

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 Yasmin. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Wisconsin by selling and distributing its products in Wisconsin and engaged in substantial commerce and business activity in Door County.

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 Yasmin. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Wisconsin by selling and distributing its products in Wisconsin and engaged in substantial commerce and business activity in Door County.

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 interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Wisconsin by selling and distributing its products in Wisconsin and engaged in substantial commerce and business activity in Door County.

7. Defendant Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Defendant Berlex Laboratories International, 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 Yasmin. At all relevant times, Defendant Berlex Laboratories International, Inc. conducted regular and sustained business in Wisconsin by selling and distributing its products in Wisconsin and engaged in substantial commerce and business activity in Door County.

8. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, and Berlex Laboratories International, Inc. are collectively referred to herein as “Bayer” or “Defendants.”

9. 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.

10. Venue in this district is appropriate under 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff was prescribed and used Yasmin in this district, and because she resided in this district at the time of her injuries.

FACTUAL BACKGROUND

Nature of the Case

11. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yasmin (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered a stroke on July 8, 2006 as a direct result of her use of Yasmin.

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

12. 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.

13. 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

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

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

20. 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.

21. 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.

22. One 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.

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

24. 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.

25. 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.

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, intracardiac 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 or Yaz.

30. Indeed, 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.

Over-Promotion of Yasmin and Yaz

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

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

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

34. 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 [.]"

35. 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."

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

37. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

38. 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.”

39. 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.”

40. 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.

41. 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

42. As a result of Defendants’ claim regarding the effectiveness and safety of Yasmin, Plaintiff Marie Becker’s medical provider prescribed and Marie Becker began using Yasmin in March of 2006. Marie Becker used Yasmin patch until July 8, 2006 when she suffered a stroke.

43. As a direct and proximate result of using Yasmin, Marie Becker suffered the injuries described above.

44. Prior to July 8, 2006, Defendants knew or should have known that use of Yasmin created a higher risk of stroke 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.

45. Therefore, at the time Marie Becker used Yasmin in March of 2006, Defendants knew or should have known that the use of Yasmin created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

46. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin, Defendants failed to warn Marie Becker and/or her health care providers of said serious risks before she used the product.

47. Had Marie Becker and/or her health care providers known the risks and dangers associated with Yasmin, she would not have used Yasmin and would not have suffered a stroke on July 8, 2006.

48. As a direct and proximate result of her use of Yasmin, Marie Becker suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her stroke.

49. As a direct and proximate result of her use of Yasmin, Marie Becker has suffered and will continue to suffer pecuniary losses.

FIRST CAUSE OF ACTION

Strict Products Liability Defective Manufacturing

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

51. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.

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

53. The Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specification such that it was unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

54. 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 Marie Becker suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

55. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability Design Defect

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

57. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.

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

59. The Yasmin birth control pills manufactured and supplied by Defendants was 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 it was more dangerous than an ordinary consumer would expect.

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

61. 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 Marie Becker suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

62. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability Defect Due to Inadequate Warning

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

64. The Yasmin birth control pills manufactured and supplied by Defendants was 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.

65. The Yasmin birth control pills manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction and was 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 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.

66. 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 Marie Becker suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

67. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Negligence

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

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

70. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of 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.

71. Defendants also failed to exercise ordinary care in the labeling of Yasmin and 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 Yasmin.

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

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

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

75. Defendants' conduct as described above, including but not limited to its failure to adequately test Yasmin, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences malicious actions and/or intentional disregard of the rights of Plaintiff, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

76. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

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

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

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

80. 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 than other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

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

82. Plaintiff Marie Becker and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Marie Becker reasonably relied upon Defendants' representations to her and/or her health care providers that 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.

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

84. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Violation of Wisconsin's Deceptive Trade Practices Act Wis. Stat. § 100.18

85. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

86. Plaintiff is a person within the meaning of the Wisconsin Deceptive Trade Practices Act (the "Act").

87. Defendants are persons, firms and/or corporations within the meaning of the Act for all purposes therein.

88. Plaintiff is a person entitled to bring a claim pursuant to the Act.

89. The false, deceptive and misleading statements and representations made by Defendants alleged above to Plaintiff, her physicians, and the public are deceptive trade practices with the meaning of the Act.

90. Defendants engaged in the deceptive trade practices alleged above, and those deceptive trade practices occurred or were committed in the course, vocation or occupation of Defendants' pharmaceutical business.

91. The deceptive trade practices that Defendants committed as alleged above significantly impacts the public as actual or potential customers of Defendants.

92. As a direct and proximate result of the deceptive trade practices committed by Defendants as alleged above, Plaintiff suffered injuries, damages, and loses as alleged herein.

93. Plaintiff is entitled to all damages permitted by Wis. Stat. § 101.18 of the Act, including pecuniary damages, attorneys' fees, and costs of this action.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount; including, but not limited to, pain, suffering, emotional distress, loss of

enjoyment of life and other non-economic damages in an amount to be determined at trial of this action;

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. Punitive damages; and

5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

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

Dated: July 6, 2009

Respectfully submitted,

s/Brian K. Matis
Brian K. Matis
BURG SIMPSON ELDREDGE
HERSH & JARDINE, P.C.
40 Inverness Drive East
Englewood, CO 80111
(303) 792-5595
(303) 708-0527 (fax)
bmatise@burgsimpson.com

OF COUNSEL:

Janet G. Abaray
Calvin S. Tregre, Jr.
BURG SIMPSON ELDREDGE
HERSH & JARDINE, P.C.
312 Walnut Street, Suite 2090
Cincinnati, OH 45202
(513) 852-5600
(513) 852-5611 (fax)
jabaray@burgsimpson.com
ctregre@burgsimpson.com