UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF ILLINOIS EAST ST. LOUIS DIVISION		
---------- X IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION ----------	§ § § § § § §	
JENNY COCHRAN ***Plaintiff,*** v.	§ § § § § §	3:09-md-02100-DRH-CJP MDL No. 2100 Judge David R. Herndon
BAYER SCHERING PHARMA AG (formerly known as Schering AG); BAYER CORORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC. (formerly known as Berlex, Inc. and Berlex Laboratories, Inc.); and BAYER HEALTHCARE, LLC. ***Defendants.***	§ § § § § § § § §	COMPLAINT AND JURY DEMAND Civil Action No.: 3:10-cv-11265-DRH-PMF

Plaintiff, JENNY COCHRAN, (hereafter "Plaintiff"), by her undersigned counsel, hereby sets forth in this claims for equitable, injunctive, and declaratory relief, and compensatory and punitive damages.

PARTIES AND JURISTICTION

1. Plaintiff JENNY COCHRAN is citizen and resident of Alabama.

2. Plaintiff was prescribed and ingested YAZ AND YASMIN. While using YAZ AND YASMIN, Plaintiff suffered cholecystitis.

3. Defendant Bayer Schering Pharma AG is a foreign defendant with its principal place of business in Germany. Defendant Bayer Schering Pharma AG 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 drug YAZ AND YASMIN. At all relevant times, Defendant Bayer Schering Pharma AG conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois. Pursuant to Case Management Order No. 9 of MDL No. 2100, Defendant Bayer Healthcare Pharmaceuticals, Inc. may be served with process by and through its registered agent for service, **Eva Gardyan-Eisenlohr, Head of Law & Patents, Bayer Schering Pharma AG, Müllerstrasse 178, D- 13353 Berlin, Germany via Certified Mail, Return Receipt Requested.**

4. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation 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 drug YAZ AND YASMIN. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois. Bayer Corporation may be served with process by and through its registered agent for service, **Illinois Corporation Service, 801 Adlai Stevenson Dr., Springfield, IL 62703.**

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 Laboratories.

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 drug Yaz. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois. Pursuant to Case Management Order No. 9 of MDL No. 2100, Defendant Bayer Healthcare Pharmaceuticals, Inc. may be served with process by and through its registered agent for service, **SOP Department, Corporation Service Company, Suite 400, 2711 Centerville Road, Wilmington, DE 19808 via Certified Mail, Return Receipt Requested.**

6. Defendant 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. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into state commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois. Bayer Healthcare LLC may be served with process by and through its registered agent for service, **Illinois Corporation Service, 801 Adlai Stevenson Dr., Springfield, IL 62703.**

7. Defendants Bayer Schering Pharma, AG, Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare, LLC are collectible referred to

herein as "Bayer" or "Defendants."

8. The court has jurisdiction over this action pursuant to the federal rules on multidistrict litigation. This action is a products liability action pertaining to Yaz, Yasmin, and Ocella and therefore is considered under the jurisdiction of MDL 2100, Cause No.: 3:09-md-012100-DRH-PMF. Pursuant to Case Management Order No. 9 of MDL 2100, Defendants will not challenge the venue of this action.

FACTUAL BACKGROUND

9. Plaintiff brings this case against the Defendants for damages associated with Plaintiff's ingestion of YAZ AND YASMIN (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants.

Bayer's Combined Oral Contraceptive- Yasmin and Yaz

10. 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 this prevents pregnancy.

11. Ocella is the generic version of Yasmin.

12. 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

13. 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, 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. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone,

14. Shortly after the introduction of combined oral contraceptives (sometime hereinafter called "birth control pills" or “the pill”) 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 did the risk of blood clots, heart attacks and strokes.

15. 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.

16. 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.

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

18. 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. 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 Federal Drug Administration ("FDA) approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins and potentially more dangerous.

19. One possible mechanism of action is that drospixenone causes potassium levels in the blood, which can lead to a condition known as hyperkalcinia if the potassium levels become too high.

20. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies or bradycardia. If left untreated, hyperkaleria can be fatal.

