

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
WESTERN DIVISION

DANIEL AND CELESTE STEUBING, §  
Individually and as Personal §  
Representative of the Estate of §  
MATTHEW STEUBING, Deceased, §  
Plaintiffs, §

vs. §

FOREST LABORATORIES, §  
Defendant. §

CASE NO. \_\_\_\_\_

JURY TRIAL DEMANDED

**COMPLAINT**

Now comes Daniel and Celeste Steubing, individually and as personal representatives of the Estate of Matthew Steubing, deceased, and file this suit against Defendant Forest Laboratories, complaining about the personal injuries to, and wrongful death of, Plaintiffs' son Matthew Steubing.

**Nature of the Case**

1. This is a South Carolina diversity, products liability, personal injury and wrongful death case arising out of the tragic death of Matthew Steubing on or about July 18, 2003, in Charleston, South Carolina. At the time of his death Mr. Steubing was under the influence of a powerful, serotonergic, psychotropic drug, Lexapro, produced and manufactured by Forest Laboratories.

## **Parties**

2. Plaintiffs Celeste and Daniel Steubing are the parents of Matthew Steubing and personal representatives of his estate. The Steubings are residents of Virginia. At the time of his death, their son Matt was visiting his brother Eric in Charleston.

3. Defendant Forest Laboratories is a pharmaceutical company. It is headquartered in New York, New York. Forest conducts business throughout the State of South Carolina and is, thus, amenable to jurisdiction in this State. It manufactures, and markets two forms of the generic compound CITALOPRAM, both of which are marketed in this country as antidepressants. Forest markets the stereoisomer version of this drug under its trade name Celexa and a single isomer version as LEXAPRO.

## **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 within this District, and the Defendant Forest Laboratories, transacted business and is, thus, “found” throughout the State of South Carolina. Therefore, venue is permissible in this District pursuant to 28 U.S.C. §1391.

## **Facts**

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

### **Serotonin, Suicide and Depression**

6. 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.

7. 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 their cerebral spinal fluid 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.

8. This hypothesis lead to the development of an entire class of drugs called “selective serotonin reuptake inhibitors” or “SSRI’s”. These drugs have been marketed in this country with extraordinary commercial success. The first SSRI drug

licensed by the FDA as an antidepressant was Prozac. It has become a virtual household word in America.

9. Eli Lilly, the manufacturer of Prozac, and its sister pharmaceutical companies like Forest Laboratories, have all marketed the SSRI drugs as if they were highly selective medicines with rifle-like precision and the ability to treat a host of maladies with one simple pill. The marketing of these drugs has capitalized on a popular notion that some undesirable human behavior is caused by a “chemical imbalance.” However, none of the SSRI manufacturers can tell us what constitutes a proper chemical **balance** of serotonin in the brain. Thus, the truth is that Lexapro 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.

10. Put another way, Defendant simply does not know exactly how or why its medication elevates the mood of some individuals, and it has no way to predict how any given individual will respond -- physically or emotionally -- to these powerful psychotropic agents. It just knows that the drug works well to a “statistically significant” degree in a population of depressed patients.

11. Lilly 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.

12. In the decade plus since the Teicher & Cole article, the debate about SSRI-induced suicidality has raged in the scientific literature, the popular media, and in the courts. For a long time prior to Matthew Steubing’s death it has been evident that there is a clear association between SSRI drugs and suicidality, and the antecedent conditions that trigger it. For example, one such antecedent condition is a pernicious neurological condition called “akathisia.” The association between SSRI drugs and akathisia, and, thence, from akathisia to suicidality, is so “generally accepted” that it is even incorporated into the “Bible” of psychiatric diagnoses in this country, *i.e.*, DSM-IV-TR, §333.99.

13. The watershed moment in the civil justice system came on June 6, 2001, when 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 SKB at “fault” for failing to test and to warn. [Question 3]. The *Tobin* court found that there was scientifically reliable, legally admissible evidence linking SSRI drugs to

homicide/suicide and thereby supporting the jury's verdict, entered judgment, and then denied SKB's motion for new trial. *Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F.Supp.2d 1278 (D.Wy. 2001).

14. These and many other developments occurred before Matthew Steubing's death. In light of them, and especially considering the fact that the FDA regulations (which establish only the "minimum safety standards") do not require proof of causality for a warning, but rather, mandate a warning whenever there is an "association" between a drug and a potentially lethal condition, 21 C.F.R. §201.57(e), Forest could and should have issued warnings about Lexapro.

