

Plaiding -

STATE OF INDIANA)
)
 COUNTY OF DELAWARE)
)
)
)
 Debra L. Tucker, individually and as Personal)
 Representative of the Estate of Rick G. Tucker,)
)
 Plaintiff,)
)
 vs.)
)
)
)
 SmithKline Beecham, dba)
 GlaxoSmithKline, a Pennsylvania)
 Corporation,)
)
 Defendant.)
)
 _____)

DELAWARE CIRCUIT COURT #5
 Case No. 18C05-0409- PL-46

Jury Trial Demand

Complaint for Wrongful Death

Comes Now Plaintiff, by counsel, who alleges:

The Parties

1. Plaintiff Debra L. Tucker is a competent adult and the surviving sister of Rick G. Tucker, deceased ("Decedent"). She is a resident of the State of Indiana, County of Delaware. She was appointed the Personal Representative of Rick G. Tucker's estate on September 9, 2004. She brings this action individually and as personal representative of the estate of her late brother and all other persons entitled to a cause of action for damages for Decedent's wrongful death.
2. Decedent is survived by no other family members.
3. Plaintiff brings this action pursuant to the applicable wrongful death statute.
4. On or about September 18, 2002, in Dunkirk, Indiana, the Decedent, Rick Tucker, a Roman Catholic priest, died by shooting himself while under the influence of the drug Paxil

FILED
 CLERK OF DISTRICT COURT
 DELAWARE COUNTY, INDIANA
 04 SEP 15 AM 10:38
 Kim D. Chung
 Clerk

which is manufactured, promoted, marketed, and distributed by the defendant SmithKline Beecham Corporation dba GlaxoSmithKline.

5. Defendant SmithKline Beecham Corporation dba GlaxoSmithKline (hereinafter referred to as "GSK") was and still is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania.

6. At all times hereinafter mentioned, defendant GSK was and still is a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil which is an alleged treatment for depression.

7. Since 1992 Paxil has been manufactured, produced, marketed, sold, distributed, merchandised, packaged, promoted, and advertised by GSK as an allegedly safe and effective drug for the treatment of depression. GSK made claims and representations—which were distributed and circulated to the medical profession and to the general public through, among other things, advertising, literature, detail people, brochures, and other methods—that Paxil was a safe and efficacious drug for the treatment of depression.

General Allegations

8. The drug paroxetine is manufactured, promoted, distributed, and marketed by GSK under the trade name Paxil and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs."

9. Like the other SSRIs, Paxil has an association with violent and suicidal behavior for some of the patients who take the drug. Paxil can and does cause "side effects" or extrapyramidal reactions, including an extremely dangerous condition called "akathisia" which is

associated with acts of self-harm and/or violence. In addition, Paxil can cause some patients to become manic, hypomanic, or even psychotic.

10. GSK touts its SSRI as a cure for a chemical imbalance in the brain which is nothing short of speculation. As one renowned psychiatrist put it: “[SSRIs] are not correcting a biochemical imbalance, these drugs create severe imbalances in the brain.” ... “The idea that human suffering, psychological suffering, is biochemical is strictly a promotional campaign, perhaps the most successful in the history of the world, created by the drug companies. We do not even have a technology, a scientific technology, for measuring what happens inside the brain ... it is literally a fabrication.”

11. Since the licensing of Paxil in 1992, the Federal Food and Drug Administration (“FDA”) has received reports under its voluntary reporting program of thousands of suicides and murders related to the administration of SSRI drugs, in which the reporting physician or other health-care professional has listed the particular drug as “suspect.” By the FDA’s own estimates the reported cases are less than 10% of the represented incidents so that the deaths reported to the FDA stand proxy for more than 20,000 SSRI-related deaths (see website www.fda.gov). As a result, the public is at the mercy of the drug companies for which SSRI drugs represent a seven billion dollar annual market. During the clinical trials of Paxil, more than one clinical investigation determined that acts of self-harm were associated with Paxil.

