IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
EVANSVILLE DIVISION

SANDRA HAYES, as Guardian of ADAM HAYES,

Plaintiff,

Case No. _____

v.

(TRIAL BY JURY DEMANDED)

MEAD JOHNSON & COMPANY, LLC, and MEAD JOHNSON NUTRITION COMPANY,

Defendants.

CIVIL COMPLAINT

COMES NOW Plaintiff Sandra Hayes, as Guardian of Adam Hayes, by counsel, pursuant to the Federal Rules of Civil Procedure, and states as follows for her Civil Complaint against Defendants Mead Johnson & Co,, LLC and Mead Johnson Nutrition Company:

I. PARTIES

1. At all times material hereto, Plaintiff Sandra Hayes was a resident of Kanawha County, West Virginia.

2. On or about May 17, 2021, Sandra Hayes was appointed Guardian of Adam Hayes by the Circuit Court of Kanawha County, West Virginia.

3. Adam Hayes was born April 17, 2003, at 24 weeks gestational age weighing 610 grams.

4. Shortly after his birth, and after having been administered Enfamil Premature 24, a cow's milk-based formula manufactured by the Defendants ("Cow's Milk Product" or "Cow's

Milk Formula"), Adam developed and was diagnosed with necrotizing enterocolitis ("NEC") in Philadelphia, Pennsylvania.

5. Defendants, Mead Johnson & Co., LLC, and Mead Johnson Nutrition Company (collectively "Mead" or "Mead Defendants") are companies based in Evansville, Indiana that manufacture, design, formulate, prepare, test, provide instructions, market, label, package, sell, and/or place into the stream of commerce in all fifty states premature infant formula, including Enfamil Premature 24.

6. 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 Indiana, and is thus a resident, citizen, and domiciliary of Delaware and Indiana.

7. 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 Indiana.

8. Upon information and belief, at all times material hereto, the individual members of Mead Johnson & Co., LLC were as follows with their citizenship listed in parentheses: Howard B. Bernick (Illinois); James M. Cornelius (Indiana); Elliot Sigal (Illinois); Michael Grobstein (Indiana); Peter Gervis Ratcliffe (Illinois); Celeste A. Clark (Ohio); Kimberly A. Casiano (Michigan); Robert S. Singer (Ohio); Anna C. Catalano (Delaware); Charles M. Urbain (Illinois); Stephen W. Golsby (Illinois); Peter Kasper Jakobsen (Illinois); Dirk Hondmann (Illinois); James J. Jobe (Illinois); Steven Altschuler (Illinois); Michael A. Sherman (Indiana); Patrick M. Sheller (New York); James E. Shiah (New York); Ian Eric Ormesher (Illinois); Michel Martinus Gerardus Cup (Illinois); Christopher Richard Stratton (Illinois); Graciela Monteagudo (Illinois); Tom

DeWeerdt (Illinois); Kathy Ann MacDonald (Illinois); Peter G. Leemputte (Illinois); Sandra Leung (New York); Lamberto Andreotti (New York); John E. Celentano (New Jersey); Jean-Marc Huet (New Jersey); William P'Pool (Illinois); Stanley D. Burhans (Illinois); Christiaan Augustijns (Illinois); Lynn H. Clark (Illinois).

9. Additionally, upon information and belief, E.R. Squibb & Sons is a ten-percent owner and/or member of Mead Johnson & Co. and is duly organized and existing under the State of Delaware with its principal place of business and headquarters in the State of New Jersey.

10. Upon information and belief, Bristol Myers Squibb Co. is a ten-percent owner and/or member of Mead Johnson & Co. and is duly organized and existing under the State of Delaware with its principal place of business and headquarters in the State of New York.

11. 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 premature babies like Adam Hayes throughout the United States and the world.

