IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY

KARA SWEET and BRANDON SWEET, Plaintiffs, v. BAYER HEALTHCARE PHARMACEUTICALS INC., Defendant.	Civil Action No.: 3-12-cv-839-H COMPLAINT WITH JURY DEMAND

Plaintiffs Kara Sweet and Brandon Sweet, by and through the undersigned attorneys, hereby bring this cause of action for personal injuries suffered as a proximate result of Plaintiff Kara Sweet 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").

PARTIES AND CITIZENSHIP

1. At all relevant times hereto, Plaintiffs Kara Sweet and Brandon Sweet (collectively "Plaintiffs") are, and at all relative times were, husband and wife.

2. At all relevant times hereto, Plaintiffs are residents and citizens of Somerset, Kentucky.

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 Kentucky, CSC-Lawyers Incorporating Service Company, 421 West Main Street, Frankfort, Kentucky 40601.

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 Kentucky 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 progestogen, directly into the uterus for birth control. Defendant admits "[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.

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

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 is a woman becomes pregnant on Mirena®.

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

24. Plaintiff Kara Sweet is currently 30 years-old.

25. Plaintiff Kara Sweet had the Mirena® IUS inserted on December 1, 2009 by Dr. Priddle. The Mirena® IUS insertion was uncomplicated and was properly placed.

26. Following the Mirena® insertion, on December 6, 2010, Dr. Priddle checked the Mirena® placement by a pelvic ultrasound and noted the Mirena® IUS placement was proper.

27. On or about January 17, 2012, Plaintiff Kara Sweet was seen by Dr. Priddle for a yearly examination. At this visit, Plaintiff Kara Sweet complained of pains and cramps in her bowls and uterine area. She also complained that felt like something is pressing on her cervix.

28. On January 17, 2012, a pelvic ultrasound was performed and the Mirena® IUS was not visualized. For this reason, an abdominal x-ray was ordered.

29. On January 31, 2012, an x-ray of Plaintiff Kara Sweet's abdomen revealed that the Mirena® IUS was in the lower pelvis lying transverse, most likely between the rectum and vagina. Removal of the Mirena® IUS was planned.

30. On January 31, 2012, Plaintiff Kara Sweet underwent surgery at Lake Cumberland Regional Hospital in Somerset, Kentucky. Under general anesthesia, the Mirena® IUS was found in the right posterior portion of the cul-de-sac next to the broad ligament. Plaintiff Kara Sweet's Mirena® IUS was then removed.

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 Kentucky.

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 Kara Sweet without substantial change in the condition in which it was sold.

34. Defendant 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 Kara Sweet.

35. Defendant 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 Kara Sweet.

36. As a direct and proximate result of Plaintiff Kara Sweets' use of Mirena®, she was forced to undergo surgical removal of the IUS, developed severe pain from the device, 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 Kara Sweet suffered profound injuries, including uterine perforation, 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. Defendant was and is engaged in the business of selling Mirena® in the State of Kentucky.

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 Kara Sweet 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 Kara Sweet.

48. As a direct and proximate cause of Plaintiff Kara Sweets' 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 Kara Sweet suffered profound injuries, including uterine

perforation, 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 Kara Sweet, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

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

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

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 Kara Sweet suffered profound injuries, including uterine perforation, 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 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. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course

of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

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 Plaintiff Kara Sweet to the dangerous risks and reactions associated with it. Even though Defendant 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 Kara Sweet used Mirena® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

64. Plaintiff Kara Sweet 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 Kara Sweet 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 Kara Sweet 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 Kara Sweet suffered profound injuries, including uterine perforation, 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. Defendant are manufacturers and/or suppliers of Mirena® and are strictly liable to Plaintiff Kara Sweet 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 Defendant 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 Kara Sweet suffered profound injuries, including uterine

perforation, 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 Kara Sweet, who purchased Mirena®. Defendant knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

80. Plaintiff Kara Sweet 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 proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Kara Sweet suffered profound injuries, including uterine perforation, 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 Kara Sweet 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 Kara Sweet suffered profound injuries, including uterine perforation, 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 Kara Sweet 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 Kara Sweet 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 Kara Sweet to use Mirena®, which caused his injury.

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

93. Defendant breached their duties to Plaintiff Kara Sweet by providing false, incomplete and/or misleading information regarding their product. Plaintiff Kara Sweet 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 Kara Sweet suffered profound injuries, including uterine perforation, 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 Kara Sweet 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 Kara Sweet so that she might rely on these fraudulent misrepresentations.

101. Plaintiff Kara Sweet 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 Kara Sweet suffered profound injuries, including uterine perforation, 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.

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 Kara Sweet 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 Kara Sweet with the intent to defraud her as herein alleged.

106. Neither Plaintiff Kara Sweet 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 Kara Sweet 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 Kara Sweet suffered profound injuries, including uterine perforation, 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 Brandon Sweet is the husband of Kara Sweet.

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

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 Brandon Sweet 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 Kara Sweet, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff Kara Sweet, 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 Kara Sweet and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff Kara Sweet and the general public.

116. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Kara Sweet suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff Kara Sweet 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.

JURY DEMAND

A jury trial is requested.

Respectfully submitted,

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3-12-cv-839-H

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
KARA SWEET AND BRANDON SWEET

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Beverly R. Storm, Arnzen, Molloy & Storm, P.S.C., 600 Greenup Street, Covington, Kentucky 41011 (859) 431-6100

DEFENDANTS
Bayer Healthcare Pharmaceuticals, Inc.

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

TORTS

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

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

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

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

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC Section1332(a)(1)
Brief description of cause:
Personal injury caused by Mirena, a birth control product

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 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Kentucky

KARA SWEET AND BRANDON SWEET

Plaintiff(s)

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.

Defendant(s)

Civil Action No. 3-12-cv-839-H

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BAYER HEALTHCARE PHARMACEUTICALS, INC.

SERVE: CSC-LAWYERS INCORPORATING SERVICE COMPANY
421 WEST MAIN STREET
FRANKFORT, KENTUCKY 40601

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: BEVERLY R. STORM
ARNZEN, MOLLOY & STORM, P.S.C.
600 GREENUP STREET
COVINGTON, KENTUCKY 41011

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: