STATE OF SOUTH CAROLINA)
)
COUNTY OF DARLINGTON)

IN THE COURT OF COMMON PLEAS

Theresa Dubose Harrison,

Plaintiff(s)

vs.

Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;

Defendant(s)

CIVIL ACTION COVERSHEET

2010-CP - 16-

10 CP 16 0392

(Please Print)
Submitted By: J. Thomas McBratney, III
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NOTE: The cover sheet and information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is required for the use of the Clerk of Court for the purpose of docketing. It must be filled out completely, signed, and dated. A copy of this cover sheet must be served on the defendant(s) along with the Summons and Complaint.

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2010 JUN 22 PM 4:18
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DARLINGTON COUNTY, S.C.

DOCKETING INFORMATION (*Check all that apply*)

*If Action is Judgment/Settlement do not complete

☒ JURY TRIAL demanded in complaint. ☐ NON-JURY TRIAL demanded in complaint.
☐ This case is subject to ARBITRATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.
☐ This case is subject to MEDIATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.
☐ This case is exempt from ADR. (Proof of ADR/Exemption Attached)

NATURE OF ACTION (*Check One Box Below*)

Contracts
- ☐ Constructions (100)
- ☐ Debt Collection (110)
- ☐ Employment (120)
- ☐ General (130)
- ☐ Breach of Contract (140)
- ☐ Other (199)

Torts - Professional Malpractice
- ☐ Dental Malpractice (200)
- ☐ Legal Malpractice (210)
- ☐ Medical Malpractice (220)

Previous Notice of Intent Case # 20___-CP-____-_____

- ☐ Notice/ File Med Mal (230)
- ☐ Other (299)

Torts – Personal Injury
- ☐ Assault/Slander/Libel (300)
- ☐ Conversion (310)
- ☐ Motor Vehicle Accident (320)
- ☐ Premises Liability (330)
- ☒ Products Liability (340)
- ☒ Personal Injury (350)
- ☐ Wrongful Death (360)
- ☐ Other (399)

Real Property
- ☐ Claim & Delivery (400)
- ☐ Condemnation (410)
- ☐ Foreclosure (420)
- ☐ Mechanic's Lien (430)
- ☐ Partition (440)
- ☐ Possession (450)
- ☐ Building Code Violation (460)
- ☐ Other (499)

Inmate Petitions
- ☐ PCR (500)
- ☐ Mandamus (520)
- ☐ Habeas Corpus (530)
- ☐ Other (599)

Judgments/Settlements
- ☐ Death Settlement (700)
- ☐ Foreign Judgment (710)
- ☐ Magistrate's Judgment (720)
- ☐ Minor Settlement (730)
- ☐ Transcript Judgment (740)
- ☐ Lis Pendens (750)
- ☐ Transfer of Structured Settlement Payment Rights Application (760)
- ☐ Other (799)

Administrative Law/Relief
- ☐ Reinstate Driver's License (800)
- ☐ Judicial Review (810)
- ☐ Relief (820)
- ☐ Permanent Injunction (830)
- ☐ Forfeiture-Petition (840)
- ☐ Forfeiture—Consent Order (850)
- ☐ Other (899)

Appeals
- ☐ Arbitration (900)
- ☐ Magistrate-Civil (910)
- ☐ Magistrate-Criminal (920)
- ☐ Municipal (930)
- ☐ Probate Court (940)
- ☐ SCDOT (950)
- ☐ Worker's Comp (960)
- ☐ Zoning Board (970)
- ☐ Public Service Commission (980)
- ☐ Employment Security Comm (991)
- ☐ Other (999)

Special/Complex /Other
- ☐ Environmental (600)
- ☐ Automobile Arb. (610)
- ☐ Medical (620)
- ☐ Other (699)
- ☒ Pharmaceuticals (630)
- ☐ Unfair Trade Practices (640)
- ☐ Out-of State Depositions (650)
- ☐ Motion to Quash Subpoena in an Out-of-County Action (660)
- ☐ Sexual Predator (510)

TRUE CERTIFIED COPY
Scott B. Singer
CLERK OF COURT/RMD
DARLINGTON COUNTY, S.C.

Submitting Party Signature: J. Thomas McBratney **Date:** 6/21/2010

SCCA / 234 (11/09)

Note: Frivolous civil proceedings may be subject to sanctions pursuant to SCRCP, Rule 11, and the South Carolina Frivolous Civil Proceedings Sanctions Act, S.C. Code Ann. §15-36-10 et. seq.

10 CP 160392

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FOR MANDATED ADR COUNTIES ONLY

Allendale, Anderson, Beaufort, Colleton, Florence, Greenville, Hampton, Horry, Jasper, Lexington, Pickens (Family Court Only), and Richland

SUPREME COURT RULES REQUIRE THE SUBMISSION OF ALL CIVIL CASES TO AN ALTERNATIVE DISPUTE RESOLUTION PROCESS, UNLESS OTHERWISE EXEMPT.

You are required to take the following action(s):

10 CP 1603982

1. The parties shall select a neutral and file a "Proof of ADR" form on or by the 210th day of the filing of this action. If the parties have not selected a neutral within 210 days, the Clerk of Court shall then appoint a primary and secondary mediator from the current roster on a rotating basis from among those mediators agreeing to accept cases in the county in which the action has been filed.

2. The initial ADR conference must be held within 300 days after the filing of the action.

3. Pre-suit medical malpractice mediations required by S.C. Code §15-79-125 shall be held not later than 120 days after all defendants are served with the "Notice of Intent to File Suit" or as the court directs. (Medical malpractice mediation is mandatory statewide.)

4. Cases are exempt from ADR only upon the following grounds:

   a. Special proceeding, or actions seeking extraordinary relief such as mandamus, habeas corpus, or prohibition;

   b. Requests for temporary relief;

   c. Appeals

   d. Post Conviction relief matters;

   e. Contempt of Court proceedings;

   f. Forfeiture proceedings brought by governmental entities;

   g. Mortgage foreclosures; and

   h. Cases that have been previously subjected to an ADR conference, unless otherwise required by Rule 3 or by statute.

5. In cases not subject to ADR, the Chief Judge for Administrative Purposes, upon the motion of the court or of any party, may order a case to mediation.

6. Motion of a party to be exempt from payment of neutral fees due to indigency should be filed with the Court within ten (10) days after the ADR conference has been concluded.

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DARLINGTON COUNTY, S.C.

Please Note: **You must comply with the Supreme Court Rules regarding ADR. Failure to do so may affect your case or may result in sanctions.**

STATE OF SOUTH CAROLINA)
)
COUNTY OF DARLINGTON)

IN THE COURT OF COMMON PLEAS
FOR THE FOURTH JUDICIAL CIRCUIT
CIVIL ACTION NO.: 2010-CP-16-_____

Theresa Dubose Harrison,

Plaintiff,

v.

Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;

Defendants.

10 CP 16 0392

SUMMONS
JURY TRIAL DEMANDED

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DARLINGTON COUNTY, S.C.

YOU ARE HEREBY SUMMONED and required to answer the Complaint in this action, of which a copy herewith is served upon you, and to serve a copy of your Answer to the said Complaint on the subscriber at McBratney Law Firm, P.A., P.O. Box 3890, Florence, South Carolina, 29502, within thirty (30) days after service hereof, or if served by certified mail within thirty-five (35) days after service, exclusive of the day of such service; and if you fail to answer the Complaint within the time aforesaid, judgment by default will be rendered against you for the relief demanded in the Complaint.

Dated at Florence, South Carolina, this 21st day of June 2010.

June 21, 2010

J. Thomas McBratney, III
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Attorneys for Plaintiff

STATE OF SOUTH CAROLINA COUNTY OF DARLINGTON	IN THE COURT OF COMMON PLEAS FOR THE FOURTH JUDICIAL CIRCUIT CIVIL ACTION NO.: 2010-CP-16-_____
Theresa Dubose Harrison, Plaintiff, v. Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG; Defendants.	10 CP 16 0392 **COMPLAINT** **JURY TRIAL DEMANDED**

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Plaintiff, Theresa Dubose Harrison, through the undersigned counsel, complaining of the Defendants respectfully alleges the following:

1. Plaintiff, Theresa Dubose Harrison, is an adult resident of Darlington County, South Carolina.

2. Defendant Bayer Corporation is a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburg, Pennsylvania 15205.

3. Defendant Bayer Healthcare LLC is 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, Pennsylvania 15205. Defendant Bayer Healthcare LLC is wholly owned by Defendant Bayer Corporation.

4. Defendant Bayer Pharmaceuticals Corporation was, at all times relevant to this complaint, a corporation organized under the laws of [illegible] with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

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DARLINGTON COUNTY, S.C.

5. As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

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6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

7. 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.

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

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of approved NDA for Yasmin.

10. Defendant Berlex Laboratories, Inc. and Berlex, Inc. are foreign corporations with their headquarters and principal places of business in the State of New Jersey.

11. Defendants Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under the new name, Bayer Healthcare Pharmaceuticals, Inc.

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

13. Defendant Bayer Schering Pharma AG is a corporate successor to Schering AG.

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

15. Defendant Bayer Schering Pharma AG's headquarters and principal place of business in the United States is 100 Bayer Road, Pittsburg, Pennsylvania n15205.

16. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, Yasmin. Bayer Schering Pharma AG manufactures the oral contraceptive, Ocella, a generic form of Yasmin, pursuant to agreements for sale and distribution in the United States.

17. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, YAZ.

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

19. Defendant Bayer AG is the third largest pharmaceutical company in the world.

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

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

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc., Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG shall be referred to hereinafter individually by name or jointly as "Defendants."

23. Defendants include any and all parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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 venture 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.

25. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the State of South Carolina, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives, YAZ, Yasmin and/or Ocella.

26. This Court has jurisdiction of this matter under Articles V and VII of the South Carolina Constitution, S.C. Code Ann. § 14-1-80, and the common law of South Carolina.

27. Venue is proper in this jurisdiction because Plaintiff resided in Darlington County, South Carolina at the time the cause of action arose. Further, Defendants, which are foreign corporations, regularly conduct substantial business in Darlington County in the State of South Carolina and introduce their products into the stream of commerce.

28. The amount in controversy exceeds, exclusive of interest and costs, the jurisdictional minimum of this Court.

Factual Background

29. Plaintiff brings this case against Defendants for damages associated with Plaintiff's ingestion of the pharmaceutical drug YAZ, Yasmin and/or Ocella (DRSP/EE), an oral contraceptive designed, exclusively manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered serious menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy in May of 2008, as a direct result of her use of YAZ,

Yasmin and/or Ocella. Plaintiff also suffered gallbladder damage, which required surgery and removal of her gallbladder.