21. If hyperkalernia 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 lead to heart attacks or the clots can break off and travel to the lungs where they can cause a pulmonary embolism or can travel to the brain causing a stroke.

22. In addition, Yaz, Yasmin, and Ocella have been linked to severe gallbladder

issues, including but not limited to, gallstones, gallbladder disease and gallbladder removal. Yaz, Yasmin, and Ocella increase the level of cholesterol in bile, which the gallbladder is primarily concerned with storing. Once the cholesterol level goes up, the gallbladder's storage abilities are slowed down, which can and often does, lead to gallstones and/or more severe gallbladder injuries.

23. 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.

24. 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.

25. 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.

26. 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.

27. These reports include deaths associated with cardiac arrhythmia, cardiac

arrest, intercardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

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

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

30. 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."

31. 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 drugs.

32. Indeed, the FDA felt Defendants' over promotion of Yaz and 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.

33. 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 YAZ AND YASMIN and Resulting Injuries

34. As a result of Defendants' claim regarding the effectiveness and safety of YAZ AND YASMIN Plaintiff suffered cholecystitis.

35. As a direct and proximate result of using YAZ AND YASMIN, the Plaintiff suffered the injuries described above.

36. Prior to Plaintiff's use of YAZ AND YASMIN, Defendants knew or should have known that the use of YAZ AND YASMIN created a higher risk of stroke than other Oral Contraceptives on the market, including by not limited to, second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

37. Therefore, at the time Plaintiff used YAZ AND YASMIN, Defendants knew or should have known that the use of YAZ AND YASMIN created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, gallbladder injury, stroke, and even death.

38. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of YAZ AND YASMIN, Defendants failed to warn Plaintiff and/or her health care providers of said serious risk before she used the product.

39. Had Plaintiff and/or her health care providers known the risks and dangers associated with YAZ AND YASMIN, she would not have used YAZ AND YASMIN and would not have suffered injuries.

40. As a direct and proximate result of her use of YAZ AND YASMIN, Plaintiff suffered physical injury.

41. As a direct and proximate result of her use of YAZ AND YASMIN, Plaintiff has suffered and continues to suffer pecuniary losses.

FIRST CAUSE OF ACTION

Negligence

42. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein.

43. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and /or distribution of YAZ AND 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.

44. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of YAZ AND YASMIN into interstate commerce 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.

45. Defendants also failed to exercise ordinary care in the labeling of YAZ AND YASMIN and failed to issue to consumers and/or their health care providers adequate warning of the risk of serious bodily injury or death due to the use of YAZ AND YASMIN.

46. Despite the fact that Defendants knew or should have known that YAZ AND YASMIN posed a risk of bodily harm to consumers, Defendants continued to manufacture and market YAZ AND YASMIN for use by consumers.

47. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described

above.

48. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages and will continue to suffer such harm, damages and economic loss in the future.

SECOND CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

49. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein.

50. Defendants are the manufacturers, designers, distributors, sellers or suppliers of YAZ AND YASMIN and made representations to Plaintiff and her physician regarding the character or quality of YAZ AND YASMIN for guidance in their decision to select YAZ AND YASMIN.

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

51. Defendants' representations regarding the character or quality of YAZ AND YASMIN were untrue.

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

53. Defendants negligently and/or intentionally misrepresented or omitted this

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

54. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

55. Plaintiff and her physician reasonably relied to Plaintiff's detriment upon

Defendants' representations that YAZ AND 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

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

THIRD CAUSE OF ACTION

Strict Products Liability

57. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as fully set forth herein.

58. Defendants, as manufacturers of pharmaceuticals, had a duty to warn of adverse drug reactions, which they knew or had reason to know, were inherent in the use of its pharmaceutical products.

59. Defendants failed to adequately warn Plaintiff, Plaintiff s physicians and the general public of the risk of YAZ AND YASMIN being used by Plaintiff.

60. Defendants failed to adequately warn of dangers inherent with YAZ AND YASMIN and the Defendants misrepresentations and inadequate disclosures to the Plaintiffs, physicians, and the general public, made the product unreasonably dangerous for normal use.

