

Selective Serotonin Reuptake Inhibitors: A Critical Look at the Antidepressants and an Assessment of Potential Liability Faced by their Manufacturers

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Abstract

Mental health is a growing and lucrative aspect of health-care. Among the ways of treating mental illness is through use of antidepressant medications, including selective serotonin reuptake inhibitors (SSRIs). This paper will address much of the critical commentary made about the SSRIs, and will consider whether the problems with this class of drugs could result in liability to the manufacturers. Included in the critique of the SSRIs is a look at whether SSRIs, including Prozac, Paxil, Zoloft, Luvox, and Celexa, are linked to violent or suicidal behavior. This paper will also consider the existence and effects of any withdrawal syndrome associated with these drugs. Finally, the paper will consider whether the drugs are over-prescribed, including a look at whether children should be prescribed SSRIs given that little FDA scrutiny has been given to the effects of these drugs on children.

I. Introduction

Mental health issues, and the ability and willingness of those who suffer from mental health problems to seek medical help, have changed drastically in recent years. According to a governmental study of mental health, Americans have achieved a “greater scientific understanding of mental illness” from the 1950s to

1996.¹The same study found that the last half-century has seen “remarkable advances in the understanding of mental health disorders...and in our appreciation of the centrality of mental health to overall health and well-being.”²The stigma and taboo of being designated as “crazy” have been replaced³by widespread acknowledgment that depression and other common mental maladies are legitimate “diseases”. It is notable, however, that some critics of the current mental health system in the United States, including Dr. Peter Breggin,⁴object to the “disease” label being placed on mental health issues.⁵

The increases in education and acceptance of mental health issues appear to create many positive effects, including increased likelihood that those suffering from mental illness will seek professional help.⁶The downside of an increased acceptance of mental health problems as legitimate medical conditions, however, is that the

¹SURGEON GENERAL OF THE UNITED STATES, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL ch. 1, (1999) <<http://www.surgeongeneral.gov/library/mentalhealth/home.html>>.

²*Id.*

³While the medical community generally recognizes the validity of mental health problems as illness, the Surgeon General’s mental health report discusses the still lingering stigma associated with mental problems by the general public. The report stresses that the social and economic impact of stigma can be severe, and notes the importance of eliminating such stigma. Although the public is more educated in general, the study notes that the public has developed, since the 1950s, more of an association between mental illness and violent behavior. The study attributes this fear to media coverage and sensationalizing of violent actions by the mentally ill, and lists the public fear of violence as a primary reason for the remaining stigma against the mentally ill. *Id.*

⁴Dr. Peter Breggin has worked as an expert witness for plaintiffs in several cases against the manufacturers of SSRIs. He has written several books discussing the problems with using these types of medication to treat psychological problems. He is a psychiatrist who attended Case Western Reserve Medical School, went on to become a teaching fellow at Harvard Medical School, and has taught at various other universities. His website may be found at www.breggin.com. See Peter R. Breggin, M.D., THE ANTIDEPRESSANT FACT BOOK 226 (2001).

⁵Dr. Breggin insists that depression should not be categorized as a disease. Instead, he believes it should be characterized as a “natural or normal human response to emotional injury and loss.” He believes that feelings, no matter how extreme, should not be confused with diseases. *Id.* at 14. Despite this view, depression and other common mental health problems are generally known as diseases in medical and layperson circles, and thus they will be referred to as diseases or illnesses throughout this paper.

⁶The Surgeon General’s mental health report states that remaining stigma may keep the rate of those suffering from mental illness who seek medical help lower than it should be. It cites studies from the 1990s claiming that “nearly two-thirds of all people with diagnosable mental disorders do not seek treatment.” Those most affected by the stigma, according to this report, are children and people from rural areas. Despite all of this, the report does affirm that, as compared to the 1950s and 1970s, “people were likelier than in the past to approach mental illness by coping with, rather than by avoiding, the problem.” See SURGEON GENERAL OF THE UNITED STATES, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL ch. 1, (1999) <<http://www.surgeongeneral.gov/library/mentalhealth/home.html>>.

affected parties may often be seeking and/or receiving ineffective or inappropriate help. With the acceptance of mental illness as a disease came the creation of a lucrative market for pharmaceutical products to “cure” the disease. Many of the major pharmaceutical manufacturers have successfully entered this market, and have gone to great lengths to attract consumers for their products.

