GERAGOS & GERAGOS
A PROFESSIONAL CORPORATION
LAWYERS
HISTORIC ENGINE CO. NO. 28
644 SOUTH FIGUEROA STREET
LOS ANGELES, CALIFORNIA 90017-3411
TELEPHONE (213) 625-3900
FACSIMILE (213) 625-1600
GERAGOS@GERAGOS.COM
MARK J. GERAGOS SBN 108325
SHELLEY KAUFMAN SBN 100696

CLIMACO, WILCOX, PECA,
TARANTINO & GAROFOLI CO., LPA
55 Public Square, Suite 1950
Cleveland, Ohio 44113
Tel: 216.621.8484
JOHN R. CLIMACO (OH # 0011456)
jrclim@climacolaw.com
DAWN M. CHMIELEWSKI (OH #0077723)
dxchmi@climacolaw.com
MARGARET M. METZINGER (OH#0065624)
mmmetz@climacolaw.com
Pro Hac Vice Application to be filed
Attorneys for Plaintiffs MELODY WILLIAMS and RONAIL WILLIAMS

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

MELODY AND RONAIL WILLIAMS,

Plaintiffs,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant.

Case No: **'12CV2669 CAB DHB**

COMPLAINT FOR:
(1) DEFECTIVE MANUFACTURING
(2) DESIGN DEFECT
(3) NEGLIGENCE
(4) FAILURE TO WARN
(5) STRICT LIABILITY
(6) BREACH OF IMPLIED WARRANTY
(7) BREACH OF EXPRESS WARRANTY
(8) NEGLIGENT MISREPRESENTATION
(9) FRAUDULENT MISREPRESENTATION
(10) FRAUD BY CONCEALMENT
(11) LOSS OF CONSORTIUM
WITH JURY DEMAND

INTRODUCTION

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

JURISDICTION AND VENUE

1. 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 places of business in states other than the state in which the named Plaintiff resides.

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

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Southern District of California.

PARTIES AND CITIZENSHIP

1. Plaintiffs Melody Williams and Ronail Williams (collectively "Plaintiffs") are, and at all relative times were, husband and wife.

2. At all relevant times hereto, Plaintiffs were residents and citizens of San Diego, California.

3. 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 Road, Wayne, New Jersey 07470. Defendant Bayer

Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in California, Corporation Service Company, 2710 Gateway Oaks Dr, Suite 150N, Sacramento, California 95833.

4. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

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

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

7. Bayer is 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®.

8. Bayer does business in California through the sale of Mirena® and other prescription drugs in the state.

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

FACTS

10. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

11. 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 μg/day of levonorgestrel, a prescription medication used as a contraceptive.

12. The federal 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®. It has been used by more than 15 million women worldwide.

13. The system releases levonorgestrel, a synthetic progestrogen, directly into the uterus for birth control. Defendants admit it 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.

14. The Mirena® intrauterine system ("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 system must be discarded and a new one inserted.

15. The package labeling recommends that Mirena® be used in women who have had at least one child.

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

17. 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.

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

19. 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 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 settings by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

20. This Simple Style program represented that 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 that at least 5% of clinical trial patients reported a decreased libido after use.

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

22. 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®.

23. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

24. Plaintiff Melody Williams is currently 32 years-old.

25. Plaintiff had the Mirena® IUS inserted on January 7, 2010 at West Coast Obstetrics & Gynecology Associates. While she suffered some mild discomfort and bleeding, the insertion was uncomplicated.

26. Following the Mirena® insertion, Plaintiff self-checked the strings on the Mirena®, finding them to be present.

27. On or about November 14, 2010, Plaintiff was seen in the Emergency Department at Sharp Memorial Hospital for foot and ankle pain after a fall. She also complained of cramping and lower abdominal pain that had started the day before, along with hematuria.

28. A CT scan of the abdomen was performed, which revealed a left ovarian cyst and an IUS which appeared to have eroded through the wall of the uterus.

29. A pelvic exam was performed and the Mirena® strings were visualized. However, attempts at removal of Mirena® in the ED were unsuccessful. Plaintiff was sent home on antibiotics and was to follow up with her physician.

30. On December 28, 2010, Plaintiff underwent surgery at Sharp Mary Birch Hospital for Women & Newborns. Under general anesthesia, the IUS was removed. It had migrated through the opening of Plaintiff's right fallopian tube (ostia).

FIRST CAUSE OF ACTION:

DEFECTIVE MANUFACTURING

31. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

32. Defendant was and is engaged in the business of selling Mirena® in the State of California.

33. 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 Melody Williams without substantial change in the condition in which it was sold.

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

35. Defendants manufactured, marketed, promoted 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 Melody Williams.

36. As a direct and proximate result of Plaintiff Melody Williams' use of Mirena®, 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.

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

38. Defendant knew and, in fact, 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 the Defendant's advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

39. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with the 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.

40. Defendant 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.

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

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

SECOND CAUSE OF ACTION:

DESIGN DEFECT

43. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

44. Defendants were and are engaged in the business of selling Mirena® in the State of California.

45. 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 Melody Williams without substantial change in the condition in which it was sold.

46. 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.

47. 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 Melody Williams.

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

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

50. Defendant 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.

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

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

THIRD CAUSE OF ACTION:

NEGLIGENCE

53. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

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

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-market testing and surveillance of Mirena®;

d. designed, manufactured, marketed, 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 Defendants knew or should have known of its adverse effects.

55. A reasonable manufacturer would or should have known that its 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 part for the increased risk.

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

FOURTH CAUSE OF ACTION:

FAILURE TO WARN

57. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

58. Mirena® is a defective and therefore an 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, require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

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

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

61. 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.

