

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

Jorge Montoya and Maria Ferrer, as the Personal
Representatives of the Estate of
Fabiola Montoya,

Plaintiffs,

DEMAND FOR JURY TRIAL

SMITHKLINE BEECHAM
CORPORATION, d/b/a GLAXOSMITHKLINE,
a Pennsylvania corporation; GLAXOSMITHKLINE, LLC,
Delaware Limited Liability Company,

Defendants.

COMPLAINT

Now come the Plaintiffs, Jorge Montoya and Maria Ferrer, as the Personal
Representatives of the Estate of Fabiola Montoya, and complaining against the defendant
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE ("GSK"), a
Pennsylvania Corporation; GLAXOSMITHKLINE, LLC, Delaware Limited Liability
Company, state:

JURISDICTION AND VENUE

1. Jurisdiction is based on diversity of citizenship under 28 U.S.C. § 1332. The matter in controversy exceeds the sum of seventy five thousand (\$75,000.00) dollars, exclusive of interest and costs.
2. This court has supplemental jurisdiction under 28 U.S.C. § 1367 with respect to claims that form part of the same case or controversy.
3. Venue is based on 28 U.S.C. § 1391(a)(2) because Defendant SmithKline.

Beecham Corporation d/b/a GlaxoSmithKline ("GSK") is a Pennsylvania corporation whose residency is in the Eastern District of Pennsylvania, but does regular business in the Southern District of Florida and a substantial part of the events or omissions on which the claims are based occurred in the Southern District of Florida.

PARTIES

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-3 above, and further alleges as follows:

4. At all times mentioned herein at the time of the Decedent's death, Luis Avelino Montoya was the dependant son of the decedent and both the decedent and Luis Avelino Montoya, were citizens of the State of Florida, Living in Miami-Dade County. Luis Avelino Montoya survives Fabiola Montoya. Plaintiffs, Jorge Montoya and Maria Ferrer are the Personal Representatives of the Estate of Fabiola Montoya and have been duly appointed as the personal representatives of the Estate of Fabiola Montoya.

5. Luis Avelino Montoya, was at all times mentioned herein, the minor or dependent child of Fabiola Montoya in accordance with Florida Statute §768.18(2) and citizens of the State of Florida and the aforementioned survived Fabiola Montoya in accordance with the Florida Wrongful Death Statute.

6. SmithKline Beecham Corporation d/b/a Glaxo SmithKline, a Pennsylvania corporation was, and still is, a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania.

7. At all times relevant, defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline was, and still is, a pharmaceutical company involved in researching,

manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public, including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets and sold said tablets in the State of Florida, including to the Plaintiff.

8. At all times relevant, defendant, GLAXOSMITHKLINE, LLC, Delaware Limited Liability Company was, and still is, a pharmaceutical company involved in researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of pharmaceuticals for distribution, sale, and use by the general public, including its antidiabetic agent rosiglitazone maleate under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets and sold said tablets in the State of Florida, including to the Plaintiff.

9. GLAXOSMITHKLINE, LLC, a Delaware Limited Liability Company authorized to do business in the State of Florida, was, and still is, a public limited company existing under and by virtue of the laws of the State of Delaware with its principal place of business in Philadelphia, Pennsylvania and sold said tablets in the State of Florida, including to the Plaintiff.

10. SmithKline Beecham Corporation d/b/a Glaxo SmithKline, a Pennsylvania corporation, GLAXOSMITHKLINE, LLC, a Delaware Limited Liability Company are hereinafter shall be collectively referred to as "GSK Defendants."

GENERAL ALLEGATIONS

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-10 above, and further alleges as follows:

11. Rosiglitazone maleate ("rosiglitazone") is researched, manufactured, sold, merchandised, advertised, promoted, labeled, analyzed, tested, distributed and marketed by the GSK Defendants under the trade names of Avandia Tablets, Avandamet Tablets, and Avandaryl Tablets (hereinafter collectively referred to as "Avandia"), and is a member of the class of drugs known as Thiazolidinediones ("TZDs"). Avandia was first approved for use in the United States by the Food and Drug Administration ("FDA") in 1999 for the use in treatment of type 2 diabetes mellitus, also known as non-insulin-dependent diabetes mellitus.

12. Most people with diabetes have risk factors such as high blood pressure and cholesterol that provide a pre-existing susceptibility for heart disease and stroke. More than 65 percent of deaths in patients with diabetes are from cardiovascular causes. The effect of any antidiabetic therapy is particularly important because the reason for antidiabetic therapy is to reduce the complications of diabetes, the most serious of which is heart disease.

