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FILED
SUPERIOR COURT OF CALIFORNIA
COUNTY OF ORANGE
CENTRAL JUSTICE CENTER

MAY 15 2009

ADAM CARLSON, Clerk of the Court

BY M. WILSON, DEPUTY

8 **IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA**
9 **IN AND FOR THE COUNTY OF ORANGE**

30-2009

11 JUNE GABRIELLI, a single woman;)
12 MARYANN SANCHEZ, individually and)
13 as Wife and Next of Kin to YSIDRO)
14 SANCHEZ;)
15 JAN MICHELLE SPEARS, individually)
16 and as Child and Next of Kin to)
17 JEANNETTE STALLINGS, deceased;)
18 ELSIE WESTON, individually and as)
19 Wife and Next of Kin to MARVIN WESTON,)
20 deceased; JANET ATKINS, individually and)
21 as Sister and next of Kin to CARTHOS)
22 SPEEDY, deceased; KATHLEEN JOHNSTON,)
23 Individually and as Wife and Next of Kin)
24 to EARL JOHNSTON, deceased;)
25 CORINE WESTMORELAND, individually and)
26 as Wife and Next of Kin to HORACE)
27 WESTMORELAND, deceased;)
28 NEAL MARTIN, individually and as)
Next of Kin to DENALTA MARTIN,)
deceased; WESLEY WALTON and)
KIMBERLY WALTON, husband and wife;)
MONA SPAETH, a single woman;)
CAROL WALLACE, a single woman;)
JOHN WHIPPLE and LINDA S. WILLIAMS,)
husband and wife; DEBORAH WARNER,)
a single woman; ELKE WHORTON, a single)
woman; NATHANIEL WILLIAMS, a single)
man; ROBERT R. WITT, a single man;)
JUANITA ROSS, a single woman;)
ANNA LEE JOHNSON, a single woman;)

CASE NO. _____ 00123217

**COMPLAINT FOR DAMAGES
AND DEMAND FOR JURY TRIAL**

[PRODUCTS LIABILITY]

- 1. Strict Liability – Failure to Warn
- 2. Negligence
- 3. Breach of Implied Warranty
- 4. Breach of Express Warranty
- 5. Fraud
- 6. Fraud By Concealment
- 7. Negligent Misrepresentation
- 8. Loss of Consortium
- 9. Wrongful Death

1 JOYCE HARDIN, a single woman;)
LEO PRATT, a single man; LINDY TUBBS,)
2 a single woman; PAULETTE MITTLEIDER,)
a single woman; RICHARD A BRUNS,)
3 a single man; RONALD WILFONG,)
a single man; IRVIN FRIEDMAN, a single)
4 man; GILES KELLY, a single man;)
LINDA BALDWIN and RONALD BALDWIN,)
5 wife and husband; GLORIA BATES, a)
6 single woman; ROBERT BRIGHT and)
7 MARY BRIGHT, husband and wife;)
STEVEN CANADAY, a single man;)
8 ETHEL CRADDOCK, a single woman;)
VIVIAN CROCKER, a single woman;)
9 JUDY ERVIN, a single woman;)
JOHN FARNARIO and ANNE FARNARIO,)
10 husband and wife; OLGA GONZALES, a)
single woman; RAY GRIFFIN and PAULINE)
11 GRIFFIN, husband and wife; WILLIE LEE)
12 GEORGE, JR., a single man; JOY KOCIC,)
a single woman; FREDRICK LIBERMAN and)
13 SANDRA LIBERMAN, husband and wife;)
MELVIN LONG, a single man; KATHRYN)
14 MARTIN and HENRY MARTIN, wife and)
husband; GERALD MOE and DEBRA MOE,)
15 husband and wife; WANDA PAULEY and)
16 RAY PAULEY, wife and husband; MYRTA)
ROMANOS and FELIPE ROMANOS, wife)
17 and husband; CURTIS RAY, a single man;)
18 IDA WEST, a single woman; MILDRED)
CRAIGHEAD and JAMES CRAIGHEAD,)
19 wife and husband,)

20 Plaintiffs,)

21 vs.)

22 SMITHKLINE BEECHAM CORPORATION,)
23 a Pennsylvania corporation d/b/a)
GLAXOSMITHKLINE; MCKESSON)
24 CORPORATION, a Delaware corporation;)
25 DOES ONE through FIFTEEN, inclusive,)

26 Defendants.)

1 For their Complaint against the Defendants for injuries and other damages caused by
2 ingestion of the prescription medication AVANDIA® (rosiglitazone maleate), alone, or
3 compounded as AVANDAMET® (rosiglitazone maleate and metformin hydrochloride) and/or
4 AVANDARYL® (rosiglitazone maleate and glimepiride) (these medications are hereinafter
5 singularly or collectively referred to as "Avandia"), Plaintiffs allege:

6 **DEMAND FOR JURY TRIAL**

7 1. Plaintiffs demand a trial by jury on all issues so triable.

8 **PARTIES**

9 2. Plaintiff JUNE GABRIELLI, a single woman, is and was at all times alleged herein a
10 citizen and resident in the City of Rancho Santa Margarita, County of Orange, State of
11 California, and brings this action individually.

12 3. Plaintiff JUNE GABRIELLI ingested Defendant's Avandia and as a result suffered severe
13 injuries and other damages.

14 4. Plaintiff MARYANN SANCHEZ, individually and as Wife and Next of Kin to YSIDRO
15 SANCHEZ, deceased, is and was at all times alleged herein a citizen and resident of the State
16 of California, and brings this action individually and as Wife and Next of Kin to YSIDRO
17 SANCHEZ, deceased.

18 5. Plaintiff MARYANN SANCHEZ's decedent, YSIDRO SANCHEZ was at all times alleged
19 herein a citizen and resident of the State of California.

20 6. Plaintiff MARYANN SANCHEZ's decedent, YSIDRO SANCHEZ, ingested Defendant's
21 Avandia and as a result suffered severe injuries resulting in his death.

22 7. Plaintiff JAN MICHELLE SPEARS, as Child and Next of Kin to JEANNETTE
23 STALLINGS, deceased, is and was at all times alleged herein a citizen and resident of the
24 State of Kentucky, and brings this action individually and as Child and Next of Kin to
25 JEANNETTE STALLINGS, deceased.

26 8. Plaintiff JAN MICHELLE SPEARS's decedent, JEANNETTE STALLINGS was at all
27 times alleged herein a citizen and resident of the State of Kentucky.

1 9. Plaintiff JAN MICHELLE SPEARS' decedent, JEANNETTE STALLINGS, ingested
2 Defendant's Avandia and as a result suffered severe injuries resulting in her death.

3 10. Plaintiff ELSIE WESTON, individually and as Wife and Next of Kin to MARVIN
4 WESTON, deceased, is and was at all times alleged herein a citizen and resident of the State
5 of Oklahoma, and brings this action individually and as Next of Kin to MARVIN WESTON,
6 deceased.

7 11. Plaintiff ELSIE WESTON's decedent, MARVIN WESTON was at all times alleged herein
8 a citizen and resident of the State of Oklahoma.

9 12. Plaintiff ELSIE WESTON's decedent, MARVIN WESTON, ingested Defendant's Avandia
10 and as a result suffered severe injuries resulting in his death.

11 13. Plaintiff JANET ATKINS, individually and as Sister and Next of Kin to CARTHOLOS
12 SPEEDY, deceased, is and was at all times alleged herein a citizen and resident of the State of
13 Indiana and brings this action individually and as Next of Kin to CARTHOLOS SPEEDY,
14 deceased.

