

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS

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IN RE YASMIN AND YAZ (DROSPIRENONE):	3:09-md-02100-DRH-PMF
MARKETING, SALES PRACTICES AND	MDL No. 2100
RELEVANT PRODUCTS LIABILITY :	
LITIGATION	Judge David R. Herndon
----- :	COMPLAINT AND JURY
	DEMAND
PAMELA SCHUCHERT,	
	:
Plaintiff	
vs.	: Civil Action No. 3:10-cv-11979-DRH-PMF
BAYER HEALTHCARE	:
PHARMACEUTICALS INC.	
	:
and	
	:
BAYER SCHERING PHARMA AG,	
	:
Defendants.	
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**COMPLAINT**

Plaintiff Pamela Schuchert, an individual, files this Complaint seeking judgment against Defendants Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG, for injuries and damages caused by her ingestion of Yaz, (generically as drospirenone and ethinyl estradiol) a combination oral contraceptive prescription medication and, in support thereof, states and alleges as follows:

**PARTIES AND JURISDICTION**

1. Plaintiff Pamela Schuchert is a resident and citizen of Chester, Illinois, located in Randolph County.

2. Plaintiff Pamela Schuchert was prescribed and purchased and ingested the prescription contraceptive medication product titled Yaz® (herein after Yaz®/Yasmin®), and suffered a stroke on or about December 16, 2008 as a proximate and direct result of using Yaz®/Yasmin®, which was designed, developed, marketed, advertised and distributed by Defendants herein.

3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.

4. Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz®/Yasmin®. At all relevant times, Bayer Corporation conducted regular and sustained business in Chester, Illinois by selling and distributing its products in Chester, Illinois and engaged in substantial commerce and business activity in Chester, Illinois.

5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex, Inc. (formally known as Berlex Laboratories, Inc.). Bayer Healthcare Pharmaceuticals, Inc. is the U.S. based pharmaceutical unit of Schering AG and is a division of Bayer AG.

6. Berlex, Inc. 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 Yaz®/Yasmin®. At all relevant times, Berlex Laboratories, Inc. conducted and sustained regular business in Chester, Illinois by selling and distributing its products in Chester, Illinois and engaged in substantial commerce and business activity in Chester, Illinois. As a result of the acquisition, Defendant Bayer Healthcare Pharmaceuticals, Inc. is obligated for its predecessor's liabilities.

7. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. is 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 drugs Yaz® and Yasmin®. At relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted and sustained regular business in Chester, Illinois by selling and distributing its products in Chester, Illinois and engaged in substantial commerce and business activity in Chester, Illinois.

8. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for Yaz®.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for Yasmin®.

10. Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories, Inc. (formally known as Berlex, Inc.). Bayer Healthcare, LLC is a resident of New York and is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either

directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz®/Yasmin®. At all relevant times, Bayer Healthcare, LLC conducted regular and sustained business in Chester, Illinois by selling and distributing its products in Chester, Illinois and engaged in substantial commerce and business activity in Chester, Illinois.

11. Defendant Bayer Schering Pharma AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

12. Defendant Bayer Schering Pharma AG, is a corporate successor of Schering AG.

13. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

14. Defendant Bayer Schering Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburg Pennsylvania 15205.

15. Defendant Bayer Schering Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, Yaz®/Yasmin®.

16. Defendant Bayer Schering Pharma AG, is the current owner of the patent(s) relating to the oral contraceptive Yaz®.

17. Bayer AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

18. Bayer AG is the third largest pharmaceutical company in the world.

19. Bayer AG is the parent/holding company of all other named Defendants.

20. Bayer AG's headquarters and principal places of business in the United States are located at 100 Bayer Road, Pittsburg, Pennsylvania, 15205.

21. Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG are collectively referred to herein as "Bayer", "Bayer Defendants", or "Defendants." Bayer Corporation, Bayer Healthcare, LLC, and Bayer AG, are collectively referred to herein as "other Bayer entities."

22. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

23. Venue is proper in this District pursuant to Pretrial Order No. 9 which authorized direct filing of cases into MDL No. 2100 in order to eliminate delays associated with transfer of cases and to promote judicial efficiency. Upon the completion of all pretrial proceedings applicable to this case, pursuant to Pretrial Order No. 9, this case will be transferred to the federal district court in the district where the Plaintiff allegedly was injured by use of Yaz®, Yasmin® or Ocella®, or where the Plaintiff resides at the time of such transfer.