II. JURISDICTION AND VENUE

12. Venue in this Court is appropriate under 28 U.S.C. § 1391.

13. The Court has jurisdiction over the subject matter under 28 U.S.C. § 1332 because the amount in controversy is in excess of $75,000.00, exclusive of costs, interest, and attorneys' fees, and there is complete diversity of citizenship among the parties.

14. This Court has personal jurisdiction over the Mead Defendants.

III. FACTUAL ALLEGATIONS

A. The Science and Scope of the Problem

15. 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. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

16. Nutrition for preterm babies, especially those who have a very low birthweight (under 1500 grams) or extremely low birth weight (under 1000 grams) like Adam, 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 is particularly vibrant here in the United States.

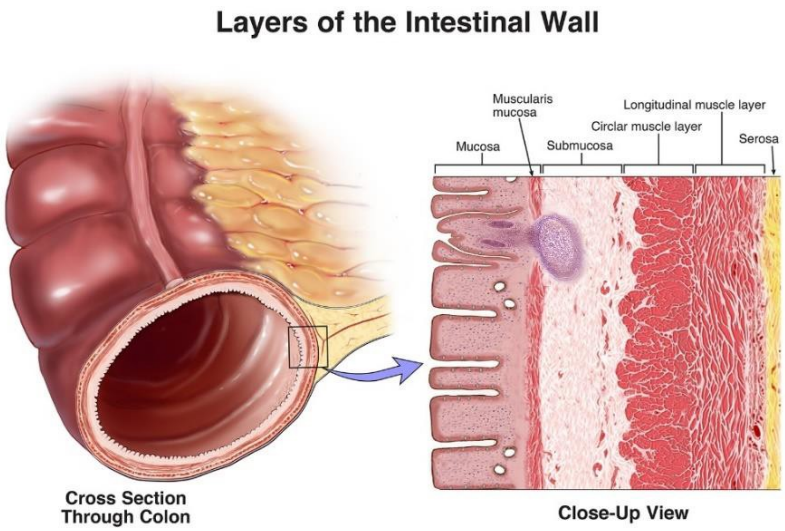
17. In utero, babies receive the majority of their nutritional needs from the placenta and swallowing amniotic fluids, but these conditions are not possible to mimic outside of the womb in neonatal care settings. Caring for preterm, low-weight babies is challenging because they typically have metabolic 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.

18. Historically, there are three types of nutrition for preterm babies: parenteral nutrition for feed intolerance such as a feeding tube, human milk whether it is the mother's own milk or donor milk, and cow's milk-based formulas and fortifiers. 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.

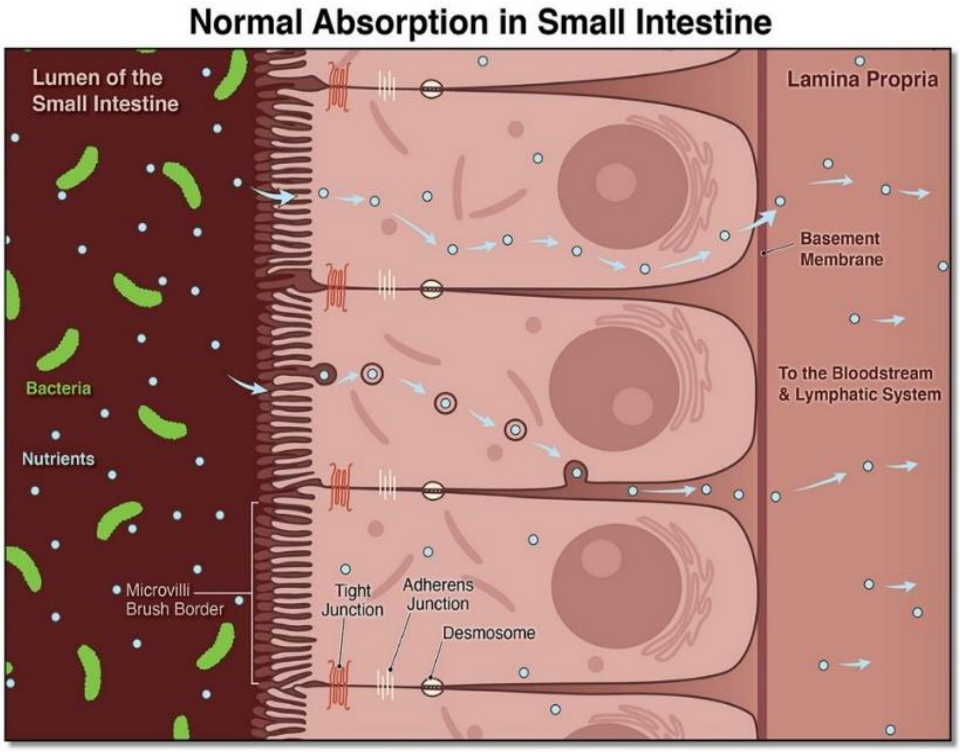
19. In the early 1980s, cow's milk-based products began to be specially designed for preterm babies. Following the concerns that emerged later in the decade with HIV and the AIDS epidemic, the practice of using human donor breast milk largely ceased, and instead, cow's milk was increasingly used in formulas.