13. During the past decade, drugs have been introduced for the treatment of type 2 diabetes that, used in monotherapy or in combination therapy, are supposed to better control the disease in patients and reduce health complications associated with diabetes, such as heart attacks, strokes, and other cardiovascular complications.

14. Before and on or about the time when Avandia was prescribed and used by Fabiola Montoya, the GSK Defendants knew, or should have known, that Avandia was associated with a significant increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

15. The risk of heart failure, also referred to as congestive heart failure, in patients taking Avandia led to labeling revisions as marketing experience and the results of further clinical trials were reviewed by the Food and Drug Administration.

16. On August 14, 2007, the warnings, precautions, and contraindications sections of the Avandia label were changed again regarding the potential increased risk of heart failure, and the following new black box warning was added to the label:

WARNING: CONGESTIVE HEART FAILURE

Thiazolidinediones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.

AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS.)

17. On November 19, 2007, the warnings, precautions, and indications sections of the Avandia label were changed again regarding the potential increased risk of myocardial ischemia, and the following language was added to the black box warning:

WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA

A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

18. Before the label changes on August 14, 2007 and November 19, 2007, Fabiola Montoya ingested Avandia and or Avandamet in or near Miami-Dade County, Florida.

19. As a direct, proximate, and legal cause of ingesting Avandia, Fabiola Montoya began having problems breathing in or about October-November 2007 and suffered from myocardial ischemia, heart attack and lethal cardiac arrhythmia including a myocardial ischemic event that resulted in hospitalization and death on or about December 26, 2010.

20. Before and at or about the time of Mrs. Montoya's ingestion of Avandia, the GSK Defendants had the knowledge, the means, and the duty to provide the medical community and the consuming public with more accurate descriptive information and more adequate warnings regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke, through all means necessary, including, but not limited to, labeling, continuing education, symposia, posters, sales calls to doctors, advertisements, and promotional materials.

21. At all times relevant, the GSK Defendants failed and refused to warn prescribing medical providers, and the consuming public, of the risks associated with Avandia that were known, or should have been known, as alleged herein.

22. At all times relevant, the GSK Defendants engaged in extensive mass media direct-to-consumer promotion, education, and advertising of Avandia for the purpose of increasing sales and stimulating consumer requests for Avandia prescriptions, independent of the advice of medical professionals.

23. At all times relevant, defendants, and each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee,

permissive user, successor in interest, or joint venturer of each other, and were acting within the time, purpose, or scope of such agency or employment or permission; and all acts or omissions alleged herein of each such defendant were authorized, adopted, approved, or ratified by each of the other defendants.

COUNT I
(Negligence)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-23 above, and further alleges as follows:

24. At all times relevant, the GSK Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Avandia for distribution, sale, and use by the general public, to ensure that Avandia's use did not result in avoidable injuries.

25. Plaintiffs' injuries as described herein were caused by the negligence and misrepresentations of the GSK Defendants through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing Avandia;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

(c) Negligently and carelessly failing to adequately warn the medical community and the general public, including Mrs. Montoya and his treating and prescribing medical provider(s), of the dangers of using Avandia;

(d) Negligently and carelessly describing and promoting Avandia as safe and effective;

(e) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;

(f) Negligently and carelessly over-promoting and promoting Avandia in a zealous and unreasonable way, without regard to its potential dangers;

26. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

27. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;

- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT II
(Negligent Pharmaco-Vigilance)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-23 above, and further alleges as follows:

28. The GSK Defendants have an ongoing duty of pharmaco-vigilance. This duty requires, among other things, the GSK Defendants to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Avandia.

29. The GSK Defendants continually receive reports from clinical trials, physicians, patients, and regulatory authorities of adverse events that occur in patients taking Avandia. Furthermore, the GSK Defendants continue to conduct clinical trials for its drugs after their drug is approved for use.

30. The GSK Defendants had the means and the resources to perform its pharmaco-vigilance duties for the entire time Avandia has been on the market in the United States.

31. The GSK Defendants have a duty to monitor epidemiological and pharmaco-vigilance data regarding their drugs and promptly report to the FDA, medical professionals, and the public, any safety concerns that arise through epidemiologic study or data.

