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This Is Not An Arbitration Case
An Assessment of Damages
Hearing Is Required.

Eric Jackson, a Minor, by **Christopher Jackson** and **Lisa Boden**, Guardians; and **Christopher Jackson and Lisa Boden**, Individually, **Plaintiffs,** **vs.** **SmithKline Beecham Corporation d/b/a, GlaxoSmithKline,** One Franklin Plaza Philadelphia, Pennsylvania 19102-1225 **Defendant.**	)	COURT OF COMMON PLEAS TRIAL DIVISION **PHILADELPHIA COUNTY** **_____TERM** **NO. _____** **IN RE: PAXIL** **JURY TRIAL DEMANDED**

COMPLAINT-CIVIL ACTION

Plaintiffs, Eric Jackson, a minor, by Christopher Jackson and Lisa Boden, Guardians, and Christopher Jackson and Lisa Boden, individually, by their attorneys, Baum Hedlund, and as for the Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is a products liability and personal injury case arising from a Paxil-induced disorder suffered by Eric Jackson as a result of his mother, Lisa Boden, having been prescribed and taking the prescription drug Paxil during her pregnancy. GSK did not timely warn the medical community and consumers generally that taking Paxil during pregnancy is associated with a significant increased risk of birth defects, respiratory problems and abnormal development of the unborn fetus.

PARTIES

2. Plaintiff Eric Jackson is a minor child who was born in Denver, Colorado on October 28, 2004. He is currently a citizen of Colorado, residing with his parents, Christopher Jackson and Lisa Boden in Denver. Eric is represented in this action by his parents, Christopher Jackson and Lisa Boden, who are his next friend pursuant to Pa. R.C.P. No. 2026.

3. Christopher Jackson is a competent adult and the father of plaintiff, Eric Jackson. He brings this action individually and on behalf of his minor son to recover the medical and other expenses incurred in treating and attempting to cure his son's disorder and related illnesses and general damages.

4. Lisa Boden is a competent adult and the mother of plaintiff, Eric Jackson. She brings this action individually and on behalf of her minor son to recover the medical and other expenses incurred in treating and attempting to cure her son's disorder and related illnesses and general damages.

5. Defendant SmithKline Beecham Corporation d/b/a 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. At all times hereinafter mentioned, defendant GSK was, and still is, a pharmaceutical company involved

in the research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil (known generically as paroxetine), an antidepressant, throughout the United States.

JURISDICTIONAL ALLEGATIONS

6. Jurisdiction is proper because GSK is a Pennsylvania corporation. Venue is proper in this District because GSK resides in this county for venue purposes and a substantial part of the events and omissions giving rise to plaintiffs' injuries occurred in this District. *See* Pa.R.C.P. 2179, as amended by 2003 Pennsylvania Court Order 8.

FACTUAL ALLEGATIONS

7. The drug "paroxetine" is manufactured, promoted, distributed, labeled and marketed by GSK under the trade name Paxil, Paxil Oral Suspension, and Paxil CR, and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs." Paxil was first approved for use in the United States by the FDA in 1992 for the treatment of depression in adults.

8. Ms. Boden took Paxil as prescribed by her treating physician while pregnant with Eric.

9. Shortly after Eric was born on October 28, 2004, in Denver, CO, he began to suffer from persistent pulmonary hypertension of the newborn ("PPHN"), a life-threatening disorder in which the newborn's arteries to the lungs remain constricted after delivery, limiting the amount of blood flow to the lungs and therefore the amount of oxygen into the bloodstream.

10. Beginning from the time that Eric developed this disorder, he has gone through several life-threatening procedures. Immediately after birth he was placed on a ventilator and was eventually placed on an oscillating ventilator which he remained on for a month. Thereafter, he underwent two cardiac catherizations, and a nissen fundoplication procedure to combat gastral reflux caused by being on a ventilator for an extended period of time. He remains on oxygen and

medications to help him breathe and continues to suffer from associated eating and digestive problems.

11. The disorder suffered by Eric was a direct result of his mother's ingestion of Paxil during her pregnancy in a manner and dosage recommended and prescribed by her doctor.

12. Prior to Ms. Boden becoming pregnant with Eric, GSK knew or should have known that children born to women who took Paxil during pregnancy were developing PPHN.

13. Prior to Ms. Boden becoming pregnant with Eric, GSK knew or should have known that Paxil crosses the placenta, which could have important implications for the developing fetus.

14. Prior to the time that Ms. Boden ingested Paxil during her pregnancy with Eric, GSK knew or should have known that Paxil posed an increased risk of congenital heart defects.

15. During the entire time Paxil has been on the market in the United States, FDA regulations have required GSK to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and Paxil. The regulations specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed GSK to issue such a warning without prior FDA approval.