The problem with treating mental health problems with drugs comes largely from two fronts. First, some mental health professionals and other critics of antidepressant medications feel that addressing the underlying problems, through treatments such as old-fashioned therapy, is the only way to truly help with the problems that manifest themselves as mental illness. These critics are concerned that today’s patients are simply being prescribed very potent antidepressant drugs by general practitioners, rather than trained psychiatrists, who understand neither the depth and nature of the mental illness nor the effectiveness and dangers of the prescribed drugs. This issue will be discussed in greater detail later in this paper, particularly with regard to the issue of over-prescription of antidepressant medications and the growing evidence regarding antidepressant withdrawal symptoms.

A second problem, according to some critics, is that many of the antidepressants do not help the mental health of the patient, and that they in fact are known to actually worsen some conditions.⁷This alleged problem is one that consists largely of competing scientific studies, and questions about the methods and validity of these studies. Given that the FDA and similar agencies around the world have approved many antidepressant drugs, the critics in this area are clearly losing their battle against the antidepressant manufacturers.

In the wake of the described changes in mental health education and perceived problems in curing mental

⁷See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* (2001) (asserting that the antidepressants are powerful stimulants that may cause mania, brain damage, and even depression, as well as other problems).

illness lies many questions concerning the potential liability faced by drug manufacturers to those individuals who are allegedly hurt by antidepressant drugs. This paper seeks to examine these liability issues, with a specific emphasis on the manufacturers of Selective Serotonin Reuptake Inhibitors (“SSRIs”)⁸, which have become some of the most commonly prescribed and lucrative drugs for their manufacturers.⁹I will approach my consideration of these liability issues by separately documenting concerns of three different kinds.

First, there is the question of whether SSRIs cause those who take them to sometimes act violently towards themselves and/or others. This has been the most common claim of plaintiffs against the manufacturers, and I will examine the most important cases and what those cases may mean to the future of such litigation. Second, there is growing concern that the SSRIs may cause a withdrawal syndrome with debilitating side effects for some people who stop taking the drugs. I will examine the research in this area and discuss the prospect of lawsuits, which have actually already begun in the form of class actions and other types of litigation brought by plaintiffs who claim to be suffering from this syndrome.

Finally, and most broadly, I will address the debate over whether the SSRIs are over-prescribed. Those who believe this is the case argue that drug manufacturers are encouraging that their drugs be used to treat a multitude of less serious problems in an attempt to bring everyone, including children, within the umbrella of people who may be prescribed SSRIs and other mental health drugs. Related to this is the concern that doctors who do not have experience or special expertise in mental health issues are regularly diagnosing mental problems and treating them with SSRIs and other antidepressants, whereas mental health experts might decide to treat the problems of the patient with therapy or other means.

⁸The SSRIs include the following drugs: Prozac, Zoloft, Paxil, Celexa, and Luvox. *See id.* at 1.

⁹According to Dr. Breggin’s book, Eli Lilly & Co. claimed that more than 35 million people had taken Prozac as of 2000. Additionally, Prozac produced more than \$2.5 billion in revenue for Eli Lilly & Co. in 1999. Combined 1999 sales of Prozac, Zoloft, and Paxil topped \$4 billion. *See id.*

Supporters of the current method of care, however, claim that increased research and education have enabled those suffering from mental disorders to now seek the kind of help that allows them to live more normal lives. They believe that today's antidepressants are important and safe innovations that respond appropriately to many problems that were previously almost impossible to treat, especially given that very few people can afford personal counseling that is often suggested as an alternative to antidepressant medications.