30. YAZ, Yasmin and Ocella 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.

31. Yasmin received FDA approval first in 2001. It is a combination of drospirenone ("DRSP"), a progestin, and ethinyl estradiol ("EE"), an estrogen. Hence, this family of drugs is often identified, or abbreviated as DRSP/EE. Ocella is a generic form of Yasmin manufactured exclusively by Bayer Schering AG for sale and distribution throughout the United States of America.

32. YAZ received approval from the FDA in 2006 and is essentially the same as Yasmin with the only difference being a slightly smaller amount of ethinyl estradiol ("EE").

33. YAZ and Yasmin were approved by the FDA for marketing in 2001 and 2006 respectively.

34. YAZ, Yasmin and Ocella all contain a "Fourth Generation" Progestin manufactured and developed by the Defendants called drospirenone or "DRSP."

35. The estrogen component in YAZ, Yasmin and Ocella is known generically as ethinyl estradiol ("EE").

36. The progestin component is generically known as drospirenone ("DRSP").

37. Yasmin contains 0.03 milligrams of ethinyl estradiol ("EE"), and YAZ contains 0.02 milligrams of ethinyl estradiol ("EE"). Similarly, the generic is made up of the foregoing formulation.

38. YAZ, Yasmin and Ocella all contain 3 milligrams of drospirenone ("DRSP").

39. YAZ, Yasmin and Ocella are different from other combined hormonal birth control pills in that they contain drospirenone ("DRSP"), 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.

40. 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.

41. 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 ("EE"), helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

42. During the 1990s, new "Third Generation" progestins were developed.

43. 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.

44. YAZ, Yasmin and Ocella contain the same estrogen component, ethinyl estradiol ("EE"), which has been used in the lower dose birth control pills for decades. However, drospirenone ("DRSP") is a new type of progestin and is considered a "Fourth Generation" progestin. No

other birth control pills contain drospirenone, ("DRSP"), except for YAZ, and the approved generic version of Yasmin, which is marketed under the trade name Ocella.

45. Since drospirenone ("DRSP") is new, there a 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 ("DRSP") has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

46. One possible mechanism of action is that drospirenone ("DRSP") 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.

47. Hyperkalemia can cause heart rhythm disturbances, such as extra systoles, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

48. 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.

49. Indeed, during the time that YAZ, Yasmin and Ocella 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. In fact, hundreds of lawsuits are now pending nationwide for injuries arising out of the use of said "DRSP/EE" contraceptives.

50. 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.

51. 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. 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. Again, hundreds of lawsuits are now pending throughout the United States for claims arising out of the use or ingestion of DRSP/EE contraceptives. Moreover, the DRSP/EE family of contraceptives has been the subject of four FDA Warning Letters, including a recent letter regarding the manufacturing process, quality control standards and related citations based upon an inspection of the manufacturing facility.

52. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years. Additional claims include injuries resulting in damage to the gallbladder, pancreas, as well as surgery related complications and permanent scarring in women of all ages.

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

54. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering injuries while using YAZ, Yasmin and Ocella.

55. Defendants market YAZ and Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, while also claiming additional benefits.

56. However, because YAZ, Yasmin and Ocella contain the "Fourth Generation" progestin drospirenone "DRSP", which is a diuretic, they present additional health risks not associated with other birth control pills.

57. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's "Fourth Generation" progestin, drospirenone ("DRSP"), by stating, "Ask about Yasmin, and the difference a little chemistry can make."

58. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone ("DRSP") 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. . ."

59. 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."

60. More recently, Defendants advertised that its product YAZ was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the condition of premenstrual dysphoric disorder or "PMDD," which is recognized by the DSM-IV as a debilitating condition that interferes with the daily living of women during certain time periods.

61. Defendants also advertised that YAZ contained the added benefit of preventing or reducing acne in teenage girls or women.

62. In response, on October 3, 2008, the FDA issued another Warning Letter to Defendants 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."

63. 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 regarding acne and premenstrual syndrome, as well as the failure to adequately underscore risks and dangers associated with the pill.

64. Bayer ultimately agreed to spend at least $20 Million on corrective TV advertisements and, among other things, to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

65. Defendants did not provide adequate warnings to doctors, the healthcare community, or the public about the risk of serious adverse events that are described in this complaint. To date, the FDA has issued four Warning Letters associated with the DRSP/EE family of oral contraceptives containing drospirenone. Again, the most recent letter called into question existing protocols for quality control and sampling of the product in the manufacturer facilities.

66. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of YAZ, Yasmin and/or Ocella without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

67. As a result of Defendants' claim regarding the effectiveness and safety of YAZ, Yasmin and/or Ocella, Plaintiff's medical provider prescribed her and she ingested a DRSP/EE oral contraceptive pill.

68. As a direct and proximate result of using a DRSP/EE or contraceptive or YAZ, Yasmin and/or Ocella, in or about May 2008, after taking YAZ, Yasmin and/or Ocella, as prescribed by her physician, Plaintiff suffered severe menstrual clotting or blood clots in her uterus, which

required an emergency hysterectomy. Plaintiff also suffered severe gallbladder damage requiring surgery and the removal of her gallbladder.

69. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella, Defendants knew or should have known that use of YAZ, Yasmin and/or Ocella created a higher risk of deaths, blood clots, cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, and/or gallbladder removal, 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.

70. Therefore, at the time Plaintiff used YAZ, Yasmin and/or Ocella, Defendants knew or should have known that the use of YAZ, Yasmin and/or Ocella created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, other injuries associated with blood clots, and even death.

71. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of YAZ, Yasmin and/or Ocella, Defendants failed to warn Plaintiff and/or her healthcare providers of said serious risks before she used the product.

72. Had Plaintiff and/or her healthcare providers known the risks and dangers associated with DRSP/EE oral contraceptives, YAZ, Yasmin and/or Ocella, she would not have used YAZ, Yasmin and/or Ocella and would not have suffered the injuries described above.

73. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella, Plaintiff suffered physical injury and extreme mental anguish and emotional distress as a result of her hysterectomy and gallbladder removal surgery.

74. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella and resulting injuries, Plaintiff suffered damages, harm, permanent injury, emotional distress, pain and suffering. Plaintiff has also incurred medical expenses and other economic harm.

COUNT ONE – FRAUDULENT CONCEALMENT

75. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

76. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella and during the time period in which Plaintiff actually used YAZ, Yasmin and/or Ocella, Defendants fraudulently suppressed material information regarding the safety and efficacy of DRSP/EE oral contraceptives, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, and the unique gallbladder damages. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of the DRSP/EE family of contraceptives strong and reach blockbuster sales in excess of $1 Billion dollars. These drugs have gained a substantial market share since their introduction into the marketplace.

77. Defendants fraudulently concealed safety issues with YAZ, Yasmin and/or Ocella in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use YAZ, Yasmin and/or Ocella.

78. At the time Defendants concealed the fact that YAZ, Yasmin and/or Ocella were not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the

healthcare community, and the general public in such a manner that they could appreciate the risks associated with using any DRSP/EE birth control pills.

79. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of the DRSP/EE family of oral contraceptives: YAZ, Yasmin and/or Ocella.

80. As a direct and proximate result of Defendants' malicious and/or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries described above.

81. It is unconscionable and outrageous that Defendants would risk the health and safety of consumers solely for financial gain. Despite the knowledge of the health and safety risks associated with YAZ, Yasmin and/or Ocella, Defendants made the conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary the Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

82. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the truth about the dangers associated with the use of YAZ, Yasmin and/or Ocella. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the healthcare community, or the general public. Without full knowledge of the dangers of the DRSP/EE family of birth control pills: YAZ, Yasmin and/or Ocella, Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by YAZ, Yasmin and/or Ocella had a valid claim.

83. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff has been injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

84. Plaintiff is entitled to judgment against the Defendants for compensatory and punitive damages in an amount to be proven at trial plus interest and costs.

COUNT TWO – STRICT LIABILITY

85. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

86. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug family of DRSP/EE pills, YAZ, Yasmin and/or Ocella, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff. The FDA recently issued a Warning Letter, the fourth Warning Letter associated with the DRSP/EE family of birth control pills, questioning the manufacturing process and quality control standards as they existed at the time of the inspection.

87. The YAZ, Yasmin and/or Ocella, DRSP/EE birth control pills used by the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

88. Plaintiff did not misuse or materially alter the YAZ, Yasmin and/or Ocella pills.

89. Defendants are strictly liable for Plaintiff's injuries in the following ways:

a. The pharmaceutical YAZ, Yasmin and/or Ocella, DRSP/EE pills, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell YAZ, Yasmin and/or Ocella;

c. Defendants failed to warn and/or place adequate warnings and instructions on YAZ, Yasmin and/or Ocella;

d. Defendants failed to adequately test YAZ, Yasmin and/or Ocella, DRSP/EE pills;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of YAZ, Yasmin and/or Ocella; and

f. A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

90. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

91. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

92. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT THREE – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

93. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

94. At the time Defendants marketed, distributed and sold YAZ, Yasmin and/or Ocella to Plaintiff, Defendants warranted that YAZ, Yasmin and/or Ocella was merchantable and fit for the ordinary purposes for which it was intended.

95. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

96. YAZ, Yasmin and/or Ocella were not merchantable or fit for their ordinary purpose because YAZ, Yasmin and/or Ocella have a propensity to lead to the serious personal injuries described in this Complaint.

97. Plaintiff reasonably relied on Defendants' representations that YAZ, Yasmin and/or Ocella was a safe means of birth control and free of defects.

98. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

99. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FOUR – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

100. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

101. Defendants sold YAZ, Yasmin and/or Ocella with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced

bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

102. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

103. YAZ, Yasmin and/or Ocella were not fit for the particular purpose of a safe birth control pill without serious risk of personal injury. The risk of serious personal injury associated with YAZ, Yasmin and/or Ocella is much higher than other birth control pills.

104. Plaintiff reasonably relied on Defendants' misrepresentations that YAZ, Yasmin and/or Ocella was a safe and effective means of birth control and free of defects.

105. As a direct and proximate result of Defendants' breach of the implied warranty of fitness for a particular purpose, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and
f. Plaintiff has incurred and will continue to incur medical expenses.

106. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FIVE – NEGLIGENT FAILURE TO WARN

107. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

108. Before Plaintiff used YAZ, Yasmin and/or Ocella, and during the period in which she used it, Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella were dangerous and created an unreasonable risk of foreseeable bodily harm to consumers.

