IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

MANDY MITLYNG,

Plaintiff,

v.

BAYER PHARMA AG; BAYER HEALTHCARE PHARMACEUTICALS, INC.; and BAYER OY,

Defendants.

Case No.: 0:16-cv-03492

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

Plaintiff Mandy Mitlyng brings this Complaint against the Defendants for personal injuries suffered as the proximate result of properly using, under prescription and as directed, an unreasonably dangerous product, known as the Mirena ® (levonorgestrel releasing intrauterine system), manufactured, advertised, sold and distributed by Defendants.

PARTIES

1. At all relevant times hereto, Plaintiff was a resident of Dakota County, Minnesota.

2. Upon information and belief, 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. Defendant Bayer can be served with process through its registered agent for service of process in Minnesota: 2345 Rice Street, Suite 230, Roseville, MN 55113.

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

4. At all relevant times, Defendant Bayer Pharma AG has transacted and conducted business in the State of Minnesota and derived substantial revenue from interstate commerce.

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

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

7. Upon information and belief, Defendant Bayer Oy is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, 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 State of Minnesota and derived substantial revenue from interstate commerce

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

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 State of Minnesota through the sale of Mirena® and other prescription drugs in this state.

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 and/or subsidiaries or related entities, the contraceptive device Mirena®.

JURISDICTION AND VENUE

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal place of business in states other than the state in which the named Plaintiff resides.

18. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Dakota County, Minnesota.

FACTS

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

21. Mirena® is an intrauterine system 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.

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

23. 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.

24. Today, more than 2 million women in the United States use Mirena®. Mirena® has been used by more than 15 million women worldwide.

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

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

27. 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.

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

29. The IUS package labeling indicates 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]

30. The package labeling indicates 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]

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

32. 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.

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[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.

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

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

35. Pseudotumor cerebri or idiopathic 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.

36. Patients with PTC or IIH 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 frequently are a result of increased pressure on the optic nerve. Patients with PTC or IIH often develop papilledema, or optic disc swelling due to increased intracranial pressure.

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

38. PTC or IIH 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 IIH, 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.

39. 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 IIH, the cerebrospinal fluid is normal.

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

41. 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 IIH.

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

43. 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 IIH is focused on halting visual loss that has already occurred.

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

45. PTC or IIH may also recur throughout a patient's lifetime.

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

47. Although experts suggest even a 6% body weight loss in patients suffering from PTC/IIH 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.

48. 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.

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

50. 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.

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

52. 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.

53. It has been estimated that approximately 1-2 people per 100,000 in the United States have PTC or IIH, 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, IIH occurred at a rate of approximately 3.3 per 100,000 per year.[4]

[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.

54. Despite the rarity of PTC/IIH, upon information and belief, women who use levonorgestrel-containing products, like the Mirena® IUS, more commonly develop the disorder.[5]

55. Upon information and belief, the synthetic hormone released by Mirena®, levonorgestrel, causes or contributes to the development of PTC/IIH, increases the risk of developing PTC/IIH, and/or worsens or exacerbates PTC/IIH.

56. Additionally, because Mirena® is known to cause rapid weight gain in women, the risk of developing PTC/IIH is even greater with Mirena® use.

57. 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."

58. 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 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.

59. 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

[5] *See* fn. 1

to the physician labeling and the patient package insert. Wyeth requested expedited review of its supplemental NDA.

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

61. The new labeling addition included under the PRECAUTIONS section 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 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."

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

> "Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) – An increase in 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."

63. By 1995, several reports of women developing PTC or IIH were reported in The New England Journal of Medicine.[6] The authors noted levonorgestrel may have contributed to the onset of the condition. The authors concluded until more information became available, patients should be screened for symptoms and the implants should be removed in patients who show increased intracranial pressure.

64. Additional studies concluded the same and noted IIH/PTC had been reported in Norplant users.[7] 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, 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."

65. Jadelle® or "Norplant® II", which is a two-rod levonorgestrel-releasing implant, also contains similar language under the "Warnings" section of its label.[8] And importantly, Jadelle® is contraindicated in patients with a history of IIH.

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[6] *See Id*.

[7] *See* Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficay 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).

[8] *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.

66. 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.

67. Both the Norplant® and Jadelle® labels included warnings of PTC/IIH specific to informing patients of the disorder.

68. 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 Drug Administration requesting withdrawal for sale of Norplant®."[9] The petition claimed a number of adverse events were related to Norplant® use, including PTC/IIH. Wyeth pulled Norplant® off the market in June of 2002.

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

70. Upon information and belief, because Mirena®'s label is devoid of any warnings of PTC or IIH, 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/IIH.

71. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

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

72. In or around December 2009, Defendant was 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.

73. The Simple Style program represented Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states at least 5% of clinical trial patients reported a decreased libido after use.

74. The Simply Style program script also intimated 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.

75. 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®.