32. The GSK Defendants breached this duty with respect to Fabiola Montoya, her treating and prescribing medical providers, and plaintiffs. The GSK Defendants learned, or should have learned, through various sources, including but not limited to, clinical trials and other adverse event reports, that there was a substantial risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke associated with the use of Avandia and

failed to inform doctors, regulatory agencies, and ordinary consumers, including Fabiola Montoya of this risk.

33. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

34. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT III

(Strict Liability—Failure to Warn)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-23 above, and further alleges as follows:

35. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

36. The GSK Defendants' extensive direct-to-consumer promotion and advertising of Avandia created the duty to warn ordinary consumers, including Fabiola Montoya, of the risks associated with Avandia alleged herein, in addition to the duty the GSK Defendants owed to medical professionals.

37. At all times relevant, ordinary consumers and prescribing medical providers would not have recognized the potential increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke associated with ingestion of Avandia in the absence of adequate warnings thereof by the GSK Defendants.

38. At all times relevant, the GSK Defendants failed to adequately warn ordinary consumers and medical providers, including Fabiola Montoya and his treating and prescribing medical providers, of the potential increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke associated with ingestion of Avandia.

39. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

40. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;

- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT IV
(Breach of Express Warranty)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-28 above, and further alleges as follows:

41. The GSK Defendants' extensive direct-to-consumer advertising of Avandia created the duty to notify ordinary consumers, including Fabiola Montoya, that Avandia was not as represented, in addition to the duty the GSK Defendants owed medical professionals.

42. At all times relevant, the GSK Defendants, by directly and indirectly advertising, marketing, and promoting Avandia for the treatment of type 2 diabetes and by placing this drug in the stream of commerce knowing that Avandia would be prescribed to patients with type 2 diabetes in reliance upon the representations of the GSK Defendants, expressly warranted to all foreseeable users of the drug, including Mrs. Montoya, that Avandia was safe and effective for the treatment of patients with type 2 diabetes without a significantly increased risk of heart failure, myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke and without a significantly increased risk of heart failure.

43. Mrs. Montoya and her treating and prescribing medical providers reasonably relied upon the aforesaid express warranties by the GSK Defendants.

44. The GSK Defendants breached the aforesaid express warranties because Avandia was not safe for the treatment of patients with type 2 diabetes.

45. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

46. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT V

(Breach of Implied Warranty)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-23 above, and further alleges as follows:

47. The GSK Defendants' extensive direct-to-consumer advertising of Avandia created the duty to notify ordinary consumers, including Fabiola Montoya, that Avandia was not safe and effective for the purposes for which it had been placed in the stream of commerce, in addition to the duty the GSK Defendants owed medical professionals.

48. The GSK Defendants impliedly warranted to all foreseeable users, including Mrs. Montoya her his prescribing medical provider(s), that Avandia was safe and effective for the purposes for which it had been placed in the stream of commerce by the GSK Defendants, and that Avandia was reasonably safe, proper, merchantable and fit for the intended purpose.

49. Mrs. Montoya and her prescribing medical providers reasonably relied upon the aforesaid implied warranties by the GSK Defendants.

50. The GSK Defendants breached the aforesaid implied warranties in that Avandia was not safe for the treatment of patients with type 2 diabetes, among other things.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT VI
(Fraud)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-23 above, and further alleges as follows:

51. In deciding whether to prescribe a drug, prescribing medical providers engage in a risk/benefit assessment in determining which drug to prescribe. Prescribing medical providers, such as Mrs. Montoya's prescribing medical provider(s), relied, and continue to rely, on the information received about Avandia from various sources, such as journal articles, journal advertisements, company literature, the Physicians' Desk Reference, labels, package inserts, and discussions with the GSK Defendants' sales people. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, prescribing medical providers, such as Mrs. Montoya's prescribing medical provider(s), cannot accurately assess the crucial risk/benefit balance for the patient or exercise proper professional judgment that is independent. Consequently, the prescribing medical provider, including Mrs. Montoya's treating and prescribing medical provider(s), could not, and cannot, act in accordance with the professional and fiduciary obligations owed to the patient, nor can patients, such as Fabiola Montoya, give informed consent to the treatment.

