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23 *Pro Hac Vice* Application to be filed

24 Attorneys for Plaintiffs MELODY WILLIAMS and RONAIL WILLIAMS

25 **IN THE UNITED STATES DISTRICT COURT**

26 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

27 **MELODY AND RONAIL WILLIAMS,**

28 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**

1 **INTRODUCTION**

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

10 **JURISDICTION AND VENUE**

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

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

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

20 **PARTIES AND CITIZENSHIP**

21 1. Plaintiffs Melody Williams and Ronail Williams (collectively
22 “Plaintiffs”) are, and at all relative times were, husband and wife.

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

25 3. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation
26 organized and existing under the laws of the State of Delaware, having a principal
27 place of business at 6 West Belt Road, Wayne, New Jersey 07470. Defendant Bayer
28

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

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

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

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

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

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

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

22
23 **FACTS**

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

26 11. Mirena® is an intrauterine system that is inserted by a healthcare
27 provider during an office visit. Mirena® is a T-shaped polyethylene frame with a
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1 steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication
2 used as a contraceptive.

3 12. The federal Food and Drug Administration (FDA) approved Defendants'
4 New Drug Application for Mirena® in December 2000. Today, more than 2 million
5 women in the United States use Mirena®. It has been used by more than 15 million
6 women worldwide.

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

11 14. The Mirena® intrauterine system ("IUS") is designed to be placed within
12 seven (7) days of the first day of menstruation and is approved to remain in the uterus
13 for up to five (5) years. If continued use is desired after five years, the old system
14 must be discarded and a new one inserted.

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

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

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

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

24 19. In or around December 2009, Defendant was contacted by the
25 Department of Health and Human Services' Division of Drug Marketing, Advertising,
26 and Communications (DDMAC) regarding a consumer-directed program entitled
27 "Mirena Simple Style Statements Program," a live presentation designed for "busy
28 moms." The Simple Style program was presented in a consumer's home or other

1 private settings by a representative from “Mom Central”, a social networking internet
2 site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

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

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

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

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

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

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

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

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

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

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

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

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8 **FIRST CAUSE OF ACTION:**

9 **DEFECTIVE MANUFACTURING**

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

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

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

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

22 35. Defendants manufactured, marketed, promoted and sold a product that
23 was not merchantable and/or reasonably suited to the use intended, and its condition
24 when sold was the proximate cause of the injuries sustained by the Plaintiff Melody
25 Williams.

26 36. As a direct and proximate result of Plaintiff Melody Williams' use of
27 Mirena®, she was forced to undergo surgical removal of the IUS, developed severe
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1 pain from the device, developed an infection, and had to undergo numerous
2 procedures.

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

5 38. Defendant knew and, in fact, advertised and promoted the use of
6 Mirena® despite their failure to test or otherwise determine the safety and efficacy of
7 such use. As a direct and proximate result of the Defendant's advertising and
8 widespread promotional activity, physicians began commonly prescribing this product
9 as safe and effective.

10 39. Despite the fact that evidence existed that the use of Mirena® was
11 dangerous and likely to place users at serious risk to their health, Defendant failed to
12 disclose and warn of the health hazards and risks associated with the Mirena® and in
13 fact acted to deceive the medical community and public at large, including all
14 potential users of Mirena® by promoting it as safe and effective.

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

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

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

25 WHEREFORE, Plaintiffs demand judgment against Defendant for
26 compensatory, statutory and punitive damages, together with interest, costs of suit,
27 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
28 common law and statutory law.

SECOND CAUSE OF ACTION:
DESIGN DEFECT

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

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

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

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

16 47. Defendant manufactured, designed, formulated, tested, packaged,
17 labeled, produced, created, made, constructed, assembled, marketed, advertised,
18 distributed and sold a product that was not merchantable and/or reasonably suited to
19 the use intended, and its condition when sold was the proximate cause of the injuries
20 sustained by the Plaintiff Melody Williams.

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

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

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

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

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

9 WHEREFORE, Plaintiffs demand judgment against Defendant for
10 compensatory, statutory and punitive damages, together with interest, costs of suit,
11 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
12 common law and statutory law.