76. Finally, Defendant falsely claimed Defendants' product required no compliance with a monthly routine.

PLAINTIFF MANDY MITLYNG DEVELOPED PTC/IIH AFTER USE OF DEFENDANTS' MIRENA

77. Plaintiff Mandy Mitlyng is currently 35 years old.

78. On or around April 9, 2010, Plaintiff had the Mirena® IUS inserted into her body, by her healthcare practitioner, Dr. Leslie Akram, without complication according to the manufacturer's instructions.

79. Plaintiff and her healthcare practitioners relied on Defendants' representations regarding Mirena® in its package insert or otherwise disseminated by Defendant in deciding to use and prescribe Mirena®.

80. After her Mirena® was placed, Plaintiff began experiencing intense headaches, blurred vision, papilledema, and nausea associated with migraine-like headaches.

81. On or around June 23, 2013, Plaintiff sought medical treatment for her symptoms.

82. On or around July 3, 2013, Plaintiff was diagnosed with pseudotumor cerebri by her healthcare provider Dr. Jack E. Hubbard.

83. Leading up to her diagnosis and afterwards, Plaintiff has been prescribed Diamox, undergone a lumbar puncture and MRI, and been to the hospital several times for treatment of her symptoms.

84. Plaintiff's IIH/PTC was caused and/or triggered by her Mirena®, and/or her Mirena® contributed to Plaintiff's development of IIH/PTC.

85. 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 (DESIGN DEFECT)

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

87. Defendant was and is engaged in the business of selling Mirena® in the State of Minnesota.

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

89. 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.

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

91. Defendant 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.

92. 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.

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

94. Defendant knew or should have known 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 IIH/PTC.

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

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

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

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.

98. A reasonable manufacturer would or should have known 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.

99. Defendant knew or should have known Mirena®, and specifically, the synthetic progestin levonorgestrel caused and/or contributed to the development of IIH/PTC, a severe and possibly irreversible brain condition that can also lead to permanent blindness.

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

101. Defendant knew or should have known an additional risk factor for developing IIH/PTC is sudden weight gain—a common side effect of Mirena®, and Defendant 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 IIH/PTC.

102. Defendant, in fact, specifically recommends 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 IIH/PTC.

103. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

104. Plaintiff demands judgment against Defendant for compensatory, and statutory damages, and other 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 – FAILURE TO WARN

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

106. Defendant 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®.

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

108. Defendant failed to adequately warn that Mirena® causes and/or contributes to the development of IIH/PTC.

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

110. Defendant knew or should have known an additional risk factor for developing IIH/PTC is sudden weight gain—a common side effect of Mirena®, and Defendant 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 IIH/PTC.

111. Defendant knew or should have known women of childbearing age, overweight women, and women with sudden weight gain, are at a higher risk of developing IIH/PTC, and yet Defendant 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.

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

113. 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 IIH/PTC.

114. Mirena® was under the exclusive control of Defendant 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/IIH.

115. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

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

117. Mirena® was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert Plaintiff or her doctor to the dangerous risks and reactions associated with it. Even though Defendant knew or should have known of the risks associated with Mirena®, it failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

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

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

120. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field and, further, Defendant had knowledge of the dangerous risks and side effects of Mirena®, including the risks of developing IIH/PTC.

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

122. Plaintiff and her healthcare practitioners relied upon the Defendants' representations regarding Mirena® in the package insert or otherwise disseminated by the Defendant.

123. Defendant 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, Defendant breached its duties.

124. Although Defendant knew, or was reckless in not knowing, of the defective nature of Mirena®, it 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®.

125. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

126. Plaintiff demands judgment against Defendant for compensatory, statutory damages, and other 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 – STRICT LIABILITY

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

128. Defendant is a manufacturer and/or supplier of Mirena® and is 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.

129. Defendant is 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.

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

131. Mirena®, manufactured and/or supplied by Defendant, 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.

132. 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.

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

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

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

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

137. Defendant breached its duty to warn Plaintiff of Mirena®'s dangers because Defendants' warnings were inadequate and Defendant failed to warn entirely of the risks of developing IIH/PTC with use of Defendants' Mirena®.

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

139. Mirena® was also defective due to inadequate pre-marketing testing.

140. Despite Defendants' knowledge of the risks associated with levonorgestrel-releasing implants, including the development of IIH/PTC, Defendant did not adequately conduct pre-market testing to account for the risks.

141. Defendant 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.

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

143. Defendant continues to fail to warn of the risk of developing IIH/PTC with use of Mirena®.

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

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

146. 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.

147. 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 Defendant.

148. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

149. Plaintiff demands judgment against Defendant for compensatory, statutory damages, and other 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 – BREACH OF IMPLIED WARRANTY

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

151. Defendant 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®.

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

153. Plaintiff relied on the skill and judgment of the Defendant, and as such, its implied warranty, in using Mirena®.

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

155. 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 IIH/PTC, a foreseeable risk, which Defendant knew or should have known of.