A. *The Science of SSRIs*

Although this paper does not seek to examine these drugs from a technical medical standpoint, it is important to summarize at a basic level what an SSRI is and what it does. The SSRIs, as the name suggests, “work by blocking the absorption of the brain chemical serotonin, making more of it available to brain cells.”¹⁰ Dr. Breggin, who will throughout this paper be cited as one of the most notable spokesmen against the use of SSRIs, offers a rather understandable summary of the workings of SSRIs:

“Serotonin is a neurotransmitter or chemical messenger that is released by one nerve cell or neuron to make another neuron fire. The serotonin is released into the synapse or space between the neurons. In the natural course of events, the serotonin is then chemically destroyed or reabsorbed back into the cell that originally released it. But SSRI antidepressants block the reabsorption (reuptake) of the serotonin, causing an excess amount of serotonin to accumulate in the synapse. With more serotonin in the synapse, the theory suggests, the activity of the system will increase.”¹¹

While there are different SSRIs available with different chemical make-ups, the general assumption is that these drugs can be discussed as a group for purposes of this paper because they all have the same basic effect on the brain.¹² Where there are material differences in the specific drugs, such as with the half-life of each,

¹⁰Claudine Chamberlain, *Prozac Prosecution Rests* (visited Feb. 24, 2002) <<http://www.abcnews.go.com/sections/living/InYourHead/allinyou>>

¹²*See id.* at 29 (stating that “Prozac, Zoloft, Paxil, Celexa, and Luvox are so similar that for most purposes they can be discussed together”).

that difference will be specified as necessary.

A major scientific question that affects the way that mental illness is discussed involves whether mental disorders are manifested, and thus can be detected, in some physical way that can be clearly seen for diagnostic purposes. The National Institute of Mental Health takes the position, in the “Science Education” section of its web site, that imaging technology can reveal pictorial evidence to show the difference in brain activity of a normal person and one suffering from mental illness.¹³This imaging technology includes Positron Emission Technology (PET), Magnetic Resonance Imaging (MRI), and Functional Magnetic Resonance Imagine (fMRI).¹⁴Dr. Breggin disagrees with the contention that such imaging can prove the differences in brains between normal brains and those affected with mental illness. He says that “doctors cannot diagnose depression from a normal brain scan because there are no consistent differences from normal brain scans.”¹⁵As an example supporting his position, he cites an actual Prozac advertisement in which a disclaimer appears on the advertisement to indicate that the brain PET scan image shown in the advertisement does not actually indicate a depressed patient.¹⁶

B. Prescription Drug Liability – General

¹³National Institute of Mental Health, (last modified Sept. 22, 1999) <<http://www.nimh.nih.gov/hotsoci/hotsoci.htm>>. Pictures are offered on this web site to demonstrate the various activities of the brain when affected by various mental illnesses.

¹⁴*See id.*

¹⁵Peter R. Breggin, M.D., THE ANTIDEPRESSANT FACT BOOK 23 (2001).

¹⁶*See id.* Breggin goes on to say that the “FDA regulations on truth and fairness in advertising undoubtedly required this disclaimer but the advertisement’s impact is hardly truthful or fair.” This final assertion is based on Breggin’s belief that the disclaimer is hidden on the periphery of the image of the brain and other primary substance of the advertisement. It should be noted that this advertisement was targeted to a sophisticated audience, as it appeared on January 19, 2001 on the back cover of the “Psychiatric News”, which is the official newspaper of the American Psychiatric Association. *Id.*

It is essential, before specifically discussing the specific liability issues of SSRI manufacturers, to review the basic standards for imposing tort liability on the manufacturers of prescription drugs. A fairly comprehensive and realistic view of the standards of liability for prescription drug makers appears in the Restatement (Third) of Torts.¹⁷Section 6 of the Restatement is entitled “Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices”.¹⁸

The Restatement describes that the drug maker is subject to liability for selling or distributing a defective product.¹⁹The product defect can involve a design or manufacturing defect, which basically means that the drug causes harm when used properly.²⁰The standard for establishing defective design is an extremely difficult one for any plaintiff to meet. That standard requires a showing that the drug could not help any class of patients for the design to be considered defective.²¹Therefore, if any group of patients is helped more than that class is hurt by the drug, the detrimental effects on other classes of patients are not enough to establish liability since the doctor is presumed to know which classes of patients can be helped. The reason for such a tough standard here is that society does not want liability potential to keep helpful drugs off the market.²²

¹⁷See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1997 Main Volume).