20. When the supply of a mother's breast milk was insufficient, a preterm formula based on cow's milk was used instead. 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 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 formulas and 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.

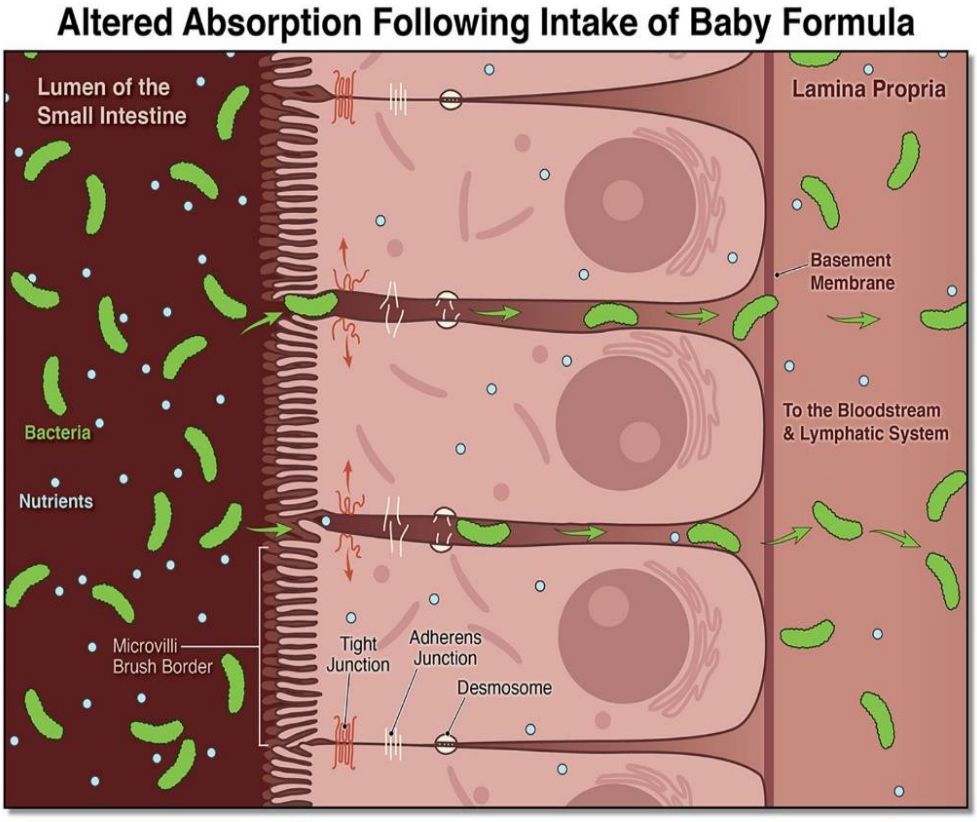
21. To illustrate the danger posed to preterm infants, this is a diagram of the normal lawyers of the baby's intestinal wall:



