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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TERI BEVILLE,

Plaintiff,

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JANSSEN PHARMACEUTICALS a/k/a ORTHO-MCNEIL PHARMACEUTICALS: JOHNSON & JOHNSON; ELI LILLY AND COMPANY, ELAN PHARMACEUTICALS, INC., SANOFI-AVENTIS U.S. LLC a/k/a AVENTIS PHARMACEUTICALS, INC.; THE ABBOTT LABORATORIES, INC.; BRISTOL-MYERS SQUIBB COMPANY, as successor to E.R. Squibb and Sons, Inc.; DART INDUSTRIES, INC., as successor to United Drug Company, Rexall Drug & Chemical Drug Company; GLAXOSMITHKLINE, as successor to Burrough-Wellcome & Co.; KREMERS-URBAN COMPANY; MALLINCKRODT, INC.; MERCK & CO., INC.; PERSON & COVEY, INC.; PHARMACIA AND UPJOHN COMPANY; PREMO PHARMACEUTICAL LABORATORIES, INC., w/s/o Corporation Trust Co.; UCB, Inc.

Case No.

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Defendants.

INTRODUCTION

This action is an individual complaint for personal injury involving the drug diethylstilbestrol ("DES"), a synthetic estrogen manufactured, distributed, marketed, and sold by Defendants. DES was promoted and prescribed to pregnant women for the prevention of miscarriage and the accidents of pregnancy for two decades, from 1948 to 1971.

DES caused injury to the reproductive tract, i.e. cancer and infertility, in many of the daughters exposed *in utero* to DES and has been the subject of thousands of previous lawsuits. This action is brought by a DES daughter who developed breast cancer from her exposure to DES *in utero*.

PARTIES

- Plaintiff Teri Beville is a resident of North Carolina, currently residing at 7212
 Archers Creek Drive in Emerald Isle, North Carolina.
- 2. Defendant Sanofi-Aventis U.S. LLC a/k/a Aventis Pharmaceuticals, Inc. is a corporation resident with a principal place of business in Bridgewater, New Jersey.
- 3. Defendant Aventis Pharmaceuticals, Inc. is the successor to William H. Rorer, Inc. formerly known as Rhone-Poulenc Rorer Pharmaceuticals, Inc.
- 4. Defendant Merck & Co., Inc. is a corporation resident with a principal place of business in Whitehouse Station, New Jersey.
- 5. Defendant Janssen Pharmaceuticals a/k/a Ortho-McNeil Pharmaceuticals is a corporation resident with a principal place of business in Somerville, New Jersey.
 - 6. Ortho-McNeil Pharmaceuticals is the successor to McNeil Lab, Inc.
- 7. Defendant Perrigo Company bought, merged or otherwise purchased codefendant ELAN
- 8. Defendant Pharmacia and Upjohn Company is a corporation resident with a principal place of business in Peapack, New Jersey.
- 9. Defendant Premo Pharmaceutical Laboratories, Inc. is a corporation resident with a principal place of business in West Trenton, New Jersey.

- 10. Defendant Bristol-Myers Squibb Company is a corporation resident with a principal place of business in Princeton, New Jersey.
- 11. Defendant Bristol-Myers Squibb Company is the successor to New Jersey-based E.R. Squibb and Sons, Inc.
- 12. Defendant Johnson & Johnson is a corporation resident with a principal place of business in New Brunswick, New Jersey.
- 13. Defendant Eli Lilly and Company is a corporation resident with a principal place of business in Indiana.
- 14. Defendant The Abbott Laboratories, Inc. is a corporation resident with a principal place of business in Abbot Park, Illinois.
- 15. Defendant Dart Industries, Inc. is a Delaware corporation with a principal place of business in Orlando, Florida.
- 16. Defendant Dart Industries is a successor to New Jersey-based United Drug Company.
- 17. Defendant Dart Industries is a successor to United-Rexall Company a/k/a Rexall

 Drug and Chemical Drug Company which was based in Boston, Massachusetts.
- 18. Defendant Elan Pharmaceuticals, Inc. is a corporation resident in Delaware with a principal place of business in Massachusetts.
- 19. Defendant Elan Pharmaceuticals, Inc. is the successor to New Jersey based Carnrick Labs.
- 20. Defendant GlaxoSmithKline is a corporation resident in Pennsylvania with a principal place of business in Philadelphia, Pennsylvania.
 - 21. Defendant GlaxoSmithKline is a successor to Burrough-Wellcome & Co.

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- 22. Defendant Kremers-Urban Company is a corporation resident in Delaware with a principal place of business in Mequon, Wisconsin.
- 23. Defendant Mallinckrodt, Inc. is a corporation resident in Delaware with a principal place of business in St. Louis, Missouri.
- 24. Defendant Person & Covey, Inc. is a corporation resident with a principal place of business in Glendale, California.
- 25. Defendant UCB, Inc. is a corporation resident with a principal place of business in Smyrna, Georgia.
- 26. Defendants Sanofi-Aventis U.S. LLC a/k/a Aventis Pharmaceuticals, Inc., The Abbott Laboratories, Inc., Bristol-Myers Squibb Company, Dart Industries, Inc., GlaxoSmithKline, Janssen Pharmaceuticals a/k/a Ortho-McNeil Pharmaceuticals, Johnson & Johnson, Kremers-Urban Company, Mallinckrodt, Inc., Merck & Co., Inc., Person & Covey, Inc., Pharmacia and Upjohn Company, Premo Pharmaceutical Laboratories, Inc., and UCB, Inc. are herein collectively referred to as "Defendants".