¹⁸Id.

¹⁹See *id.* at § 6(a) (stating that “a manufacturer of a prescription drug...who sells or otherwise distributes a defective drug...is subject to liability for harm to persons caused by the defect”).

²⁰See *id.* at § 6(b) (stating that “a prescription drug...is defective if at the time of sale or other distribution the drug... (1) contains a manufacturing defect” or “(2) is not reasonably safe due to defective design”).

²¹See *id.* at § 6(c) (stating that “A prescription drug...is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug...are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug...for any class of patients”).

²²See *id.* at § 6 cmt. f. (stating that the tough standard for liability “shows appropriate deference to the regulated market, where the FDA and learned intermediaries select which drugs should be available to the public generally and which drugs should be given to individual patients, respectively. It does not, on the other hand, wholly exempt defendants from liability”).

Given that the standard for establishing a defective product is so difficult to reach, it should not be surprising that the most common and potentially the most successful type of action against the SSRI manufacturers is one that alleges a “failure to warn” by the manufacturer.²³The Restatement lists the failure to warn and instruct as the only other, in addition to the claims for defective design and manufacture, basis for asserting liability against prescription drug makers.²⁴For liability to attach to the manufacturers, the risk of harm must have been reasonably foreseeable at the time of sale.²⁵The manufacturer cannot avoid this standard of reasonable foreseeability by ignoring what could potentially be a risk. In fact, the “manufacturers have the responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal.”²⁶As a result of this duty to test the product, the claims against SSRI manufacturers often are stated in two parts, seeking liability for a failure to warn and for a failure to further test the drug.

The Restatement (Third) of Torts describes the conditions for holding a manufacturer liable due to a failure to warn or instruct about the product’s use and effects.²⁷That description, which very closely mimics both case law and scholarly interpretation of the subject, is as follows:

“§6(d): A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are provided to:

- (1): prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings;
- or

²³See *id.* at § 6 cmt. d. (stating that “Failure to instruct or warn is the major basis of liability for manufacturers of prescription drugs”).

²⁴See *id.* at § 6(b) (listing the liability claims against prescription drug makers).

²⁵See *id.* at § 6 cmt. g.

²⁶*Id.*

²⁷See *id.* at § 6(d).

(2): the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”

§6(d)(1), therefore, requires the manufacturer to give reasonable instructions and warnings only to the prescribing physicians. This is the defined form of what is known as the learned intermediary doctrine, which has been used to shield manufacturers from liability by assuming that doctors will use reasonable instructions and warnings in their best professional judgment to best serve their patients.^{28, 29}

In practice, the learned intermediary doctrine has often been used to excuse the manufacturer from giving any direct warning to the ultimate consumers of drugs. The reasoning behind the traditional rule that consumers do not have to be informed in the same way as doctors was that consumers, who are assumed to have no medical training or expertise, are in no position to evaluate warnings in a reasonable and independent fashion that will best benefit their own medical condition.³⁰ §6(d)(2), on the other hand, is rooted in recent cases and changes in the industry and leaves the door open for a duty to warn and inform the end user. The gist of §6(d)(2) is the creation of a duty to warn the consumer in cases where providing a warning only to the doctor will not reduce the set of risks to the consumer as a result of the warnings and instructions provided to the doctor.³¹ §6(d)(2), by opening the door for a duty to warn the consumer, suggests an

²⁸See *id.* at § 6 cmt. d. (stating that “warnings of unavoidable risks allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the drug”).

