

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

**IN RE YASMIN AND YAZ (DROSPIRENONE)  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION**

**3:09-md-02100-DRH-PMF  
MDL No. 2100**

**This document relates to:**

**MELISSA MICHAEL,**

**Judge David R. Herndon**

**Plaintiff,**

**Complaint & Jury Demand**

**v.**

**Civil Action No.:**

**BAYER HEALTHCARE PHARMACEUTICALS,  
INC., BAYER SCHERING PHARMA AG,  
BAYER CORPORATION,  
BAYER HEALTHCARE LLC,  
BAYER HEALTHCARE AG, and BAYER AG,**

**Defendants.**

**PLAINTIFF'S ORIGINAL COMPLAINT**

Plaintiff, Melissa Michael, by her attorney, Spencer Marc Aronfeld, on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

**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 Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. Plaintiff is filing this Complaint as permitted by Case Management Order # 9

issued by Judge David R. Herndon of this Court. Plaintiff states that but for that Order # 4 permitting direct filing into the Southern District of Illinois, Plaintiff would have filed in the United States District Court for the Southern District of Florida, which is where Plaintiff lived at the time that she used the product at issue and suffered the injury alleged in this Complaint. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the Southern District of Florida as set forth in Case Management Order # 49.

3. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2100 as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Florida, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of Florida and the State of Illinois unrelated to Plaintiff's claims.

#### **PARTY PLAINTIFF**

4. Plaintiff, Melissa Michael, is a citizen of the United States of America, and is a resident of Loxahatchee, Palm Beach County, Florida.

6. Plaintiff, Melissa Michael, used Yaz until, in or around 2006.

7. As result of using Defendants' Yaz, Plaintiff Melissa Michael, was caused to suffer including, but not limited to, gall stones, resulting in a cholecystectomy, in April 2011, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

8. The injuries and damages sustained by Plaintiff, Melissa Michael, were caused by Defendants' Yasmin.

9. Plaintiff did not know, and could not have known, that her injuries were caused

by a defective product until at least January 2011.

**PARTY DEFENDANTS**

10. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

11. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

12. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Illinois and in the State of Texas, and derived substantial revenue from interstate commerce.

13. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. expected or should have expected that its acts would have consequences within the United States of America, in the State of Texas, and in the State of Illinois, and derived substantial revenue from interstate commerce.

14. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of approved New Drug Application No. 21-676 for YAZ.

15. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. markets YAZ and Yasmin in the United States.

16. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is a

pharmaceutical company domiciled in Germany.

17. Defendant BAYER SCHERING PHARMA AG is formerly known as Schering AG and is the same corporate entity as Bayer Schering Pharma Schering AG.

18. Upon information and belief, Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006. Bayer Schering Pharma AG was rename BAYER PHARMA AG effective July 2011.

19. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin.

20. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

21. Defendant BAYER SCHERING PHARMA AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin, and Ocella.

22. Upon information and belief, Defendant BAYER SCHERING PHARMA AG has transacted and conducted business in the State of Illinois and in the State of Florida, and derived substantial revenue from interstate commerce.

23. Upon information and belief, Defendant BAYER SCHERING PHARMA AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Florida, and in the State of Illinois, and derived substantial revenue from interstate commerce.

24. Upon information and belief, and at all relevant times Defendant BAYER SCHERING PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

25. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

26. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

27. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin.

28. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Illinois and in the State of Florida by selling and distributing its products in the State of Illinois and engaged in substantial commerce and business activity in the State of Illinois and in the State of Florida.

29. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New York.

30. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois and in the State of Florida, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC and as such,

for purposes of establishing diversity of citizenship, Defendant BAYER HEALTHCARE LLC is a citizen of Indiana and Pennsylvania.

31. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of Florida, and derived substantial revenue from interstate commerce.

32. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

33. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER SCHERING PHARMA AG.

34. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois and in the State of Florida, and derived substantial revenue from interstate commerce.

35. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of Florida, and derived substantial revenue from interstate commerce.

36. Upon information and belief, at all relevant times, Defendant BAYERHEALTHCARE AG exercises dominion and control over Defendants BAYER

CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER SCHERING PHARMA AG.

37. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

38. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

39. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

40. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois and in the State of Florida, and derived substantial revenue from interstate commerce.

41. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Florida, and in the State of Illinois, and derived substantial revenue from interstate commerce,

42. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

43. Defendants. BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG shall, hereinafter, be collectively referred to as "Bayer" or "Defendants."

## NATURE OF THE CASE

### Bayer's Combined Oral Contraceptives — Yasmin and Yaz

44. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

45. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

### Yasmin and Yaz Contain a "Fourth Generation" Progestin

46. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

47. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

48. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

49. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when

combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

50. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

51. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

52. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

53. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

54. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

55. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the

potassium levels become too high.

56. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

57. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

58. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

59. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

60. In February 2003, a paper entitled Thromboembolism Associated With the New Contraceptive Yasmin was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

61. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

62. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

63. Some deaths reported occurred in women as young as 17 years old.

64. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

### **Over-Promotion of Yasmin and Yaz**

65. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

66. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

67. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

68. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone[.]”

69. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

70. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the more serious condition of premenstrual dysphoric disorder or "PMDD."

71. Defendants also advertised that Yaz contained the added benefit of preventing or

reducing acne.

72. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

73. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

74. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

75. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

#### **Plaintiff's Use of Yasmin and Resulting Injuries**

76. As a result of Defendants claim regarding the effectiveness and safety of Yasmin, Plaintiff, Melissa Michael's, medical provider prescribed and Melissa Michael used Yasmin until July 2008. In July 2008, Plaintiff Melissa Michael was diagnosed with a gall stones, which resulted in a cholecystectomy.

77. As a direct and proximate result of using Yasmin, Plaintiff Melissa Michael suffered the injuries described above.

78. Prior to Plaintiff's use of Yasmin Defendants knew or should have known that use Yasmin created a higher risk of serious personal injury than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

79. Therefore, at the time Plaintiff used Yasmin, Defendants knew or should have known that the use of Yasmin created an increased risk to consumers of serious personal injury, including gall bladder disease, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

80. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin, Defendants failed to adequately warn Plaintiff Melissa Michael and/or her health care providers of said serious risks before she used the products.

81. Had Plaintiff Melissa Michael and/or her health care providers known of the increased risks and dangers associated with Yasmin, she would not have used the product and would not have suffered the gall bladder disease and the resulting cholecystectomy in July 2008.

82. As a direct and proximate result of her use of Yasmin, Plaintiff Melissa Michael has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including, but not limited to, suffering from the gall bladder disease and resulting cholecystectomy, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.

83. Further, as a direct and proximate result of her use of Yasmin, Plaintiff Melissa Michael has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

84. Plaintiff Melissa Michael has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yasmin.

## **FIRST CAUSE OF ACTION**

### **Products Liability**

#### **Defective Manufacturing**

85. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

86. Defendants were the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin.

87. Defendants' Yasmin was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications.

88. As a direct and proximate result of Plaintiff Melissa Michael use of Yasmin as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants, as well as Defendants' failure to comply with federal requirements and standards, Plaintiff Melissa Michael suffered harm, damages, and economic loss.

89. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

## **SECOND CAUSE OF ACTION**

### **Strict Products Liability**

### **Defect in Design or Formulation**

90. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

91. Defendants' Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce, was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

92. At the time that Defendants manufactured the Yasmin birth control pills, Defendants acted unreasonably in designing or formulating the product, and Defendants' conduct was a proximate cause of Plaintiffs harm.

93. Specifically, the Yasmin birth control pill product manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of Defendants, it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.

94. The foreseeable risks associated with the design or formulation of Defendants' Yasmin include, but are not limited to, the fact that the design or formulation of Defendants' Yasmin was more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

95. At the time the Yasmin birth control product left the control of Defendants, the design or formulation was so unreasonable that a reasonable person, such as Plaintiff Melissa Michael would not have used or consumed the Yasmin birth control product.

96. As a direct and proximate result of Plaintiff Melissa Michael's use of Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of

commerce by Defendants, as well as Defendants failure to comply with federal requirements and standards, Plaintiff Melissa Michael suffered harm, damages, and economic loss.

97. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

### **THIRD CAUSE OF ACTION**

#### **Strict Products Liability**

#### **Defect Due to Inadequate Warning or Instruction and**

#### **Inadequate Post-Marketing Warning or Instruction**

98. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

99. The Yasmin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants was defective due to inadequate warning or instruction because the Defendants knew or should have know that the product was unreasonably dangerous by creating significant risks of serious bodily harm and death to consumers, including Plaintiff Melissa Michael, and they failed to adequately warn consumers and/or their health care providers of such risks.

100. The Yasmin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by the Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Yasmin, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious bodily harm and death.

101. Defendants acted unreasonably in failing to provide adequate warnings and/or instructions, and in failing to provide adequate post-marketing warnings or instructions, regarding the increased risks of serious bodily harm and death to consumers, such as Plaintiff, Melissa Michael.

102. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff, Melissa Michael, suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

103. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

#### **FOURTH CAUSE OF ACTION**

##### **Negligence**

104. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

105. Defendants owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of Defendants' Yasmin including a duty to ensure that its product did not contain contaminants that posed a risk of bodily harm and adverse events, including death.

106. Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, distribution, marketing, sale, and/or post-sale surveillance of Defendants' Yasmin in that Defendants knew or should have known that Defendants' Yasmin could cause such significant bodily harm and death and was not safe for

administration to consumers.