JURISDICTION AND VENUE

- 27. Jurisdiction is proper because Defendants are subject to personal jurisdiction in this Court.
 - a. All Defendants transact or transacted business in the State of New Jersey.
 Defendants intentionally avail or availed themselves of the New Jersey market through their marketing and sales of their products in the state of New Jersey.
 - b. Many of Defendants are principally located in the State of New Jersey, including:

- i. Aventis Pharmaceuticals located in Bridgewater, New Jersey;
- ii. Merck & Co., Inc. located in White House Station, New Jersey;

- iii. Ortho-McNeil Pharmaceuticals located in Somerville, New Jersey;
- iv. Pharmacia and Upjohn Company located in Peapack, New Jersey; and
- v. Premo Pharmaceutical Laboratories located in West Trenton, New Jersey.
- vi. Bristol-Myers Squibb Company located in Princeton, New Jersey.
- vii. Johnson & Johnson located in New Brunswick, New Jersey.
- 28. Plaintiff is seeking damages in excess of \$75,000. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1332.
 - 29. Venue is proper in the District of New Jersey pursuant to 28 U.S.C. § 1391.

FACTS CONCERNING DEFENDANTS RELATIONSHIP TO PLAINTIFF

30. Defendants manufactured, distributed, market and sold DES at the time Plaintiff Teri Beville was in gestation.

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- 31. Plaintiff Teri Beville was born in California on August 4, 1965.
- 32. Plaintiff Teri Beville's mother bought and ingested DES during her pregnancy. Her physician prescribed said drug during the pregnancy, which was manufactured and sold by the Defendants.
- 33. Other than her exposure to DES *in utero*, Ms. Beville has no known genetic, behavioral, or environmental predilection to breast cancer.
- 34. In January 1986, during the birth of her first child, Ms. Beville was told she had a bicornuate uterus.
- 35. Reproductive tract structural differences, including bicornuate uteruses, are a known side effect of DES exposure in utero.

- 36. In March 2011, Ms. Beville received a mammogram which revealed an abnormal mass in her right breast. She then received a breast biopsy which revealed an infiltrating ductal carcinoma.
- 37. In May 2011, Ms. Beville underwent double mastectomy surgery to have both of her breasts removed. During the surgery, a 2.8 cm invasive carcinoma was removed from her right breast.
- 38. In July 2011, Ms. Beville started TCH chemotherapy treatment, including Taxotere, Carboplatin and Herceptin. She completed treatment one year later in July 2012.
- 39. Following chemotherapy treatment, Ms. Beville underwent multiple revision surgeries to have her breasts reconstructed.
- 40. As a result of Plaintiff Teri Beville's exposure to DES in utero, she suffered injuries, including, but not limited to, breast cancer, pain and suffering, medical expenses, loss of wages, and loss of enjoyment of life.

FACTS CONCERNING DIETHYLSTILBESTROL (DES)

- 41. Diethylstilbestrol (DES) is a synthetic estrogen.
- 42. DES was invented by British researchers in 1937, but was never patented.
- 43. DES was therefore available for production by any pharmaceutical company that obtained the required FDA approval.
- 44. In 1941, 12 drug manufacturers sought and obtained FDA approval to market DES for ailments not related to pregnancy.
- 45. In 1947, the drug manufacturers sought and obtained FDA approval to market DES to pregnant women for the prevention of miscarriages.

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- 46. Beginning in 1948, Defendants manufactured, marketed, advertised, and sold DES in the United States of America for use by pregnant women to prevent miscarriage or "accidents of pregnancy".
- 47. Between 1941 and 1971, DES was prescribed by physicians to pregnant women to prevent miscarriage and avoid other problems related to pregnancy.

FACTS CONCERNING RECOMMENDED DOSE OF DES

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- 48. Prior to the sale of DES for use in pregnancy, DES was indicated, by Defendants and others, for daily doses of 0.1 mg. This dose was considered sufficient to be "pharmacologically effective."
- 49. In 1948, Dr. George Smith and Dr. Olive Smith conducted an uncontrolled, apocryphal, and unscientific study purporting to show that DES reduced the incidence of miscarriage. Their results could not be replicated by other studies, see e.g., M.E. Davis and N.W. Fugo, "Effects of Various Sex Hormones on Excretion of Pregnandiol Early in Pregnancy," 65 Proceedings of the Soc. Experimental Biol. and Med. 39 (1947). The study was found to be lacking in scientific rigor. See Arthur King, "Threatened and Repeated Abortion: Present Status of Therapy," 1 Obstetrics and Gynecology 104 (1953).
- 50. Nonetheless, the "Smith & Smith" regimen was embraced and adopted and promulgated by Defendants. This regimen called for DES throughout pregnancy, beginning with 5 mg per day and increasing each week to 125 mg per day.
- 51. This regimen resulted in exposure of developing fetuses, during gestation, to an average of 16,100 mg of DES.
- 52. This DES was absorbed while fetuses were still developing their breast tissue *in* utero.

53. In 1948, Defendants manufactured, marketed, promoted, advertised, and sold massive dose DES therapy throughout the United States for use by pregnant women. The use of DES was advertised to prevent threatened miscarriage or "accidents of pregnancy" by using the method described by Smith and Smith.