15 14. Plaintiff JANET ATKINS' decedent, CARTHOLOS SPEEDY, deceased, is and was at all
16 times alleged herein a citizen and resident of the State of Indiana.

17 15. Plaintiff JANET ATKINS' decedent, CARTHOLOS SPEEDY, ingested Defendant's
18 Avandia and as a result suffered severe injuries resulting in his death.

19 16. Plaintiff KATHLEEN JOHNSTON, individually and as Wife and Next of Kin to EARL
20 JOHNSTON, deceased, is and was at all times alleged herein a citizen and resident of the
21 State of Arizona, and brings this action individually and as Next of Kin to EARL JOHNSTON,
22 deceased.

23 17. Plaintiff KATHLEEN JOHNSTON's decedent, EARL JOHNSTON, is and was at all times
24 alleged herein a citizen and resident of the State of Arizona.

25 18. Plaintiff KATHLEEN JOHNSTON's decedent, EARL JOHNSTON, ingested Defendant's
26 Avandia and as a result suffered severe injuries resulting in his death.

27 19. Plaintiff CORINE WESTMORELAND, individually and as Wife and Next of Kin to
28 HORACE WESTMORELAND, deceased, is and was at all times alleged herein a citizen and

1 resident of the State of Georgia, and brings this action individually and as Next of Kin to
2 HORACE WESTMORELAND, deceased.

3 20. Plaintiff CORINE WESTMORELAND's decedent, HORACE WESTMORELAND, is and
4 was at all times alleged herein a citizen and resident of the State of Georgia.

5 21. Plaintiff CORINE WESTMORELAND's decedent, HORACE WESTMORELAND,
6 ingested Defendant's Avandia and as a result suffered severe injuries resulting in his death.

7 22. Plaintiff NEAL MARTIN, individually and as Next of Kin to DENALTA MARTIN,
8 deceased, is and was at all times alleged herein a citizen and resident of the State of
9 Oklahoma, and brings this action individually and as Next of Kin to DENALTA MARTIN,
10 deceased.

11 23. Plaintiff NEAL MARTIN's decedent, DENALTA MARTIN, is and was at all times alleged
12 herein a citizen and resident of the State of Oklahoma.

13 24. Plaintiff NEAL MARTIN's decedent, DENALTA MARTIN ingested Defendant's Avandia
14 and as a result suffered severe injuries resulting in her death.

15 25. Plaintiffs WESLEY WALTON and KIMBERLY WALTON, husband and wife, are and
16 were at all times alleged herein citizens and residents of the State of Oklahoma, and bring this
17 action in their individual capacities.

18 26. Plaintiff WESLEY WALTON ingested Defendant's Avandia and as a result suffered
19 severe injuries and other damages.

20 27. Plaintiff MONA SPAETH, a single woman, is and was at all times alleged herein a citizen
21 and resident of the State of Oklahoma, and brings this action individually.

22 28. Plaintiff MONA SPAETH ingested Defendant's Avandia and as a result suffered severe
23 injuries and other damages.

24 29. Plaintiff CAROL WALLACE, a single woman, is and was at all times alleged herein a
25 citizen and resident of the State of Montana, and brings this action individually.

26 30. Plaintiff CAROL WALLACE ingested Defendant's Avandia and as a result suffered
27 severe injuries and other damages.

1 31. Plaintiffs JOHN WHIPPLE and LINDA S. WILLIAMS, husband and wife, are and were at
2 all times alleged herein citizens and residents of the State of Oklahoma, and bring this action in
3 their individual capacities.

4 32. Plaintiff JOHN WHIPPLE ingested Defendant's Avandia and as a result suffered severe
5 injuries and other damages.

6 33. Plaintiff DEBORAH WARNER, a single woman, is and was at all times alleged herein a
7 citizen and resident of the State of Ohio, and brings this action individually.

8 34. Plaintiff DEBORAH WARNER ingested Defendant's Avandia and as a result suffered
9 severe injuries and other damages.

10 35. Plaintiff ELKE WHORTON, a single woman, is and was at all times alleged herein a
11 citizen and resident of the State of Oklahoma, and brings this action individually.

12 36. Plaintiff ELKE WHORTON ingested Defendant's Avandia and as a result suffered severe
13 injuries and other damages.

14 37. Plaintiff NATHANIEL WILLIAMS, a single man, is and was at all times alleged herein a
15 citizen and resident of the State of Florida, and brings this action individually.

16 38. Plaintiff NATHANIEL WILLIAMS ingested Defendant's Avandia and as a result suffered
17 severe injuries and other damages.

18 39. Plaintiff ROBERT R. WITT, a single man, is and was at all times alleged herein a citizen
19 and resident of the State of Kentucky, and brings this action individually.

20 40. Plaintiff ROBERT R. WITT ingested Defendant's Avandia and as a result suffered severe
21 injuries and other damages.

22 41. Plaintiff JUANITA ROSS, a single woman, is and was at all times alleged herein a
23 citizen and resident of the State of Oklahoma, and brings this action individually.

24 42. Plaintiff JUANITA ROSS ingested Defendant's Avandia and as a result suffered severe
25 injuries and other damages.

26 43. Plaintiff ANNA LEE JOHNSON, a single woman, is and was at all times alleged herein a
27 citizen and resident of the State of Florida, and brings this action individually.

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1 44. Plaintiff ANNA LEE JOHNSON ingested Defendant's Avandia and as a result suffered
2 severe injuries and other damages.

3 45. Plaintiff JOYCE HARDIN, a single woman, is and was at all times alleged herein a citizen
4 and resident of the State of Oklahoma, and brings this action individually.

5 46. Plaintiff JOYCE HARDIN ingested Defendant's Avandia and as a result suffered severe
6 injuries and other damages.

7 47. Plaintiff LEO PRATT, a single man, is and was at all times alleged herein a citizen and
8 resident of the State of Oklahoma, and brings this action individually.

9 48. Plaintiff LEO PRATT ingested Defendant's Avandia and as a result suffered severe
10 injuries and other damages.

11 49. Plaintiff LINDY TUBBS, a single woman, is and was at all times alleged herein a citizen
12 and resident of the State of Oklahoma, and brings this action individually.

13 50. Plaintiff LINDY TUBBS ingested Defendant's Avandia and as a result suffered severe
14 injuries and other damages.

15 51. Plaintiff PAULETTE MITTLEIDER, a single woman, is and was at all times alleged herein
16 a citizen and resident of the State of North Dakota, and brings this action individually.

17 52. Plaintiff PAULETTE MITTLEIDER ingested Defendant's Avandia and as a result suffered
18 severe injuries and other damages.

19 53. Plaintiff RICHARD A. BRUNS, a single man, is and was at all times alleged herein a
20 citizen and resident of the State of Oklahoma, and brings this action individually.

21 54. Plaintiff RICHARD A. BRUNS ingested Defendant's Avandia and as a result suffered
22 severe injuries and other damages.

23 55. Plaintiff RONALD WILFONG, a single man, is and was at all times alleged herein a
24 citizen and resident of the State of Oklahoma, and brings this action individually.

25 56. Plaintiff RONALD WILFONG ingested Defendant's Avandia and as a result suffered
26 severe injuries and other damages.

27 57. Plaintiff IRVIN FRIEDMAN, a single man, is and was at all times alleged herein a citizen
28 and resident of Maryland, and brings this action individually.