## **FACTUAL BACKGROUND**

### **Nature of the Case**

24. Plaintiff Pamela Schuchert brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yaz®/Yasmin® (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz®/Yasmin®, Plaintiff Pamela Schuchert suffered a stroke.

### **Bayer's Combined Oral Contraceptives - Yaz®/Yasmin® and Yasmin**

25. Yaz® and Yasmin® are birth control pills manufactured and marketed by Defendants. 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.

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

**Yaz® and Yasmin® contain a "Fourth Generation" Progestin.**

27. The estrogen component in Yaz® and Yasmin® 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.

28. Yaz® and Yasmin® 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.

29. 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.

30. 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.

31. 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.

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

33. 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 Yaz® and Yasmin® marketed under the trade name Ocella.

34. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact, studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

35. A dangerous effect of drospirenone is that it acts as a diuretic, which can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia if the potassium levels become too high. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal. 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. The diuretic nature of drospirenone also attributes to blood clot formation elsewhere in the body.

36. An additional dangerous effect of drospirenone is that in acting as a diuretic, it affects the kidney by blocking the aldosterone receptors. Aldosterone is a hormone that increases the reabsorption of sodium and water and the secretion of potassium in the kidneys, resulting in dehydration. Dehydration, may lead to the formation of gall stones. Blocking the aldosterone receptor may also increase the levels of cholesterol in the blood. An excess of cholesterol, calcium and phosphate in the gallbladder reduces gallbladder emptying and results in gallbladder disease.

37. Upon information and belief, Defendants knew or should have known that the use of drospirenone in Yaz®/Yasmin® causes arrhythmia, cardiac arrest/heart attack, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, and/or gallbladder disease.

38. During the brief time that Yaz® and Yasmin® 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.

39. 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.

40. 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.

41. 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 Yaz®/Yasmin® have been filed with the FDA.

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

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

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

45. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yaz®/Yasmin® over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that “oral contraceptives with . . . drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogesterel.” Lidegard, et al., Hormonal contraception and risk of venous thromboembolism: national follow up study, THE BRITISH MEDICAL JOURNAL 2009, 330: 2921.

46. The second study found that Yaz®/Yasmin® users have twice the risk of a clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et al., The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study. THE BRITISH MEDICAL JOURNAL 2009, 339: B2921.

47. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the use of Yaz®/Yasmin®, but they have, through their marketing and advertising campaigns, urged women to use Yaz®/Yasmin® instead of birth control pills that present a safer alternative.

#### **Over-Promotion of Yaz®/Yasmin®**

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

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

50. For example, prior to its sale to 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."

51. 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 [.]”

52. 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."

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

54. Defendants also advertised that Yaz®/Yasmin® contained the added benefit of preventing or reducing acne.

55. In response, on October 3, 2008, the FDA issued another warning letter to Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz®/Yasmin® for medical conditions beyond the limits of the FDA approval, and adding that "Yaz®/Yasmin® 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."

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

57. Indeed, the FDA felt Defendants' over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz®/Yasmin® advertisements regarding acne and premenstrual syndrome.

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

**Plaintiff's Use of Yaz®/Yasmin® and Resulting Injuries**

59. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Yaz®/Yasmin®, including Defendants' regarding Yaz®/Yasmin®'s reduction or prevention of acne, Plaintiff Pamela Schuchert's medical provider prescribed and Plaintiff Pamela Schuchert began using Yaz®/Yasmin® in or about August 2008.

60. As a direct and proximate result of using Yaz®/Yasmin®, Plaintiff Pamela Schuchert suffered a stroke.

61. Prior to Plaintiff Pamela Schuchert's use of Yaz®/Yasmin®, Defendants knew or should have known that use of Yaz®/Yasmin® created a higher risk of blood clots 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.

62. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz®/Yasmin®, Defendants failed to warn Plaintiff Pamela Schuchert and/or her health care providers of said serious risks before she used the product.

63. Had Plaintiff Pamela Schuchert and/or her health care providers known the risks and dangers associated with Yaz®/Yasmin®, she would not have used Yaz®/Yasmin® and would not have suffered a stroke.

64. Plaintiff did not know, nor should she have reasonably discovered through the use of reasonable diligence, that Yaz®/Yasmin® wrongfully caused her stroke and that she had a claim against Defendants until less than one year prior to the date of filing this action.