54. The Defendants' proposed Smith & Smith regimen exposed Plaintiff to up to 125 mg of DES per day, over a thousand times the "pharmacologically effective" dosage referred to above.

FACTS CONCERNING KNOWN TOXIC EFFECTS OF EXCESSIVE DOSES OF DES

- 55. By the 1930's, the scientific community was aware that DES had teratogenic and carcinogenic characteristics.
- 56. By the 1930's, the scientific community was also aware that natural estrogens had teratogenic and carcinogenic characteristics.
- 57. In 1939, Professors Greene, Burrill, and Ivy reported that rats given DES gave birth to rats with malformed female reproductive organs. See R.R. Greene, et al., "Experimental Intersexuality: the Paradoxical Effects of Estrogens on the Sexual Development of the Female Rat," 74 Anatomical Record 429 (1939).
- 58. At least one other study expressed concerns about the potential toxicity of DES to humans. See C.L. Buxton and Earl Engle, "Effects of the Therapeutic Use of Diethylstilbestrol," 113 J. Am. Med. Ass'n 2318 (1939).
 - 59. The Defendants disregarded these studies and the warnings contained therein.
- 60. Scientists working with Defendant Eli Lilly and Company found that DES "is one of few examples that a man-made chemical is actually more potent than the natural substance of

the same class." The report entitled "The New Synthetic Estrogen, Stilbestrol" studied the effects of DES on rats and found that "[n]o visceral changes were observed except those of the endocrine organs and the female genital tract. There was definite hypertrophy of the uterus, adrenals, and pituitary gland, but atrophy of ovaries and thymus. See K.K. Chen, "The New Synthetic Estrogen, Stilbestrol," 3 Quart. Bull. Ind. Univ. Med. Center 15 (1941) ("Chen Study").

- 61. The Chen Study was published and available to all Defendants.
- 62. The Defendants ignored the results of the Chen Study.
- 63. The Defendants did not warn physicians regarding the results of the Chen Study.
- 64. The Defendants did not warn the public regarding the results of the Chen Study.
- 65. The Defendants did not take any specific action as a result of the Chen Study findings.
- 66. Rather the Defendants joined together to coordinate their applications to the Food and Drug Administration (FDA) for initial approval of DES and for its use as a miscarriage preventative.
- 67. Under the FDA regulations at the time, the FDA made no risk/benefit analysis as to whether DES was safe with regard to its utility. By the time the FDA made such determinations, DES was placed on a list of drugs to examine, but such examination did not take place until after DES was removed from the market in 1971.
- 68. Defendants' official labeling for DES specifically addressed the risk of breast cancer to women who took DES, but deleted any mention any carcinogenic or teratogenic risk to a fetus exposed *in utero*.

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- 69. In their submission to the FDA for the use of DES in pregnancy, Defendants relied on uncontrolled and unscientific case studies of women regarding the safety and efficacy of DES.
- 70. In their submission to the FDA for use of DES in pregnancy, Defendants conducted no controlled human or animal studies regarding the safety or efficacy of DES.
- 71. Despite Defendants' awareness of breast carcinogenicity in humans, Defendants conducted no further tests or studies of any type to examine the effect of DES on a fetus.
- 72. Defendants' refusal to conduct further tests or studies was despite knowledge in the scientific community that a risk was likely. The state of the art at the time would have allowed such risks to be discovered had they been tested for.
- 73. The Smith & Smith regimen recommended dosages caused excessive proliferation of fetal breast buds, acceleration of fetal breast tissue, excessive epithelial duct branching, disruption of cytoarchitecture, disruption of mammary gland self-regulation, and disruption of gene signaling pathways.
- 74. These changes contributed to a significantly increased risk of breast cancer, later in life, to women exposed to DES *in utero*, like Plaintiff Teri Beville.

FACTS CONCERNING FETAL DES EXPOSURE

- 75. Defendants were aware, from the above studies and others dating from the beginning of the twentieth century, that estrogen could cross the placenta and affect a developing fetus.
- 76. Additionally, studies of DES prior to 1947 showed that the drug targeted estrogen receptor cells in the sexual organs, including breast tissue, and that DES resisted the female fetus's metabolic protective processes.

- 77. In as early as 1937, scientists found that estrogens could cross the placenta and affect a child *in utero*. See William R. Lyons, "The Hormonal Basis of Witches Milk," 37 Proceedings of the Society for Experimental Biol. and Med. 207 (1937).
- 78. In 1955, a published study reported that DES received by a pregnant mother passed through the placental barrier and was transmitted to the fetus. See Sidney J. Peck, M.D., "Effects of Stilbestrol Therapy in Pregnancy on Bleeding Tendencies in the Mother and Infant," 5 Obstetrics and Gynecology 81 (1955).
- 79. From the sources mentioned above, and from the state of scientific knowledge at the time, Defendants had actual knowledge that DES would travel transplacentally to incite and/or promote delayed carcinogenesis in those who were exposed to the drug, including both the recipient and the child *in utero*.
- 80. Not one of the Defendants submitted studies or other information regarding the ability of DES to incite and/or promote delayed carcinogenesis to the FDA.
- 81. Not one of the Defendants published or alerted the medical community about even the possibility that DES could incite and/or promote delayed carcinogensis.
- 82. Even as Defendants prepared to manufacture, sell, and/or promote DES for prevention of miscarriage, reputable doctors raised questions about the safety and efficacy of DES. See Gordon Rosenblum and Eugene Melinkoff, "Preservation of the Threatened Pregnancy with Particular Reference to the Use of Diethylstilbestrol," 55 West. J. Surgery, Obstetrics, and Gynecology 597 (1947).
- 83. Questions about whether DES would affect the unborn child were ignored by Defendants.