1 58. Plaintiff IRVIN FRIEDMAN ingested Defendant's Avandia and as a result suffered severe
2 injuries and other damages.

3 59. Plaintiff GILES KELLY, a single man, is and was at all times alleged herein a citizen and
4 resident of the State of North Carolina, and brings this action individually.

5 60. Plaintiff GILES KELLY ingested Defendant's Avandia and as a result suffered severe
6 injuries and other damages.

7 61. Plaintiffs LINDA BALDWIN and RONALD BALDWIN, wife and husband, are and were at
8 all times alleged herein citizens and residents of the State of Massachusetts, and bring this
9 action in their individual capacities.

10 62. Plaintiff LINDA BALDWIN ingested Defendant's Avandia and as a result suffered severe
11 injuries and other damages.

12 63. Plaintiff GLORIA BATES, a single woman, is and was at all times alleged herein a citizen
13 and resident of the State of Georgia and brings this action individually.

14 64. Plaintiff GLORIA BATES ingested Defendant's Avandia and as a result suffered severe
15 injuries and other damages.

16 65. Plaintiffs ROBERT BRIGHT and MARY BRIGHT, husband and wife, are and were at all
17 times alleged herein citizens and residents of the State of West Virginia, and bring this action in
18 their individual capacities.

19 66. Plaintiff ROBERT BRIGHT ingested Defendant's Avandia and as a result suffered severe
20 injuries and other damages.

21 67. Plaintiff STEVEN CANADAY, a single man, is and was at all times alleged herein a
22 citizen and resident of the State of West Virginia, and brings this action individually.

23 68. Plaintiff STEVEN CANADAY ingested Defendant's Avandia and as a result suffered
24 severe injuries and other damages.

25 69. Plaintiff ETHEL CRADDOCK, a single woman, is and was at all times alleged herein a
26 citizen and resident of the State of Texas, and brings this action individually.

27 70. Plaintiff ETHEL CRADDOCK ingested Defendant's Avandia and as a result suffered
28 severe injuries and other damages.

1 71. Plaintiff VIVIAN CROCKER, a single woman, is and was at all times alleged herein a
2 citizen and resident of the State of Virginia, and brings this action individually.

3 72. Plaintiff VIVIAN CROCKER ingested Defendant's Avandia and as a result suffered
4 severe injuries and other damages.

5 73. Plaintiff JUDY ERVIN, a single woman, is and was at all times alleged herein a citizen
6 and resident of the State of South Carolina, and brings this action individually.

7 74. Plaintiff JUDY ERVIN ingested Defendant's Avandia and as a result suffered severe
8 injuries and other damages.

9 75. Plaintiffs JOHN FARNARIO and ANNE FARNARIO, husband and wife, are and were at
10 all times alleged herein citizens and residents of the State of Ohio, and bring this action in their
11 individual capacities.

12 76. Plaintiff JOHN FARNARIO ingested Defendant's Avandia and as a result suffered severe
13 injuries and other damages.

14 77. Plaintiff OLGA GONZALES, a single woman, is and was at all times alleged herein a
15 citizen and resident of the State of Oklahoma, and brings this action individually.

16 78. Plaintiff OLGA GONZALES ingested Defendant's Avandia and as a result suffered
17 severe injuries and other damages.

18 79. Plaintiffs RAY GRIFFIN and PAULINE GRIFFIN, husband and wife, are and were at all
19 times alleged herein citizens and residents of the State of Michigan, and bring this action in
20 their individual capacities.

21 80. Plaintiff RAY GRIFFIN ingested Defendant's Avandia and as a result suffered severe
22 injuries and other damages.

23 81. Plaintiff WILLIE LEE GEORGE, JR., a single man, is and was at all times alleged herein
24 a citizen and resident of the State of Illinois and brings this action individually.

25 82. Plaintiff WILLIE LEE GEORGE, JR. ingested Defendant's Avandia and as a result
26 suffered severe injuries and other damages.

27 83. Plaintiff JOY KOCIC, a single woman, is and was at all times alleged herein a citizen and
28 resident of the State of Florida, and brings this action individually.

1 84. Plaintiff JOY KOCIC ingested Defendant's Avandia and as a result suffered severe
2 injuries and other damages.

3 85. Plaintiffs FREDRICK LIBERMAN and SANDRA LIBERMAN, husband and wife, are and
4 were at all times alleged herein citizens and residents of the State of New Jersey, and bring this
5 action in their individual capacities.

6 86. Plaintiff FREDRICK LIBERMAN ingested Defendant's Avandia and as a result suffered
7 severe injuries and other damages.

8 87. Plaintiff MELVIN LONG, a single man, is and was at all times alleged herein a citizen
9 and resident of the State of Utah, and brings this action individually.

10 88. Plaintiff MELVIN LONG ingested Defendant's Avandia and as a result suffered severe
11 injuries and other damages.

12 89. Plaintiffs KATHRYN MARTIN and HENRY MARTIN, husband and wife, are and were at
13 all times alleged herein citizens and residents of the State of Florida, and bring this action in
14 their individual capacities.

15 90. Plaintiff KATHRYN MARTIN ingested Defendant's Avandia and as a result suffered
16 severe injuries and other damages.

17 91. Plaintiffs GERALD MOE and DEBRA MOE, husband and wife, are and were at all times
18 alleged herein citizens and residents of the State of Minnesota, and bring this action in their
19 individual capacities.

20 92. Plaintiff GERALD MOE ingested Defendant's Avandia and as a result suffered severe
21 injuries and other damages.

22 93. Plaintiffs WANDA PAULEY and RAY PAULEY, wife and husband, are and were at all
23 times alleged herein citizens and residents of the State of West Virginia and bring this action in
24 their individual capacities.

25 94. Plaintiff WANDA PAULEY ingested Defendant's Avandia and as a result suffered severe
26 injuries and other damages.

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1 95. Plaintiffs MYRTA ROMANOS and FELIPE ROMANOS, wife and husband, are and were
2 at all times alleged herein citizens and residents of the State of Texas, and bring this action in
3 their individual capacities.

4 96. Plaintiff MYRTA ROMANOS ingested Defendant's Avandia and as a result suffered
5 severe injuries and other damages.

6 97. Plaintiff CURTIS RAY, a single man, is and was at all times alleged herein a citizen and
7 resident of the State of Illinois, and brings this action individually.

8 98. Plaintiff CURTIS RAY ingested Defendant's Avandia and as a result suffered severe
9 injuries and other damages.

10 99. Plaintiff IDA WEST, a single woman, is and was at all times alleged herein a citizen and
11 resident of the State of Georgia, and brings this action individually.

12 100. Plaintiff IDA WEST ingested Defendant's Avandia and as a result suffered severe
13 injuries and other damages.

14 101. Plaintiffs MILDRED CRAIGHEAD and JAMES CRAIGHEAD, wife and husband, are and
15 were at all times alleged herein citizens and residents of the State of West Virginia, and bring
16 this action in their individual capacities.

17 102. Plaintiff MILDRED CRAIGHEAD ingested Defendant's Avandia and as a result suffered
18 severe injuries and other damages.

19 103. As used herein and as the context requires, "Plaintiffs" may refer to the Plaintiffs who are
20 alleged to have ingested Avandia and/or Plaintiffs' decedents who are alleged to have ingested
21 Avandia and/or the spouses of the Plaintiffs who are alleged to have ingested Avandia and/or
22 the Plaintiffs presenting the claims of their respective decedents who are alleged to have
23 ingested Avandia.