12. The suicide-violence issue was well known to GSK for many years and well before Father Tucker’s death. This knowledge was publicly brought to GSK’s attention in a February 1990 article by two highly reputed Harvard psychiatrists concerning Paxil-induced *de novo* suicidal ideation.

13. The commonality of the SSRI drugs is based on the theory that they stop or slow the natural reprocessing (“reuptake”) of serotonin in the body thus increasing the amount of serotonin. Serotonin has long been scientifically recognized as associated with violence and suicide.

14. The potential for violence and suicide is a class-wide effect of SSRI drugs—such as Paxil—which purport to “selectively” inhibit the reuptake of serotonin by blocking serotonin receptor sites. In two peer-reviewed scientific articles by Pfizer’s Dr. Roger Lane, the association and risk of violence and suicide for all SSRI drugs, including Paxil, is thoroughly discussed. *SSRI-Induced extrapyramidal side-effects and akathisia: implications for treatment*, Journal of Psychopharmacology, 12(2)(1998), pp. 192-214; Lane and Baldwin, *Selective Serotonin Reuptake Inhibitor-Induced Serotonin Syndrome: Review*, Journal of Clinical Psychopharmacology, 17(3)(1997), pp. 208-22. As Dr. Lane writes, these conditions are sometimes hard to detect and diagnose, although not so hard to treat. *E.g.* “SSRI-induced akathisia is a relatively rare event but is frequently unrecognized when it does occur.” For this reason, it is imperative that both physicians and their patients be forewarned and alerted. The drug companies, including GSK, must tell what they know concerning the their drugs’ dangers. Though GSK has now done so—through a change to its prescribing information Warnings Section or “label” as it is known in the industry—it could and should have issued these warnings before Father Tucker’s death.

15. Before Father Tucker’s death, GSK had failed to inform either U.S. physicians or patients of Paxil’s known risks as documented by Dr. Lane’s publications and other scientific literature. Its U.S. package insert and marketing materials did **not** warn about the association

with and risk of akathisia, did **not** warn about the risk of psychosis, and did **not** warn that Paxil is associated with acts of violent and/or self-harm.

16. GSK aggressively distributed and marketed Paxil, encouraging all types of physicians (including those who have no specialized training or expertise in the mental health field such as the physician who prescribed Paxil for Father Tucker) to dispense and prescribe Paxil, not only for depression but also for other maladies.

17. GSK advertises Paxil both in professional medical publications and, more recently, in "direct to consumer" advertising. GSK has so aggressively marketed Paxil that its over-promotion has nullified what warnings GSK has given regarding this drug. Thus, GSK's legal liability is predicated not only upon those things which it failed to tell prescribing physicians and patients but also on its affirmative misrepresentations.

First Cause of Action for Wrongful Death

18. Plaintiff incorporates herein by reference Paragraphs 1 through 17 inclusive as though fully set forth at length.

19. On or about August 28, 2002, Decedent, Father Rick Tucker, first began taking Paxil. The drug was prescribed for Decedent by his family physician. Decedent filled his prescription the same day and then ingested/consumed Paxil over an approximately three-week period. During that time Decedent experienced and endured grievous pain and suffering from Paxil's side effects including, but not limited to, agitation, anxiety, an inability to concentrate and work, confusion, and suicidal thinking. On September 18, 2002, Decedent died by shooting himself in St. Mary's Catholic Church rectory in Dunkirk, Indiana, where he was the pastor.

20. Father Tucker's injuries and death described herein were caused by the negligence

and misrepresentations of GSK through their agents, servants and/or employees acting within the course and scope of their employment including among other things:

- (a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Paxil;
- (b) Failing to properly and adequately test Paxil for its intended use for the treatment of depression;
- (c) Failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions of Paxil;
- (d) Being careless and negligent in that GSK knew or should have known that Paxil was a substance known to produce life-threatening effects upon certain users including, but not limited to, akathisia and acts of self-harm;
- (e) Negligently and carelessly failing to adequately warn the medical community, the general public, and Decedent in particular of the dangers, contra-indications, and side effects from the use of Paxil;
- (f) Negligently and carelessly representing that Paxil was safe for use for many purposes intended when, in fact, it was unsafe for certain users;
- (g) Negligently and carelessly failing to conduct sufficient testing programs to determine whether or not Paxil was safe for use as stated and advertised by GSK;
- (h) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;
- (I) Negligently and carelessly failing to conduct randomized clinical trials or other scientifically valid tests to determine the extent of Paxil's association with life-threatening or

even fatal adverse events;

(j) Negligently and carelessly over-promoting Paxil in a zealous and unreasonable way, without regard to the potential danger that it poses for patients.

