Neonatal Intensive
2 Care Unit (NICU) at Riverside Community Hospital.

3 9. Baby Sophie was intravenously fed Similac Special Care, while in the
4 NICU.

5 10. After being fed Similac Special Care, on October 24, 2019, Baby
6 Sophie was diagnosed with Necrotizing Enterocolitis (“NEC”) while in the NICU.
7 She developed the following symptoms: vomiting, blood in her stool, difficulty
8 breathing, and an elevated white blood cell count.

9 11. At the time Baby Sophie was diagnosed with and treated for NEC,
10 Plaintiff was unaware of the fact that the Defendant’s cow’s milk based products fed
11 to their baby caused or substantially contributed to the development of NEC and
12 resulting injuries.

13 **THE SCIENCE**

14 12. According to the World Health Organization (“WHO”), babies born
15 prematurely, or “preterm,” are defined as being born alive before 37 weeks of
16 pregnancy are completed, like Sophie Bowden. The WHO estimates that
17 approximately 15 million babies are born preterm every year and that number is
18 rising.

19 13. Nutrition for preterm babies, like Sophie Bowden, is significantly
20 important. Since the United States ranks in the top ten countries in the world with
21 the greatest number of preterm births, the market of infant formula and fortifiers is
22 particularly vibrant.

23 14. Originally, cow’s milk-based products were believed to be good for the
24 growth of premature, low birth weight babies; however, science and research have
25 advanced for decades confirming the significant dangers of the Defendant’s cow’s
26 milk-based products in causing Necrotizing Enterocolitis (“NEC”) and/or
27 substantially contributing to death in preterm and severely preterm, low-weight
28 infants, along with many other health complications and long-term risks to babies,

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

6 15. As early as 1990, a prospective, multicenter study on 926 preterm
7 infants found that NEC was six to ten times more common in exclusively formula-
8 fed babies than in those fed breast milk alone and three times more common than in
9 those who received formula plus breast milk. Babies born at more than 30 weeks
10 gestation confirmed that NEC was rare in those whose diet included breast milk, but
11 it was 20 times more common in those fed formula only. A. Lucas, T. Cole, *Breast*
12 *Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

13 16. In a study published in 2007 it was reported: "The use of an
14 exclusive HUM [Human] diet is associated with significant benefits for
15 extremely premature infants <1259 g BW. The benefits include decreased NEC
16 rates, mortality, late-onset sepsis, PDA, BPD, ventilator days, and ROP.
17 Importantly, while evaluating the benefits of using an exclusive HUM-based
18 protocol, it appears that there were no feeding-related adverse outcomes. This
19 study demonstrates that an exclusive HUM diet provides important benefits
20 beyond NEC." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention:*
21 *Improving Outcomes with an Exclusive Human Milk-Based Diet.* (Breastfeeding
22 *Medicine.* 2016, Nov 2., 11(2):70-75.)

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

1 18. In 2011, the U.S. Surgeon General published a report titled, “The
2 Surgeon General’s Call to Action to Support Breastfeeding.” In it, the Surgeon
3 General warned that “for vulnerable premature infants, formula feeding is associated
4 with higher rates of [NEC].” U.S. Dep’t. of Health & Human Serv., Off. of Surgeon
5 Gen., “The Surgeon General’s Call to Action to Support Breastfeeding,” p. 1, (2011).
6 This same report stated that premature infants who are not breast fed are 138% more
7 likely to develop NEC. Id., Table 1, p. 2.

8 19. In 2012, the American Academy of Pediatrics issued a policy statement
9 that all premature infants should be fed an exclusive human milk diet because of the
10 risk of NEC associated with the consumption of cow’s milk-based products. The
11 Academy stated that “[t]he potent benefits of human milk are such that all pre-term
12 infants should receive human milk ... If the mother’s own milk is
13 unavailable...pasteurized donor milk should be used.” Breastfeeding and the Use
14 of Human Milk, PEDIATRICS, 129:e827-e841 (2012).

15 20. A study published in 2013 showed that, out of 104 the premature infants
16 participating in the study receiving an exclusive human-milk based diet, all 104
17 exceeded targeted growth standards, as well as length, weight, and head
18 circumference gain. The authors concluded that “this study provides data showing
19 that infants can achieve and mostly exceed targeted growth standards when receiving
20 an exclusive human milk-based diet.” A. Hair, et al., *Human Milk Feed Supports*
21 *Adequate Growth in Infants \leq 1250 Grams Birthweight*, BMC RESEARCH NOTES,
22 6- 459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding
23 cow’s milk-based products, but the practice continued largely due to extensive and
24 aggressive marketing campaigns conducted by infant formula companies.

25 21. In another study published in 2013 it was reported: “This is the first
26 randomized trial in EP [Extremely Premature] infants of exclusive HM [Human
27 Milk] vs. PF [Preterm Formula]. The significantly shorter duration of TPN and
28 lower rate of surgical NEC support major changes in the strategy to nourish EP

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