- 84. In 1948, as part of an investigation into the exposure of human women to DES in early pregnancy, investigators found it "possible for the administration of hormones during the period of sex differentiation to result in some alteration of the form of the reproductive system." See M.E. Davis and E.L. Potter, "The response of the human fetal reproductive system to the administration of diethylstilbestrol and testosterone propionate during early pregnancy," 42 Endocrinology 370, 371 (1948).
- 85. By 1950, the United States Department of Agriculture (USDA) reported that mink fed DES suffered from reproductive anomalies. See Robert K. Enders, et al., "Mink Production in Relation to Stilbestrol," 16 Fur J. 4, 10 (1950). The United States government compensated mink farmers for these DES-deformed mink.
- 86. In 1959, the FDA outlawed the use of DES in poultry as the drug was too carcinogenic to chickens. Defendants again ignored the notice of harm and took no action at this time to determine if there was a cancer risk to humans.
- 87. Case studies also appeared in the medical literature describing malformations of human reproductive organs in children exposed to DES *in utero*. In 1959, Dr. Alfred M. Bongiovanni of the Children's Hospital of Philadelphia reported his observation of the masculinization of female infants whose mothers had been administered DES and no other hormones during pregnancy, stating that "[s]uch an occurrence in man is regarded as unusual in the face of the widespread use of estrogenic hormones during gestation, but it is not without its precedent in experimental biology, in which field the paradoxical effects of estrogens on the female infant have been described." See Alfred M. Bongiovanni, et al., "Masculinization of the Female Infant Associated with Estrogenic Therapy Alone During Gestation: Four Cases," 19 J. Clinical Endocrinology and Metabolics 1004 (1959).

- 88. Following the publication of Dr. Bongiovanni's case study, Defendants did not make further inquiries regarding the safety or efficacy of DES.
- 89. Defendants knew that DES could cause breast cancer, and provided warnings regarding the risk to pregnant women taking the drug.
- 90. For example, Defendants's Manual published in 1960 noted that DES "may cause or contribute to mammary or genital carcinoma in females."
- 91. However, despite knowledge that DES could pass *in utero*, Defendants failed to warn that DES could expose a fetus daughter to the same risk of breast cancer. At no time before 1971 did any Defendant state that there was a risk of cancer to a child exposed to DES *in utero*.
- 92. Defendants did not conduct any adequate human or animal tests regarding the safety of daughters exposed *in utero* to DES.
- 93. Although DES was known to have estrogenic, carcinogenic and teratogenic effects, Defendants did not conduct a single controlled prospective study in humans or animals to test for safety or efficacy of DES *in utero*.

FACTS CONCERNING LACK OF EFFICACY IN PREVENTING MISCARRIAGE

94. Also in 1950, studies came out debunking the efficacy of DES to prevent miscarriage. See e.g., Edward M. Davis and Nicholas W. Fugo, "Steroids in the Treatment of Early Pregnancy Complication," 142 J. Am. Med. Ass'n 778 (1950); E.D. Colvin, et al., "Salvage Possibilities in Threatened Abortion," 59 Am. J. Obstetrics and Gynecology 1208 (1950); R.E. Crowder, et al., "The Management of Threatened Abortion: A Study of 100 Cases," 60 Am. J. Obstetrics and Gynecology 896 (1950); Ralph A. Reis, et al., "The Management of the Pregnant Diabetic Woman and Her Newborn Infant," 60 Am. J. Obstetrics and Gynecology 1023 (1950).

- 95. Despite these and other studies, Defendants continued to promote DES as a safe and effective drug for the prevention of miscarriages.
- 96. In 1951, Defendant Eli Lilly and Company published a promotional text called De Re Medica, which stated that DES was the "most effective" drug for prevention of miscarriage.

 This promotional text was published despite the contemporary research to the contrary.
- 97. All Defendants made similar statements, either through pamphlets and brochures mailed to doctors, delivered by sales representatives, or by advertisements in medical and pharmaceutical publications.
- 98. All Defendants relied on similar erroneous statements from other manufacturers of DES to help sell and promote the product to unsuspecting women. For twenty years Defendants represented to the medical community and women that DES prevented miscarriage despite scientific evidence showing that said representations were indeed false.
- 99. Defendants represented to the medical community and women that DES prevented miscarriage despite findings from numerous scientific studies including, but not limited to, the following:
 - a. J.H. Ferguson, "Effect of stilbestrol on pregnancy compared to the effect of a placebo," 65 Am. J. Obstetrics Gynecology 592 (1953). In 1952, James Ferguson, M.D. published the results of his controlled study in which 200 pregnant women were given DES and 200 pregnant women in a control group were given a placebo. Dr. Ferguson concluded that DES was not effective for the conditions for which it was being promoted.
 - b. David Robinson and Landrum Shettles, "The Use of Diethylstilbestrol in Threatened Abortion," 63 Am. J. Obstetrics and Gynecology 1330 (1952).