65. As a direct and proximate result of her use of Yaz®/Yasmin®, Plaintiff Pamela Schuchert suffered and will continue to suffer physical injury, including but not limited to, conscious pain and suffering, as a result of her stroke.

66. As a direct and proximate result of Plaintiff Pamela Schuchert's use of Yaz®/Yasmin®, Plaintiff Pamela Schuchert has suffered and will continue to suffer pecuniary losses.

## **COUNT I**

### **Products Liability Defective Manufacturing As to All Defendants**

67. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

68. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz®/Yasmin®.

69. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

70. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated

from product specification such that they were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

71. As a direct and proximate result of Plaintiff Pamela Schuchert's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Pamela Schuchert suffered and will continue to suffer personal injuries, economic and non-economic damages.

72. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff Pamela Schuchert's rights, so as to warrant the imposition of punitive damages.

## **COUNT II**

### **Products Liability Design Defect As to All Defendants**

73. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

74. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz®/Yasmin®.

75. The Yaz®/Yasmin® birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

76. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary consumer would expect.

77. The foreseeable risks associated with the design or formulation of the Yaz®/Yasmin® birth control pills, include, but are not limited to, the fact that the design or formulation of Yaz®/Yasmin® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

78. Additionally, Defendants advised consumers and the medical community that Yaz®/Yasmin® contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yaz®/Yasmin® versus other oral hormonal birth control pills.

79. Had Defendants adequately tested the safety of Yaz®/Yasmin® versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed, Yaz®/Yasmin®.

80. As a direct and proximate result of Plaintiff Pamela Schuchert's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Pamela Schuchert suffered and will continue to suffer personal injuries, economic and non-economic damages, including pain and suffering.

81. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally

disregarded Plaintiff Pamela Schuchert's rights, so as to warrant the imposition of punitive damages.

### **COUNT III**

#### **Products Liability Defect Due to Inadequate Warning As to All Defendants**

82. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

83. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction and was unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

84. The Yaz®/Yasmin® birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yaz®/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 injury and death.

85. As a direct and proximate result of Plaintiff Pamela Schuchert's use of Yaz®/Yasmin® as manufactured, designed, sold, supplied and introduced into the stream of



commerce by Defendants, Plaintiff Pamela Schuchert suffered and will continue to suffer personal injuries, economic and non-economic damages.

86. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff Pamela Schuchert's rights, so as to warrant the imposition of punitive damages.

#### **COUNT IV**

##### **Negligence As to All Defendants**

87. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

88. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz®/Yasmin® into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events. Defendants also had the duty to ensure that all of its communications to consumers, including Plaintiff Pamela Schuchert and her healthcare providers, were truthful.

89. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz®/Yasmin® into interstate commerce and in communications regarding Yaz®/Yasmin® in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

90. Defendants further failed to exercise ordinary care in the labeling of Yaz®/Yasmin® in that Defendants failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yaz®/Yasmin®.

91. Plaintiff Pamela Schuchert and her healthcare providers reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product, including that Yaz®/Yasmin® was as safe or safer than 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.

92. Despite the fact that Defendants knew or should have known that Yaz®/Yasmin® posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz®/Yasmin® for use by consumers.

93. Defendants knew or should have known that consumers, including Plaintiff Pamela Schuchert, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

94. As a direct and proximate result of Defendants' negligence, Plaintiff Pamela Schuchert suffered and will continue to suffer personal injuries, economic and non-economic damages.

## **COUNT V**

### **Fraud As to All Defendants**

95. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

96. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz®/Yasmin® and made representations to Plaintiff and her healthcare providers regarding the character or quality of Yaz®/Yasmin® for guidance in their decision to select Yaz®/Yasmin®.

97. Specifically, Defendants represented that Yaz®/Yasmin® was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

98. Defendants' representations regarding the character or quality of Yaz®/Yasmin® were untrue.

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

100. Defendants fraudulently misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe or safer than, and as or more effective than, other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

101. Plaintiff Pamela Schuchert and her healthcare providers reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Pamela Schuchert reasonably relied upon Defendants' representations to her and/or her healthcare providers that Yaz®/Yasmin® was safer than 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.

102. As a direct and proximate result of Defendants' fraudulent misrepresentations or omissions, Plaintiff Pamela Schuchert suffered and will continue to suffer personal injuries and economic and non-economic damages, including pain and suffering.

103. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff Pamela Schuchert's rights so as to warrant the imposition of punitive damages.

## **COUNT VI**

### **Breach of Express Warranty As to All Defendants**

104. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

105. The Bayer Defendants expressly warranted that Yaz®/Yasmin® was a safe and effective prescription contraceptive.

106. The Yaz®/Yasmin® birth control pill manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

107. As a direct and proximate result of the Bayer Defendants' breach of warranty, Plaintiff Pamela Schuchert has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

108. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff Pamela Schuchert's rights so as to warrant the imposition of punitive damages.

## **COUNT VII**

### **Breach of Implied Warranty**

#### **As to All Defendants**

109. Plaintiff Pamela Schuchert incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

110. At the time the Defendants designed, manufactured, marketed, sold, and distributed Yaz®/Yasmin® for use by Plaintiff Pamela Schuchert, Defendants knew of the use for which Yaz®/Yasmin® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

111. Plaintiff Pamela Schuchert reasonably relied upon the skill and judgment of the Defendants as to whether Yaz®/Yasmin® was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

112. Contrary to such implied warranty, Yaz®/Yasmin® was not of merchantable quality or safe for its intended use, because the product was reasonably dangerous as described above.

113. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff Pamela Schuchert has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

114. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff Pamela Schuchert's rights so as to warrant the imposition of punitive damages.

## **COUNT VIII**

### **Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act**

#### **As to All Defendants**

115. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

116. At all times relevant, the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 et seq., (hereinafter “IFCA”) prohibits “the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact...in the conduct of any trade or commerce” and declares such acts or practices as unlawful.

117. Defendants violated the IFCA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Yaz®/Yasmin®. Defendants communicated the purported benefits of Yaz®/Yasmin® while failing to disclose the serious and dangerous side effects related to the use of Yaz®/Yasmin® with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Yaz®/Yasmin®, respectively.

118. As a result of violating the IFCA Defendants caused Plaintiff to be prescribed and to use Yaz®/Yasmin®, causing severe injuries and damages as previously described herein.

119. As a result of Defendants’ violations of the IFCA, Plaintiff Cheryl Tubbs seeks treble damages and costs as provided by the Act.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of \$75,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Attorneys' fees, expenses, and costs of this action;
4. Such further relief as this Court deems necessary, just, and proper.

### **JURY DEMAND**

Plaintiff Pamela Schuchert hereby demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED,

/s/Kristine Kraft

Roger C. Denton, Esq.

Kristine K. Kraft, Esq.

Elizabeth M. Wilkins, Esq.

Megan M. Vanderbeek, Esq.

**SCHLICHTER, BOGARD & DENTON**

100 South 4<sup>th</sup> Street, Suite 900

Saint Louis, MO 63102

Telephone: (314) 621-6115

Fax: (314) 621-7151

[rdenton@uselaws.com](mailto:rdenton@uselaws.com)

[kkraft@uselaws.com](mailto:kkraft@uselaws.com)

[bwilkins@uselaws.com](mailto:bwilkins@uselaws.com)

[mvanderbeek@uselaws.com](mailto:mvtanderbeek@uselaws.com)

Attorneys for Plaintiffs

## 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 THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**

PAMELA SCHUCHERT

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

(c) Attorney's (Firm Name, Address, and Telephone Number)

Schlichter Bogard & Denton, 100 South 4th Street Suite 900, Saint Louis, MO 63136, 314-621-6115

**DEFENDANTS**

Bayer HealthCare Pharmaceuticals, Inc., Bayer Schering Pharma AG.

County of Residence of First Listed Defendant New Castle County, DE  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION**

(Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 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)

- |   | PTF                                   | DEF                        |  | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|--|----------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated <i>or</i> Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated <i>and</i> 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            |

**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	<b>PERSONAL INJURY</b> <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	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <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"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <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)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<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"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <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	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <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	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	

**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
- ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC Section 1332

Brief description of cause:

Product Defect Resulting in Serious Personal Injury**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$ 75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE David R. HerndonDOCKET NUMBER 09-MD-2100

DATE

SIGNATURE OF ATTORNEY OF RECORD

08/17/2010/s/ Kristine K. Kraft**FOR OFFICE USE ONLY**

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_



**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44****Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

**III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V. Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

**VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.