24 104. Defendant SmithKline Beecham Corporation d/b/a GLAXOSMITHKLINE (hereinafter,
25 "GSK"), at all times alleged herein, is and was a corporation formed under the laws of the State
26 of Pennsylvania, and duly authorized to transact business in the State of California, GSK makes
27 a variety of prescription drugs, including Avandia.

28

1 105. At all times alleged herein, GSK is and was engaged in substantial commerce and
2 business activity within the County of Orange, State of California. Further, or in the alternative,
3 at all times alleged herein, GSK has and had sufficient contacts within the County of Orange,
4 State of California, to subject them to the jurisdiction of this Court.

5 106. At all times alleged herein, GSK is and was engaged in substantial commerce and
6 business activity nationally, and specifically within the State of California among other States,
7 where Plaintiffs resided and/or ingested Avandia.

8 107. At all times alleged herein, GSK includes and included any and all parents, subsidiaries,
9 affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind,
10 their predecessors, successors and assigns and their officers, directors, employees, agents,
11 representatives and any and all other persons acting on their behalf.

12 108. Defendant MCKESSON CORPORATION (hereinafter, "McKesson"), at all times alleged
13 herein, is and was a corporation organized and existing under the laws of the State of
14 Delaware, with its principal place of business in San Francisco, California, duly authorized to
15 transact business in the State of California. At all times alleged herein, McKesson is and was
16 engaged in the business of marketing, distributing, promoting, advertising and selling Avandia
17 nationwide and specifically within the State of California, among other States, where Plaintiffs
18 resided and/or ingested Avandia.

19 109. Upon information and belief and subject to discovery of information within the exclusive
20 control of Defendants, at a bare minimum, McKesson distributed the Avandia ingested by those
21 Plaintiffs and decedents alleged herein to have ingested Avandia.

22 110. At all times alleged herein, McKesson includes any and all parents, subsidiaries,
23 affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind,
24 their predecessors, successors and assigns and their offices, directors, employees, agents,
25 representatives and any and all other persons acting on their behalf.

26 111. Plaintiffs do not know the true names of the Defendants sued herein as DOES ONE
27 through FIFTEEN, inclusive. Plaintiffs allege that each of the fictitiously named Defendants is
28

1 responsible in some manner for the occurrences herein alleged, and caused the injuries and
2 damages sustained by Plaintiffs as herein alleged.

3 112. At all times alleged herein, use of the collective term "Defendants" refers to all named
4 Defendants herein as well as Defendants DOES ONE through FIFTEEN.

5 113. At all times alleged herein, Defendant identified herein as, or discovered to be,
6 corporations or other business entities were acting by and through officers, employees, agents,
7 and contractors, who were acting within the course and scope of said office, employment,
8 agency, or contractual authority.

9 114. At all times alleged herein, each of the Defendants was the agent and employee of every
10 other Defendant in doing the acts herein alleged, and was, at all times, acting within the
11 purpose and scope of said agency and employment and all of said acts and conduct were
12 ratified and approved by said Defendants.

13 FACTUAL BACKGROUND

14 115. There are three types of diabetes: 1) Type 1 diabetes; (2) Type 2 diabetes; and
15 Gestational Diabetes. Type 1 and 2 are chronic, progressively worsening diseases associated
16 with a variety of cardiovascular complications. Gestational diabetes generally occurs during
17 pregnancy and women that develop gestational diabetes are more likely to develop Type 2
18 diabetes. Type 1 diabetes "results from the body's failure to produce insulin, the hormone that
19 'unlocks' the cells of the body, allowing glucose to enter and fuel them. It is estimated that 5-
20 10% of Americans who are diagnosed with diabetes have Type 1 diabetes.¹"

21 116. The most common type of diabetes is Type 2 diabetes. Type 2 diabetes occurs where
22 the body fails to properly use insulin (insulin resistance), combined with relative insulin
23 deficiency. Insulin, which is made in the pancreas, helps the body's cells use sugar from the
24 bloodstream, which comes from foods and drinks. Sugar is a source of energy for cells². The
25

26
27 ¹ <http://www.diabetes.org/about-diabetes.jsp>

28 ² *Id.*

1 third type, gestational diabetes, affects about 4% of all pregnant women – about 135,000 cases
2 in the United States each year³.

3 117. Most people with diabetes have health problems – or risk factors – such as high blood
4 pressure and cholesterol that increase the risk for heart disease and stroke. More than 65% of
5 people with diabetes die from heart disease or stroke. With diabetes, heart attacks occur
6 earlier in life and often result in death. Other risks include, but are not limited to, blindness,
7 kidney disease, nervous system diseases, amputation, sexual dysfunction, diabetic
8 ketoacidosis, and diabetic coma⁴.

9 118. Cardiovascular disease (CVD) is the main cause of death in these patients. Thus, it is
10 important that an antidiabetic agent reduce the risk of cardiovascular injury.

11 119. During the past decade, numerous drugs have been introduced for the treatment of Type
12 2 diabetes that, used in monotherapy or in combination therapy, are supposed to better control
13 the disease in patients and reduce the health complications often associated with diabetes,
14 such as heart attacks, stroke and other cardiovascular complications.

15 120. GSK is a pharmaceutical manufacturer with net income (adjusted earnings) in 2006 of
16 approximately \$10.6 billion. GSK developed the antidiabetic drug Avandia and submitted it for
17 approval by the United States Food and Drug Administration (“FDA”).

18 121. The FDA initially approved Avandia in 1999 as safe and effective for treating Type 2
19 diabetes mellitus.

20 122. Avandia belongs to a class of drugs known as Thiazolidinediones (TZDs), a novel class
21 of insulin-sensitizing antidiabetic agents. In the USA and Canada, the two TZDs indicated for
22 use in Type 2 diabetes mellitus are rosiglitazone and pioglitazone. A third, troglitazone
23 (Rezulin) has been removed from the market because of an association with significant
24 hepatotoxicity.

25 123. The antidiabetic actions of TZDs are likely mediated by their interaction with the nuclear
26 receptor peroxisome proliferator-activated receptor-gamma (PPAR γ).

27
28 ³ *Id.*

⁴ *Id.*

1 124. PPAR γ is a DNA-binding nuclear hormone receptor that has been shown to regulate
2 bone mass, energy expenditure and glucose metabolism.

3 125. Defendants marketed and sold Avandia (and its related medications Avandamet and
4 Avandaryl) through the medical community to 6 million patients in the United States.

5 126. Avandia would not have been initially approved and/or would not have been allowed to
6 be sold with the label permitted by the FDA and/or would have been withdrawn from the market
7 and/or would have carried a different and more stringent label, had the FA been fully informed
8 by Defendants of all the facts regarding the safety and efficacy of Avandia.

9 127. Large numbers of medical providers and patients in California and throughout the United
10 States have been and are being misled about Avandia's true efficacy and risks.

11 128. Defendants have engaged in repeated and persistent fraud by misrepresenting,
12 concealing and otherwise failing to disclose to physicians and patients, including Plaintiffs,
13 information in its control concerning the safety and effectiveness of Avandia.

14 129. Defendants have misrepresented information concerning the safety and efficacy of
15 Avandia for treating diabetes. For instance, Defendants have allowed positive information
16 about Avandia to be disclosed, publicly, but have withheld and concealed negative information
17 concerning the safety and effectiveness of the drug as treatment for diabetic patients. Thus,
18 Defendants have prevented physicians and patients, including the Plaintiffs and the Plaintiffs'
19 physicians, from properly and independently exercising informed judgment.

