UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

17-MD-2767 (PAE)

MDL No. 2767

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NICHOLE THOMAS,

Plaintiff,

vs.

BAYER HEALTHCARE PHARMACEUTICALS, INC.,

BAYER PHARMA AG, AND

BAYER OY.

Defendants.

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COMPLAINT AND JURY DEMAND

Civil Action No._____

Plaintiff, Nichole Thomas ("Plaintiff"), tenders the following as her Complaint and Jury Demand against Defendants, Bayer Healthcare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy (hereinafter collectively referred to as "Bayer" or "Defendants"), for personal injuries suffered as a proximate result of Plaintiff Nichole Thomas being prescribed and properly using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system).

## PARTIES

1. Plaintiff Nichole Thomas is a citizen and resident of Antioch (Davidson County), Tennessee.

2. Defendant Bayer Healthcare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of

business at 100 Bayer Boulevard, Whippany (Morris County), New Jersey 07981. Bayer Healthcare Pharmaceuticals Inc. is a citizen of Delaware and/or New Jersey.

3. Defendant Bayer Pharma AG is a company domiciled in Germany and is the parent/holding company of Defendant Bayer Healthcare Pharmaceuticals, Inc. Bayer Pharma AG is a citizen of Germany.

4. At all relevant times, Defendant Bayer Pharma AG has transacted and conducted business in the States of Tennessee and New Jersey, and it has derived substantial revenue from interstate commerce.

5. At all relevant times, Defendant Bayer Pharma AG expected or should have expected that its acts would have consequences within the United States of America, and the States of Tennessee and New Jersey.

6. Upon information and belief, Defendant Bayer Pharma AG exercises dominion and control over Defendant Bayer Healthcare Pharmaceuticals, Inc.

7. Defendant Bayer Oy is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, Finland. Bayer Oy is a citizen of Finland.

8. Upon information and belief, Defendant Bayer Oy is the current owner of the trademark relating to Mirena®.

9. At all relevant times, Defendant Bayer Oy has transacted and conducted business in the States of Tennessee and New Jersey, and it has derived substantial revenue from interstate commerce.

10. At all relevant times, Defendant Bayer Oy expected or should have expected that its acts would have consequences within the United States of America, and the States of Tennessee and New Jersey.

11. Defendant Bayer was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

12. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operated as an integrated specialty pharmaceuticals business under the new name, Bayer Healthcare Pharmaceuticals, Inc.

13. Defendant Bayer Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for the contraceptive device Mirena®.

14. Defendants are in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system Mirena®.

15. Defendants do business in the States of Tennessee and New Jersey through the sale of Mirena® and other prescription drugs in these states.

16. At all relevant times, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena®.

## JURISDICTION AND VENUE

17. Plaintiff avers that the federal judicial district in which Plaintiff's Mirena was inserted was Tennessee; and the federal judicial district in which Plaintiff currently resides is the Middle District of Tennessee. But for the Order permitting direct filing into the Southern District of New York pursuant to Order No. 3, Plaintiff would have filed her

case in the United States District Court for the Middle District of Tennessee.

**FACTS**

18. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

19. Mirena® is an intrauterine system that is inserted by a healthcare practitioner during an office visit. Mirena® is a t-shaped polyethylene frame with a steroid reservoir that releases 20 μg/day of levonorgestrel, a prescription medication used as a contraceptive. Mirena® contains 52 mg of levonorgestrel.

20. Defendant Bayer Healthcare Pharmaceuticals, Inc. designed, marketed, distributed, advertised, promoted, and/or sold Mirena® in the United States at certain times.

21. Defendant Bayer Oy sold Mirena® to Defendant Bayer Healthcare Pharmaceuticals, Inc. until September 1, 2008, at which time Bayer Oy sold Mirena® to Defendant Bayer Pharma AG, which resold Mirena® to Defendant Bayer Healthcare Pharmaceuticals, Inc.

22. Defendant Bayer Pharma AG designed, developed, and researched all Mirena® sold by Defendant Bayer Healthcare Pharmaceuticals, Inc. in the United States.

23. The federal Food and Drug Administration ("FDA") approved Defendant's New Drug Application for Mirena® in December 2000.

24. In 2009, the FDA approved Mirena® for treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.

25. Today, more than 2 million women in the United States use Mirena®.

Mirena® has been used by more than 15 million women worldwide.

26. The Mirena® intrauterine system ("IUS") releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control.

27. Defendants admit, "[i]t is not known exactly how Mirena works," but suggests that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

28. The IUS is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old IUS must be discarded and a new IUS inserted.

29. The IUS package labeling recommends that Mirena® be used in women who have had at least one child.[1]

30. The IUD package labeling recommends that Mirena® be placed at least six weeks post-partum.

31. The IUS package labeling indicates that Mirena® should be used *with caution* in patients who have: "Migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia."[2]

32. The package labeling indicates that removal of Mirena® *should be considered* if patients develop for the first time: "Migraine, focal migraines with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia."[3]

33. Transient cerebral ischemia is similar to a stroke in that it is caused by disruption of cerebral blood flow. Like a stroke, this disruption is often caused by a blood

[1] *See* 08/07/2013 Mirena Label "Full Prescribing Information" , p. 2, available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021225s032lbl.pdf.
[2] *See Id*., p. 14.
[3] *See Id*., p. 15.

clot blocking a blood vessel leading to the brain. It is often described as a "mini-stroke."

34. Upon information and belief, these indications are specifically designed to caution healthcare providers about a possible increased risk of transient cerebral ischemia or stroke with Mirena® use.

35. Mirena®'s label does not sufficiently warn about non-stroke neurological conditions such as pseudotumor cerebri ("PTC"), also known as intracranial hypertension ("IH").

36. Mirena®'s label makes no mention of PTC/IH, despite a known link between levonorgestrel and PTC/IH.

37. Defendants also provide a "Patient Information Booklet" to physicians to be given to patients at the time of Mirena insertion.

38. Defendants' Mirena® "Patient Information Booklet" also makes no mention of PTC/IH, despite a known link between levonorgestrel and PTC/IH.

39. Upon information and belief, Defendants did no clinical testing of Mirena® and its known link to the development of IH/PTC, despite over a decade of literature indicating further testing regarding levonorgestrel and IH/PTC is needed.

## Pseudotumor Cerebri Also Known As Intracranial Hypertension

40. Pseudotumor cerebri or intracranial hypertension is a condition that develops in the skull when a person's cerebrospinal fluid becomes elevated, causing increased pressure. Fluid builds up in the skull and is not released and absorbed at the proper rate. PTC derives its name from the fact that the condition acts like a tumor but it is not actually a tumor.

41. Patients with PTC or IH typically develop symptoms of severe migraines or

migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies. Visual problems and symptoms are a result of increased pressure on the optic nerve. Patients with PTC or IH often develop papilledema, or optic disc swelling due to increased intracranial pressure.

42. PTC or IH patients may also develop a "whooshing" or ringing in the ear, clinically called tinnitus.

43. PTC or IH is frequently diagnosed after a lumbar puncture, or spinal tap, is performed which allows a physician to evaluate the level of cerebrospinal fluid in the skull. When patients present with symptoms of PTC or IH, they often first undergo an MRI, CT scan, and/or other diagnostic radiology tests to rule out an actual tumor or blood clot in the brain.

44. A lumbar puncture is a diagnostic, and sometimes, therapeutic procedure by which a physician inserts a hollow needle into the subarachnoid space in the lumbar area, or lower back of a patient, and draws cerebrospinal fluid ("CSF") from the patient. The collected cerebrospinal fluid is tested to rule out infection or inflammation in the fluid that may be responsible for the elevated pressure. In patients with PTC or IH, the cerebrospinal fluid is normal.

45. In some cases, a lumbar puncture may provide some immediate relief to a patient suffering from PTC or IH, but it does not cure the condition. Conversely, a lumbar puncture may result in a post-lumbar puncture headache, bleeding or back pain.

46. Normal intracranial pressure is considered between 5 and 15 millimeters of mercury (mmHg). Pressure above the 15 mmHg range may lead to a diagnosis of PTC or IH.

47. Failure to correctly diagnose and treat PTC or IH may lead to permanent vision loss and even blindness.

48. There is currently no treatment to reverse permanent injury to the optic nerves caused by increased intracranial pressure. Because of this, treatment of PTC or IH is focused on halting visual loss that has already occurred.

49. Although PTC or IH is considered reversible in some patients, it may take years before normal pressure is maintained. It also may be irreversible in some cases.

50. PTC or IH may also recur throughout a patient's lifetime.

51. Treatment of PTC or IH may include weight loss, frequent lumbar punctures, or medication. Frequently, the medicine Acetazolamide (Diamox®) is prescribed to patients suffering from PTC or IH. Diamox® comes with its own set of adverse reactions.

52. Although experts suggest that even a 6% body weight loss in patients suffering from PTC/IH can relieve the symptoms, many women suffering from this disorder while on Mirena® who lose 6% of their body weight or more experience no relief and their condition does not improve.

53. In severe cases, therapeutic shunting, which involves surgical insertion of a tube to help drain cerebrospinal fluid from the lower back or from the skull, is recommended.

