

CAUSE NO. GN301745

STEVE AND LINDA BALAS,	§	IN THE DISTRICT COURT OF
INDIVIDUALLY and as	§	
PERSONAL REPRESENTATIVES of	§	
the ESTATE of BRIAN BALAS,	§	
DECEASED; and	§	
DARLENE BALAS, INDIVIDUALLY,	§	
and as NEXT FRIEND of	§	
CHASE LOGAN HOELSCHER,	§	
AERIAL ELIZABETH HOELSCHER,	§	
and LAUREN PAGE HOELSCHER	§	
	§	
vs.	§	TRAVIS COUNTY, TEXAS
	§	
SMITHKLINE BEECHAM	§	
CORPORATION a/k/a	§	
GLAXOSMITHKLINE,	§	
CRC HEALTH CORPORATION d/b/a	§	
STARLITE RECOVERY CENTER, and	§	
HERBERT C. MUNDEN, JR., M.D.	§	200TH JUDICIAL DISTRICT

PLAINTIFFS' FIRST AMENDED PETITION

Now come Linda and Steve Balas, Individually and as Personal Representatives of the Estate of Brian Balas, Deceased, and Darlene Balas, widow of Brian Balas and mother of his three step-children named above, and jointly file this suit against the above named defendants seeking justice for the personal injuries to, and wrongful death of, Brian Thomas Balas.

Nature of the Case and Discovery Level Required

1. This is a products liability, personal injury (survival) and wrongful death case arising out of the tragic death of Brian Balas on or about March 13, 2003 in Kerr

County, Texas. At the time of his death Brian Balas was under the influence of the powerful, serotonergic, psychotropic drug Paxil, which is manufactured and marketed by the Defendant GlaxoSmithKline. Discovery in this case should be conducted under Level 3, pursuant to Rule 190.4, Texas Rules of Civil Procedure.

Parties

2. Plaintiffs Linda and Steve Balas are the parents of Brian Balas and the Personal Representatives of his Estate. They have standing to pursue both the Survival claims and their own Wrongful Death claims. Plaintiff Darlene Balas is his widow and the mother of his three step-children, Chase Logan Hoelscher, Aerial Elizabeth Hoelscher, and Lauren Page Hoelscher. She and her children have standing to seek Wrongful Death damages.

3. Defendant SmithKline Beecham Corporation, formerly known as SmithKline Beecham Corporation and SmithKline Corporation and a/k/a Glaxo SmithKline [hereinafter GSK] is a Pennsylvania corporation doing business in the State of Texas. It manufactures and markets a serotonergic, psychoactive medication called Paxil. GSK may be served with citation through its registered agent for service of process: Corporation Service Company, 800 Brazos, Austin, Texas 78701.

4. The Defendant CRC Health Corporation does business in Kerr County, Texas under the name of Starlite Recovery Center. It is a foreign corporation and pursuant to Tex. Civ. Prac. & Rem. Code §17.044, the Texas Secretary of State is the

proper agent for service on this Defendant because CRC Health Corporation d/b/a Starlite Recovery Center has engaged in business in Texas, does not have a designated agent for service of process in Texas, and the lawsuit arises out of the actions of Defendant in Texas. This court has specific jurisdiction because the Plaintiffs' claims arise out of contacts this Defendant maintains with the State of Texas. The Texas Secretary of Service may serve this suit on Defendant CRC at their Office located at 105 N. Bascomtic, 2nd Floor, San Jose, CA 95128.

5. The Defendant HERBERT C. MUNDEN, JR., M.D., is a duly licensed practicing physician in the State of Texas and at the time of the incident in question, he was the Medical Director of Starlite Recovery Center. He may be served with citation by serving him at 19435 Burnet Road, Suite 114, Austin, Texas 78758.

Jurisdiction and Venue

6. The amounts sought for damages are within the jurisdictional requirements of this Court. Venue is proper under the provision of §15.002, Texas Civil Practices and Remedies Code.

