IN RE YAZ®, YASMIN®, OCELLA® LITIGATION v. BAYER CORP., BAYER HEALTHCARE, LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, INTENDIS INC., BAYER AG, TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., BARR PHARMACEUTICALS LLC (formerly known as BARR PHARMACEUTICALS, INC.), BARR LABORATORIES, INC., JANE DOE DISTRIBUTORS (1-50), JILL DOE MANUFACTURERS (1-50), JACK DOE WHOLESALERS (1-50), JAKE DOE SELLERS (1-50), JOHN DOE MARKETERS (1-50), JOAN DOE FORMULATORS (1-50), JIM DOE HEALTH CARE PROVIDERS (1-50), and JEAN DOE (1-50),	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION:** **BERGEN COUNTY** Case No. 287 **CIVIL ACTION**

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form Civil Action Complaint upon personal knowledge, investigative efforts, information and belief. This Master Long Form Civil Action Complaint is intended to operate as an administrative device to set forth most of the potential claims Plaintiffs may assert against Defendants in this litigation. This is being filed and served pursuant to Case Management Order 10, and is intended to be accompanied by a Short Form Complaint. Accordingly, Plaintiffs allege as follows:

I. PARTIES

A. Plaintiffs

1. This Complaint is a Master Long Form Complaint filed for all Plaintiffs, and if applicable, for Plaintiffs' spouses, children, decedents or wards represented by Plaintiffs' counsel. By operation of the Order of this Court, all allegations pled herein are deemed pled in any Short-Form Complaint hereafter filed.

2. As more particularly set forth herein, each plaintiff maintains that the pharmaceutical drugs, Yaz®, Yasmin®, and Ocella® are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lacked proper warnings of the dangers associated with their use.

3. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' negligent and wrongful misconduct in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, and sale of the combination contraceptives known as Yaz®, Yasmin®, Ocella® (hereinafter referred to as "Yaz®," "Yasmin®", "Ocella®" or collectively as "the Products"), which are combination hormonal birth control pills containing an estrogen component, ethinyl estradiol and a progestin, drospirenone.

B. Defendants

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

5. 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.

6. Berlex Laboratories, Inc. and Berlex, Inc. were corporations organized under the laws of the Federal Republic of Germany with their headquarters and principal places of business at Montville, New Jersey, with a post office address of P.O. Box 1000, Montville, New Jersey, 07045, and a place of business at 6 West Belt Road, Wayne, New Jersey 07470.

7. 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.

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

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

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

11. Defendant Bayer Healthcare LLC is and at all relevant times was a corporation organized under the laws of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania.

12. Defendant Bayer Healthcare LLC is a wholly owned subsidiary of Defendant Bayer Corporation.

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

14. Defendant Bayer Schering Pharma AG is a corporate successor to Schering AG. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

15. Defendant Bayer Schering Pharma AG is the current owner of the trademark relating to the oral contraceptive Yaz®.

16. Defendant Bayer Schering Pharma AG is the current owner of the trademark relating to the oral contraceptive Yasmin®.

17. Defendant Bayer Schering Pharma AG is the current owner of the patent relating to the combination oral contraceptive known as compositions of estrogen-drospirenone complexes.

18. Defendant Bayer Schering Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, PA 15205.

19. Defendant Intendis Inc. is a 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 parent holding company that is organized and exists under the laws of the Federal Republic of Germany and is headquartered at Kaiser-Wilhelm Allee, 51368 Leverkusen, Germany.

22. Defendant Bayer AG is the parent holding company of all other named Bayer and Berlex entities.

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

24. Defendant Bayer Corporation is a United States holding company with its headquarters and principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

25. Defendant Bayer Corporation is the North American subsidiary of Defendant Bayer AG. Defendant Bayer Corporation encompasses the corporate-center functions that support Bayer subgroups in North America: Bayer Crop Science, Bayer Healthcare and Bayer Material Science.

26. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Schering Pharma AG, and Bayer AG shall be referred to herein individually by name or collectively as "Bayer" or "Bayer Defendants."

27. Defendant Barr Pharmaceuticals LLC, formerly known as Barr Pharmaceuticals, Inc. (collectively referred to as "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 with its principal place of business in Woodcliff Lake, 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 Summit Avenue, Montvale, New Jersey.

29. BLI was a wholly owned subsidiary of BPI.

30. Defendants BLI and BPI shall be referred to herein individually by name or collectively as "Barr" or "Barr Defendants."

31. Defendant Teva Pharmaceutical Industries Ltd ("Teva Ltd") is and at all relevant times was a pharmaceutical corporation organized under the laws of Israel maintaining 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 relevant times was a pharmaceutical company organized under the laws of Delaware with its principal place of business located at 18-01 River Road, Fairlawn, NJ 04410.

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" or the "Teva Defendants."

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

36. On or about December 23, 2008, Teva acquired Barr and integrated Barr as a wholly owned subsidiary.

37. Teva USA through BLI distributes the generic form of Yasmin® in the U.S. under the Barr Laboratories label, Ocella®.

38. Bayer Defendants, Barr Defendants, and Teva Defendants shall be referred to collectively as "Defendants." Intendis, Inc. shall also be included as one of the "Defendants" only in the case of a Plaintiff who was prescribed Yaz by a dermatologist and/ or the dermatologist's nurse practitioner or physician assistant and/or if a Plaintiff had a

dermatologist and/or the dermatologist's nurse practitioner or physician assistant recommend that she discuss Yaz with another health care provider.

39. Bayer Corporation supplies BLI and Teva USA with the generic form of Yasmin®.

40. At all relevant times, Bayer performed all pharmacovigilance in connection with the reporting of complaints and adverse events in association with the use of the Products.

41. At all relevant times, Defendants included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

42. 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.

43. 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 New Jersey, either directly or indirectly through third-parties, subsidiaries or related entities, the oral contraceptives Yaz®, Yasmin®, and/or Ocella®.

44. There exists and at all times mentioned herein there existed a unity of interest in ownership between and among all Defendants such that any individuality and

separateness between and among them has ceased. Because Defendants are the alter egos of one another and exert control over each other, adherence to the fiction of the separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

45. At all times relevant to the matters alleged in this Complaint, each Defendant acted as the agent of the other Defendants and acted within the course and scope of the agency, regarding the acts and omissions alleged. Together, Defendants acted in concert and/or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves at the expense of Plaintiffs.

46. Jane Doe Distributors (1-50), Jill Doe Manufacturers (1-50), Jack Doe Wholesalers (1-50), Jake Doe Sellers (1-50), John Doe Marketers (1-50), Joan Doe Formulators (1-50), Jim Doe Health Care Providers (1-50), and Jean Doe (1-50), are corporations, partnerships, companies, or other entities involved in the marketing, design, development, manufacture, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution, prescription or release of the Products, whose identities are not presently known by Plaintiffs. The Doe defendants are sued individually in their official capacity.

II. FACTUAL ALLEGATIONS

47. Defendants are the current market leaders in the oral contraceptive products, Yaz®, Yasmin®, and Ocella®.

48. Plaintiffs bring this case against Defendants for damages associated with ingestion of the Products, which were designed, manufactured, marketed and distributed by Defendants.

49. Yaz®, Yasmin®, and Ocella® are birth control pills. 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.

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

51. Each tablet of Yasmin® contains a combination of 3 mg. of drospirenone and 0.03 mg. of ethinyl estradiol.

52. Yaz® received FDA approval in 2006 and is essentially the same as Yasmin®, except there is a slightly smaller amount of ethinyl estradiol (0.02 mg.) in Yaz® and the dosing regimen is somewhat different. Yasmin® is delivered in a 21/7 dosing regimen, while Yaz® is delivered in a 24/4 dosing regimen.

53. 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 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 . . .

54. On or about December 23, 2008, Teva acquired Barr and integrated Barr as a wholly owned subsidiary.

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

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.