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- Paul Pedowitz and Edmund L. Shievin, "The Pregnant Diabetic," Bulletin of the New York Academy of Medicine 440 (1952).
- d. W.J. Dieckmann, et al. "Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?" 66 Am. J. Obstetrics Gynecology 1062 (1953). In 1953, a controlled, double-blind study of DES as a miscarriage preventative found that DES was less effective than a placebo.
- 100. Defendants were aware of the above studies casting doubt on the efficacy of DES in preventing miscarriages. However, they continued to promote DES as safe and effective for use in pregnancy and prevention of miscarriage.
- 101. Even after the studies above, Defendant Eli Lilly and Company, the industry leader in drugs such as DES, placed product literature in the Physician's Desk Reference specifically referring to the schedule of DES application recommended by Dr. George Smith and Dr. Olive Smith. Other defendants made similar statements in their literature and/or promotional efforts.
- 102. In fact, there is no, and there has never been, reliable scientific evidence that DES is or was effective in preventing miscarriage.
- 103. At no time before 1971 did any Defendant voluntarily re-evaluate the use of DES for the prevention of miscarriage.
- 104. In 1971, the FDA issued a Drug Bulletin advising physicians to stop prescribing DES to pregnant women.
 - 105. In 1997, the last United States manufacturer stopped making and marketing DES.
- 106. In 1998, the FDA listed DES on a *Federal Register* notice of drugs that had been withdrawn or removed from the market for reasons of safety or effectiveness.

FACTS CONCERNING DEFENDANTS ACTIONS OR LACK THEREOF

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- 107. Additionally, the medical professionals employed by Defendants to monitor DES reports, studies, and adverse events were not obstetricians, gynecologists, or otherwise trained or knowledgeable about reproductive issues.
- 108. Even in the absence of testing by Defendants, independent scientific studies showed that DES was not safe or effective for use by pregnant women or their offspring. Defendants ignored these independent scientific studies.
- 109. Defendants knew, or should have known, that DES was a teratogen and carcinogen and was linked to cancer in the offspring of those exposed to DES.
- 110. Defendants knew, or should have known, that DES was not effective for prevention of miscarriage.
- 111. Defendants knew, or should have known, that the studies they provided to the Food and Drug Administration and the medical community regarding DES were not reliable, complete, nor accurate.
- 112. Defendants knowingly and intentionally promoted DES for use in pregnancy as safe and effective to prevent the threat of miscarriage. In doing so, Defendants disregarded the published literature that warned of the risks and criticized the efficacy of DES.
- 113. Defendants fraudulently deceived the Food and Drug Administration, the obstetrical profession, and the mother of Plaintiff and similar plaintiffs by knowingly and intentionally withholding adverse literature and studies or the paucity of testing. This fraudulent deception occurred notwithstanding the Defendants duty to provide to the FDA and the medical profession all relevant studies and literature, both favorable and unfavorable.

114. As a result of the manufacturing, marketing, advertising, promotion, distribution and/or sale of DES by Defendants, Plaintiff Teri Beville suffered breast cancer because she was exposed to DES *in utero*.

COUNT I NEGLIGENCE

- 115. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 116. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of DES, including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.
- 117. Defendants, as the manufacturers and sellers of DES, had a duty to provide adequate warnings and instructions about the dangers and adverse effects from using DES.
- 118. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of DES because Defendants knew, or should have known, that:
 - a. DES was not effective in preventing miscarriage among pregnant women.
 - b. DES was toxic and carcinogenic in both pregnant mothers and children exposed in utero to DES.
- 119. Defendants failed to exercise due care in the labeling of DES and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury, because Defendants knew, or should have known, that:

- a. DES was not effective in preventing miscarriage among pregnant women.
- b. DES was toxic and carcinogenic in both pregnant mothers and children exposed in utero to DES.
- 120. Defendants continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that DES posed a serious risk of bodily harm to consumers.
- 121. Defendants knew, or should have known, that consumers, such as Teri Beville, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care.
- 122. As a direct and proximate consequence of Defendants' negligence, Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT II FAILURE TO WARN

- 123. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 124. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce DES and in the course of same, directly advertised or marketed the product to

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consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product.

- 125. Defendants, as the manufacturer and/or seller of DES, had a duty to provide adequate warnings and/or instructions about the risks associated with use of DES.
- 126. Defendants did not provide an adequate warning because it did not effectively convey all information essential to make the use of DES reasonably safe.
- 127. Defendants did not provide an adequate warning because it did not communicate sufficient information on the risks associated with use of DES.
- 128. Defendants did not provide an adequate warning because Defendants' DES warning was not a warning a reasonably prudent manufacturer or seller in the same or similar circumstances would have provided to people intended to use its product.
- 129. Defendants, as designers and manufacturers of pharmaceutical products, are held to the level of knowledge of an expert in the field.
- 130. Defendants, as the manufacturers and sellers of DES, are required to keep reasonably familiar with the adverse effects of consumers using DES, including adverse effects revealed in studies and clinical trials.
- 131. Defendants were not reasonably familiar with the adverse effects of consumers using DES.
 - a. There were documented studies revealing the toxic and carcinogenic properties of DES.
 - b. There were documented studies revealing DES had no effect on miscarriages or other pregnancy problems.