54. A lumbar-peritoneal shunt ("LP shunt") is commonly used to treat severe cases of PTC/IH. An LP shunt involves inserting a tube between vertebrae in the lumbar region of the spine into the subarachnoid cavity.

55. A ventriculo-peritoneal shunt ("VP shunt") may also be used, which

involves insertion of a tube through a patient's skull usually behind a patient's ear.

56. Both types of shunting procedures work to relocate excess cerebrospinal fluid to the abdominal cavity, where it can be absorbed.

57. Unfortunately, therapeutic shunting procedures have high failure and revision rates and often require several repeat or revision surgeries. Additionally, a patient's shunt may need frequent adjustment, which may also require surgical intervention, to find the right setting for a particular patient's needs.

58. Brain stent procedures, typically performed by interventional neuroradiologists are alternatives to shunting, and involve metal stents positioned to expand portions of cerebral veins that have become narrowed due to the increased pressure, in order to allow blood to drain more freely and relieve fluid pressure in the brain.

59. It has been estimated that approximately 1-2 people per 100,000 in the United States have PTC or IH, although reports suggest the prevalence of the disorder is increasing. In 1994, a study found that in females between the ages of 15 to 44, IH occurred at a rate of approximately 3.3 per 100,000 per year.[4]

60. Despite the rarity of PTC/IH, women who use levonorgestrel-containing products, like the Mirena® IUS, more commonly develop the disorder.[5]

61. The synthetic hormone released by Mirena®, levonorgestrel, causes or contributes to the development of PTC/IH, increases the risk of developing PTC/IH, and/or worsens or exacerbates PTC/IH.

62. Additionally, because Mirena® is known to cause rapid weight gain in

[4] *See* John B. Alder & F.T. Fraunfelder, *Letter to the Editor: Levonorgestrel Implants and Intracranial Hypertension*, 332 New Eng. J. Med. 1720, 1720-21 (1995), available at http://www.nejm.org/doi/full/10.1056/NEJM199506223322519.
[5] *See* fn. 1

women, the risk of developing PTC/IH is even greater with Mirena® use.

**The Hormone In Mirena: Levonorgestrel or "LNG"**

63. Progestins, like LNG, are synthetic progesterones, and may also be called progestogens or protestagens.[6]

64. LNG is a second-generation progestin structurally related to testosterone.[7]

65. Notably, third and fourth generation progestins were developed in an effort to reduce known side effects of second generation progestins.[8]

66. LNG acts differently from other progestins, progestogens, or synthetic progesterones, because it possesses broader binding affinities to different types of hormonal receptors than almost all other progestins used today.[9]

67. Specifically, LNG more strongly or easily binds to and activates the progesterone, androgen, and mineralocorticoid receptors of cells than other progestins.[10]

68. LNG is one of the most androgenic progestins on the market today, meaning that it acts more like testosterone in an individual's body than most other progestins.[11]

69. Other progestins more selectively bind to the progesterone receptor, and less to other receptors like the androgen and mineralcorticoid receptors of cells.[12]

70. Because LNG is more active on certain hormonal receptors (including, for example, the androgen and mineralocorticoid receptors) than other progestins, smaller

[6] Richard A. Edgren and Frank Z. Stanczyk, *Nomenclature of the Gonane Progestins*, 60 CONTRACEPTION 313 (1999).
[7] Frank Z. Stanczyk, *All Progestins Are Not Created Equal*, 68 STEROIDS 879 (2003).
[8] Regine Sitruk-Ware, *New Progestogens for Contraceptive Use*, 12 HUM. REPROD. UPDATE 169, 170 (2006).
[9] *See id*.
[10] *Id.* at 171 tbl. II; Kuhl et al., *Comparative Pharmacology of Newer Progestogens*, 51 DRUGS 188, 197 tbl. I (1996); ; Michael Juchem and Kunhard Pollow, *Binding of Oral Contraceptive Protestogens to Serum Proteins and Cytoplasmic Receptor*, 163 Am. J. Obstet. and Gyn. 2171, 2177 tbls. V-VI (1990).
[11] *See, e.g.*, Stanczyk, *All Progestins Not Equal*, *supra* at 889. *See also* Sitruk-Ware, *supra* at 171 tbl. II; Kuhl et al., *supra* at 197 tbl. I; Juchem, *supra* at 2177 tbls. V-VI .
[12] *See* Sitruk-Ware, *supra* at 171 tbl. II; Kuhl et al., *supra* at 197 tbl. I; Juchem, *supra* at 2177 tbls. V-VI .

doses of LNG do not necessarily mean fewer hormonal effects.[13]

71. LNG's broad and strong binding affinities for numerous hormone receptors increase the risk of hormonal side effects, including the risk of IH/PTC.

72. When taken alone, LNG also acts differently from most other progestins, because it significantly decreases sex hormone binding globulin ("SHBG").[14]

73. SHBG is a sex steroid transport protein which regulates the availability of free, or hormonally active, sex steroid hormones by binding to sex steroids such as testosterone, estradiol, and LNG itself.[15]

74. Low levels of SHBG may result in stronger hormonal effects of LNG, testosterone, and estradiol, or other hormones with binding affinities for SHBG, due to the greater availability of unbound, free, and hormonally active sex steroids.[16]

75. As a result of LNG's direct effect of suppressing SHBG, serum LNG amounts (bound, free, or both) may vary widely between individuals who use LNG-releasing contraceptives like Mirena®.[17]

76. LNG's propensity to suppress SHBG, where, as with Mirena®, it is used alone, increases the risk of systemic hormonal side effects, including IH/PTC.

77. Because total LNG serum levels does not accurately reflect the propensity

[13] *See* Stanczyk, *All Progestins Not Equal*, *supra* at 890 tbl. 7; Delwood C. Collins, *Sex Hormone Receptor Binding, Progestin Selectivity, and the New Oral Contraceptives*, 170 AM. J. OBSTET. GYNECOL. 1508 (1994).
[14] Kenneth Fotherby, *Levonorgestrel: Clinical Pharmacokinetics*, 28 CLIN. PHARMACOKINETICS 203 (1995); Cekan, et al., *The Interaction between Sex Hormone Binding Globulin and Levonorgestrel Released from Vaginal Rings in Women*, 31 CONTRACEPTION 431, 431 (1985).
[15] Fotherby, *supra* at 206.
[16] Alvarez, et al., *Sex Hormone Binding Globulin and Free Levonorgestrel Index in the First Week After Insertion of Norplant Implants*, 58 CONTRACEPTION 211, 211, 213 (1998).
[17] Olsson, et al., *Plasma levels of levonorgestrel and free levonorgestrel index in women using Norplant implants or two covered rods (Norplant-2)*, 35 CONTRACEPTION 215, 225 (1987).

of LNG to cause or contribute to hormonal side effects,[18] Mirena®'s labeling is misleading, inadequate, and false.

78. Rather, in order amount in order to accurately inform healthcare providers and the public of Mirena®'s propensity for causing hormonal effects, Mirena®'s labeling should provide the degree of SHBG reduction observed, total SHBG in blood serum, the amount of free serum LNG, and/or the free levonorgestrel index ("FLI") observed with Mirena®, in a manner which is usable and informative to healthcare providers.[19]

79. In addition to Defendant's failure to describe the suppressive effects of LNG upon SHBG levels, Defendant's description of systemic exposure to LNG are calculated in a manner which obfuscates and confuses healthcare practitioners and consumers who seek to compare hormonal exposure and systemic effects while on Mirena® with that of other hormonal contraceptives.

80. While LNG is bound to SHBG, it is hormonally inactive. Only unbound, or free, LNG is hormonally active, and only free, hormonally active LNG may cause progestogenic effects.

81. The appropriate measure of systemic LNG exposure is the amount of free, unbound, and hormonally active LNG present in blood serum or blood plasma.[20]

82. Total LNG levels (which include both bound and unbound LNG) are misleading when compared to combination hormonal contraceptives that contain both LNG and an estrogen (most commonly, ethinyl estradiol ("EE")).

83. Use of EE, or other estrogenic compounds, in combination with LNG

[18] *See* Kuhl, *supra* at 194.
[19] *See, e.g.*, Fotherby, *supra* at 206-207; Olsson, *supra* at 225.
[20] Fotherby, *supra* at 206-207; Kuhl, *supra* at 194; Olsson, *supra* at 225.

results in higher total serum LNG levels due to EE's proliferative effects upon SHBG levels.[21]

84. Although total serum LNG levels are higher with use of EE, the free, unbound, and hormonally active proportion of LNG in combination hormonal contraceptives is decreased in comparison to progestin-only contraceptives, like Mirena, which use LNG.[22]

85. Thus, Defendants' representations are misleading, because EE-plus-LNG-containing products may make total serum LNG appear higher than that of LNG-only products, even though free or unbound (and thus, active) LNG may be greater in a LNG-only product.

86. In addition, total serum LNG may spike for various reasons, including due to changes in individual metabolic clearance rates, within Mirena®'s five-year period.

87. As a result, some women using Mirena® may experience total serum levels of LNG far outside the maximums provided for various time points in Mirena®'s label.