16. Thus, prior to Ms. Boden's pregnancy with Eric, GSK had the knowledge, the means and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between Paxil and birth defects and other disorders that could effect the unborn fetus, through all means necessary including but not limited to labeling, continuing education, symposiums, posters, sales calls to doctors, etc. GSK failed to do any of those things.

COUNT I

NEGLIGENCE & NEGLIGENCE PER SE

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

18. At all times mentioned herein, GSK was under a duty to exercise reasonable care in advertising, marketing, promotion and labeling of Paxil to ensure that Paxil's use did not result in avoidable injuries.

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

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

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the possibility that Paxil can interfere with the proper development of an unborn fetus;

(c) Being careless and negligent in that GSK knew or should have known that Paxil was a substance that would be actively transported through the placenta during pregnancy and could inhibit the health and development of the fetus;

(d) Negligently and carelessly failing to adequately warn the medical community, the general public, and plaintiffs of the dangers of using Paxil during pregnancy;

(e) Negligently and carelessly representing that Paxil was safe for use during pregnancy, when in fact, GSK knew or should have known that it was unsafe for this use;

(f) Negligently and carelessly promoting Paxil as safe and effective for use with pregnant women when, in fact, it was unsafe;

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

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

(i) GSK promoted Paxil for use with pregnant women despite the fact that GSK knew or should have known that Paxil is associated with an increased risk of congenital abnormalities and pulmonary problems.

20. Furthermore, GSK's negligence was an un-excused breach of statutory duty established by federal regulations because plaintiffs have suffered from the kind of harm the regulations were designed to prevent and plaintiffs are members of the particular class of persons that those regulations were set out to protect.

21. At all times herein mentioned, upon information and belief, the above-described culpable conduct by GSK was a proximate cause of plaintiffs' injuries. GSK knew or should have known that Paxil could be dangerous and unsafe for pregnant women and the developing fetus.

22. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Eric Jackson has sustained pecuniary loss resulting from the pain and suffering from PPHN, by the surgeries and procedures he has already undergone, and the surgeries and procedures that he will need to undergo in the future, as well as his inability to enjoy his life as a normal child without the presence of PPHN, and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

23. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs Christopher Jackson and Lisa Boden have incurred general and medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, for the above reasons, plaintiffs demand judgment in their favor and against GSK for an amount in excess of $50,000.00, compensatory damages and costs of suit in an amount to be determined upon the trial of this matter.

COUNT II

NEGLIGENT PHARMACO-VIGILANCE

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

25. GSK has an ongoing duty of pharmaco-vigilance. As part of this duty, GSK is required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Paxil. GSK continually receives reports from its own clinical trials, practicing physicians, individual patients, and regulatory authorities of adverse events that occur in patients taking Paxil and its other marketed drugs. Furthermore, GSK continues to conduct clinical trials for its marketed drugs long after the drug is approved for use. GSK has a duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information it learns, or should have learned, about its marketed drugs once that information becomes available to GSK, whether through GSK clinical trials, other outside sources, or pharmaco-vigilance activities. Specifically, when GSK learns, or should have learned, of new safety information associated with its marketed drugs, it has a duty to promptly disseminate that data to the public. GSK also has a duty to monitor epidemiological and pharmaco-vigilance data regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

26. GSK breached this duty with respect to plaintiffs. GSK, through various sources, including but not limited to, clinical trials and other adverse event reports, learned that there was a

substantial risk of pulmonary problems and birth defects associated with Paxil use during pregnancy and failed to inform doctors, regulatory agencies, and the public of this risk. GSK had the means and the resources to perform its pharmaco-vigilance duties for the entire time Paxil has been on the market in the United States.

27. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Eric Jackson has sustained pecuniary loss resulting from the pain and suffering from PPHN, by the surgeries and procedures he has already undergone, and the surgeries and procedures that he will need to undergo in the future, as well as his inability to enjoy his life as a normal child without the presence of PPHN, and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

28. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs Christopher Jackson and Lisa Boden have incurred general and medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, for the above reasons, plaintiffs demand judgment in their favor and against GSK for an amount in excess of $50,000.00, compensatory and costs of suit in an amount to be determined upon the trial of this matter.

COUNT III

FAILURE TO WARN
(Restatement Second of Torts §388)

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

30. At all times herein mentioned, Paxil was unsafe for use by pregnant women, and GSK knew or should have known that said product was unsafe.

31. At all times herein mentioned, using Paxil during pregnancy was associated with a significantly increased risk of serious pulmonary problems and birth defects and GSK knew or

should have known that said product is unsafe when taken during pregnancy because of the said effects.

