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R. WEISS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, CIVIL TRIAL DIVISION

IN RE: YAZ®, YASMIN®, OCELLA®, GIANVI® LITIGATION ***APPLICABLE TO ALL CASES***	**SEPTEMBER TERM, 2009** **No. 1307**

NOTICE TO PLEAD

NOTICE You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in

AVISO Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siquientes, usted tiene veinte (20) dias de plazo al partir de la fecha de lan demanda y la notificacion. Hace falta asentar una comparesencia

Case ID: 090901307

writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you. YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. **PHILADELPHIA COUNTY BAR ASSOCIATION** LAWYER REFERRAL AND INFORMATION SERVICE 1101 MARKET STREET, 11TH FLOOR PHILADELPHIA, PENNSYLVANIA 19107 TELEPHONE: (215) 238-1701

escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiendandes u otros derechos importantes para uted. LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIOI, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL. **ASOCIACION DE LICENCIADOR DE PHILADELPHIA** VICIO DE REFERENCIA DE INFORMACION LEGAL 1101 MARKET STREET, 11TH FLOOR PHILADELPHIA, PENNSYLVANIA 19107 TELEFONO: (215) 238-1701

Case ID: 090901307

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IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, CIVIL TRIAL DIVISION

IN RE: YAZ®, YASMIN®, OCELLA®, GIANVI® LITIGATION	**SEPTEMBER TERM, 2009**
	No. 1307
APPLICABLE TO ALL CASES	

PLAINTIFFS' SECOND AMENDED MASTER
LONG-FORM COMPLAINT AND JURY DEMAND

Case ID: 090901307

Pursuant to *Case Management Order No. 1* by the Honorable Sandra M. Moss entered September 17, 2009, the undersigned attorneys for Plaintiffs in the Yasmin®, Yaz®, Ocella® and Gianvi® consolidated Mass Tort actions bring this *Second Amended Master General Long-Form Complaint and Jury Demand* against the following Defendants:

1. **BAYER CORPORATION,**
2. **BAYER HEALTHCARE, LLC,**
3. **BAYER PHARMACEUTICALS CORPORATION,**
4. **BAYER HEALTHCARE PHARMACEUTICALS, INC.,**
5. **BERLEX LABORATORIES, INC.,**
6. **BERLEX, INC.,**
7. **BAYER SCHERING PHARMA AG,**
8. **INTENDIS INC.**
9. **BAYER AG,**
10. **TEVA PHARMACEUTICAL INDUSTRIES LTD,**
11. **TEVA PHARMACEUTICALS USA,**
12. **BARR PHARMACEUTICALS, INC.,**
13. **BARR PHARMACEUTICALS, LLC.,**
14. **BARR LABORATORIES, INC.**

Plaintiffs, by and through counsel, and for their *Second Amended Complaint* against Defendants, allege as follows:

Case ID: 090901307

I. THE PARTIES

A. PLAINTIFFS

1. Pursuant to the Order of this Court, this *Second Amended Complaint* is a Master Complaint filed for all Plaintiffs, and if applicable, Plaintiffs' spouses, children, decedents or wards represented by Plaintiffs' counsel who has signed onto or agreed to the *Second Amended Master Long Form Complaint* and, by operation of such order, all allegations pleaded herein are deemed pleaded in any "*Short-Form Complaint*" previously filed.

B. DEFENDANTS

1) The Bayer/Schering/Berlex Defendants

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

3. Defendant BAYER HEALTHCARE LLC ("BHL") is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

4. Defendant BHL is wholly owned by Defendant BC.

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

6. As of January 1, 2008, Defendant BPC was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC ("BHP").

Case ID: 090901307

7. Defendant BHP is and at times relevant was, 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.

8. Defendant BHP 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.

9. Defendant BHP is the holder of the approved New Drug Application ("NDA") for Yaz®.

10. Defendant BHP is the holder of the approved New Drug Application ("NDA") for Yasmin®.

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

12. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceutical business under the new name, Bayer Healthcare Pharmaceuticals, Inc.

13. Defendant BAYER SCHERING PHARMA AG, ("BSP") formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

14. Defendant BSP is a corporate successor to Schering AG.

Case ID: 090901307

15. Schering AG was renamed BSP effective December 29, 2006.

16. Defendant BSP headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

17. Defendant BSP is the current owner of the patent(s) relating to the oral contraceptive, Yasmin®.

18. Defendant BSP is the current owner of the patent(s) relating to the oral contraceptive, Yaz®.

19. Defendant Intendis Inc. is a specialized global pharmaceutical company that is organized and exists under the laws of the State of New Jersey with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Pine Brook, New Jersey 07058-1000.

20. Intendis Inc. entered into a co-promotion agreement with Bayer Healthcare Pharmaceuticals, Inc. relating to the promotion of YAZ to dermatologists in the United States.

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

22. Defendant BAYER AG is the third largest pharmaceutical company in the world.

23. Defendant BAYER AG is the parent/holding company of all other named Defendants.

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

25. Defendants BC, BHL, BPC, BHP, BERLEX LABORATORIES, INC. and BERLEX, INC., BSP and BAYER AG, shall be referred to herein individually by name or collectively as "BAYER" or the "BAYER DEFENDANTS" or collectively with all Defendants as "Defendants."