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

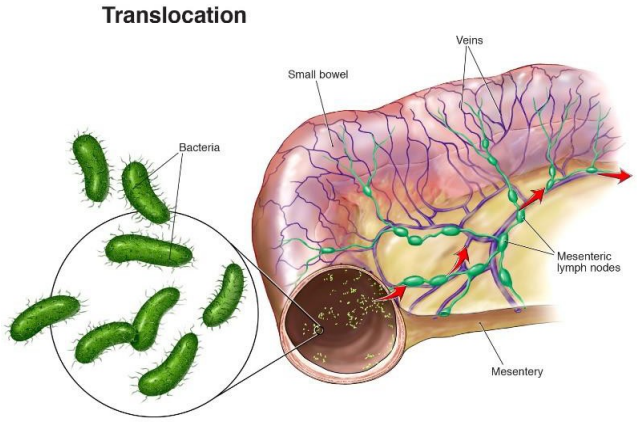


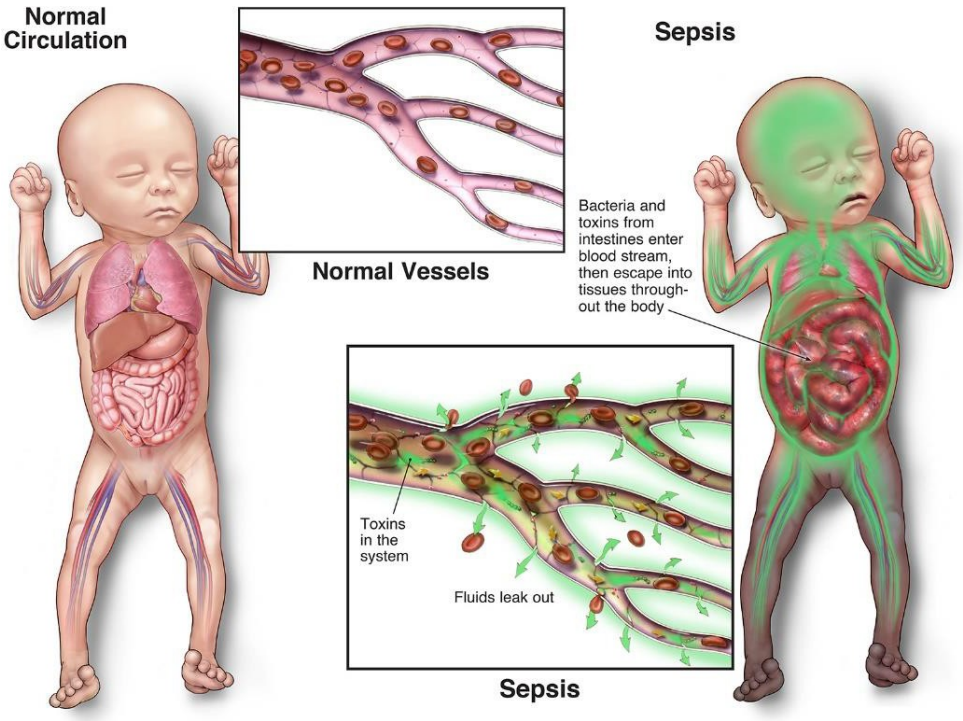
23. The diagram below shows how the absorption is significantly altered following the intake of Cow's Milk Products:



24. Specifically, this figure demonstrates what the breakdown of the tight junctions looks like after a preterm baby ingests the Cow's Milk Formula. As a result, the harmful bacteria and toxins are able to enter the baby's bloodstream and lymphatics,which induces an inflammatory response (not pictured) in the baby's intestinal walls.

