

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

ANGELA BECK
13125 Kay Street
Paulding, Ohio 45879

and

MARTIN BECK
13125 Kay Street
Paulding, Ohio 45879

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

) 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

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) *Counsel for Plaintiffs*

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Company))
50 W. Broad St. Suite 1800)
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 07405)

and)

BERLEX, INC.)
c/o CSC-Lawyers Incorporating)
Service (Corporation Service)
Company))
340 Changebridge Road)
Montville, NJ 07405)

and)

BAYER SCHERING PHARMA AG)
MÜLLERSTRASSE 178)
13353 BERLIN, GERMANY)

and)

BAYER AG)
BAYERWERK, GEBÄUDE W11,)
KAISER-WILHELM-ALLEE)
51368 LEVERKUSEN, GERMANY)

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 Angela and Martin Beck, 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. §§ 2307.71-2307.80), fraud, civil conspiracy and commercial bribery, 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 Angela Beck has suffered injuries to her person including, but not limited to, a pulmonary embolism.

THE PARTIES

3. Plaintiff Angela Beck, (herein “Plaintiff”), resides in the village of Paulding, Paulding County, Ohio.
4. Plaintiff is married to Plaintiff Martin Beck, who also resides in the village of Paulding, Paulding 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, 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, 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, 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, YAZ.
16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved New Drug Application (“NDA”) for 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, YAZ.
20. 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 German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.
21. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.
22. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.
23. Defendant BAYER SCHERING PHARMA AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.
24. At all times relevant, Defendant BAYER SCHERING PHARMA AG 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, YAZ.
25. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

26. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.
27. Defendant BAYER AG is the third largest pharmaceutical company in the world.
28. Defendant BAYER AG is the parent/holding company of all other named Defendants.
29. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.
30. At all times relevant, Defendant BAYER AG 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, YAZ.
31. 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 YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.
32. 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 YAZ into interstate commerce, including in the Northern District of Ohio, and derived substantial revenue from these activities.

33. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, Bayer AG, John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as “Defendants.”
34. 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.
35. 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

36. 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.
37. 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.
38. 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 YAZ within this District.

39. 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

40. 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.
41. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).
42. Combination birth control pills are referred to as combined hormonal oral contraceptives.
43. Yasmin was approved by the FDA in April, 2001.
44. 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).
45. 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.
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. 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.
49. The use of YAZ has a prothrombotic effect resulting in thrombosis such as the pulmonary embolism suffered by Plaintiff.
50. Defendants ignored the correlation between the use of YAZ and increased thrombosis formation despite the wealth of scientific information available.
51. Upon information and belief, Defendants knew or should have known about the correlation between the use of YAZ and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of YAZ.
52. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that YAZ had been tested and was found to be safe and/or effective for its indicated use.
53. 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 YAZ for

use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

54. Defendants knew and were aware or should have been aware that YAZ had not been sufficiently tested, was defective in its design and testing, and/or that it lacked adequate and/or sufficient warnings.
55. Defendants knew or should have known that 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 downplayed warnings.
56. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:
 - A. That YAZ is not as safe as other available contraceptives;
 - B. That the risks of adverse events with YAZ (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;
 - C. That the risks of adverse events with 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 YAZ; and
 - F. That YAZ was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.
57. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of YAZ.
58. 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 YAZ, including Plaintiff.

59. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of 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 YAZ as a contraceptive.
60. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.
61. 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.
62. 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 YAZ, as set forth herein.
63. 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 YAZ.
64. 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 ANGELA BECK

65. Plaintiff was first prescribed YAZ by her health care provider in approximately April of 2007.
66. 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.
67. As a result of using Defendants' product YAZ, a few months later in approximately the end of June, early July 2007, 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.
68. 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

Statutory Products Liability (R.C. § 2307.71-2307.80)

69. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
70. Defendants are manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the drug, YAZ.
71. YAZ reached the ultimate users without substantial change in the condition it was sold.
72. The drug was defective due to inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, in its design pursuant to the provisions of Ohio Revised

Code § 2307.75 and/or in its failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

73. Said defect was a result of Defendants' failures including, but not limited to:
- A. 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 potential risks and serious side effects of the drug;
 - B. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;
 - C. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, a pulmonary embolism, and other serious and life threatening side effects;
 - D. 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;
 - E. 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;
 - F. 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
 - G. 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.
74. Plaintiff was using YAZ in the manner for which it was intended and/or in a reasonably foreseeable manner.
75. Plaintiff was not aware of and reasonably could not have discovered the dangerous nature of YAZ.

76. As a result of the foregoing acts and omissions, 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.

Fraud

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

78. Defendants having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of YAZ described herein, owed a duty not to deceive the public regarding its drug's safety and to provide accurate and complete information regarding the product.

79. Since the drug's approval and on multiple occasions to the present date, Defendants fraudulently misrepresented information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's safety.

80. 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.

81. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product.

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

83. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.
84. 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.

Civil Conspiracy and Commercial Bribery

85. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
86. 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 drug YAZ, and to convince their patients and others of the safety and effectiveness of YAZ.

Loss of Consortium

87. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
88. 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 Martin Beck has suffered the loss of companionship, society, services, and consortium of his wife.

Punitive Damages

89. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
90. 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, Plaintiffs pray 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 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: May 26, 2009

Respectfully Submitted,

/s/David W. Zoll
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Counsel for Plaintiffs

JURY DEMAND

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

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