²⁹Ellen Relkin, *Warnings in Pharmaceutical Cases: Is the Learned Intermediary Obsolete in the New Millennium?*, in ASS’N OF TRIAL LAWYERS OF AMERICA ANNUAL CONVENTION REFERENCE MATERIALS VOLUME 2: SECTION ON TOXIC, ENVIRONMENTAL AND PHARMACEUTICAL TORTS (July, 2000), available in Ann.2000 ATLA-CLE 2713 (stating that “virtually all jurisdictions recognize some variant of the learned intermediary defense in the context of a prescription drug case”).

³⁰See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b. (1997 Main Volume) (stating that “The rationale supporting this “learned intermediary” rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy”).

³¹See *id.* at cmt. e. (stating that “Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-

erosion of any rigid interpretation of the learned intermediary doctrine. The exact status of that doctrine has received substantial attention in recent years. It is crucial to examine the recent transformation of the learned intermediary doctrine, as this history has been the catalyst that has led to the suggestion of a duty to warn the consumer in the Restatement.

C. Learned Intermediary Doctrine Analysis

As noted above, §6(d)(2) of the Restatement opens the door to a duty to warn more than just the doctor. Comment b of that section of the Restatement sheds some light on the reasoning behind this expansion. Comment b states that “in certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decision-maker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly.”³²This comment recognizes what is in fact a reality in today’s medical care. It is common for physicians to prescribe certain drugs without a thorough evaluation or even an actual visit by the patient.³³With such a low level of interaction between the patient and the doctor, it is not realistic to think that the doctor is filling the role that the legal system was set up to assume. Thus, there appear to be at least two easily implementable options.

The first is a heightened set of prescribing restrictions for doctors. Doctors would loathe this option due to

care provider”).

³²*Id.* at cmt. b.

³³Janet L. Holt, *Documents from Paxil Case May Aid Plaintiffs Harmed by Antidepressants*, TRIAL, September, 2001, at 84, 86 (quoting attorney George “Skip” Murgatroyd as saying that “General practitioners prescribe these drugs with no psychiatric evaluations. Sometimes they’re even giving out samples. They are just not aware of the dangers”).

concerns over their autonomy and their ability to have a profitable practice. This option also may also not be practical today, given that there is less doctor-patient communication than in the past, a situation that has become somewhat necessitated by the financial restrictions of managed health-care.

The second option is for a requirement to warn consumers directly, rather than only the doctors, about the negative aspects of taking the drug. This would allow informed choices by the consumer and at least come closer to providing the protection to the consumer that was originally thought to be adequate under the learned intermediary doctrine. Yvonne Bukstein advanced a form of this option in a University of Pittsburgh Law Review comment in Fall, 1987.³⁴ Her article focused on the shortcomings of the learned intermediary doctrine, and suggested that the manufacturers should be forced to provide a package insert that would be passed to each prescription drug consumer by the pharmacist.³⁵ This would further educate the patient, and the doctor's role would only change to the extent that the patient would want to further inquire about the risks of the product.³⁶

As noted above, the reduced role by doctors in the prescription process as compared to the traditional notion of the doctor's role is one of the primary reasons advanced by advocates who suggest a need for a duty to warn consumers directly. One of the primary factors that has caused this reduction in the role of the doctor as advisor is the proliferation of direct to consumer advertising.³⁷ The contention by those who seek to expand the duty to warn is that advertising transforms the consumer from an unknowing passive party to one who actually comes to the doctor requesting (or demanding) a particular drug.³⁸

³⁴Yvonne Bukstein, Comment, *Drug Products Liability: Duty to Warn*, 49 U. PITT. L. REV. 283 (1987).

³⁵*See id.* at 303.

³⁶*See id.* at 304.

³⁷*See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. e. (1997 Main Volume) (noting that direct to consumer advertising, along with mass dispersion of a medication and specific FDA requirements for package inserts with a drug, are factors that are most likely to require a warning to go directly to the consumer).