- 132. Defendants knew, or should have known, and adequately warned that their products created a risk of serious and dangerous side effects.
- 133. Defendants' failure to adequately warn existed before DES left the control of Defendants.
- 134. Plaintiff Teri Beville's mother's use of DES was reasonably foreseeable and as instructed.
- 135. The DES used by Plaintiff's mother had not been substantially altered in a way that was not reasonably foreseeable.
- 136. Plaintiff's mother would have followed adequate warnings and/or instructions if they had been provided with DES.
- 137. Defendantss' failures to adequately warn was a proximate cause of Ms. Beville's personal injury.
- 138. Defendants downplayed the serious and dangerous side effects of their product to encourage sales of the product; consequently, Defendants placed their profits above their customers' safety.
- 139. The product was defective when it left the possession of Defendants in that it contained insufficient warnings to alert Plaintiff's mother and/or her healthcare providers to the dangerous risks and reactions associated with it.
- 140. Even though Defendants knew or should have known of the risks and adverse events associated with their product, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.
- 141. Defendants had a continuing duty to warn consumers of DES, including Plaintiff's mother, of the dangers associated with their product, and by negligently and/or

wantonly failing to adequately warn of the dangers of the use of its product, Defendants breached their duty.

- 142. Although Defendants knew, or should have known, of the defective nature of DES, they continued to design, manufacture, market, and sell the product without providing adequate warnings and instructions concerning the use of its product so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by DES.
- 143. Defendants' failure to warn extended beyond the product's label and into other media available to Defendants, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.
- 144. As a direct and proximate result of Defendants' failure to adequately warn or other acts and omissions of Defendants described herein, Plaintiff Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT III BREACH OF EXPRESS WARRANTY

145. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

- 146. Defendants, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that DES was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, and was adequately tested and fit for its intended use.
- 147. At the time of making such express warranties, Defendants knew and/or should have known that DES did not conform to the express warranties and representations and that, in fact, the product was not safe and had numerous serious side effects, of which Defendants had full knowledge and did not accurately or adequately warn.
- 148. The DES manufactured and sold by Defendants did not conform to these representations because it caused serious injury to pregnant women and fetuses *in utero*, including Plaintiff Teri Beville, when used in routinely administered dosages.
- 149. Defendants breached their express warranties because their product was and is defective for its intended purpose.
- 150. Consumers relied on Defendants' express warranties regarding the safety and efficacy of the product in purchasing and consuming the product.
- 151. Members of the medical community, including physicians and other healthcare professionals, relied on Defendants representations and express warranties in connection with the use recommendation, description, and dispensing of Defendants' DES products.
- 152. As a foreseeable, direct, and proximate result of Defendants' breach of express warranties, Plaintiff Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of

comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IV BREACH OF IMPLIED WARRANTY

- 153. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 154. At all times relevant to this action, Defendants manufactured, distributed, recommended, merchandised, advertised, promoted, and/or sold DES for use in pregnant women in preventing miscarriages and other pregnancy problems.
- 155. Defendants knew of this intended use of DES at the time Defendants marketed, sold, and distributed their products, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.
- 156. Defendants impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Plaintiff Teri Beville's mother, her physicians and healthcare providers, that DES was safe and of merchantable quality and fit for the oxdinary purpose for which the product was intended and marketed to be used.
- 157. Defendants' representations and implied warranties were false, misleading, and inaccurate because their products were defective, and not of merchantable quality.
- 158. At the time Defendants' product was promoted, marketed, distributed, and/or sold, Defendants knew of the use for which DES was intended and impliedly warranted their products to be of merchantable quality and safe and fit for such use.

- 159. Plaintiff Teri Beville's mother, her physicians and her healthcare providers, along with members of the general medical community, reasonably relied on the superior skill and judgment of Defendants, as manufacturer, developer, distributor, and seller of DES, as to whether DES was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was manufactured and sold.
- 160. Contrary to Defendants' implied warranties, DES was not of merchantable quality and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein.
- 161. Defendants breached their implied warranty because the product was not safely fit for its intended use and purpose.
- 162. Defendants placed DES into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and DES was expected to and did reach Plaintiff Teri Beville's mother without substantial change in the condition in which it was manufactured and sold.
- 163. As a foreseeable, direct, and proximate result of Defendants' breach of implied warranties, Plaintiff Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT V FRAUDULENT MISREPRESENTATION

- 164. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 165. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the Food and Drug Administration (FDA), and consumers, including Plaintiff Teri Beville's mother and her health care providers, that DES had been adequately tested in clinical trials and was found to be safe and effective.
- 166. Defendants knew or believed at the time they made these fraudulent misrepresentations, that these misrepresentations were false and fraudulent regarding the dangers and risks associated with use of DES in pregnant women. Defendants made these fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of their product.
- 167. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community and the public, and also inducing the medical community and the public, to recommend, prescribe, dispense, and purchase their DES products.
- 168. Defendants' fraudulent misrepresentations intentionally concealed the following material information:
 - a. Defendants represented through their labeling, advertising, marketing material, advertisements, and packaging that DES was effective at preventing miscarriages and other pregnancy problems.
 - b. Defendants represented through their labeling, advertising, marketing materials, advertisements, and packaging that DES had been tested and was found to be safe and effective for use in pregnant women.

169. Defendants were under a duty to disclose to physicians and healthcare providers, the defective design and formulation of DES, which design and formulation heightened the risk of suffering the injuries, diseases, and maladies more specifically described in this Complaint.