88. Women may also experience total serum levels far outside the maximums listed in Mirena®'s label on an ongoing basis.

89. Spikes in LNG levels may result in an increased risk of progestogenic side effects.

90. Because maximal observed total serum concentrations are not provided in Mirena®'s label, the extent of potential exposure to LNG is impossible to calculate based on the Mirena®'s label.

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[21] Kuhl, *supra* at 194; Noe, et al., *Changes in Serum Levels of SHBG, Endogenous Ligands and Levonorgestrel Induced by Ethinyl Estradiol in Norplant Users*, 45 CONTRACEPTION 187 (1992).
[22] Fotherby, *supra* at 207.

91. In addition, Mirena®'s labeling fails to fully distinguish the amount of total LNG in blood serum from the total amount of other progestins in blood serum in a way that allows for useful comparisons of hormonal content.

92. In particular, Mirena®'s label fails to provide total serum or free LNG levels in moles. Instead, the label provides this information in picograms per milliliter of blood serum.

93. Grams, micrograms or picograms are measurements of the weight or mass of a substance.

94. Units of LNG in moles allow healthcare practitioners and consumers to compare the number of LNG molecules per volume of blood serum, rather than the weight or mass of LNG per volume of blood serum.

95. LNG content in picograms or grams must be divided by LNG's molecular weight, also known as molar mass, in order to determine LNG content in moles.

96. The molecular weight of LNG differs from the molecular weights of other progestins.

97. As a result, comparisons of LNG content in blood serum given in grams or picograms may skew comparisons between progestins.

98. Even if Mirena® use results in more moles of free LNG than other types of hormonal contraception using a different progestin, amounts given in picograms per milliliter may appear lower than the other progestin, if the molecular weight of LNG is less than the molecular weight of the other progestin.

**Defendants' Representations Regarding Mirena and LNG**

99. Since December 6, 2000, Mirena's label has contained a single sentence which warns that metabolic clearance rates, something which may vary several-fold between individuals, may cause LNG serum levels to increase.

100. However, Mirena's label and marketing materials downplay and cover up this risk in an effort to portray Mirena as a "low" or "no" hormone contraceptive.

101. Notably, Mirena®'s label fails to identify factors that could diminish metabolic clearance rates, and therefore increase LNG serum levels.

102. Metabolic clearance rates are not only widely variable among individuals as a matter of genetics or body habitus, but may also be affected by things as mundane as taking common prescription or over-the-counter medications.

103. Defendants also fail to objectively identify the impact that a low metabolic clearance rate may have on LNG serum levels while using Mirena®.

104. As a result, Mirena®'s label is insufficient, inadequate, and inaccurate, as it fails to inform healthcare practitioners and patients of the full scope of the wide variability of LNG serum levels between individuals in a useful or informative manner.

105. Furthermore, Mirena®'s label, patient education, and marketing materials have consistently emphasized that Mirena is a "low" or "no" hormone contraceptive, and that serum LNG with Mirena® is "stable" and "without peaks and troughs".

106. These materials do not reference variability in metabolic clearance rates while making these claims, do not inform healthcare practitioners or patients that low metabolic clearance rates may result in increased LNG serum levels, or provide any information regarding how much serum LNG may increase with a low or lower metabolic

clearance rate.

107. As a result, Defendants' actions have misled consumers and healthcare practitioners into believing that serum LNG remains low or practically non-existent, despite the propensity for significant differences between patients due to different metabolic clearance rates.

108. From December 6, 2000 until at least July 21, 2008, Mirena's label stated that: "The plasma concentrations achieved by MIRENA® are lower than those seen with levonorgestrel contraceptive implants and with oral contraceptives."

109. From at least July 21, 2008 to October 1, 2009, Mirena's label stated that: "The plasma concentrations achieved by Mirena are lower than those seen with levonorgestrel contraceptive implants and with oral contraceptives."

110. In claiming that plasma LNG is lower with Mirena than with oral contraceptives, the label omits the material information that free LNG may be greater than that seen with combination oral contraceptives that also contain EE (LNG-plus-EE contraceptives).

111. In claiming that plasma LNG is lower with Mirena than with oral contraceptives, the label omits the material information that free LNG, and thus progestogenic effects, may be higher with Mirena because it contains LNG alone.

112. In claiming that plasma LNG is lower with Mirena than with oral contraceptives, the label omits the material information that due to EE's effect of increasing SHBG and thus total serum LNG, total serum LNG or other progestins may appear artificially high with oral contraceptives, as compared to total serum LNG with Mirena.

113. In claiming that plasma LNG is lower with Mirena than with oral

contraceptives, the label omits the material information that in reality, free LNG causes progestogenic effects, and free LNG may be higher with Mirena than with combined oral contraceptives.

114. In claiming that plasma LNG is lower with Mirena than with oral contraceptives, the label omits the material information that oral contraceptives may use different progestins, which may have fewer progestogenic or other hormonal effects compared to LNG, despite a higher total or free serum level.

115. Defendant has consistently represented that Mirena® is a "low" or "no" hormone contraceptive with limited or no systemic effects in Mirena®'s labeling, patient education, and marketing materials.

116. Until October 1, 2009, Mirena®'s label claimed that: "The plasma concentrations achieved by MIRENA® are lower than those seen with levonorgestrel contraceptive implants and with oral contraceptives. Unlike oral contraceptives, plasma levels with MIRENA® do not display peaks and troughs."[23]

117. Mirena®'s label continues to claim that it releases a "low" amount of hormone directly into the uterus.[24]

118. From December 6, 2000 to present, Mirena's Patient Information Booklet has been devoid of any warnings that systemic hormonal side effects may occur while using Mirena.

119. From December 6, 2000 to present, Mirena's Patient Information Booklet

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[23] *Compare id.* at 4 *and* NDA 021225 Suppl. 019, [Mirena®] Labeling Revision at 3 (July 21, 2008), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021225s019lbl.pdf, *with* NDA 021225 Suppl. 027, [Mirena®] Labeling Revision at 19 (Oct. 1, 2009), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021225s027lbl.pdf.

[24] *See* Oct. 1, 2009 Mirena® Labeling Revision, *supra* n. 23, at 19.

has claimed that "[o]nly small amounts of the hormone [LNG] enter your blood."

120. On or before July 21, 2008 until October 1, 2010, Mirena's Patient Information Booklet claimed, "Levonorgestrel is a progestin hormone often used in birth control pills; however, unlike many birth control pills, Mirena does not contain an estrogen."

121. From May 29, 2014 to present, Mirena's Patient Information Booklet has claimed that "Mirena is a small flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel that is often used in birth control pills. Because Mirena releases levonorgestrel into your uterus, only small amounts of the hormone enter your blood. Mirena does not contain estrogen."

122. Mirena's Patient Information Booklet contains no information regarding the wide variance in serum LNG which is possible between individuals who use Mirena, as described above.

123. Mirena's Patient Information Booklet misleads consumers, and misled Plaintiff, into the belief that serum levels of LNG are always extremely low, and that Mirena causes little to no systemic or hormonal side effects.

124. Defendants have also used direct-to-consumer advertising in the form of television and radio commercials, as well as other video or audio clips to market Mirena.

125. Since December 6, 2000, these patient education and marketing materials have misrepresented Mirena as a low or no hormone contraceptive with few or no systemic effects, and a lower hormone option than other hormonal contraceptives.

126. Defendants have also used key opinion leaders and sales representatives to market Mirena to healthcare professionals.

127. Since December 6, 2000, key opinion leaders and sales representatives have misrepresented Mirena as a low or no hormone contraceptive with few or no systemic effects, and a lower hormone option than other hormonal contraceptives, consistent with Mirena's labeling.

128. Defendants have marketed Mirena® as being a better "low hormone" or "no hormone" contraceptive option for women who cannot use other hormonal contraceptives from December 6, 2000 to the present.

129. Mirena®'s label, patient education, and marketing materials rely upon total serum LNG levels to support "low" or "no" hormone claims, rather than comparing free, unbound, and hormonally active amounts of LNG.

130. For example, Defendants' website for Mirena®, which both patients and healthcare practitioners are encouraged to visit, currently advises consumers that "Mirena® is estrogen-free. It releases small amounts of levonorgestrel, a progestin hormone found in many birth control pills, locally into your uterus at a slow and steady rate. Only small amounts of hormone enter your blood."[25]

131. Defendants' representations to healthcare professionals specifically rely upon total serum LNG to support the claim that Mirena® is a low hormone contraceptive.[26]

132. From December 6, 2000 to present, Mirena®'s label has claimed that Mirena® releases LNG in such a way that blood plasma or blood serum LNG levels are "stable" and "without peaks and troughs".[27]

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[25] Bayer HealthCare Pharmaceuticals, *How Does Mirena® Work?*, MIRENA®: CONSUMER SITE, http://www.Mirena®-us.com/about-Mirena®/how-Mirena®-works.php (last visited March 2, 2015).