³⁸Philip R. Alper, M.D., *No: "Direct-to-Consumer" Advertising of Prescription Drugs Is More Harmful Than Helpful to Consumers*, (Nov. 25, 1999) <> (stating that "Patients have made appointments with me (I am a practicing internist) to ask about drugs they heard a newly educated consumer puts the doctor in a difficult position. As Dr. Alper puts it, "giving a patient a prescription for a medically inappropriate or relatively non-cost-effective drug he or she has requested is often much easier – and is always faster – than refusing with an explanation."³⁹ And if the doctor does refuse to write the prescription, the patient may move to

While it may still be assumed that no doctor will prescribe medication that has no reasonable relationship to some apparent condition of the patient, there is worry, as Dr. Alper suggested, that doctors will prescribe the drug specifically requested by a patient in cases where that drug is in some range of prescribable drugs. The problem is that the requested drug, although one of the possible options, would sometimes not be the best option in the doctor's expert opinion if that doctor had the option to choose independently of the patient the course of treatment thought best by the doctor.

Along the same line of worry is that a patient may believe that they are suffering from some malaise they have heard about on a television commercial.⁴¹ Where this is the case, the doctor is likely to diagnose the condition suggested by the patient wherever it is reasonable, rather than simply starting from scratch and making a diagnosis independent of what the layman patient believes he has. Although the patient in this case may not request a specific drug, the advertising has suggested to the patient the prospect of having some condition for which that manufacturer's drug is intended to help.

Since the doctor's judgment and independence is compromised in each of these situations, the argument is that the consumer should be warned directly by the manufacturer of all effects of the drug to assure that the decision they are now making in tandem with the doctor is an informed decision.⁴²

another doctor who will write the patient's preferential prescription, thus causing the first doctor to lose the patient and the related revenue.⁴⁰

⁴¹See *id.* at 779 n.260 (citing Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 843-44 (1991)).

⁴²See *Perez v. Wyeth Lab.*, 161 N.J. 1 (1999) for an example of the duty to warn extending to patients based on extensive direct to consumer advertising of the product by the drug maker. See also Amy D. White, Note, *The Mass Marketing of Prescription Drugs and Its Effect on the Learned Intermediary Doctrine*, 25 OKLA. CITY U. L. REV. 745, 748 n.16 (2000) (quoting the plaintiffs' attorney in *Perez*: "the decision marks the first time a court has stated that a company that does direct to consumer advertising has an obligation to warn the consumer").

D. FDA Approval and the Duty to Warn

Drug manufacturers have attempted to defend themselves by saying that their compliance with FDA labeling requirements precludes them from any tort liability. Among the reasons put forth for this view by the drug makers is that the FDA regulations are meant to be comprehensive in order to unnecessarily overdetter doctors from prescribing what many believe to be a helpful form of medication. This defense has been attacked on two fronts.

First, and most broadly, is the claim that the FDA merely sets a minimum labeling requirement, and that state tort law can require more of the manufacturer. The court in *Motus v. Pfizer, Inc.*⁴³ addressed this claim directly when Pfizer claimed preemption precluded state tort liability rules from holding Pfizer liable for not giving more than the FDA required warning. The *Motus* court stated that “most courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims.”⁴⁴ The court also uses the federal statute itself in support of this proposition, citing 21 C.F.R. sec. 314.70(c)(2)(i) for the proposition that manufacturers are permitted to strengthen warning labels without FDA advance permission.⁴⁵ The second attack on this defense by the drug manufacturers is based on a fraud theory.⁴⁶ Under this theory, the claim is that the company withheld

⁴³127 F.Supp.2d 1085 (C.D. Cal. 2000).

