

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

FILED

NOV 29 2007

Phil Lombardi, Clerk
U.S. DISTRICT COURT

1.JENNIFER HAYES AND 2. JUSTIN HAYES,)
INDIVIDUALLY AND AS)
NEXT FRIENDS OF 3. K.H., A MINOR,)

Plaintiffs,)

vs.)

1. SMITHKLINEBEECHAM CORPORATION)
d/b/a GLAXOSMITHKLINE,)

Defendant.)

Case No.

07 CV - 682 CVE SAJ

COMPLAINT

Plaintiffs Jennifer and Justin Hayes, individually, and as parents and next friends of K.H., a minor, for their claims against Defendant, SmithKlineBeecham Corporation d/b/a GlaxoSmithKline, allege and state as follows:

I. PARTIES, JURISDICTION AND VENUE

1. Plaintiffs Jennifer Hayes and Justin Hayes are the parents of K.H., a minor.
2. Plaintiffs Jennifer Hayes and Justin Hayes are residents of the State of Oklahoma and have resided in Bartlesville, Oklahoma, located within the northern district of Oklahoma at all pertinent times hereto.
3. K.H. is a minor who was born in Bartlesville, Oklahoma on December 1, 2005. She has resided in Bartlesville, Oklahoma at all pertinent times hereto.
4. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter "GSK") is a Pennsylvania corporation with its principal place of business in Philadelphia, Pennsylvania. GSK designed, manufactures and markets a medication, the generic name of which is "paroxetine" and the brand name of which is "Paxil."
5. This Court has personal jurisdiction over Defendant GSK in that Defendant GSK had substantial contacts with the State of Oklahoma.
6. This Court has subject matter jurisdiction pursuant to the provisions of 28

FLS/P

U.S.C. § 1332 (Diversity of Citizenship), in that the amount in controversy exceeds, exclusive of interest and costs, the sum of Seventy-Five Thousand and No/100 Dollars (\$75,000), and the parties are citizens of different states.

7. Venue is appropriate in this district pursuant to Title 28 U.S.C. §1391(a)(2) because a substantial part of the events and omissions giving rise to the claims herein occurred in the State of Oklahoma where the Plaintiff Jennifer Ann Hayes took the drug “Paxil” and where her child, K.H. was born with injuries which are the subject of this suit.

II. Facts Common to All Allegations

A. Prozac - the First SSRI

8. In January of 1988, Eli Lilly launched Prozac in this country. It was the first of a new generation of antidepressant medications which are commonly called Selective Serotonin Reuptake Inhibitors, or SSRI's for short. Prozac became a huge, multi-billion dollar per year commercial success (and a household word in the process).

9. Because medications of this nature are not tested in pregnant women and because there was some basis for fearing that they might be teratogenic, Lilly has actively discouraged women from taking it during their pregnancies.

B. Paxil-the Potential Teratogen

10. Meanwhile, in Philadelphia, one of GSK's corporate forebearers, the "SmithKline Beecham" company, was conducting clinical trials on the SSRI drug paroxetine. The New Drug Application (NDA) was finalized in October of 1989, and the drug was ultimately approved by the FDA and launched as ‘Paxil’ in 1992. It, too, became a huge commercial success, garnering, at its zenith, over three billion dollars in annual sales revenues for GSK.

11. Like Prozac, Paxil was not tested in pregnant women. Unlike Lilly, however, GSK did not discourage the use of Paxil in pregnant women. Indeed, to the contrary, through a variety of means, until September of 2005, it actually encouraged doctors to prescribe Paxil to women of childbearing age, to women who were trying to conceive, and, amazingly, even

to pregnant women.

12. Paxil is a potential human teratogen, which is to say, it is certainly “associated” with, and, with reasonable medical probability, it “causes” birth defects. In our society, there is almost nothing more alarming to expectant parents than a drug or other substance that could harm their child, and absolutely no one that is more in need of protection under the law than innocent, unborn children. Indeed, it was the horrifying images of Thalidomide-induced “flipper babies” that led to the 1962 amendments to the federal Food, Drug and Cosmetic Act. These amendments were designed to empower this federal agency a charter to protect consumers.

13. GSK was on actual or constructive notice of the potential teratogenic effects of Paxil long before Plaintiff Jennifer Hayes conceived her son, K.H.. The facts which put it on notice include evidence, *inter alia*, from animal studies and from human adverse event reporting from the time the drug was launched until the time that Plaintiff Jennifer Hayes conceived K.H..