Facts

It has become necessary to file this suit as a result of the following facts.

Serotonin, Suicide and Aggression

7. Serotonin, which is commonly identified in scientific literature as “5HT,” is an important and naturally occurring chemical which is found in the brain and throughout other parts of the human body. It is one of a number of informational chemicals in brain called “neurotransmitters.” Among other things, it is widely believed in the scientific community that this brain chemical is some how and in some way related to mood. However, it also affects inhibition, self-control, impulse, and aggressiveness.

8. Some years ago, it was reported from a series of autopsies that people who had committed suicide seemed to have lower levels of the serotonin metabolite, 5HIAA, in the synaptic clefts of their brains than people who had died of other causes. From this somewhat facile observation, researchers postulated that, if a drug could be devised which would increase the serotonergic levels in the brain, that it might enhance mood, and, thereby, reduce depression.

9. This hypothesis lead to the development of an entire class of drugs called “selective serotonin reuptake inhibitors” or “SSRI’s” which have been marketed in this country with extraordinary commercial success. The first such drug licensed by the FDA as an antidepressant was Prozac, which has become a virtual household word in America. GSK’s Paxil is also a highly commercialized and successful SSRI.

10. The manufacturers of SSRI drugs have marketed them as if they were highly selective medicines with rifle-like precision and the ability to treat a host of maladies with one simple pill. For example, in addition to the original indicated use as an antidepressant, Paxil has now been approved for, and is widely advertised in direct-to-consumer television ads, as a psychoactive treatment for “social anxiety” and other anxiety disorders.

11. The marketing of these drugs has capitalized on a popular notion that some undesirable human behavior is caused by a “chemical imbalance.” However, neither GSK nor any of the other SSRI manufacturers can tell us what constitutes a proper chemical **balance** of serotonin in the brain. Thus, the truth is that Paxil and its serotonergic cousins lie somewhere on the continuum between “magic bullets and snake oil.” Healy, *THE ANTIDEPRESSANT ERA* (Harvard Press, 1998) at p.4.

12. Put another way, Defendant GSK simply does not know exactly how or why Paxil elevates the mood of some individuals. They just know that the drug works well to a “statistically significant” degree in a population of depressed patients.

First Alarms – in the Public Eye

13. Eli Lilly & Company secured FDA approval to market **PROZAC** as an antidepressant in the Fall of 1987, and launched the drug into the US market in early 1988. By early 1990, the potential for **PROZAC**-induced suicidality was raised in the

public forum via the publication of an article by two highly respected Harvard psychiatrists, one of whom had been a clinical investigator for **PROZAC**. The article, entitled “*Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment*,” was coauthored by Drs. Martin Teicher and Jonathan Cole, along with Nurse Carol Glod, and was published in volume 147:2 of the American Journal of Psychiatry. Subsequent to this, the issue of whether SSRI drugs cause or trigger violent or suicidal behavior has received significant attention, both in professional journal articles and in the popular press.

14. In the year following publication of the Teicher, Cole & Glod article, a prominent suicidologist and neuro-psychopharmacologist, Dr. J. John Mann, coauthored a paper with his colleague Dr. Kapur, in which they discuss the phenomenon of iatrogenic suicide and postulate that there may well be a “small vulnerable subpopulation” of patients for whom these drugs pose a paradoxical risk of suicide or aggression. Dr. Mann was subsequently hired by GSK as an expert witness in the Paxil homicide/suicide case of *Tobin v. SmithKline Beecham*, discussed below.

15. In his 1991 paper, and again in 1992, Dr. Mann laid out four study protocols which could be used by the SSRI manufacturers to test the hypothesis that the SSRI drugs pose a risk of violence and suicide for a “small vulnerable

subpopulation” of patients. The tests would have either proven or disproven the causal relationship. However, as noted below, neither GSK nor any of the other SSRI manufacturers chose to conduct these prospective tests. Nor has GSK bothered to publish the one internal study that it did regarding Paxil and aggression.