Case ID: 090901307

INTENDIS INC. shall also be included with "BAYER" or "BAYER DEFENDANTS" only in cases where the Plaintiff was prescribed YAZ by a dermatologist, the dermatologist's nurse practitioner or physician assistant or if a Plaintiff had a dermatologist, the dermatologist's nurse practitioner or physician assistant recommend that she discuss Yaz with another health care provider.

2) The Barr/Teva Defendants

26. Defendant BARR PHARMACEUTICALS, INC., ("BPI") is, and at all times relevant was, a corporation organized under the laws of the state of Delaware having regularly established places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677; 109 Morgan Lane, Plainsboro, New Jersey 08536; and 265 Livingston Street, Northvale, New Jersey 07647.

27. Defendant BARR PHARMACEUTICALS, LLC., ("BPL") is, and at all relevant times was, a corporation organized under the laws of the state of Delaware having regularly established places of business at 255 Summitt Avenue, Montvale, New Jersey.

28. Defendant BARR LABORATORIES, INC. ("BLI") is, and at all times relevant was, a corporation organized under the laws of the state of Delaware having regular and established places of business at One Belmont Avenue, Bala Cynwyd, Pennsylvania and 255 Summitt Avenue, Montvale, New Jersey.

29. BLI was a wholly owned subsidiary of BPI.

30. Defendants BPI, BPL, and BLI shall be referred to herein individually by name or collectively as "BARR" and/or the "BARR DEFENDANTS" or collectively with all Defendants as "Defendants").

Case ID: 090901307

31. Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD ("TEVA LTD"), is, and was at all times relevant a pharmaceutical corporation organized under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

32. Defendant TEVA PHARMACEUTICALS USA, INC. ("TEVA USA") is, and at all times relevant a pharmaceutical company organized under the laws of Delaware with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania.

33. Defendant TEVA USA is an indirect wholly-owned subsidiary of TEVA LTD.

34. Defendants TEVA LTD and TEVA USA, shall be referred to herein individually by name or collectively as "TEVA" and/or the "TEVA DEFENDANTS" or collectively with all Defendants as "Defendants."

35. TEVA is among the top 20 pharmaceutical companies and among the largest generic pharmaceutical companies in the world.

36. The BAYER DEFENDANTS, the BARR DEFENDANTS and the TEVA DEFENDANTS shall be collectively referred to herein as "Defendants."

37. On or about June 30, 2008, BAYER issued a "*PressReleasePoint*" announcing in relevant part:

> **Bayer concludes supply and licensing agreements for Yasmin® and YAZ® with Barr for the United States**
>
> - Appeal of court decision invalidating Yasmin patent will continue
> - Further growth of Bayer's Women's Healthcare Business Unit expected
>
> **Berlin/Leverkusen, June 24, 2008** – Bayer and Barr Laboratories Inc. today signed supply and licensing agreements for Yasmin® and YAZ® for the United States. Bayer will supply U.S. generics manufacturer Barr, starting July 1, 2008 at the latest, with a generic version of its oral

Case ID: 090901307

> contraceptive Yasmin, which Barr will market solely in the United States. Barr will pay Bayer a fixed percentage of the revenues from the product sold by Barr.
>
> Bayer will continue to pursue its appeal of a March 2008 New Jersey court's decision that invalidated Bayer's U.S. patent '531 for Yasmin. If Bayer prevails in its appeal, Bayer will receive a larger share of Barr's revenues from the product.
>
> "The agreements allow us to participate in the U.S. market for generic oral contraceptives in partnership with an established player," said Dr. Gunnar Riemann, Member of the Board of Management of Bayer HealthCare AG. "We expect our global Women's Healthcare business to continue posting high-single-digit to low-double-digit percentage annual growth rates in the coming years thanks to the products we already have on the market and to new, promising developmental products."
>
> It has also been agreed that Bayer will grant Barr a license to market a generic version of YAZ – like Yasmin, a product in the drospirenone family – in the United States starting July 1, 2011. Bayer will supply Barr with the product for this purpose. Should Bayer lose patent lawsuits in the United States against other companies concerning YAZ, at that time Bayer will begin supplying the product to Barr and Barr will begin marketing generic YAZ in the United States. Barr will pay Bayer a fixed percentage of the revenues from the product sold by Barr.
>
> The companies have agreed not to disclose further details of the agreements . . .

38. On or about October 20, 2008, BPL was registered with the Delaware Secretary of State.

39. On or about December 23, 2008, TEVA acquired BARR and integrated BARR as a wholly owned subsidiary.

40. On or about December 23, 2008, BPI was merged out and its corporate registration was suspended. BPL was the merger survivor.

41. On April 1, 2009, TEVA issued a *Press Release* announcing in relevant part:

Case ID: 090901307

Teva Announces Approval Of Generic Yaz® Tablets

Jerusalem, Israel, April 1, 2009 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced that the U.S. Food and Drug Administration has granted approval for the Company's Abbreviated New Drug Application (ANDA) to market its generic version for Bayer Healthcare Pharmaceuticals' oral contraceptive Yaz® (Drospirenone and Ethinyl Estradiol) Tablets. As the first company to file an ANDA containing a paragraph IV certification for this product, Teva has been awarded a 180-day period of marketing exclusivity.

Annual sales of Yaz® were approximately $616 million in the United States for the twelve months that ended December 30, 2008, based on IMS sales data.

