**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**
**WESTERN DIVISION**

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| **CAROLYN FERRARA**,<br><br>**Plaintiff,**<br><br>v.<br><br>**BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, and BAYER OY,**<br><br>**Defendants.** | **Case No. _____**<br>**Hon.**<br><br>**JURY TRIAL DEMANDED** |

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## COMPLAINT

Plaintiff Carolyn Ferrara ("Plaintiff"), by and through her undersigned attorneys, hereby brings this cause of action for personal injuries suffered as a proximate result of Plaintiff being prescribed and using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all relevant times, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Bayer Healthcare Pharmaceuticals, Inc. ("Bayer"), Bayer Pharma AG, and Bayer Oy.

## PARTIES AND CITIZENSHIP

1. At all relevant times, Plaintiff was a resident and citizen of Berkshire County in the Commonwealth of Massachusetts.

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 6 West Belt Rd., Wayne, New Jersey 07470. Defendant Bayer can be served with process through its registered agent for service of process in Massachusetts, Corporation Service Company, 84 State St., Boston, MA 02109.

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

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

5. Upon information and belief, Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for contraceptive device Mirena.

6. Upon information and belief, Defendant Bayer Pharma AG f/k/a Bayer Schering Pharma AG is, and at all relevant times, was a global pharmaceutical corporation organized under the laws of Germany.

7. Upon information and belief, Defendant Bayer Pharma AG f/k/a Bayer Schering Pharma AG has transacted and conducted business in the Commonwealth of Massachusetts and derived substantial revenue from interstate commerce.

8. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG f/k/a Bayer Schering Pharma AG expected or should have expected that its acts would have consequences within the United States of America, and the Commonwealth of Massachusetts in particular, and derived substantial revenue from interstate commerce.

9. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG f/k/a Bayer Schering Pharma AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Mirena ® for use as an intrauterine contraceptive device.

10. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG f/k/a Bayer Schering Pharma AG was formerly known as Schering AG and is the same corporate entity as Schering AG.

11. Upon information and belief, effective July 1, 2011, Bayer Schering Pharma AG was renamed Bayer Pharma AG. Bayer Pharma AG is the same corporate entity as Bayer Schering Pharma AG.

12. 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.

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

14. Upon information and belief, at all relevant times, Defendant Bayer Oy has transacted and conducted business in the Commonwealth of Massachusetts and derived substantial revenue from interstate commerce.

15. Upon information and belief, 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 Commonwealth of Massachusetts in particular, and derived substantial revenue from interstate commerce.

16. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, division, franchises, partners, joint ventures, and organizational

units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

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

18. At all relevant times, Defendants were engaged in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and healthcare products for women, including the intrauterine contraceptive system, Mirena®.

19. Defendants do business in Massachusetts through the sale of Mirena® and other prescription drugs in the state.

20. At all relevant times, Defendants engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and 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

21. 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 Defendants are incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

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

23. 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 claim occurred, in part, in the District of Massachusetts.

**FACTS**

24. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

25. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 milligrams per day of levonorgestrel, a prescription medication used as a contraceptive.

26. The Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. Fifteen million women worldwide used Mirena®.

27. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admit "[i]t is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

28. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first 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 system must be discarded and a new one inserted.

29. The package labeling recommends Mirena® be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after Mirena use.

30. Mirena®'s label does not warn about spontaneous migration of the IUS, but only states migration may occur if the uterus is perforated during insertion.

31. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

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

33. In or around December 2009, Defendants received a communique from the Department of Health and Human Services, Division of Drug Marketing, Advertising, and Communications (DDMAC). It related to a Bayer's consumer directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple 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.

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

35. The Simple Style program script also intimated Mirena® use helps patients "[l]ook and feel great." Again, DDMAC noted these claims were unsubstantiated and Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

36. 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®.

37. Finally, Defendants falsely claimed that Defendants' product required no periodic check-up or monthly routine.

38. Plaintiff Carolyn Ferrara was born January 22, 1986.

39. Plaintiff's provider, Susan J. Yates, MD, inserted the Mirena® IUS on or about August 18, 2011, in the city of North Adams at Northern Berkshire Healthcare. While she suffered some mild discomfort, the insertion was uncomplicated.

40. After suffering extreme pain, on or about December 13, 2013, Plaintiff underwent laparoscopy to remove her Mirena IUD in the city of North Adams at North Adams Regional Hospital by Charles O'Neill, MD.

41. This procedure carries with it risks, such as adverse reaction to anesthesia, infection, perforation of other organs, and adhesion formation, to name a few.

42. The procedure was necessary because the device had perforated the anterior rightward aspect of pelvis.

## FIRST CAUSE OF ACTION
## DEFECTIVE MANUFACTURING

43. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

44. Defendants were and are engaged in the business of selling Mirena® in the Commonwealth of Massachusetts.

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

46. Defendants introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefor. The unreasonably dangerous nature of Mirena® caused serious harm to Plaintiff.

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

48. As a direct and proximate result of Plaintiff's Mirena® usage, she was forced to undergo surgical removal of the IUS, developed severe pain from the device, developed an infection, and had to undergo numerous procedures.