14. Any reasonable, responsible company should have taken immediate and forceful steps to protect future patients and their unconceived children. Thus, it is specifically alleged that, long before Plaintiff Jennifer Hayes conceived K.H., a reasonable pharmaceutical company in the same or similar circumstances as GSK should have warned doctors and patients about this risk, and should, in fact, have discouraged the use of this drug for patients who might conceive. Instead, GSK did exactly the opposite.

C. An Innocent Child with a Malformed Heart

15. In 2005, Jennifer and Justin Hayes were excited to be adding a third child to their family. Both prior two children born to the couple had been healthy, with well-operating hearts. Jennifer had been prescribed Paxil CR in January of 2005. She refilled her last prescription on March 1, 2005, and she took the drug as prescribed throughout that month.

16. The pregnancy with K.H. was uneventful. The couple went to Jane Phillips Medical Center in their hometown to deliver the baby they would name K.H.. At delivery, K.H.’s heart beat erratically. Because this is not uncommon, baby K.H. was initially

transferred to the nursery for observation.

17. A few hours later, a nurse heard a murmur and baby K.H.'s heart still did not function correctly. Within a few hours, baby K.H. was rushed by Life Flight to St. Francis Children's Hospital in Tulsa, Oklahoma. Just a few hours after delivery, Jennifer checked out the hospital to be with her baby.

18. At St. Francis, Jennifer Hayes's and Justin Hayes's hopes for a healthy baby were quickly dashed. Testing would reveal that baby K.H. suffered from severe pulmonic stenosis. His pulmonic valve was almost entirely closed. A heart catheterization the first day almost killed him. That same day, K.H. underwent his first open-heart surgery. A second surgery a few days later was required to cope with massive fluid build-up around his lungs. A third surgery the second week of life was required to pack down his right diaphragm. On Christmas Eve, K.H. suffered an IV infiltration in his right hand resulting in a severe burn. Debridement and a skin graft followed.

19. In February of 2006, K.H. got pneumonia as a result of pulmonary hypertension caused by his weakened heart. A month stay in the hospital followed. After a brief return home, another hospitalization and heart catheterization followed.

20. Baby K.H. spent the first seven months of his life on a ventilator. Three additional months were spent breathing through a tube in his throat.

21. K.H. is now almost two years old. He is still using a feeding tube, unable to feed by mouth. Only a well-stocked pharmacy can provide the large collection of drugs he must take every day to stay alive. K.H.'s drug list includes Viagra four times a day, Digoxin twice a day, Lasix twice a day, Diuril twice a day, Zantac three times a day, Iron twice a day, baby aspirin once per day, and three breathing treatments done a minimum of five times per day, and he undergoes Neosporin swabs twice per day. Due to these medicines, K.H. cannot be vaccinated for chickenpox, and K.H. may die if he contracts the virus.

22. Baby K.H.'s life will be far from normal. Because K.H.'s heart valve is damaged and the blood in his heart does not flow right, he is at risk for clotting. That means the possibility of heart attack, stroke and pulmonary embolism exists. K.H. is prohibited from being in direct sunlight due to his medications. K.H. spends a lot of time looking through the windows of his home watching his two older brothers play outside. K.H. sees a variety of therapists to improve his speech and motor skills.

23. K.H.'s parents are caring for him one day at a time. There is substantial uncertainty in his future care. The shunt his doctors put in his heart to reduce the strain on his heart may need correction. He currently has significant gastro-esophageal problems. Plaintiffs Jennifer Hayes and Justin Hayes pray K.H.'s pulmonary hypertension will resolve and that he will never need a heart and lung transplant as a result.

24. Because K.H. is a growing child and will continue to grow for some time, K.H. may require additional open-heart surgeries in the future.

25. A summary of present and future problems which can be reasonable anticipated for K.H. include, but is not limited to, the following:

- a. Restriction on physical activities.
- b. Future open-heart surgery and/or heart-lung transplant.
- c. Constant medical monitoring and supervision.
- d. Inability to obtain medical insurance.
- e. Limitations on employability and a concomitant reduction of earnings potential.
- f. Life-long treatment with medications.
- g. Decreased life expectancy.