In 2008, Teva's subsidiary Barr Pharmaceuticals, Inc. entered into a supply and licensing agreement with Bayer. Under this agreement, Teva has the right to launch an authorized generic version of Yaz® on July 1, 2011, or earlier in certain circumstances.

42. Bayer Corporation supplies BARR and TEVA USA with the generic form of Yasmin®.

43. TEVA USA through BARR distributes the generic form of Yasmin® in the U.S. under the Barr Laboratories label, Ocella®.

44. Bayer Corporation supplies BARR and TEVA USA with the generic form of Yaz®.

45. TEVA USA through BARR distributes the generic form of Yaz® in the U.S. under the Barr Laboratories label, Gianvi®.

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

Case ID: 090901307

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

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

48. 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 Commonwealth of Pennsylvania, either directly or indirectly through third-parties, subsidiaries or related entities, the oral contraceptives, Yaz®, Yasmin® , Ocella® and Gianvi.

II. JURISDICTION AND VENUE

49. Jurisdiction over Defendants is based on 42 Pa. C.S.A § 5301 and is therefore proper in this Court.

50. Venue is proper pursuant to Pa. R.C.P. No. 2179 as Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

51. The amount in controversy exceeds, exclusive of interest and costs, the sum of fifty thousand ($50,000.00) dollars.

III. FACTUAL ALLEGATIONS

A. Nature of the Case

52. Plaintiffs bring this case against Defendants for damages associated with ingestion of one or more of the pharmaceutical drugs Yaz®, Yasmin®, Ocella® or Gianvi®

Case ID: 090901307

(ethinyl estradiol and drospirenone), which are oral contraceptives designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiffs suffered various injuries, serious physical pain and suffering, medical, hospital and surgical expenses, loss of consortium and/or death and funeral expenses as a direct result of their use of Yaz®, Yasmin®, Ocella® or Gianvi®.

B. Yasmin®, Yaz®, Ocella® and Gianvi Contain a "Fourth Generation" Progestin

53. Yasmin®, Yaz®, Ocella® and Gianvi® are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. These steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

54. Yasmin® received FDA approval in 2001. It is a combination of drospirenone, a progestin, and ethinyl estradiol, an estrogen.

55. Each tablet of Yasmin® contains a combination of 3 mg of the progestin, drospirenone, and 0.03 mg of the estrogen, ethinyl estradiol.

56. Yaz® received FDA approval in 2006 and is essentially the same as Yasmin®; the only difference is a slightly smaller amount of ethinyl estradiol (0.02 mg).

57. Yasmin® and Yaz® were approved by the FDA for marketing in 2001 and 2006 respectively.

58. Ocella®, the generic version of Yasmin®, received FDA approval in March, 2008.

Case ID: 090901307

59. Gianvi®, the generic version of Yaz®, received FDA approval in April, 2009.

60. Yasmin®, Yaz®, Ocella® and Gianvi® contain the progestin drospirenone which is a "fourth generation" progestin.

61. The estrogen component in Yasmin®, Yaz®, Ocella® and Gianvi® is known as ethinyl estradiol.

62. The progestin component in Yasmin®, Yaz®, Ocella® and Gianvi® is known as drospirenone.

63. Yasmin® and Ocella® contain 0.03 milligrams of ethinyl estradiol.

64. Yaz® and Gianvi® contain 0.02 milligrams of ethinyl estradiol.

65. Yasmin®, Yaz®, Ocella® and Gianvi® contain 3 milligrams of drospirenone.

66. Yasmin®, Yaz®, Ocella® and Gianvi® are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States.

67. Drospirenone was not marketed in the United States prior to its use in Yasmin®.

68. Drospirenone is a diuretic and as such, creates unique risks as compared to other oral contraceptives.

69. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of developing blood clots and suffering 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 amount of estrogen. As the amount of estrogen used was reduced, so too did the risk of developing blood clots and suffering heart attacks and strokes.

Case ID: 090901307

70. During this time, new progestins were developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with a lower dose of the estrogen, ethinyl estradiol, helped to reduce the risk of developing blood clots and suffering heart attacks and strokes. The second generation progestins were considered safer for women to use.

71. During the 1990's, new "third generation" progestins were developed.

72. Unfortunately, the "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of the development of blood clots in deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk, the FDA required that products containing third generation progestins include a warning of the potentially higher risk of developing a thrombosis.

73. Yasmin®, Yaz®, Ocella® and Gianvi® contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades. However, drospirenone, a new type of progestin, is considered a "fourth generation" progestin. No other birth control pill contains drospirenone.

74. According to IMS sales data, Ocella® had annual sales of approximately $170.2M in the United States for the twelve months ending December 31, 2008.

75. Since drospirenone is new, research data is not available to support its safe use. Studies performed prior to FDA approval, however, indicate that drospirenone has certain effects that are different, and potentially more dangerous than traditional second generation progestins.

Case ID: 090901307

76. As a diuretic, drospirenone can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia (elevated blood potassium level).

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

78. If Hyperkalemia disrupts normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can lead to a heart attack, the clot can break off and travel to the lungs where it can cause a pulmonary embolism, it can travel to the legs where it can cause a deep vein thrombosis; or it can travel to the brain where it can cause a stroke.

79. In addition, drospirenone can cause gallbladder disease and kidney stone formation which have been reported with the use of drospirenone in Yasmin®, Yaz®, Ocella® and Gianvi®. As a result, surgical intervention is often required.

