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ATTORNEY FOR PLAINTIFFS

HOLLI CARTER, on her own behalf and as
Parent and Natural Guardian of J.C., a minor
16 Carmen Drive
Cape May, NJ 08210
Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC
Illinois Corporation Service Co.
801 Adlai Stevenson Drive
Springfield, IL 62703

MEAD JOHNSON NUTRITION COMPANY
Illinois Corporation Service Co.
801 Adlai Stevenson Drive
Springfield, IL 62703

ABBOTT LABORATORIES
CT Corporation System
208 So. Lasalle Street, Suite 814

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

Chicago, IL 60604

THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM d/b/a PENNSYLVANIA
HOSPITAL
3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE
133 South 36th Street
Philadelphia, PA 19104

Defendants

JURY TRIAL DEMANDED

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFIA
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HOLLI CARTER, ON HER OWN BEHALF
BEHALF AND AS PARENT AND NATURAL GUARDIAN
OF J.C., A MINOR
16 CARMEN DRIVE
CAPE MAY, NJ 08210

PLAINTIFFS

v.

MEAD JOHNSON & COMPANY, LLC
ILLINOIS CORPORATION SERVICE Co.
801 ADLAI STEVENSON DRIVE
SPRINGFIELD, IL 62703

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THE PENNSYLVANIA HOSPITAL OF
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HEALTH SYSTEM D/B/A PENNSYLVANIA

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Holli Carter is a natural adult person and a resident of New Jersey. Ms. Carter is the parent and natural guardian of J.C., a minor. Ms. Carter’s address is 16 Carmen Drive, Cape May, New Jersey 08210.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

J.C.'s NEC Diagnosis

11. J.C. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on October 6, 2014.

12. Upon information and belief J.C. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth.

13. Upon information and belief shortly after J.C. first ingested the Defendant Manufacturers' products, he developed NEC.

14. J.C. suffered injuries and has continued to suffer long term health effects.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

17. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

18. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

19. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

20. A Surgeon General report, *The Surgeon General's Call to Action to Support Breastfeeding*, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

21. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

22. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

23. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

24. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

25. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

26. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

27. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

28. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

29. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

***The Defendant Manufacturers' False And Misleading Marketing
Regarding Cow's Milk-Based Infant Products***

30. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

31. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

32. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

33. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

34. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

35. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

36. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

37. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

38. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

39. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

40. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

41. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

42. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



43. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

44. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

45. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

46. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

47. Mead cites no medical literature or research to guide the use of its products.

48. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

49. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

50. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

51. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

52. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

53. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

54. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

55. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

56. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

57. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience “changing hospital systems and influencing policy,” and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that “[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC).”

58. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

59. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

60. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

61. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

62. Penn Medicine’s failure to warn of the risks posed by the Defendant Manufacturers’ products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers’ cow’s milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare professionals and medical staff as a means of converting them into “extra salespersons.”

Safer Alternative Designs

63. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

64. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

65. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION **COUNT I: STRICT LIABILITY FOR DESIGN DEFECT** **(Against Abbott and Mead)**

66. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

68. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

69. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

70. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

71. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

72. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

73. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

74. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

75. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

76. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

77. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

78. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

79. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

- d. Failed to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

80. Abbott’s and Mead’s products contained cow’s milk at the time they left the manufacturing facility.

81. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers’ products, the Injured Infant were fed cow’s milk-based products, which caused and/or increased risk of their developing NEC.

82. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow’s milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

83. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

84. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

86. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

87. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

88. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

89. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow’s milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

90. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

91. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

95. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

96. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

97. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
 - c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
 - d. That cow's milk-based products were safe for premature infants; and/or
 - e. That cow's milk-based products were necessary for optimum growth; and/or
 - f. That cow's milk-based products were similar or equivalent to breast milk; and/or
 - g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
 - h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
 - i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.
98. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.
99. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.
100. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to

allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

101. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

102. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;

- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

103. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

104. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

105. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

106. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

107. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

108. Abbott and Mead were negligent or careless in not determining those representations to be false.

109. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

110. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable

reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

111. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

112. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;

- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

113. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

114. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

115. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

116. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

117. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

118. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

119. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

120. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

121. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

122. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

123. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

124. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably

dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

125. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

126. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

127. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

128. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

129. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

130. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

131. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

132. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

134. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

135. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

136. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

137. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

138. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

139. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

140. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

141. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

142. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

143. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

144. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

145. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

146. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

147. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

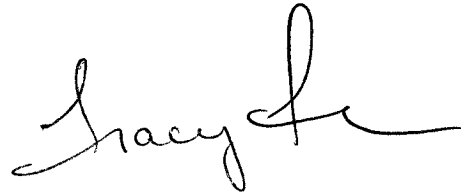
DEMAND FOR JURY TRIAL

148. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



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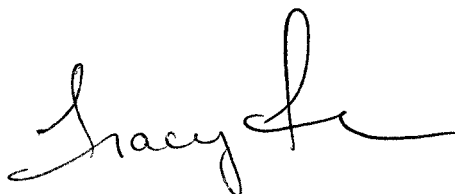
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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

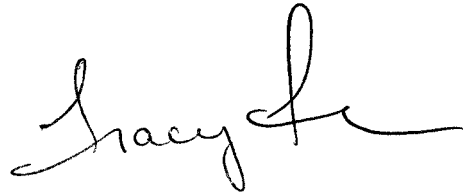
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

A handwritten signature in black ink, appearing to read "Tracy Finken", written in a cursive style. The signature is positioned above a horizontal line.

Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.

A handwritten signature in black ink, appearing to read "Tracy Finken", written in a cursive style. The signature is positioned above a horizontal line.

Tracy Finken

Date: March 24, 2022