56. On June 24, 2008, BLI, which is now a wholly owned subsidiary of Teva USA, announced that it had entered into a supply and licensing agreement with Bayer for distribution of Ocella®, which is the generic version of Yasmin®. According to Bayer's Press Release, under the terms of that agreement, Bayer supplies Ocella® to Barr and Barr distributes Ocella® in the U.S. under the Barr Laboratories label.

57. According to IMS sales data, Ocella® had annual sales of approximately $170.2 million in the United States for the period ending December 31, 2008.

THE "FOURTH GENERATION" PROGESTIN, DROSPIRENONE

58. Shortly after the introduction of COCs in the 1960s, 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, the risk of developing blood clots and suffering heart attacks and strokes was also reduced.

59. During the 1970s and 1980s, 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, helped to reduce the risk of developing blood clots and suffering heart attacks and strokes even further than the reduction of the estrogen dose alone. The second generation progestins were considered safer for women to use.

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

61. Unfortunately, these "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"), despite the fact that the amount of estrogen in those pills was kept low. 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 suffering a thromboembolic event.

62. The Products contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades. However, drospirenone, this new type of progestin, is considered a "fourth generation" progestin. No other birth control pill contains drospirenone.

63. Drospirenone was not marketed in the United States prior to its use in Yasmin®. Drospirenone is an analog of the potassium sparing diuretic, spironolactone, and therefore, creates unique risks for it users as compared to other oral contraceptives.

64. COCs with Drospirenone carries a comparable degree of risk as those COCs with "third generation" progestin, but do not carry a warning label conveying the true increased risk.

65. In April 2010, after hundreds of serious adverse events had been reported, Bayer issued a new label for both Yaz® and Yasmin®. This new label continues to obscure the true risks associated with the products.

OVER-PROMOTION OF YASMIN® AND YAZ®

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

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

68. However, because the Products contain the drospirenone, which is a diuretic, these drugs present additional health risks not associated with other birth control pills.

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

70. 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* [.]"

71. 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.*"

72. 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."

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

74. 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.*"

75. 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®.

76. On October 3, 2008, in response to these ads, the FDA issued another warning letter to Defendant Bayer 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 can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems.*"

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

78. 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.

79. Indeed, the FDA felt Defendants' over-promotion of Yaz® was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz® advertisements regarding acne and premenstrual syndrome.

community and the public about the risk of serious adverse events that are described in this Complaint.

81. Defendants were aware that reliable and simple blood tests for inherited thrombophilias have been available that can screen patients most susceptible to the thrombotic effects of their Products. Yet, Defendants entirely failed to recommend that physicians utilize those tests before prescribing the Products, thereby subjecting those most at risk of thromboembolic events to that risk, when those women could have entirely avoided the risk had the tests been recommended in the Products' labeling.

82. Defendants were aware of the enhanced risk of utilizing their Products among patients who had undertook prolonged travel such as trans-continental flights, yet Defendants failed to warn the physicians and the patients that they should avoid such travel while on the product, or at a minimum, be cognizant of blood clot symptomatology while on or after such travels, so that preventative measures could be taken and prompt treatment of a developing clot could be obtained.

83. Defendants were aware of the substantially enhanced risk of utilizing their Products in patients who had orthopedic injuries that required their limb(s) to be casted, splinted or otherwise immobilized. Yet, Defendants failed to warn the physicians and patients that they should discontinue the Products if the patient suffered an injury that required immobilization.

84. Drospirenone can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia (elevated blood potassium level).

85. Hyperkalemia can cause heart rhythm disturbances, such as extra systoles, pauses, or bradycardia; and more significantly, it can cause ventricular tachycardia or fibrillation—life threatening dysrhythmias. If left untreated, hyperkalemia can be fatal.

86. When hyperkalemia disrupts normal heart rhythms, the flow of blood through the heart is slowed to the point that it significantly decreases cardiac output, which may cause death. Blood clots in the coronary artery can lead to heart attacks. Blood clots in the legs can cause deep vein thromboses, and may break off and travel to the lungs causing pulmonary emboli. Additionally, clots that travel to the brain can lead to a debilitating stroke.

87. The use of the Products has harmful effects on blood plasma resulting in the development of thromboses, such as sinus thrombosis, pulmonary emboli, deep vein thrombosis, and portal vein thrombosis.

88. Drospirenone can also cause gallbladder disease and kidney stone formation which have been reported with the use of the Products. As a result, surgical intervention is often required.

89. The use of Yasmin/Yaz/Ocella has harmful effects on the gallbladder by increasing the cholesterol saturation of bile, which causes gallbladder disease

90. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of their marketed drugs, including the Products. Defendants continually receive reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking the

Products and defendants' other marketed drugs. Furthermore, defendants continue to conduct clinical trials for their marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to defendants, whether through defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when defendants learn, or should have learned, of new safety information associated with their marketed drugs, they have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

91. During the brief time that the Products have been sold in the United States, hundreds of reports of injuries and death associated with these products have been submitted to the FDA. The FDA's adverse event data indicates numerous serious adverse events have been associated with the Products, 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, and include serious injuries to women of childbearing age.

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

93. Because of underreporting, the actual number of people who suffered side effects associated with these medications is expected to be 10 to 100 times more than reported.

94. Reports of elevated potassium levels are frequently included among the causes of death of women who died while using the Products.

95. 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 instead of Yasmin®. *See* Sheldon, *Dutch GPs Warned Against New Contraceptive Pill*, BRIT. MED. J. 324:869 (April 13, 2002). This recommendation resulted from reports of 40 cases of venous thrombosis among women taking Yasmin®.

96. In February 2003, a paper entitled "*Thromboembolism Associated With the New Contraceptive Yasmin®*" was published in the *British Medical Journal*. *See* van Grootheest, et al., *Thromboembolism Associated With the New Contraceptive Yasmin®*, BRIT. MED. J. 326:257 (Feb. 1, 2003). The report detailed a Netherlands Pharmacovigilance Centre report of five additional cases of thromboembolism, including two deaths where Yasmin® was suspected as the cause.

97. Two recent studies released in August 2009 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 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 levonorgestrel." Lidegaard, *et al.*, "*Hormonal Contraception and Risk of Venous Thromboembolism: National Follow Up Study*," BRIT. MED. J. 330:B2921 (May 27, 2009).

98. 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 levonorgestrel. Vandenbroucke, *et al*, "*The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestin Type: Results of the MEGA Case-Control Study*," BRIT. MED. J. 339:B2921 (May 29, 2009).

99. As a result of Defendants' failure to provide marketing, advertising, and promotion materials that accurately warned of the serious risks of the Products, medical providers have prescribed and Plaintiffs ingested the Products, thus causing Plaintiffs severe and permanent personal injuries.

DEFENDANTS FRAUDULENTLY CONCEALED THE INCREASED RISKS ASSOCIATED WITH INGESTION OF THE PRODUCTS.

100. Despite the wealth of scientific evidence, Defendants not only ignored the increased risk of injuries and failed to convey the increased risks associated with use of the Products, but through their marketing and advertising campaigns, they concealed the fact that the Products carried greater risks than other equally efficacious birth control pills and urged women to take their products over those that present a safer alternative.

101. Defendants' failure to convey complete safety information or follow up on the known increased risks associated with the use of the Products and their concealment of those increased risks from the FDA, Plaintiffs, and the medical community constitute fraudulent concealment that equitably toll the applicable statutes of limitations.

102. As a result, Plaintiffs could not have commenced this action previously because both the injury and the fact that it was caused by the conduct of another were not known or discoverable through the exercise of reasonable diligence.

103. Indeed, Plaintiffs could not have commenced this suit sooner as technical, was uniquely in the possession of Defendants, had not been discovered, identified or determined in the public literature prior to the time period within which this action would have been authorized.

104. Defendants are estopped from relying on the statute of limitations defense because Defendants actively failed to convey, obscured and actively concealed the increased risks associated with the Products by, among other things, suppressing reports and failing to disclose increased risks to physicians. Instead of revealing the increased risks, Defendants have continued to represent the Products as safe for their intended use.