80. Indeed, during the brief time that Yasmin®, Yaz®, Ocella® and Gianvi® have been sold in the United States, hundreds of reports of injury and death associated with these products have been submitted to the FDA.

81. In April 2002, THE BRITISH MEDICAL JOURNAL reported that the DUTCH COLLEGE OF GENERAL PRACTITIONERS recommended that older second generation birth control pills should be prescribed in lieu of Yasmin®. This recommendation resulted from reports of 40 cases of venous thrombosis among women taking Yasmin®.

82. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin®* was published in the BRITISH MEDICAL JOURNAL. The report detailed

Case ID: 090901307

a Netherlands Pharmacovigilance Centre report of five additional cases of thromboembolism, including two deaths, where Yasmin® was suspected as the cause.

83. The FDA's adverse event data indicates staggering, serious adverse events that have been associated with Yasmin®, Yaz®, Ocella® and Gianvi® including but not limited to heart arrhythmias, electrolyte imbalance, hyponatremia, hyperkalemia, hyperkalemic arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, strokes, transient ischemic attacks, blood clot formation, gall bladder and kidney disease and/or sudden death.

84. In fact, from the first quarter of 2004 through the third quarter of 2008, the FDA received reports for more than 50 deaths where the decedents were users of Yasmin®, Yaz® and Ocella®. Because of underreporting, the actual number of people who suffered side effects associated with these medications is actually 10 to 100 times more than reported.

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

86. Some of the deaths reported occurred in women as young as 17 years old.

87. Reports of elevated potassium levels are frequently included among the causes of death of women who died while using Yasmin®, Yaz® or Ocella®.

88. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yasmin® or Yaz® over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral

Case ID: 090901307

contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that "oral contraceptives with . . . drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogesterel. Lidegard, et al., *Hormonal contraception and risk of venous thromboembolism: national follow up study,* THE BRITISH MEDICAL JOURNAL 2009, 330:B2921.

89. The second study found that Yasmin® or Yaz® users have twice the risk of a clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et al, *The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study.* THE BRITISH MEDICAL JOURNAL 2009, 339:B2921.

90. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the use of Yasmin®, Yaz®, Ocella® and Gianvi® but they have, through their marketing and advertising campaigns, urged women to use Yasmin®, Yaz®, Ocella® or Gianvi® instead of birth control pills that present a safer alternative.

C. <u>Over-Promotion of Yasmin® and Yaz®</u>

91. Defendants market Yasmin® and Yaz® as effective for the treatment of premenstrual dysphoric disorder (hereinafter referred to as "PMDD"), premenstrual syndrome (hereinafter referred to as "PMS") and moderate acne, in addition to its FDA-approved use as an oral contraceptive.

Case ID: 090901307

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

93. Defendants market Yasmin® and Yaz® as lacking certain side-effects, such as weight gain, bloating and water retention, common to many other oral contraceptives.

94. However, because Yasmin®, Yaz®, Ocella® and Gianvi® contain the fourth generation progestin drospirenone, which is a diuretic, these drugs present additional health risks not associated with other birth control pills.

95. For example, Defendant Berlex Laboratories promoted Yasmin's® fourth generation progestin, drospirenone, by stating, "*Ask about Yasmin®, and the difference a little chemistry can make.*"

96. On July 10, 2003, the FDA objected to the characterization that drospirenone was beneficial as 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* [.]"

97. 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.*"

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

Case ID: 090901307

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

100. In one of Defendants' commercials cited by the FDA, the song "*We're Not Gonna Take It*" plays in the background, while a series of young, fashionably dressed women kick away or puncture floating signs with labels saying "irritability" and "feeling anxious." Meanwhile, a voiceover promotes Yaz® as a "*pill that goes beyond the rest, with benefits like the ability to maintain clear skin.*"

101. Another one of the Defendants' commercials is set to the tune of "*Goodbye to You*" and shows a variety of women next to balloons marked "*headaches,*" "*acne*" and "*feeling anxious*", which float away, presumably after taking Yaz®.

102. On October 3, 2008, in response to these ads, the FDA issued another warning letter to Defendants for the misleading advertisement, reiterating that its 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 drospirenone ... which*

Case ID: 090901307

can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

103. The FDA further warned the Defendants that Yaz® "*does not result in completely clear skin*" and that Defendants' "*TV Ads misleadingly overstate the efficacy of the drug.*"

104. Indeed, the FDA felt the 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.

105. During 2008, when the ads in question were broadcast on television, Defendants' sales of Yaz® in the United States increased to approximately $616 million, from about $262 million in 2007. For 2008, Defendants' sales of Yasmin® totaled about $382 million, or about 11 percent of the United States market.

106. In February 2009, Bayer Corporation settled 27 claims with Attorneys General across the country, including Pennsylvania Attorney General, Thomas W. Corbett, Jr., for misleading marketing and sales practices of Yaz® and Yasmin®. The litigation alleged that Defendant Bayer Corporation overemphasized the benefits and minimized the risks of Yaz® and Yasmin®.