16. Following one of the test designs laid out by Dr. Mann, Lilly drafted a “rechallenge” protocol to test the hypothesis. Patients to be included in the study were those who fit the unique, signature pattern of the phenomenon as observed by Lilly scientists.

17. At the time Lilly recognized the attributes of this distinct phenomenon and devised the rechallenge protocol, Dr. David Wheadon was a Lilly employee and listed clinical investigator for the proposed study. He subsequently became employed by GSK, where he now serves in an extremely high executive level capacity. Thus, when GSK acquired the substantial talents of Dr. Wheadon, they also fell heir to his knowledge about this latent danger posed by the SSRI drugs for a “small vulnerable subpopulation” of patients.

18. In the decade plus since the original Teicher article came out, there has been a host of other, peer-reviewed scientific literature linking the SSRI drugs to violence – both self-directed and other directed. For example, in the year 2000 a peer reviewed article was published by Donovan and colleagues reporting on an

epidemiological study, funded in part by both Eli Lilly and SmithKline Beecham (GSK's predecessor). The article reports that, to a statistically significant degree, with a "*p*-value" of .001, the incident of deliberate self-harm of people on SSRI medications is 5.5 times higher than that of people on the more traditional tricyclic antidepressants. Donovan, et.al., "*Deliberate Self-Harm and Antidepressant Drugs: Investigation,*" British J. Psych. 2000 Dec; 177 (6): 551-56, table 3.

19. In June of that same year, the latest edition of the Diagnostic and Statistics Manual, *i.e.* the DSM-IV-TR was published. Section 333.99 of that revision lays out the causal link from SSRI drugs to akathisia and thence to either violence or suicide.

20. Despite the scientific evidence, however, neither GSK nor any of the other SSRI manufacturers have conducted any prospective, double-blind studies designed to determine causation (one way or the other) or to measure the incidence rate of this phenomenon. Nor have they issued specific warnings designed to apprise the prescribing medical community or the ingesting public that this latent danger inheres in their medications.

Hidden Internal Studies

21. On or about October 3, 1990 a representative of the FDA asked Dr. Thomas Donnelly at GSK “to submit a detailed response to the public’s concern” about SSRI induced violence/suicide.”

22. Apparently unknown to or unrecognized by the FDA was the fact that, hidden in the voluminous NDA submission for paroxetine and masked in statistical mishmash, in its November 1989 submission to the FDA, in support of its NDA for paroxetine, Beecham Laboratories (GSK’s precursor) had listed a number of different episodes of violent and/or suicidal acts which its own investigators and the company had determined to be either “definitely” or “probably” causally related to the patient’s ingestion of Paxil.

23. Plaintiffs are uncertain about the extent of GSK’s internal studies or its reporting to the FDA concerning them. What they do know for fact, however, is that on or about June 28, 1999, GSK finalized and reviewed an internal study concerning Paxil’s association with aggression, both self and other directed. The study was subsequently revised. In this study, GSK recognized two very important things. First, it acknowledged that “the single best predictor of aggression is a prior history of aggression.” This is extremely important in the context of this case because Brian Balas had absolutely no history of aggression towards others or himself before he

ingested Paxil. Second, GSK realized that “aggressive behavior exhibited by patients with no history of suicide attempts is related to altered serotonergic function.” Obviously, this, too, is important because Paxil is specifically designed to alter a person’s serotonergic functioning.

24. Other significant findings in the Aggression Study include a common pattern of violence occurring in patients who had both alcohol and Paxil. This is significant because Paxil (a) reduces the inhibitions of people so that they are more prone to drink, and (b) potentiates the effects of the alcohol when they do.

25. The Aggression Study reported 25 different incidents involving homicide by patients on Paxil. Of these, six – like Brian Balas – killed themselves after assaulting another person. One of the six patients who killed someone else and then themselves was a man named Donald Schell from Gillette, Wyoming. Mr. Schell had absolutely no prior history of violent behavior. But after two days on Paxil, he shot and killed his wife, his daughter, his granddaughter, and then himself.