109. Defendants had a duty to exercise reasonable care to warn consumers of YAZ, Yasmin and/or Ocella of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

110. Despite the fact that Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella was dangerous, Defendants were negligent, grossly negligent, willful and wanton in failing to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

111. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton failure to warn the medical community and consumers, including Plaintiff, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

112. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

113. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SIX - NEGLIGENCE

114. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

115. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of YAZ, Yasmin and/or Ocella, including a duty to assure that the product did not cause unreasonable, dangerous side effects to its users.

116. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of YAZ, Yasmin and/or Ocella in that Defendants k new or should have known that the drug created a high risk of unreasonable harm. The FDA has actually issued a Warning Letter with regard to the manufacture of DRSP (drospirenone), in addition to the aforementioned way in which the DRSP oral contraceptive family was marketed.

117. Defendants were negligent, grossly negligent, willful and wanton in the design, manufacture, advertising, warning, marketing and sale of YAZ, Yasmin and/or Ocella in one or more of the following ways:

a. Failing to use due care in designing and manufacturing YAZ, Yasmin and/or Ocella so as to avoid the aforementioned risks to individuals;

b. Failing to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse side effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failing to provide adequate training and instruction to medical care providers for the appropriate use of YAZ, Yasmin and/or Ocella. Alternatively, the Defendants failed to truthfully provide such training and/or instruction to medical care providers for the use of DRSP/EE birth control pills;

d. Placing an unsafe product into the stream of commerce; and

e. In otherwise failing to use that degree of care and caution which an ordinarily prudent person would exercise under the circumstances.

118. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

119. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

120. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SEVEN – NEGLIGENT MISREPRESENTATION

121. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

122. Prior to Plaintiff first using YAZ, Yasmin and/or Ocella and during the period in which she used YAZ, Yasmin and/or Ocella, Defendants misrepresented that DRSP/EE family of oral contraceptives was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of DRSP/EE birth control pills, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life-threatening.

123. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

124. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with DRSP/EE oral contraceptives, that their representations regarding either YAZ, Yasmin and/or Ocella, or the DRSP/EE family of oral contraceptives, were false, and that they had a duty to disclose the dangers of DRSP/EE contraceptive pills.

125. Defendants made false representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing YAZ, Yasmin and/or Ocella.

126. Plaintiff justifiably and reasonably relied on Defendants' misrepresentations and nondisclosures by purchasing and using YAZ, Yasmin and/or Ocella.

127. As a direct and proximate result of Defendants' negligent misrepresentations and nondisclosures, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

128. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

129. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT EIGHT – BREACH OF EXPRESS WARRANTY

130. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

131. Defendants expressly warranted that YAZ, Yasmin and/or Ocella was safe and effective to members of the consuming public, including Plaintiff.

132. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

133. Defendants marketed, promoted and sold YAZ, Yasmin and/or Ocella as a safe method of birth control.

134. YAZ, Yasmin and/or Ocella does not conform to Defendants' express representations because YAZ, Yasmin and/or Ocella is not safe and has serious side effects, including death.

135. The manufacturer of a product is responsible for adequately warning and instructing the consuming public with regard to the proper use and application of a product as long as their product in on the market and the responsibility to do so rests upon the manufacturer.

136. Defendants breached their express warranty in one or more of the following ways:

a. YAZ, Yasmin and/or Ocella was defectively designed and placed into the stream of commerce in a defective and unreasonably dangerous condition;

b. Failing to warn and/or place adequate warning and instructions on the DRSP/EE family of contraceptives – YAZ, Yasmin and/or Ocella;

c. Failing to adequately test YAZ, Yasmin and/or Ocella; and

d. Failing to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury from YAZ, Yasmin and/or Ocella.

137. Plaintiff reasonably relied upon Defendants' warranty that YAZ, Yasmin and/or Ocella was safe and effective when she purchased and used the product.

138. As a direct and proximate result of Defendants' breach of warranty, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

139. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

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COUNT NINE - FRAUD

140. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

141. Defendants widely advertised and promoted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive.

142. Defendants had a duty to disclose material information about the serious side effects to consumers such as Plaintiff.

143. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive, Defendants had a duty to disclose all facts about the risks associated with use of YAZ, Yasmin and/or Ocella, including the risks described in this Complaint. Defendants intentionally failed to disclose this material information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' unreasonably dangerous product.

144. Plaintiff reasonably and justifiably relied on the completeness and accuracy of Defendants' partial disclosures regarding the safety and efficacy of YAZ, Yasmin and/or Ocella. Had Plaintiff been aware of the hazards associated with YAZ, Yasmin and/or Ocella, Plaintiff would not have consumed the product that proximately led to Plaintiff's injuries and damages.

145. Defendants' advertisements regarding YAZ, Yasmin and/or Ocella materially misrepresented that DRSP/EE oral contraceptives were a safe and effective means of birth control.

146. Defendants knew their representations were false and intentionally withheld the truth for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase and consume YAZ, Yasmin and/or Ocella.

147. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with YAZ, Yasmin and/or Ocella with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

a. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff was injured and damaged as follows: Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and
f. Plaintiff has incurred and will continue to incur medical expenses.

148. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

149. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

WHEREFORE, Plaintiff demands judgment against Defendants and prays for the following relief:

10 CP 160392

1. Compensatory damages;
2. Treble damages on all applicable counts;
3. Punitive damages on all applicable counts;
4. Pre and post-judgment interest;
5. Reasonable attorneys' fees, costs, and expert fees; and
6. Any other relief as this court may deem equitable and just.

FILED
2010 JUN 21 PM 4:49
SCOTT B. SUGGS
CLERK OF COURT/R.M.C.
DARLINGTON COUNTY, S.C.

June 21, 2010

J. Thomas McBratney

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Attorneys for Plaintiff

TRUE CERTIFIED COPY,
Scott B. Suggs
CLERK OF COURT/RMC
DARLINGTON COUNTY, S.C.

STATE OF SOUTH CAROLINA)
)
COUNTY OF DARLINGTON)

IN THE COURT OF COMMON PLEAS
FOR THE FOURTH JUDICIAL CIRCUIT
CIVIL ACTION NO.: 2010-CP-16-0392

Theresa Dubose Harrison,

Plaintiff,

v.

Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;

Defendants.

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2010 JUL 20 PM 1:45
SCOTT B. SUGGS
CLERK OF COURT/R.O.D.
DARLINGTON COUNTY, S.C.

SUMMONS
JURY TRIAL DEMANDED

YOU ARE HEREBY SUMMONED and required to answer the Amended Complaint in this action, of which a copy herewith is served upon you, and to serve a copy of your Answer to the said Complaint on the subscriber at McBratney Law Firm, P.A., P.O. Box 3890, Florence, South Carolina, 29502, within thirty (30) days after service hereof, or if served by certified mail within thirty-five (35) days after service, exclusive of the day of such service; and if you fail to answer the Complaint within the time aforesaid, judgment by default will be rendered against you for the relief demanded in the Complaint.

Dated at Florence, South Carolina, this 20th day of July 2010.

July 20, 2010

J. Thomas McBratney

J. Thomas McBratney, III
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Attorneys for Plaintiff

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Scott B. Suggs
CLERK OF COURT/R.O.D.
DARLINGTON COUNTY, S.C.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**AMENDED COMPLAINT**
	)	**JURY TRIAL DEMANDED**
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	

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CLERK OF COURT/R.M.D.
DARLINGTON COUNTY, S.C.

Plaintiff, Theresa Dubose Harrison, through the undersigned counsel, complaining of the Defendants respectfully alleges the following:

1. Plaintiff, Theresa Dubose Harrison, is an adult resident of Darlington County, South Carolina.

2. Defendant Bayer Corporation is a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburg, Pennsylvania 15205.

3. Defendant Bayer Healthcare LLC is 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, Pennsylvania 15205. Defendant Bayer Healthcare LLC is wholly owned by Defendant Bayer Corporation.

4. Defendant Bayer Pharmaceuticals Corporation was, at all times relevant to this complaint, 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.

TRUE CERTIFIED COPY
Scott B. Suggs
CLERK OF COURT/RMO
DARLINGTON COUNTY, S.C.

5. As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

7. 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.

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

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of approved NDA for Yasmin.

10. Defendant Berlex Laboratories, Inc. and Berlex, Inc. are foreign corporations with their headquarters and principal places of business in the State of New Jersey.

11. Defendants Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under the new name, Bayer Healthcare Pharmaceuticals, Inc.

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

13. Defendant Bayer Schering Pharma AG is a corporate successor to Schering AG.

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

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

16. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, Yasmin. Bayer Schering Pharma AG manufactures the oral contraceptive, Ocella, a generic form of Yasmin, pursuant to agreements for sale and distribution in the United States.

17. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, YAZ.

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

19. Defendant Bayer AG is the third largest pharmaceutical company in the world.

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

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

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc., Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG shall be referred to hereinafter individually by name or jointly as "Defendants."

23. Defendants include any and all parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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 venture 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.

25. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the State of South Carolina, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives, YAZ, Yasmin and/or Ocella.

26. This Court has jurisdiction of this matter under Articles V and VII of the South Carolina Constitution, S.C. Code Ann. § 14-1-80, and the common law of South Carolina.

27. Venue is proper in this jurisdiction because Plaintiff resided in Darlington County, South Carolina at the time the cause of action arose. Further, Defendants, which are foreign corporations, regularly conduct substantial business in Darlington County in the State of South Carolina and introduce their products into the stream of commerce.

28. The amount in controversy exceeds, exclusive of interest and costs, the jurisdictional minimum of this Court.

Factual Background

29. Plaintiff brings this case against Defendants for damages associated with Plaintiff's ingestion of the pharmaceutical drug YAZ, Yasmin and/or Ocella (DRSP/EE), an oral contraceptive designed, exclusively manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered serious menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy in January of 2006, as a direct result of her use of YAZ,

Yasmin and/or Ocella. Plaintiff also suffered gallbladder damage, which required surgery and removal of her gallbladder.

30. YAZ, Yasmin and Ocella 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.

31. Yasmin received FDA approval first in 2001. It is a combination of drospirenone ("DRSP"), a progestin, and ethinyl estradiol ("EE"), an estrogen. Hence, this family of drugs is often identified, or abbreviated as DRSP/EE. Ocella is a generic form of Yasmin manufactured exclusively by Bayer Schering AG for sale and distribution throughout the United States of America.

32. YAZ received approval from the FDA in 2006 and is essentially the same as Yasmin with the only difference being a slightly smaller amount of ethinyl estradiol ("EE").