105. Had the users of the products, including Plaintiffs, known the full extent of the risks and dangers associated with the use of the products, said users would never have used the products and incurred the injuries they did.

106. As a result of the manufacture, marketing, advertising, promotion, distribution, and the sale of the Products without adequate warnings about the risks of serious injuries, Plaintiffs have sustained severe and permanent personal injuries.

107. As a result of Defendants' claim regarding the effectiveness and safety of the Products, Plaintiffs' medical providers prescribed and Plaintiffs ingested the Products.

108. As a direct and proximate result of Defendants' negligence, suppression, concealment of information, and other wrongful conduct, and the unreasonably dangerous and defective characteristics of the Products, Plaintiffs suffered severe and permanent physical injuries. Plaintiffs have endured substantial pain and suffering. Plaintiffs have incurred significant expenses for medical care and treatment, and will continue to incur such expenses in

the future. Plaintiffs have suffered and will continue to suffer economic losses and have otherwise been physically, emotionally, and economically injured. Plaintiffs are entitled to compensatory damages from Defendants as a result of their wrongful, callous, and careless concealment.

III. CLAIMS FOR RELIEF

109. Plaintiffs reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

110. At the time of Plaintiffs' injuries, Defendants' pharmaceutical drugs the Products, were defective and unreasonably dangerous to foreseeable consumers, including Plaintiffs.

111. Certain Plaintiffs were prescribed, purchased and were injured as a result of ingestion of the Products in New Jersey. As a result, Plaintiffs put Defendants on notice of the following claims arising under New Jersey law.

COUNT I
PRODUCT LIABILITY ACT— DEFECTIVE DESIGN
(N.J.S.A. 2A: 58C-2, *et seq.*)

112. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

113. At all times material hereto, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, distributed, or have recently acquired entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Products used by the Plaintiffs, as described above.

114. The Products were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the products without substantial or material

change in the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

115. At all times relevant, the Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, including Plaintiffs.

116. The Products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of the Products.

117. The Products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective in design and formulation, because when they left the hands of Defendants' manufacturers and suppliers they were unreasonably dangerous and also were more dangerous than the ordinary consumer would expect.

118. At all times herein mentioned, the Products were in a defective condition and were unsafe, and Defendants knew and had reason to know that the Products were defective and unsafe, especially when the Products were used in a form and manner instructed and provided by Defendants.

119. The Products were defective in that there were safer alternative designs that were not utilized.

120. Defendants knew or should have known, at all times material hereto, that the Products were in a defective condition, and were and are inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

121. At the time of Plaintiffs' use of the Products, the Products were being used for their intended purpose, and in a manner normally intended, namely for birth control, the provision of estrogen and progestin, and/or the regulation of menses.

122. Defendants had a duty to create products that were not unreasonably dangerous for their normal, common, intended use.

123. The Products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants were manufactured defectively because the Products left the hands of Defendants in a defective condition and were unreasonably dangerous for the intended use for which they were manufactured and sold.

124. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products that created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiffs.

125. Plaintiffs could not, by the reasonable exercise of care, have discovered the Products' defects and perceived their danger before their ingestion of the products.

126. The Products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants were defective due to inadequate warnings and instructions, since Defendants knew or should have known that the Products created a risk of serious and dangerous side effects, including but not limited to severe blood clots, pulmonary emboli, heart attacks, strokes, gallbladder removal, coma, death, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to adequately test for and warn of these risks.

127. The Products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants were defective by design because Defendants were aware at the time the Products were marketed that the intake of hormones contained in the Products would result in a potassium level much higher than the levels associated with oral contraceptives of earlier generations.

128. The Products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because Defendants knew or should have known the risks of serious side effects, including, but not limited to, strokes, emboli, blood clots, heart attacks, coma, and death, as well as other serious and permanent health consequences from the Products.

129. Defendants also failed to provide adequate warning for consumers use of the product, and Defendants continue to improperly advertise, market, label, and promote the Products to the public and the medical community.

130. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiffs.

131. Defendants' defective design of the Products and their over marketing through advertisements, together with the provision of inadequate warnings accompanying the Products were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

132. The defects in Defendants' products were substantial and contributing factors in causing Plaintiffs' injuries.

133. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous

side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

134. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT II
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A: 58C-2, *et seq.*)

135. Plaintiffs reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

136. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released the Products into the stream of commerce, and in the course of same, directly advertised or marketed the Products to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk associated with the use of the Products.

137. The Products were under the exclusive control of Defendants and were not accompanied by appropriate warnings regarding the adverse side effects and complications associated with the use of the Products, nor with adequate warnings regarding the comparative severity, duration and extent of the risk of injuries with such use of the Products.

138. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Products; no medical care provider would have prescribed—and no consumer would have used— the Products, had those facts been made known to such providers and consumers.

139. Defendants' warnings were overwhelmed and downplayed and otherwise suppressed by Defendants' overwhelming advertisement campaign, that did not demonstrate that the Products presented multiple and dangerous medical risks.

140. Defendants failed to perform or otherwise facilitate adequate testing; such testing would have shown that the Products posed serious and potential life threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiffs.

141. The Products, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released

into the stream of commerce by Defendants, were defective due to inadequate post marketing warnings and/or instructions because, after Defendants knew or should have known of the risk of serious and potentially life threatening side effects and complications from the use of the Products, Defendants failed to provide adequate warnings to medical care providers, the FDA, and the consuming public, including Plaintiffs, and continued to promote the Products aggressively.

142. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injury and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

143. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT III
PRODUCT LIABILITY ACT; BREACH OF EXPRESS WARRANTIES (N.J.S.A. 12A:2-313, *et seq.*)

144. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

145. Defendants expressly warranted to Plaintiffs by and through Defendants and/or their authorized agents, that the Products were of merchantable quality and safe, effective, fit and proper for their intended use.

146. Defendants have provided the following warranties with respect to the Products:

a. Defendants affirmatively stated in their marketing materials that Yasmin® and Yaz® are effective for the treatment of PMDD, PMS, and moderate acne, in addition to their FDA-approved use as oral contraceptives.

b. Defendants market the Products as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

c. Defendants market the Products as lacking certain side-effects, such as weight gain, bloating and water retention, common to many other oral contraceptives. However, the progestin drospirenone in the Products is a diuretic and presents additional health risks not associated with other birth control pills.

d. Berlex Laboratories promoted Yasmin® by stating, *"Ask about Yasmin®, and the difference a little chemistry can make."* However, 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* [.]"

147. Defendants made affirmations of fact to Plaintiffs and their physicians related to the Products, to the effect that the Products shall conform to the descriptions provided in Defendants' marketing materials.

148. In deciding to purchase and prescribe the Products, Plaintiffs and their physicians relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Products were not safe and were unfit for the uses for which they were intended.

149. The Products failed to provide the same benefits and efficacy as other oral contraceptives, as Defendants promised.

150. Defendants breached their warranty of the safety, efficacy, and benefits of the Products over other birth controls by continuing sales and marketing campaigns highlighting the safety of the Products, while Defendants knew of the dangerous and defective characteristics of the Products.

151. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse

cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

152. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT IV
WRONGFUL DEATH
(N.J.S.A. 2A: 31-1, *et seq.*)

153. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

154. As a result of the acts and/or omissions of Defendants as set forth herein, Decedent suffered serious emotional and bodily injuries resulting in her death.

155. Plaintiffs (as Decedent's surviving relative, husband, father, mother, and child, etc.) are entitled to recover the damages the Decedent would have received if she were

living, as a result of the acts and/or omissions of Defendants as specifically pled herein pursuant to N.J.S.A. 2A:31-4.

