UNITED STATES DISTRICT COURT
Southern District of Florida

DAISY GARDNER LESTER,
Plaintiff,

vs.

SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE,
Defendant.

CASE NO.:

COMPLAINT

COMES NOW the Plaintiff, Daisy Gardner Lester, by and through the undersigned attorneys, and brings this action against the Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter referred to as "GSK" or "Defendant"), and alleges as follows:

1. This is an action to recover damages for the personal injuries sustained by the Plaintiff, Daisy Gardner Lester (hereinafter referred to as "Plaintiff"), as a direct and proximate result of the wrongful conduct of the Defendant in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting and selling of the widely-used diabetes prescription drugs Avandia®, Avandamet® and Avandaryl® (rosiglitazone maleate) (hereinafter referred to as "Avandia").

JURISDICTION AND VENUE

2. This is an action for damages which exceed seventy-five thousand dollars ($75,000.00), excluding fees and costs.

3. This Honorable Court has jurisdiction over this matter pursuant to 28 U.S.C.A. §1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00, and because there is complete diversity of citizenship between Plaintiff and the Defendant.

4. Venue is proper in this United States Judicial District pursuant to 13 U.S.C. §1391. The Plaintiff, Daisy Gardner Lester, purchased the dangerous product, Avandia, in the Southern

District of Florida and Plaintiff resided in this District. Defendant marketed, advertised and distributed said dangerous product in the District, thereby Defendant received substantial financial benefit and profits from said dangerous product in this District.

5. At all relevant times herein, GSK was in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling its product, Avandia. Further, GSK designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold Avandia in interstate commerce, including Florida. GSK did and still does substantial business in the State of Florida, within this Federal District. GSK advertised Avandia, received substantial compensation and profits from sales of Avandia and made material omissions of fact and misrepresentations and breaches of warranties regarding this drug, all within this District.

PLAINTIFF'S ALLEGATIONS

6. Plaintiff files this action against the named Defendant for personal injuries which occurred as a result of the ingestion by the Plaintiff of the defective and dangerous pharmaceutical antidiabetic drug Avandia® which was researched, created formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, supplied, packaged and/or sold by Defendant as more fully detailed below.

7. Plaintiff, Daisy Gardner Lester, was and is a citizen and resident of Miami-Dade County, State of Florida, and is sui juris. The Plaintiff brings these civil actions for equitable relief, monetary restitution, and/or compensatory and punitive damages for injuries and suffered as a direct result of her exposure to Avandia.

8. Plaintiff was diagnosed with Diabetes Mellitus Type II.

9. Plaintiff was prescribed and ingested Avandia, a pharmaceutical product designed and manufactured by Defendant, for her diabetes condition for several years and as a result, developed congestive heart failure in 2003.

10. Plaintiff named herein has filed this lawsuit within the applicable statute of limitations period. Plaintiff named herein acted with diligence in attempting to discover any and all injuries inflicted upon Plaintiff, as a result of her ingestion of Avandia.

11. Due to Defendant's actions, Plaintiff did not discover, was prevented from discovering and/or could not have discovered her injuries earlier because of the Defendant's fraudulent misrepresentations, concealment of the facts and/or nature of the injuries involved, as more specifically alleged herein.

DEFENDANT

12. Defendant is a Pennsylvania corporation, with its principal place of business located at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania. SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a wholly-owned subsidiary of GlaxoSmithKline, PLC, and also conducts pharmaceutical research and development in the United States under the corporate fictitious name GlaxoSmithKline ("GSK").

13. Upon information and belief, the Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), was formed as a result of the merger of pharmaceutical corporations Glaxo Wellcome, Inc. and SmithKline Beecham, Inc. As the surviving entity, GSK is liable for the actions and inactions of all the companies involved in the mergers.

14. At all times relevant to this lawsuit, Defendant manufactured, advertised, labeled, marketed, promoted, sold and distributed Avandia in the United States, including the State of Florida.

15. At all times material to this lawsuit, Defendant was engaged in the business of, or was a successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing and/or selling the prescription drug product collectively known as Avandia, as an antidiabetic medication, to the general public, including Plaintiff.

16. At all times material to this lawsuit, Defendant was authorized to do business within the State of Florida and derived substantial revenues from products designed and sold in Florida, within this Federal District.

INTRODUCTION

17. Defendant manufactured, promoted, distributed, labeled and marketed rosiglitazone under the trade name(s) of Avandia® tablets, Avandamet® tablets and Avandaryl® tablets.

