

**IN THE U.S. DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

**JANE DOE**  
123 Main Street  
Toledo, OH 43612

and

**JOHN DOE**  
123 Main Street  
Toledo, OH 43612

Plaintiffs,

v.

**BAYER CORPORATION**  
c/o CSC-Lawyers Incorporating  
Service (Corporation Service  
Company)  
50 W. Broad St. Suite 1800  
Columbus, OH 43215

and

**BAYER HEALTHCARE LLC,**  
c/o CSC-Lawyers Incorporating  
Service (Corporation Service  
Company)  
50 W. Broad St. Suite 1800  
Columbus, OH 43215

and

**BAYER PHARMACEUTICALS  
CORPORATION,**  
c/o CSC-Lawyers Incorporating  
Service (Corporation Service  
Company)  
50 W. Broad St. Suite 1800

) CASE NO.

) JUDGE

) **COMPLAINT WITH JURY DEMAND**  
) **ENDORSED HEREON**

) David W. Zoll (0008548)

) Michelle L. Kranz (0062479)

) Pamela A. Borgess (0072789)

) ZOLL, KRANZ & BORGESS, LLC

) 6620 W. Central Ave., Suite 200

) Toledo, OH 43617

) (419) 841-9623

) Fax: (419) 841-9719

) Email: david@toledolaw.com

) michelle@toledolaw.com

) pamela@toledolaw.com

) *Counsel for Plaintiffs*

Columbus, OH 43215 )  
)  
and )  
)  
**BAYER HEALTHCARE** )  
**PHARMACEUTICALS INC.** )  
c/o CSC-Lawyers Incorporating )  
Service (Corporation Service )  
Company) )  
50 W. Broad St. Suite 1800 )  
Columbus, OH 43215 )  
)  
and )  
)  
**BERLEX LABORATORIES, INC.** )  
c/o CSC-Lawyers Incorporating )  
Service (Corporation Service )  
Company) )  
340 Changebridge Road )  
Montville, NJ 07045 )  
)  
and )  
)  
**BERLEX, INC.** )  
c/o CSC-Lawyers Incorporating )  
Service (Corporation Service )  
Company) )  
340 Changebridge Road )  
Montville, NJ 07045 )  
)  
and )  
)  
**JOHN DOE MANUFACTURERS** )  
**A-Z** )  
[Real Names and Addresses )  
Unknown] )  
)  
and )  
)  
**JOHN DOE DISTRIBUTORS A-Z** )  
[Real Names and Addresses )  
Unknown] )  
)  
Defendants. )

---

Now come Jane and John Doe, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

**NATURE OF THE ACTION**

1. This is an action for strict product liability (Ohio R.C. § 2307.71 *et seq.*), fraudulent misrepresentation, civil conspiracy and commercial bribery, loss of consortium, and punitive damages brought by Plaintiff for damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff Jane Doe has suffered injuries to her person including, but not limited to, a pulmonary embolism.

**THE PARTIES**

3. Plaintiff Jane Doe, (herein “Plaintiff”), resides in the village of Toledo, Lucas County, Ohio.

4. Plaintiff is married to Plaintiff John Doe, who also resides in the village of Toledo, Lucas County, Ohio.

5. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

6. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

7. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

8. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

9. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

10. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

11. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

12. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a

principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

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

15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. applied for and received U.S. marketing approval of Yasmin and YAZ by the FDA, and is the holder of approved New Drug Application (“NDA”) for Yasmin and YAZ.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Ohio,

either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yasmin and YAZ.

20. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

21. Defendants John Doe Distributors A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yasmin and YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., and John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as “Defendants.”

23. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of

any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

24. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

### **JURISDICTION AND VENUE**

25. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

26. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of YAZ, as well as Plaintiff's resulting injuries.

27. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitution pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Yasmin and YAZ within this District.

28. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

### **FACTS**

### **Yasmin and YAZ Background**

29. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

30. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).

31. Combination birth control pills are referred to as combined hormonal oral contraceptives.

32. Yasmin was approved by the FDA in April, 2001.

33. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

34. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

35. Shortly after the introduction of combined oral contraceptives in the 1960s, 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.

36. 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.

37. During the 1990s, 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.

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

39. 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.

40. Since drospirenone in birth control 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.

41. 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.

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

43. 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.

44. Another effect is a substantially increased risk of gallbladder complications.

45. 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.

46. 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.

47. 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.

48. 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.

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

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

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

### **Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and YAZ**

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

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

54. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

55. Indeed, the FDA felt Defendants' over-promotion of YAZ was so severe that it required Bayer to run new TV advertisements to correct the previous misleading YAZ advertisements.

56. 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.

57. Defendants ignored the correlation between the use of Yasmin and YAZ and increased thrombosis formation despite the wealth of scientific information available.

58. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of Yasmin and YAZ.

59. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and was found to be safe and/or effective for its indicated use.

60. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and

healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

61. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.

62. Defendants knew or should have known that Yasmin and YAZ had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

63. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

- a. That Yasmin/YAZ is not as safe as other available contraceptives;
- b. That the risks of adverse events with Yasmin/YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;
- c. That the risks of adverse events with Yasmin/YAZ was not adequately tested and/or known by Defendants;
- d. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, physical pain, and mental anguish;
- e. That patients needed to be monitored more regularly than normal while using Yasmin/YAZ; and/or
- f. That Yasmin/YAZ was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

64. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

65. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and YAZ, including Plaintiff.

66. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

67. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

68. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

69. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

70. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

71. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ in a timely manner, yet

they failed to provide such warning.

**FACTS REGARDING PLAINTIFF JANE DOE**

72. Plaintiff was prescribed YAZ by her health care provider.

73. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

74. As a result of using Defendants' product YAZ, in March of 2008, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

75. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least April of 2009.

**CAUSES OF ACTION**

**COUNTS I-IV**

**Defective Manufacturing/Construction (R.C. § 2307.74)**

**Defective Design/Formulation (R.C. § 2307.75)**

**Defective Warning/Instruction (R.C. § 2307.76)**

**Defective Due to Nonconformity with Representation (R.C. § 2307.77)**

76. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

77. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drugs, Yasmin and YAZ, that were placed into the stream of commerce.

78. The Yasmin and YAZ birth control pills were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

79. The Yasmin and YAZ birth control pills manufactured, designed, sold, distributed, supplied, promoted and/or placed in the stream of commerce by Defendant were defective in their:

- a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;
- b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;
- c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or
- d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

80. Specifically, Defendants' failures, which permitted defective drugs, Yasmin and YAZ, to be placed in the stream of commerce, include, but are not necessarily limited to:

- a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of Yasmin and YAZ;
- b. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the substantially increased risks and serious side effects of the drug;
- c. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;
- d. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious increased side effects, including, but not limited to, a pulmonary embolism, and other serious and life threatening side effects;

- e. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, a pulmonary embolism and other serious and life threatening side effects;
- f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;
- g. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and
- h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

81. Yasmin and YAZ were unsafe for normal or reasonably anticipated use.

82. Plaintiff was using the drug in the manner for which it was intended and/or in a reasonably foreseeable manner.

83. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

84. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

85. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**COUNT V**  
**Fraudulent Misrepresentation**

86. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

87. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Yasmin and YAZ, owed a duty not to deceive the Plaintiff, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their drug.

88. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq.*

89. Since the drug's approval in April of 2001, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the public ad campaigns which were the subject of the FDA's 2003, 2008 and 2009 warnings.

90. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

91. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding Yasmin and YAZ.

92. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

93. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

94. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

95. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**COUNTS VI-VII**  
**Civil Conspiracy and Commercial Bribery**

96. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

97. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these

entities to use the drugs Yasmin and YAZ, and to convince their patients and others of the safety and effectiveness of Yasmin and YAZ.

**COUNT VIII**  
**Loss of Consortium**

98. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

99. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff. Plaintiff John Doe has suffered the loss of companionship, society, services, and consortium of his wife.

**COUNT IX**  
**Punitive Damages**

100. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

101. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

- A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of \$75,000;
- B. For an award of punitive or exemplary damages against Defendants and each of them in excess of \$75,000;

- C. For reasonable attorneys' fees and costs;
- D. For pre-judgment interest; and
- E. For such further and other relief the court deems just, equitable, and proper.

Dated: July 21, 2009

Respectfully Submitted,

/s/David W. Zoll  
David W. Zoll (0008548)  
ZOLL, KRANZ & BORGESS, LLC  
6620 W. Central Ave., Suite 200  
Toledo, OH 43617  
(419) 841-9623  
Fax: (419) 841-9719  
Email: david@toledolaw.com

/s/Michelle Kranz  
Michelle L. Kranz (0062479)  
ZOLL, KRANZ & BORGESS, LLC  
6620 W. Central Ave., Suite 200  
Toledo, OH 43617  
(419) 841-9623  
Fax: (419) 841-9719  
Email: michelle@toledolaw.com

/s/Pamela A. Borgess  
Pamela A. Borgess (0072789)  
ZOLL, KRANZ & BORGESS, LLC  
6620 W. Central Ave., Suite 200  
Toledo, OH 43617  
(419) 841-9623  
Fax: (419) 841-9719  
Email: pamela@toledolaw.com

*Counsel for Plaintiffs*

**JURY DEMAND**

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

/s/David W. Zoll  
David W. Zoll (0008548)