26. K.H. will be at risk his entire life. His medical care will be enormously expensive even if everything goes well for him. He will never participate in sports, or in any other activity that would strain a normal heart. His parents, despite their love and affection, will be under tremendous strain for the rest of their lives caring for him. Perhaps one day he will be able to eat without a tube. These problems that K.H. faces are a direct and proximate result of Defendant selling and even promoting Paxil to the American public, including Jennifer Hayes, and her physicians for use during pregnancy.

D. Paxil Is the Most Likely Cause of K.H.'s Heart Malformation

27. Neither Jennifer Hayes nor Justin Hayes have any family history of heart defects. Nor was Jennifer Hayes exposed to any other potential teratogen during her pregnancy. Moreover, genetic testing on K.H. has failed to identify any chromosomal cause of his malformed heart.

E. GSK Belatedly Warns About the Teratogenic Potential of Paxil

28. In September of 2005, and again in December of 2005, GSK published some compilations of data concerning the epidemiological association or "signal" between Paxil and birth defects. The "relative risk," which is one barometer by which epidemiologists commonly measure the "strength" of an association, was 2.26. Under generally accepted epidemiological principles, pharmaceutical companies like GSK usually argue that a relative risk of 2.0+ correlates to the "preponderance" of evidence which is required for legal proceedings.

29. Indeed, on December 4, 2006, the American College of Obstetricians and Gynecologists warned pregnant women and those who were planning for pregnancy that they should avoid taking Paxil because it can increase the risk of birth defects. ACOG further recommended that women who were already taking Paxil early in their pregnancy should have a fetal echocardiogram to determine what damages had already been done to their babies' hearts.

III. LEGAL THEORIES

FIRST CAUSE OF ACTION

MANUFACTURER'S PRODUCT LIABILITY (STRICT LIABILITY)

30. At all material times, Paxil was defective and unreasonably dangerous by reason of its marketing and inadequate warnings when introduced into the stream of commerce by Defendant GSK, and Defendant GSK is strictly liable for injuries caused by such defects, including all injuries suffered by Plaintiffs and their son, K.H..

31. As a direct and proximate cause of the Defendant's marketing conduct, Plaintiffs Jennifer Hayes and Justin Hayes incurred and will incur damages, including but not limited to the following: emotional distress, medical and medical related expenses, and lost wages.

32. Further, as a direct and proximate cause of the Defendant's marketing conduct, Plaintiffs' child, K.H., has suffered and/or will suffer in the future serious and permanent injury, including but not limited to, medical and medical related expenses, loss of earning capacity, lost wages, physical and mental pain and suffering, and other damages.

WHEREFORE, Plaintiffs Jennifer Hayes and Justin Hayes, individually, and as parents and next friends of K.H., pray for judgment against Defendant GSK for their Second Cause of Action in an amount in excess of Seventy-Five Thousand and No/100 Dollars (\$75,000), plus interest, costs and such other damages as the Court deems appropriate.

SECOND CAUSE OF ACTION
NEGLIGENCE

33. GSK's was negligent in its marketing, labeling, and promoting of Paxil. GSK's negligence was a proximate cause of K.H.'s injuries and of her parents' mental anguish and financial damages, including but not limited to, medical and medical related expenses incurred on behalf of K.H.. Plaintiffs thus sue for GSK's tortious acts of commission and omission, which include but are not limited to design defects, overpromotion, negligent advertising, failure to test, failure to warn, making negligent misrepresentations and/or nondisclosures, and negligence in the conduct of its pharmacovigilance activities, all of which were proximate causes of the injuries to K.H.. Plaintiffs also sue for the negligent infliction of emotional distress on K.H.'s parents, Jennifer and Justin Hayes. GSK's negligence was a proximate cause of these injuries and damages.

34. As a direct and proximate cause of the Defendant's negligent conduct, Plaintiffs Jennifer Hayes and Justin Hayes incurred and will incur damages, including but no limited to the following: emotional distress, medical and medical related expenses, and lost wages.

35. Further, as a direct and proximate cause of the Defendant's negligent conduct, Plaintiffs' child, K.H., has suffered and/or will suffer in the future serious and permanent

injury, including but not limited to, medical and medical related expenses, loss of earning capacity, lost wages, physical and mental pain and suffering, and other damages.

WHEREFORE, Plaintiffs Jennifer Hayes and Justin Hayes, individually, and as parents and next friends of K.H., pray for judgment against Defendant GSK for their Second Cause of Action in an amount in excess of Seventy-Five Thousand and No/100 Dollars (\$75,000), plus interest, costs and such other damages as the Court deems appropriate.