156. Plaintiffs are entitled to recover punitive damages and damages for the pain and suffering caused to Decedent from the acts and omissions of Defendants as specifically pled herein, including, without limitation, punitive damages pursuant to N.J.S.A. 2A:15-3, Decedent's pecuniary injury, together with all hospital, medical and funeral expenses as specifically provided for under New Jersey Wrongful Death Act, N.J.S.A. 31-1, *et seq.*

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V
SURVIVAL ACTION
(N.J.S.A. 2A: 15-3)

157. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

158. As a result of the actions and inactions of Defendants, Decedent was caused to suffer before her death.

159. Plaintiffs, on behalf of the Decedents' estates, seeks damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute) against Defendants. Plaintiffs, in his/her/their own right, seek damages compensable under the Survival Act (or any successor statute) against Defendants.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and

disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI
PUNITIVE DAMAGES
UNDER THE COMMON LAW AND PRODUCT LIABILITY ACT
(N.J.S.A. 2A:58C-1)

160. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

161. 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 the the public at large, including Plaintiffs, by making false representations about the safety of the Products. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of the Products despite available information demonstrating the Products carried an increased risk of serious and even fatal side effects to the users.

162. Defendants were or should have been in possession of evidence demonstrating that the Products caused increased risk of serious side effects. Nevertheless, they continued to market the product by providing false and misleading information with regard to safety and efficacy.

163. At all times relevant herein, Defendants:

a. knew that the Products were dangerous;

b. concealed the dangers and health risks from Plaintiffs, and the public;

c. made misrepresentations to Plaintiffs and the public as to the safety and efficacy of the Products;

d. with full knowledge of the health risks associated with the Products and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold an/or distributed the product for routine use.

164. At all times relevant hereto, Defendants by and through an officer, director, or managing agent, authorized sales representative, employee and/or other agent to engaged in malicious, fraudulent and oppressive conduct towards Plaintiffs and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiffs and the general public.

165. The acts and/or omissions of Defendant as set forth *supra*, were also such knowing and willful failures to warn of adverse effects inherent in the use of the Products, that they constituted malicious, willful, wanton, and/or reckless conduct within the meaning of the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.2 *et seq.*

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

ASSERTION OF CLAIMS BY PLAINTIFFS INJURED OUTSIDE OF NEW JERSEY

166. Plaintiffs reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

167. Certain Plaintiffs were prescribed, purchased and/or were injured as a result of ingestion of the Products outside of New Jersey. To the extent the Court chooses to apply the law of a state other than New Jersey for such Plaintiffs, Plaintiffs intend to put

Defendants on notice of claims which may be asserted by the individual Plaintiffs from the following states and jurisdictions:

COUNT VII
STRICT LIABILITY

168. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

169. At the time of Plaintiffs' injuries, the Products were defective and unreasonably dangerous to foreseeable consumers, including Plaintiffs.

170. Plaintiffs from Alaska, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, and North Dakota, and such other states where the common law, the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third)* are adopted, bring strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third))* against Defendants.

171. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert claims against Defendants under the following statutes:

a. Alabama Code § 6-2-38(1) (Ala 1976);

b. Ark. Code Ann. § 16-116-102(5);

c. the Colorado Product Liability Act of 1977, Colo. Rev. Stat. Ann. §§ 13-21-401 to 13-21-406 (2009);

d. the Connecticut Products Liability Act, Conn. Gen. Stat. §§ 52-240(a), 52-240(b), 52-572m-52-572q, and 52-577a (2005);

e. the Georgia Products Liability Act, O.C.G.A. § 51-1-11, *et seq.*;

f. the Idaho Products Liability Reform Act (the ILPRA"), Idaho Code §§ 6-1401, *et seq.*;

g. the Indiana Products Liability Act ("IPLA"), Inc. Code Ann. § 34-20-1-1 *et seq.*;

h. the Kansas Product Liability Act, Kan. Stat. Ann. § 60-3302, *et seq.* (2005);

i. the Kentucky Product Liability Act, Ky. Rev. Stat. Ann. § 411.300 (Michigan 1992) *et seq.*;

j. the Louisiana Product Liability Act, La. Rev. Stat. Ann. § 9:2800.51 *et seq.*;

k. the Mississippi Product Liability Act, Miss. Code Ann. § 11-1-63 (1993) *et seq.*

172. The Products ingested by Plaintiffs were in the same or substantially similar condition as they were when they left the possession of Defendants.

173. Plaintiffs did not misuse or materially alter the Products.

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

a. The Products, as designed, manufactured, sold and supplied by Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition causing injury to Plaintiffs;

b. The product defects created a situation that was potentially dangerous to Plaintiffs and other women;

c. Defendants failed to properly market, design, manufacture, distribute, supply and sell the Products;

d. Defendants failed to warn and place adequate warnings and instructions on the Products;

e. Defendants failed to adequately test the Products;

f. Defendants failed to provide timely and adequate post-marketing warnings and instructions long after they knew of the risk of injury associated with the use of the Products;

g. A feasible alternative design existed that was capable of preventing Plaintiffs' injuries; and,

h. Defendants' products caused injuries and losses that are of the kind that made each product a basis for strict liability.

175. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Defendants' conduct, as described above, was extreme and outrageous.

176. Defendants risked the lives of the consumers 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, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT VIII
NEGLIGENCE

177. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

178. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of the Products, including a duty to assure that the Products did not cause unreasonable, dangerous side-effects to users.

179. Defendants failed to exercise ordinary care in the manufacture, sale, marketing, quality assurance, quality control, and distribution of the Products into the stream of commerce, in that Defendants knew or should have known that the drugs created a high risk of unreasonable harm.

180. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to Plaintiffs. Defendants, through clinical trials and other adverse event reports, learned that there were serious problems with the Products' use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants had the means and

the resources to perform their pharmacovigilance duties for the entire time the Products have been on the market in the United States.

181. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia,* failing to report each adverse drug experience concerning the Products that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning the Products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence per se

182. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of the Products in that, among other things, they:

183. Defendants' negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, assembling, selling, and distributing the Products without thoroughly and adequately testing it;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, designing, assembling, and distributing the Products while concealing and suppressing test results;

c. Not conducting sufficient studies and tests to determine whether or not the Products were safe for its intended use, because Defendants knew or had reason to know that the Products were indeed unsafe and unfit for use by reason of the dangers to its users; including Plaintiffs' physicians, the general public, or the FDA, as soon as Defendants knew or should have known of the dangers of the use of the Products, such that the intake of hormones together with drospirenone contained in and through the Products would result in a dangerous plasma levels of potassium and estrogen (ethinyl estradiol) much higher than the levels associated with intake of second generation oral contraceptives;

e. Concealing, suppressing, failing to warn about, and/or failing to follow up on the adverse results of clinical testing that occurred, which indeed indicated that the Products had a high risk of serious and dangerous adverse health effects and consequences;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably foreseeably come into contact with, and more particularly, use the Products;

g. Advertising and recommending the use of the Products, while suppressing and concealing the known dangers inherent in the use of the Products;

h. Representing that the Products were safe for their intended use when they were actually unsafe for their intended purpose, and representing that the Products had equivalent safety and efficacy to other forms of contraception;

i. Suppressing, concealing, and omitting information concerning FDA warnings, recommendations, and observations from Plaintiffs, Plaintiffs' physicians,

healthcare professionals and the public, while at the same time knowing that the Products were unsafe, dangerous, and/or nonconforming with FDA regulations;

j. Suppressing, concealing, omitting, and/or misrepresenting information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Products, as compared to other forms of contraception;

k. Defendants were negligent in the design, research, development, manufacture, production, promotion, assembling, packaging, advertising, distribution, testing, marketing, and sale of the Products, because Defendants:

l. Failed to use due care in the design, research, manufacture, and development of the Products so as to avoid the aforementioned risks to individuals when Yaz®/Yasmin® was used for contraceptive purposes;

m. Advertised, marketed, and promoted the Products for uses other than for FDA-approved contraceptive purposes, *i.e.*, for the treatment of migraine headaches and other off-label uses;

n. Failed to design and manufacture the Products so as to ensure that the amount of estrogen (ethinyl estradiol) contained in the Products and transmitted would not result in estrogen blood levels greatly exceeding the levels associated with intake from older generations of oral contraceptives;

o. Failed to provide that their products were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of the Products and that use of the Products could and would result in a plasma level of potassium and a plasma

level of estrogen (ethinyl estradiol) greatly exceeding those associated with oral ingestion of estrogens in older generations of oral contraceptives;

p. Failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of the Products;

q. Failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA;

r. Failed to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations; and

s. Were otherwise careless or negligent.

