UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ASHLEY LOLLAR and JIMMY LOLLAR, Individually and on behalf of the Estate of H.G.L., a Deceased Minor,	§	
Plaintiffs,	§	**CIVIL ACTION NO. _____**
v.	§	
MEAD JOHNSON & COMPANY, LLC, and MEAD JOHNSON NUTRITION COMPANY,	§	**JURY DEMAND**
Defendants.	§	

PLAINTIFFS' ORIGINAL COMPLAINT

1. Ashley Lollar and Jimmy Lollar, Individually and on behalf of the Estate of H.G.L., a Deceased Minor, Plaintiffs, bring the following claims against Defendants and respectfully state:

PARTIES

2. Plaintiffs, Ashley Lollar and Jimmy Lollar, Individually and on behalf of the Estate of H.G.L., a Deceased Minor, are residents of Tyler, Texas. Plaintiffs are the biological parents of H.G.L., and they reside in Tyler, Texas.

3. Defendants, Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company, (collectively, "Mead") are companies based in Illinois that manufacture, design, formulate, prepare, test, provide instructions, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Texas, premature infant formula including Enfamil and Enfamil Human Milk Fortifier.

4. Mead Johnson & Company, LLC was at all times material hereto and is now a limited liability company duly organized and existing under the laws of the State of Delaware with its principal place of business and headquarters in the State of Illinois. According to the Illinois Secretary of State, both Mead Johnson & Company, LLC and Mead Johnson Nutrition Company are registered to do business in Illinois. Service of process on this Defendant can be completed by serving its registered agent, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701-4234.

5. Mead Johnson Nutrition Company 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 global headquarters in the State of Illinois and global operations center in the State of Indiana, and is thus a resident, citizen, and domiciliary of Delaware, Illinois, and Indiana. Service of process on this Defendant can be completed by serving its registered agent, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701-4234.

6. Mead Johnson Nutrition Company self-proclaims to be recognized as "a world leader in pediatric nutrition" and traces its history back to the company's founding in 1905 by Edward Mead Johnson, Sr. It claims to be the "only global company focused primarily on infant and child nutrition" and that its "singular devotion has made our flagship 'Enfa' line the leading infant nutrition brand in the world." Boasting "more than 70 products in over 50 countries," it claims that its "products are trusted by millions of parents and healthcare professionals around the world." It is this trust that Defendants Mead have intentionally exploited for their own pecuniary gain at the expense of vulnerable families, like Baby H.G.L.'s, throughout the United States and the world.

JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) because this controversy is between citizens of different states and the amount in controversy exceeds $75,000. None of the members of Mean Johnson & Company, LLC are citizens of the State of Texas.

8. Venue is proper in this judicial district pursuant to 13 U.S.C. §1391, *et seq.* because all or a substantial part of the events giving rise to the subject claims occurred within this District.

9. This Court has personal jurisdiction over Defendants as Defendants are authorized to conduct business and do conduct business in the State of Texas. Defendants have marketed, promoted, distributed, and/or sold their Cow's Milk Products in the State of Texas, and Defendants 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.

10. 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 Plaintiffs' claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Defendants transact substantial business in this District.

FACTS

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 H.G.L. 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 H.G.L., 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).

20. 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 Defendants.

21. 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).

22. 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.*

23. 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).

24. 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).

25. 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

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

27. The Defendants 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, the 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 the Defendants.

28. The Defendants are also able to hook a customer base for other products they manufacture as the customer base ages. For example, 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.

29. The Defendants' 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 Defendants falsely advertise 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.

30. 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).

31. 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.

32. While the Defendants 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, the Defendants 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*.

33. In addition to perpetuating the myth that these Cow's Milk Products are similar to breast milk, Defendants have 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.

34. 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.

35. 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).

36. 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.

37. Defendants Mead call their reward program "Enfamil Family Beginnings" and also offer "up to $400 in free gifts, baby formula coupons, baby formula samples, special offers, and other savings."

38. Defendants Mead have employed tactics designed to reduce a mother's confidence in giving their babies their own breast milk and induce them into purchasing the Cow's Milk Products. They launched Enfamil "Human Milk Fortifier" in the U.S. specifically targeting babies born prematurely or with low birth weight. The term "human milk fortifier" in and of itself is misleading as it does not disclose that Cow's Milk Products are being used.

39. Defendants Mead falsely boast of their commitment to science on their website and claim that "Enfamil is backed by decades of breast milk research and multiple clinical studies" and they claim that "to create our best formulas, we collaborated on some of the most intensive breast milk studies to date." All the while, Defendants track the mothers' searches through cookies and other electronic surveillance to more strategically target the vulnerable consumer.