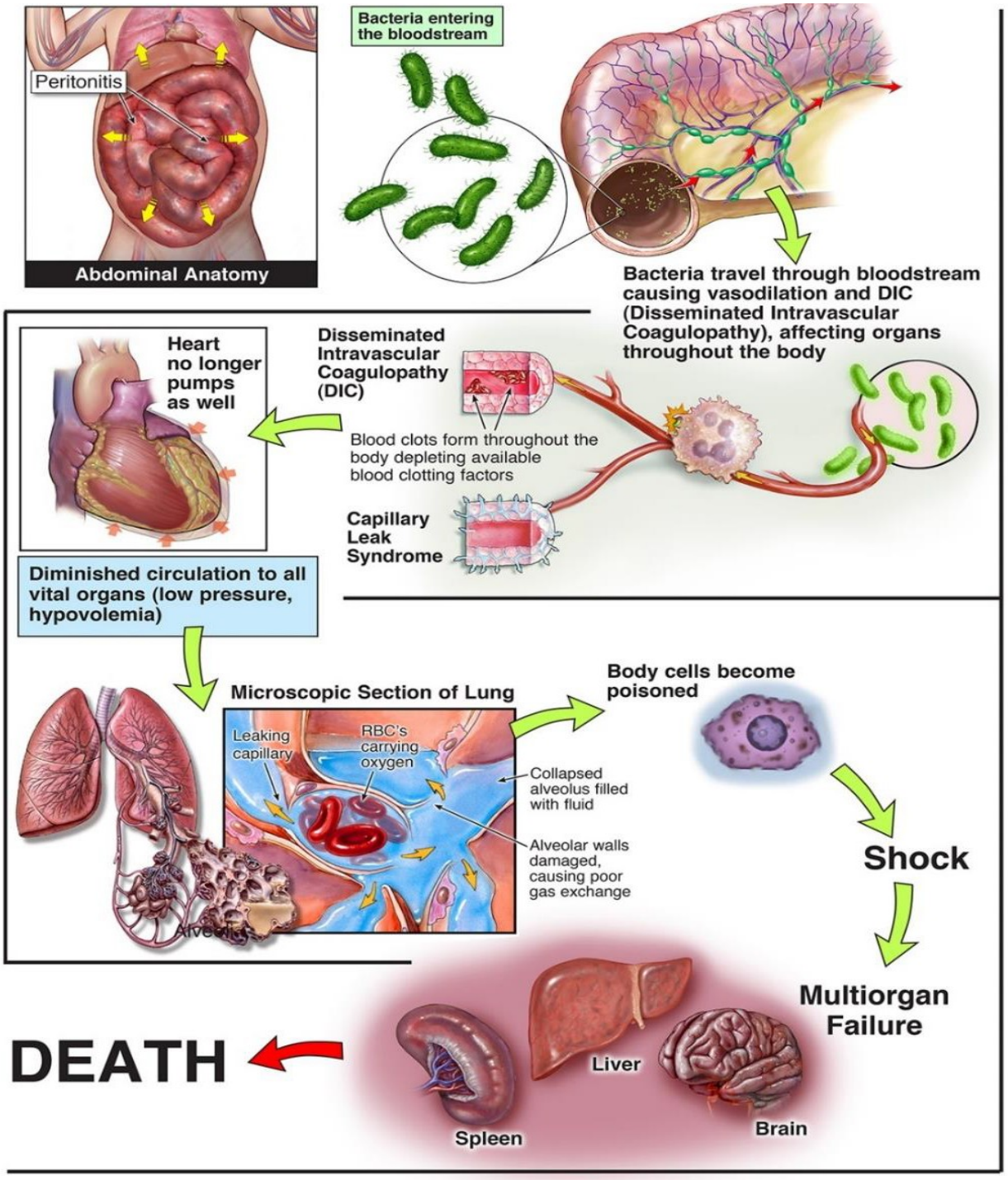
The figure to the right demonstrates the intestinal veins and lymphatics that transport the harmful bacteria and toxins that have entered the baby'sintestinal wall following the ingestion of the Cow's Milk Products.