⁴⁴*Id.* at 1092 (citing and quoting the following cases for the proposition that FDA requirements are minimum standards: *Hill v. Searle Lab.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Kociemba v. Searle & Co.*, 680 F.Supp. 1293, 1299 (D.Minn. 1988), citing *Graham v. Wyeth Lab.*, 666 F.Supp. 1483 (D.Kan. 1987), *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981), and *Salmon v. Parke Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975); and *Mazur v. Merck & Co.*, 742 F.Supp. 239, 247 (E.D. Pa. 1990).

⁴⁵*Id.* at 1094.

⁴⁶Ellen Relkin, *Warnings in Pharmaceutical Cases: Is the Learned Intermediary Obsolete in the New Millennium?*, in ASS'N OF TRIAL LAWYERS OF AMERICA ANNUAL CONVENTION REFERENCE MATERIALS VOLUME 2: SECTION ON TOXIC, ENVIRONMENTAL AND PHARMACEUTICAL TORTS (July, 2000), available in Ann.2000 ATLA-CLE 2713 (suggesting the “fraud on the FDA theory”

information from or provided false information to the FDA, and thus the FDA labeling requirements turned out to be less stringent than they would have been if they had been presented with all of the relevant and accurate information.⁴⁷Dr. Breggin believes that there has been widespread fraud committed on the FDA. He claims to have found, while assisting in discovery against Eli Lilly & Co. (“Eli Lilly”), evidence that Eli Lilly had “systematically mislabeled many kinds of adverse reactions” of patients in order to misstate or understate in its reports to the FDA the actual problems that were caused by Prozac.⁴⁸

E. Substantive SSRI Analysis

Using the general liability standards for prescription drugs as a backdrop, I will now turn to the primary focus of this paper, namely the application of these general rules to some of the specific issues involving SSRIs. The first area to be discussed is the liability of SSRI manufacturers where claimants assert that the SSRI caused the user to become violent toward himself and/or others.

II. The Link Between SSRIs and Violent Behavior

A starting point for examining the violent and suicidal behavior alleged to be linked to taking SSRI medication is Dr. Breggin’s “The Anti-Depressant Fact Book”.⁴⁹Since Dr. Breggin has worked on many of the cases against the SSRI manufacturers as one of the primary scientific and medical advisors for the plaintiffs, as one reason why a warning that was given by the manufacturer should be invalidated, given that the warning may have been different (or the drug not approved at all) if the FDA had received all of the relevant information).

⁴⁷See *Motus v. Pfizer, Inc.*, 127 F.Supp.2d 1085 at 1100 (C.D. Cal. 2000) (stating that “state suits may complement the regulatory methods of promoting safety by directly flushing out more information about the risks of drugs and indirectly encouraging manufacturers to make complete risk disclosures to the FDA.” The Pfizer argument that additional state requirements would over deter doctors from prescribing Zoloft was rejected based on a combination of this possibility for increased disclosure and the fact that Pfizer presented no persuasive evidence that over deterrence would result from a strengthened warning label).

⁴⁸Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 6 (2001).

⁴⁹Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* (2001).

his specific theories have been put forth in courts of law and thus are most relevant in addressing the alleged link.⁵⁰ The most important of his medical theories is that SSRIs can cause mania, akathisia, and depression, which all then can result in a greater likelihood of violent or suicidal behavior in the patient.⁵¹ He also alleges that the FDA has not acted diligently to uncover the side effects of drugs such as Prozac because they are associated too closely with the drug companies to act independently in evaluating their products.⁵² His information comes primarily from various scientific studies, as well as inside information he has obtained through the discovery process as a result of working for the plaintiffs in cases against manufacturers.

