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IN RE: AVANDIA LITIGATION	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY, PA
	:	FEBRUARY TERM, 2008 NO. 02733
	:	**JURY TRIAL DEMANDED**

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may be entered against you by the court without further notice for any money claims in this complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAYWER. IF YOU CANNOT AFFORD TO HIRE A LAYWER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lawyer Referral and Information Service
1101 Market Street, 11th Floor
Philadelphia, PA 19107-2911
(215) 238-6333

Le han demandado a usted en la corte. Si usted quiere defenderse de estas de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrtia sus defenses o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notification. Ademas, la corte puede decidir a favor del demandante y requiere que usted compla con todas las provisions de esta demanda. Usted puede perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO. VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PENNSYLVANIA

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

PLAINTIFFS' GENERAL MASTER LONG-FORM COMPLAINT AND JURY DEMAND

Pursuant to an Order by the Honorable Allan Tereshko, the undersigned attorneys for plaintiffs in "Avandia" actions bring the Master General Long-Form Complaint against the following defendant:

Smithkline Beecham Corporation d/b/a Glaxosmithkline
One Franklin Plaza
Philadelphia, PA 19101-1225

PLAINTIFFS

1. This Complaint is a Master Complaint filed for all plaintiffs represented by a plaintiff's counsel who has signed agreement to the Master Long Form Complaint. All allegations pleaded herein are deemed pleaded in any "Short-Form" Complaint hereafter filed. Notwithstanding that the law of another State might apply under a conflict of laws analysis, the Master Long Form Complaint is filed under Pennsylvania law and may be adopted by a resident of any State except Michigan. Every plaintiff who uses this Master Long Form Complaint and any Short Form Complaint based hereon agrees that Pennsylvania substantive law applies.

DEFENDANT

2. Defendant SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE (hereinafter "GSK" or "Defendant") is a Pennsylvania corporation with its principal business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania. GSK is in the

business of, *inter alia,* formulating, developing, manufacturing, marketing, distributing, and selling, for profit, pharmaceutical products, or drugs, including the widely-used diabetes prescription drug Avandia (rosiglitazone), throughout the United States, including in and for the Commonwealth of Pennsylvania.

GENERAL ALLEGATIONS

3. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are prone to heart problems, and indeed, two-thirds of diabetics die of heart problems.

4. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet. Only one other drug like it, pioglitazone, sold as Actos and Actopluset by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Avandia faces only one competitor for that market.

5. Avandia had a total U.S. sales of $2.2 billion in 2006, slightly less than the $2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between $90 and $170. Avandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

6. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, cardiac injuries, heart attack, liver damage, liver failure, stroke and severe

injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

7. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

8. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was impaired due to GSK's failure to warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

9. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to

disclose thee dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

10. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and continues to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

> Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.
>
> * * *
>
> Phase I trials typically involve health volunteers. *These trials study the safety of the drug and its interaction with the body,* for example, its concentration and duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.
>
> Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues.*
>
> If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required,* in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

http://www.gsk.com/research/clinical/index/html (emphasis supplied).

11. GSK has also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer." http://www.gsk.com/about/index.htm.

12. Based on these representations, upon which some if not all Plaintiffs relied, including the omission from the Avandia labeling of the danger of increased risk of adverse

cardiovascular events as a result of ingesting Avandia, these Plaintiffs purchased and ingested Avandia believing that the drug would be safe and effective.

13. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

14. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

15. It was not until August 14, 2007, when GSK was required by the FDA, that GSK updated the Avandia label with a Black Box warning regarding cardiac injuries stating: "Thiazolidinediones, including rosiglitazone, cause or exacerbate cardiac injuries in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patients 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.

16. It was not until November 19, 2007, when GSK was required by the FDA, that GSK updated the Avandia label with a Black Box warning regarding myocardial ischemia, stating: "...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 oral 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. (5.2)

17. To date, GSK has failed to adequately warn or inform consumers, including plaintiffs' prescribing physicians of the known defects in Avandia that can lead to increased risk of cardiovascular events, specifically including myocardial infarction, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiffs. GSK knew or should of known that Avandia increased the risk of myocardial infarction, congestive heart failure, and other ischemic diseases prior to September 2005 .

18. As a result of using Avandia Plaintiffs have been exposed to a hazardous and dangerous substance, causing the injuries more fully described hereinafter.