25. The image above is a simplified view of the major organs of the baby's chest and abdomen, as well as its circulatory system. The box at the top shows a magnified view of the normal functioning of small blood vessels and capillaries of the tissues throughout the body. As shown, tight intercellular junctions lining the capillaries prevent plasma from escaping into the surrounding tissues. By contrast, the baby depicted to the right is in distress, as is illustrated by its capillary bed where bacteria and toxins (shown in green) were transported from the intestines and spread to the rest of her body. These toxins further breakdown and weaken the tight, intercellular junctions, and as a result, bacteria, toxins, and plasma escape into the surrounding interstitial spaces resulting in a condition known as "third-spacing," and sepsis.

26. This harmful process is further illustrated in the series of images, below. This process all begins with the administration of Cow's Milk Products and as shown in the illustration, can lead to sepsis, multi-system organ failure, and death.



27. As early as 1990, a prospective, multicenter study on 926 preterminfants 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).

28. The state of science as reflected in the 1990 study has since been confirmed, time and again, further establishing the causal link between exposure to cow's milk-based formula, such as Enfamil Premature 24, and the development of necrotizing enterocolitis and related conditions in premature, low-birth weight babies.

The Marketing

29. Notwithstanding strong and overwhelming medical evidence to the contrary, the Mead Defendants have marketed their Cow's Milk Products as an equally safe alternative to breast milk and have promoted these products as necessaryfor additional nutrition and growth. The Mead Defendants have specifically marketed their formulas as necessary to the growth and development of preterm infants, when instead, these products pose a known and substantial risk to these babies.

30. The Mead 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 oftime in the neonatal intensive care units of hospitals. By doing this, the Mead 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 Mead Defendants.

31. The Mead 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 Mead 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.

32. 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, DividingLabor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000).

33. 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]."

34. 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.

35. While the Mead 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.

36. In the decades since adoption of the Code, the Mead 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, StatusReport 2018*. Geneva: World Health Org., 2018, p.21.

37. These companies continue to aggressively market because it works, especially since they consistently employ unfair and deceptive tactics from the inception of a mother's use of Cow's Milk Products.

38. In addition to perpetuating the myth that these Cow's Milk Products are similar to breast milk, the Mead 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 Cow's Milk Products.

39. Another study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. 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.

40. Manufacturers have also repeatedly used their relationships with hospitals and the discharge process to encourage mothers to substitute Cow's Milk Products for human breast milk even after they leave the hospital.

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. 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. 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.*

43. Another advertisement titled "The Judgment Stops Here," is a documentary-styled ad, that 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 favoror 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. The Mead Defendants likewise promote a range of products for "premature and low weight" babies on their website: Enfamil Human Milk Fortifier Liquid HighProtein, 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 AcidifiedLiquid, Enfamil Human Milk Fortifier Powder, Enfamil 24, and DHA & ARA Supplement. However, the Mead Defendants do not make it clear which products are made from Cow's Milk Products and they fail to alert customers to any dangers.

45. Upon information and belief, the Defendants specifically target parents of preterm infants in their marketing.

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. The Mead Defendants have separately designed competing, systematic, powerful, and misleading marketing campaigns to deceive mothers to believe that: (1) Cow's Milk Formula is 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 Mead 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.

48. The Mead 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.

49. 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 Adam Hayes.

The Inadequate Warnings

50. 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.

51. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk Products, including the significant risk of NEC, 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.

52. In fact, the Mead Defendants did not provide any warning on their labeling, websites or marketing that discussed the risk of NEC and death with use of their Cow's Milk Products with preterm infants.