[26] Bayer HealthCare Pharmaceuticals, *Mechanism of Action: Uses local delivery*, MIRENA®: FOR HEALTHCARE PROFESSIONALS, http://hcp.Mirena®-us.com/lets-talk-about-Mirena®/mechanism-of-action.php (last visited March 2, 2015).

[27] *See* Center for Drug Evaluation and Research, [Mirena®] Approved Labeling (Dec. 6, 2000), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-225.pdf_Mirena®_Prntlbl.pdf.

133. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials regarding the propensity of LNG to suppress SHBG.

134. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials stating that SHBG suppression may increase the risk of hormonal side effects.

135. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials regarding the propensity for total serum LNG to spike while using Mirena®, or that spikes in total serum LNG may increase the risk of hormonal side effects.

136. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials regarding the greater potency of LNG on certain receptors, including but not limited to the progesterone receptor, as compared to other progestins.

137. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials that the greater potency of LNG on numerous hormone receptors, compared to other progestins, increases the risk of hormonal side effects.

138. From December 6, 2000 to present, Defendants have failed to provide any information in Mirena®'s labeling, patient education, and marketing materials regarding the important distinction between total serum LNG while on LNG-only products versus LNG-plus-EE products.

139. From at least December 6, 2000 to present, Defendants have failed to

distinguish between total serum LNG while on LNG-only versus LNG-plus-EE products, misleading healthcare providers, patients, the public, and the FDA by suggesting that systemic exposure to LNG with Mirena is less than systemic exposure to LNG with combined hormonal contraceptives.

140. From December 6, 2000 to present, Defendants have failed to provide accurate and complete information in Mirena®'s label, patient education, and marketing materials concerning maximum observed total LNG serum levels at different time points, providing only a range which is not clearly designated as a standard deviation or a percentile range.

141. From December 6, 2000 to present, Defendants' failure to provide complete information in Mirena®'s label, patient education, and marketing materials concerning maximum observed total LNG serum levels at different time points has resulted in misrepresentation of serum levels in individual Mirena users, which have the potential to be much higher.

142. Defendants have failed to provide the information above in order to mislead and defraud healthcare providers, patients, the FDA, and the public regarding Mirena's systemic effects and hormonal side effects.

143. As a result of Defendants' omissions and affirmative misrepresentations regarding LNG and Mirena®'s systemic effects, healthcare professionals and consumers do not know the full potential for hormonal side effects with the use of Mirena, including the potential for developing PTC/IH.

**Norplant® and Other Long-Term LNG-Releasing Contraceptives Warn of PTC/IH**

144. In 1991, a levonorgestrel-releasing implant called Norplant® became

available in the United States, after its manufacturer obtained FDA approval on December 10, 1990. Norplant® was developed by the Population Council and distributed in the United States by Wyeth-Ayerst Laboratories as the "Norplant System."

145. Norplant® consists of a set of six small silicone capsules, each containing 36 mg of levonorgestrel, which were implanted subdermally in the upper arm and effective as contraception for five years. Norplant® was estimated to release levonorgestrel initially at about 85 μg/day followed by a decline to about 50 μg/day after nine months and to about 35 μg/day by 18 months with a further decline to about 30 μmg/day.

146. In February 1993, Wyeth submitted a supplemental new drug application to the FDA for the Norplant System, requesting the addition of "idiopathic intracranial hypertension" and other modifications to the PRECAUTIONS section of Norplant System's physician labeling. The supplemental NDA also requested other modifications to the physician labeling and the patient package insert. Wyeth requested expedited review of its supplemental NDA.

147. On March 26, 1993, the FDA approved the supplemental NDA, including its proposed addition of warnings regarding PTC/IH to the Norplant System.

148. The new labeling addition included under the PRECAUTIONS section stated:

> "idiopathic intracranial hypertension (pseudotumor cerebri, benign idiopathic intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care.

> NORPLANT SYSTEM should be removed from patients experiencing this disorder."

149. A warning for PTC/IH was also added to the patient package insert and stated:

> "idiopathic intracranial hypertension (pseudotumor cerebri, benign idiopathic intracranial hypertension) – An increase in idiopathic intracranial pressure has been reported in NORPLANT SYSTEM users. Symptoms may include headache (associated with a change in the frequency, pattern, severity, or persistence, of particular importance are those headaches that do not stop) and visual disturbances. Contact your physician or health-care provider if you experience these symptoms. While a causal relationship is unclear, your health-care provider may recommend that the NORPLANT SYSTEM be removed."

150. By 1995, several reports of women developing PTC or IH were reported in The New England Journal of Medicine.[28] The authors noted that levonorgestrel may have contributed to the onset of the condition. The authors concluded that until more information became available, patients should be screened for symptoms and the implants should be removed in patients who show increased intracranial pressure.

151. Additional studies concluded the same and noted that IH/PTC had been reported in Norplant users.[29] By 2001, Norplant®'s label included an entry under the "Warnings" section for "Idiopathic Intracranial Hypertension" that stated:

> "Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT (levonorgestrel implants (unavailable in us)) SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern,

[28] *See Id*.

[29] *See* Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficacy and Acceptability*, 55 Drugs 861, 877 (1998); Karen R. Meckstroth & Philip D. Darney, *Implantable Contraception*, 27 Obstet Gynecol Clin North Am 781, 796 (2000); and Wysowski DK, Green L., *Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System.*, 85 Obstet Gynecol. 538-42 (1995).

> severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms, particularly obese patients or those with recent weight gain, should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT (levonorgestrel implants (unavailable in us)) SYSTEM should be removed from patients experiencing this disorder."

152. Jadelle® or "Norplant® II", which is a two-rod levonorgestrel-releasing implant, also contains similar language under the "Warnings" section of its label.[30] And importantly, Jadelle® is contraindicated in patients with a history of IH.

153. Jadelle® was approved in the United States in 1996 for up to three years use and in 2002 for up to five years use. However, Jadelle® has never been marketed in the United States.

154. Jadelle® was also developed by The Population Council, but is now manufactured, marketed, and distributed by Defendants outside of the United States.

155. In Jadelle®'s prescribing information, Defendants specifically warn that benign intracranial hypertension (another name for PTC/IH) has been reported in users of levonorgestrel implants, that the diagnosis should be considered if persistent headache and/or visual disturbances occur in Jadelle® users, and particularly in an obese user or a user who has recently gained weight, and that Jadelle® should be removed if a patient is diagnosed with the condition.

156. Both the Norplant® and Jadelle® labels included warnings of PTC/IH specific to informing patients and physicians of the disorder.

157. By the mid-1990s, tens of thousands of lawsuits were filed claiming injuries due to Norplant®. In 1996, the FDA received a "Citizen's Petition before the Food and

[30] *See* 11/22/2002 "Norplant II" Jadelle® Label, p. 10 available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20544se2-003_jadelle_lbl.pdf.

Drug Administration requesting withdrawal for sale of Norplant®."[31] The petition claimed a number of adverse events were related to Norplant® use, including PTC/IH. Wyeth pulled Norplant® off the market in June of 2002.

158. Despite a wide body of information available to Defendants regarding the connection between levonorgestrel and PTC/IH, Mirena®'s label is devoid of any warning regarding PTC or IH.

159. Upon information and belief, because Mirena®'s label is devoid of any warnings of PTC or IH, once a patient's healthcare provider rules out transient cerebral ischemia or stroke as a cause of symptoms of migraine and/or asymmetrical visual loss, the healthcare provider will not typically know or advise a patient with PTC to remove Mirena®, which causes or contributes to the development and/or progression of PTC/IH.

160. Defendants have a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

161. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC") regarding a consumer-directed advertising program entitled "Mirena® Simple Style Statements Program," a live presentation designed for "busy moms." The Simply Style program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

162. The Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC

[31] *See* http://pop.org/content/norplant-background-a-pri-petition-888.

determined these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

163. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can caused a number of side effects, including weight gain, acne, and breast pain or tenderness.

164. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

165. Finally, Defendants falsely claimed that Mirena® required no compliance with a monthly routine.

## PLAINTIFF NICHOLE THOMAS DEVELOPED PTC/IH AFTER USE OF DEFENDANT'S MIRENA

166. Plaintiff Nichole Thomas is currently 30 years old.

167. Upon information and belief, in or around August 2016, Plaintiff had the Mirena® IUS inserted into her body without complication according to the manufacturer's instructions by her healthcare provider at Tennessee Women's Care in Hermitage, Tennessee.

168. Upon information and belief, Plaintiff received Defendants' "Patient Information Booklet" when her healthcare provider placed her Mirena®.

169. Upon information and belief, Plaintiff and her healthcare providers relied on Defendants' representations regarding Mirena® in its package insert, Patient Information Booklet, or otherwise disseminated by Defendants in deciding to use and

prescribe Mirena®.

170. Upon information and belief, Plaintiff received, read and relied upon Defendants' "Patient Information Booklet," and/or other representations made by Defendants when deciding to use Mirena.

171. Upon information and belief, after her Mirena® was placed, among other things, Plaintiff began experiencing headaches and blurred vision.

172. Upon information and belief, in or around June 2017, Plaintiff sought treatment for vision symptoms by her optometrist at Vision Works in Antioch, Tennessee.