18. Rosiglitazone is a member of a class of drugs known as Thiazolidinediones (TZDs).

19. Avandia® was first approved for use in the United States in 1999 for the use in treatment of Type II diabetes mellitus, also known as non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes.

20. In 2002, Avandamet®, a single pill combination of Avandia® and metformin, was approved in the United States for use in treatment of Type II diabetes mellitus.

21. In 2005, Avandaryl®, a single pill combination of Avandia® and Amaryl®, likewise was approved in the United States for use in treatment of Type II diabetes mellitus.

22. Cardiovascular disease (CVD) is the main cause of death in diabetes patients. Therefore, it is important that an anti-diabetic agent reduce, or at least not exacerbate the risk of cardiovascular injury.

23. During the past decade, numerous drugs have been introduced for the treatment of Type II diabetes that, used in mono-therapy or in combination therapy, are intended to better control diabetes in patients and thereby reduce the health complications often associated with diabetes, such as heart attacks, strokes, heart injury and other cardiovascular complications.

24. TZDs are a novel class of insulin-sensitizing antidiabetic agents. In the USA and Canada, two TZDs were indicated for use in Type II diabetes mellitus, rosiglitazone and pioglitazone. A third, troglitazone (Rezulin), has been removed from the market because of an association with significant hepatoxicity.

25. The anti-diabetic actions of TZDs are likely mediated by their interaction with the nuclear receptor peroxisome proliferator-activated receptor-gamma (PPARγ).

26. Plaintiff was prescribed, ingested, used or otherwise was exposed to the drug rosiglitazone ("Avandia") to treat her diabetes condition.

DEFENDANT KNEW OR SHOULD HAVE KNOWN THAT INGESTING AVANDIA INCREASES THE RISK OF MYOCARDIAL INFARCTION, STROKE AND OTHER SERIOUS HEART INJURIES OR DEATH

27. Defendant knew as early as 1999 that Avandia was unreasonably dangerous and could also cause heart attacks, strokes, serious cardiovascular injuries and death.

28. In 1999, John B. Buse, M.D., Ph.D., a diabetes expert and Chief of the Division of Endocrinology at the University of North Carolina, Chapel Hill, raised concerns about Avandia and heart problems, including the risk of heart attack, cardiovascular injury and death.

29. Defendant attempted to silence Dr. Buse and further conceal the true nature of Avandia risks by threatening Dr. Buse with a $4 million lawsuit and characterizing him as a liar.[1]

30. In response to Defendant's accusation, Dr. Buse sent a three-page letter to Dr. Tadataka Yamada, Defendant's Chairman of Research and Development. In the letter, Dr. Buse wrote, "I may disagree with GSK's interpretation of that data...I am not for sale...Please call off the dogs. I cannot remain civilized much longer under this kind of heat." As a result of Defendant's threats, Dr. Buse eventually signed a clarifying statement with the company.

31. On March 15, 2000, Dr. Buse wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia: "I would like you to know exactly what my concerns are regarding rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program (whether the number we accept as the truth is the 18.6% at 4mg bid in the package insert or the "average of 12%" now being discussed), one would expect an increase in cardiovascular

[1] John Buse, M.D. Congressional Hearing Transcript (June 6, 2007)

events...Based on studies with statin and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks[2]."

32. Dr. Buse was not the only person to alert Defendant to the increased risk of heart attack, serious cardiovascular injury and death associated with Avandia. Shortly after Dr. Buse raised concerns related to increased risk of cardiovascular injuries associated with Avandia, Public Citizen filed a petition, on March 7, 2000, seeking immediate class labeling changes for all marketed TZDs, including rosiglitazone[3].

33. To date, scientists, including those at GSK, have conducted three separate meta-analyses regarding the safety and efficacy of rosiglitazone. Each meta-analysis has found that the use of rosiglitazone increases the risk of cardiovascular-related injury.

34. The first analysis, performed by GSK, was presented to the FDA in August of 2006. This meta-analysis combined the results of 42 separate double-blinded, randomized, controlled clinical trials to assess the efficacy of rosiglitazone for treatment of Type II diabetes, compared to either placebo or other anti-diabetic therapies. The combined studies included 8,604 patients on rosiglitazone and 5,633 patients randomized to a variety of alternative therapeutic regimens, including placebos. GSK's own meta-analysis found an overall increase in the incidence of myocardial ischemia in rosiglitazone-treated patients.

