

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA**

SHANNON and KIMBERLY DISMUKE
Individually, and as Next Friends of
TAYLOR DISMUKE, A Minor
Plaintiffs,

vs.

SMITHKLINE BEECHAM CORP., d/b/a
GLAXOSMITHKLINE,
Defendant



CIVIL ACTION NO. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Shannon and Kimberly Dismuke file this suit against Smithkline Beecham Corporation, d/b/a GlaxoSmithKline. For cause of action, Plaintiffs would show the Court and Jury the following:

Nature of the Case

1. In this diversity jurisdiction, personal injury case Plaintiffs are seeking damages for personal injuries sustained by their daughter Taylor who was born with serious heart malformations as a result of the fact that her mom, Kimberly Dismuke, took GSK’s medication “Paxil” during the first trimester of her pregnancy.

Parties

2. The minor plaintiff Taylor Dismuke is a child who was born in Greenville, South Carolina on November 7, 2000. Plaintiffs Shannon and Kimberly Dismuke are her parents. All three are citizens of South Carolina.

3. Defendant Smithkline Beecham Corporation, d/b/a “GlaxoSmithKline” [hereinafter “GSK”] is a Pennsylvania corporation with headquarters 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.”

Jurisdiction and Venue

4. Jurisdiction is based on diversity of citizenship. 28 U.S.C. §1332. The amount in controversy is substantially in excess of Seventy Five Thousand Dollars (\$75,000), exclusive of interest and costs. The actions giving rise to this cause of action happened in this District, and GSK transacts business in, and is “found” throughout the State of South Carolina. Therefore, venue is appropriate in this district. 28 U.S.C. §1391.

Facts

This suit has been necessitated by the following facts:

Prozac - the First SSRI

5. 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).

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

Paxil – the Potential Teratogen

7. 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.

8. 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 child bearing age, to women who were trying to conceive, and, amazingly, even to pregnant women.

9. Paxil is a potential human teratogen, which is to say, it is certainly “associated” with, and, in reasonably 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.

10. GSK was on actual or constructive notice of the potential teratogenic effects of Paxil long before Kimberly Dismuke conceived her daughter Taylor. 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 Shannon Dismuke conceived Taylor.

11. Any reasonable, responsible company should have taken immediate and forceful steps to protect future patients and their as yet unconceived children. Thus, it is specifically alleged that, long before Shannon conceived Taylor, a reasonable pharmaceutical company in the same or similar circumstances as GSK was in 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.

An Innocent Child with a Malformed Heart¹

12. Kimberly and Shannon Dismuke were excited. Twenty-seven weeks into her pregnancy, Kimberly was having her ultrasound. An image produced by high frequency sound waves would introduce Kim and Shannon to their baby. As the gender was identified, their references to “it” would now be “he” or “she”. During the ultrasound, they found out that the “it” would now be “she”. A little girl. A little girl they would name Taylor.

13. But their excitement was short lived. There was a problem. The flow of blood through Taylor’s heart and lungs didn’t look quite right. The configuration of the large vessels of her tiny heart wasn’t normal. Instead of originating in two separate chambers of her heart, Taylor’s pulmonary artery and aorta had a common origin, or “trunk.” Kim and Shannon were told that this mixed the oxygen-depleted blood in her right ventricle with the freshly oxygenated blood in her left ventricle. Additionally, there was a sizeable hole in the wall that separated those two chambers. The net result of the mixing of the blood from the veins with that in the arteries would be to reduce the amount of oxygen available for Taylor’s tissue, organs and cells.

14. The advance warnings from these ultrasound findings allowed Kim to give birth to Taylor under the best conditions possible. An induction of labor was scheduled in a special hospital in Charleston, South Carolina. It had a special pediatric cardiology intensive care unit.