173. Upon information and belief, in or around June 2017, Plaintiff underwent MRI and PET imaging procedures to rule out intracranial abnormalities at Vanderbilt University Medical Center in Nashville, Tennessee.

174. Upon information and belief, in or around June 2017, Plaintiff also underwent a diagnostic lumbar puncture to evaluate increased intracranial pressure.

175. As a result of the injuries she suffered as a result of the defective and unreasonably dangerous Mirena® IUS, she has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

**COUNT I**
**NEGLIGENCE**

176. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

177. Defendants were and are engaged in the business of selling Mirena® in the State of Tennessee.

178. The Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants, and was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

179. Defendants owed a duty to provide a reasonably safe product and to warn Plaintiff, patients, the FDA, prescribing physicians, the healthcare community, and other foreseeable users of the foreseeable risks associated with Mirena®.

180. Defendants owed a duty to design the Mirena® in a way to prevent foreseeable harm to patients like the Plaintiff.

181. Defendants owed a duty to test its Mirena® in a manner that was commensurate with the dangers associated with it.

182. Defendants owed a duty to test Mirena® based on Defendants' intended use of the Mirena as long-term contraception and/or long-term treatment for heavy menstrual bleeding.

183. Defendants owed a duty to test Mirena® based on Defendants' intended use of the Mirena to expose Mirena users to levonorgestrel on a daily basis for long-term (up to five years) treatment.

184. The foreseeable risks associated with the design or formulation of Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

185. The foreseeable risks associated with the design or formulation of Mirena® include, but are not limited to, the development of IH/PTC, and rapid or sudden weight

gain, which is also a risk factor in the development of IH/PTC.

186. The foreseeable risks associated with Defendants' Mirena® design outweigh its utility for the foreseeable uses for which it is prescribed to patients like the Plaintiff.

187. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

188. Defendants failed to adequately and properly test the Mirena® both before and after placing it on the market.

189. A prudent seller in the exercise of ordinary care would and should have discovered and foreseen the dangerous and defective condition of Mirena® and its potential to cause severe conditions, including PTC/IH, when placing the product on the market.

190. As a direct and proximate cause of Plaintiff's use of Mirena®, she has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

191. Defendants placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

192. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive device despite its lack of efficacy and potential for serious permanent side effects, including IH/PTC.

193. Defendants knew or should have known that Mirena®, and specifically, the synthetic progestin levonorgestrel, causes and/or contributes to the development of IH/PTC, a severe and possibly irreversible brain condition.

194. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

195. There are contraceptives on the market, including the 10-year copper IUD ParaGard®, with safer alternative designs in that they do not expose patients to levonorgestrel, which is known to be associated with the development of IH/PTC.

196. Upon information and belief, Defendants failed to use reasonable care in designing Mirena® in that Defendants:

a. failed to properly and thoroughly test Mirena® before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;

c. failed to conduct sufficient post-marketing testing and surveillance of Mirena®;

d. designed, manufactured, marketing, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failed to exercise due care when advertising and promoting Mirena®; and

f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendant knew or should have known of its adverse effects.

197. A reasonable manufacturer would or should have known that the risks created by Mirena® were unreasonably greater than that of other contraceptives and that Mirena® had no clinical benefit over such other contraceptives that compensated in whole

or part for the increased risk.

198. Defendants knew or should have known that Mirena®, and specifically, the synthetic progestin levonorgestrel causes and/or contributes to the development of IH/PTC, a severe and possibly irreversible brain condition that can also lead to permanent blindness.

199. Despite an increasing number of adverse events, including reports of intracranial hypertension, blindness, papilledema, and increased intracranial pressure, Defendants have made no effort to warn physicians, the healthcare community, or patients of the risk of developing IH/PTC with Mirena®.

200. Defendants knew or should have known that an additional risk factor for developing IH/PTC is sudden weight gain—a common side effect of Mirena—and Defendants did nothing to warn patients, physicians, or the healthcare community that Mirena® could cause rapid or sudden weight gain, which increases the risk of developing IH/PTC.

201. Defendants, in fact, specifically recommend Mirena® for use in women of childbearing age and for use in women who have recently given birth, further misrepresenting Mirena®'s safety regarding its risk of developing IH/PTC.

202. Likewise, Defendants knew or should have known that Mirena, a levonorgestrel-releasing IUD, should be removed immediately to avoid exacerbation of injuries, once a patient is diagnosed with papilledema, IH/PTC, or once a patient develops symptoms consistent with these conditions, and Defendants have made no effort to warn patients, physicians, the healthcare community, or the public of this fact.

203. An ordinarily prudent manufacturer, with knowledge of Mirena®'s risks, including IH/PTC, would not have placed Mirena® on the market.

204. Defendants are also therefore liable for the negligent researching, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control and/or distribution of Mirena®.

205. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

206. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT II**
**DESIGN DEFECT**

207. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

208. Defendants were and are engaged in the business of selling Mirena® in the State of Tennessee.

209. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold, and otherwise released into the stream of commerce the pharmaceutical Mirena®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers.

210. The Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised,

distributed, and sold by Defendants, and was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

211. Defendants' Mirena® was unreasonably dangerous for the use for which it was intended, and its unreasonably dangerous condition existed when it left the control of Defendants.

212. Defendants' Mirena® is defective and unreasonably dangerous because it releases and exposes patients long-term to levonorgestrel, which is known to cause, contribute to, and/or trigger the development of IH/PTC.

213. Defendants' Mirena® is defective because it failed to perform in a manner reasonably expected in light of its nature an intended function.

214. The foreseeable risks associated with the design or formulation of Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

215. The foreseeable risks associated with the design or formulation of Mirena® include, but are not limited to, the development of IH/PTC, and rapid or sudden weight gain, which is also a risk factor in the development of IH/PTC.

216. The foreseeable risks associated with Defendant's Mirena design outweigh its utility for the foreseeable uses for which it is prescribed to patients like the Plaintiff.

217. The risks inherent in Mirena's design, including the risks of developing IH/PTC, outweigh the utility of Mirena so designed.

218. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and

sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

219. Defendants placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

220. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive device despite its lack of efficacy and potential for serious permanent side effects, including IH/PTC.

221. Defendants knew or should have known that Mirena®, and specifically, the synthetic progestin levonorgestrel, causes and/or contributes to the development of IH/PTC, a severe and possibly irreversible brain condition.

222. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

223. There are contraceptives on the market, including the 10-year copper IUD ParaGard®, with safer alternative designs because they do not expose patients to levonorgestrel, which is known to cause, contribute to, and/or trigger the development of IH/PTC.

224. These safer alternatives would have prevented or significantly reduced the risk of developing IH/PTC, without substantially impairing their utility.

225. These safer alternatives were both technologically and economically feasible when Defendants' Mirena® left the control of Defendants.

226. Defendants' Mirena® is unreasonably dangerous in its design, in that the hormone released by Mirena causes, contributes to, and/or triggers the development of

IH/PTC.

227. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

228. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT III**
**FAILURE TO WARN**

229. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

230. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold, and otherwise released into the stream of commerce the pharmaceutical Mirena®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

231. Defendants knew or should have known that Mirena®, and specifically, the synthetic progestin levonorgestrel caused and/or contributed to the development of IH/PTC, a severe and possibly irreversible brain condition.

232. Defendants failed to adequately warn that Mirena® causes and/or contributes to the development of IH/PTC.

233. Defendants failed to warn the FDA, patients, physicians, the healthcare community, and the public at large of the risks associated with Mirena®, including that use of Mirena causes, contributes to, and/or triggers the development of IH/PTC.

234. Likewise, Defendants knew or should have known that Mirena®, a levonorgestrel-releasing IUD, should be removed immediately to avoid exacerbation of injuries, once a patient is diagnosed with papilledema, IH/PTC, or once a patient develops symptoms consistent with these conditions, and Defendants have made no effort to warn patients, physicians, the healthcare community, or the public of this fact.

235. Defendants did not disclose an unreasonably dangerous condition regarding its Mirena®, namely, that the hormones in Mirena® can cause or substantially contribute to the development of papilledema and/or IH/PTC.

236. Despite an increasing number of adverse events, including reports of intracranial hypertension, blindness, papilledema, and increased intracranial pressure, Defendants have made no effort to warn physicians, the healthcare community, or patients of the risk of developing IH/PTC with Mirena®.

237. Defendants knew or should have known that an additional risk factor for developing IH/PTC is sudden weight gain—a common side effect of Mirena®, and Defendants did nothing to warn patients, physicians, or the healthcare community that Mirena®'s could cause rapid or sudden weight gain, which increases the risk of developing IH/PTC.

238. Defendants knew or should have known that women of childbearing age, overweight women, and women with sudden weight gain, are at a higher risk of developing IH/PTC, and yet Defendants failed to adequately warn that Mirena® causes and/or

contributes to the development of the disorder, and that in combination with these other risk factors, Mirena® use presents even a greater risk of developing the disorder.

239. Defendants also knew or should have known that Mirena® users who are diagnosed with papilledema and/or IH/PTC, and/or who begin suffering from the symptoms of papilledema and/or IH/PTC, should have their Mirena® removed immediately, and yet Defendants failed to warn or instruct of this fact.