32. At all times hereinafter mentioned and before Ms. Boden's ingestion of Paxil during her pregnancy, neither members of the medical community nor members of the general public knew the dangers existed with respect to Paxil's association with birth defects.

33. Ms. Boden used Paxil in the manner in which GSK intended it to be used.

34. Ms. Boden used or otherwise ingested Paxil in the amount and manner and for the purpose recommended by GSK.

35. At all times material hereto, U.S.-marketed Paxil was not accompanied by complete and proper warnings for safe, informed use; the labeling accompanying Paxil did not warn physicians in general, or plaintiffs in particular, of the dangers inherent in its use, particularly of the drug's association with PPHN and birth defects. Further, the labeling failed to adequately inform physicians in general, or plaintiffs in particular, of Paxil's association with a significantly increased risk of birth defects and other disorders effecting the unborn fetus if a woman ingests Paxil during her pregnancy and oversold Paxil's benefits, thus depriving physicians of necessary information needed to perform an adequate risk/benefit analysis. Furthermore, GSK failed to adequately warn doctors and the medical community of this dangerous risk using the other mediums at its disposal, including, but not limited to, medical journal articles, sales representatives, Dear Doctor letters, presentations, conferences, medical school information, and all of its promotional material and activities.

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

37. Paxil, as used by Ms. Boden during her pregnancy with Eric, was defective and unreasonably dangerous when sold by GSK, who is liable for the injuries arising from its manufacture and Ms. Boden's use.

38. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Eric Jackson has sustained pecuniary loss resulting from the pain and suffering from PPHN, by the surgeries and procedures he has already undergone, and the surgeries and procedures that he will need to undergo in the future, as well as his inability to enjoy his life as a normal child without the presence of PPHN, and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

39. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs Christopher Jackson and Lisa Boden have incurred general and medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, for the above reasons, plaintiffs demand judgment in their favor and against GSK for an amount in excess of $50,000.00, compensatory and costs of suit in an amount to be determined upon the trial of this matter.

COUNTS IV & V

BREACH OF EXPRESS AND IMPLIED WARRANTY

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

41. At all times hereinafter mentioned, upon information and belief, defendant, by directly and indirectly advertising, marketing, and promoting Paxil for the treatment of women during pregnancy and by placing this drug in the stream of commerce knowing that Paxil would be prescribed to pregnant women in reliance upon the representations of defendant, expressly warranted to all foreseeable users of the drug, including Ms. Boden, that Paxil was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

42. The defendant impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Paxil to all foreseeable users, including Ms. Boden, that Paxil was safe and effective for the purposes for which it had been placed in the stream of commerce by defendant, including for the treatment of pregnant women, and that Paxil was reasonably safe, proper, merchantable and fit for the intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

43. That at all time hereinafter mentioned, plaintiffs relied upon the aforesaid express and implied warranties by defendant.

44. That at all times hereinafter mentioned, Ms. Boden's use of Paxil was consistent with the purposes for which defendant directly and indirectly advertised, marketed and promoted Paxil, and Ms. Boden's use of Paxil was reasonably contemplated, intended, and foreseen by defendant at the time of the distribution and sale of Paxil by defendant, and, therefore, Ms. Boden's use of Paxil was within the scope of the above-described express and implied warranties.

45. Defendant breached the aforesaid express and implied warranties because Paxil was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because Ms. Boden's use of Paxil for treatment during her pregnancy caused Eric's disorder.

46. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Eric Jackson has sustained pecuniary loss resulting from the pain and suffering from PPHN, by the surgeries and procedures he has already undergone, and the surgeries and procedures that he will need to undergo in the future, as well as his inability to enjoy his life as a normal child without the presence of PPHN, and additional general damages in a sum in excess of the jurisdictional minimum of this Court.

47. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs Christopher Jackson and Lisa Boden have incurred general and medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, for the above reasons, plaintiffs demand judgment in their favor and against GSK for an amount in excess of $50,000.00, compensatory damages and costs of suit in an amount to be determined upon the trial of this matter.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

1. For general damages in a sum exceeding this court's jurisdictional minimum;
2. For reasonable medical expenses according to proof;
3. For all damages as allowed by law;
4. For prejudgment interest and post-judgment interest as allowed by law;
5. For delay damages pursuant to Pa. R.C.P. No. 238;
6. For punitive and exemplary damages as allowed by law;
7. For the costs of suit herein incurred; and
8. For such other and further relief as this Court may deem just and proper.

Dated: October 16, 2006

Respectfully Submitted,

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Attorneys for Plaintiffs

JURY TRIAL DEMAND

Plaintiffs herein invoke their right to a trial by a jury of 12 persons.

Dated: October 16, 2006

Respectfully Submitted,

Cara J. Luther, Esq.