15. When Taylor was born on November 7, 2000, predictably her oxygen levels were low. She was immediately transferred to the ICU. Nine days later she had her first open heart surgery. Her doctors—using plastic tubing and part of a pig’s

¹ Long prior to the filing of this suit, Kimberly’s and Taylor’s medical records were provided to counsel for GSK. Therefore, it is anticipated that GSK has ample information to comply with its obligation under Rule 8(b), Fed.R.Civ.P., to either admit or deny these specific averments.

heart—reconfigured her heart to decrease the mixing of the blood from her veins with that from her arteries. They also repaired the hole in her heart.

16. Initially, the surgery helped Taylor. But in the first several months of her life her doctors noticed that one of her heart valves wasn't functioning properly. They also noted that one of her chambers had become enlarged. This necessitated a second heart operation.

17. At nine months of age, Taylor had her second open-heart procedure. More plastic tubing. More reconfiguration. But this time her truncal valve was replaced with an artificial valve called a St. Jude prosthesis. That frightened Kim and Shannon beyond words. (St. Jude is the patron saint of hopeless causes).

18. Taylor is now six years old and is clinically stable. There have been frequent visits to the emergency room because of periodic problems she has with being under-oxygenated. She's medicated. She's monitored. And, for the most part, she is leading a relatively normal life for a child her age. But her life will be far from normal.

19. Because Taylor has artificial hemodynamics—unnatural flowing and pumping of blood through the heart—she's at risk for clotting. That means the possibility of heart attack, stroke and pulmonary embolism. She is now being anti-coagulated and in the future will have to take prescription blood thinners to protect herself. Because of the side effects of these drugs, she will have to restrict her activities to those which involve no contact. That means no basketball, no softball, no volleyball, no cheerleading, no roller skating and no skiing. Worse yet—much worse yet—another side effect of these blood thinners is that they're destructive of fetal tissue. They are also in a class of drugs called “TERATOGENS”, which literally translates to “monster makers.”

20. Taylor will be on these drugs all of her life. She will never be able to

have children. The same drugs that are essential to protect her life would be devastating to any child in her womb. Therefore, her doctors have advised that Taylor will have to be sterilized soon after she goes through those biological changes which signal the onset of womanhood.

21. Because she is a growing child and will continue to grow for some time, Taylor will have to have additional open-heart surgeries in the future. As her body and her heart grow in size, the tubing, conduits and artificial valves will remain the same size. They will have to be replaced.

22. A summary of present and future problems which can be reasonable anticipated for Taylor would include the following:

- a. Anti-coagulant medication for life.
- b. Sterilization because of her medication.
- c. Restriction on physical activities because of her medication.
- d. Necessity for antibiotic coverage before any dental procedure.
- e. Necessity for antibiotic coverage before any gastrointestinal procedure.
- f. Necessity for antibiotic coverage before any urinary procedure.
- g. Even under the best of circumstances, multiple future open-heart surgeries.
- h. Constant medical monitoring and supervision.
- i. Inability to obtain medical insurance.
- j. Limitations on her employability and a concomitant reduction of earnings potential.

23. Taylor Dismuke will be at risk her entire life. Her medical care will be enormously expensive—even if everything goes well for her. She will never have her own children and will be tiptoeing through life trying to avoid contact of any kind,

infections of any magnitude and any situation which would require increased cardiac output. All because of a pill that her mother was encouraged to take during her pregnancy.

Paxil Is the Most Likely Cause of Taylor's Heart Malformation

24. Neither Shannon nor Kimberly Dismuke have any family history of birth defects. Nor was Shannon exposed to any other potential teratogen during her pregnancy. Moreover, genetic testing on her parents and on Taylor herself have “ruled out” any chromosomal predisposition towards birth defects.

25. If Paxil is teratogenic, as herein alleged, then, without question, it is the most likely or most probable explanation for Taylor heart malformation.

GSK Belatedly Warns About the Teratogenic Potential of Paxil

26. 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. [PF, correct?] 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. *See e.g. Daubert II.*² Therefore, the preponderance of evidence, from GSK's own studies, as well as other scientific evidence, suggests that Paxil is, indeed, a teratogen.

27. 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

² *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir.), cert. denied, 516 U.S. 869 (1995).

pregnancy should have a fetal echocardiogram to determine what damages had already been done to their babies' hearts.