156. 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 Defendant inadequately warned of the risks of developing IIH/PTC and/or papilledema, and/or

that the Mirena® should be removed once these conditions, and/or symptoms of these conditions, develop.

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

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

159. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

160. Plaintiff demands judgment against Defendant for compensatory, statutory, and other 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 EXPRESS WARRANTY

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

162. 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 Defendant for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendant had knowledge of the foreseeable purposes for

which Mirena® was to be used and Defendant warranted Mirena® to be in all respects safe, effective and proper for such purposes.

163. 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 IIH/PTC, and rapid and sudden weight gain, which also contributes to the risk of developing IIH/PTC.

164. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

165. Plaintiff demands judgment against Defendant for compensatory, and statutory 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 – NEGLIGENT MISREPRESENTATION

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

167. Defendant, 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®.

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

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

170. These misrepresentations were made by Defendant with the intent to induce Plaintiff to use Mirena®, which Plaintiff was induced and did act, and which caused injury.

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

172. Defendant breached its duties to Plaintiff by providing false, incomplete and/or misleading information regarding its product.

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

174. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

175. Plaintiff demands judgment against Defendant for compensatory, and statutory 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 – FRADULENT MISREPRESENTATION

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

177. Defendant, 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®.

178. Defendant 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 IIH/PTC, that it should be removed immediately upon diagnosis with papilledema and/or IIH/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.

179. Defendant fraudulently misrepresented 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 IIH/PTC.

180. Defendant fraudulently misrepresented 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 IIH/PTC.

181. 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.

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

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

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

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

186. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

187. Plaintiff demands judgment against Defendant for compensatory, and statutory 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 – FRAUD BY SUPPRESSION AND CONCEALMENT

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

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

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

191. Defendant had a duty to disclose to Plaintiff and Plaintiff's healthcare providers 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 IIH/PTC.

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

193. Defendant 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.

194. 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.

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

196. 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.

197. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, 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.

198. Plaintiff demands judgment against Defendant for compensatory, and statutory 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 – UNJUST ENRICHMENT

199. Plaintiff restate the allegations set for above as if fully rewritten herein.

200. Defendants have enjoyed enormous revenues from sales of Mirena®.

201. It is unjust to allow Defendants to earn revenues and retain the benefits and profits from Mirena® while Plaintiff suffered injuries and damages as stated herein.

COUNT X – VIOLATION OF THE MINNESOTA FALSE ADVERTISING ACT

202. Plaintiff restate the allegations set forth above as if fully rewritten herein, and further alleges as follows:

203. The Minnesota False Advertising Act, Minn. Stat. § 325F.67, states:

> Any person, firm, corporation, or association who, with intent to sell . . . anything offered by such person, firm, corporation, or association, directly or indirectly, to the public, for sale or distribution, or with intent to increase the consumption thereof, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or any interest therein . . . places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, . . . an advertisement of any sort regarding . . . anything so offered to the public, for use, consumption, purchase, or sale, which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall . . . be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

204. As described in the preceding paragraphs of this Complaint, in advertising Mirena® through various means in Minnesota, including but not limited to television, radio, internet, the products label, pamphlets, and letters, Defendants made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

205. Defendants' campaign was widespread, reaching all corners of Minnesota.

206. Upon information and belief, Defendants knew that their assertions, representations, and/or statements of fact were false when they made them, thus intending to defraud Plaintiff, other consumers, and the medical community by inducing them to purchase Mirena®.

207. Plaintiff and her physicians were induced by those misrepresentations, causing them to purchase Mirena® and use for birth control methods.

208. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from PTC/IIH. Plaintiff has therefore suffered damages as a result of using Mirena®. Plaintiff has also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff's direct medical losses and costs include care for physician care, monitoring,

treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

209. Where, as here, Plaintiff claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiff to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325F.67, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325F.67.

COUNT XI – VIOLATION OF THE MINNESOTA UNLAWFUL TRADE PRACITICES ACT

210. Plaintiff reinstates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

211. Section 325D.13 of the Minnesota Unlawful Trade Practices Act states "[n]o person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients, or origin of such merchandise."

212. Mirena® qualifies as "merchandise" within the meaning of the Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.10.

213. Defendants qualify as "persons" within the meaning of the Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.10.

214. As described in preceding paragraphs, Defendants did not disclose the Mirena® would cause PTC/IIH in patients prescribed this birth control product, including Plaintiff.

215. Rather than disclosing that information to Plaintiff and her physicians, Defendants knowingly misrepresented the quality of the Mirena® in numerous ways:

a. Representing through statements and advertisements that Mirena® has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that Mirena® is of a particular standard, quality, or grade when it differs materially from that representation; and

c. Representing through statements and advertisements that Mirena® has uses, benefits, or characteristics that have been otherwise proven incorrect.