107. Despite the fact that Defendants knew or should have known that Defendants' Yasmin in posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Defendant's Yasmin for administration to patients.

108. Defendants knew of should have known that consumers such as Plaintiff Melissa Michael would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

109. As a direct and proximate result of Defendant's negligence, Plaintiff Melissa Michael suffered harm, damages, and economic loss.

110. Defendant's conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

## **FIFTH CAUSE OF ACTION**

### **Breach of Express Warranty**

111. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

112. Defendants expressly warranted that Defendants' Yasmin was of merchantable quality and safe for use by consumers and uses, including Plaintiff Melissa Michael, for its intended purpose.

113. Defendants breached said express warranties in that Defendants' Yasmin was not safe and fit for its intended use and, in fact, caused debilitating and lethal adverse effects.

114. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Melissa Michael suffered harm, damages, and economic loss.

115. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

## **SIXTH CAUSE OF ACTION**

### **Breach of Implied Warranty**

116. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

117. At the time Defendants manufactured, marketed, sold, and distributed Yasmin, Defendants knew of the use for which Defendants' Yasmin was intended and impliedly warranted that Defendants' Yasmin to be of merchantable quality and safe for such use.

118. Plaintiff Melissa Michael and her medical providers reasonably relied upon the skill, judgment and representations of Defendants as to whether Defendants' Yasmin was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

119. Contrary to the implied warranty, Defendants' Yasmin was unsafe for its intended use and was not of merchantable quality because it was unreasonably dangerous as described herein.

120. As a direct and proximate result of Defendant's breach of warranty, Plaintiff Melissa Michael suffered harm, damages, and economic loss.

121. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

## **SEVENTH CAUSE OF ACTION**

### **Negligent Misrepresentation and/or Fraud**

122. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

123. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yasmin and, while engaged in the course of such business, made representations to Plaintiff and her physician regarding the character and/or quality of Yasmin for guidance in their decision to select Yasmin for Plaintiff's use.

124. Specifically, Defendants represented that their product was just as safe, and just as effective or more effective, than other birth control products on the market.

125. Defendants' representations regarding the character or quality of Yasmin were untrue.

126. Defendants had actual knowledge based upon studies, published reports, and clinical experience that their product Yasmin created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.

127. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their product as safe and effective in order to avoid losses and sustain profits in their sales to consumers.

128. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Plaintiff and her physician.

129. Plaintiff Melissa Michael and her physician reasonably relied to her detriment

upon Defendants' misrepresentations and/or omissions in their labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Melissa Michael reasonably relied upon Defendants' representations to her and/or her health care providers that Yasmin was just as safe and effective as other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

130. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff Melissa Michael suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

131. Defendants' conduct as alleged in this Complaint constitutes aggravated or egregious fraud, malice, and/or willful or wanton conduct, so as to warrant the imposition of punitive damages.

### **EIGHTH CAUSE OF ACTION**

#### **Violation of Florida Deceptive and Unfair Trade Practices Act Fla. Stat. §501.204.**

132. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

133. At all times relevant, the Florida Deceptive and Unfair Trade Practices Act, (hereinafter "FDUTPA") protects consumers against false, misleading, or deceptive business practices, unconscionable actions, and breaches of warranty.

134. As set forth in this Complaint, and upon information and belief, Defendants knowingly utilized false, deceptive, and misleading practices in their sale of Yasmin.

135. Defendants' actions were in or affected commerce.

136. Defendants' false, deceptive, and misleading practices constitute unfair or deceptive acts or practices in Florida.

137. Plaintiff Melissa Michaels reasonably relied on Defendants' deceptions and misrepresentations to her detriment.

138. Plaintiff Melissa Michaels was injured as a direct and proximate result of Defendants' deceptive trade practices act that were in violation of Florida FDUTPA, Fla. Stat. § 501.204.

139. Plaintiff Melissa Michaels seeks all damages available under Fla. Stat. § 502.207, including, but not limited to compensatory damages, civil penalties, and attorney's fees.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable through local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial in accordance with Case Management Order #9 issued by United States District Court Judge David R. Herndon.

Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish

Defendants and deter future similar conduct.

2. Awarding all applicable statutory damages of the state whose laws will govern this action;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury as to all issues.

Dated: November 22, 2011

Respectfully submitted,

By: /s/ Spencer Marc Aronfeld

Spencer Marc Aronfeld JD

Aronfeld Trial Lawyers

Florida Bar No. 0905161

3132 Ponce de Leon Blvd.

Coral Gables, FL 33143

Tel. (305) 441-0440

Fax (305) 441-0198

Email: [Aronfeld@aronfeld.com](mailto:Aronfeld@aronfeld.com)

Attorney for Plaintiff