61. YAZ AND YASMIN manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of injury from YAZ AND YASMIN use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and continued to aggressively promote YAZ AND YASMIN, causing the Plaintiff to suffer harm.

62. YAZ AND YASMIN was placed into the stream of commerce by the Defendants, in a defective and unsafe condition in. that the foreseeable risks of its use exceeded the benefits associated with the design or formulation.

63. Defendants knew or should have known at the time of manufacturing YAZ AND YASMIN that defective in design or formulation and that YAZ AND YASMIN created a risk of harm to consumers such as Plaintiff and members of the putative class when used in the way it was intended to be used and in a manner which was reasonably foreseeable by the Defendants.

64. Defendants knew or should have known of YAZ AND YASMIN's defective nature at the time of its manufacture, but continued to design, manufacture, market, promote, represent to the consuming public, prescribing doctors, and Plaintiff that YAZ AND YASMIN was safe for the sole purpose of maximizing sales and profits at the expense of the public health and safety in conscious disregard of foreseeable harm caused by YAZ AND YASMIN.

FOURTH CAUSE OFACTION

Breach of Express Warranty

65. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein.

66. Defendants made express representations to the consuming public at large through their aggressive marketing and advertising campaigns relative to their product, YAZ AND YASMIN.

67. Defendants through their detail sales representatives, made representations of the safety and efficacy of their product, YAZ AND YASMIN.

68. YAZ AND YASMIN does not conform to the express representations made through Defendants' advertising and marketing efforts.

69. YAZ AND YASMIN does not conform to the express representations made by Defendants' agents/sales representatives.

70. Defendants' conduct in this matter was a contributing cause of injuries and damages suffered by Plaintiff.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty of Fitness for a Particular Purpose

71. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein.

72. The Defendants impliedly warranted that they would sell and deliver YAZ AND YASMIN in a condition that was ft for the particular purposes for which it was intended.

73. The Defendants knew that the Plaintiff intended to use YAZ AND YASMIN for the particular purpose of medication and that as such, that the medication needed to be safe for use by Plaintiff.

74. Plaintiff relied upon the skill and judgment of the Defendants that YAZ AND YASMIN was safe for its intended use.

75. YAZ AND YASMIN was not safe for its intended use in that it was defective and caused serious side effects and the Defendants therefore breached their implied warranty of fitness for a particular purpose.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability

76. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein.

77. At all times material hereto, the Defendants marketed, sold and distributed YAZ AND YASMIN and knew and promoted the use for which the aforesaid drug was being used by Plaintiff and impliedly warranted to Plaintiff and members of the putative class that YAZ AND YASMIN was of merchantable quality and fit for the ordinary purpose for which it was intended.

78. Plaintiff reasonably relied on the skill, expertise and judgment of the Defendants and its representations as to the fact that YAZ AND YASMIN was of merchantable quality.

79. YAZ AND YASMIN manufactured and supplied by the Defendants was not of

merchantable quality, as warranted by the Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMIITATION

80. The running of any statute of limitation has been tolled by reason of the Defendant's fraudulent conduct. The Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' prescribing physicians the true associated with taking YAZ AND YASMIN.

81. As a result of the Defendant's actions; Plaintiffs and Plaintiffs' prescribing physicians were unaware, and could not reasonably have known or have learned throw reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendant's acts and omission.

PRAYER OR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory damages and punitive damages together with interest, costs of suit and attorney's fees and such other relief as the Court deems proper and as follows:

A. Damages in amount to be determined at trial;

B. Pre judgment and post-judgment interest at the maximum rate allowable at law;

C. Treble, exemplary, and/or punitive damages in an amount

to be determined at trial;

D. The costs and disbursements incurred by Plaintiffs

in connection with this action, including reasonable attorneys' fees as may be allowed by law;

E. All statutory damages; and,

F. Such other and further relief available under all applicable state or federal law and any relief the Court deems just and appropriate.

Respectfully submitted:

By: ____s/ Adam T. Funk___
ADAM T. FUNK
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