Paxil Causes Homicide and Suicide

26. On June 6, 2001, an eight person jury rendered its verdict in the case of *Tobin v. SmithKline Beecham*, Civil Action No. 00-CV-0025-Bea, in the United States District Court for the District of Wyoming. The jury found that “Paxil can cause some individuals to commit suicide and/or homicide.” [Question 1]. It also found that Paxil

had caused this same man, Donald Schell, to kill his family and then himself. (The jury also found GSK's precursor company at "fault" for failing to test and to warn. [Question 3]).

27. Prior to the trial, the *Tobin* Court had rejected GSK's claim that there is no scientifically reliable, legally admissible evidence linking Paxil to homicide and suicide. After the trial, the Court promptly court entered Judgment on the verdict. Subsequently, it denied GSK's motion for new trial, reaffirming its prior decision that there is, indeed, scientifically reliable, legally admissible evidence of causation. *Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F.Supp.2d 1278 (D.Wy. 2001). Since that time, at least two other federal district courts have rejected similar *Daubert* based challenges by an SSRI manufacturer.

28. Because of the *Tobin* verdict, GSK is and should be collaterally estopped to deny either (a) that Paxil can, indeed, cause some individuals to commit suicide and/or homicide, and (b) that it is at "fault" for failing to warn and failing to test.

Identifying the "Small Vulnerable Subpopulation" at Risk

29. No one knows for sure just what genetic or other factors may predispose some patients to the risk of SSRI-induced violence about which Dr. Mann and others have written. But the SSRI manufacturers like GSK do have one very major **clue**. Unfortunately, instead of using that clue to develop screening tests, which could be

widely employed to weed out at-risk patients before they took the drug, GSK and its SSRI cohorts have suppressed this information.

30. The clue is that there is a segment of the general population, approximately 8 to 11% in size, which simply cannot metabolize these drugs in an effective manner. The reason is because they have a genetic problem relating to the cytochrome P450 isoenzyme P450IID6 that metabolizes Paxil.

Drug Marketing and Promotion

31. All of the manufacturers of serotonergic antidepressants, including GSK, have aggressively marketed these drugs. The marketing efforts within the medical community have focused on primary care doctors, who constitute the majority of prescribers for such drugs. These doctors typically do not have expertise in either human behavior or brain chemistry/psychopharmacology, and, yet, they have been encouraged by the manufacturers of the serotonergic drugs to believe that they can diagnose depression, and treat it with serotonergic drugs.

32. One of the things that has made these marketing efforts so successful is that the SSRI and other new serotonergic drugs are not particularly inherently toxic. That is to say that it is extremely difficult for a person to kill themselves via an overdose of such drugs. For this reason, until the Donovan article referenced above came out, it was relatively easy for the purveyors of the SSRI's to portray them as less

likely to contribute to suicidal behavior, which is, obviously, a potential concern for any depressed patient.

33. In spite of this fact, the only “precautions” given by any of the SSRI manufacturers in their package inserts about suicide tells physicians not to prescribe too many pills at one time. This “precaution” is extremely misleading because it gives the prescribing physician a false sense of security.

34. Dr. Martin Brecher of the FDA recognized the problem when, in 1991, he commented on Eli Lilly’s proposed protocols to study the question of whether fluoxetine (Prozac) causes suicide as follows:

I am skeptical whether dichotomizing on the basis of the presence or absence of poisoning with an antidepressant will provide any insight regarding possible fluoxetine associated suicidality. **Most of the fluoxetine suicides have not been by overdose, but rather by gunshot, jumping, hanging or drowning.**

FDA memorandum dated February 26, 1991. (This is the same man who, four months before, on October 3, 1990, had asked GSK’s precursor to “submit a detailed response to the public’s concern” about “violence-ideation and suicide-ideation” of patients taking Paxil.) Like many of these people, Brian Balas used a gun to shoot an innocent young child and then to take his own life.