- 170. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous injuries and damages to persons who used the product.
- 171. Defendants' intentional concealment and omissions of material fact concerning the safety of the DES was undertaken purposefully, willfully, wantonly, fraudulently, with intent to mislead, with reckless disregard for the health and safety of consumers, and to induce physicians and healthcare providers to purchase, prescribe, administer and/or dispense Defendants' product; and to mislead consumers into reliance upon Defendants' fraudulent misrepresentations to use Defendants' products as a safe and effective medication to prevent miscarriage and other pregnancy problems.
- 172. At the time Defendants made these misrepresentations, through its officers, directors, agents, representatives, and employees, and at the times Plaintiff Teri Beville's mother was administered Defendants' product, both consumers and prescribing physicians were unaware of Defendants' falsehoods, and reasonably believed their misrepresentations to be true.
- 173. Defendants knew and had reason to know that their products were at great risk of causing serious personal injury to users of DES, and that using DES was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given by Defendants.
- 174. In reliance upon Defendants' false and fraudulent misrepresentations, Plaintiff
 Teri Beville's mother was induced to, and did reasonably rely upon Defendants'
 misrepresentations regarding the safety and efficacy of Defendants' product. Defendants knew

and had reason to know that Plaintiff's mother, her physicians and her healthcare providers, in using Defendants' product, did not have the ability to determine the true facts intentionally concealed by Defendants, and would not have used the product if the true facts regarding the product had been known.

- 175. As a result of Defendants' research and testing or lack thereof, Defendants willfully, wrongfully, and intentionally distributed false information including, but not limited to, assuring the public, healthcare providers and physicians, that Defendants' products were safe for use. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed from the medical community and other consumers the true results of Defendants' studies and research, which revealed the true risks of serious harm associated with the use of the product.
- 176. Defendants had a duty when disseminating information to the public to provide truthful information, and a parallel duty not to deceive the public, the medical community, and the FDA.
- 177. The information distributed by Defendants to the public, the medical community, and the FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of DES in pregnant women.
- 178. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of their products to the public at large, and Plaintiff's mother in particular, for the purpose of influencing the sales of a product known by Defendants to be dangerous and defective.

- 179. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and purposefully.
- 180. As a direct and proximate consequence of Defendants' fraudulent misrepresentations, Plaintiff Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VI NEGLIGENT MISREPRESENTATION

- 181. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 182. Defendants had a duty to accurately and truthfully represent to consumers, the medical community, and the FDA the truth regarding Defendants' claims that Defendants' product had been tested, and found to be safe and effective for its stated purposes.
- 183. The misrepresentations made by Defendants, in fact, were false and Defendants were careless or negligent in ascertaining the truth of the representations at the time Defendants made the misrepresentations.
 - 184. Defendants represented and marketed DES as being safe and effective.
- 185. After Defendants became aware of the risks of DES, Defendants failed to communicate to the public, the medical community, and the FDA that the use of DES was not safe or effective for its stated purposes.

- 186. Defendants failed to exercise ordinary care in making representations concerning their products and Defendants' manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce. Defendants negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the product's unreasonable, dangerous and adverse side effects associated with the use of the product.
- 187. Defendants breached their duty in representing to the public, the medical community, and the FDA that Defendants' product did not carry the risk of serious side effects such as those suffered by Plaintiff Teri Beville and other similarly situated patients.
- 188. Defendants failed to warn the public of the defective condition of DES, as manufactured and/or supplied by Defendants.
- 189. Defendants negligently misrepresented material facts about DES in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.
- 190. The above misrepresentations were made to the general public, the medical community, and the FDA.
- 191. These misrepresentations by Defendants were justifiably relied on by the general public, the medical community, and the FDA.
- 192. Consequently, Plaintiff's mother's use of DES was to her detriment and her daughter's detriment, as Defendants' negligent misrepresentations proximately caused Plaintiff Teri Beville's injury and diagnoses.
- 193. As a foreseeable, direct, and proximate result of Defendants' negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Defendants knew, or had

reason to know, that Defendants' product had not been sufficiently tested, that the product lacked adequate, accurate, and prominent warnings, and that use of the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

194. As a direct and proximate consequence of Defendants' negligent misrepresentations, Plaintiff Teri Beville sustained serious personal injuries and related losses.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VII DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

- 195. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 196. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent concealment.
- 197. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

- 198. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to

 Defendants' fraudulent concealment through affirmative misrepresentations and omissions as described in this Complaint.
- 199. As a result of Defendants' fraudulent concealment, Plaintiff was unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged herin and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VIII PUNITIVE DAMAGES

- 200. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 201. <u>Defendants sold DES to healthcare providers throughout the United States</u> without doing adequate testing to ensure that DES was reasonably safe for use in pregnant women.
- 202. <u>Defendants sold DES to healthcare providers throughout the United States in spite</u>
 of their knowledge that DES could pass through the placental barrier and transmit to the fetus.
 thereby causing severe and debilitating injuries.