35. A second meta-analysis, conducted by Dr. Steven Nissen and Kathy Wolski titled *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes,* was published on May 21, 2007 in the New England Journal of Medicine. Nissen and Wolski reviewed data available to them through published literature, the FDA website and GSK's clinical-trials registry. The analysis included a review of 42 clinical trials involving nearly 28,000 patients. Nissen and Wolski concluded that "rosiglitazone was associated with a significant increase in the risk of myocardial

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[2] Letter from Dr. Buse to FDA (March 15, 2000)

[3] Public Citizen's Petition to the FDA requesting that it immediately require labeling for diabetes drugs troglitazone (Rezulin), rosiglitazone (Avandia) and pioglitazone (Actos)(HRG Publication #1514)(March 7, 2000)

infarction and with an increase in the risk of death from cardiovascular causes that had borderline significance."

36. On July 30, 2007, the FDA presented the results of its own study, the third meta-analysis. Similar to the GSK and the Nissen and Wolski findings, the FDA found an increased risk of heart attack, cardiovascular death, stroke and other serious ischemic related adverse events in diabetics that took rosiglitazone. The FDA recommended that a boxed warning be placed in the Avandia label warning of those risks.

37. Thus, while GSK's rosiglitazone-containing drugs were marketed and sold by GSK as anti-diabetic agents that reduce a diabetic patient's risk of heart attacks, meta-analysis studies, including one conducted by GSK itself, showed to the contrary, that rosiglitazone actually increased those risks.

FIRST CLAIM FOR RELIEF
STRICT LIABILITY – FAILURE TO WARN

38. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

39. Avandia was defective and unreasonably dangerous when Avandia was manufactured, packaged, assembled, labeled, marketed, distributed, supplied, placed in the stream of commerce and left the possession of the Defendant in that it contained warnings which were misleading regarding the purported benefits associated with Avandia and were inadequate and insufficient to alert physicians and consumers, such as Plaintiff, to the dangerous risks and reactions associated with Avandia, including, but not limited to, congestive heart failure, heart attack, heart injury, excessive fluid retention, hypervolemia and severe injury to the heart which could result in cardiac arrest, other serious, life-threatening side effects, and death.

40. The physician prescribed Avandia to Plaintiff for its intended purposes, i.e. antidiabetic agent.

41. The prescribing physician could not have discovered any defect in Avandia through the exercise of reasonable care.

42. The Defendant, as manufacturer of prescription devices, is held to the level of knowledge of an expert in the field.

43. The prescribing physician did not have substantially the same knowledge as the manufacturer or distributor, who should have communicated an adequate warning to the prescribing physician.

44. The warnings that were given by the Defendant to the prescribing physicians were not adequate, accurate, nor clear and were ambiguous.

45. Defendant actively sought to "bury" the limited warnings in the fine print of the materials provided to the prescribing physician, and knowingly and intentionally failed to display those warnings prominently in order to hide from prescribing physicians and the consuming public the true risks of severe and life threatening complications which had been reported in association with Avandia, including but not limited to, congestive heart failure, heart attack, heart injury, excessive fluid retention, hypervolemia and severe injury to the heart which could result in cardiac arrest and death.

46. Defendant failed to give adequate post-marketing warnings or instructions for the use of Avandia. After Defendant knew or should have known of the risk of injury from Avandia use, Defendant failed to provide adequate warnings to users or consumers and continued to aggressively promote the product to doctors, hospitals, and directly to consumers.

47. The Defendant had a continuing duty to warn the prescribing physicians of the dangers associated with Avandia use.

48. Defendant's Avandia marketing, including direct-to-consumer advertising and promotions directed toward health care professionals, was a sustained campaign for more than seven years, characterized by misrepresentations by commission and omission as to the risks and benefits, particularly as to substantial increased risk of congestive heart failure, heart attack, heart injury, excessive fluid retention, hypervolemia and severe injury to the heart which could result in cardiac arrest as suffered by Plaintiff associated with the ingestion of the drug.

49. The public, including the Plaintiff, and prescribing physicians, including Plaintiff's prescribing physicians, reasonably relied upon Defendant's misrepresentations as to Avandia's risks

and benefits in deciding to take it and prescribe it.

50. As a direct and legal result of Defendant's failure to warn, Plaintiff suffered congestive heart failure.

SECOND CLAIM FOR RELIEF

STRICT LIABILITY – DEFECTIVE DESIGN

51. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

52. At all times material hereto, Defendant has engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the drug Avandia, which was defective and unreasonably dangerous to consumers.

