

Donnel Cross is a resident of Kentucky and Sandra McFadden is a resident of South Carolina. At the time of his death, Mr. Cross was also a resident of Kosciusko, Mississippi.

3. Defendant Forest Laboratories is a pharmaceutical company. It is headquartered in New York, New York. Forest conducts business throughout the State of Mississippi 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 stereo-isomer 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 Mississippi. 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 led 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 Leon Cross' 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 Leon Cross and his 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, Mississippi 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 Mississippi 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 Mississippi law.

26. Additionally, on information and belief, it is alleged that Forest, before and after it manufactured the particular batch of Lexapro that killed Leon Cross, 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 Leon Cross' injuries and death.

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

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 Leon Cross

29. On December 11, 1922, Leon Cross was born in Attala County, Mississippi. Eighty-one years later, he would die a tragic death in the same county.

For fifty-seven of his eighty-one years, Mr. Cross was married to Ella Mae Cross. They had five children during their marriage. One of their children died, and the remaining four are plaintiffs in this case. He had seven grandchildren and one great grandchildren.

For a man his age, Leon Cross was in excellent health. In the late spring of 2004, however, he began experiencing bouts of abdominal pain. After considerable testing, his physicians felt that he had a stricture of his sigmoid colon. They recommended a surgical procedure to him—the removal of the narrowed portion of the colon. But Mr. Cross resisted. He had never had surgery before, and the thought of undergoing an abdominal procedure was frightening to him. Eventually, however, he gave in and the surgery was scheduled.

The combination of the pain he was experiencing and the anticipation of the impending surgery began to take their toll on Mr. Cross. He went to the emergency room of his local hospital and spoke with the emergency room physician. The diagnosis was anxiety/depression and mood disorder, in other words, Mr. Cross was upset about his upcoming surgery. To help him get through this crisis, the emergency room physician prescribed Lexapro, 10 mg, once a day.

Mr. Cross, as instructed, took his Lexapro every day—for three days. Then he killed himself.

Leon Cross had no psychiatric history. Until he took his first Lexapro, he had never taken a psychoactive medication of any kind. He was a farmer, a veteran of World War II and a leader in his community. He was a Deacon in his church for over fifty years, was involved in many church activities and was the president of his Bible study class.

Legal Theories and Causes of Action

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

30. 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).

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

32. 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.

33. Under the Mississippi "heeding presumption" case law, there is a rebuttable presumption that Mr. Cross' 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 Mr. Cross' injuries and death.

Damages and Remedies

34. This suit is brought, *inter alia*, pursuant to the Mississippi Wrongful Death Act, §15-51-20, for the exclusive benefit of Mr. Cross' family. Plaintiffs seek all damages permitted under this statute and the case law construing it.

35. Additionally, suit is brought under the Mississippi Survival Statute, §15-5-90, to recover damages for the enormous pain and anguish which Mr. Cross himself must have endured prior to his death.

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

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

Jury Demand

38. 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 June, 2005.

Respectfully submitted,

Howard Gunn
P.O. Box 157
Aberdeen, Mississippi 39730
Telephone: (662) 369-9844
ATTORNEY FOR PLAINTIFFS

OF COUNSEL:

Andy Vickery
Texas State Bar No. 20571800
Paul Waldner
Texas State Bar No. 20679800
VICKERY & WALDNER, LLP
One Riverway Drive, Suite 1150
Houston, TX 77056-1920
Telephone: 713-526-1100
Facsimile: 713-523-5939
Email: andy@justiceseekers.com
paul@justiceseekers.com
(Admission *pro hac vice* to be sought)