The Role of the FDA and the Legal/Factual Consequences of Same

35. Like all manufacturers of pharmaceuticals, GSK's manufacture and marketing of Paxil is "regulated" by the FDA. Most of the courts which have addressed the issue have realized that, because the FDA standards are only "minimum" goals, and because the Supreme Court has specifically held that the regulation of product safety via products liability litigation is a matter of state prerogative, that a drug company's approval by the FDA or compliance with FDA standards or regulations—including FDA approved labeling—is not dispositive of any legal issues. Compliance or non-compliance, is evidentiary, and, indeed, non-compliance might, under applicable state law, even rise to the level of negligence *per se*.

36. But, although the Paxil label has been approved by the FDA, in fact, GSK has violated FDA regulations about warnings. Specifically, 21 CFR §201.57 provides that drug product "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." Another regulation permits a drug company to strengthen a warning without waiting for FDA approval. GSK has failed to do this, particularly with regard to the dangers of SSRI induced violence and suicide.

37. For years there has been “reasonable evidence of an association” between serotonergic drugs and akathisia, the serotonin syndrome, and violence/suicide. And, yet, the drug companies like GSK have taken a cavalier attitude toward that evidence and insisted that, unless/until someone absolutely proves a “causal relationship” via either a randomized clinical trial or large scale epidemiological study, that they will not warn either the physicians or the public about these dangers. Indeed, even **after** the *Tobin* plaintiffs proved the causal relationship to the satisfaction of both Court and Jury, GSK has steadfastly refused to warn physicians, pharmacists or patients that Paxil increases the risk of violence and suicide for a “small vulnerable subpopulation” of patients.

38. This is a particularly unreasonable and pernicious stance to take because, as a practical matter, only the pharmaceutical companies themselves could conduct such studies, and they are not about to conduct tests which could, and likely would, kill the geese that are laying golden eggs.

39. It is against this backdrop of events that the Court and Jury must consider the untimely death of Brian Balas.

The Tormented Last Days and Wrongful Death of Brian Balas

40. Brian Thomas Balas was born on August 25, 1969 in Houston, Texas to Steve and Linda Balas. Brian was a model child through high school and college.

After graduation, he worked for a brief time as an aide to a conservative, Republican congressman. After returning home, Brian worked as a rice farmer, hunting guide and hospital administrator. He was well respected in his community.

41. After the death of his only sibling in 1996, Brian developed panic attacks. He tried to cope with his grief by drinking too much. He struggled with both his grief and his drinking for several years. Significantly, however, at no time during these periods of either drinking or medical treatment did Brian exhibit any violent or aggressive tendencies. At least not before he got Paxil.

42. On September 23, 2000, Brian married Darlene Russell Hoelscher on his parents' ranch in Eagle Lake, Texas. Darlene has three children from a prior marriage who were not fathered by Brian Balas. However, the children were included in the marriage ceremony and Brian was making plans to adopt them prior to the time of his death.

43. On December 19, 2000, Brian was prescribed Paxil by Dr. Jason Baron at West Oaks Hospital in Houston. Apparently the prescription was supposed to help him with alcohol consumption, **not** depression. Therefore, it was an "off-label" use. On information and belief, Plaintiffs allege that GSK has tacitly, if not overtly, encouraged physicians to prescribe Paxil for non-approved or "off-label" uses.

44. Brian took Paxil fairly regularly from December 19th until the time of his death. After he began taking Paxil, Brian began to hallucinate and have other signs and symptoms of a drug-induced psychosis. And, after he took Paxil, this gentle, non-violent man who had even stopped hunting, became violent.

45. Brian fled from his home. His wife and parents tried desperately to retrieve him and to get help for him. Indeed, on or about March 6, 2001, he was brought to Starr County Memorial Hospital after police found him running around town with a knife to his neck and chest. He stated he felt anxious and wanted help. He had been drinking alcohol.

46. Brian was then transferred to the Defendant Starlite Recovery Center in Center Point, Texas where he was treated by the Defendant Munden. Although these defendants were uninformed or ill-informed about the latent dangers of Paxil-induced violence, they should have been aware of Brian's extremely precarious state. They could and should have protected him and others, and were negligent in failing to do so.