107. In response, Bayer Corporation acknowledged that it was the proper party to resolve claims relating to the sales and marketing of Yaz® and Yasmin® and the Consent Order clearly bears the signature of George J. Lykos, the Senior Vice President, Chief Legal Officer and Secretary of Bayer Corporation. Mr. Lykos is the only person who signed the consent judgment on behalf of Bayer Corporation. Bayer Corporation ultimately agreed to spend at least

Case ID: 090901307

$20 million on corrective TV advertisements and to submit all Yaz® advertisements over the next six years to the FDA for advanced screening.

108. In the corrective advertisements for Yaz® an actress states "You may have seen some Yaz commercials recently that were not clear," an actress says in the new corrective television spot, as she looks into the camera. "The F.D.A. wants us to correct a few points in those ads."

109. Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this Complaint.

110. As a result of the manufacture, marketing, advertising, promotion, distribution, and the sale of Yasmin®, Yaz®, Ocella® and Gianvi® without adequate warnings about the risks of serious injuries, Plaintiffs have sustained severe and permanent personal injuries.

111. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs' medical providers prescribed and Plaintiffs ingested Yasmin®, Yaz®, Ocella® or Gianvi®

Case ID: 090901307

D. The Plaintiffs' Use of Yasmin®, Yaz®, Ocella® and Gianvi and Their Resulting Injuries

112. Prior to Plaintiffs' use of Yasmin®, Yaz®, Ocella® or Gianvi®, Defendants knew or should have known that use of Yasmin®, Yaz®, Ocella® and Gianvi® created a higher risk of death, cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, deep vein thrombosis, stroke, transient ischemic attacks, gallbladder disease and removal, kidney disease and injury and other physical injuries and diseases, than those associated with 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.

113. Therefore, at the time that the Plaintiffs used Yasmin®, Yaz®, Ocella® and Gianvi®, Defendants knew or should have known that the use of Yasmin®, Yaz®, Ocella® and Gianvi® created an increased risk of serious personal injury and death to consumers.

114. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin®, Yaz®, Ocella® and Gianvi®, Defendants failed to warn Plaintiffs and their health care providers of the serious risks before Plaintiffs used the drug.

115. Had Plaintiffs and their heath care providers known the risks and dangers associated with Yasmin®, Yaz®, Ocella® and Gianvi®, they would not have used Yasmin®, Yaz®, Ocella® or Gianvi® and would not have suffered injuries as described above.

116. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs have suffered death, serious permanent physical injury, life-changing, life-altering pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical and funeral

Case ID: 090901307

expenses and other expenses related to diagnosis and treatment thereof, for which Defendants are liable. As a direct and proximate result of Plaintiffs use of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs have suffered and will continue to suffer pecuniary and other losses.

117. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of Yasmin®, Yaz®, Ocella® and Gianvi® and their resulting injuries, Plaintiffs have suffered damages and harm, including but not limited to, emotional distress. Plaintiffs have incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort.

118. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and have been deprived of their ordinary pursuits and enjoyments of life. Plaintiffs' spouses have lost, presently and in the future, their spouse's companionship, services, society and the ability of Plaintiffs' spouses in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs' spouses have been caused mental anguish and suffering.

119. To the extent that the law of another forum is applied to any aspect of the case, Plaintiffs incorporate by reference that law and make any and all claims that may be available under the law.

Case ID: 090901307

IV. CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY

120. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

121. At the time of Plaintiffs' injuries, Defendants' pharmaceutical drug Yasmin®, Yaz®, Ocella®, and Gianvi®, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiffs.

122. The Yasmin®, Yaz®, Ocella® and Gianvi® ingested by Plaintiffs was in the same or substantially similar condition as it was when it left the possession of Defendants.

123. Plaintiffs did not misuse or materially alter the Yasmin®, Yaz® , Ocella® and Gianvi®.

124. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. The pharmaceutical Yasmin®, Yaz®, Ocella® and Gianvi® as designed, manufactured, sold and supplied by the Defendants, was 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 Yasmin®, Yaz®, Ocella® and Gianvi®;

c. Defendants failed to warn and place adequate warnings and instructions on Yasmin®, Yaz®, Ocella® and Gianvi®;

Case ID: 090901307

d. Defendants failed to adequately test Yasmin®, Yaz®, Ocella® and Gianvi®;

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 Yasmin®, Yaz®, Ocella® and Gianvi®; and,

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

125. Defendants' actions and omissions were the direct and proximate cause of Plaintiffs' injuries.

126. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

127. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

Case ID: 090901307

128. At the time Defendants marketed, distributed and sold Yasmin®, Yaz®, Ocella® and Gianvi® to Plaintiffs, Defendants warranted that Yasmin®, Yaz®, Ocella® and Gianvi® was merchantable and fit for the ordinary purposes for which it was intended.

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

130. Yasmin®, Yaz®, Ocella® and Gianvi® were not merchantable and fit for its ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this Complaint.

131. Plaintiffs reasonably relied on Defendants' representations that Yasmin®, Yaz® Ocella® and Gianvi® were safe and free of defects and was a safe means of birth control, treatment for acne, PMDD and/or PMS, and other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

132. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injury.

133. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Case ID: 090901307

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of $50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

COUNT III
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

134. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

135. Defendants manufactured, supplied and sold Yasmin®, Yaz®, Ocella® and Gianvi® with an implied warranty that it was fit for the particular purpose of a safe means of birth control, treatment for acne, PMDD and/or PMS, and other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

136. Members of the consuming public, including Plaintiffs, were the intended third-party beneficiaries of the warranty.

137. Yasmin®, Yaz®, Ocella® and Gianvi® were not fit for the particular purpose as a safe means of birth control, treatment for acne, PMDD and/or PMS, and for the other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation, without serious risk of personal injury, which risk is much higher than other birth control pills.