COUNT I
NEGLIGENCE

19. Plaintiffs repeat and reiterate the allegations previously set forth herein.

20. That at all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design manufacture, testing processing, marketing advertising, labeling, packaging distribution, and sale of Avandia, and Defendants knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

21. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, was not reasonably safe for such use, and furthermore, Defendants failed to adequately warn of the increased risk of serious cardiovascular events which Defendants knew or should have known about.

22. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardiovascular events and by failing to adequately warn the trusting public and prescribing health care providers of the true, complete, and accurate risk and the lack of efficacy of Avandia.

23. The aforesaid incident and the injuries sustained by Plaintiffs were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff, on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including Plaintiff and Plaintiff's prescribing physician, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

24. Defendants failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:

a. Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendants knew, or should have known, carried the risk of serious; life-threatening side effects;

b. Failure to adequately test the product prior to placing the drug Avandia on the market;

c. Failure to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;

d. Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;

e. Failure to advise consumers, such as plaintiff, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death;

f. Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death;

g. Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and

h. Any and all other acts of negligence with respect to Avandia which may be shown at trial.

25. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiffs.

26. That as a result of the aforesaid occurrence, the permanent injuries sustained by Plaintiffs resulting therefrom, Plaintiffs suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

27. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
NEGLIGENT MISREPRESENTATIONS

28. Plaintiffs repeat and reiterate the allegations previously set forth herein.

29. GSK represented and marketed Avandia as being safe and effective.

30. After GSK became aware of the risks of ingesting Avandia, however, GSK failed to communicate to the Plaintiffs and other members of the general public, that the ingestion of this drug could have the increased risk of serious cardio-vascular events.

31. Therefore, Plaintiff brings this cause of action against GSK under the theory of negligent misrepresentation for the following reasons:

a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;

b) GSK failed to warn the Plaintiffs, and other consumers, of the defective condition of Avandia, as manufactured and/or supplied by GSK;

c) GSK, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Avandia in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, GSK made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

d) the above misrepresentations were made to the Plaintiff, as well as the general public;

e) the Plaintiffs and his healthcare providers justifiably relied on GSK's misrepresentations; and

f) Consequently, the Plaintiffs' ingestion of Avandia was to his detriment and to the detriment of each of the Plaintiffs. GSK's negligent misrepresentations proximately caused the Plaintiffs' injuries and monetary losses.

32. WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
WRONGFUL DEATH

33. Plaintiffs repeat and reiterate the allegations previously set forth herein.

34. As a direct and proximate result of the aforesaid, some of the Plaintiffs who ingested the defendant's product Avandia were caused to contract the diseases and injuries

described herein, causing extreme pain, suffering and mental anguish, and died as direct and proximate result of defendant's negligence as alleged herein.

35. WHEREFORE, Plaintiffs demand judgment against Defendant GSK, in the amount in excess of $75,000.00, together with exemplary damages in an amount to be determined upon the trial of this Action.

COUNT IV
SURVIVAL ACTION

36. Plaintiffs repeat and reiterate the allegations previously set forth herein.

37. Plaintiffs bring this action on behalf of the Estates of their decedents under 42 Pa. C.S.A. § 8302, and the applicable decisional law.

38. Plaintiffs claim on behalf of said Estates damages suffered by the reason of the death of the decedents, including but not limited to and pain and suffering of Decedents prior to their deaths.

39. WHEREFORE, Plaintiffs demand judgment against Defendant GSK, in an amount in excess of $75,000.00, together with exemplary damages in an amount to be determined upon the trial of this Action.

COUNT V
LOSS OF CONSORTIUM

40. Plaintiffs repeat and reiterate the allegations previously set forth herein.

41. Plaintiff's spouse was at all times relevant herein, the husband/wife of Plaintiff and as such, lives and cohabits with her/him.

42. By reason of the foregoing, Plaintiffs' spouse has been caused, presently and in the future the loss of his companionship, services, society has been lost, and as such Plaintiffs' spouse, has been caused great mental anguish and suffering.

43. By reason of the foregoing, Plaintiffs' spouse has necessarily paid and has become liable to pay for medical aid, treatment, and for medications, and will necessarily incur further expenses of a similar nature in the future.

44. WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendant as follows:

(1) Compensatory damages in an amount in excess of the jurisdictional amount as provided by law and to be supported by the evidence at trial;

(2) An award of attorneys' fees, pre-judgment and post-judgment interest, and cost of suit, as provided by law;

(3) Such other legal and equitable relief as this Court deems just and proper. Awarding pre-judgment and post-judgment interest to the Plaintiffs;

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Respectfully submitted,

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FELDMAN AND SMALLEY, P.C.

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