47. Brian eloped from Starlite on March 12, 2001. He then began a spree of irrational violence that was totally incompatible with his values, morals, and personality. First, on the next day, he stole an elderly woman's car. He then attacked a 96-year-old woman in her home hitting her on the head with a frying pan while she

was getting him a glass of water. Then, later that afternoon, he randomly shot a 21-year old college student named Julie Beasley with a high powered rifle. Ms. Beasley was out in a field studying mistletoe. Balas shot her in the right arm and left hip and left her to die in the field. Miraculously, through sheer guts and determination, Julie Beasley crawled out to the road, was discovered by police, and – after a harrowing life-flight – she pulled through. Julie Beasley was a complete innocent, and she suffered enormous, life-altering injuries and damages. Indeed, it is a true miracle that she is alive today.

48. After shooting Julie Beasley, Brian took her car and fled the scene. Julie Beasley provided information to the police about the car which he was driving and they gave chase. As the police closed in on him, Brian Balas – son, husband, and father – took his own life. It is clear to all who knew Brian Balas that, in his right mind, he never would have done this.

49. Prior to taking Paxil, Brian Balas had no significant history of psychosis, suicidal ideation or violent behavior. There is no family history of mental illness of any kind. Despite his efforts to detoxify from alcohol in the past and to get treatment for his panic attacks, Brian Balas never exhibited psychotic, suicidal or violent behavior.

Legal Theories and Causes of Action

All of these facts are cognizable under two well-recognized separate theories of law in Texas which support the following two causes of action.

50. FIRST: Defendant GSK is strictly liable under the principles of Restatement (Second) of Torts, §§402A and 402B, and the new Restatement (Third) of Torts, for marketing defects and misrepresentations.

51. SECOND: All three Defendants' conduct is unreasonable, or negligent, and was a proximate cause of Brian Balas' injuries and his ultimate death. The negligence of GSK includes failure to warn, failure to test, failure to implement appropriate patient screening mechanisms, and over-promotion of Paxil. The negligence of Starlite and Dr. Munden was in failing to recognize and treat Brian's psychotic condition and in failing to supervise, monitor, or restrain him for his own protection and safety.

52. As noted above, GSK is collaterally estopped to deny either (a) that Paxil does cause some individuals to commit suicide and/or homicide, or (b) that it is at "fault" under the law for failing to warn and failing to test.

Damages and Remedies

53. Plaintiffs sue under the Texas Survival Statute to recover personal injury damages on behalf of Brian Balas from the time of his initial ingestion of Paxil until his

death. The evidence will show that this was an awful, tortured period of time in his life. He was estranged from his family, on the lam, and, much of the time, he was outright psychotic.

54. Plaintiffs also sue under the Texas Wrongful Death Act for wrongful death damages. In addition to his surviving parents and spouse, a claim is made on behalf of his step-children, whom he formally and ceremonially “married” at the same time that he married their mother.

55. The amount of actual damages is alleged to be in the millions, and the *ad damnum* will be particularized on request.

56. As noted above, GSK has acted with full awareness of the fact that, for a “small vulnerable subpopulation” of patients taking its drug, Paxil can be like a death sentence. Its conscious indifference in the face of that knowledge, particularly in the wake of the *Tobin* verdict, warrants imposition of a substantial award of exemplary or punitive damages. Consequently, upon a showing and finding of requisite culpability, Plaintiffs seek appropriate punitive or exemplary damages under the Texas Constitution and other law.

57. Plaintiffs are also entitled to recover prejudgment interest and costs of court.

Jury Demand

58. Plaintiffs hereby invoke their right to trial by jury.

WHEREFORE, Plaintiffs pray that the Defendants be cited to appear and answer herein, and that, after a trial, they receive such monetary damages and other relief as is sought herein and appropriate under the law and the facts.

Respectfully submitted,

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