40. 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).

41. 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).

42. 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).

43. 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.*

44. Defendants Mead promote a range of products for "premature and low weight" babies on their website: Enfamil Human Milk Fortifier Liquid High Protein, Enfamil Milk Fortifier Liquid Standard Protein, Enfamil NeuroPro Enfacare, Enfamil Premature 20 Cal, Enfamil Premature 24 Cal, Enfamil Premature 24 Cal/fl oz HP, Enfamil Premature 30 Cal, Enfamil Human Milk Fortifier Acidified Liquid, Enfamil Human Milk Fortifier Powder, Enfamil 24, and DHA & ARA Supplement. However, Defendants Mead do not make it clear which products are made from Cow's Milk Products and they fail to alert customers to any dangers.

45. Defendants Mead employ tools and tactics on their website designed to mask the dangers posed by their products to babies and infants. Defendant Mead uses bright colors and drop-down menus, while asking questions like, "Is your baby getting DHA as experts recommend? Enfamil believes your baby deserves more of that DHA."

46. Defendants also pay 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 Defendants 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 Defendants have 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 Defendants 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 Defendants 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, the Defendants also attempt 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 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.

50. Thus, despite the existence of alternative and safe human milk-based fortifiers, these Defendants continue 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 H.G.L.

The Inadequate Warnings

51. Defendants promote 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, Defendants did not warn parents or medical providers of the risk of NEC, nor did Defendants 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, neither of the Defendants 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. Product information on Enfamil's human milk fortifiers does not warn of any of the risks associated with Cow's Milk Products.

55. Thus, Defendants do 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 H.G.L. and the Dangerous, Defective Products

56. Baby H.G.L. was born prematurely at East Texas Medical Center in Jacksonville, Texas on August 25, 2015. Baby H.G.L. was preterm at 27 weeks, with a low birth weight of approximately (3 lbs. 2 oz.).

57. Baby H.G.L. was fed donor breast milk until she was approximately 7 weeks old, when she began taking Enfamil formula.

58. On September 16, 2015, Baby H.G.L. began showing signs of illness. She had begun to swell, and her coloring had changed to gray. After consulting with Children's Hospital in Dallas, Texas, it was determined that Baby H.G.L. had necrotizing enterocolitis. Baby H.G.L. was immediately flown to Children's Hospital.

59. On September 17, 2015, Baby H.G.L. underwent an exploratory laparotomy. Although her condition initially improved after the surgery, her health soon declined rapidly. Baby H.G.L. died from necrotizing enterocolitis the night of September 17, 2015.

60. At the time of his diagnosis, Baby H.G.L.'s parents were unaware of the fact that Defendants' Cow's Milk-Based Products Baby H.G.L. was fed caused or substantially contributed to the development of NEC and ultimately to her death.

STRICT LIABILITY CAUSE OF ACTION – DESIGN DEFECT

61. Plaintiffs adopt and re-allege each paragraph set forth above.

62. At all times material to this action, Defendants Mead were 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 H.G.L.

63. Defendants Mead, 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 Defendants Mead, were 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. Defendants Mead specifically marketed and created their Cow's Milk Products for use as nutrition and nutritional supplements for preterm infants, like Baby H.G.L.

66. Defendants Mead'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 August 2015, Defendants Mead 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. Defendants Mead 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 Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits for premature infants like Baby H.G.L.

70. Despite the foregoing, the Defendants 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 H.G.L., 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. Defendants 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. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants 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 H.G.L. suffered serious bodily injury, which resulted in death.

NEGLIGENCE CAUSES OF ACTION

73. Plaintiffs adopt and re-alleges each paragraph set forth above as if fully set forth herein.

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

77. Defendants Mead 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 H.G.L.;

i. Failing to provide evidence-based instructions or guidance 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. Defendants Mead knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Baby H.G.L.

79. Defendants Mead 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 Defendants Mead carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely preterm infants like Baby H.G.L.

81. As a direct and proximate result of the negligence of Defendants Mead, Baby H.G.L. suffered serious bodily injury, which resulted in death.

FAILURE TO WARN

82. Plaintiffs adopt and re-alleges each paragraph set forth above as if fully set forth herein.

83. Defendants Mead, 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. Defendants Mead, 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 Defendants' Cow's Milk Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

85. Defendants Mead, 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. Defendants Mead 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, Defendants Mead 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. Defendants Mead, 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. Defendants Mead, 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. Defendants Mead, 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. Defendants Mead 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 Defendants' Cow's Milk Products;

e. Failed to provide instructions to consumers and health care providers that the Defendants' 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 are 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 Defendants Meads' failure to warn, Baby H.G.L. suffered serious bodily injury, which resulted in death.