33. YAZ and Yasmin were approved by the FDA for marketing in 2001 and 2006 respectively.

34. YAZ, Yasmin and Ocella all contain a "Fourth Generation" Progestin manufactured and developed by the Defendants called drospirenone or "DRSP."

35. The estrogen component in YAZ, Yasmin and Ocella is known generically as ethinyl estradiol ("EE").

36. The progestin component is generically known as drospirenone ("DRSP").

37. Yasmin contains 0.03 milligrams of ethinyl estradiol ("EE"), and YAZ contains 0.02 milligrams of ethinyl estradiol ("EE"). Similarly, the generic is made up of the foregoing formulation.

38. YAZ, Yasmin and Ocella all contain 3 milligrams of drospirenone ("DRSP").

39. YAZ, Yasmin and Ocella are different from other combined hormonal birth control pills in that they contain drospirenone ("DRSP"), 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.

40. 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.

41. 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 ("EE"), helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

42. During the 1990s, new "Third Generation" progestins were developed.

43. 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 "DVI") 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.

44. YAZ, Yasmin and Ocella contain the same estrogen component, ethinyl estradiol ("EE"), which has been used in the lower dose birth control pills for decades. However, drospirenone ("DRSP") is a new type of progestin and is considered a "Fourth Generation" progestin. No

other birth control pills contain drospirenone, ("DRSP"), except for YAZ, and the approved generic version of Yasmin, which is marketed under the trade name Ocella.

45. Since drospirenone ("DRSP") is new, there a 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 ("DRSP") has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

46. One possible mechanism of action is that drospirenone ("DRSP") 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.

47. Hyperkalemia can cause heart rhythm disturbances, such as extra systoles, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

48. 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.

49. Indeed, during the time that YAZ, Yasmin and Ocella 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. In fact, hundreds of lawsuits are now pending nationwide for injuries arising out of the use of said "DRSP/EE" contraceptives.

50. 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.

51. 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. 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. Again, hundreds of lawsuits are now pending throughout the United States for claims arising out of the use or ingestion of DRSP/EE contraceptives. Moreover, the DRSP/EE family of contraceptives has been the subject of four FDA Warning Letters, including a recent letter regarding the manufacturing process, quality control standards and related citations based upon an inspection of the manufacturing facility.

52. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years. Additional claims include injuries resulting in damage to the gallbladder, pancreas, as well as surgery related complications and permanent scarring in women of all ages.

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

54. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering injuries while using YAZ, Yasmin and Ocella.

55. Defendants market YAZ and Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, while also claiming additional benefits.

56. However, because YAZ, Yasmin and Ocella contain the "Fourth Generation" progestin drospirenone "DRSP", which is a diuretic, they present additional health risks not associated with other birth control pills.

57. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's "Fourth Generation" progestin, drospirenone ("DRSP"), by stating, "Ask about Yasmin, and the difference a little chemistry can make."

58. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone ("DRSP") 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. . ."

59. 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."

60. More recently, Defendants advertised that its product YAZ was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the condition of premenstrual dysphoric disorder or "PMDD," which is recognized by the DSM-IV as a debilitating condition that interferes with the daily living of women during certain time periods.

61. Defendants also advertised that YAZ contained the added benefit of preventing or reducing acne in teenage girls or women.

62. In response, on October 3, 2008, the FDA issued another Warning Letter to Defendants 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."

63. 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 regarding acne and premenstrual syndrome, as well as the failure to adequately underscore risks and dangers associated with the pill.

64. Bayer ultimately agreed to spend at least $20 Million on corrective TV advertisements and, among other things, to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

65. Defendants did not provide adequate warnings to doctors, the healthcare community, or the public about the risk of serious adverse events that are described in this complaint. To date, the FDA has issued four Warning Letters associated with the DRSP/EE family of oral contraceptives containing drospirenone. Again, the most recent letter called into question existing protocols for quality control and sampling of the product in the manufacturer facilities.

66. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of YAZ, Yasmin and/or Ocella without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

67. As a result of Defendants' claim regarding the effectiveness and safety of YAZ, Yasmin and/or Ocella, Plaintiff's medical provider prescribed her and she ingested a DRSP/EE oral contraceptive pill.

68. As a direct and proximate result of using a DRSP/EE or contraceptive or YAZ, Yasmin and/or Ocella, in or about January 2006, after taking YAZ, Yasmin and/or Ocella, as prescribed by her physician, Plaintiff suffered severe menstrual clotting or blood clots in her uterus, which

required an emergency hysterectomy. Plaintiff also suffered severe gallbladder damage requiring surgery and the removal of her gallbladder.

69. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella, Defendants knew or should have known that use of YAZ, Yasmin and/or Ocella created a higher risk of deaths, blood clots, cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, and/or gallbladder removal, 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.

70. Therefore, at the time Plaintiff used YAZ, Yasmin and/or Ocella, Defendants knew or should have known that the use of YAZ, Yasmin and/or Ocella created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, other injuries associated with blood clots, and even death.

71. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of YAZ, Yasmin and/or Ocella, Defendants failed to warn Plaintiff and/or her healthcare providers of said serious risks before she used the product.

72. Had Plaintiff and/or her healthcare providers known the risks and dangers associated with DRSP/EE oral contraceptives, YAZ, Yasmin and/or Ocella, she would not have used YAZ, Yasmin and/or Ocella and would not have suffered the injuries described above.

73. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella, Plaintiff suffered physical injury and extreme mental anguish and emotional distress as a result of her hysterectomy and gallbladder removal surgery.

74. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella and resulting injuries, Plaintiff suffered damages, harm, permanent injury, emotional distress, pain and suffering. Plaintiff has also incurred medical expenses and other economic harm.

COUNT ONE – FRAUDULENT CONCEALMENT

75. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

76. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella and during the time period in which Plaintiff actually used YAZ, Yasmin and/or Ocella, Defendants fraudulently suppressed material information regarding the safety and efficacy of DRSP/EE oral contraceptives, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, and the unique gallbladder damages. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of the DRSP/EE family of contraceptives strong and reach blockbuster sales in excess of $1 Billion dollars. These drugs have gained a substantial market share since their introduction into the marketplace.

77. Defendants fraudulently concealed safety issues with YAZ, Yasmin and/or Ocella in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use YAZ, Yasmin and/or Ocella.

78. At the time Defendants concealed the fact that YAZ, Yasmin and/or Ocella were not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the

healthcare community, and the general public in such a manner that they could appreciate the risks associated with using any DRSP/EE birth control pills.

79. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of the DRSP/EE family of oral contraceptives: YAZ, Yasmin and/or Ocella.

80. As a direct and proximate result of Defendants' malicious and/or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries described above.

81. It is unconscionable and outrageous that Defendants would risk the health and safety of consumers solely for financial gain. Despite the knowledge of the health and safety risks associated with YAZ, Yasmin and/or Ocella, Defendants made the conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary the Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

82. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the truth about the dangers associated with the use of YAZ, Yasmin and/or Ocella. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the healthcare community, or the general public. Without full knowledge of the dangers of the DRSP/EE family of birth control pills: YAZ, Yasmin and/or Ocella, Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by YAZ, Yasmin and/or Ocella had a valid claim.

83. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff has been injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

84. Plaintiff is entitled to judgment against the Defendants for compensatory and punitive damages in an amount to be proven at trial plus interest and costs.

COUNT TWO – STRICT LIABILITY

85. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

86. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug family of DRSP/EE pills, YAZ, Yasmin and/or Ocella, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff. The FDA recently issued a Warning Letter, the fourth Warning Letter associated with the DRSP/EE family of birth control pills, questioning the manufacturing process and quality control standards as they existed at the time of the inspection.

87. The YAZ, Yasmin and/or Ocella, DRSP/EE birth control pills used by the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

88. Plaintiff did not misuse or materially alter the YAZ, Yasmin and/or Ocella pills.

89. Defendants are strictly liable for Plaintiff's injuries in the following ways:

a. The pharmaceutical YAZ, Yasmin and/or Ocella, DRSP/EE pills, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell YAZ, Yasmin and/or Ocella;

c. Defendants failed to warn and/or place adequate warnings and instructions on YAZ, Yasmin and/or Ocella;

d. Defendants failed to adequately test YAZ, Yasmin and/or Ocella, DRSP/EE pills;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of YAZ, Yasmin and/or Ocella; and

f. A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

90. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

91. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

92. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT THREE – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

93. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

94. At the time Defendants marketed, distributed and sold YAZ, Yasmin and/or Ocella to Plaintiff, Defendants warranted that YAZ, Yasmin and/or Ocella was merchantable and fit for the ordinary purposes for which it was intended.

95. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

96. YAZ, Yasmin and/or Ocella were not merchantable or fit for their ordinary purpose because YAZ, Yasmin and/or Ocella have a propensity to lead to the serious personal injuries described in this Complaint.

97. Plaintiff reasonably relied on Defendants' representations that YAZ, Yasmin and/or Ocella was a safe means of birth control and free of defects.

98. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

99. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FOUR – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

100. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

101. Defendants sold YAZ, Yasmin and/or Ocella with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced

bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

102. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

103. YAZ, Yasmin and/or Ocella were not fit for the particular purpose of a safe birth control pill without serious risk of personal injury. The risk of serious personal injury associated with YAZ, Yasmin and/or Ocella is much higher than other birth control pills.

104. Plaintiff reasonably relied on Defendants' misrepresentations that YAZ, Yasmin and/or Ocella was a safe and effective means of birth control and free of defects.

105. As a direct and proximate result of Defendants' breach of the implied warranty of fitness for a particular purpose, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and
f. Plaintiff has incurred and will continue to incur medical expenses.

106. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FIVE – NEGLIGENT FAILURE TO WARN

107. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

108. Before Plaintiff used YAZ, Yasmin and/or Ocella, and during the period in which she used it, Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella were dangerous and created an unreasonable risk of foreseeable bodily harm to consumers.

109. Defendants had a duty to exercise reasonable care to warn consumers of YAZ, Yasmin and/or Ocella of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

110. Despite the fact that Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella was dangerous, Defendants were negligent, grossly negligent, willful and wanton in failing to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

111. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton failure to warn the medical community and consumers, including Plaintiff, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

112. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

113. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SIX - NEGLIGENCE

114. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

115. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of YAZ, Yasmin and/or Ocella, including a duty to assure that the product did not cause unreasonable, dangerous side effects to its users.

116. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of YAZ, Yasmin and/or Ocella in that Defendants k new or should have known that the drug created a high risk of unreasonable harm. The FDA has actually issued a Warning Letter with regard to the manufacture of DRSP (drospirenone), in addition to the aforementioned way in which the DRSP oral contraceptive family was marketed.