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

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

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

65. Defendant, as manufacturers of pharmaceutical drugs, are 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®.

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

67. Defendant had a continuing duty to warn consumers, including Plaintiff Melody Williams 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 their duty.

68. Although Defendant knew, or were reckless in not knowing, of the defective nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, 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®.

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

/ / /

/ / /

FIFTH CAUSE OF ACTION:

STRICT LIABILITY

70. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

71. Defendants is a manufacturer and/or supplier of Mirena® and are strictly liable to Plaintiffs for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

72. 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 suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

73. 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 the design or formulation.

74. 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 the Defendants failed to adequately warn of these risks.

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

76. 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.

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

SIXTH CAUSE OF ACTION:

BREACH OF IMPLIED WARRANTY

78. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

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

80. Plaintiff Melody Williams reasonably relied on the skill and judgment of the Defendant, and as such their implied warranty, in using Mirena®.

81. Contrary to same, 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 was used.

82. As a direct and proximateresult of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Melody Williams suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

SEVENTH CAUSE OF ACTION:

BREACH OF EXPRESS WARRANTY

83. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

84. 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 Melody Williams 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.

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

86. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Melody Williams suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

EIGHTH CAUSE OF ACTION:

NEGLIGENT MISREPRESENTATION

87. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

88. 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®.

89. Defendant falsely represented to Plaintiff Melody Williams that Mirena® was a safe and effective contraceptive option. The representations by Defendant were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

90. At the time the aforesaid representations were made, Defendant concealed from Plaintiff Melody Williams and her health care providers, information about the propensity of Mirena® to cause great harm. Defendant negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

91. These misrepresentations were made by Defendant with the intent to induce Plaintiff Melody Williams to use Mirena®, which caused her injury.

92. At the time of Defendant's misrepresentations and omissions, Plaintiff Melody Williams was ignorant of the falsity of these statements and reasonably believed them to be true.

93. Defendant breached their duties to Plaintiff Melody Williams by providing false, incomplete and/or misleading information regarding their product. Plaintiff Melody Williams reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena®.

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

NINTH CAUSE OF ACTION:

FRAUDULENT MISREPRESENTATION

95. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

96. 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®.

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

98. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff Melody Williams was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

99. Defendant knew this information to be false, incomplete and misleading.

100. Defendant intended to deceive and mislead Plaintiff Melody Williams so that she might rely on these fraudulent misrepresentations.

101. Plaintiff Melody Williams had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

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

WHEREFORE, Plaintiffs demand 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 the common law and statutory law.

TENTH CAUSE OF ACTION:

FRAUD BY CONCEALMENT

103. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

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

105. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff Melody Williams with the intent to defraud her as herein alleged.

106. Neither Plaintiff Melody Williams 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.

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

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

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

/ / /

/ / /

ELEVENTH CAUSE OF ACTION:

LOSS OF CONSORTIUM

109. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

110. Plaintiff Ronail Williams is the husband of Melody Williams.

111. As a result of the medical conditions developed by his wife and the medical treatment and hospitalization that she endured, Plaintiff Ronail Williams:

a. lost a substantial measure of his wife's household services; and

b. lost, and will continue to lose in the future, a substantial measure of his wife's consortium.

112. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Ronail Williams suffered injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

113. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

114. At all times relevant herein, Defendant:

a. knew that Mirena® was dangerous and ineffective;

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

c. made misrepresentations to Plaintiff Melody Williams, 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.

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

116. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Melody Williams suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

WHEREFORE, Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

/ / /

/ / /

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant 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 the common law and statutory law.

DATED: November 2, 2012

GERAGOS & GERAGOS, APC
CLIMACO, WILCOX, PECA,
TARANTINO & GAROFOLI CO., LPA

By: */S/Mark J.Geragos*
MARK J. GERAGOS
geragos@geragos.com
Attorneys for Plaintiffs
MELODY WILLIAMS and
RONAIL WILLIAMS

JURY DEMAND

A jury trial is requested.

DATED: November 2, 2012

GERAGOS & GERAGOS, APC
CLIMACO, WILCOX, PECA,
TARANTINO & GAROFOLI CO., LPA

By: */S/Mark J.Geragos*
MARK J. GERAGOS
geragos@geragos.com
Attorneys for Plaintiffs
MELODY WILLIAMS and
RONAIL WILLIAMS

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

'12CV2269 CAB DHB

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
MELODY AND RONAIL WILLIAMS,

(b) County of Residence of First Listed Plaintiff San Diego, California
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
MARK J. GERAGOS SBN 108325
GERAGOS & GERAGOS, APC
644 S. Figueroa Street, Los Angeles, California 90017 (213) 625-3900

DEFENDANTS
BAYER HEALTHCARE PHARMACEUTICALS INC.,

County of Residence of First Listed Defendant Wayne, New Jersey
(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)*

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 400 State Reapportionment
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 410 Antitrust
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 430 Banks and Banking
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 450 Commerce
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 460 Deportation
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Mgmt. Relations	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Med. Malpractice		☐ 791 Empl. Ret. Inc. Security Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
☐ 196 Franchise				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	☐ 510 Motions to Vacate Sentence	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 220 Foreclosure	☐ 441 Voting	Habeas Corpus:	☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)	☐ 871 IRS—Third Party 26 USC 7609	☐ 896 Arbitration
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 530 General	☐ 465 Other Immigration Actions		☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			
	☐ 448 Education	☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

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

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:
Defective Manufacturing, Breach of Express Warranty, Fraudulent Misrepresentation and Loss of Consortium.

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

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

DATE 11/02/2012
SIGNATURE OF ATTORNEY OF RECORD /S/ Mark J. Geragos

FOR OFFICE USE ONLY

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