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**IN THE COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY, PENNSYLVANIA**

IN RE AVANDIA LITIGATION : February Term, 2008  
: :  
: : No. 2733  
: :

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**SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE'S  
MASTER LONG-FORM ANSWER, NEW MATTER, AND  
DEMAND FOR JURY TRIAL**

Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), by its undersigned counsel, hereby files this Master Long-Form Answer, New Matter, and Demand for Jury Trial in response to Plaintiffs' General Master Long-Form Complaint and Jury Demand ("Complaint") filed pursuant to Case Management Order No. 1.

This Master Long-Form Answer is not intended to and shall not waive any applicable defenses available to GSK, and GSK hereby reserves the right to respond to any specific allegation raised in a later-filed short-form complaint. Moreover, GSK reserves the right to file counterclaims, crossclaims and/or third-party complaints in connection with any particular individual action, if appropriate.

In Re: Avandia Litigation-ANCOM



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This Master Long-Form Answer shall be deemed to respond to the allegations of all future-filed short-form complaints based on allegations contained in Plaintiffs' Master Long-Form Complaint.

**PLAINTIFFS**

1. GSK states Paragraph 1 of the Complaint was deemed amended by Section VII (1) of Case Management Order No. 2, and reads as follows:

This is a Master Complaint filed on behalf of plaintiffs who took Avandia. All allegations pleaded herein are deemed pleaded in any "Short-Form" Complaint hereafter filed. Every plaintiff who uses this Master Long Form Complaint and any Short Form Complaint based hereon proposes that Pennsylvania substantive law applies.

Because Paragraph 1 of the Complaint contains averments to which no responsive pleading is required it is deemed denied.

**DEFENDANT**

2. GSK denies the allegations contained in Paragraph 2 of the Complaint, except admits that: (i) SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, P.O. Box 7929, Philadelphia, Pennsylvania. It is further admitted that GSK conducts business in the Commonwealth of Pennsylvania, and throughout the United States, and that Avandia® is a thiazolidinedione antidiabetic agent indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is further admitted that GSK marketed and sold Avandia®, Avandamet®, and Avandaryl® (collectively "Avandia") for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications and with FDA approved warnings regarding risks and benefits of the medication.

**GENERAL ALLEGATIONS**

3. Pursuant to Pennsylvania Rule of Civil Procedure 1029 (e), Paragraphs three through forty-four of the Complaint are denied..

**PRAYER FOR RELIEF**

4. GSK denies that Plaintiffs are entitled to any of the requested relief set forth in Plaintiffs' Prayer for Relief, including all subparts therein.

**DEMAND FOR JURY TRIAL**

5. GSK admits that Plaintiffs have demanded a jury trial in this action.

WHEREFORE, defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline respectfully requests that the Court enter judgment in its favor dismissing the Complaint with prejudice, that GSK be awarded the costs, disbursements, and attorneys' fees it incurred in defense of this action, and that GSK be granted any other relief to which it may be entitled.

**NEW MATTER<sup>1</sup>**

6. Defendant GSK, by its counsel, pleading in the alternative and without prejudice to its other pleadings, alleges the following defenses as New Matter. By virtue of asserting these defenses, GSK does not assume any burden of proof not otherwise legally assigned to it and does not concede or assume that Pennsylvania law applies to the claims of any plaintiff not a resident of Pennsylvania.

7. GSK hereby incorporates all preceding paragraphs of its Answer as if set forth fully herein.

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<sup>1</sup> Pursuant to the terms of Case Management Order No. 1, no responsive pleading is required to the New Matter contained herein.

**FIRST DEFENSE**

8. Plaintiffs' Complaint fails, in whole or in part, to state a claim upon which relief can be granted.

**SECOND DEFENSE**

9. Discovery may show that Plaintiffs' claims are barred, in whole or in part, by applicable statutes of limitations, statutes of repose, the doctrine of laches and/or as a result of the failure to allege and/or comply with conditions precedent to applicable periods of limitations and repose.