240. Mirena® is a defective and unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the increased risk of developing IH/PTC.

241. Mirena® was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians, including the increased risk of developing PTC/IH.

242. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

243. Defendants downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendants placed profits above their customers' safety.

244. Mirena® was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiff or her doctor to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks associated with Mirena®, they failed to provide

warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

245. Defendants, before and/or after approval of Mirena®, withheld from or misrepresented to the FDA required information, including information regarding the link between PTC and levonorgestrel, that was material and relevant to the performance of the Mirena and was causally related to the Plaintiff's injuries.

246. Plaintiff used Mirena® as intended and as indicated by the package labeling in a reasonably foreseeable manner.

247. Plaintiff could not have discovered any defect in Mirena® through the exercise of reasonable care.

248. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Mirena®, including the risks of developing IH/PTC.

249. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

250. Plaintiff and her healthcare practitioners relied upon the Defendants' representations regarding Mirena® in the package insert, Patient Information Booklet, or otherwise disseminated by the Defendants.

251. Defendants had a continuing duty to warn consumers, including Plaintiff and her physicians, and the medical community, of the dangers associated with Mirena®, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duties.

252. Although Defendants knew, or was reckless in not knowing, of the defective

nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, distribute and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

253. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

254. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT IV**
**STRICT LIABILITY**

255. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

256. Defendants manufacturers and/or suppliers of Mirena® and are strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling, and placing Mirena® into the stream of commerce.

257. Defendants are engaged in the business of manufacturing and selling the Mirena® IUS and placing it into the stream of commerce where it was expected to and did reach the Plaintiff.

258. Defendants' Mirena® was expected to, and did, reach the Plaintiff without substantial change in the condition in which it was sold.

259. Defendants placed their product, Mirena®, on the market knowing that it is to be used without inspection for defects. Mirena® proved to have defects which caused injury to Plaintiff.

260. Mirena®, manufactured and/or supplied by Defendants, was defective in design or formulation in that when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other contraceptives.

261. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with design or formulation.

262. Defendants' Mirena® is defective because it failed to perform in a manner reasonably expected in light of its nature an intended function.

263. Defendants' Mirena® was not merchantable and reasonably suited to the uses for which it is intended, including the uses for which it was prescribed to the Plaintiff, and its condition, when sold to the Plaintiff, proximately caused her injuries.

264. A reasonable alternative design existed which would have eliminated or reduced Plaintiff's injuries. Other methods of contraception do not pose the risks that Mirena® use presents, including the risk of developing IH/PTC.

265. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of developing IH/PTC, and the Defendants failed to adequately warn of these

risks.

266. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena®, along with its common side effect of rapid or sudden weight gain, created, among other things, a risk of developing IH/PTC, and the Defendants failed to adequately warn of these risks.

267. Defendants owed Plaintiff a duty to warn of Mirena®'s dangers, including the increased risk of developing IH/PTC, when used in its intended manner for contraception and/or to treat heavy menstrual bleeding.

268. Defendants breached their duty to warn Plaintiff of Mirena®'s dangers because Defendants' warnings were inadequate and Defendants failed to warn entirely of the risks of developing IH/PTC with use of Defendants' Mirena®.

269. Defendants failed to adequately warn Plaintiff or her physicians of the increased risk of developing IH/PTC with use of Mirena® and failed to warn that Mirena® should be immediately removed once Plaintiff is diagnosed with IH/PTC, and/or papilledema, and/or suffers characteristics, symptoms, or manifestations of IH/PTC and/or papilledema.

270. Mirena® was also defective due to inadequate pre-marketing and/or post-marketing testing.

271. Despite Defendants' knowledge of the risks associated with levonorgestrel-releasing implants, including the development of IH/PTC, Defendants did not adequately conduct pre-market and/or post-market testing to account for the risks.

272. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known

of the extreme risks associated with Mirena®, and continues to promote Mirena® in the absence of those adequate warnings.

273. Despite Defendants' knowledge of an increasing number of adverse events reporting IH/PTC or its symptoms, including papilledema, diplopia (double vision), severe migraine-like headaches, and blindness, Defendants did nothing to alert the healthcare community or patients or otherwise warn of these risks.

274. Defendants owed a post-sale duty to warn patients, including Plaintiff, of the dangers posed by Mirena® in light of an increasing number of adverse events of IH/PTC, papilledema, blindness, or other related symptoms, and Defendants failed in their duty to provide these post-sale warnings.

275. Defendants continue to fail to warn of the risk of developing IH/PTC with use of Mirena®.

276. An ordinarily prudent manufacturer, with knowledge of Mirena®'s risks, including IH/PTC, would not have placed Mirena® on the market.

277. Plaintiff and her healthcare providers relied upon Defendants' representations regarding Mirena® in the package insert, Patient Information Booklet, or otherwise disseminated by Defendants, when deciding to prescribe and use Mirena®.

278. Had Defendants properly warned of the risks associated with Mirena®, including the risk of developing IH/PTC and that Mirena® should be removed immediately once a patient is diagnosed with or suffers symptoms of IH/PTC, Plaintiff's healthcare providers would not have prescribed Mirena® to the Plaintiff, and Plaintiff would not have used Mirena®.

279. Defendants' Mirena® is defective because it is unreasonably dangerous and

does not meet the reasonable expectations of an ordinary consumer with respect to its safety; that is, Mirena® is an unreasonably dangerous product in a condition not contemplated by the ultimate consumer, including Plaintiff, and is not fit for its intended purpose.

280. Plaintiff's Mirena® was defective, left the Defendants' control in a defective condition, was unaltered by Plaintiff or her physicians, and the defects are traceable to the Defendants.

281. A reasonable manufacturer with knowledge of Mirena's dangerous condition would not have placed Mirena on the market.

282. Defendants are strictly liable under Tenn. Code Ann. §29-28-106, for placing an unreasonably dangerous product on the market that is not safe for its intended use, which was expected to, and did, reach the Plaintiff without alteration, and was inserted and used pursuant to the Defendant's instructions.

283. Defendants' Mirena® was a substantial factor or legal cause in producing the development of Plaintiff's PTC/IH condition, and proximately caused Plaintiff's PTC/IH condition.

284. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

285. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such

relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT V**
**BREACH OF IMPLIED WARRANTY**

286. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

287. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®.

288. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

289. Defendants impliedly warranted Mirena® as a safer type of hormonal birth control that would not produce progestogenic side effects by warranting that it was an extremely low hormonal contraceptive.

290. Plaintiff relied on the skill and judgment of the Defendants, and as such, their implied warranty, in using Mirena®.

291. Plaintiff used Defendants' Mirena® for the ordinary purposes for which it is indicated for use, and Plaintiff's physician inserted the Mirena® pursuant to the Defendants' instructions.

292. Mirena® was defective and not of merchantable quality or safe or fit for its intended use because it is unreasonably dangerous and unfit for the ordinary purpose for which it is intended and was used. Specifically, Mirena® is unreasonably dangerous, unmerchantable, and unfit for the ordinary purpose for which it is intended and was used because it causes and/or contributes to the development of IH/PTC, a foreseeable risk,

which Defendants knew or should have known of.

293. Defendants' Mirena® does not meet the reasonable expectations of an ordinary consumer, including the Plaintiff, as to its safety and is not reasonably safe for its intended purpose and use because it is defectively designed and because Defendants inadequately warned of the risks of developing IH/PTC and/or papilledema, and/or that the Mirena® should be removed once these conditions, and/or symptoms of these conditions, develop.

294. Defendants had reason to know that Plaintiff would purchase Mirena® for the purpose of contraception and/or heavy menstrual bleeding.

295. Defendants had reason to know that Plaintiff would rely on Defendants' skill or judgment to furnish and produce Mirena® in a safe and appropriate manner.

296. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

297. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT VI**
**BREACH OF EXPRESS WARRANTY**

298. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

299. The aforementioned designing, manufacturing, marketing, formulating,

testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendants warranted Mirena® to be in all respects safe, effective and proper for such purposes.

300. Defendants expressly warranted Mirena in its label, which was directly intended to benefit Plaintiff.

301. Defendants' express warranties in the Mirena label were intended for the product's consumers, including the Plaintiff.

302. Defendants expressly warranted Mirena in its Patient Information Booklet, which was intended to benefit Plaintiff and intended to be provided directly to Plaintiff.

303. Defendants expressly warranted Mirena® in advertisements and/or brochures, which Plaintiff read and relied upon.

304. Defendants expressly represented to Plaintiff, her physician(s), healthcare providers, and/or the FDA that Mirena® was safe and fit for the uses in which it is intended.

305. Further, Defendants' promotional and marketing activities, including television commercials, pamphlets, and brochures stated or implied that Mirena® is safe and fit for its intended uses, that it did not produce severe side effects, including IH/PTC, and that it was adequately tested.

306. Defendants expressly warranted Mirena® as a safer type of hormonal birth control that would not produce progestogenic side effects by warranting that it was an extremely low hormonal contraceptive.