20 130. The decision to prescribe or ingest a drug is based on the balance between (a) the
21 benefit the patient is likely to derive from the treatment, including the harm or benefit, if any, of
22 providing no treatment or an alternative treatment and (b) the risk that the proposed treatment
23 will cause the patient harm and the nature and severity of the harm.

24 131. In deciding whether to prescribe or to ingest a drug, physicians and patients rely on their
25 assessment of information received about the drug. Such information must be accurate and
26 provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the
27 information is false or misleading, neither the patient nor the physician can accurately assess
28 the crucial risk/benefit balance or exercise independent judgment.

1 132. At all times material hereto, Defendants did manufacture, create, design, test, label,
2 sterilize, package, distribute, supply, market, sell, advertise, warn, and/or otherwise caused the
3 Avandia to be placed into the stream of commerce, and ultimately to be ingested by the
4 Plaintiffs.

5 133. Avandia has been widely advertised, marketed and represented by the Defendants as a
6 safe and effective antidiabetic agent.

7 134. The product warnings for Avandia in effect during the relevant time period were vague,
8 incomplete or otherwise wholly inadequate, both substantively and graphically, to alert
9 prescribing physicians as well as consumer patients of the actual risks associated with the
10 Avandia.

11 135. The Defendants marketed the Avandia heavily as safe and effective treatment for
12 diabetes, promising fewer side effects than other similar treatments including the other TZDs on
13 the market.

14 136. The Defendants marketed Avandia as the most effective means of treating Type 2
15 diabetes mellitus, claiming to be more effective than older antidiabetics and other TZDs on the
16 market.

17 137. Defendants' marketing efforts were designed and implemented to create the impression
18 in physicians' and Plaintiffs' minds that Avandia is safe and effective for patients, and that it
19 carried/carries less risk of side effects and adverse reactions than other available treatments.

20 138. The marketing and promotion efforts of GSK, its advertisers and sales force served to
21 overstate the benefits of Avandia, and minimize and downplay the risks associated with the
22 drug. These promotional efforts were made, while fraudulently withholding important safety
23 information from the physicians, the FDA, and the public, specifically that GSK was aware of
24 numerous reports of congestive heart failure, heart attacks, strokes, and other serious
25 cardiovascular injuries and death associated with the use of Avandia, well beyond the
26 background rate, and well beyond the rate of other antidiabetic agents.

27 139. Concealing or providing inaccurate or biased information that is material to a prescribing
28 decision misleads the physician and the patient.

1 GSK STUDIES CONCERNING THE SAFETY AND EFFICACY
2 OF AVANDIA IN TREATING TYPE 2 DIABETES

3 140. Defendants boast rosiglitazone as a safe and effective antidiabetic, claiming that
4 rosiglitazone is safer and more effective than older antidiabetic agents and other TZDs.

5 141. Defendants have overstated the efficacious value of rosiglitazone and has understated
6 the risk associated with rosiglitazone.

7 **Efficacy**

8 142. Defendants have promoted and marketed Avandia as being more effective than older
9 antidiabetic agents and other TZDs; however, there is no direct evidence that lowering glucose
10 or glycosylated hemoglobin (Hb_{A1c}) levels with rosiglitazone reduces the risks of microvascular
11 or macrovascular disease or mortality in patients with Type 2 diabetes. There is some evidence
12 that other oral hypoglycemics do succeed in doing so⁵.

13 143. Moreover, researchers recently concluded that older antidiabetic agents are as effective
14 or superior to rosiglitazone⁶.

15 144. There have been three meta-analysis conducted. Each meta-analysis has found that
16 Avandia increases the risk of cardiovascular-related injury.

17 145. A meta-analysis combines the result of several studies that address a set of related
18 research hypotheses.

19 146. The first analysis was performed by GSK and was handed over to the FDA in August of
20 2006. The meta-analysis consisted of 42 separate double-blinded, randomized, controlled
21 clinical trials to assess the efficacy of rosiglitazone for treatment of Type 2 diabetes compared
22 to either placebo or other antidiabetic therapies in patients with Type 2 diabetes. The combined
23 studies included 8,604 patients on rosiglitazone and 5,633 patients randomized to a variety of
24 alternative therapeutic regiments, including placebo.

25
26
27 ⁵ UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with
conventional treatment and risk of complications in patients with type 2 diabetes; UKPDS 33. *The Lancet* 1998; 352:837-853.

28 ⁶ See Bolen, et al. *Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus*. *Annals of Internal Medicine*. (Sept. 2007).

1 147. GSK's own meta-analysis found an overall incidence of myocardial ischemia in
2 rosiglitazone-treated subjects. The risk equated to more than a 30 percent excess risk of
3 myocardial ischemic events in rosiglitazone-treated patients.

4 148. A second meta-analysis conducted by Dr. Steven Nissen and Kathy Wolski titled *Effect*
5 *of Rosiglitazone on the Risk of Myocardial Infarction and Death Cardiovascular Causes* was
6 published on May 21, 2007, in the New England Journal of Medicine. ("NEJM").

7 149. Nissen and Wolski reviewed data available to them through published literature, the
8 FDA's website, and GSK's clinical-trials registry. The analysis included a review of 42 clinical
9 trials involving nearly 28,000 patients.

10 150. Nissen and Wolski concluded, "[r]osiglitazone was associated with a significant increase
11 in the risk of myocardial infarction and with an increase in the risk of death from cardiovascular
12 causes that had borderline significance⁷."

13 151. Patients suffering from Type 2 diabetes mellitus have a higher risk of experiencing a
14 heart attack within seven years than non-diabetic patients. A diabetic taking Avandia has a
15 much greater risk of suffering a heart attack or serious cardiovascular event – an estimate 43
16 percent or greater increase when compared with other diabetic drugs or placebo.

17 152. On July 30, 2007, the FDA presented its results of the FDA meta-analysis. Similar to the
18 GSK and Nissen/Wolski findings, the FDA likewise found an increased risk of heart attack,
19 cardiovascular death, stroke and other serious ischemic related adverse events and ultimately
20 recommended that a boxed warning be placed on the Avandia label.

21 153. Thus, while GSK's rosiglitazone-containing drugs are marketed and sold by Defendants
22 as antidiabetic agents that reduce a diabetic patient's risk of heart attacks, studies conducted
23 by GSK show that rosiglitazone actually increases those risks by 43 percent according to the
24 Nissen/Wolski meta-analysis and by 31 percent according to GSK's own meta-analysis.

25 **GSK Has Mislead the Medical Community and the**
26 **Public About the Efficacy and Safety of Avandia**

27
28 ⁷ Nissen SE and Wolski K., *Effects of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*,
N. Eng J. Med; 356, May 21, 2007.

1 154. The product warnings for the Avandia in effect during the relevant time period were
2 vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert
3 prescribing physicians as well as consumer patients of the actual risks associated with Avandia.
4 Defendants have and continue to market Avandia as a safer and more effective antidiabetic
5 agent than other antidiabetics on the market. However, even prior to the approval of Avandia in
6 the United States market, Defendants knew or should have known of the significantly increased
7 risks of heart attacks, cardiovascular-related deaths, strokes or other serious and life-
8 threatening conditions, which they concealed from the medical community and patients,
9 including Plaintiffs.