53. The product Avandia manufactured, supplied, and/or sold by the Defendant was defective in design or formulation when it left the hands of the manufacturers and/or sellers and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation of the product.

54. Defendant actually knew of the defective nature of the Defendant's product Avandia, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Defendant's product Avandia.

55. There were safer alternative methods and designs on the market for the like product.

56. At all times material, Avandia was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by the Defendant in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including the Plaintiff, to risks which exceeded the benefits of this drug;

b. This drug was insufficiently tested;

c. This drug caused harmful side effects that outweighed any potential utility;

d. This drug was not accompanied by adequate labeling, instructions for use and/or earnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including the Plaintiff, of the potential risks and serious side effects associated with its use, thereby rendering the Defendant liable to the Plaintiff.

57. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Avandia should not have been marketed in that condition.

58. At all times material, the drug Avandia was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of this medication across the United States, including the Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

59. At all times, Plaintiff used Avandia for its intended or reasonably foreseeable purpose. As a direct and proximate result of the defective and unreasonably dangerous condition of Avandia, the Plaintiff suffered congestive heart failure for which she is entitled to recover for loss, damage and injury, pursuant to the law.

60. As a direct and proximate result of the defective and unreasonably dangerous condition of Avandia, the Plaintiff had been injured in health, strength and activity and suffered physical injuries, as

well as pain, suffering and loss of consortium. The Plaintiff is entitled to recover from Defendant for all lawful losses, damages and injuries.

61. As a direct and proximate result of the defective and unreasonably dangerous condition, the Plaintiff required reasonable and necessary health care treatment and services and incurred expenses for which the Plaintiff is entitled to damages.

62. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers including the Plaintiff.

63. In that the Defendant knowingly withheld and/or misrepresented vital information to the general public, including the Plaintiff, which misinformation was material and relevant to the harm in question, punitive damages in an amount to be determined at trial are appropriate to punish the Defendant and deter them from similar conduct in the future.

THIRD CLAIM FOR RELIEF
NEGLIGENT DESIGN

64. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

65. Defendant designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the pharmaceutical drug Avandia which it knew would be used by Plaintiff and others. At the time the Avandia was manufactured and sold to Plaintiff by Defendant, it was defective in design and unreasonably dangerous, subjecting users to risks which exceeded the benefits of the product, and for which other safer products were available.

66. Alternatively, when the Avandia product was manufactured and sold to Plaintiff by Defendant, the product was defective in design and formulation, making use of the product more dangerous than other drugs for Diabetes Mellitus Type II.

67. The Avandia sold to Plaintiff reached Plaintiff without substantial change. Plaintiff was unaware of the dangerous propensities of the product until well after her use and subsequent

cardiac injury. Plaintiff ingested the Avandia without making any changes or alterations.

68. In designing and testing Avandia, Defendant failed to exercise the ordinary care that a careful and prudent drug manufacturer would exercise in the same or similar circumstances.

69. As a direct and proximate result of the negligent design of the Avandia that Plaintiff ingested, Plaintiff has been damaged.

70. Defendant's actions were performed with conscious disregard for the safety of users of Avandia, including the Plaintiff.

71. As a direct and proximal result of Defendant's negligent design of Avandia, Plaintiff suffered congestive heart failure.

FOURTH CLAIM FOR RELIEF
FRAUD

72. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

73. At all times material hereto, Defendant was engaged in the business of manufacturing, marketing, distributing, promoting, and selling the Defendant's product Avandia.

74. Defendant recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, material adverse information regarding the safety and efficacy of Avandia.

75. Defendant made misrepresentation to material facts to, and omitted and/or concealed material facts from the Plaintiff and her prescribing physician in the labeling, advertising, marketing, distribution and sale of the Defendant's product Avandia regarding its safety and efficacy.