117. Defendants were negligent, grossly negligent, willful and wanton in the design, manufacture, advertising, warning, marketing and sale of YAZ, Yasmin and/or Ocella in one or more of the following ways:

a. Failing to use due care in designing and manufacturing YAZ, Yasmin and/or Ocella so as to avoid the aforementioned risks to individuals;

b. Failing to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse side effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failing to provide adequate training and instruction to medical care providers for the appropriate use of YAZ, Yasmin and/or Ocella. Alternatively, the Defendants failed to truthfully provide such training and/or instruction to medical care providers for the use of DRSP/EE birth control pills;

d. Placing an unsafe product into the stream of commerce; and

e. In otherwise failing to use that degree of care and caution which an ordinarily prudent person would exercise under the circumstances.

118. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

119. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

120. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SEVEN – NEGLIGENT MISREPRESENTATION

121. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

122. Prior to Plaintiff first using YAZ, Yasmin and/or Ocella and during the period in which she used YAZ, Yasmin and/or Ocella, Defendants misrepresented that DRSP/EE family of oral contraceptives was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of DRSP/EE birth control pills, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life-threatening.

123. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

124. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with DRSP/EE oral contraceptives, that their representations regarding either YAZ, Yasmin and/or Ocella, or the DRSP/EE family of oral contraceptives, were false, and that they had a duty to disclose the dangers of DRSP/EE contraceptive pills.

125. Defendants made false representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing YAZ, Yasmin and/or Ocella.

126. Plaintiff justifiably and reasonably relied on Defendants' misrepresentations and nondisclosures by purchasing and using YAZ, Yasmin and/or Ocella.

127. As a direct and proximate result of Defendants' negligent misrepresentations and nondisclosures, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

128. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

129. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT EIGHT – BREACH OF EXPRESS WARRANTY

130. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

131. Defendants expressly warranted that YAZ, Yasmin and/or Ocella was safe and effective to members of the consuming public, including Plaintiff.

132. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

133. Defendants marketed, promoted and sold YAZ, Yasmin and/or Ocella as a safe method of birth control.

134. YAZ, Yasmin and/or Ocella does not conform to Defendants' express representations because YAZ, Yasmin and/or Ocella is not safe and has serious side effects, including death.

135. The manufacturer of a product is responsible for adequately warning and instructing the consuming public with regard to the proper use and application of a product as long as their product in on the market and the responsibility to do so rests upon the manufacturer.

136. Defendants breached their express warranty in one or more of the following ways:

a. YAZ, Yasmin and/or Ocella was defectively designed and placed into the stream of commerce in a defective and unreasonably dangerous condition;

b. Failing to warn and/or place adequate warning and instructions on the DRSP/EE family of contraceptives – YAZ, Yasmin and/or Ocella;

c. Failing to adequately test YAZ, Yasmin and/or Ocella; and

d. Failing to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury from YAZ, Yasmin and/or Ocella;

137. Plaintiff reasonably relied upon Defendants' warranty that YAZ, Yasmin and/or Ocella was safe and effective when she purchased and used the product.

138. As a direct and proximate result of Defendants' breach of warranty, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

139. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT NINE - FRAUD

140. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

141. Defendants widely advertised and promoted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive.

142. Defendants had a duty to disclose material information about the serious side effects to consumers such as Plaintiff.

143. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive, Defendants had a duty to disclose all facts about the risks associated with use of YAZ, Yasmin and/or Ocella, including the risks described in this Complaint. Defendants intentionally failed to disclose this material information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' unreasonably dangerous product.

144. Plaintiff reasonably and justifiably relied on the completeness and accuracy of Defendants' partial disclosures regarding the safety and efficacy of YAZ, Yasmin and/or Ocella. Had Plaintiff been aware of the hazards associated with YAZ, Yasmin and/or Ocella, Plaintiff would not have consumed the product that proximately led to Plaintiff's injuries and damages.

145. Defendants' advertisements regarding YAZ, Yasmin and/or Ocella materially misrepresented that DRSP/EE oral contraceptives were a safe and effective means of birth control.

146. Defendants knew their representations were false and intentionally withheld the truth for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase and consume YAZ, Yasmin and/or Ocella.

147. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with YAZ, Yasmin and/or Ocella with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

a. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff was injured and damaged as follows: Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and
f. Plaintiff has incurred and will continue to incur medical expenses.

148. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

149. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

WHEREFORE, Plaintiff demands judgment against Defendants and prays for the following relief:

1. Compensatory damages;
2. Treble damages on all applicable counts;
3. Punitive damages on all applicable counts;
4. Pre and post-judgment interest;
5. Reasonable attorneys' fees, costs, and expert fees; and
6. Any other relief as this court may deem equitable and just.

July 20, 2010

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c/o Corporation Service Company
1703 Laurel Street
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CORPORATION SERVICE COMPANY®

Notice of Service of Process

WAS / ALL
Transmittal Number: 7842233
Date Processed: 07/21/2010

Primary Contact:
Gary D. McConnell
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-9741

Copy of transmittal only provided to:
Lisa Andrasko
Jennifer Makuch
Service Process
Richard Winkle
R. Meece
Ana Hartner
Melody Hamel

Entity:	Bayer Healthcare Pharmaceuticals Inc Entity ID Number 2636824
Entity Served:	Bayer Pharmaceuticals Corporation
Title of Action:	Theresa Dubose Harrison vs. Bayer Corporation
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court:	Darlington County Circuit Court, South Carolina
Case Number:	2010-CP-16-0392
Jurisdiction Served:	South Carolina
Date Served on CSC:	07/21/2010
Answer or Appearance Due:	30 Days
Originally Served On:	CSC
How Served:	Certified Mail
Sender Information:	J. Thomas McBratney 843-662-8155

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Notice of Service of Process

null / ALL
Transmittal Number: 7842298
Date Processed: 07/21/2010

Primary Contact: Gary D. McConnell
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-9741

Copy of transmittal only provided to: Lisa Andrasko
Jennifer Makuch
Service Process
Richard Winkle
R. Meece
Ana Hartner
Melody Hamel

Entity:	Bayer Healthcare Pharmaceuticals Inc Entity ID Number 2636824
Entity Served:	Bayer Healthcare Pharmaceuticals Inc
Title of Action:	Theresa Dubose Harrison vs. Bayer Corporation
Document(s) Type:	Summons and Amended Complaint
Nature of Action:	Product Liability
Court:	Darlington County Court of Common Pleas, South Carolina
Case Number:	2010-CP-16-0392
Jurisdiction Served:	South Carolina
Date Served on CSC:	07/21/2010
Answer or Appearance Due:	35 Days
Originally Served On:	CSC
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Notice of Service of Process

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Transmittal Number: 7842334
Date Processed: 07/21/2010

Primary Contact:
Gary D. McConnell
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-9741

Copy of transmittal only provided to:
Richard Winkle
Lisa Andrasko
Jennifer Makuch
Service Process
R. Meece
Ana Hartner
William Dodero
Melody Hamel

Entity:	Bayer HealthCare LLC Entity ID Number 2486988
Entity Served:	Bayer Healthcare LLC
Title of Action:	Theresa Dubose Harrison vs. Bayer Corporation
Document(s) Type:	Summons and Amended Complaint
Nature of Action:	Product Liability
Court:	Darlington County Court of Common Pleas, South Carolina
Case Number:	2010-CP-16-0392
Jurisdiction Served:	South Carolina
Date Served on CSC:	07/21/2010
Answer or Appearance Due:	35 Days
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Transmittal Number: 7842313
Date Processed: 07/21/2010

Primary Contact: Gary D. McConnell
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-9741

Copy of transmittal only provided to: Richard Winkle
Ana Hartner
Service Process
Jennifer Makuch
Lisa Andrasko
Melody Hamel

Entity:	Bayer Corporation Entity ID Number 2486849
Entity Served:	Bayer Corporation
Title of Action:	Theresa Dubose Harrison vs. Bayer Corporation
Document(s) Type:	Summons and Amended Complaint
Nature of Action:	Product Liability
Court:	Darlington County Court of Common Pleas, South Carolina
Case Number:	2010-CP-16-0392
Jurisdiction Served:	South Carolina
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McBRATNEY LAW FIRM, P.A.

ATTORNEYS AT LAW
OVER 40 YEARS OF REPRESENTING SC RESIDENTS

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PHYSICAL ADDRESS
300 RAINBOW DRIVE
SUITE 207
FLORENCE, SC 29501

July 26, 2010

The Honorable Scott B. Suggs
Clerk of Court
Fourth Judicial Circuit
One Public Square
Darlington, SC 29532

RE: Theresa Dubose Harrison v Bayer
Case No.: 10-CP-16-0392

Dear Mr. Suggs:

Enclosed please find for filing the original and two copies of the Second Amended Summons and Complaint in the above captioned matter.

Please return the certified copies of same in the enclosed, self-addressed, stamped envelope.

Sincerely,

J. Thomas McBratney, III

JTMIII/ne
Encl.

STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,)	
)	
Plaintiff,)	
)	
v.)	**SECOND AMENDED SUMMONS**
)	**JURY TRIAL DEMANDED**
Bayer Corporation; Bayer Healthcare, LLC;)	
Bayer Pharmaceuticals Corporation; Bayer)	
Healthcare Pharmaceuticals, Inc.; Berlex)	
Laboratories, Inc.; Berlex, Inc.; Bayer)	
Schering Pharma AG; and Bayer AG;)	
)	
Defendants.)	
)	

YOU ARE HEREBY SUMMONED and required to answer the Amended Complaint in this action, of which a copy herewith is served upon you, and to serve a copy of your Answer to the said Complaint on the subscriber at McBratney Law Firm, P.A., P.O. Box 3890, Florence, South Carolina, 29502, within thirty (30) days after service hereof, or if served by certified mail within thirty-five (35) days after service, exclusive of the day of such service; and if you fail to answer the Complaint within the time aforesaid, judgment by default will be rendered against you for the relief demanded in the Complaint.

Dated at Florence, South Carolina, this 20th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
MCBRATNEY LAW FIRM, P.A.
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Attorneys for Plaintiff

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
Plaintiff,	)	
v.	)	**SECOND AMENDED COMPLAINT**
	)	**JURY TRIAL DEMANDED**
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
Defendants.	)	

Plaintiff, Theresa Dubose Harrison, through the undersigned counsel, complaining of the Defendants respectfully alleges the following:

1. Plaintiff, Theresa Dubose Harrison, is an adult resident of Darlington County, South Carolina.

2. Defendant Bayer Corporation is a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburg, Pennsylvania 15205.

3. Defendant Bayer Healthcare LLC is 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, Pennsylvania 15205. Defendant Bayer Healthcare LLC is wholly owned by Defendant Bayer Corporation.