216. Defendants therefore knowingly misrepresented, in connection with the sale of Mirena®, the true quality of Mirena®.

217. Plaintiff and her physicians were induced by those misrepresentations, causing them to purchase Mirena® and use the medical device as their method of birth control.

218. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered intense headaches, blurred vision, papilledema, and nausea. Plaintiff has therefore suffered damages and will continue to incur medical expenses as a result of using Mirena®. Plaintiff has also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff's direct medical losses and costs include care for physician care, monitoring,

treatment, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

219. Where, as here, Plaintiff's claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiff to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325D.15, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; and, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325D.15.

COUNT XII – VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICES ACT

220. Plaintiff restates the allegations set forth above as if fully rewritten herein.

221. The Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.44, provides a private cause of action when a business causes a likelihood of confusion as to the certification of goods or services; represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have; represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; advertises

goods or services with intent not to sell them as advertised; or engages in any other conduct which creates a likelihood of confusion among consumers.

222. Defendants caused a likelihood of confusion as to the quality, benefit, sponsorship, approval, characteristics, and use of the Mirena® in the following ways:

a. Representing through statements and advertisements that the Mirena® has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Mirena® is of a particular standard, quality, or grade when it differs materially from that representation; and

c. Representing through statements and advertisements that the Mirena® has uses, benefits, or characteristics that have been otherwise proven incorrect.

223. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered intense headaches, blurred vision, papilledema, and nausea, requiring additional medical evaluation and treatment. Plaintiff has therefore suffered damages and will continue to incur medical expenses as a result of using Mirena®. Plaintiff has also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, pursuant to Section 325D.45 of the Minnesota Trade Practices Act, Plaintiff is entitled to injunctive relief, costs, and attorneys' fees, as requested below.

COUNT XIII – VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

224. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein, and further alleges as follows:

225. Defendants have a statutory duty to refrain from making false and/or fraudulent representations and/or from engaging in deceptive acts or practices in the sale and promotion of Mirena® pursuant to the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. §§ 325F.69, et seq.;

226. Defendants engaged in unfair, deceptive, false, and/or fraudulent acts and/or trade practices in violation of the Minnesota Prevention of Consumer Fraud Act, including, but not limited to:

a. Publishing instructions and product material containing inaccurate and incomplete factual information regarding Mirena®.

b. Misrepresenting the nature, quality, and characteristics of Mirena®.

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding;

d. Misrepresenting the alleged benefits of Mirena®;

e. Failing to disclose material information concerning known side effects of Mirena®;

f. Misrepresenting the quality of Mirena®; and

g. Uniformly communicating the purported benefits of Mirena® while failing to disclose the serious and dangerous side-effects related to the use of Mirena® and its safety, efficacy, and usefulness.

227. Defendants' conduct in connection with Mirena ® was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely, and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of Mirena®.

228. These deceptive trade practices occurred in the course of Defendants' business.

229. These deceptive trade practices significantly impacted Plaintiff and the public as actual or potential consumers of Defendants' product Mirena®.

230. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.

231. Plaintiff was an actual consumer of Defendants' product Mirena®.

232. Defendants' conduct as described above was a material cause of Plaintiff's decision to purchase Mirena®.

233. As a direct, foreseeable, and proximate cause of Defendants' deceptive trade practices, Plaintiff suffered actual damages, including personal injuries, economic damages, and non-economic damages.

234. Defendants conduct was wanton, egregious, and reckless.

235. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss

and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

236. Where, as here, Plaintiff claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiff to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325F.67, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325F.67.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants and each of them, individually and jointly and severally, and requests:

1. Compensatory damages;
2. Statutory damages and relief;
3. Costs and expenses of this litigation;
4. Reasonable attorneys' fees and costs as provided by law;
5. Equitable relief in the nature of disgorgement;
6. Restitution to remedy Defendants' unjust enrichment; and
7. All other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demand a trial by jury of all claims in this Complaint so triable.

Respectfully submitted,

By: */s/ David M. Langevin*

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JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Mandy Mitlyng

(b) County of Residence of First Listed Plaintiff Dakota
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
McSweeney/Langevin
2116 2nd Ave. S.
Minneapolis, MN 55404 612-746-4646

DEFENDANTS
Bayer Pharma AG, et al

County of Residence of First Listed Defendant Out of State Corporation
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
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- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

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- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

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- ☐ 465 Other Immigration Actions

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- ☐ 423 Withdrawal 28 USC 157

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- ☐ 830 Patent
- ☐ 840 Trademark

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- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
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- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
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- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332
Brief description of cause:
Plaintiff is alleging personal injury caused by using Defendants' product.

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY
(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/14/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/David M. Langevin

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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