52. In caring for themselves, and as part of diabetes management, type 2 diabetes patients had, and have, the option to refrain from using certain prescription drugs or to request alternative treatments in order to minimize health risks. In deciding whether to refrain from using Avandia, or to request alternatives, ordinary consumers relied, and continue to rely, on information received about Avandia from various sources, such as direct-to-consumer and other advertisements, company literature, and package inserts. Such information must be accurate and provide an unbiased picture

of a drug's safety and efficacy in treating a condition. If the information is false or misleading, ordinary consumers, such as Mrs. Montoya, could not, and cannot, accurately assess their options to refrain from using Avandia or to request alternatives.

53. Concealing adverse information and providing inaccurate or biased information that is material to a decision misleads the prescribing medical providers and misleads the patient, as was the case with Mrs. Montoya and her treating and prescribing medical provider(s). This misleading information, along with omissions of material facts related to Avandia's safety, cause health care providers, ordinary consumers, and the general public to be misled about Avandia's risks and benefits and deprive prescribing medical providers from making a proper risk/benefit assessment as to the use of Avandia and deprive ordinary consumers from properly weighing their options.

54. The GSK Defendants' advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that Avandia was safe for human use; had no unacceptable side effects; had fewer side effects than other antidiabetic agents; and would not interfere with daily life.

55. The GSK Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of Avandia. The GSK Defendants, through promotional literature, deceived potential users and prescribers of said drug by relying on only allegedly positive information, including testimonials from allegedly satisfied users and celebrity spokespersons, and manipulating statistics to suggest widespread acceptability, while concealing, misstating and downplaying the known adverse and serious health effects. The GSK Defendants falsely and deceptively kept relevant information from potential Avandia users and minimized prescriber concerns regarding the safety and efficacy of Avandia and over-promoted the drug.

56. In particular, the GSK Defendant engaged in the following actions, although not limited to the following actions, that constitute false and deceptive misrepresentations or omissions regarding Avandia:

(a) The GSK Defendants marketed and continue to market Avandia to ordinary consumers and medical professionals as a safer and more effective antidiabetic agent than other antidiabetic agents on the market;

(b) The GSK Defendants attempted to silence Dr. John B. Buse, a diabetes expert and head of endocrinology at the University of North Carolina, Chapel Hill, by threatening him with a \$4 million lawsuit and by characterizing him as a liar after he raised concerns about Avandia and heart problems in 1999;

(c) The GSK Defendants failed to warn consumers and the medical community about the increased risk of heart problems associated with Avandia, and continue to do so, despite having knowledge of these health risks;

(d) The GSK Defendants promoted Avandia in violation of the Federal Food, Drug, and Cosmetic Act, which was the subject of a July 17, 2001, FDA Warning Letter;

(e) The GSK Defendants' sales representatives engaged in false or misleading promotional activities with respect to the risk information in Avandia's label;

57. When said representations and/or omissions were made by the GSK Defendants, it knew those representations and/or omissions to be false or misleading, or willfully, wantonly, recklessly, and consciously disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by the GSK Defendants with the intent of defrauding and deceiving the public in general and the medical community and with the intent of inducing the public

to request and ingest Avandia and the medical community to recommend, prescribe, and dispense Avandia.

58. The aforementioned misrepresentations by the GSK Defendants were reasonably relied upon by Mrs. Montoya and his prescribing medical provider(s) to their detriment.

59. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

60. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT VII
(Loss of Consortium)

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-60 above and paragraphs 63 through 78, and further alleges as follows:

61. Plaintiff Luis Avelino Montoya and Fabiola Montoya, were at all times mentioned herein, were mother and dependant son and lived together as a family.

62. As a direct and proximate cause of the injuries to Fabiola Montoya and subsequently her death, Luis Avelino Montoya has been deprived and will continue to be deprived of the consortium, services, society, comfort, companionship of his mother.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against defendants as follows:

- a. For general damages according to proof;
- b. For special damages according to proof;
- c. For punitive and exemplary damages according to proof;
- d. For pre-judgment and post-judgment interest as allowed by law;
- e. For costs of suit incurred herein;
- f. Funeral expenses; and
- g. For such other and further relief as this court may deem just and proper.

COUNT VIII
Wrongful Death-Estate Claim

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-28 above, and further alleges as follows:

63. This is an action for Wrongful Death Action pursuant to Florida Wrongful Death Act, Sections 768.16-768.26 of the Florida Statutes.

64. At all times relevant, the GSK Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing,

testing, distributing and marketing of Avandia for distribution, sale, and use by the general public, to ensure that Avandia's use did not result in avoidable injuries.