4. Defendant Bayer Pharmaceuticals Corporation was, at all times relevant to this complaint, 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.

5. As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

7. 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.

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

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of approved NDA for Yasmin.

10. Defendant Berlex Laboratories, Inc. and Berlex, Inc. are foreign corporations with their headquarters and principal places of business in the State of New Jersey.

11. Defendants Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under the new name, Bayer Healthcare Pharmaceuticals, Inc.

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

13. Defendant Bayer Schering Pharma AG is a corporate successor to Schering AG.

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

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

16. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, Yasmin. Bayer Schering Pharma AG manufactures the oral contraceptive, Ocella, a generic form of Yasmin, pursuant to agreements for sale and distribution in the United States.

17. Defendant Bayer Schering Pharma AG is the current owner of the patents relating to the oral contraceptive, YAZ.

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

19. Defendant Bayer AG is the third largest pharmaceutical company in the world.

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

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

22. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc., Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG shall be referred to hereinafter individually by name or jointly as "Defendants."

23. Defendants include any and all parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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 venture 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.

25. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the State of South Carolina, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives, YAZ, Yasmin and/or Ocella.

26. This Court has jurisdiction of this matter under Articles V and VII of the South Carolina Constitution, S.C. Code Ann. § 14-1-80, and the common law of South Carolina.

27. Venue is proper in this jurisdiction because Plaintiff resided in Darlington County, South Carolina at the time the cause of action arose. Further, Defendants, which are foreign corporations, regularly conduct substantial business in Darlington County in the State of South Carolina and introduce their products into the stream of commerce.

28. The amount in controversy exceeds, exclusive of interest and costs, the jurisdictional minimum of this Court.

Factual Background

29. Plaintiff brings this case against Defendants for damages associated with Plaintiff's ingestion of the pharmaceutical drug YAZ, Yasmin and/or Ocella (DRSP/EE), an oral contraceptive designed, exclusively manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered serious menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy in June of 2006, as a direct result of her use of YAZ,

Yasmin and/or Ocella. Plaintiff also suffered gallbladder damage, which required surgery and removal of her gallbladder.

30. YAZ, Yasmin and Ocella 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.

31. Yasmin received FDA approval first in 2001. It is a combination of drospirenone ("DRSP"), a progestin, and ethinyl estradiol ("EE"), an estrogen. Hence, this family of drugs is often identified, or abbreviated as DRSP/EE. Ocella is a generic form of Yasmin manufactured exclusively by Bayer Schering AG for sale and distribution throughout the United States of America.

32. YAZ received approval from the FDA in 2006 and is essentially the same as Yasmin with the only difference being a slightly smaller amount of ethinyl estradiol ("EE").

33. YAZ and Yasmin were approved by the FDA for marketing in 2001 and 2006 respectively.

34. YAZ, Yasmin and Ocella all contain a "Fourth Generation" Progestin manufactured and developed by the Defendants called drospirenone or "DRSP."

35. The estrogen component in YAZ, Yasmin and Ocella is known generically as ethinyl estradiol ("EE").

36. The progestin component is generically known as drospirenone ("DRSP").

37. Yasmin contains 0.03 milligrams of ethinyl estradiol ("EE"), and YAZ contains 0.02 milligrams of ethinyl estradiol ("EE"). Similarly, the generic is made up of the foregoing formulation.

38. YAZ, Yasmin and Ocella all contain 3 milligrams of drospirenone ("DRSP").

39. YAZ, Yasmin and Ocella are different from other combined hormonal birth control pills in that they contain drospirenone ("DRSP"), 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.

40. 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.

41. 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 ("EE"), helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

42. During the 1990s, new "Third Generation" progestins were developed.

43. 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.

44. YAZ, Yasmin and Ocella contain the same estrogen component, ethinyl estradiol ("EE"), which has been used in the lower dose birth control pills for decades. However, drospirenone ("DRSP") is a new type of progestin and is considered a "Fourth Generation" progestin. No

other birth control pills contain drospirenone, ("DRSP"), except for YAZ, and the approved generic version of Yasmin, which is marketed under the trade name Ocella.

45. Since drospirenone ("DRSP") is new, there a 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 ("DRSP") has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

46. One possible mechanism of action is that drospirenone ("DRSP") 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.

47. Hyperkalemia can cause heart rhythm disturbances, such as extra systoles, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

48. 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.

49. Indeed, during the time that YAZ, Yasmin and Ocella 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. In fact, hundreds of lawsuits are now pending nationwide for injuries arising out of the use of said "DRSP/EE" contraceptives.

50. 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.

51. 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. 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. Again, hundreds of lawsuits are now pending throughout the United States for claims arising out of the use or ingestion of DRSP/EE contraceptives. Moreover, the DRSP/EE family of contraceptives has been the subject of four FDA Warning Letters, including a recent letter regarding the manufacturing process, quality control standards and related citations based upon an inspection of the manufacturing facility.

52. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years. Additional claims include injuries resulting in damage to the gallbladder, pancreas, as well as surgery related complications and permanent scarring in women of all ages.

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

54. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering injuries while using YAZ, Yasmin and Ocella.

55. Defendants market YAZ and Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, while also claiming additional benefits.

56. However, because YAZ, Yasmin and Ocella contain the "Fourth Generation" progestin drospirenone "DRSP", which is a diuretic, they present additional health risks not associated with other birth control pills.

57. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's "Fourth Generation" progestin, drospirenone ("DRSP"), by stating, "Ask about Yasmin, and the difference a little chemistry can make."

58. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone ("DRSP") 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. . ."

59. 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."

60. More recently, Defendants advertised that its product YAZ was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the condition of premenstrual dysphoric disorder or "PMDD," which is recognized by the DSM-IV as a debilitating condition that interferes with the daily living of women during certain time periods.

61. Defendants also advertised that YAZ contained the added benefit of preventing or reducing acne in teenage girls or women.

62. In response, on October 3, 2008, the FDA issued another Warning Letter to Defendants 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."

63. 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 regarding acne and premenstrual syndrome, as well as the failure to adequately underscore risks and dangers associated with the pill.

64. Bayer ultimately agreed to spend at least $20 Million on corrective TV advertisements and, among other things, to submit all YAZ advertisements to the FDA for advanced screening for the next six years.

65. Defendants did not provide adequate warnings to doctors, the healthcare community, or the public about the risk of serious adverse events that are described in this complaint. To date, the FDA has issued four Warning Letters associated with the DRSP/EE family of oral contraceptives containing drospirenone. Again, the most recent letter called into question existing protocols for quality control and sampling of the product in the manufacturer facilities.

66. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of YAZ, Yasmin and/or Ocella without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

67. As a result of Defendants' claim regarding the effectiveness and safety of YAZ, Yasmin and/or Ocella, Plaintiff's medical provider prescribed her and she ingested a DRSP/EE oral contraceptive pill.

68. As a direct and proximate result of using a DRSP/EE or contraceptive or YAZ, Yasmin and/or Ocella, in or about June 2006, after taking YAZ, Yasmin and/or Ocella, as prescribed by her physician, Plaintiff suffered severe menstrual clotting or blood clots in her uterus, which

required an emergency hysterectomy. Plaintiff also suffered severe gallbladder damage requiring surgery and the removal of her gallbladder.

69. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella, Defendants knew or should have known that use of YAZ, Yasmin and/or Ocella created a higher risk of deaths, blood clots, cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, and/or gallbladder removal, 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.

70. Therefore, at the time Plaintiff used YAZ, Yasmin and/or Ocella, Defendants knew or should have known that the use of YAZ, Yasmin and/or Ocella created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, other injuries associated with blood clots, and even death.

71. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of YAZ, Yasmin and/or Ocella, Defendants failed to warn Plaintiff and/or her healthcare providers of said serious risks before she used the product.

72. Had Plaintiff and/or her healthcare providers known the risks and dangers associated with DRSP/EE oral contraceptives, YAZ, Yasmin and/or Ocella, she would not have used YAZ, Yasmin and/or Ocella and would not have suffered the injuries described above.

73. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella, Plaintiff suffered physical injury and extreme mental anguish and emotional distress as a result of her hysterectomy and gallbladder removal surgery.

74. As a direct and proximate result of her use of YAZ, Yasmin and/or Ocella and resulting injuries, Plaintiff suffered damages, harm, permanent injury, emotional distress, pain and suffering. Plaintiff has also incurred medical expenses and other economic harm.

COUNT ONE – FRAUDULENT CONCEALMENT

75. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

76. Prior to Plaintiff's use of YAZ, Yasmin and/or Ocella and during the time period in which Plaintiff actually used YAZ, Yasmin and/or Ocella, Defendants fraudulently suppressed material information regarding the safety and efficacy of DRSP/EE oral contraceptives, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, and the unique gallbladder damages. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of the DRSP/EE family of contraceptives strong and reach blockbuster sales in excess of $1 Billion dollars. These drugs have gained a substantial market share since their introduction into the marketplace.

77. Defendants fraudulently concealed safety issues with YAZ, Yasmin and/or Ocella in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use YAZ, Yasmin and/or Ocella.

78. At the time Defendants concealed the fact that YAZ, Yasmin and/or Ocella were not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the

healthcare community, and the general public in such a manner that they could appreciate the risks associated with using any DRSP/EE birth control pills.

79. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of the DRSP/EE family of oral contraceptives: YAZ, Yasmin and/or Ocella.

80. As a direct and proximate result of Defendants' malicious and/or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries described above.

81. It is unconscionable and outrageous that Defendants would risk the health and safety of consumers solely for financial gain. Despite the knowledge of the health and safety risks associated with YAZ, Yasmin and/or Ocella, Defendants made the conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary the Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

82. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the truth about the dangers associated with the use of YAZ, Yasmin and/or Ocella. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the healthcare community, or the general public. Without full knowledge of the dangers of the DRSP/EE family of birth control pills: YAZ, Yasmin and/or Ocella, Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by YAZ, Yasmin and/or Ocella had a valid claim.

83. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff has been injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

84. Plaintiff is entitled to judgment against the Defendants for compensatory and punitive damages in an amount to be proven at trial plus interest and costs.

COUNT TWO – STRICT LIABILITY

85. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

86. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug family of DRSP/EE pills, YAZ, Yasmin and/or Ocella, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff. The FDA recently issued a Warning Letter, the fourth Warning Letter associated with the DRSP/EE family of birth control pills, questioning the manufacturing process and quality control standards as they existed at the time of the inspection.