WRONGFUL DEATH DAMAGE CLAIMS

94. Plaintiffs adopt each paragraph set forth above as if fully set forth herein.

95. Plaintiffs, Ashley Lollar and Jimmy Lollar, are Texas statutory wrongful death beneficiaries of H.G.L., deceased. Defendants are corporations.

96. Defendants' wrongful acts and/or omissions, including the defectively designed, marketed and manufactured product, caused the death of H.G.L.

97. H.G.L., deceased, would have been entitled to bring an action for injury had she lived.

98. Plaintiffs have each suffered an actual injury.

99. Plaintiffs have suffered pecuniary loss in the past and will suffer pecuniary loss in the future. Plaintiffs have suffered loss of love, companionship, society, and affection in the past and will suffer this loss in the future.

100. Plaintiffs have suffered mental anguish and loss of companionship and society in the past and will suffer such damages in the future.

101. Plaintiffs adopt and claim entitlement to exemplary damages as set forth previously herein.

102. Defendants' wrongful conduct complained of herein was a proximate and/or producing cause of Plaintiffs' damages.

SURVIVAL DAMAGE CLAIM – H.G.L.

103. Plaintiffs adopt each paragraph above as if fully set forth herein.

104. Plaintiffs Ashley Lollar and Jimmy Lollar are heirs of the Estate of H.G.L., and no administration of the Estate has taken place, and none is necessary. As such, Ashley Lollar and Jimmy Lollar are the legal representatives of the Estate of H.G.L.

105. H.G.L., deceased, had a legal cause of action for personal injury before she died.

106. H.G.L., deceased, would have been entitled to bring an action for injury if she had lived.

107. Defendants' wrongful conduct and defectively designed, marketed and manufactured product(s) alleged herein caused H.G.L.'s injuries.

108. Prior to her death, H.G.L. suffered conscious pain, suffering, and mental anguish.

109. H.G.L. incurred medical expenses associated with her injury and funeral and burial expenses associated with her death.

110. H.G.L.'s Estate adopts and claims entitlement to exemplary damages as set forth previously herein.

111. Defendants' wrongful acts and/or omissions, including the defectively designed, marketed and manufactured product(s), complained of herein, were a proximate and/or producing cause of H.G.L.'s injuries.

DAMAGES

112. The elements of damages which Plaintiffs seek to recover from the Defendants include compensation for the following:

a. Plaintiffs, Ashley Lollar and Jimmy Lollar, are Texas statutory wrongful death beneficiaries of H.G.L., deceased. Plaintiffs seek all wrongful death damages recoverable under Tex. Civ. Prac. & Rem. Code §§ 71.001-71.051, including, but not limited to, pecuniary loss in the past and pecuniary loss in the future, the loss of love, companionship, society, and affection in the past and in the future, and mental anguish in the past and future;

b. Survival damages on behalf of the Estate of H.G.L.;

c. Mental anguish and suffering sustained by Plaintiffs from date of injury to time of trial;

d. Mental anguish and suffering which is reasonably anticipated to be suffered by Plaintiffs in the future;

e. Reasonable and necessary medical expenses incurred by Plaintiffs from the date of injury to time of trial;

f. Reasonable and necessary medical expenses reasonably anticipated to be sustained by Plaintiffs in the future;

g. Exemplary damages;

h. Funeral and burial costs; and

i. The maximum allowable pre-judgment and post-judgment interest on any damages they may be awarded and pray to recover all court costs associated with this action.

JURY DEMAND AND PRAYER

113. Plaintiffs request that a jury be convened to try the factual issues of this case.

114. Plaintiffs pray that judgment be entered in her favor against Defendants, jointly and severally, for all damages, as requested herein, the costs of bringing this action, for prejudgment and post-judgment interest at the maximum legal rate, and for such other relief, at law or in equity, to which they may be justly entitled.

Respectfully submitted,

/s/ Jeffrey T. Embry
Jeffrey T. Embry
State Bar No. 24002052
Attorney-In-Charge
Matthew L. Montgomery
State Bar No. 24041509
Margaret C. Pennell
State Bar No. 24116893
Hossley & Embry, LLP
515 S. Vine Ave.
Tyler, Texas 75702
Ph. 903-526-1772
Fax. 903-526-1773
jeff@hossleyembry.com
matt@hossleyembry.com
meg@hossleyembry.com

ATTORNEYS FOR PLAINTIFFS