53. The Mead Defendants do not warn the users, the parents, or the medical providers and staff that these Cow's Milk Products can cause NEC, nor do they provide any guidance on how to avoid or reduce the risks of NEC while using their products. Unfortunately, this means that vulnerable consumers continueto use and buy these products, resulting in greater health care costs and in more preventable deaths.

Adam Hayes and the Dangerous, Defective Product

54. Adam Hayes was born on April 17, 2003, at Capital Health System at Mercer, in Trenton, New Jersey.

55. Adam was born extremely premature at just 24 weeks gestational age.

56. At birth, Adam weighed 610 grams.

57. Adam's height was just 31 cm, or approximately one foot long.

58. Beginning on April 27, 2003, Adam was fed the Mead Defendants' bovine-based formula, Enfamil Premature 24, four times a day.

59. Two days later, Adam began to throw up bile—an early sign of NEC—and Enfamil was temporarily discontinued.

60. Between May 3, 2003 and May 5, 2003, Adam was again fed Enfamil Premature 24 four times a day.

61. Adam developed an esophageal perforation on May 5, 2003, and was again discontinued from oral feedings.

62. Shortly thereafter, however, Adam was placed back on oral feedings, along with intravenous nutrition, from May 7, 2003 to May 9, 2003.

63. Upon information and belief, the oral feedings were again Enfamil Premature 24.

64. All told, Adam was fed bovine-based Enfamil Premature 24 as many as 28 times within the first month of life.

65. By May 9, 2003, and after substantial feedings with the Mead Defendants' bovine-based formula, Adam had developed serious gastrointestinal symptoms, including:

a. Abdominal distention;

b. Dilated bowel loops;

c. Ileal perforation; and

d. Observable free air in abdominal x-rays.

66. On May 10, 2003, Adam was transferred to St. Christopher's Children's Hospital in Philadelphia, Pennsylvania due to his worsening condition.

67. At St. Christopher's, Adam was diagnosed with necrotizing enterocolitis and a peritoneal drain was placed.

68. Upon information and belief, Adam suffered from Stage IIIA necrotizing enterocolitis.

69. On July 17, Adam's eye exam reported a pre-threshold Retinopathy of Prematurity ("ROP") stage 3 zone 2. A number of ophthalmic exams were completed from July 17, 2003 to August 2, 2003.

70. On August 2, 2003, it was determined that Adam would require laser surgery for threshold ROP.

71. On August 4, Adam was transferred to St. Christopher's Hospital for Laser Surgery of both eyes.

72. Additionally, upon information and belief, and as a direct result of Adam's exposure to Enfamil Premature 24 and subsequent development of necrotizing enterocolitis, Adam developed cerebral palsy.

73. To date, Adam still lives with the chronic, permanent, and lasting effects of his exposure to the Mead Defendants' bovine-based Enfamil Premature 24 formula and developing necrotizing enterocolitis, including but not limited to partial blindness and cerebral palsy.

COUNT I – STRICT LIABILITY

74. Plaintiffs reallege Paragraphs 1 through 73 as though fully set forthherein.

75. 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, including but not limited to Enfamil Premature 24, which are defectively designed and/or unreasonably dangerous to consumers, including Adam Hayes.

76. The Mead Defendants, 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.

77. At all times material to this action, the Cow's Milk Products manufactured, distributed and/or sold by The Mead Defendants, 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.

78. The Mead Defendants specifically marketed and created their Cow's Milk Products for use as nutrition and nutritional supplements for preterm infants, like Adam Hayes.

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

80. Prior to April 2003, the Mead Defendants 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.

81. The Mead Defendants 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.

82. Scientific data and well-researched studies have concluded that the Cow's Milk Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for extremely premature infants like Adam Hayes.

83. Despite the foregoing, the Defendants sold and marketed their defective and/or unreasonably dangerous products to extremely preterm infants.

84. 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;

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

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 safer design alternatives for preterm infant formula;

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.