15. However, Forest never did so. On information and belief it is alleged that Forest never warned about the association between its drug and adult suicidality or its antecedent conditions, and never asked the FDA for permission to warn. Pleading further, on information and belief, it is alleged that the FDA never told Forest that it could not warn about Lexapro induced suicidality, or about any precursor side effect, including akathisia, disinhibition or emotional lability, sleep disturbances, mania, hypomania or psychosis or threatened it with any legal proceedings if it did so warn.

16. Lexapro is a powerful psychoactive drug in the same "SSRI" class as Prozac, Paxil, and Zoloft. For years it has been known that serotonin functioning is directly related to aggression and violence, both directed at one's self and at others.

17. Lexapro may help some of the patients who take them. Unfortunately, however, there is a “small vulnerable subpopulation” of patients who are at an increased risk of violence and suicide as a result of taking Lexapro and other SSRI drugs.

18. Forest has known about this small vulnerable subpopulation for years. And, yet, they have failed to conduct any prospective tests to determine the frequency of this phenomenon or to develop means of identifying, screening, and protecting those patients who are in this risk group. It has also utilized material misrepresentations to promote and market its drugs. And, perhaps most importantly, as noted above Forest has also failed to warn prescribing physicians, pharmacists, and patients about this risk or to instruct them on the known ways to reduce or ameliorate the risk.

19. On March 22, 2004, the FDA itself finally realized that the association between these serotonergic medications and suicidality was important enough to merit a warning. It issued a “Public Health Advisory” in which it “recommended,” among other things, that Forest issue a warning about this association viz. a viz. both of its CITALOPRAM drugs, i.e., Celexa and Lexapro. Forest has now complied with this recommendation. Unfortunately, however, this warning was “too little/too late” for the Steubing family.

20. Subsequently, on October 15, 2004, based on its finding that “causality has been established” between SSRI drugs and pediatric suicidality, the FDA has ordered Forest to put

**BLACK BOX WARNINGS**

about Lexapro induced suicidality in the pediatric and adolescent population on the Lexapro label.

21. Separate and apart from the minimum standards of the FDA regulations, South Carolina law requires drug makers like Forest to act reasonably and responsibly, and holds them legally accountable if they fail to do so. Forest could, and should, have taken affirmative steps to warn doctors, pharmacists, and patients about the association between suicidality and its precursor conditions long, long before the FDA made it do so. There are many means that they could have employed to educate people about this risk. One, of course, is via a formal change in the label or “prescribing information.” The FDA regulations specifically permit a company to “add or strengthen” a warning without waiting for FDA approval. Another would have been to do what Wyeth Pharmaceuticals did on August 22, 2003, when it issued a “Dear Doctor” letter to physicians in this country about the increased risk of suicidality for children and adolescents on the serotonergic drug Effexor. Yet another would be via personal advice from its sales staff.

22. There are undoubtedly many other ways that Forest could have “gotten the word out.” That would have been the reasonable and responsible thing to do. That, with respect, is what the South Carolina law requires.

23. But that course of action would have been bad for business. Prozac has now gone generic, and both Paxil and Zoloft are facing “generic intrusion” in the near future. That has created a market opportunity for Forest. In order to penetrate this lucrative market, Forest has promoted and over-promoted both Celexa and Lexapro. They have made material misrepresentations about the safety of these drugs, and have totally failed to warn about the increased risk of suicide. On information and belief, its overpromotion activities include “direct-to-consumer” advertising. Legally, its duty to warn is commensurate with such advertising.

24. In addition to misrepresentations and failure to warn, Forest has also failed to test or investigate. It has not conducted any prospective, double-blind studies designed to determine causation (one way or the other) or to measure the incidence rate of this phenomenon, and neither has it adequately investigated the instance of suicidality of patients taking Celexa or Lexapro.

### **A Word about FDA Regulatory Requirements**

25. Forest has failed to comply with the FDA's warning requirements. Specifically, it failed to issue a warning about the increased risk of suicidality and its precursor conditions in a timely manner, as required by 21 C.R.R. §201.57. This violation of FDA regulations constitutes negligence *per se* under South Carolina law.

26. Additionally, on information and belief, it is alleged that Forest, before and after it manufactured the particular batch of Lexapro that killed Matthew Steubing, withheld from or misrepresented to the FDA required information that was material and relevant to the performance of the drug and was causally related to Matthew Steubing's injuries and death.

27. It is against this backdrop of events that the Court and Jury must consider the untimely death of Matthew Steubing.

28. Under these circumstances, Forest may not hide behind FDA regulation, and the FDA's belated actions or earlier inactions with regard to Lexapro and suicidality, even with regard to the failure to warn theory.