**THIRD DEFENSE**

10. The Philadelphia Court of Common Pleas may be an improper venue for this action. GSK reserves its rights to move for dismissal or transfer of this action based on improper or inconvenient venue.

**FOURTH DEFENSE**

11. Some or all of Plaintiffs' claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, Plaintiffs' prescribing physicians were in the position of learned intermediaries and/or sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Avandia.

**FIFTH DEFENSE**

12. Plaintiffs' alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by Plaintiffs' failure to exercise reasonable care and diligence to mitigate Plaintiffs' alleged damages.

**SIXTH DEFENSE**

13. Any and all damages alleged in the Complaint may have been caused by misuse of the product, failure to use the product properly, or negligent use of the product, and therefore the risk was assumed.

**SEVENTH DEFENSE**

14. Plaintiffs' claims are barred because GSK complied with applicable statutes and any and all requirements and regulations of the United States Food and Drug Administration ("FDA"). Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, development, testing, marketing, distribution and sale of this prescription drug, and that Avandia was neither defective nor unreasonably dangerous.

**EIGHTH DEFENSE**

15. Plaintiffs' claims are preempted by federal law in that Avandia was manufactured and labeled in a manner consistent with the state of the art at the relevant time and approved by the FDA.

**NINTH DEFENSE**

16. Some or all of Plaintiffs' claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the restatement (Second) of Torts and/or barred by the Restatement (Third) of Torts.

**TENTH DEFENSE**

17. Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have

prevented the harm alleged by Plaintiffs without substantially impairing the usefulness of intended purpose of the product.

#### **ELEVENTH DEFENSE**

18. GSK at all times discharged any duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations with the then-existing states of medical and scientific knowledge.

#### **TWELFTH DEFENSE**

19. GSK's conduct did not cause, proximately cause, solely cause, or solely proximately cause the injuries and/or damages alleged by Plaintiff.

#### **THIRTEENTH DEFENSE**

20. Plaintiffs' claims are barred in whole or in part by the applicable provisions of the United States Constitution, the Pennsylvania Constitution and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include, but are not limited to, the First Amendment to the Constitution of the United States and/or Article I, Section 7 of the Constitution of the Commonwealth of Pennsylvania because GSK's commercial speech regarding Avandia was neither false nor misleading.

#### **FOURTEENTH DEFENSE**

21. To the extent that Plaintiffs later request punitive damages, such claims violate, and are therefore barred by the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, the corresponding provisions of the Pennsylvania Constitution and/or any other State or Commonwealth of the United States whose laws might be deemed controlling in this case, on grounds including the following:

(a) It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

(b) The procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution;

(c) The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award of punitive damages, which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

(d) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages, which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

(e) The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts and thus violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

(f) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

(g) The procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment to the United States Constitution;

(h) The award of punitive damages to Plaintiffs in this action would constitute a deprivation of property without due process of law; and

(i) The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

#### **FIFTEENTH DEFENSE**

22. To the extent Plaintiffs later request punitive or exemplary damages, GSK specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards, including but not limited to, those standards of limitation which arose in *BMW of North America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003), and *Phillip Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

#### **SIXTEENTH DEFENSE**

23. Plaintiffs' claims are barred and/or this Court should abstain from adjudicating these claims, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Avandia, and is specifically charged with determining the content of warnings and labeling for prescription drugs. Granting the relief requested in Plaintiffs' Complaint would impermissibly infringe upon and/or conflict with applicable federal laws, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., regulations and policies in violation of the Supremacy Clause of the United States Constitution.

**SEVENTEENTH DEFENSE**

24. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

**EIGHTEENTH DEFENSE**

25. The injuries or damages allegedly sustained by Plaintiffs can be attributed to several causes and accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained, if any. If any liability is found against GSK, any such liability being expressly denied, then said liability will constitute less than 50% of the total liability assigned to all persons liable, and as such, the liability of GSK to Plaintiffs for non-economic loss shall be limited, and shall not exceed GSK's equitable share.

**NINETEENTH DEFENSE**

26. Any verdict or judgment rendered against GSK must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit, and, to the extent that Plaintiffs' expenses have been paid by collateral sources, GSK may be entitled to a setoff of damages, if any, as allowable under applicable law.