10 155. In fact, in 1999, John B. Buse, M.D., Ph.D., (the current President, Medicine & Science,
11 of the American Diabetes Association), a diabetes expert and Chief of the Endocrinology
12 Division of the Department of Medicine at the University of North Carolina (UNC) School of
13 Medicine, raised concerns about Avandia and heart problems.

14 156. Instead of warning the public about this risk, GSK attempted to silence Dr. Buse by
15 threatening him with a \$4 million lawsuit and by characterizing him as a liar⁸.

16 157. In response to GSK's pressure, Dr. Buse sent a three-page letter to Dr. Tadataka
17 Yamada, GSK's Chairman of Research and Development. In the letter, Dr. Buse wrote, "I may
18 disagree with GSK's interpretation of that data . . . I am not for sale . . . Please call off the dogs.
19 I cannot remain civilized much longer under this kind of heat." Eventually, Dr. Buse signed a
20 clarifying statement with the company to help ease investor concerns.

21 On March 15, 2000, John Buse, M.D., wrote a letter to the FDA again raising concerns about
22 a "worrisome trend in cardiovascular deaths and severe adverse events" associated with
23 Avandia: I would like you to know exactly what my concerns are regarding rosiglitazone as a
24 clinical scientist and my approach as a clinician. On the basis of the increase in LDL
25 concentration seen in the clinical trial program (whether the number we accept as the truth is
26 the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed)
one would expect an increase in cardiovascular events . . . Based on studies with stains 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 weeks⁹

27
28 ⁸ John Buse, M.D. Congressional Hearing Transcript (June 6, 2007).

⁹ Letter from Dr. Buse to FDA (March 15, 2000).

1 158. Around the same time period, March 7, 2000, Public Citizen filed a petition for immediate
2 class labeling changes for all marketed TZDs¹⁰. In an independent investigation of the TZDs,
3 Public Citizen, after studying reviews by FDA Medical Officers, Statisticians, and
4 Pharmacologists, transcripts of FDA advisory committee meetings, and scientific literature on
5 troglitazone, rosiglitazone, and pioglitazone, argued that information associating rosiglitazone to
6 heart attacks and serious cardiovascular injuries “was never included in the label, or seriously
7 understated¹¹.”

8 159. Public Citizen cited studies submitted to the FDA for approval that evidenced lack of
9 efficacy and increase in cardiovascular risks.

10 160. Public Citizen argued that nowhere in the product insert was there any mention of
11 myocardial infarction even where it was found that “acute myocardial infarctions occurred in 22
12 patients (0.5%) on rosiglitazone and was fatal in six, a result “higher than in other treatment
13 arms”.

14 161. In the monotherapy trial (#011), chest pain was reported in 0.0% (placebo patients),
15 1.7% (patients on 2 mg bid rosiglitazone) and 3.3% (patients on 4 mg bid); five patients on
16 rosiglitazone had acute myocardial infarctions¹².

17 162. This is obviously a major concern since diabetics are already susceptible to an increased
18 risk of cardiovascular injury.

19 163. Yet, even with this information available to it, Defendants failed to warn consumers and
20 the medical community about the increased risk of heart attacks and other serious injuries
21 associated with Avandia.

22 164. Moreover, GSK has repeatedly engaged in a pattern of conduct of deliberately avoiding
23 FDA recommendations as which concerns relating to public hazards should be warned about.
24
25

26
27 ¹⁰ 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).

28 ¹¹ *Id.* At 1

¹² *Id.* At 6

1 165. For instance, after the FDA required GSK to change its label on February 8, 2001 to
2 reflect a risk of heart failure observed in patients on Avandia and insulin, GSK defied FDA
3 recommendations by engaging in false and misleading promotional activities.

4 166. In a letter dated February 22, 2001, the FDA's Division of Drug Marketing, Advertising
5 and Communications (DDMAC) informed GSK that all promotional materials for Avandia should
6 be revised to prominently include the new risks, no later than March 8, 2001.

7 167. GSK responded on March 1, 2001, wherein GSK committed to include the new risk
8 information by March 8, 2001.

9 168. However, instead of complying with FDA requirements GSK's sales representatives
10 engaged in false or misleading promotional activities with respect to the new risk information in
11 Avandia's product labeling.

12 In a Warning Letter dated July 17, 2001, the FDA warned GSK that they had
13 engaged in a continual violation of federal regulations in their promotional
14 activities for the marketing of Avandia. In that July 17, 2001 letter, the FDA
15 warned that the DDMAC had been monitoring its marketing of Avandia and had:
16 concluded that GSK has promoted Avandia in violation of the Federal Food, Drug,
17 and Cosmetic Act (Act) and its implementing regulations. See 21. U.S.C. §331(a),
18 (b) and 352(a), (n).

17 Specifically, during the 10th Annual American Association of Clinical
18 Endocrinologists (AAACE) Meeting in San Antonio, Texas, on May 2-6, 2001,
19 representatives of GSK made oral representations denying the existence of
20 serious new risks associated with Avandia at GSK's promotional exhibit booth.
21 Additionally, GSK displayed Exhibit panels (AV013G) at the meeting that
22 minimized these new risks associated with Avandia.

21 Your promotional activities that minimize serious new risks are particularly
22 troublesome because we have previously objected, in two untitled letters, to your
23 dissemination of promotional material for Avandia that failed to present any risk
24 information Avandia or minimized the hepatic risk associated Avandia. Despite
25 your assurances that such violative promotion of Avandia had ceased, your
26 violative promotion of Avandia has continued¹³.

27
28 ¹³ Letter from Thomas Abrams, R.Ph., MBA, Director of the FDA's Division of Drug Marketing, Advertising and
Communications to JP Garnier, Chief Executive Officer, GlaxoSmithKline (July 17, 2001) (on file with the FDA).

1 169. Following that May 21, 2007 NEJM publication of the Nissen/Wolski meta-
2 analysis, the FDA issued a safety alert for Avandia and advised patients who take it to
3 consult their doctors.

4 170. On June 1, 2007, GSK published a "Dear Avandia Patient" letter, which
5 responded to the "recent press coverings about the safety of Avandia." Therein, GSK
6 stated that it "stands firmly behind Avandia" and that "Avandia is the most widely studied
7 medicine for type 2 diabetes" and that the evaluation of clinical trials by "well-informed
8 experts and researchers has been encouraging."

9 171. At the congressional hearing on June 6, 2007, the FDA indicated that a black box
10 warning should be added to rosiglitazone (Avandia), for increased risk of heart failure.

11 172. On July 30, 2007, the FDA held an FDA Advisory Committee Hearing on the safety of
12 Avandia. The panel was determining whether to recommend keeping the label the same,
13 adding a black box warning, or taking Avandia off the market altogether.

14 173. Dr. David Graham, testifying on behalf of the FDA, called for withdrawing Avandia and
15 estimated that its toxic effects on the heart had caused up to 205,000 heart attacks and strokes,
16 some fatal, from 1999 to 2006. For every month that Avandia is sold, Dr. Graham said 1,600 to
17 2,200 patients will suffer more of those problems.

18 174. The FDA provided testimony that Avandia offers no unique benefits compared to other
19 drugs in battling diabetes, but that all indications point to increased risks of heart attack and
20 sudden death.

21 175. The panel of advisers to the FDA voted 20-to-3 that Avandia increases the risks of heart
22 attacks.

23 176. Defendants, through their affirmative misrepresentations and omissions, actively
24 concealed from Plaintiffs and their physicians the true and significant risks associated with
25 taking Avandia. The running of any applicable Statute of Limitations has been tolled by reason
26 of Defendants' fraudulent concealment.