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

185. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any

form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

186. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

187. 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 imposition of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX
NEGLIGENT CLAIMS UNDER THE APPLICABLE LAWS OF CONNECTICUT

188. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

189. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of the Products, including a duty to assure that the Products did not cause unreasonable, dangerous side-effects to users.

190. Defendants failed to exercise ordinary care in the manufacture, sale, marketing, quality assurance, quality control, and distribution of the Products in that Defendants knew or should have known that the drugs created a high risk of unreasonable harm.

191. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT X
COMMON LAW FRAUD
(against Bayer Defendants only)

192. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

193. Defendants falsely and fraudulently represented to the medical and healthcare community, Plaintiffs, the FDA, and the public that the Products had been tested and were found to be safe and effective for contraceptive purposes.

194. The representations made by Bayer were, in fact, false.

195. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Products.

196. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiffs, and the public, and also inducing the medical community, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the Products for use as a means of birth control and for off-label uses, including the treatment of migraines, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiffs.

197. In representations to Plaintiffs and/or to Plaintiffs' healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That the Products were not as safe as other forms of contraception;

b. That the intake of hormones contained in the Products would result in a plasma level of estrogen (ethinyl estradiol) much higher than that associated with other COCs;

c. That the risk of adverse events with the Products was higher than those with other COCs;

d. That the risk of adverse events with the Products were not adequately tested and were known by Defendants;

e. That the limited clinical testing revealed the Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other oral birth control methods, including thrombotic and other serious physical injuries;

f. That Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. That Defendants were aware of dangers in the Products in addition to and above and beyond those associated with other COCs;

h. That the Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of strokes, emboli, blood clots, heart attacks, coma, and death, as well as other severe and permanent health consequences, at a much more significant rate than other forms of oral contraceptives;

i. That patients needed to be monitored more regularly than usual while using the Products;

j. That the Products were manufactured negligently;

k. That the Products were manufactured defectively; and

l. That the Products were designed negligently, and designed defectively.

198. Defendants were under a duty to disclose to Plaintiffs and their physicians, the defective nature of the Products, including, but not limited to, the heightened risks of the hormones contained in the Products.

199. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Products.

200. Defendants' concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Products; and/or to mislead Plaintiffs into reliance and cause Plaintiffs to use the Products.

201. At the time these representations were made by Defendants, and at the time Plaintiffs used the Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

202. Defendants knew and had reason to know that the Products could and would cause severe and grievous personal injury to the users of the Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

203. In reliance upon these false representations, Plaintiffs were induced to, and did use the Products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Products, as described in detail herein.

209. Defendants intentionally failed to inform the public, including Plaintiffs, that drospirenone can cause an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia (elevated blood potassium level.)

210. Defendants failed to inform Plaintiffs, the public, and the medical community that hyperkalemia can cause heart rhythm disturbances and can cause ventricular tachycardia or fibrillation. When hyperkalemia disrupts normal health rhythms, the flow of blood through the heart is slowed to the point that it significantly decreases cardiac output, which may cause death. Blood clots in the legs can cause deep vein thromboses, and may break off and travel to the lungs causing pulmonary emboli. Clots that travel to the brain can lead to a debilitating stroke.

211. Defendants chose to over-promote the safety, efficacy and benefits of the Products instead. For example, Defendants advertised that Yaz® contained the added benefit of preventing or reducing acne and treating headaches and anxiety.

212. Defendants promoted Yaz® for medical conditions beyond the limits of the FDA approval, therefore, the FDA issued a warning letter on October 3, 2008 in response to Defendants' misleading ads. The FDA also required Bayer to run new TV advertisements to correct the misleading Yaz® advertisements regarding acne and premenstrual syndrome.

213. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiffs; to gain the confidence of the public, the medical community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Products.

214. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Products did not present serious health risks.

215. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

216. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiffs, Plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiffs, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use, and request the Products and their healthcare professionals to dispense, recommend, or prescribe the Products.

217. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives, including oral contraceptives.

218. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiffs, as well as their healthcare professionals, into a false sense of security, so that Plaintiffs and their healthcare providers would rely on Defendants' representations, and Plaintiffs would request and purchase the Products, and that their healthcare providers would dispense, prescribe, and recommend the Products.

219. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Products.

220. At the time the representations were made, Plaintiffs and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover the false representations of Defendants, nor would Plaintiffs with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

221. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Products, Plaintiffs would not have purchased, used, or relied on Defendants' products.

222. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiffs.

223. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their

lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

224. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

225. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for Plaintiffs' well-being, Plaintiffs are entitled to punitive or exemplary damages as well as compensatory damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XI
FRAUDULENT CONCEALMENT

226. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

227. Plaintiffs from Alabama, Arizona, California, Colorado, Delaware, Georgia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin and such other states as recognize such a cause of action bring this fraudulent concealment claim under the common law.

228. Throughout the relevant time period, Defendants knew that the Products were defective and unreasonably unsafe for their intended purpose.

229. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiffs, their physicians and the medical community that the Products were defective, unsafe, unfit for the purposes intended, and that they were not of merchantable quality.

230. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Products;

b. Defendants knowingly made false claims about the safety and quality of the Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the Products from Plaintiffs.

231. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Products.

232. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Products, and that their healthcare providers would dispense, prescribe, and recommend the Products, and Plaintiffs justifiably acted or relied upon, to their detriment, the concealed and/or non-disclosed facts as evidenced by their purchase of the Products.

233. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians from acquiring material information regarding the lack of safety and effectiveness of the Products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

234. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

235. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical,

health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XII
CONSTRUCTIVE FRAUD
(against Bayer Defendants only)

236. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

237. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs.

238. Despite their unique knowledge regarding the defective nature of the Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Products, as compared to other forms of contraception.

239. For example, a recent study has found that the progestin drospirenone is associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogestrel. Lidegaard, *et al.*, "Hormonal Contraception and Risk of Venous Thromboembolism: National Follow Up Study," *The British Medical Journal* 2009, 330:B2921. A second study found that Yasmin® and Yaz® users have twice the risk of a clotting event than

users of birth control pills that contain levonorgestrel. 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.

240. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Products had a higher risk of adverse effects, in addition to, and exceeding those associated with other oral birth control methods. Instead, Defendants have misrepresented the safety and efficacy of the Products.

241. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Products. Plaintiffs and the medical community have relied upon Defendants' representations.

242. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

243. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their

lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

244. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

245. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for Plaintiffs' well-being, Plaintiffs are entitled to punitive or exemplary damages as well as compensatory damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XIII
NEGLIGENT MISREPRESENTATION

246. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

247. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs and the public, that the Products had been tested and found to be safe and effective for birth control. The representations made by Defendants, in fact, were false.

248. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality

assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

249. Defendants breached their duty in representing that the Products have no serious side effects different from older generations of birth control pills to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

250. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, but not limited to, severe blood clots, pulmonary emboli, deep vein thromboses, strokes, heart attacks, gallbladder removal, coma, death, and other severe and personal injuries, which are permanent and lasting in nature.

251. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any

form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

252. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XIV
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

253. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

254. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

255. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase the Products sold and distributed by Defendants.

256. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

257. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XV
BREACH OF EXPRESS WARRANTY

258. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

259. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

260. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Products.

261. At all relevant times, Defendants intended that the Products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other oral contraceptives, and that it was adequately tested and fit for its intended use.

262. At all relevant times, Defendants were aware that consumers, including Plaintiffs, would use the Products; which is to say that Plaintiffs were foreseeable users of the Products.

263. Plaintiffs were at all relevant times in privity with Defendants.

264. The Products were expected to reach and did in fact reach consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

265. Defendants breached various express warranties with respect to the Products including the following particulars:

a. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons,

seminar presentations, publications, notice letters, and regulatory submissions that the Products was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Products;

b. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Products were as safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

c. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Products were as more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.

266. In reliance upon Defendants' express warranty, Plaintiffs used the Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

267. At the time of making such express warranties, Defendants knew or should have known that the Products do not conform to these express representations because the Products were not safe and has numerous serious side effects that were substantially more prevalent than with other oral contraceptives, many of which Defendants did not accurately warn about, and is thus unreasonably unsafe for its intended purpose.

268. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Products.

269. Defendants breached its express warranties to Plaintiffs in that the Products was not of merchantable quality, safe and fit for its intended use, or adequately tested.

270. Defendants breached the express warranty that the Products were safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other oral contraceptives, and that it was adequately tested and fit for its intended use in violation of the following:

a. Ala. Code § 7-2-313;

b. Alaska St. § 45.02.313;

c. Ariz. Rev. Stat. Ann. § 47-2313;

d. Ark. Code Ann. § 4-2-313;

e. Calif. Comm. Code § 2313;

f. Co. Rev. St. § 4-2-313;

g. Conn. Gen. Stat. Ann. § 42a-2-313;

h. 6 Del. C. § 2-313;

i. D.C. Code Ann. § 28:2-313;

j. Fla. Stat. Ann. § 672.313;

k. O.C.G.A. § 11-2-313;

l. Haw. Rev. Stat. § 490:2-313;

m. Id. Code § 28-2-313;

n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-313;

o. Ind. Code Ann. § 26-1-2-313;

p. Iowa Code Ann. § 554.2313;

q. Kans. Stat. Ann. § 84-2-313;

r. Ky. Rev. Stat. § 355.2-313;

s. La. Rev. Stat. §§ 2800.54, 2800.58;

t. Me. Rev. Stat. Ann. tit. 11, § 2-313;

u. Md. Code Ann., Com. Law § 2-313;

v. Mass. Gen. Laws Ann. Ch. 106, § 2-313;

w. Mich. Comp. Laws Ann. § 440.2313;

x. Minn. Stat. Ann. § 336.2-313;

y. Miss. Code Ann. § 75-2-313;

z. Mo. Rev. Stat. Ann. § 400.2-313;

aa. Mont. Code Ann. § 30-2-313;

ä. Neb. Rev. Stat. U.C.C. § 2-313, *et seq.*;

ö. Nev. Rev. Stat. U.C.C. § 104.2313, *et seq.*;

dd. N.H. Rev. Stat. Ann. § 382-A:2-313, *et seq.*;

bb. N.M. Stat. Ann. § 55-2-313, *et seq.*;

ff. N.Y. U.C.C. Law 2-313, *et seq.*;

gg. N.C. Gen. Stat. Ann. § 25-2-313, *et seq.*;'

ee. N.D. Cent. Code § 41-02-30, *et seq.*;

ff. Ohio Rev. Code Ann. § 1302.26, *et seq.*;

gg. Okla. Stat. tit. 12A, § 2-313 *et seq.*;

hh. Or. Rev. Stat. § 72.3130, *et seq.*;

ii. 13 Pa. Stat. Ann. § 2313, *et seq.*;

mm. R.I. Gen. Laws § 6A-2-313, *et seq.*;

nn. S.C. Code. Ann. § 36-2-313, *et seq.*;

ll. S.D. Stat. 57A-2-313, *et seq.*;

mm. Tenn. Code Ann. § 47-2-313, *et seq.*;

qq. Tex. Bus. & Com. Code Ann. § 2.313, *et seq.*;

oo. Ut. Code Ann. § 70A-2-313, *et seq.*;

ss. Va. Code Ann. § 8.2-313, *et seq.*;

qq. Vt. Stat. Ann. tit. 9A, § 2-313, *et seq.*;

rr. Wa. Rev. Code § 62A.2-313, *et seq.;*

vv. W. Va. Code § 46-2-313, *et seq.*;

tt. Wis. Stat. Ann. § 402.313, *et seq.*;

xx. Wyo. Stat. § 34.1-2-313, *et seq.*.

As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally, and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XVI
BREACH OF IMPLIED WARRANTY

271. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

272. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Products.

273. At all relevant times, Defendants intended that the Products be used in the manner that Plaintiffs or Plaintiffs' Decedent in fact used it and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

274. Defendants were aware that consumers, including Plaintiffs or Plaintiffs' Decedents, would use the Products as an oral contraceptive; which is to say that Plaintiffs or Plaintiffs' Decedents were foreseeable users of the Products.

275. Plaintiffs or Plaintiffs' Decedent were at all relevant times in privity with Defendants.

276. The drug was expected to reach and did in fact reach consumers, including Plaintiffs or Plaintiffs' Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

277. Defendants breached various implied warranties with respect to the Products, including the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Products;

b. Defendants represented that the Products were safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

c. Defendants represented that the Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.

278. In reliance upon Defendants' implied warranty, Plaintiffs or Plaintiffs' Decedents used the Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

279. Defendants breached their implied warranty to Plaintiffs or Plaintiffs' Decedents in that the Products were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of the following statutes:

a. Ala. Code §§ 7-2-314, *et seq.*;

b. Alaska. Stat. §§ 45.02.314, *et seq.*;

c. Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*;

d. Ark. Code Ann. §§ 4-2-314, *et seq.*;

e. Cal. Comm. Code §§ 2314, *et seq.*;

f. Colo. Rev. Stat. §§ 4-2-314, *et seq.*;

g. Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*;

h. Del. Code Ann. tit. 6, §§ 2-314, *et seq.*;

i. D.C. Code Ann. §§ 28:2-314, *et seq.*;

j. Fla. Stat. Ann. §§ 672.314, *et seq.*;

k. O.C.G.A. §§ 11-2-314, *et seq.*;

l. Haw. Rev. Stat. §§ 490:2-314, *et seq.*;

m. Id. Code §§ 28-2-314, *et seq.*;

n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*;

o. Indiana Code Ann. §§ 26-1-2-314, *et seq.*;

p. Iowa Code Ann. §§ 554.2314, *et seq.*;

q. Kan. Stat. Ann. §§ 84-2-314, *et seq.*;

r. Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*;

s. La. Civ. Code Ann. art. 2520, *et seq.* and is liable for redhibition under this statute;

t. Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*;

u. Md. Code Ann., Com. Law §§ 2-314, *et seq.*;

v. Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*;

w. Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*;

x. Minn. Stat. Ann. §§ 336.2-314, *et seq.*;

y. Miss. Code Ann. §§ 75-2-314, *et seq.*;

z. Mo. Rev. Stat. Ann. §§ 400.2-314, *et seq.*;

aa. Mont. Code Ann. §§ 30-2-314, *et seq.*;

ä. Neb. Rev. Stat. §§ 2-314, *et seq.*;

ö. Nev. Rev. Stat. §§ 104.2314, *et seq.*;

dd. N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*;

bb. N.J. Stat. Ann. §§ 12A:2-314, *et seq.*;

cc. N.M. Stat. Ann. § 55-2-314, *et seq.*;

gg. N.Y. U.C.C. Law §§ 2-314, *et seq.*;

hh. N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*;

ff. N.D. Cent. Code §§ 41-02-31, *et seq.*;

gg. Ohio Rev. Code Ann. §§ 1302.27, *et seq.*;

hh. Okla. Stat. tit. 12A, §§ 2-314 *et seq.*;

ii. Or. Rev. Stat. §§ 72.3140, *et seq.*;

jj. 13 Pa. Stat. Ann. §§ 2314 *et seq.*;

nn. R.I. Gen. Laws §§ 6A-2-314, *et seq.*;

oo. S.C. Code Ann. §§ 36-2-314, *et seq.*;

pp. S.D. Codified Laws §§ 57A-2-314, *et seq.*;

nn. Tenn. Code Ann. §§ 47-2-314, *et seq.*;

rr. Tex. Bus. & Com. Code Ann. §§ 2.314, *et seq.*;

pp. Utah Code Ann. §§ 70A-2-314, *et seq.*;

tt. Va. Code Ann. §§ 8.2-314, *et seq.*;

rr. Vt. Stat. Ann. §§ 9A-2-314, *et seq.*;

ss. Wash. Rev. Code §§ 62A.2-314, *et seq.*;

ww. W. Va. Code §§ 46-2-314, *et seq.*;

uu. Wis. Stat. Ann. §§ 402.314, *et seq.*;

yy. Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*.

280. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia,* deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiffs' inability to use any form of hormonal contraceptives and/or hormone replacement therapy for the duration of their lives, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

281. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT XVII
VIOLATION OF CONSUMER PROTECTION LAWS

282. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

283. Plaintiffs purchased and used the Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

284. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs and injury.

285. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

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

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.

287. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients,

physicians and consumers was to create demand for and sell the Products. Each aspect of Defendants' conduct combined to artificially create sales of the Products.

288. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Products.

289. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

290. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

291. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

292. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of:

a. Ala. Code §§ 8-19-1 *et seq.*;

b. Alaska Stat. §§ 45.50.471 *et seq.*;

c. Ariz. Rev. Stat. Ann. §§ 44-1522 *et seq.*;

d. Ark. Code Ann. §§ 4-88-101 *et seq.*;

e. Cal. Civ. Code §§ 1770 *et seq.* and Cal. Bus. & Prof. Code §§ 17200 *et seq.*;

f. Colo. Rev. Stat. §§ 6-1-105 *et seq.*;

g. Conn. Gen. Stat. §§ 42-110a *et seq.*;

h. Del. Code Ann. tit. 6, §§ 2511 *et seq.* and §§ 2531 *et seq.*;

i. D.C. Code Ann. §§ 28-3901 *et seq.*;

j. Fla. Stat. Ann. §§ 501.201 *et seq.*;

k. O.C.G.A. §§ 10-1-372 *et seq.*;

l. Haw. Rev. Stat. §§ 480-1 *et seq.*;

m. Id. Code Ann. §§ 48-601 *et seq.*;

n. Ill. Comp. Stat. Ann ch. 815, 505/1 *et seq.*;

o. Ind. Code Ann. §§ 24-5-0.5-1 *et seq.*;

p. Iowa Code Ann. §§ 714.16 *et seq.*;

q. Kan. Stat. Ann. §§ 50-623 *et seq.*;

r. Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*;

s. La. Rev. Stat. Ann. §§ 51:1401 *et seq.*;

t. Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq.*;

u. Md. Code Ann., Com. Law §§ 13-101 *et seq.*;

v. Mass. Gen. Laws Ann. Ch. 93A *et seq.*;

w. Mich. Comp. Laws §§ 445.901 *et seq.*;

x. Minn. Stat. §§ 325D.43 *et seq.* and §§ 325F.67 *et seq.*;

y. Miss. Code Ann. §§ 75-24-1 *et seq.*;

z. Mo. Ann. Stat. §§ 407.010 *et seq.*;

æ. Mont. Code Ann. §§ 30-14-101 *et seq.*;

ä. Neb. Rev. Stat. §§ 59-1601 *et seq.*;

ö. Nev. Rev. Stat. §§ 598.0903 *et seq.*;

dd. N.H. Rev. Stat. Ann. §§ 358-A:1 *et seq.*;

bb. N.M. Stat. Ann. §§ 57-12-1 *et seq.*;

ff. N.Y. Gen. Bus. Law §§ 349 *et seq.* and §§ 350-e *et seq.*;

dd. N.C. Gen. Stat. §§ 75-1.1 *et seq.*;

ee. N.D. Cent. Code §§ 51-12-01 *et seq.* and §§ 51-15-01 *et seq.*;

ff. Ohio Rev. Code Ann. §§ 1345.01 *et seq.*;

gg. Okla. Stat. tit. 15 §§ 751 *et seq.*;

hh. Or. Rev. Stat. §§ 646.605 *et seq.*;

ll. 73 Pa. Stat. §§ 201-1 *et seq.*;

jj. R.I. Gen. Laws. §§ 6-13.1-1 *et seq.*;

kk. S.C. Code Ann. §§ 39-5-10 *et seq.*;

oo. S.D. Codified Laws §§ 37-24-1 *et seq.*;

mm. Tenn. Code Ann. §§ 47-18-101 *et seq.*;

qq. Tex. Bus. & Com. Code Ann. §§17.41 *et seq.*;

oo. Utah Code Ann. §§ 13-11-1 *et seq.*;

pp. Vt. Stat. Ann. tit. 9, §§ 2451 *et seq.*;

qq. Va. Code Ann. §§ 59.1-196 *et seq.*;

rr. Wash. Rev. Code. §§ 19.86.010 *et seq.*;

vv. W. Va. Code §§ 46A-6-101 *et seq.*;

tt. Wis. Stat. Ann. §§ 100.20 *et seq.*; and

uu. Wyo. Stat. Ann. §§ 40-12-101 *et seq.*

293. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability

under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

294. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Products were fit to be used for the purpose for which they were intended, when in fact the drugs were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

295. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

296. Defendants had actual knowledge of the defective and dangerous condition of the Products and failed to take any action to cure such defective and dangerous conditions.

297. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which birth control to use and prescribe.

298. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

299. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

300. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XVIII
WRONGFUL DEATH

301. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

302. Plaintiffs as Decedent's surviving relative (wife, husband, father, mother, etc.), the next of kin, statutory heir, or survivor of Decedent bring herein this wrongful death claim.

303. Decedent died as a direct and proximate result of the Products and are survived by various family members, named and unnamed.

304. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love and consortium.

305. Plaintiffs as Decedent's surviving relative (husband, father, mother, child, etc.) or court appointed representative, are entitled to recover damages as Decedent would have if she were living, as a result of the acts and/or omissions of Defendants as specifically pled herein pursuant to the following statutes;

a. Ala. Code § 6-5-410;

b. Alaska Stat. § 09.55.580;

c. Ariz. Rev. Stat. § 12-611,12-612 and 12-613;

e. Cal. Civ. Code § 377.60 *et seq.*;

f. Colo. Rev. Stat. § 13-21-201, -202, -203;

g. Conn. Gen. Stat. § 52-555;

h. Del. Code Ann. Tit 10 § 3724;

i. D.C. Code Ann. § 16-2701;

j. Fla. Stat. Ann. § 768.16 -768.26;

k. O.C.G.A. § 51-4-1;

l. Haw. Rev. Stat. § 663-3;

m. Idaho Code Ann. § 5-311;

n. Ill. Comp. Stat. ch. 740, 180/2;

o. Ind. Code § 34-23-1-1;

p. Iowa Code § 611.22;

q. Kan. Stat. Ann. § 60-1901;

r. Ky. Rev. Stat § 411.130;

s. La. Civ. Code Ann. art. 2315.2;

t. Me. Rev. Stat. tit. 18A, § 2-804;

u. Md. Code Ann. § 3-901,902,904;

v. Mass. Gen. Laws Ann. Ch. 229, § 2;

w. Mich. Comp. Laws § 600.2922;

x. Minn. Stat. § 573.02;

y. Miss. Code Ann. § 11-7-13;

z. Mo. Rev. Stat. § 537.080, Mo. Rev. Stat. § 537.090;

aa. Mont. Code Ann. § 27-1-513;

bb. Neb. Rev. Stat. § 30-809 and § 30-810;

cc. Nev. Rev. Stat. Ann. § 41.085;