**TWENTIETH DEFENSE**

27. GSK is entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute of any other state whose substantive law might control the action.

**TWENTY-FIRST DEFENSE**

28. To the extent some or all of the injuries alleged in the Complaint were caused by preexisting medical conditions, subsequent medical conditions, and the natural course

of those conditions of the Plaintiffs, by an idiosyncratic reaction, operation of nature, or act of God, Plaintiffs' claims are barred in whole or in part.

**TWENTY-SECOND DEFENSE**

29. To the extent that Plaintiffs request attorneys' fees, such request is improper under applicable law.

**TWENTY-THIRD DEFENSE**

30. The damages allegedly sustained by Plaintiffs, if any, were not legally caused by GSK but instead were legally caused by intervening and superseding causes or circumstances.

**TWENTY-FOURTH DEFENSE**

31. Any alleged act or omission by GSK concerning the manufacture, distribution, marketing, and/or sale of Avandia and/or any other conduct in relation thereto was at all times unintentional and resulted from a bona fide error notwithstanding the use of reasonable procedures adopted to avoid any such error, and GSK made an appropriate correction, repair, replacement, or remedy to the goods once notified of the same.

**TWENTY-FIFTH DEFENSE**

32. GSK's acts were at all times done in good faith and without malice, with respect to each and every purported cause of action in Plaintiffs' Complaint.

GSK hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this list to assert such defenses.

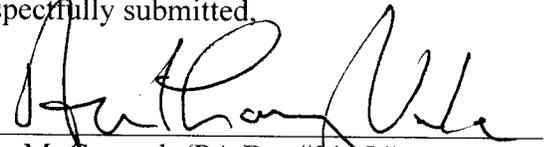
WHEREFORE, defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline respectfully requests that the Court enter judgment in its favor dismissing the

Complaint with prejudice, that GSK be awarded the costs, disbursements, and attorneys' fees it incurred in defense of this action, and that GSK be granted any other relief to which it may be entitled.

**DEMAND FOR JURY TRIAL**

GSK demands trial by jury on all issues so triable.

Respectfully submitted,



Date: October 7, 2008

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*Attorneys for Defendant SmithKline Beecham  
Corporation d/b/a GlaxoSmithKline*

**VERIFICATION**

I, Janice M. Landwehr, hereby state that I am Senior Paralegal for SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“GSK”), a corporation, and am authorized by GSK to make this verification on its behalf. The averments of fact and denials of fact set forth in the foregoing Master Long-Form Answer, New Matter and Demand for Jury Trial have been assembled by authorized employees, attorneys and outside counsel. I am not personally familiar with some of the information contained therein, but am aware that it has been gathered from people who are knowledgeable regarding the subject matter at the request of and with the direction of counsel to GSK. I am informed and verify that the facts stated therein are true and correct to the best of my knowledge, information and belief. I understand that this verification is made subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsifications to authorities.

DATED: October 7, 2008

  
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Janice M. Landwehr

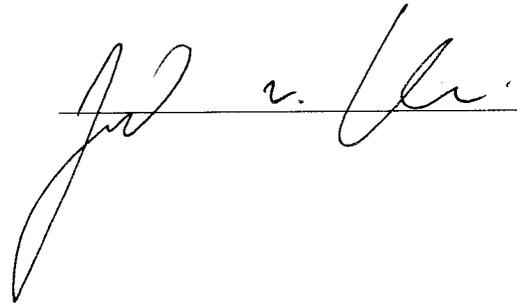
**CERTIFICATE OF SERVICE**

I, Jared N. Klein, hereby certify that on October 7, 2008 a true and correct copy of the foregoing document was served via electronic mail and United States mail, postage prepaid, upon the following:

Sol H. Weiss, Esquire  
Anapol, Schwartz, Weiss, Cohan, Feldman and Smalley, P.C.  
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Date: October 7, 2008.

A handwritten signature in black ink, appearing to read "Jared N. Klein", is written over a horizontal line.