87. The YAZ, Yasmin and/or Ocella, DRSP/EE birth control pills used by the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

88. Plaintiff did not misuse or materially alter the YAZ, Yasmin and/or Ocella pills.

89. Defendants are strictly liable for Plaintiff's injuries in the following ways:

a. The pharmaceutical YAZ, Yasmin and/or Ocella, DRSP/EE pills, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell YAZ, Yasmin and/or Ocella;

c. Defendants failed to warn and/or place adequate warnings and instructions on YAZ, Yasmin and/or Ocella;

d. Defendants failed to adequately test YAZ, Yasmin and/or Ocella, DRSP/EE pills;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of YAZ, Yasmin and/or Ocella; and

f. A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

90. As a direct and proximate result of Defendants' wrongful conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

91. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

92. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT THREE – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

93. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

94. At the time Defendants marketed, distributed and sold YAZ, Yasmin and/or Ocella to Plaintiff, Defendants warranted that YAZ, Yasmin and/or Ocella was merchantable and fit for the ordinary purposes for which it was intended.

95. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

96. YAZ, Yasmin and/or Ocella were not merchantable or fit for their ordinary purpose because YAZ, Yasmin and/or Ocella have a propensity to lead to the serious personal injuries described in this Complaint.

97. Plaintiff reasonably relied on Defendants' representations that YAZ, Yasmin and/or Ocella was a safe means of birth control and free of defects.

98. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

99. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FOUR – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

100. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

101. Defendants sold YAZ, Yasmin and/or Ocella with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits, such as reduced

bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

102. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.

103. YAZ, Yasmin and/or Ocella were not fit for the particular purpose of a safe birth control pill without serious risk of personal injury. The risk of serious personal injury associated with YAZ, Yasmin and/or Ocella is much higher than other birth control pills.

104. Plaintiff reasonably relied on Defendants' misrepresentations that YAZ, Yasmin and/or Ocella was a safe and effective means of birth control and free of defects.

105. As a direct and proximate result of Defendants' breach of the implied warranty of fitness for a particular purpose, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

106. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT FIVE – NEGLIGENT FAILURE TO WARN

107. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

108. Before Plaintiff used YAZ, Yasmin and/or Ocella, and during the period in which she used it, Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella were dangerous and created an unreasonable risk of foreseeable bodily harm to consumers.

109. Defendants had a duty to exercise reasonable care to warn consumers of YAZ, Yasmin and/or Ocella of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

110. Despite the fact that Defendants knew or had reason to know that YAZ, Yasmin and/or Ocella was dangerous, Defendants were negligent, grossly negligent, willful and wanton in failing to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous risks associated with DRSP/EE oral contraceptives or of the facts that make DRSP/EE oral contraceptives likely to be dangerous.

111. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton failure to warn the medical community and consumers, including Plaintiff, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

112. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

113. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SIX - NEGLIGENCE

114. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

115. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of YAZ, Yasmin and/or Ocella, including a duty to assure that the product did not cause unreasonable, dangerous side effects to its users.

116. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of YAZ, Yasmin and/or Ocella in that Defendants k new or should have known that the drug created a high risk of unreasonable harm. The FDA has actually issued a Warning Letter with regard to the manufacture of DRSP (drospirenone), in addition to the aforementioned way in which the DRSP oral contraceptive family was marketed.

117. Defendants were negligent, grossly negligent, willful and wanton in the design, manufacture, advertising, warning, marketing and sale of YAZ, Yasmin and/or Ocella in one or more of the following ways:

a. Failing to use due care in designing and manufacturing YAZ, Yasmin and/or Ocella so as to avoid the aforementioned risks to individuals;

b. Failing to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse side effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failing to provide adequate training and instruction to medical care providers for the appropriate use of YAZ, Yasmin and/or Ocella. Alternatively, the Defendants failed to truthfully provide such training and/or instruction to medical care providers for the use of DRSP/EE birth control pills;

d. Placing an unsafe product into the stream of commerce; and

e. In otherwise failing to use that degree of care and caution which an ordinarily prudent person would exercise under the circumstances.

118. As a direct and proximate result of Defendants' negligent, grossly negligent, willful and wanton conduct as described above, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

119. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

120. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT SEVEN – NEGLIGENT MISREPRESENTATION

121. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

122. Prior to Plaintiff first using YAZ, Yasmin and/or Ocella and during the period in which she used YAZ, Yasmin and/or Ocella, Defendants misrepresented that DRSP/EE family of oral contraceptives was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of DRSP/EE birth control pills, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life-threatening.

123. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

124. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with DRSP/EE oral contraceptives, that their representations regarding either YAZ, Yasmin and/or Ocella, or the DRSP/EE family of oral contraceptives, were false, and that they had a duty to disclose the dangers of DRSP/EE contraceptive pills.

125. Defendants made false representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing YAZ, Yasmin and/or Ocella.

126. Plaintiff justifiably and reasonably relied on Defendants' misrepresentations and nondisclosures by purchasing and using YAZ, Yasmin and/or Ocella.

127. As a direct and proximate result of Defendants' negligent misrepresentations and nondisclosures, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

128. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

129. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

COUNT EIGHT – BREACH OF EXPRESS WARRANTY

130. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

131. Defendants expressly warranted that YAZ, Yasmin and/or Ocella was safe and effective to members of the consuming public, including Plaintiff.

132. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

133. Defendants marketed, promoted and sold YAZ, Yasmin and/or Ocella as a safe method of birth control.

134. YAZ, Yasmin and/or Ocella does not conform to Defendants' express representations because YAZ, Yasmin and/or Ocella is not safe and has serious side effects, including death.

135. The manufacturer of a product is responsible for adequately warning and instructing the consuming public with regard to the proper use and application of a product as long as their product in on the market and the responsibility to do so rests upon the manufacturer.

136. Defendants breached their express warranty in one or more of the following ways:

a. YAZ, Yasmin and/or Ocella was defectively designed and placed into the stream of commerce in a defective and unreasonably dangerous condition;

b. Failing to warn and/or place adequate warning and instructions on the DRSP/EE family of contraceptives – YAZ, Yasmin and/or Ocella;

c. Failing to adequately test YAZ, Yasmin and/or Ocella; and

d. Failing to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury from YAZ, Yasmin and/or Ocella;

137. Plaintiff reasonably relied upon Defendants' warranty that YAZ, Yasmin and/or Ocella was safe and effective when she purchased and used the product.

138. As a direct and proximate result of Defendants' breach of warranty, Plaintiff was injured and damaged as follows:

a. Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;

b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;

c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;

d. Plaintiff has suffered physical pain and suffering;

e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and

f. Plaintiff has incurred and will continue to incur medical expenses.

139. Plaintiff is entitled to judgment against the Defendants for compensatory damages in an amount to be proven at trial.

COUNT NINE - FRAUD

140. Plaintiff adopts and incorporates all preceding and succeeding paragraphs as if set forth in their entirety herein.

141. Defendants widely advertised and promoted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive.

142. Defendants had a duty to disclose material information about the serious side effects to consumers such as Plaintiff.

143. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted YAZ, Yasmin and/or Ocella as a safe and effective oral contraceptive, Defendants had a duty to disclose all facts about the risks associated with use of YAZ, Yasmin and/or Ocella, including the risks described in this Complaint. Defendants intentionally failed to disclose this material information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' unreasonably dangerous product.

144. Plaintiff reasonably and justifiably relied on the completeness and accuracy of Defendants' partial disclosures regarding the safety and efficacy of YAZ, Yasmin and/or Ocella. Had Plaintiff been aware of the hazards associated with YAZ, Yasmin and/or Ocella, Plaintiff would not have consumed the product that proximately led to Plaintiff's injuries and damages.

145. Defendants' advertisements regarding YAZ, Yasmin and/or Ocella materially misrepresented that DRSP/EE oral contraceptives were a safe and effective means of birth control.

146. Defendants knew their representations were false and intentionally withheld the truth for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase and consume YAZ, Yasmin and/or Ocella.

147. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with YAZ, Yasmin and/or Ocella with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

a. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff was injured and damaged as follows: Plaintiff suffered severe menstrual clotting or blood clots in the uterus, which required an emergency hysterectomy;
b. Plaintiff suffered gallbladder damage requiring the removal of her gallbladder;
c. Plaintiff suffered and continues to suffer from depression, extreme mental anguish and emotional distress;
d. Plaintiff has suffered physical pain and suffering;
e. Plaintiff has suffered permanent physical injury including, but not limited to, the loss of her ability to have children; and
f. Plaintiff has incurred and will continue to incur medical expenses.

148. Defendants' conduct was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, YAZ, Yasmin and/or Ocella, by suppressing the information concerning the safety and efficacy problems from the general public. Defendants chose profits over consumer safety and made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants conduct warrants an award of punitive damages.

149. Plaintiff is entitled to judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs, attorneys' fees, and all such other relief as may be proven at trial and as the Court deems appropriate.

WHEREFORE, Plaintiff demands judgment against Defendants and prays for the following relief:

1. Compensatory damages;
2. Treble damages on all applicable counts;
3. Punitive damages on all applicable counts;
4. Pre and post-judgment interest;
5. Reasonable attorneys' fees, costs, and expert fees; and
6. Any other relief as this court may deem equitable and just.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
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tm.mcbratneylawfirm@gmail.com
Attorneys for Plaintiff

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
	)	
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CERTIFICATE OF SERVICE**
	)	
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	
	)	

I hereby certify the Second Amended Complaint has been served on South Carolina Local Counsel at the following address:

Daniel B. White, Esq.
GALLIVAN, WHITE & BOYD, P.A.
55 Beattie Place, Suite 1200
P.O. Box 10589 (29603)
Greenville, SC 29601
864.271.5342 (Direct)
864.271.7502 (Fax)

Dated at Florence, South Carolina, this 26th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
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Attorneys for Plaintiff

McBRATNEY LAW FIRM, P.A.

ATTORNEYS AT LAW
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PHYSICAL ADDRESS
300 RAINBOW DRIVE
SUITE 207
FLORENCE, SC 29501

July 26, 2010

The Honorable Scott B. Suggs
Clerk of Court
Fourth Judicial Circuit
One Public Square
Darlington, SC 29532

RE: Theresa Dubose Harrison v Bayer
Case No.: 10-CP-16-0392

Dear Mr. Suggs:

Enclosed please find for filing the original and two copies of the Proof of Service to Bayer Corporation in the above captioned matter.