138. Plaintiffs reasonably relied on Defendants' representations that Yasmin®, Yaz®, Ocella® and Gianvi® were safe and effective for use as a birth control method.

Case ID: 090901307

139. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

140. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of $50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

COUNT IV
NEGLIGENT FAILURE TO WARN

141. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

142. Before Plaintiffs ingested Yasmin®, Yaz®, Ocella® and Gianvi® during the period in which they used the drugs, Defendants knew or had reason to know that Yasmin®, Yaz®, Ocella® and Gianvi® were dangerous and created an unreasonable risk of bodily harm to consumers.

143. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Yasmin®, Yaz®, Ocella® and Gianvi® likely to be dangerous.

Case ID: 090901307

144. Despite the fact that Defendants knew or had reason to know that Yasmin®, Yaz®, Ocella® and Gianvi® were dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiffs, of the dangerous conditions and facts that made Yasmin®, Yaz®, Ocella® and Gianvi® likely to be dangerous.

145. The Plaintiffs' injuries were the direct and proximate result of Defendants' failure to warn of the dangers of Yasmin®, Yaz®, Ocella® and Gianvi®.

146. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT DESIGN DEFECT

147. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

148. Defendants are the manufacturer, seller, distributor, marketer, and supplier of Yasmin®, Yaz®, Ocella® and Gianvi® which were negligently designed.

Case ID: 090901307

149. Defendants failed to exercise reasonable care in designing, developing, formulating, manufacturing, inspecting, testing, packaging, selling, distributing, labeling, marketing, and promoting Yasmin®, Yaz®, Ocella® and Gianvi® which were defective and presented an unreasonable risk of harm to consumers, such as Plaintiffs.

150. As a result, Yasmin®, Yaz®, Ocella® and Gianvi® contain defects in their design which render the drugs dangerous to consumers, such as Plaintiffs, when used as intended or as reasonably foreseeable to Defendants. The design defects render Yasmin®, Yaz®, Ocella® and Gianvi® more dangerous than other birth control pills and cause an unreasonable increased risk of injury including but not limited to: heart arrhythmias, electrolyte imbalance, hyponatremia, hyperkalemia, hyperkalemic arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, strokes, transient ischemic attacks, blood clot formation, gall bladder and kidney disease and sudden death.

151. Plaintiffs used Yasmin®, Yaz®, Ocella® and Gianvi® in a reasonably foreseeable manner, and substantially as intended by Defendants.

152. Yasmin®, Yaz®, Ocella® and Gianvi® were not materially altered or modified after manufactured by Defendants and before used by Plaintiffs.

153. The design defects directly rendered Yasmin®, Yaz®, Ocella® and Gianvi® defective and were the direct and proximate result of Defendants' negligence and failure to use reasonable care in designing, testing, and manufacturing Yasmin®, Yaz®, Ocella® and Gianvi®.

154. As a direct and proximate result of Defendants' negligent design of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs suffered injury.

Case ID: 090901307

155. Despite the fact that Defendants knew or should have known that Yasmin®, Yaz®, Ocella® and Gianvi® were defectively designed, contained design defects, and caused an unreasonable risk of harm, Defendants designed, manufactured, sold, and marketed Yasmin®, Yaz®, Ocella® and Gianvi® to consumers, including the medical community and Plaintiffs, and failed to warn consumers, the medical community, and Plaintiffs of the increased risk of harm relative to other birth control pills.

156. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE

157. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

158. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of Yasmin®, Yaz®, Ocella® and Gianvi®, including a duty to assure that the product did not cause unreasonable, dangerous side-effects to users.

Case ID: 090901307

159. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of Yasmin®, Yaz®, Ocella® and Gianvi® in that Defendants knew or should have known that the drugs created a high risk of unreasonable harm.

160. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Yasmin®, Yaz®, Ocella® and Gianvi® in that, among other things, they:

a. Failed to use due care in designing and manufacturing Yasmin®, Yaz®, Ocella® and Gianvi® so as to avoid the aforementioned risks to individuals;

b. Failed 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 effects. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Yasmin®, Yaz®, Ocella® and Gianvi®;

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

e. Were otherwise careless or negligent.

161. Despite the fact that Defendants knew or should have known that Yasmin®, Yaz®, Ocella® and Gianvi® caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market Yasmin®, Yaz®, Ocella® and Gianvi® to consumers, including the medical community and Plaintiffs.

Case ID: 090901307

162. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

163. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

164. Prior to Plaintiffs' first use of Yasmin®, Yaz®, Ocella® or Gianvi® and during the period in which they used Yasmin®, Yaz®, Ocella® or Gianvi®, Defendants misrepresented that Yasmin®, Yaz®, Ocella® and Gianvi® were a safe and effective means of birth control, treatment for acne, PMDD and/or PMS, and other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

165. Defendants also failed to disclose material facts regarding the safety and efficacy of Yasmin®, Yaz®, Ocella® and Gianvi®, including information regarding increased adverse events, harmful side-effects, and results of clinical studies showing that use of the medication could be life- threatening.