307. Plaintiff read and relied upon Defendants' express warranties in its Patient Information Booklet and/or in other information, including marketing and promotional material, disseminated by Defendants.

308. Plaintiff's physician(s) read and relied upon Defendants' express warranties in the Mirena label and/or in other information, including marketing and promotional material, disseminated by Defendants.

309. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects, including the development of IH/PTC, and rapid and sudden weight gain, which also contributes to the risk of developing IH/PTC.

310. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

311. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

## COUNT VII
## NEGLIGENT MISREPRESENTATION

312. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

313. Defendants have misrepresented the nature and/or actions of LNG.

314. Defendants have misrepresented LNG's effects on SHBG levels.

315. Defendants have misrepresented LNG's effects due to the binding affinities of LNG.

316. Defendants have misrepresented that total serum LNG in grams is the appropriate measure of hormonally active LNG.

317. Defendants have misrepresented the differences between LNG and other progestins and/or combined oral contraceptives.

318. Defendants have misrepresented differences in serum levels of LNG due to various factors, including individual metabolic clearance rates.

319. Defendants have misrepresented that Mirena® is a “low” or “no” hormone contraceptive.

320. Defendants have misrepresented that LNG levels are "stable" and "without peaks and troughs".

321. Defendants have misrepresented that Mirena® causes few to no systemic effects.

322. Defendants have misrepresented that serum or plasma concentrations of LNG with Mirena® are lower than with other contraceptives.

323. Defendants have misrepresented that Mirena causes or contributes to fewer systemic hormonal effects compared to other hormonal contraceptives.

324. At the timeframes discussed herein, these misrepresentations were made in Mirena's labeling, patient education, and marketing materials, which were produced and distributed by Defendants with the intent to defraud Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public.

325. Likewise, Defendants made these representations to Plaintiff in advertising,

in the Patient Information Booklet, and/or in other marketing intended for consumers, prior to Plaintiff's insertion, when she received the Patient Information Booklet, and when she had her Mirena inserted.

326. Defendants additionally used key opinion leaders, thought leaders and/or sales representatives to make these misrepresentations to physicians, including Plaintiff's physicians, throughout Mirena®'s post-marketing period and prior to Plaintiff's insertion.

327. Defendants had pecuniary interest in transaction in which Plaintiff purchased Mirena, because they earned money as a result of the transaction.

328. Defendants supplied the above false information for the guidance of others, including Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public, in the business transaction of purchasing Defendants' product, Mirena.

329. Plaintiff's pecuniary losses were caused by her justifiable reliance upon Defendant's false information.

330. Defendant failed to exercise reasonable care or competence in obtaining or communicating the above false information.

331. Plaintiff and her healthcare practitioners reasonably relied and actually relied upon the above misrepresentations.

332. As a result of the above misrepresentations, Defendants have negligently misrepresented that Mirena® is safe and effective and does not cause side effects like PTC/IH or other neurological conditions.

333. But for these misrepresentations, Plaintiff would not have purchased Mirena.

334. Defendants, having undertaken the designing, manufacturing, marketing,

formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena®, owed a duty to provide accurate and complete information regarding Mirena®.

335. Defendants have made false statements of material facts, of which Defendants were careless and/or negligent in ascertaining the truth of, with an intention of inducing Plaintiff and/or her healthcare providers to act upon them.

336. Plaintiff and her healthcare providers did take action in prescribing and using Defendants' Mirena® in reliance upon Defendants' false statements of material facts, which has caused damage and injuries to Plaintiff as described herein.

337. Defendants falsely represented to Plaintiff and Plaintiff's healthcare providers that Mirena® was a safe and effective contraceptive option and/or treatment for heavy menstrual bleeding. The representations by Defendants were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

338. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and her healthcare providers information about the propensity of Mirena® to cause great harm, including the increased risk of developing IH/PTC, and the increased risk of suffering severe consequences due to not removing Mirena® once a patient experiences symptoms of papilledema and/or IH/PTC. Defendants negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

339. These misrepresentations were made by Defendants with the intent to induce Plaintiff to use Mirena® and to induce Plaintiff's healthcare providers to prescribe Mirena®, which Plaintiff and her healthcare providers were induced and did act, and which

caused injury.

340. At the time of Defendants' misrepresentations and omissions, Plaintiff was unaware of the falsity of these statements and reasonably believed them to be true.

341. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding its product.

342. Plaintiff and her healthcare providers reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when using and prescribing Mirena®.

343. Defendants' representations that Mirena is safe and effective depend upon its marketing, patient education, and labeling claims that Mirena releases a low amount of hormone directly into the uterus, that hormone levels are stable and without peaks and troughs, that the amount of hormone is less than other hormonal contraceptives, and that there are few or no systemic effects.

344. However, Mirena is not safe and is dangerous to the health of its users because it has a propensity for causing hormonal side effects, including but not limited to causing or contributing to the development of IH/PTC.

345. Defendants negligently misrepresented that Mirena does not have the propensity to cause or contribute to IH/PTC or hormonal side effects generally.

346. Plaintiff and her healthcare providers reasonably believed that Mirena releases a low amount of hormone directly into the uterus, that hormone levels are stable and without peaks and troughs, that the amount of systemic hormone is less than other hormonal contraceptives, and that it is so minimal that there are few or no systemic effects, such as IH/PTC.

347. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

348. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT VIII**
**FRAUDULENT MISREPRESENTATION**

349. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

350. Defendants have affirmatively misrepresented that Mirena® is a "low" or "no" hormone contraceptive.

351. Defendants have affirmatively misrepresented that LNG levels are "stable" and "without peaks and troughs".

352. Defendants have affirmatively misrepresented that Mirena® causes few to no systemic effects.

353. Defendants have affirmatively misrepresented that serum or plasma concentrations of LNG with Mirena® are lower than with use of other contraceptives.

354. Defendants have affirmatively misrepresented that Mirena causes or contributes to fewer systemic hormonal effects compared to other hormonal contraceptives.

355. The above representations are in fact false.

356. Defendants knew of the falsity of these misrepresentations, or they were made with reckless disregard as to their truth or falsity.

357. At the timeframes discussed herein, these affirmative misrepresentations were made in Mirena's labeling, patient education, and marketing materials, which were produced and distributed by Defendant with the intent to defraud, Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public.

358. Likewise, Defendants made these representations to Plaintiff in advertising, in the Patient Information Booklet, or in other marketing materials intended for consumers prior to Plaintiff's insertion, when she received the Patient Information Booklet, and when she had her Mirena inserted.

359. Defendants additionally used key opinion leaders, thought leaders and/or sales representatives to make these misrepresentations to physicians, including Plaintiff's physicians, throughout Mirena®'s post-marketing period and prior to Plaintiff's insertion.

360. Defendant made the above misrepresentations in order to induce Plaintiff, Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public to act upon them.

361. Plaintiff and her healthcare practitioners reasonably and actually relied upon the above affirmative misrepresentations.

362. As a result of these affirmative misrepresentations, Defendants have fraudulently misrepresented that Mirena® is safe and effective and does not cause side effects like PTC/IH or other neurological conditions.

363. The above misrepresentations were material to the transaction; but for these affirmative misrepresentations, Plaintiff would not have purchased Mirena.

364. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

365. Defendants have made false statements of material facts, of which Defendants knew or believed to be false, with an intention of inducing Plaintiff and/or her healthcare providers to act upon them.

366. Plaintiff and her healthcare providers did take action in prescribing and using Defendants' Mirena® in reliance upon Defendants' false statements of material facts, which has caused damage and injuries to Plaintiff as described herein.

367. Defendants fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm, including its propensity to cause and/or contribute to the development of IH/PTC, that it should be removed immediately upon diagnosis with papilledema and/or IH/PTC, or any of the symptoms thereof, and that it leads to other risk factors for developing the disorder, including sudden and increased weight gain.

368. Defendants fraudulently misrepresented that Mirena® was safe for use in women of child-bearing age, in women who have recently had a child, and in women without regard to their weight or body mass index, despite having actual knowledge that Mirena® is unreasonably dangerous and defective because its use creates an increased risk of developing IH/PTC.

369. Defendants fraudulently misrepresented that Mirena® caused few, if any, adverse reactions and side effects, and fraudulently misrepresented that Mirena® would

not lead to neurologic side effects, including the development of IH/PTC.

370. Specifically, Defendant fraudulently misrepresented that such side effects could not or would not occur due to the low systemic hormonal effects of Mirena by representing Mirena as releasing a low amount of hormone directly into the uterus, representing that hormone levels are stable and without peaks and troughs, and representing that the amount of hormone is less than other hormonal contraceptives, including those containing EE.

371. These representations were, in fact, false, because, as described herein, the nature of LNG, and even more specifically, of LNG-only releasing contraceptives, does not make Mirena comparable to other types of hormonal contraception, including those that contain EE or other progestins.

372. However, Mirena is not safe and is dangerous to the health of its users because it has a propensity for causing hormonal side effects, including but not limited to causing or contributing to the development of IH/PTC.

373. Specifically, Defendant has made representations to the FDA from at least 1997 to the present that while using Mirena, individuals experience very low systemic LNG levels, that the level of systemic hormone is much lower than is seen with other hormonal contraceptives, and that hormone levels are stable and without peaks and troughs.