65. Plaintiffs' injuries as described herein were caused by the negligence and misrepresentations of the GSK Defendants through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing Avandia;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

(c) Negligently and carelessly failing to adequately warn the medical community and the general public, including Mrs. Montoya and his treating and prescribing medical provider(s), of the dangers of using Avandia;

(d) Negligently and carelessly describing and promoting Avandia as safe and effective;

(e) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;

(f) Negligently and carelessly over-promoting and promoting Avandia in a zealous and unreasonable way, without regard to its potential dangers;

66. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

67. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

68. As a direct and proximate result of the GSK Defendants', negligence, the ESTATE of Fabiola Montoya, has sustained economic damages in the form of funeral expenses and a loss of net accumulations to the Estate.

69. At all times material hereto, the acts or omissions of the GSK Defendants, were done with the knowledge of substantial likelihood of death or serious bodily injury to the Decedent, Fabiola Montoya , and constitute gross negligence.

WHEREFORE, Jorge Montoya, Luis Avelino Montoya and Maria Ferrer as the personal representative of THE ESTATE OF Fabiola Montoya, demands entry of judgment against the GSK Defendants for compensatory damages, taxable costs as the prevailing party, trial by jury on all issues so triable as a matter of right, and further relief that is deemed to be just and proper by this Court under all of the prevailing facts and circumstances of the case, including, but not limited punitive damages upon a proffer of appropriate conduct on the part of the GSK Defendants.

COUNT IX
Survivor Action, Luis Avelino Montoya

Plaintiffs, readopt and reaver all the allegations contained in Paragraphs 1-28 above, and further alleges as follows:

70. This is an action for Wrongful Death Action pursuant to Florida Wrongful Death Act, Sections 768.16-768.26 of the Florida Statutes.

71. At all times relevant, the GSK Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Avandia for distribution, sale, and use by the general public, to ensure that Avandia's use did not result in avoidable injuries.

72. Plaintiffs' injuries as described herein were caused by the negligence and misrepresentations of the GSK Defendants through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing Avandia;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Avandia and heart failure, and the association between Avandia and myocardial ischemia and ischemic events such as cardiovascular mortality, myocardial infarction, and stroke.

(c) Negligently and carelessly failing to adequately warn the medical community and the general public, including Mrs. Montoya and his treating and prescribing medical provider(s), of the dangers of using Avandia;

(d) Negligently and carelessly describing and promoting Avandia as safe and effective;

(e) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;

(f) Negligently and carelessly over-promoting and promoting Avandia in a zealous and unreasonable way, without regard to its potential dangers;

73. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya suffered injury to her health, strength, and activity and severe and lasting physical and

mental pain and suffering, and eventually death, all to her general damages in an amount in excess of the minimum jurisdictional amount of this court.

74. As a direct and proximate cause of the conduct, acts, and omissions of the GSK Defendants, Mrs. Montoya incurred, hospital, medical, and related expenses, funeral expenses, the reasonable and total value of which to be proven at the time of trial.

75. As a direct and proximate result of the GSK Defendants', negligence, the ESTATE of Fabiola Montoya, has sustained economic damages in the form of funeral expenses and a loss of net accumulations to the Estate.

76. At all times material hereto, the acts or omissions of the GSK Defendants, were done with the knowledge of substantial likelihood of death or serious bodily injury to the Decedent, Fabiola Montoya , and constitute gross negligence.

77. As a direct and proximate result of the GSK Defendants', negligence, breach of warranty, failure to warn, fraud, negligent pharmaco vigilance, the Plaintiff, Luis Avelino Montoya , as survivor of his mother, the Decedent, Fabiola Montoya, has sustained mental pain and suffering from the death of his, mother, under the horrifying circumstances of her death, and a future loss of support and services, and such losses will continue in the future.

78. At all times material hereto, the acts or omissions of the GSK Defendants, were done with the knowledge of substantial likelihood of death or serious bodily injury to the Decedent, Fabiola Montoya, and constitute gross negligence.

WHEREFORE, Jorge Montoya and Maria Ferrer as Personal Representatives of the Estate of Fabiola Montoya, demands entry of judgment against the GSK Defendants for compensatory damages, taxable costs as the prevailing party, trial by jury on all issues so triable as a matter of right,

and further relief that is deemed to be just and proper by this Court under all of the prevailing facts and circumstances of the case, including, but not limited punitive damages upon a proffer of appropriate conduct on the part of the GSK Defendants.

79. The Plaintiff demands a trial by jury on all claims triable by jury.

Dated: May 19, 2011

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