THIRD CAUSE OF ACTION

DECEPTIVE TRADE PRACTICES

36. GSK's conduct in misrepresenting, misleading, and nondisclosure of the dangers inherent in the use of Paxil and subsequent sale to consumers such as Plaintiffs constitutes a violation of Oklahoma's Consumer Protection Act. OKLAHOMA ST. T. 15 § 753(A)(5, 20).

37. As a direct and proximate cause of the Defendant's deceptive trade practices, Plaintiffs Jennifer Hayes and Justin Hayes incurred and will incur damages, including but no limited to the following: emotional distress, medical and medical related expenses, and lost wages.

38. Further, as a direct and proximate cause of the Defendant's deceptive trade practices, Plaintiffs' child, K.H., has suffered and/or will suffer in the future serious and permanent injury, including but not limited to, medical and medical related expenses, loss of earning capacity, lost wages, physical and mental pain and suffering, and other damages.

WHEREFORE, Plaintiffs Jennifer Hayes and Justin Hayes, individually, and as parents and next friends of K.H., pray for judgment against Defendant GSK for their Third Cause of Action for damages in an amount in excess of Seventy-Five Thousand and No/100 Dollars (\$75,000), plus interest, costs, attorney fees, treble damages and such other damages

as the Court deems appropriate.

FOURTH CAUSE OF ACTION
BREACH OF WARRANTY

39. GSK's conduct also constitutes a breach of the express warranties that are created by law by virtue of its affirmations, promises, and descriptions of Paxil as being appropriate for pregnant women, as well as the implied warranties of merchantability and fitness for a particular purpose. OKLAHOMA ST. T. 12A § 2-313, § 2-314, and § 2-315. Taylor K.H. is a third party beneficiary of these warranties. OKLAHOMA ST. T. 12A § 2-318.

40. As a direct and proximate cause of the Defendant's breach of warranty, Plaintiffs Jennifer Hayes and Justin Hayes incurred and will incur damages, including but not limited to the following: emotional distress, medical and medical related expenses, and lost wages.

41. Further, as a direct and proximate cause of the Defendant's breach of warranty, Plaintiffs' child, K.H., has suffered and/or will suffer in the future serious and permanent injury, including but not limited to, medical and medical related expenses, loss of earning capacity, lost wages, physical and mental pain and suffering, and other damages.

WHEREFORE, Plaintiffs Jennifer Hayes and Justin Hayes, individually, and as parents and next friends of K.H., pray for judgment against Defendant GSK for their Third Cause of Action in an amount in excess of Seventy-Five Thousand and No/100 Dollars (\$75,000), plus interest, costs and such other damages as the Court deems appropriate.

FIFTH CAUSE OF ACTION
PUNITIVE DAMAGES

42. At all material times, Defendant GSK's conduct in its promoting, selling,

marketing and as otherwise set forth hereinabove in regard to Paxil demonstrated a reckless disregard for the health, safety, and welfare of others, including Plaintiffs and their son, K.H.. As such, Plaintiffs are entitled to recover punitive damages against Defendant GSK.

No Election or Waiver

43. The facts, circumstances and claims set forth above are pled cumulatively and alternatively, with no election or waiver of remedies until such time as the trier of fact has decided disputed issues of fact.

Jury Demand

44. Plaintiffs hereby exercise their constitutional right to trial by jury.

Damages

45. As a direct and proximate result of defendant's negligence, Plaintiff K.H. suffered injuries and damages, including but not limited to:

- a. Physical pain and mental anguish in the past and future.
- b. Damage to earning capacity.
- c. Disfigurement in the past and future.
- d. Physical impairment in the past and future.
- e. Medical expenses in the past and future.

46. As a direct and proximate result of defendant's negligence, Plaintiffs Jennifer and Justin Hayes suffered damages, including but not limited to:

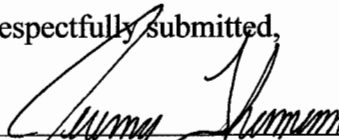
- a. Mental anguish in the past and future.
- b. Loss of consortium in the past and future.
- c. Medical expenses in the past and future.
- h. Loss of household services in the past and future

Prayer

47. WHEREFORE, Plaintiffs ask for judgment against defendant for the following:

- a. Actual and punitive damages in an amount to be proven at trial.
- b. Prejudgment and post-judgment interest.
- c. Costs of suit.
- d. All other relief the Court deems appropriate.

Respectfully submitted,



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