76. Defendant deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from consumers, including the Plaintiff, prescribing physicians, and the medical,

pharmaceutical and/or scientific communities, that the Defendant's product Avandia was safe when used as intended. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

a. Failing to disclose, and/or intentionally concealing, the results of tests showing the potential risks of severe reactions, such as heart attack, stroke and/or death;

b. Failing to include adequate warnings with the Defendant's product Avandia about the potential and actual risks and the nature, scope, severity and duration of serious adverse effects of the Defendant's product Avandia;

c. Concealing and/or providing false or inaccurate information regarding the known risks of severe reactions, such as heart attack, stroke and/or death;

d. Concealing the known incidents of serious reactions, including heart attack, stroke and/or death, as previously alleged herein;

e. That studies have shown that patients given Avandia suffered 2.19 times the number of heart attacks or strokes compared with those taking placebos;

f. That despite knowing of the foregoing risks, the Defendant continued to market and promote the drug as safe, failing to advise the Food and Drug Administration, the public at large and the Plaintiff in particular, of the risks associated with the ingestion of Avandia.

77. Defendant intentionally concealed facts known to them, as alleged herein, in order to ensure increased sales of the Defendant's product Avandia.

78. Defendant had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendant's representations that the Defendant's product Avandia was safe for its intended purpose were false, as the Defendant's product Avandia was, in fact, dangerous to the health of the Plaintiff. Moreover, the Defendant knew that its statements were false, knew of incidents of serious reactions, including heart attack, stroke and/or death, and knew that its omissions rendered their statements false or misleading.

79. Further, Defendant failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of the Defendant's product Avandia, and failed to disclose that the Defendant's product Avandia caused serious reactions, including heart attack, stroke and/or death, among other serious adverse effects. Defendant also failed to exercise reasonable care in communicating the information concerning the Defendant's product Avandia to the Plaintiff; and/or concealed facts that were known to the Defendant.

80. The misrepresentations of and/or active concealment by Defendant constitute a continuing tort. Indeed, through Defendant's product inserts, Defendant continued to misrepresent the potential risks and serious side effects associated with the use of Avandia. Moreover, Defendant had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Avandia in a timely manner, yet it failed to provide such warning.

81. Plaintiff was not aware of the falsity of the foregoing representations, nor was the Plaintiff aware that material facts concerning the safety of the Defendant's product Avandia had been concealed or omitted. In reliance upon the Defendant's misrepresentations (and the absence of disclosure of the serious health risks), the Plaintiff ingested the Defendant's product Avandia. Had the Plaintiff known the true facts concerning the risks associated with the Defendant's product Avandia, she would not have taken them.

82. The justifiable reliance by the Plaintiff upon the Defendant's misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning the Defendant's product Avandia. Plaintiff was not in a position to know the true facts, because the Defendant aggressively promoted the use of the Defendant's product Avandia and concealed the risks associated with its use, thereby inducing the Plaintiff, and her prescribing physician to use the Defendant's product Avandia.

83. As a direct and proximate result of the Defendant's misrepresentations, and/or concealment, the Plaintiff suffered an injury and harm as previously alleged herein, ascertainable

economic loss, including the purchase price of the Defendant's product Avandia, out-pocket costs of medical tests and treatment, medical care and/or services, and other costs incidental to the Plaintiff's ingestion of harmful and defective products.

84. Defendant's conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with conscious or reckless disregard of the rights and safety of consumers such as the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter them from similar conduct in the future.

FIFTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRRANTY

85. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

86. Defendant manufactured, marketed, sold and distributed the Defendant's product Avandia.

87. At the time Defendant designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the Defendant's product Avandia for use by the Plaintiff, the Defendant knew of the purpose for which the Defendant's product Avandia was intended and impliedly warranted the Defendant's product Avandia to be of merchantable quality and safe and fit for such use.

88. Plaintiff and her prescribing physician reasonably relied on the skill, superior knowledge, and judgment of the Defendant as to whether the Defendant's product Avandia was of merchantable quality and safe and fit for its intended use.

89. Plaintiff used the Defendant's product Avandia which was provided to the Plaintiff's prescribing physician by the Defendant. Due to the Defendant's wrongful conduct as alleged herein, the Plaintiff could not have known about the risks and side effects associated with the Defendant's product Avandia until after the Plaintiff ingested it.

90. Contrary to such implied warranty, the Defendant's product Avandia was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the product was and is unmerchantable, in a defective condition and unreasonably dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above. Use of Avandia carried a risk of, among other things, heart attack, stroke and/or death, and other serious and life-threatening side effects.

91. As a direct and proximate result of the Defendant's breach of implied warranty, the Plaintiff suffered injury and harm as previously alleged herein, ascertainable economic loss, including compensation arising from the purchase price of the Defendant's product Avandia, out-pocket costs of medical tests and treatment, medical care and/or services, and other costs incidental to the Plaintiff's ingestion of said harmful and defective products.

92. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish the Defendant and deter them from similar conduct in the future.

SIXTH CLAIM FOR RELIEF
BREACH OF EXPRESS WARRRANTY

93. Plaintiff repeats and incorporates herein by reference the allegations made in the above Paragraphs.

94. Defendant expressly warranted through both its aggressive marketing and advertising campaigns, and its detail sales representatives that Avandia was safe and well accepted by patients and was safe for long-term use.

95. Avandia does not conform to these express representations because Avandia is not safe and has high levels of serious, life-threatening side effects.

96. As a direct and proximate result of the breach of said warranties, the Plaintiff has been damaged, and is therefore entitled to damages as described herein.

SEVENTH CLAIM FOR RELIEF

NEGLIGENCE

97. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

98. Defendant, directly or indirectly, negligently and/or defectively designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Avandia.

99. Defendant owed a duty to consumers of the Defendant's product Avandia, including the Plaintiff, to use reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of the Defendant's product Avandia, including a duty to ensure that the Defendant's product Avandia did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

100. Defendant failed to exercise reasonable care in the warning about, designing, testing, labeling, manufacturing, marketing, sale, and/or distribution of the Defendant's product Avandia and breached its duties to the Plaintiff in that, and not by way of limitation, they did not warn of the known risks associated with the use of the Defendant's product Avandia and did not exercise an acceptable standard of care, i.e., what a reasonably prudent manufacturer or seller would have known and warned about. Moreover, the product lacked sufficient warnings of the hazards and dangers to users of said product, and failed to provide safeguards to prevent the injuries sustained by Plaintiff. Defendant failed to properly test the Defendant's product Avandia prior to its sale, and as a result subjected users to an unreasonable risk of injury when its product was used as directed and recommended.

101. Defendant additionally breached its duty and was negligent in its actions, misrepresentations and omissions toward the Plaintiff, in part, in the following ways:

a. Failing to exercise due care in designing, developing and manufacturing Defendant's product Avandia so as to avoid the aforementioned risks to individuals using these products;

b. Failing to include adequate warnings with the Defendant's product Avandia that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to its potential risks and serious side effects;

c. Failing to adequately and properly test the Defendant's product Avandia before placing it on the market;

d. Failing to conduct sufficient testing on the Defendant's product Avandia, which if properly performed, would have shown that the Defendant's product Avandia had serious side effects, including, but not limited to, heart attack, stroke, and/or death, and other serious injuries;

e. Failed to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, that use of the Defendant's product Avandia carried a risk of heart attack, stroke, and/or death and other serious side effects;

f. Failed to provide adequate post-marketing warnings or instructions after the Defendant knew, or should have known, of the significant risks of reactions from the use of the Defendant's product Avandia;

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

h. Was otherwise careless or negligent.

102. Defendant knew, or should have known, that the Defendant's product Avandia caused unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiff, were not aware. Defendant nevertheless advertised, marketed, promoted, sold and/or distributed the Defendant's product Avandia knowing of its unreasonable risks of injury.

103. Defendant knew or should have known that consumers such as the Plaintiff would suffer injury as a result of the Defendant's failure to exercise reasonable care as described above.

104. Upon information and belief, Defendant knew or should have known of the defective nature of the Defendant's product Avandia, as set forth herein, but continued to design, manufacture, market, and sell the Defendant's product Avandia so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendant's product Avandia.

105. Defendant failed to disclose to the Plaintiff and the general public facts known or available to them, as alleged herein, in order to ensure continued and increased sales of the Defendant's product Avandia. This failure to disclose deprived the Plaintiff of the information necessary for her to weigh the true risks of taking the Defendant's product Avandia against the benefits.

106. As a direct and proximate result of the Plaintiff's use of the Defendant's product Avandia, the Plaintiff sustained injury, compensable loss and damages.

107. By virtue of the Defendant's negligence, the Defendant has directly, foreseeably and proximately caused the Plaintiff suffer congestive heart failure. As a result, the imposition of punitive damages against the Defendant is warranted.

108. As a direct and proximate result of the Defendant's negligence, the Plaintiff suffered injury and harm as previously alleged herein, ascertainable economic loss, arising from the purchase price of Defendant's product Avandia, out-pocket costs of medical tests and treatment, medical care and/or services, and other costs incidental to the Plaintiff's ingestion of harmful and defective products.