Case ID: 090901307

166. Defendants had a duty to provide Plaintiffs, 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.

167. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with Yasmin®, Yaz®, Ocella® and Gianvi® that their representations regarding Yasmin®, Yaz®, Ocella® and Gianvi® were false, and that they had a duty to disclose the dangers Yasmin®, Yaz®, Ocella® and Gianvi®.

168. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiffs, to act in reliance by purchasing Yasmin®, Yaz®, Ocella® and Gianvi®.

169. Plaintiffs justifiably relied on Defendants' representations and nondisclosures by purchasing and using Yasmin®, Yaz®, Ocella® and Gianvi®.

170. Defendants' misrepresentations and omissions regarding the safety and efficacy of Yasmin®, Yaz®, Ocella® and Gianvi® was the direct and proximate cause of Plaintiffs' injuries.

171. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

Case ID: 090901307

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

172. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

173. Defendants expressly warranted that Yasmin®, Yaz®, Ocella® and Gianvi® were safe and effective to members of the consuming public, including Plaintiffs.

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

175. Defendants marketed, promoted and sold Yasmin®, Yaz®, Ocella® and Gianvi® as a safe means of birth control, treatment for acne, PMDD and/or PMS, and other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

176. Yasmin®, Yaz®, Ocella® and Gianvi® do not conform to these express representations because Yasmin®, Yaz®, Ocella® and Gianvi® are not safe and have serious side-effects, including death.

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

a. Yasmin®, Yaz®, Ocella® and Gianvi® as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in

Case ID: 090901307

to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on Yasmin®, Yaz®, Ocella® and Gianvi®;

c. Defendants failed to adequately test Yasmin®, Yaz®, Ocella® and Gianvi®; and,

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Yasmin®, Yaz®, Ocella® and Gianvi®.

178. Plaintiffs reasonably relied upon Defendants' warranty that Yasmin®, Yaz®, Ocella® and Gianvi® were safe and effective when they purchased and used the medication.

179. Plaintiffs' injuries were the direct and proximate result of Defendants' breach of their express warranty.

180. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of $50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

Case ID: 090901307

COUNT IX
FRAUD

181. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

182. Prior to Plaintiffs' use of Yasmin®, Yaz®, Ocella® and Gianvi® and during the period in which Plaintiffs actually used Yasmin®, Yaz®, Ocella® and Gianvi®, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yasmin®, Yaz®, Ocella® and Gianvi®, including information regarding increased adverse events, pre and post marketing deaths, the high number of severe adverse event reports compared to other birth control pills, the increased risk of venous and thrombotic clotting, pulmonary embolism, deep vein thrombosis, heart attack, stroke, transient ischemic attack, and kidney and gallbladder disease, among others. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone. As described above, drospirenone has several well known serious side-effects that are not seen in other forms of birth control. Plaintiffs believe that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Yasmin®, Yaz®, Ocella® and Gianvi® strong.

183. Defendants fraudulently concealed the safety issues associated with Yasmin®, Yaz®, Ocella® and Gianvi® in order to induce physicians to prescribe and patients, including Plaintiffs, to purchase and use Yasmin®, Yaz®, Ocella® and Gianvi®.

184. At the time Defendants concealed the fact that Yasmin®, Yaz®, Ocella® and Gianvi® were not safe, Defendants were under a duty to communicate this information to Plaintiffs, physicians, the FDA, the healthcare community, and the general public in such a

Case ID: 090901307

manner that they could appreciate the risks associated with using Yasmin®, Yaz®, Ocella® and Gianvi®.

185. Defendants, at all times relevant hereto, withheld information from the FDA which they were required to report.

186. Plaintiffs and the Plaintiffs' prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of Yasmin®, Yaz®, Ocella® and Gianvi®.

187. Plaintiff's prescribing physicians were not provided with the necessary information by the Defendants, to provide an adequate warning to the Plaintiffs.

188. Yasmin®, Yaz®, Ocella® and Gianvi® were improperly marketed to the Plaintiffs and their prescribing physicians as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the medications' risks.

189. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiffs and Plaintiffs' prescribing physicians, Defendants caused or contributed to Plaintiffs' injuries.

190. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiffs. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Yasmin®, Yaz®, Ocella® and Gianvi®. Defendants' outrageous conduct rises to the level necessary that Plaintiffs 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.

Case ID: 090901307

191. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yasmin®, Yaz®, Ocella® and Gianvi® as described herein. Defendants did not disclose this information to the Plaintiffs, their prescribing physicians, the healthcare community and the general public. Without full knowledge of the dangers of Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs and Plaintiffs' lawyers could not evaluate whether a person who was injured by Yasmin®, Yaz®, Ocella® and Gianvi® had a valid claim.

192. Defendants widely advertised and promoted Yasmin®, Yaz®, Ocella® and Gianvi® as a safe and effective medication and/or as a safe and effective means of birth control, treatment for acne, PMDD and/or PMS, and other medical benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

193. Defendants had a duty to disclose material information about serious side-effects to consumers such as Plaintiffs.

194. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Yasmin®, Yaz®, Ocella® and Gianvi® as a safe and effective medications, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiffs, to purchase Defendants' dangerous product.

195. Had Plaintiffs been aware of the hazards associated with Yasmin®, Yaz®, Ocella® and Gianvi®, Plaintiffs would not have consumed the product that led proximately to Plaintiffs' adverse health effects.