Legal Theories – Causes of Action

The foregoing facts and circumstances are legally cognizable under one or more of the following theories of law which are well-recognized in South Carolina.

28. FIRST: Strict Liability. South Carolina adopted strict liability in 1974 via legislative enactment. S.C. Code § 15-73-10 et seq. GSK is in the “business of selling” Paxil, and, due to its teratogenetic potential, Paxil is in a “defective condition unreasonably dangerous to the user or consumer” within the meaning of the statute. The Paxil which Kimberly Dismuke took reached her without substantial change in its condition. Therefore, GSK is strictly liable. Indeed, this case exemplifies the rationale for strict liability. There is something about GSK’s product Paxil that enables it to cause birth defects. GSK has made literally billions of dollars promoting this medication. GSK is the one in the best position to take measures to protect the public against the teratogenicity of Paxil and the one in the best position to bear the financial brunt of Taylor Dismuke’s injuries. Accordingly, GSK should be strictly liable, without regard to fault.

29. SECOND: Negligence. GSK’s conduct is unreasonable and/or negligent, and was a proximate cause of Taylor Dismuke’s injuries and of her parents’ mental anguish and financial damages. Plaintiffs thus sue for GSK’s tortious acts of commission and omission, which include but are not limited to design defects, overpromotion, negligent advertizing, 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 Taylor Dismuke. Plaintiffs also sue for the negligent infliction of emotional distress on Taylor’s parents Shannon and Kimberly Dismuke. GSK’s negligence

was a proximate cause of these injuries and damages.

30. THIRD: Unfair Trade Practices. 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 South Carolina's Unfair Trade Practices Act, § 39-5-10 et seq., as well as the federal consumer protection act. Because the GSK's conduct has been repeated on countless occasions and/or is capable of repetition it is, therefore, specifically cognizable under the South Carolina Unfair Trade Practices Act. Also, because the GSK knew or should have known that its conduct was violative of the South Carolina Unfair Trade Practices Act, the Court should treble the damages.

31. FOURTH: Breach of Warranty. 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. S.C. Code §§ 36-2-313 – 36-2-315. Taylor Dismuke is a third party beneficiary of these warranties. §36-2-318.

Damages and Remedies

32. Plaintiffs sue to recover all of their common law and statutory damages, both for themselves and for Taylor. Obviously, the financial damages alone are in the millions of dollars. The *ad damnum* will be particularized upon request.

33. Under South Carolina negligence law, a company that acts in a reckless, willful, or wanton manner may be liable for punitive or exemplary damages. The South Carolina Court of Appeals recently elaborated that, “[w]hen evidence exists that suggests a defendant is aware of a dangerous condition and does not take action to minimize or avoid the danger, sufficient evidence exists to create a jury issue as to whether there is clear and convincing evidence of ‘willfulness’ for purposes of

awarding punitive damages.”³The evidence of GSK’s awareness of the teratogenic potential of Paxil is alleged, on information and belief, to be “clear.” Whether it is “convincing” is, of course, up to the jury. Therefore, if, at the end of the day, clear and convincing evidence demonstrates that GSK acted with this requisite degree of culpability at or prior to the time that Taylor was conceived, and that this conduct contributed to Taylor Dismuke’s birth defects, then Plaintiffs seek punitive or exemplary damages in an amount to be determined by the jury.

34. Plaintiffs seek treble damages, attorneys fees, and costs of suit, for GSK’s misrepresentations and/or deceptive acts or practice in accordance with S.C. Code § 39-5-140. Plaintiffs are also entitled to recover prejudgment interest, attorneys fees, damages, and costs of court.

No Election or Waiver

35. 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

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

³ *Mishoe v. QHG of Lake City, Inc.*, 366 S.C. 195, 621 S.E.2d 363 (S.C.App.,2005).

WHEREFORE, Plaintiffs pray that GSK be cited to appear and answer herein, and that, following trial, they recover such monetary damages and other relief as is appropriate under the law.

Respectfully submitted,

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