27 177. As a result of Defendants' actions, Plaintiffs and prescribing physicians were unaware,
28 and could not have reasonably known or have learned through reasonable diligence, that

1 Plaintiffs had been exposed to the risk identified in this Complaint, and that those risks were the
2 direct and proximate result of Defendants' acts, omissions and misrepresentations.

3 178. Defendants' actions amounted to over promotion.

4 179. Defendants' actions do not meet the criteria necessary to overcome the "Reasonable
5 Expectations Doctrine"; thus, they may not rely upon the "Learned Intermediary Doctrine" to
6 escape liability.

7 180. At all times pertinent, Defendant McKesson was privy to the above information, and did
8 assist in the marketing and distribution of Avandia, and did assist in the "over promotion",
9 knowing that Plaintiffs and/or their prescribing physicians would justifiably rely upon the
10 information received in the marketing and distribution process.

11 181. The Defendants thereby acted with fraud, malice, oppression and a conscious disregard
12 for the Plaintiffs' and general public's safety, who accordingly requests that the trier of fact, in
13 the exercise of sound discretion, award additional damages for the sake of example and for the
14 purpose of punishing the Defendants for their conduct, in an amount sufficiently large to be an
15 example to others and deter the Defendants and others from engaging in similar conduct in the
16 future. The aforesaid wrongful conduct was done with the advance knowledge, authorization,
17 and/or ratification of an officer, director, and/or managing agent of Defendants.

18 **FIRST CAUSE OF ACTION**

19 **[Strict Product Liability; Failure to Warn]**

20 182. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
21 allegation contained in Paragraphs 1-183, inclusive, of this Complaint.

22 183. Defendants manufactured, sold and/or distributed Avandia to Plaintiffs to be used to
23 increase insulin sensitivity without causing serious effects, harm, or injury.

24 184. At all times alleged herein, Avandia was dangerous and presented a substantial danger
25 to diabetic patients and these risks and dangers were known or knowable at the time of
26 manufacture, sale or distribution to Plaintiffs. Ordinary consumers would not have recognized
27 the potential risks and dangers the Avandia posed to diabetic patients because its uses were
28 specifically promoted to improve the health of diabetic patients. The Avandia was used by

1 Plaintiffs in a way reasonably foreseeable to all Defendants. Defendants failed to provide
2 warnings of such risks and dangers to Plaintiffs as described herein.

3 185. As a result of the defective dangerous condition of Avandia manufactured and/or
4 supplied by the Defendants, and each of them, Plaintiffs suffered grievous, serious and severe
5 injuries and will continue to suffer consequences of those injuries, all to their detriment and
6 damage in a sum within the jurisdiction of this Court.

7 186. As a result of Plaintiffs' ingestion of the defective Avandia and subsequent grievous,
8 serious, and severe injuries, their spouses have been and will continue to be deprived of
9 consortium, society, comfort, protection and service, thereby causing and continuing to cause
10 them grief, sorrow, mental anguish, emotional distress and pain and suffering.

11 187. As a result of Plaintiffs' decedents' ingestion of the defective Avandia that ultimately
12 caused their deaths, the heirs have been and will continue to be deprived of consortium,
13 society, comfort, protection and service, thereby causing and continuing to cause them grief,
14 sorrow, mental anguish, emotional distress and pain and suffering.

15 In doing the acts herein alleged, the Defendants acted with oppression, fraud and malice and
16 Plaintiffs are therefore entitled to punitive damages to deter Defendants and others from
17 engaging in similar conduct in the future. Said wrongful conduct was done with advance
18 knowledge, authorization and/or ratification of an officer, director and/or managing agent of the
19 Defendants.

20 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

21 **SECOND CAUSE OF ACTION**

22 **[Negligence]**

23 190. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
24 allegation contained in Paragraphs 1-189, inclusive, of this Complaint.

25 191. Defendants, and each of them, and their representatives were manufacturers and/or
26 distributors of Avandia. At all times herein, Defendants had a duty to properly manufacture,
27 compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide
28 proper warnings and prepare for use and sell the aforesaid product.

1 192. Defendants, and each of them, so negligently and carelessly manufactured,
2 compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed,
3 recommended, displayed, sold, examined, failed to examine and supplied aforesaid product,
4 that it was dangerous and unsafe for the use and purpose for which it was intended, that is,
5 increasing insulin sensitivity without causing serous injury, harm, or effect, in Plaintiffs and
6 others similarly situated. As a result of the carelessness and negligence of Defendants,
7 Plaintiffs ingested the Avandia in the manner intended by the manufacturer and, as a result,
8 Plaintiffs suffered grievous, serious and severe injuries and will continue to suffer
9 consequences of those injuries.

10 193. As a result of the carelessness and negligence of Defendants that resulted in Plaintiffs'
11 decedents' ingestion of Avandia that ultimately caused their death, their heirs have been and
12 will continue to be deprived of consortium, society, comfort, protection and service, thereby
13 causing and continuing to cause them grief, sorrow, mental anguish, emotional distress and
14 pain and suffering.

15 194. As a result of the carelessness and negligence of Defendants that resulted in Plaintiffs'
16 ingestion of Avandia and subsequent grievous, serious and severe injuries, their spouses have
17 been and will continue to be deprived of consortium, society, comfort, protection and service,
18 thereby causing and continuing to cause them grief, sorrow, mental anguish, emotional distress
19 and pain and suffering.

20 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

21 **THIRD CAUSE OF ACTION**

22 **[Breach of Implied Warranty]**

23 195. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
24 allegation contained in Paragraph 1-194, inclusive, of this Complaint.

25 196. Defendants impliedly warranted that Avandia, which Defendants designed,
26 manufactured, assembled, promoted, sold and distributed to Plaintiffs were merchantable and
27 fit and safe for ordinary use. Defendants further impliedly warranted that Avandia was fit for the
28

1 particular purpose of increasing insulin sensitivity in diabetic patients without causing serious
2 harm, injury or effect including, but not limited to, death.

3 197. Defendants' Avandia was defective, unmerchantable and unfit for ordinary use when
4 sold and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to
5 severe and permanent injuries. Therefore, Defendants breached the implied warranties of
6 merchantability and fitness for a particular purpose when Avandia was sold to Plaintiffs, in that
7 the Avandia was defective and failed to increase insulin sensitivity without serious harm in
8 diabetic patients as represented and intended.

9 198. As a result of Defendants breach of the implied warranties of merchantability and fitness
10 for a particular purpose, Plaintiffs have sustained and will continue to sustain the injuries and
11 damages described herein and are therefore entitled to compensatory damages.

12 199. After Plaintiffs were made aware their injuries were a result of the aforesaid product,
13 Avandia, Defendants had ample and sufficient notice of breach of said warranty.

14 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

15 **FOURTH CAUSE OF ACTION**

16 **[Breach of Express Warranty]**

17 200. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
18 allegation contained in Paragraphs 1-199, inclusive, of this Complaint.

19 201. Defendants expressly warranted to Plaintiffs and/or their authorized agents or sales
20 representatives, in publications, and other communications intended for medical patients, and
21 the general public, that Avandia was safe, effective, fit and proper for its intended use.

22 202. Plaintiffs and their physicians reasonably relied upon the skill and judgment of
23 Defendants, and upon said express warranty, in using the aforesaid product. The warranty and
24 representations were untrue in that the product caused severe injury to Plaintiffs and was
25 unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiffs to
26 sustain damages and injuries herein alleged.