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14 **THIRD CAUSE OF ACTION:**

15 **NEGLIGENCE**

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

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

- 20 a. failed to properly and thoroughly test Mirena® before releasing the
21 drug to market;
- 22 b. failed to properly and thoroughly analyze the data resulting from
23 the premarketing tests of Mirena®;
- 24 c. failed to conduct sufficient post-market testing and surveillance of
25 Mirena®;
- 26 d. designed, manufactured, marketed, advertised, distributed, and
27 sold Mirena® to consumers, including Plaintiff, without an
28 adequate warning of the significant and dangerous risks of

- 1 Mirena® and without proper instructions to avoid the harm which
2 could foreseeably occur as a result of using the drug;
- 3 e. failed to exercise due care when advertising and promoting
4 Mirena®; and
- 5 f. negligently continued to manufacture, market, advertise, and
6 distribute Mirena® after Defendants knew or should have known
7 of its adverse effects.

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

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

16 WHEREFORE, Plaintiffs demand judgment against Defendant for
17 compensatory, statutory and punitive damages, together with interest, costs of suit,
18 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
19 common law and statutory law.

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21 **FOURTH CAUSE OF ACTION:**

22 **FAILURE TO WARN**

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

25 58. Mirena® is a defective and therefore an unreasonably dangerous product,
26 because its labeling fails to adequately warn consumers and prescribers of, among
27 other things, the risk of migration of the product post-insertion, uterine perforation
28 post-insertion, or the possibility that device complications such as migration and

1 perforation may cause abscesses, infections, require surgery for removal and/or may
2 necessitate hysterectomy, oophorectomy, and other complications.

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

9 60. Mirena® was under the exclusive control of Defendant and was
10 unaccompanied by appropriate warnings regarding all of the risks associated with its
11 use. The warnings given did not accurately reflect the risk, incidence, symptoms,
12 scope or severity of such injuries to the consumer or physicians. The promotional
13 activities of Defendant further diluted or minimized the warnings given with the
14 product.

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

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

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

26 64. Plaintiff could not have discovered any defect in Mirena® through the
27 exercise of reasonable care.
28

1 65. Defendant, as manufacturers of pharmaceutical drugs, are held to the
2 level of knowledge of an expert in the field and, further, Defendant had knowledge of
3 the dangerous risks and side effects of Mirena®.

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

6 67. Defendant had a continuing duty to warn consumers, including Plaintiff
7 Melody Williams and her physicians, and the medical community of the dangers
8 associated with Mirena®, and by negligently and/or wantonly failing to adequately
9 warn of the dangers associated with its use, Defendant breached their duty.

10 68. Although Defendant knew, or were reckless in not knowing, of the
11 defective nature of Mirena®, they continued to manufacture, design, formulate, test,
12 package, label, produce, create, made, construct, assemble, market, advertise,
13 distribute and sell Mirena® without providing adequate warnings and instructions
14 concerning the use of Mirena® so as to maximize sales and profits at the expense of
15 the public health and safety, in knowing, conscious, and deliberate disregard of the
16 foreseeable harm caused by Mirena®.

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

21 WHEREFORE, Plaintiffs demand judgment against Defendant for
22 compensatory, statutory and punitive damages, together with interest, costs of suit,
23 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
24 common law and statutory law.

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1 **FIFTH CAUSE OF ACTION:**

2 **STRICT LIABILITY**

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

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

9 72. Mirena®, manufactured and/or supplied by Defendant, was defective in
10 design or formulation in that when it left the hands of the manufacturer and/or
11 suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary
12 consumer would expect and more dangerous than other contraceptives.

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

16 74. Mirena® was also defective due to inadequate warnings or instructions
17 because the manufacturer knew or should have known that Mirena® created, among
18 other things, a risk of perforation and migration and associated infections or
19 conditions and the Defendants failed to adequately warn of these risks.

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

21 76. Defendant failed to provide adequate initial warnings and post-marketing
22 warnings or instructions after the manufacturer and/or supplier knew or should have
23 known of the extreme risks associated with Mirena® and continues to promote
24 Mirena® in the absence of those adequate warnings.

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

1 WHEREFORE, Plaintiffs demand judgment against Defendant for
2 compensatory, statutory and punitive damages, together with interest, costs of suit,
3 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
4 common law and statutory law.

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

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

10 79. Defendant manufactured, designed, formulated, tested, packaged,
11 labeled, produced, created, made, constructed, assembled, marketed, advertised,
12 distributed and sold Mirena® as safe for use by the public at large, including Plaintiff,
13 who purchased Mirena®. Defendants knew the use for which their product was
14 intended and impliedly warranted the product to be of merchantable quality, safe and
15 fit for use.