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

50. Defendants knew and, in reality, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendants' advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

51. Despite the fact that evidence existed that using Mirena® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Mirena® and in fact acted to deceive the

medical community and public at large, including all potential users of Mirena® by promoting it as safe and effective.

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

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

54. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

**SECOND CAUSE OF ACTION**
**DESIGN DEFECT**

55. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

56. Defendants were and are engaged in the business of selling Mirena® in the Commonwealth of Massachusetts.

57. The Mirena® 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.

58. The foreseeable risks associated with the design or formulation of the 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 or reasonably foreseeable manner.

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

60. As a direct and proximate cause of Plaintiff's Mirena® usage, she was forced to undergo surgical removal of the Mirena®, developed severe pain, suffered from infection, and underwent numerous procedures.

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

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

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

64. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

**THIRD CAUSE OF ACTION**
**NEGLIGENCE**

65. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges:

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

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

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

c. failed to conduct sufficient postmarket testing and surveillance of Mirena®;

d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm that 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 Defendants knew or should have known of its adverse effects.

67. A reasonable manufacturer would or should have known that the risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or in part for the increased risk.

As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, the Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

**FOURTH CAUSE OF ACTION**
**FAILURE TO WARN**

68. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth, herein, and further alleges as follows:

69. Mirena® is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post-insertion, or the possibility that device complications, such as migration and perforation, may cause abscesses, infections, surgery for removal, and hysterectomy, oophorectomy, and other complications.

70. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, sold and otherwise released into the stream of commerce the pharmaceutical, Mirena® and 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®.

71. 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 given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

72. Defendants downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendants placed its profits above its customer's safety.

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

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

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

76. Defendants, as manufacturers of pharmaceuticals, are held to the level of knowledge of an expert in the field; moreover, Defendants knew of the dangerous risks and side effects of Mirena®.

77. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physicians.

78. 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 wantonly failing to adequately warn of the dangers associated with its use. Defendants breached their duty.

79. Although Defendants knew, or should have known, 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 warning 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®.

80. As a direct and proximate result of one more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues incurring medical and hospital expenses.

**FIFTH CAUSE OF ACTION:**
**STRICT LIABILITY**

81. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

82. Defendants manufacture and supply 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.

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

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

85. 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 perforation and migration and associated infections or conditions and Defendant failed to adequately warn of these risks.

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

87. Defendants failed to provide adequate initial warnings and post-marketing warnings and/or instructions after the manufacturer and 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.

88. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

**SIXTH CAUSE OF ACTION:**
**BREACH OF IMPLIED WARRANTY**

89. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

90. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold Mirena® as safe for the public at large, including Plaintiff, who purchased Mirena®. Defendants knew the use for which its product was intended and impliedly warranted the product to be of merchantable quality, safe, and fit for use.

91. Plaintiff reasonably relied on the skill and judgment of Defendants, and as such, its implied warranty in using Mirena®.

92. Contrary to this warranty, Mirena® was 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 used.

93. As a direct and proximate result of Defendants' wrongful acts and omission, Plaintiff suffered profound injuries, required medical treatment, and incurred, and continues to incur, medical and hospital expenses.

**SEVENTH CAUSE OF ACTION:**
**BREACH OF EXPRESS WARRANTY**

94. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

95. The aforementioned manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, 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 making these express warranties, Defendants knew 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 use.

96. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

97. As a direct and proximate result of one or more of these wrongful acts or omissions, Plaintiff suffered profound injuries, required medical treatment, and incurred, and continues to incur, medical and hospital expenses

**EIGHTH CAUSE OF ACTION:**
**FRAUDULENT MISREPRESENTATION**

98. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

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

100. Defendants fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

101. 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.

102. Defendants knew this information to be false, incomplete, and misleading.

103. Defendants intended to deceive and mislead Plaintiff so that she might rely on these fraudulent misrepresentations.

104. Plaintiff had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate, and fraudulent misrepresentations.

105. As a direct and proximate result of one or more of these wrongful acts or omissions, Plaintiff suffered profound injuries, required medical treatment, and incurred, and continues to incur, medical and hospital expenses.

**NINTH CAUSE OF ACTION:**
**FRAUD BY CONCEALMENT**

106. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

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

108. Defendants intentionally, willfully, and maliciously concealed and suppressed the facts set forth above from Plaintiff with the intent to defraud her as alleged in this complaint.

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

110. As a proximate result of the concealment and suppression of the facts set forth above, Plaintiff proximately sustained damages as described above.

111. As a direct and proximate result of one or more of these wrongful acts or omissions, Plaintiff suffered profound injuries, required medical treatment, and incurred, and continues to incur, medical and hospital expenses.

**REQUEST FOR PUNITIVE DAMAGES**

112. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

113. At all relevant times, Defendants:

a. Knew that Mirena® was dangerous and defective;

b. Concealed the dangers and health risks from Plaintiff, her physicians, pharmacists, and 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, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold Mirena® for routine use.

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

115. As a direct and proximate result of one more of these wrongful acts or omissions, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Defendants are liable.

## PRAYER FOR RELIEF

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

## JURY DEMAND

Plaintiff demands a trial by jury as to all issues.

Dated: March 19, 2015

Respectfully submitted,

/s/ Kimberly Dougherty

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