1 203. As soon as the true nature of the product and the fact that the warranty and
2 representations were false, were ascertained, said Defendants had ample and sufficient notice
3 of the breach of said warranty.

4 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

5 **FIFTH CAUSE OF ACTION**

6 **[Fraud]**

7 204. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
8 allegation contained in Paragraphs 1-203, inclusive, of this Complaint.

9 205. Defendants falsely and fraudulently represented to Plaintiffs, their physicians and to
10 members of the general public that the aforesaid product was safe, effective, reliable,
11 consistent, and better than the other similar products due to its ability to increase insulin
12 sensitivity without causing serious harm when used in the manner intended by the
13 manufacturer. The representations by said Defendants were in fact, false. The true facts
14 include, but are not limited to the fact that the aforesaid product was not safe to be used and
15 was, in fact, dangerous to the health and body of Plaintiffs.

16 206. When the Defendants made these representations, they knew that they were false.
17 Defendants made said representations with the intent to defraud and deceive Plaintiffs, with the
18 intent to induce Plaintiff to act in the manner herein alleged, that is to use the aforementioned
19 product for increasing insulin sensitivity.

20 207. At the time Defendants made the aforesaid representations, Plaintiffs took the actions
21 herein alleged. Plaintiffs and their physicians were ignorant of the falsity of these
22 representations and reasonably believe them to be true. In reliance upon said representations,
23 Plaintiffs were induced to, and did, use the aforesaid products as herein described. If Plaintiffs
24 had known the actual facts, they would not have taken such action. The reliance of Plaintiffs
25 and their physicians upon Defendants' representations were justified because said
26 representations were made by individuals and entities who appeared to be in a position to know
27 the true facts.

1 208. As a result of Defendants' fraud and deceit, Plaintiffs were caused to sustain the herein
2 described injuries and damages.

3 209. In doing the acts herein alleged, the Defendants acted with oppression, fraud, and
4 malice and Plaintiffs are therefore entitled to punitive damages to deter Defendants and others
5 from engaging in similar conduct in the future. Said wrongful conduct was done with advance
6 knowledge, authorization and/or ratification of an officer, director and/or managing agent of
7 Defendants.

8 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

9 **SIXTH CAUSE OF ACTION**

10 **[Fraud By Concealment]**

11 210. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
12 allegation contained in Paragraphs 1-209, inclusive, of this Complaint.

13 211. At all times mentioned herein, Defendants had the duty and obligation to disclose to
14 Plaintiffs and to their physicians, the true facts concerning the aforesaid product, Avandia; that
15 is, that said product was dangerous and defective, lacking efficacy for its purported use and
16 lacking safety in normal use, and how likely it was to cause serious consequences to users
17 including injuries and possible death. Defendants made the affirmative representations as set
18 forth above to Plaintiffs and their physicians and the general public prior to the date Avandia
19 was ingested by Plaintiffs, while concealing material facts.

20 212. At all times herein mentioned, Defendants willfully, and maliciously concealed facts as
21 set forth above from Plaintiffs and their physicians and therefore Plaintiffs, with the intent to
22 defraud as herein alleged.

23 213. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the
24 facts set forth above, and had they been aware of said facts, they would not have acted as they
25 did, that is, reasonably would not have relied upon said representations of safety and efficacy
26 and utilized the Avandia for increasing insulin sensitivity. Defendants' representations were a
27 substantial factor in Plaintiffs utilizing Avandia for increasing insulin sensitivity.

1 214. As a result of the concealment of the facts set forth above, Plaintiffs were caused to
2 sustain the herein described injuries and damages.

3 215. In doing the acts herein alleged, the Defendants acted with oppression, fraud, and
4 malice, and Plaintiffs are therefore entitled to punitive damages to deter Defendants and others
5 from engaging in similar conduct in the future. Said wrongful conduct was done with advance
6 knowledge, authorization and/or ratification of an officer, director and/or managing agent of
7 Defendants.

8 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

9 **SEVENTH CAUSE OF ACTION**

10 **[Negligent Misrepresentation]**

11 216. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
12 allegation contained in Paragraphs 1-215, inclusive, of this Complaint.

13 217. At all relevant times herein, Defendants represented to Plaintiffs and their physicians that
14 the Avandia was safe to use to increase insulin sensitivity knowing that the Avandia was
15 defective in causing injuries described herein.

16 218. The Defendants made the aforesaid representations with no reasonable ground for
17 believing them to be true when Defendants' own data showed the Avandia to be defective and
18 dangerous when used in the intended manner.

19 219. The aforesaid representations were made to the physicians prescribing Avandia prior to
20 the date it was prescribed to Plaintiffs and their physicians with the intent that Plaintiffs and their
21 physicians rely upon such misrepresentations about the safety and efficacy of Avandia.
22 Plaintiffs and their physicians did reasonably rely upon such representations that the aforesaid
23 product was safe for use to aid in the treatment of increasing insulin sensitivity.

24 220. The representations by said Defendants to Plaintiffs were false, and thereby caused
25 Plaintiffs to sustain the injuries and damages described herein.

26 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.
27
28

1 **EIGHTH CAUSE OF ACTION**

2 **[Loss of Consortium]**

3 221. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
4 allegation contained in Paragraphs 1-220, inclusive, of this Complaint.

5 222. Those Plaintiffs alleged to be the spouses of Plaintiffs who ingested Avandia and
6 suffered grievous, serious, and sever injuries bring this cause of action for loss of consortium.

7 223. By reason of the injuries described herein sustained by Plaintiffs who ingested Avandia
8 and suffered grievous, serious and severe injuries, their spouses have been and will continue to
9 be deprived of consortium, society, comfort, protection and service, thereby causing and
10 continuing to cause them grief, sorrow, mental anguish, emotional distress and pain and
11 suffering.

12 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

13 **NINTH CAUSE OF ACTION**

14 **[Wrongful Death]**

15 224. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every
16 allegation contained in Paragraphs 1-223, inclusive, of this Complaint.

17 225. Those Plaintiffs bringing this action on behalf of decedents alleged to have ingested
18 Avandia that resulted in their death bring this claim for wrongful death on behalf of the heirs of
19 their respective decedents.

20 226. As a result of Plaintiffs' decedents' ingestion of the defective Avandia that ultimately
21 caused their death, their heirs have been and will continue to be deprived of consortium,
22 society, comfort, protection and service, thereby causing and continuing to cause them grieve,
23 sorrow, mental anguish, emotional distress and pain and suffering, and are entitled to damages
24 for wrongful death.

25 **WHEREFORE**, Plaintiffs pray for judgment against Defendants as hereinafter set forth.
26
27
28


1 PRAYER FOR RELIEF

2 Plaintiffs pray that judgment be entered in favor of Plaintiffs in such aggregate sum as
3 will fairly and reasonably compensate Plaintiffs for damages arising out of Defendants conduct
4 as described herein. The conduct of Defendants, as alleged herein, was a direct, proximate
5 and producing cause of the damages to Plaintiffs and the following general and specific
6 damages:

- 7 1. For general damages in a sum within the jurisdiction of this Court;
8 2. For medical, hospital, and incidental expenses, according to proof;
9 3. For loss of earnings and for loss of earning capacity, according to proof;
10 4. For punitive or exemplary damages; and
11 5. For such other relief as the Court deems just and proper.

12
13 DATED: May 14, 2009

14 Respectfully submitted,

15 

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