### **The Wrongful Death of Matthew Steubing**

29. Around 9 p.m. on July 17, 2003, Matthew Steubing called his mother Celeste. Matt was supposed to be driving back home to Winchester, Virginia from visiting his brother Eric in Charleston. He told his mom that he was in Roanoke, about three and a half hours from home. He told her he loved her. A few hours later,

Matthew Steubing jumped to his death from the Cooper River Bridge. He was pronounced dead at 3:27 a.m. on July 18, 2003. He was 18 years old.

30. Matthew Steubing loved to play basketball. He had been playing since he was eight years old. He had always dreamed of starting his senior year and hoped to be a star of the team. However, the winter of his senior year didn't turn out like he wanted it to. The coach seemed to favor another player. Matt wasn't getting to play as much as he wanted to. He was very disappointed. He started to appear withdrawn and sad. He lost interest in school and his normal activities. Once a happy and outgoing boy, he was spending more and more time alone on the couch watching television.

31. Matthew's mother Celeste noticed the changes in Matthew and encouraged him to get counseling to talk about his feelings. His counselor suggested that he might benefit from some medication. He saw his family physician on May 13, 2003. After a 15-minute visit, Matthew was handed samples of Lexapro. After only two doses, Matthew was nauseous, couldn't sleep and couldn't go to school. His mother called the doctor and was told to cut Matthew's dose in half for a while. Matthew took 5mg of Lexapro until May 31, 2003 when he returned to a 10mg dose.

32. Matthew exhibited many of the classic side effects caused by SSRI medications like Lexapro. He was restless and paced the floor. He isolated from friends and family. He missed school and quit his job over a disagreement with his

manager. He began to tell his family that people were staring at him and making fun of him. Matthew's family believed that it was the stress of his senior year and graduation that were making him act that way. They were told that Lexapro would help.

33. After Matthew's graduation, he went down to South Carolina to visit his brother, Eric. He spent ten days in Charleston with Eric relaxing and thinking about what he was going to do next. Eric noticed that Matt was restless. Matt also made several strange comments to his brother about people staring at him. Matthew left to return home to Virginia on the morning of July 17, 2003. He hugged his brother goodbye. No one saw him alive again. After nine weeks and three days on Lexapro he jumped from the Cooper River Bridge to his death.

### **Legal Theories and Causes of Action**

All of these facts are cognizable under several well-recognized theories of law in South Carolina as follows:

34. FIRST: Defendant Forest Laboratories are strictly liable for designing and manufacturing a defective product and for marketing it with inadequate and/or legally defective labeling and via material misrepresentations. Restatement (Second) of Torts, §§402A and 402B, and the new Restatement (Third).

35. SECOND: Defendant is liable because Lexapro was defective and potentially harmful to its consumers/users, including Plaintiffs' son, and because

adequate warnings were not provided with the product or after manufacture, and as such was unsafe to an extent beyond that contemplated by an ordinary user and consumer.

36. THIRD: Defendant's conduct is unreasonable, or negligent, and was a proximate cause of Plaintiffs' decedent's injuries and death. The manufacturer was negligent for failing to warn, failing to test or otherwise to investigate the association between Lexapro and suicidality and their precursor conditions, including akathisia, and for misrepresenting and over-promoting both drugs.

37. Under the South Carolina "heeding presumption" case law, there is a rebuttable presumption that Matthew's doctor would have heeded a legally adequate warning from the drug manufacturers. Consequently, in law and in fact, Forest's tortious conduct was a legal cause of Matthew's injuries and death.

### **Damages and Remedies**

38. This suit is brought, *inter alia*, pursuant to the South Carolina Wrongful Death Act, §15-51-20, for the exclusive benefit of Matthew's parents. Plaintiffs seek all damages permitted under this statute and the case law construing it. Plaintiffs may also have a separate cause of action under the Virginia Wrongful Death Act.

39. Additionally, suit is brought under the South Carolina Survival Statute, §15-5-90, to recover damages for the enormous pain and anguish which Matthew himself must have endured prior to his death.

40. The amount of damages is alleged to be in the millions of dollars, and will be particularized upon request.

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

**Jury Demand**

42. Plaintiffs hereby invoke their constitutional right to trial by jury.

WHEREFORE, Plaintiffs pray that Defendant Forest Laboratories be cited to appear and answer herein, and that, after a trial, they receive such monetary damages and other relief, including all other general and special damages allowable by law, as are appropriate under the law and the facts.

DATED this \_\_\_\_\_ day of May, 2005.

Respectfully submitted,

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(Admission *pro hac vice* to be sought)