- 203. Defendants ignored reports from health care providers throughout the United States and elsewhere that DES could lead to severe and debilitating injuries such as those suffered by the Plaintiff and numerous other women. Rather than doing adequate testing, P Defendants chose instead to continue to market and sell DES as safe and effective to pregnant women.
- 204. Defendants knew DES was unreasonably dangerous in light of its risks of severe personal injuries which were permanent and lasting in nature, risk of pain and suffering, and risk of loss of life's enjoyment.
- 205. Defendants withheld material information from the medical community and the public in general regarding the safety and efficacy of DES for use in pregnant women.
- 206. Defendants knew and recklessly disregarded the fact that DES causes debilitating and potentially life altering personal injury.
- 207. Defendants misstated and misrepresented data so as to minimize the perceived risk of injuries and so as to maximize the alleged efficacy of DES for use in pregnant women.
- 208. Notwithstanding the foregoing, Defendants continued to aggressively market DES to pregnant women, without disclosing the true risks associated with the product.
- 209. Defendants knew of product's defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell DES to pregnant women so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff Teri Beville.
- 210. Defendants conduct as described herein shows willful misconduct, malice, fraud, wantonness, and oppression which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages for past medical and hospital costs and expenses, lost wages, loss of comfort, love, society, companionship, emotional care and overall support; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- a. Compensatory damages to Plaintiff for past damages, including, but not limited to conscious pain and suffering, medical and hospital costs, and lost wages, loss of comfort, love, society, companionship, emotional care and overall support, together with interest and costs as provided by law;
- b. Restitution and disgorgement of profits;
- c. Reasonable attorneys' fees;
- d. The costs of these proceedings;
- e. All ascertainable economic damages;
- f. Punitive damages; and
- g. Such other and further relief as this Court deems just and proper.

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DEMAND FOR JURY TRIAL

Demand is hereby made for trial by jury.

Dated: February 18, 2014

Respectfully Submitted,

Mark T. Sadaka, MSPH, Esq. Attorney for Plaintiff Teri Beville Sadaka Associates LLC 20 North Van Brunt Street, Suite 4 Englewood, New Jersey 07631

Tel.: (201) 266-5670 Fax: (201) 266-5671

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The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS TERI BEVILLE				DEFENDANTS JANSSEN PHARMACEUTICALS a/k/a ORTHO-MCNEIL PHARMACEUTICALS; JOHNSON & JOHNSON; et al					
(b) County of Residence of First Listed Plaintiff Carteret (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence of First Listed Defendant Middlesex (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.					
(c) Attorneys (Firm Name, Address, Fimail and Telephone Number) Mark T. Sadaka 20 North Van Brunt Street, STE 4, Englewood, NJ 07631 201-266-5670; mark@sadakafirm.com				Attorneys (If Kn	aown)				
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)				TIZENSHIP OF PI	RINCIPA	L PARTIES			
1 U.S. Government			Citiz	(For Diversity Cases Only) PT ten of This State		Incorporated or Print of Business In Ti		PTF	DEF
☐ 2 U.S. Government				izen of Another State Incorporated and Principal Place of Business In Another State Izen or Subject of a					5 5
		Citizen or Subject of a 3 3 Foreign Nation 6 6 6 Foreign Country							
IV. NATURE OF SUIT	1 17	ORFEITURE/PENALTY	BAN	IKRUPTCY	OTHER	STATUT	ES		
CONTRACT ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment	PERSONAL INJURY 310 Airplane 315 Airplane Product	PERSONAL INJUR 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPEI 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Product Liability PRISONER PETITIO Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other: 540 Mandamus & Oth 550 Civil Rights 555 Prison Condition 560 Civil Detainee Conditions of Confinement	Y 0 6 6 7 0 7 0 7 NS 0 7	CAPOR 25 Drug Related Seizure of Property 21 USC 881 90 Other LABOR 10 Fair Labor Standards Act 20 Labor/Management Relations 40 Railway Labor Act 51 Family and Medical Leave Act 90 Other Labor Litigation 91 Employee Retirement Income Security Act IMMIGRATION 62 Naturalization Application 65 Other Immigration Actions	422 Appe 423 With 28 U PROPE 820 Copy 830 Pater 840 Tradi 861 Blac 863 DIW 864 SSIE 865 RSI (al 28 USC 158 drawal ISC 157 RTY RIGHTS rrights It emark .SECURITY (1395ff) k Lung (923) C/DIWW (405(g)) D Title XVI	375 False C 400 State Re 410 Antitrus 430 Banks a 450 Comme 460 Deporta 470 Rackete Corrupt 480 Consun 490 Cable/S 850 Securiti Exchan 890 Other S 891 Agricul 895 Freedon 895 Freedon 896 Arbitral 899 Admini Act/Rev	laims Act eapportion st and Bankir erce ation eer Influen Organizat ner Credit sat TV tes/Communge statutory A tlural Acts nmental M m of Inforn tion istrative Pr view or Af v Decision utionality	nment ng nced and ntions nodities/ Actions fatters mation rocedure
	moved from	Appellate Court	Rec	(specify)	er District	☐ 6 Multidistr Litigation			
VI. CAUSE OF ACTIO	ON Brief description of ca	mce.		(Do not cite jurisdictional state) g in the development	of breast	cancer			
VII. REQUESTED IN COMPLAINT:		DEMAND \$ CHECK YES only if demanded in complaint: 10,000,000.00 JURY DEMAND: ✓ Yes □ No							
VIII. RELATED CAS IF ANY		DOCKET NUMBER							
DATE SIGNATURE OF AFFORDEY OF RECORD 02/18/2014 FOR OFFICE USE ONLY									
	MOUNT	APPLYING IFP		JUDGE _		MAG. JU	DGE		

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box. Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)
- III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin. Place an "X" in one of the six boxes.
 - Original Proceedings. (1) Cases which originate in the United States district courts.
 - Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 - Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing
 - Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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Date and Attorney Signature. Date and sign the civil cover sheet.