Please return the certified copies of same in the enclosed, self-addressed, stamped envelope.

Sincerely,

J. Thomas McBratney, III

JTMIII/ne
Encl.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**PROOF OF SERVICE**
	)	
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	

Please accept the attachment as proof of service of the Summons and Complaint on the following Defendant:

1. Bayer Corporation.

The Summons and Complaint was served pursuant to Rule 4(d)(3) of the South Carolina Rules of Civil Procedure.

Dated at Florence, South Carolina, this 26th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
MCBRATNEY LAW FIRM, P.A.
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Attorneys for Plaintiff

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1. Article Addressed to:

BAYER CORPORATION
C/O CORPORATION SERVICE COMPANY
1703 LAUREL ST.
COLUMBIA, SC 29201

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) K Hamilton
C. Date of Delivery 7/21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

JUL 21 2010

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from servi) 7008 1140 0000 1403 5512

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

McBRATNEY LAW FIRM, P.A.

ATTORNEYS AT LAW
OVER 40 YEARS OF REPRESENTING SC RESIDENTS

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PHYSICAL ADDRESS
300 RAINBOW DRIVE
SUITE 207
FLORENCE, SC 29501

July 26, 2010

The Honorable Scott B. Suggs
Clerk of Court
Fourth Judicial Circuit
One Public Square
Darlington, SC 29532

RE: Theresa Dubose Harrison v Bayer
Case No.: 10-CP-16-0392

Dear Mr. Suggs:

Enclosed please find for filing the original and two copies of the Proof of Service to Bayer Healthcare Pharmaceuticals in the above captioned matter.

Please return the certified copies of same in the enclosed, self-addressed, stamped envelope.

Sincerely,

J. Thomas McBratney

J. Thomas McBratney, III

JTMIII/nc
Encl.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**PROOF OF SERVICE**
	)	
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	
	)	

Please accept the attachment as proof of service of the Summons and Complaint on the following Defendant:

1. Bayer Healthcare Pharmaceuticals, Inc.

The Summons and Complaint was served pursuant to Rule 4(d)(3) of the South Carolina Rules of Civil Procedure.

Dated at Florence, South Carolina, this 26th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
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Attorneys for Plaintiff

SENDER: COMPLETE THIS SECTION

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1. Article Addressed to:

BAYER HEALTHCARE PHARMACEUTICALS
c/o CORPORATION SERVICE COMPANY
1703 LAUREL ST.
COLUMBIA, SC 29201

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) K Hamilton C. Date of Delivery 7.1.21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

JUL 21 2010

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7008 1140 0000 1403 5550

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

McBratney Law Firm, P.A.

ATTORNEYS AT LAW
Over 40 years of representing SC Residents

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PHYSICAL ADDRESS
300 Rainbow Drive
Suite 207
Florence, SC 29501

July 26, 2010

The Honorable Scott B. Suggs
Clerk of Court
Fourth Judicial Circuit
One Public Square
Darlington, SC 29532

RE: Theresa Dubose Harrison v Bayer
Case No.: 10-CP-16-0392

Dear Mr. Suggs:

Enclosed please find for filing the original and two copies of the Proof of Service to Bayer Pharmaceuticals Company in the above captioned matter.

Please return the certified copies of same in the enclosed, self-addressed, stamped envelope.

Sincerely,

J. Thomas McBratney, III

JTMIII/ne
Encl.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**PROOF OF SERVICE**
	)	
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	
	)	

Please accept the attachment as proof of service of the Summons and Complaint on the following Defendant:

1. Bayer Pharmaceuticals Company;

The Summons and Complaint was served pursuant to Rule 4(d)(3) of the South Carolina Rules of Civil Procedure.

Dated at Florence, South Carolina, this 26th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
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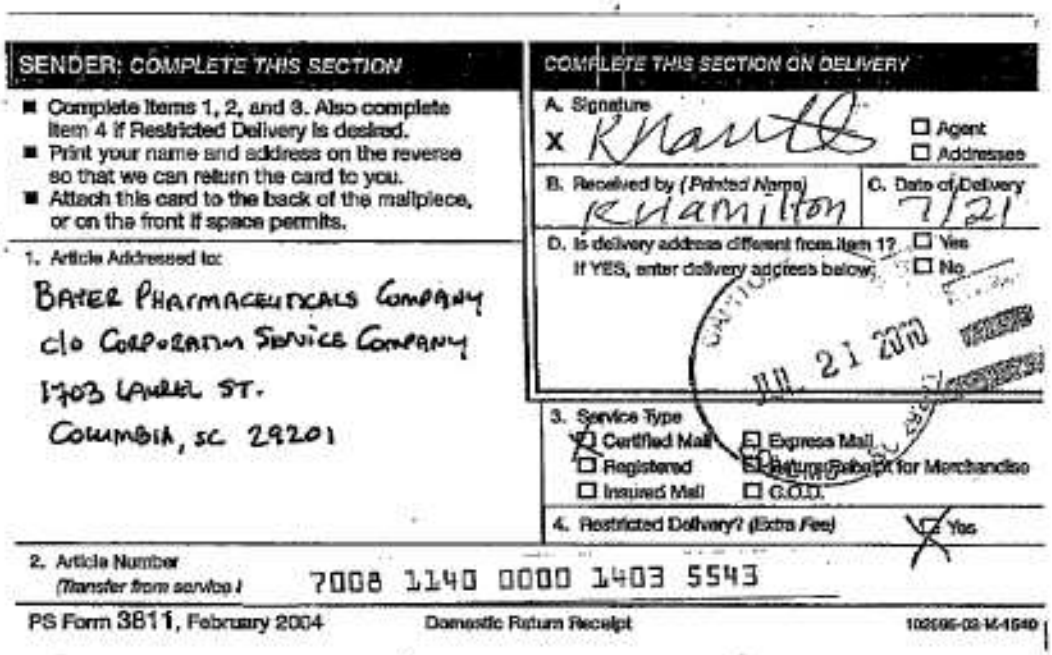
Attorneys for Plaintiff



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- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

BAYER PHARMACEUTICALS COMPANY
c/o CORPORATION SERVICE COMPANY
1703 LAUREL ST.
COLUMBIA, SC 29201

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X R Hamilton ☐ Agent ☐ Addressee

B. Received by (Printed Name) R HAMILTON
C. Date of Delivery 7/21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

JUL 21 2010

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☒ Yes

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300 RAINBOW DRIVE
SUITE 207
FLORENCE, SC 29501

July 26, 2010

The Honorable Scott B. Suggs
Clerk of Court
Fourth Judicial Circuit
One Public Square
Darlington, SC 29532

RE: Theresa Dubose Harrison v Bayer
Case No.: 10-CP-16-0392

Dear Mr. Suggs:

Enclosed please find for filing the original and two copies of the Proof of Service to Bayer Healthcare LLC in the above captioned matter.

Please return the certified copies of same in the enclosed, self-addressed, stamped envelope.

Sincerely,

J. Thomas McBratney, III

JTMIII/ne
Encl.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FOURTH JUDICIAL CIRCUIT
COUNTY OF DARLINGTON	)	CIVIL ACTION NO.: 2010-CP-16-0392
Theresa Dubose Harrison,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**PROOF OF SERVICE**
	)	
Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; Berlex, Inc.; Bayer Schering Pharma AG; and Bayer AG;	)	
	)	
Defendants.	)	
	)	

Please accept the attachment as proof of service of the Summons and Complaint on the following Defendant:

1. Bayer Healthcare LLC;

The Summons and Complaint was served pursuant to Rule 4(d)(3) of the South Carolina Rules of Civil Procedure.

Dated at Florence, South Carolina, this 26th day of July 2010.

July 26, 2010

J. Thomas McBratney, III
James T. McBratney, Jr.
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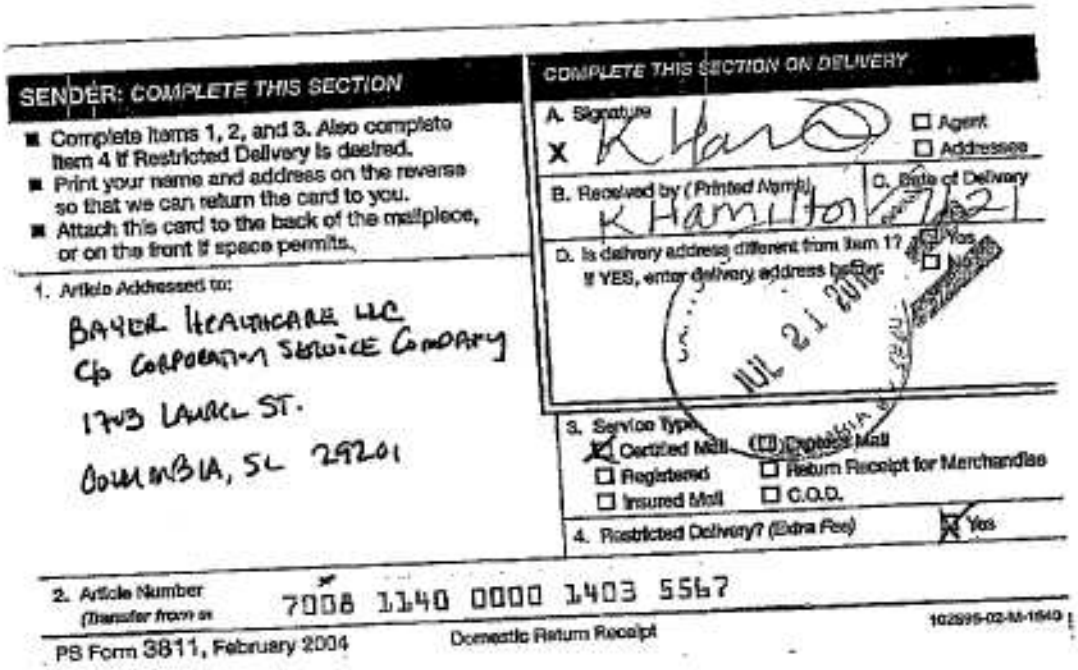
Attorneys for Plaintiff



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- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

BAYER HEALTHCARE LLC
C/O CORPORATION SERVICE COMPANY
1703 LAUREL ST.
COLUMBIA, SC 29201

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X K Hamilton ☐ Agent ☐ Addressee

B. Received by (Printed Name) K Hamilton C. Date of Delivery 7/21

D. Is delivery address different from item 1? ☑ Yes
If YES, enter delivery address below: ☐ No

JUL 21 2010

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☒ Yes

2. Article Number (Transfer from service label) 7008 1140 0000 1403 5567

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540