dd. N.H. Rev. Stat. Ann. § 556.12;

ee. N.M. Stat. Ann. § 41-2-1 and § 41-2-3;

ff. N.Y. CLS EPTL § 5-4.1;

gg. N.C. Gen. Stat. § 28A-18-2;

hh. N.D. Cent. Code, § 32-21-01 and § 32-21-03;

ii. Ohio Rev. Code Ann. § 2125.02(D);

jj. Okla. Stat. tit. 12, § 1053(A);

kk. Or. Rev. Stat. § 30.020;

ll. 42 Pa. Stat. Ann. § 8301;

mm. R.I. Gen. Laws § 10-7-1, 10-7-2 thru 10-7-7;

nn. S.C. Code Ann. § 15-51-10,-20, -40;

oo. S.D. Codified Laws § 15-4-1;

pp. Tenn. Code Ann. § 20-5-107,113;

qq. Tex. Civ. Prac. & Rem. Code Ann. §§ 71.001;

rr. Utah Code Ann. S 78-11-7;

ss. Vt. Stat. Ann. tit. 14, § 1491-1492;

tt. Va. Code Ann. § 8.01-50;

uu. Wa. Rev. Code § 4.20.010, Wa. Rev. Code § 4.20.020;

vv. W. Va. Code § 55-7-5, W. Va. Code § 55-7-6;

ww. Wis. Stat. § 895.04;

xx. Wyo. Stat. § 1-38-102.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XIX
SURVIVAL ACTION

306. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

307. Plaintiffs are the next of kin, statutory heir, and survivor of Decedent, and brings herein this survival claim.

As a direct and proximate result of Defendants' conduct outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, and expenses of hospitalization, medical and nursing care and treatment, monitoring, and loss of earnings as well as loss of ability to earn money and other economic damages prior to Decedent Plaintiffs' death.

308. Plaintiffs, on behalf of the Decedents' estates, seeks damages compensable against Defendants under the following statutes (or any successor statute). Plaintiffs, in his/her/their own right, seek damages compensable against Defendants.

a. Ala. Code § 6-5-462;

b. Alaska Stat. 09.55.580;

c. Ariz. Rev. Stat. Ann. § 14-3110;

d. Cal. Code Civ. Proc. § 377.30;

e. Colo. Rev. Stat. § 13-20-101;

f. Conn. Gen. Stat. Ann. § 52-599 *et seq.*;

g. Del. Code Ann. tit. 10, § 3702;

h. D.C. Code Ann. § 12-101;

i. Fla. Stat. Ann. § 46;

j. O.C.G.A. § 9-2-40;

k. Haw. Rev. Stat. § 663-7 and 663-8;

l. Idaho Code § 5-327;

m. Ill. Comp. Stat. ch. 755, 5/27-6;

n. Ind. Code Ann. § 34-9-3-1;

o. Iowa Code Ann. § 611.20;

p. Kan. Stat. Ann. § 60-1801;

q. Ky. Rev. Stat. § 411.133;

r. La. Civ. Code Ann. art.. 2315.1;

s. Me. Rev. Stat tit. 18A, § 3-817;

t. Md. Code Ann., Com. Law § 6-401;

u. Mass. Gen. Laws. Ann. Ch. 228, § 1 *et seq.*;

v. Mich. Comp. Laws Ann. § 600.2921;

w. Minn. Stat. Ann. § 573.01;

x. Miss. Code Ann. § 11-7-13

y. Mo. Rev. Stat. Ann. § 537.020;

z. Mont. Code Ann. § 27-1-501;

aa. Neb. Rev. Stat.. § 25-1401;

bb. Nev. Rev. Stat. Ann. § 41.100;

cc. N.H. Rev. Stat. Ann. § 556:9;

dd. N.M. Stat. Ann. § 37-2-;

ee. N.Y. Cls. Eptl. § 11-3.2;

ff. N.C. Gen. Stat. § 28A-18-1;

gg. N.D. Cent. Code, § 28-01-26.1;

hh. Ohio Rev. Code Ann § 2305.21;

ii. Okla. Stat. tit. 12, § 1051;

jj. Or. Rev. Stat. § 115.305;

kk. 42 Pa. Stat.. § 8302;

ll. R.I. Gen. Laws § 9-1-6;

mm. S.C. Code Ann. § 15-5-90;

nn. S.D. Codified Laws § 15-4-2;

oo. Tenn. Code Ann. § 20-5-102, 106 (2010) Tenn. Code Ann. § 20-5-108;

pp. Tex. Civ. Prac. & Rem. Code Ann. § 71.021;

qq. Utah Code Ann. § 78B-3-107;

rr. Vt. Stat. Ann. tit. 14, § 1451-1453;

ss. Va. Code Ann. § 8.01-25;

tt. Rev. Code Wash. (ARCW) § 4.20.046; Rev. Code Wash. (ARCW) § 4.20.060;

uu. W. Va. Code § 55-7-8;

vv. Wis. Stat. Ann. § 895.01;

ww. Wyo. Stat. Ann. § 1-4-101.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

CLAIMS ASSERTED BY ALL PLAINTIFFS

309. Plaintiffs reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

310. Plaintiffs intend to put Defendants on notice of the following claims arising under the common law.

COUNT XX
GROSS NEGLIGENCE

311. Plaintiffs repeat and reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

312. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but

nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

313. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

314. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

315. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXI
UNJUST ENRICHMENT

316. Plaintiffs repeat and reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

317. Defendants are and at all times were the manufacturer, sellers, and/or supplier of the prescription medications, the Products.

318. Plaintiffs paid for the Products for the purpose of contraception.

319. Defendants have accepted payment by Plaintiffs for the purchase of the Products.

320. Plaintiffs have not received the safe and effective contraceptive for which they paid.

321. It would be inequitable for Defendants to keep this money if Plaintiffs did not in fact receive a safe and effective contraceptive.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXII
LOSS OF CONSORTIUM

322. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

323. At all relevant times hereto, the Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Plaintiffs' injuries.

324. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

325. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

326. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

327. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

328. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXIII
PUNITIVE DAMAGES

329. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

330. At all times relevant hereto, Defendants knew or should have known that the Products were inherently more dangerous with respect to the risks of deep vein thrombosis, pulmonary emboli, portal vein thrombosis, renal vein thrombosis, sagittal sinus thrombosis, other ischemic events or infarcts leading to injuries and death, heart arrhythmias, myocardial

infarction, other adverse cardiovascular events, stroke, transient ischemic attack, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature than contraceptive pills using second generation progestin.

331. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Products.

332. Defendants misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety of the Products.

333. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control including COCs using a second generation progestin.

334. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control and recklessly failed to advise the FDA of same.

335. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the clotting risks caused by the Products.

336. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risk of side effects where there were safer alternative methods of birth control.

337. Defendants knew of the Products defective and unreasonably dangerous nature, but continue to manufacture, produce, assemble, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by the Products.

338. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the potentially life threatening side effects of the Products in order to ensure continued and increased sales.

339. Defendants intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the Products against their benefits.

340. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with

interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits;

3. Reasonable attorneys' fees;

4. The costs of these proceedings;

5. All ascertainable economic damages;

6. Punitive damages;

7. Survival damages (if applicable);

8. Wrongful death damages (if applicable); and

9. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

Dated: _____, 2010 _____

Plaintiffs' Liaison Counsel

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Respectfully submitted,

Dated: _____, 2010

_____

Plaintiffs' Liaison Counsel

CERTIFICATION PURSUANT TO RULE 4:5-1

Pursuant to Rule 4:5-1, upon information and belief the undersigned certifies that the matter in controversy is not the subject of any other action pending in any other court or of a pending arbitration proceeding nor is any other action or arbitration contemplated. Further, upon information and belief, she/he is not aware of any other party who should be joined in this action.

Dated: _____, 2010 _____

Plaintiffs' Liaison Counsel

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4 is hereby designated as trial counsel in this matter.

Dated: _____, 2010 _____