21. Before Decedent first took Paxil, GSK—based upon the state of knowledge as it existed at the time—knew or should have known that Paxil could be dangerous and unsafe for the general public’s use and knew or should have known that it was a substance associated with preoccupation about and acts of self-harm.

22. As a direct and proximate result of the aforesaid conduct of GSK, Decedent died, and Plaintiff has sustained pecuniary loss resulting from the loss of Decedent's society, comfort, attention, protection, care, love, affection, services, economic support, and general damages in a sum in excess of the jurisdictional minimum of this Court.

23. As a further proximate result of GSK’s conduct, Plaintiff has incurred expenses for funeral, burial, and other costs pertaining to Decedent's death in amounts to be ascertained.

Wherefore, Plaintiff prays for judgment against GSK as hereinafter set forth.

Second Cause of Action for Strict Liability

24. Plaintiff incorporates herein by reference Paragraphs 1 through 23 inclusive as though fully set forth at length.

25. At all times herein mentioned, Paxil was unsafe for some people who took it, and GSK knew or should have known that said product was unsafe.

26. At all times herein mentioned, Paxil produced serious and sometimes fatal side effects, and GSK knew or should have known that said product could be unsafe because of said side effects.

27. At all times hereinafter mentioned and before Decedent's ingestion of Paxil, neither members of the medical community nor members of the general public knew of the dangers existing with respect to Paxil's administration, side effects, or inadequate testing. 28.

Decedent used Paxil in the manner in which the GSK intended it to be used.

29. Decedent used or otherwise ingested Paxil in the amounts and manner and for the purpose recommended by GSK.

30. At all times material hereto, Paxil—in the U.S.—was not accompanied by complete and proper warnings for safe, informed use; the labeling accompanying Paxil did not warn physicians in general and Decedent in particular of the dangers inherent in its use, particularly of the drug's association with violence and self-harm.

31. GSK promoted and maintained Paxil on the market with the knowledge of Paxil's unreasonable risk to the public in general and specifically to Decedent.

32. Paxil as used by Decedent was defective and unreasonably dangerous when sold by GSK who is strictly liable for the injuries arising from its manufacture and Decedent's use.

33. As a direct and proximate result of the foregoing, Decedent died, and Plaintiff has sustained pecuniary loss resulting from the loss of Decedent's society, comfort, attention, protection, services and support, and general damages in a sum in excess of the jurisdictional minimum of this Court.

34. As a further proximate result of GSK's conduct, Plaintiff has incurred expenses for funeral, burial, and other costs pertaining to Decedent's death in amounts to be proved at trial.

Wherefore, Plaintiff prays for judgment against GSK as hereinafter set forth.

Third Cause of Action for Breach of Implied Warranty

35. Plaintiff incorporates herein by reference Paragraphs 1 through 34 inclusive as though fully set forth at length.

36. Paxil is available in the United States only by prescription. GSK represented and warranted to physicians and the public in general (the prescribers and users of the product) that Paxil was safe and efficacious.

37. Decedent used Paxil in accordance with his physician's recommendation and in the manner GSK intended.

38. Decedent did nothing contrary to the packaging insert literature provided by GSK with respect to the use of Paxil.

39. As a result of GSK's manufacture and sale of Paxil, there arose certain implied warranties running from GSK to Decedent as purchaser and user of Paxil. Among the implied warranties were that:

- (a) Paxil was of merchantable quality;
- (b) Paxil was fit for its primary purpose;
- (c) Paxil was fit for the particular purpose for which it was intended;
- (d) Paxil was not defective; and
- (e) Paxil was safe and efficacious.