EIGHTH CLAIM FOR RELIEF
GROSS NEGLIGENCE

109. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

110. Defendant had a duty to exercise reasonable care in the warning about the design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product Avandia,

including a duty to ensure that the Defendant's product Avandia did not cause users to suffer from unreasonable and dangerous side effects.

111. Defendant failed to exercise reasonable care in the warning about the design, testing, manufacture, marketing, labeling, sale, and/or distribution of the Defendant's product Avandia, in that the Defendant knew or should have known that taking the Defendant's product Avandia caused unreasonable and life-threatening injuries, as alleged herein.

112. Defendant was grossly negligent in the warning about the design, testing, manufacture, marketing, labeling, sale, and/or distribution of the Defendant's product Avandia in that it:

a. Failed to provide adequate warnings with the Defendant's product Avandia regarding its possible risks and adverse effects as well as the comparative severity and duration of such adverse effects;

b. Failing to exercise due care in designing, developing and manufacturing the Defendant's product Avandia so as to avoid the aforementioned risks to individuals;

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

d. Was otherwise grossly negligent.

113. Although the Defendant knew, or recklessly disregarded, the fact that the Defendant's product Avandia caused potentially lethal side effects, the Defendant continued to market the product Avandia to consumers, including the Plaintiff, without disclosing these side effects.

114. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as the Plaintiff would suffer injury as a result of the Defendant's failure to exercise reasonable care as described above.

115. Defendant knew of, or recklessly disregarded the defective nature of the Defendant's product Avandia, as set forth herein, but continued to design, manufacture, market, and sell the Defendant's product Avandia so as to maximize sales and profits at the expense of the health and safety of the general public including the Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the Defendant's product Avandia.

116. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of the Defendant described herein, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, the Plaintiff suffered injury and harm as previously alleged herein, including ascertainable economic loss, including the purchase price of the Defendant's product Avandia, out-pocket costs of medical tests and treatment, medical care and/or services, and other costs incidental to the Plaintiff's ingestion of harmful and defective products.

117. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of the Defendant, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, the Plaintiff was required to obtain medical and/or hospital care, attention, and services.

118. Defendant's aforementioned conduct was committed with knowing, conscious, and/or deliberate disregard for the rights and safety of consumers such as the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter them from similar conduct in the future. Defendant continued to promote the efficacy and safety of the Defendant's product Avandia, while providing little or no warnings, and downplayed any risks, even after the Defendant knew of the risks and injuries associated with their use.

NINTH CLAIM FOR RELIEF
NEGLIGENT FAILURE TO WARN

119. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

120. Defendant owed Plaintiff a duty to warn of any dangerous defects or side effects; a duty to assure its product did not cause users unreasonable and dangerous risks, reactions, and side effects; and a duty to provide adequate post-market surveillance and warnings as it learned of Avandia's substantial dangers.

121. Defendant breached its duty of reasonable care to Plaintiff in that Defendant failed to:

a. Conduct sufficient testing which, if properly performed, would have shown that Avandia had serious side effects, including cardiothrombotic events, cardiac injury, and other serious side effects, and warn users of those risks; and/or

b. Include adequate warnings with the Avandia products that would alert users to the potential risks and serious side effects from the drugs; and/or

c. Warn Plaintiff that use of Avandia carried a risk of death or permanent disability from cardiothrombotic events, cardiac injuries and other serious side effects; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Avandia; and/or

e. Include other appropriate warnings

122. Defendant knew or should have known that Avandia was unreasonably dangerous and that it had serious side effects about which the general public would not be aware. Defendant nevertheless advertised, marketed and promoted its product knowing there were safer methods and products for Diabetes Mellitus Type II.

123. As a direct and proximate result of Defendant's negligence and breaches of its duty of reasonable care, Plaintiff was damaged.

124. Defendant's conduct was done with conscious disregard for the safety of users of Avandia, including Plaintiff.

WHEREFORE, The Plaintiff requests trial by jury and that the Court grant the following relief against the Defendant, GSK, on all counts of this Complaint, including:

(A) Money Damages representing fair, just and reasonable compensation for respective common law and statutory claims;

(B) Punitive and/or Treble Damages pursuant to state law;

(C) Disgorgement of profits and restitution of all costs;

(D) Attorneys' fees pursuant to state law;

(E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on the Plaintiff's behalf;

(F) Costs of suit; and

(G) Such other relief as is deemed just, equitable and appropriate.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial in this action.

Dated this 2nd day of May 2011.

Respectfully submitted,

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