Case ID: 090901307

196. Defendants' advertisements regarding Yasmin®, Yaz®, Ocella® and Gianvi® made material misrepresentations to the effect that Yasmin®, Yaz®, Ocella® and Gianvi® were safe and effective medications, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiffs, to purchase such product. Plaintiffs relied on these material misrepresentations when deciding to purchase and consumer Yasmin®, Yaz®, Ocella® and Gianvi®.

197. Upon information and belief, Plaintiffs aver that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Yasmin®, Yaz®, Ocella® and Gianvi® with the purpose of preventing consumers, such as Plaintiffs, from discovering these hazards.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
VIOLATION OF CONSUMER PROTECTION LAWS

198. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

199. Plaintiffs purchased and used Yasmin®, Yaz®, Ocella® and Gianvi® primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

200. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

Case ID: 090901307

a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and,

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

201. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Yasmin®, Yaz®, Ocella® and Gianvi®.

202. Defendants uniformly communicated the purported benefits of Yasmin®, Yaz®, Ocella® and Gianvi® while failing to disclose the serious and dangerous side-effects related to the use of Yasmin®, Yaz®, Ocella® and Gianvi® and of the true state of Yasmin®, Yaz®, Ocella® and Gianvi® regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiffs in the marketing and advertising campaign described herein.

203. Defendants' conduct in connection with Yasmin®, Yaz®, Ocella® and Gianvi® was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Yasmin®, Yaz®, Ocella® and Gianvi®.

204. As a result of these violations of consumer protection laws, Plaintiffs have incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of

Case ID: 090901307

opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
LOSS OF CONSORTIUM

205. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

206. Plaintiffs were at all times relevant hereto the spouse of co-plaintiff and as such lives and cohabits with her.

207. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

208. For the reasons set forth herein, Plaintiffs have been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society and the ability of the Plaintiffs' spouses have in those respects been impaired and depreciated, and the martial association between husband and wife has been altered, and, accordingly, the Plaintiffs have been caused great mental anguish.

209. The Plaintiffs are entitled to punitive damages because Defendants' failure to warn was reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs, by making false

Case ID: 090901307

representations about the safety of their products. Defendants downplayed, understated and disregarded their knowledge of the serious and permanent side-effects associated with the use of Yasmin®, Yaz®, Ocella® and Gianvi® despite available information demonstrating that the product was likely to cause serious and sometimes fatal side-effects to its users.

210. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side-effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to the safety and efficacy of Yasmin®, Yaz®, Ocella® and Gianvi®.

211. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

212. As a result of Defendants' conduct, Plaintiffs suffered the injuries and damages specified herein.

213. Accordingly, Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XII
WRONGFUL DEATH

214. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

Case ID: 090901307

215. Plaintiffs Decedents' spouse brings this claim on behalf of himself and as the Decedents' lawful beneficiary. The Decedents' lawful beneficiaries include the Decedents' beneficiaries.

216. As a direct and proximate result of the conduct of the Defendants and the defective nature of Yasmin®, Yaz®, Ocella® and Gianvi® as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

217. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs, Administrators of Decedents' estates, bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to 42 Pa. C.S.A. §8301.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIII
SURVIVAL ACTION

218. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

Case ID: 090901307

219. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouses, as Administrators of the Estates of Decedents, brings this claim on behalf of the estates for damages under 42 Pa. C.S.A. §8302.

220. As a direct and proximate result of the conduct of Defendants, Decedents and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estates of the Decedents pursuant to 42 Pa C.S.A. §8302.

221. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing psychological damage.

222. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses, as Administrators of the estates of the Decedents, brings the claim on behalf of the estates for damages under 42 Pa C.S.A. §8302, and in their own right.

Case ID: 090901307

223. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

224. As a result of the Defendants' conduct, the Plaintiffs suffered the injuries and damages specified herein.

225. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

V. JURY TRIAL DEMANDED

Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants for damages including exemplary damages if applicable to which they are entitled by law, as well as all costs of this action, to the full extent of the law including:

1. judgment for Plaintiffs and against Defendants;
2. damages to compensate Plaintiffs for injuries sustained as a result of the use of Yasmin®, Yaz®, Ocella® and Gianvi® for past and future lost of income proven at trial;
3. physical pain and suffering of the Plaintiffs; and any and all damages allowed under the law and laws or other statutes and laws that apply and for loss of consortium;
4. pre and post judgment interest at the lawful rate;

Case ID: 090901307

5. exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;

6. damages available for wrongful death and survival;

7. a trial by jury on all issues of the case; and,

8. for any other relief as this court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied including but not limited to reasonable attorneys' fees and costs and expert fees.

Respectfully submitted,

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Plaintiffs' Liaison Counsel

Date: 11-9-10

Case ID: 090901307

VERIFICATION

I, Michael M. Weinkowitz Esquire, hereby state that I am the attorney in this action and co- *Plaintiffs' Liaison Counsel* and verify that the statements made in the foregoing *Second Amended Master Complaint* are true and correct to the best of my knowledge, information and belief. I understand that the statements therein are made subject to the penalties of 18 P.A. C.S.A. §4904 relating to unsworn falsification to authorities.

MICHAEL M. WEINKOWITZ

Date: 11-9-10

Case ID: 090901307