40. Decedent took Paxil in reliance on the skill and judgment of GSK who knew or should have known that Decedent would so rely.

41. Notwithstanding the above-mentioned warranties and GSK's knowledge or implied knowledge of the ordinary purposes for which Paxil would be used, Paxil was defective when it left GSK's hands, and thus it was unmerchantable and unsuitable for the ordinary and

particular purpose for which it was used.

42. . . . GSK accordingly breached its implied warranties to Decedent.

43. As a direct and proximate result of GSK's breach of warranty, Decedent died, and Plaintiff has sustained damages and other losses as set forth herein.

Wherefore, Plaintiff prays for judgment against GSK as hereinafter set forth.

Fourth Cause of Action for Breach of Express Warranty

44. Plaintiff incorporates herein by reference Paragraphs 1 through 43 inclusive as though fully set forth at length.

45. At all times herein mentioned, GSK utilized packaging, journal articles, and advertising media to urge the use, purchase, and utilization of Paxil and expressly warranted to physicians, to Decedent, and to other members of the general public that Paxil was effective, safe, and proper for its intended use.

46. GSK represented to the consumer who would use Paxil and to the physicians who would prescribe it—without a complete disclosure of Paxil's side effects—that Paxil was safe and efficacious for people suffering from depression, which amounted to an express warranty of Paxil's safety and efficacy.

47. GSK knew or in the exercise of reasonable diligence should have known that Paxil had the serious side effects set forth herein.

48. Decedent relied on GSK's express warranty representations in the use of Paxil, but Paxil was not effective, safe, and proper for its intended use as warranted in that Paxil failed and was dangerous when put to its intended use.

49. As a direct and proximate result of GSK's breach of express warranty, Decedent

died, and Plaintiff has sustained damages and other losses as set forth herein.

Wherefore, Plaintiff prays for judgment against GSK as hereinafter set forth.

Fifth Cause of Action for Punitive Damages

50. Plaintiff incorporates herein by reference Paragraphs 1 through 49 inclusive as though fully set forth at length.

51. At all times herein mentioned, the actions of GSK, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Decedent in particular and to the general public in that GSK did wilfully and knowingly place the dangerous and defective drug Paxil on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public.

52. At all times relevant herein, GSK's conduct was malicious, fraudulent, and oppressive toward Decedent in particular and the public generally, and GSK conducted itself in a willful, wanton, and reckless manner. Despite GSK's specific knowledge as set forth above, GSK deliberately recommended, manufactured, produced, marketed, sold, distributed, merchandized, labeled, promoted, and advertised the dangerous and defective drug Paxil. All of the foregoing constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public. Thus GSK is guilty of reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of Decedent and others which proximately caused the injuries resulting in Decedent's death. Therefore, Plaintiff requests punitive and exemplary damages in an amount to be determined at trial to deter GSK from continuing its conscious disregard of the rights and safety of the public at large and to set an

example so GSK—as well as other similarly situated drug manufacturers—will refrain from acting in a manner that is wanton, malicious, and in utter, conscious disregard of the rights of a large segment of the public.

53. Plaintiff brings this punitive damage claim pursuant to *Durham v. U-Haul International, et. al.*, decided by the Indiana Court of Appeals on January 13, 2000.

Wherefore, Plaintiff, by counsel prays for judgment against GSK as follows:

1. For general damages in a sum exceeding this court's jurisdictional minimum;
2. For reasonable funeral, burial, and related expenses;
3. For all damages as allowed by law;
4. For punitive damages according to proof;
5. For prejudgment interest as allowed by law;
6. For the costs of suit herein incurred; and
7. For such other and further relief as this Court may deem just and proper.

Respectfully Submitted,

By: 

Dylan A. Vigh #21856-64

DULIK & VIGH

Attorneys for Plaintiff

225 N. Delaware Street

Indianapolis, Indiana 46204

Telephone 317-269-3422

Facsimile 317-269-3428