374. Additionally, Defendant has made representations to the healthcare community and the public from at least December 6, 2000 to the present that while using Mirena, individuals experience very low systemic LNG levels, that the level of systemic hormone is much lower than is seen with other hormonal contraceptives, and that hormone levels are stable and without peaks and troughs.

375. Therefore, Plaintiff and her healthcare providers were unaware that systemic LNG levels may be much higher than is represented on Mirena's label, that hormone levels may be as high or higher than hormone levels with other hormonal contraceptives, that hormone levels with Mirena may display peaks and troughs and may not be stable, and that Mirena may cause or contribute to hormonal side effects, including but not limited to developing IH/PTC.

376. Defendants made these misrepresentations to the FDA, the public, patients, physicians, and the healthcare community at large, throughout Defendants' pre- and post-marketing period and continuing to the present.

377. Defendants made these misrepresentations to Plaintiff and her healthcare providers, with the intent to induce Plaintiff and her healthcare providers to use and prescribe Mirena®, and with the intent to defraud Plaintiff and her healthcare providers.

378. Defendants made these misrepresentations when initially obtaining FDA approval, when obtaining a new indication for heavy menstrual bleeding, during Mirena's entire post-marketing period, and continuing to the present.

379. Defendants made these misrepresentations prior to Plaintiff's physicians prescribing Plaintiff Mirena® and prior to her insertion.

380. Defendants made these misrepresentations in advertisements, marketing, commercials, promotional materials, reports, press releases, campaigns, billboards, and instructional material and labeling.

381. Defendants made these misrepresentations in its "Patient Information Booklet" provided to Plaintiff and other Mirena patients at the time of insertion.

382. Defendants made these misrepresentations through contact with Plaintiff's

physicians in material provided to Plaintiff's physicians through Defendants' sales representatives, or through communication with Plaintiff's physicians by Defendants' sales representatives.

383. Defendants also made these misrepresentations through promotional and educational campaigns specifically targeting prescribing physicians, including, upon information and belief, Plaintiffs' physicians.

384. Defendants intended to defraud the FDA, prescribing physicians, patients, the public, and Plaintiff and Plaintiff's physicians in making these misrepresentations.

385. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

386. Defendants knew this information to be false, incomplete and misleading and/or made fraudulent misrepresentations recklessly and without regard to its truth or falsity.

387. Defendants intended to deceive and mislead Plaintiff and her healthcare practitioners so that they might rely on these fraudulent misrepresentations.

388. Plaintiff and her healthcare practitioners had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

389. Plaintiff and her healthcare practitioners were deceived by Defendants' fraudulent misrepresentations.

390. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and

future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

391. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**COUNT IX**
**FRAUD BY SUPPRESSION AND CONCEALMENT**

392. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

393. Defendants have omitted, suppressed or concealed the nature and/or actions of LNG, in the following ways:

394. Defendants have omitted or concealed the LNG's effects on SHBG levels.

395. Defendants have omitted or concealed hormonal effects due to the binding affinities of LNG.

396. Defendants have omitted or concealed the that free serum LNG in moles is the appropriate measure of hormonally active LNG.

397. Defendants have omitted or concealed the differences between LNG and other progestins and/or combined oral contraceptives.

398. Defendants have omitted or concealed the differences in serum levels of LNG due to various factors.

399. Defendants have omitted or concealed the maximum observed serum concentrations with Mirena.

400. Defendants have omitted or concealed that serum LNG may spike or increase after insertion either temporarily or permanently.

401. Defendants have omitted or concealed that Mirena® causes systemic effects.

402. Defendants have omitted or concealed that serum or plasma concentrations of LNG with Mirena® may be higher than with other contraceptives.

403. Defendants have omitted or concealed that Mirena causes or contributes to systemic hormonal effects as with other hormonal contraceptives.

404. Defendants knew of the falsity or materiality of these omissions, or they were made with reckless disregard as to their truth or materiality.

405. Defendants have defrauded Plaintiffs and her healthcare providers into the reasonable belief that Mirena® is safe and effective and does not cause side effects like PTC/IH or other neurological conditions by the omission, suppression, and concealment of these material facts.

406. Defendant omitted the above information in order to induce Plaintiff, Plaintiff, her healthcare providers, the healthcare community, patients, the FDA, and the public to act by purchasing Mirena.

407. The above omissions were material to the transaction; but for these omissions, Plaintiff would not have purchased Mirena.

408. Defendants had a duty and obligation to disclose to Plaintiff and Plaintiff's healthcare providers that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

409. Defendants had a duty to disclose to Plaintiff and Plaintiff's healthcare providers that Mirena® causes and/or contributes to the development of IH/PTC, and that it can also cause rapid or sudden weight gain, which also contributes to the development

of IH/PTC.

410. Defendants had a duty to disclose to Plaintiff and Plaintiff's healthcare providers that Mirena® is particularly unsafe for use in overweight women of childbearing age, or in women who experience sudden weight gain, who are already at an increased risk of developing IH/PTC.

411. Defendants had a duty to disclose to Plaintiff and Plaintiff's healthcare providers that Mirena® should be removed immediately if a patient using Mirena® is diagnosed with IH/PTC and/or papilledema, and/or develops any of the symptoms, characteristics, or manifestations of either IH/PTC or papilledema.

412. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff and Plaintiff's healthcare providers with the intent to defraud her as alleged herein.

413. Defendants had a duty and obligation to disclose the maximum observed levels of LNG with Mirena, that hormone levels may be as high or higher than hormone levels with other hormonal contraceptives, that hormone levels with Mirena may display peaks and troughs and may not be stable, and that Mirena may cause or contribute to hormonal side effects, including but not limited to developing IH/PTC.

414. Defendants induced Plaintiff and her healthcare providers to choose Mirena by inducing them to believe that Mirena is a low or no hormone product, with few if any hormonal side effects, and which displays stable serum LNG levels without peaks or troughs.

415. Neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

416. Defendants' fraudulent suppression of the above facts induced Plaintiff to use Mirena® and induced Plaintiff's healthcare providers to prescribe the Plaintiff Mirena®.

417. Defendants fraudulently concealed this information from the FDA, the public, patients, physicians, and the healthcare community at large, throughout Defendant's pre- and post- marketing period and continuing to the present.

418. Defendants fraudulently concealed this information when initially obtaining FDA approval, when obtaining a new indication for heavy menstrual bleeding, during Mirena®'s entire post-marketing period, and continuing to the present.

419. Defendants fraudulently concealed this information in advertisements, marketing, commercials, promotional materials, reports, press releases, campaigns, billboards, and instructional material and labeling.

420. Defendants also fraudulently concealed this information in its "Patient Information Booklet" provided to Plaintiff and other Mirena® patients at the time of insertion.

421. Defendants additionally used key opinion leaders, thought leaders and/or sales representatives to conceal this information in representations to physicians, including Plaintiff's physicians, throughout Mirena®'s post-marketing period and prior to Plaintiff's insertion.

422. Defendants made affirmative false representations to the FDA, healthcare providers, Plaintiff and other Mirena® users, and the public at large that Mirena® does not cause neurological conditions like PTC/IH.

423. Defendants fraudulently concealed information regarding nervous system

disorders and neurological disorders like PTC/IH with use of Mirena®.

424. Defendants fraudulently concealed information regarding the symptoms of PTC/IH, including, but not limited to, headaches, a change in headaches, migraines, vision problems, and/or papilledema.

425. Defendants intended to defraud the FDA, prescribing physicians, patients, the public, and Plaintiff and Plaintiff's physicians by fraudulently concealing this information.

426. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

427. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm.

428. Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems appropriate pursuant to the common law and statutory law.

**REQUEST FOR PUNITIVE DAMAGES**

429. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

430. At all times relevant herein, Defendants:

a. knew that Mirena® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena®; and

d. with full knowledge of the health risks associated with Mirena® and without adequate warnings of the same, manufactured, designed, formulated, testing, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® for routine use.

431. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct toward Plaintiff and the public, acted with willful and wanton and/or conscious and/or reckless disregard for the safety of Plaintiff and the general public.

432. Defendants consciously and deliberately engaged in wanton disregard of the rights and safety of the Plaintiff.

433. Defendants had actual knowledge of Mirena®'s defective nature and capacity to cause injury because of its increased risk of developing IH/PTC and Defendants failed to, and continue to fail to take any action to correct the problem.

434. Plaintiff's injuries are a result of fraud, malice, and/or gross negligence on the part of the Defendants.

435. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff is entitled to a recovery of punitive damages.

**WHEREFORE,** Plaintiff demands judgment against the Defendants and requests:

a. A trial by jury;

b. Judgment against Defendants for all compensatory and punitive damages allowable to Plaintiff;

c. Judgment against Defendants for all other relief sought by Plaintiff under

this Complaint;

d. An order for all costs and attorneys' fees; and

e. Such further relief which the Court deems just and appropriate.

Dated: September 4, 2018

Respectfully submitted,

By: [redacted]

[redacted]

*Attorneys for the Plaintiff*