85. As a direct and proximate result of the Cow's Milk Products' unreasonably dangerous condition, Adam Hayes suffered serious bodily injury and emotional distress.

COUNT II – NEGLIGENCE

86. Plaintiffs reallege Paragraphs 1 through 85 as though fully set forth herein.

87. The Mead Defendants, as the manufacturers and/or sellers of Cow's Milk Product, owed a duty to the consuming public in general, and Adam Hayes 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, when said product is used in its intended manner.

88. The Mead Defendants, 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.

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

90. The Mead Defendants breached the duty owed to Plaintiff 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 their products were safe for preterm infants;

d. Failing to collect data to determine when and how their 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 their products causing NEC;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of their products causing NEC;

h. Failing to stop or deter their products from being fed to extremely preterm infants like Adam Hayes;

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 their Cow's Milk Products in order to avoid NEC in preterm infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula;

l. Failing to adopt an adequate or sufficient quality control program; and/or

m. Failing to inspect or test their products with sufficient care.

91. The Mead Defendants knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Adam Hayes.

92. The Mead Defendants 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.

93. Scientific data and well researched studies have concluded that the Cow's Milk Products of the Mead Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for extremely preterm infants like Adam Hayes.

94. As a direct and proximate result of the negligence of the Mead Defendants, Adam Hayes suffered serious bodily injury and emotional distress.

COUNT III – FAILURE TO WARN

95. Plaintiffs reallege Paragraphs 1 through 94 as though fully set forth herein.

96. The Mead Defendants, as the manufacturers and/or sellers of Cow's Milk Products, owed a duty to the consuming public in general, and Adam Hayes 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.

97. The Mead Defendants, 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.

98. The Mead Defendants, 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.

99. The Mead Defendants 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 theuse of Cow's Milk Products with preterm infants, specifically including but not limited to the risk of NEC.

100. Rather than provide adequate warnings, the Mead Defendants 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 healthcare providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

101. In addition to 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.

102. 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.

103. The Mead Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature knew of the significant risk of NEC with preterm infants.

104. The Mead Defendants, through their knowledge, review, and survey of the scientific literature, knew that the use of Cow's Milk Products with preterm infants could cause severe injury, including but not limited to NEC.

105. The Mead Defendants 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;

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 their products to preterm infants in order to decrease the risk of NEC;

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 its Cow's Milk Products could cause their baby to develop NEC;

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 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 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 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 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.

106. As a direct and proximate result of the Mead Defendants' failure to warn, Adam Hayes suffered serious bodily injuries and emotional distress.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Sandra Hayes, as Guardian of Adam Hayes, prays that this Honorable Court enter judgment against Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company as follows:

i. For damages to be determined by the jury in an amount exceeding the minimum jurisdictional amount of this Court, and adequate to compensate Plaintiff for all the injuries and damages sustained as a direct and proximate result of Defendants' acts and omissions;

ii. For all general and special damages caused by the tortious conduct of the Defendants, including but not limited to damages for:

a. Severe personal injuries sustained by Adam Hayes, including but not limited to necrotizing enterocolitis, partial blindness, and cerebral palsy;

b. Expenses for the medical care and treatment of Adam Hayes;

c. Economic damages, including but not limited to lost wages and lost earning capacity;

c. Non-economic damages, including but not limited to damages for pain and suffering and severe emotional distress; and

g. Punitive damages as a result of Defendant's gross negligence and/or willful, wanton, and/or reckless disregard of the lawful rights and well-being of Adam Hayes; and

iii. For the costs of litigating this case and Plaintiff's reasonable attorneys' fees;

iv. For pre- and post-judgment interest as may be allowable by law; and

v. For all other relief to which Plaintiff is entitled by West Virginia law.

PLAINTIFF DEMANDS A TRIAL BY JURY.

By counsel,

/s/ Timothy D. Houston
Timothy D. Houston (*pro hac* pending)
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