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

18 81. Contrary to same, Mirena® was not of merchantable quality or safe or fit
19 for its intended use, because it is unreasonably dangerous and unfit for the ordinary
20 purpose for which it was used.

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

25 WHEREFORE, Plaintiffs demand judgment against Defendant for
26 compensatory, statutory and punitive damages, together with interest, costs of suit
27 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
28 common law and statutory law.

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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,

1 assembling, advertising, and distributing of Mirena®, owed a duty to provide
2 accurate and complete information regarding Mirena®.

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

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

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

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

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

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

25 WHEREFORE, Plaintiffs demand judgment against Defendant for
26 compensatory, statutory and punitive damages, together with interest, costs of suit,
27 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
28 common law and statutory law.

NINTH CAUSE OF ACTION:

FRAUDULENT MISREPRESENTATION

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

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

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

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

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

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

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

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

24 WHEREFORE, Plaintiffs demand judgment against Defendants for
25 compensatory, statutory and punitive damages, together with interest, costs of suit,
26 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
27 common law and statutory law.
28

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.

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1 **ELEVENTH CAUSE OF ACTION:**

2 **LOSS OF CONSORTIUM**

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

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

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

- 8 a. lost a substantial measure of his wife's household services; and
9 b. lost, and will continue to lose in the future, a substantial measure
10 of his wife's consortium.

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

13 WHEREFORE, Plaintiffs demand judgment against Defendant for
14 compensatory, statutory and punitive damages, together with interest, costs of suit,
15 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
16 common law and statutory law.

17
18 **REQUEST FOR PUNITIVE DAMAGES**

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

21 114. At all times relevant herein, Defendant:

- 22 a. knew that Mirena® was dangerous and ineffective;
23 b. concealed the dangers and health risks from Plaintiff Melody
24 Williams, physicians, pharmacists, other medical providers, the
25 FDA, and the public at large;
26 c. made misrepresentations to Plaintiff Melody Williams, her
27 physicians, pharmacists, hospitals and medical providers and the
28

1 public in general as previously stated herein as to the safety and
2 efficacy of Mirena®; and

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

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

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

17 WHEREFORE, Plaintiffs demand judgment against Defendant for
18 compensatory, statutory and punitive damages, together with interest, costs of suit,
19 attorneys' fees and all such other relief as the Court deems appropriate pursuant to the
20 common law and statutory law.

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1 **PRAYER FOR RELIEF**

2 Plaintiffs demand judgment against Defendant for compensatory, statutory and
3 punitive damages, together with interest, costs of suit, attorneys' fees and all such
4 other relief as the Court deems appropriate pursuant to the common law and statutory
5 law.

6 DATED: November 2, 2012

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

10 By: */S/Mark J. Geragos*
11 MARK J. GERAGOS
12 geragos@geragos.com
13 Attorneys for Plaintiffs
14 MELODY WILLIAMS and
15 RONAIL WILLIAMS

16 **JURY DEMAND**

17 A jury trial is requested.

18 DATED: November 2, 2012

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

22 By: */S/Mark J. Geragos*
23 MARK J. GERAGOS
24 geragos@geragos.com
25 Attorneys for Plaintiffs
26 MELODY WILLIAMS and
27 RONAIL WILLIAMS
28

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.)

<p>I. (a) PLAINTIFFS MELODY AND RONAIL WILLIAMS,</p> <p>(b) County of Residence of First Listed Plaintiff <u>San Diego, California</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p>(c) Attorneys <i>(Firm Name, Address, and Telephone Number)</i> MARK J. GERAGOS SBN 108325 GERAGOS & GERAGOS, APC 644 S. Figueroa Street, Los Angeles, California 90017 (213) 625-3900</p>	<p>DEFENDANTS BAYER HEALTHCARE PHARMACEUTICALS INC.,</p> <p>County of Residence of First Listed Defendant <u>Wayne, New Jersey</u> <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys <i>(If Known)</i></p>
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<p>II. BASIS OF JURISDICTION <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input checked="" type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input checked="" type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;"></td> <td style="width:10%; text-align: center;">PTF</td> <td style="width:10%; text-align: center;">DEF</td> <td style="width:33%;"></td> <td style="width:10%; text-align: center;">PTF</td> <td style="width:10%; text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

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

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 _____