A. Did the Manufacturers Hide Scientific Information from U.S. Regulators?

Dr. Breggin states that Dr. Richard Kapit, who was the chief medical officer in the Prozac approval process for the FDA,⁵³ found some disturbing evidence of effects of Prozac that were never given proper weight by the FDA. In his “Safety Review” in 1986, Dr. Kapit warned that Prozac could actually worsen the condition of some depressed patients.⁵⁴ At that time, he suggested that Prozac be labeled to warn doctors of this potential effect.⁵⁵ While the FDA did not act on this suggestion, it is notable that the labels for Prozac in Germany, France, and Great Britain all warn that stimulatory effects of Prozac could in fact lead to suicide.⁵⁶ Although the United States approved Prozac without mentioning the link to suicide, they have since required the manufacturer to mention the existence of a link to suicide “without confirming that it was

⁵⁰Craig Offman, *Prozac indignation: How a little-known Harvard clinician needled sleeping giant Eli Lilly*, (May 17, 2000) <www.salon.com/health/feature/2000/05/17/backlash/>.

⁵¹See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* (2001).

⁵²See *id.* at 79.

⁵³*Id.*

⁵⁴See *id.*

⁵⁵See *id.*

⁵⁶See *id.* at 80.

a proven adverse reaction”.⁵⁷ One general explanation for the alleged violent effect of SSRIs, in simplified terms, is that SSRIs can work as powerful stimulants.⁵⁸ The stimulation of depressed minds, as the theory goes, more likely leads to impulsive behavior that the depressed patient would not otherwise have the energy or motivation to carry out without the added stimulation.

B. Akathisia

A more specific explanation of the alleged link between SSRIs and violent behavior is that Prozac and the other SSRIs are thought by some to cause akathisia, which is a neurological stimulation and agitation of such serious proportions that it can cause violence, suicide, and depression.⁵⁹ According to Dr. Breggin, “akathisia is like being tortured from within. It’s like the screeching of chalk down a board, only it’s going down your spinal column.”⁶⁰ The drug companies, who are aware of the extreme nature of akathisia, argue generally that their products do not cause akathisia.⁶¹ As a secondary argument, the drug companies have argued at trial that even if akathisia can be caused by the SSRIs, that does not mean that the particular individual at the center of the particular controversy was actually suffering from akathisia at the time he committed the act.⁶²

⁵⁷ *Id.*

⁵⁸ *See id.* at 46, (noting that all of the SSRIs can cause stimulation, although concededly not to the same extent. Dr. Breggin also states that they can each yield sedative effects. These opposite effects, according to Dr. Breggin, are further showing of the lack of understanding of how the brain reacts to these drugs).

⁵⁹ *See id.* at 87 (citing the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders IV (1994), which states that “Akathisia may be associated with dysphoria (painful emotions), irritability, aggression, or suicide attempts”).

⁶⁰ Rob Waters, *My antidepressant made me do it!*, (July 19, 1999) <<http://www.salon.com/health/feature/1999/07/19/zolofit/print.html>>.

⁶¹ *See* Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>>.

⁶² *See id.* (quoting Andy Vickery, who stated that Eli Lilly “argued that even if Prozac causes akathisia, Forsyth still did not suffer from it. They (Eli Lilly) contended that akathisia is characterized by both an outer and an inner restlessness, and that he didn’t have akathisia because he didn’t display any outward signs of restlessness”).

C. Mania

A final and related piece of the scientific explanation for the violent behavior of some patients taking antidepressants is that the drugs are known to cause mania. The American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders, IV (1994)", states that mania is associated with violence and other criminal acts.⁶³ That manual also states that mania may be caused or incited by antidepressant medication.⁶⁴ This APA manual "is the official source for diagnosis in psychiatry. It is used in most research, in the FDA approval process, and by insurance carriers."⁶⁵ While the labels for the antidepressants note that the drugs may lead to mania and other similar effects, there is no mention of any causal link between the drugs and violence.⁶⁶ That is left for doctors to determine, and often the doctors are not informed to the extent that they will conclude that the dangerous combination of a depressed person and the agitating effects of antidepressants may result in violent or suicidal actions by the patient.

The scientific evidence that has accumulated involving Prozac and other SSRIs' tendencies to cause worsening conditions and violent behavior may result in liability to the manufacturer in a variety of ways. The most notable is the above-described duty to warn. While the manufacturers may have met the standards of the FDA, that may not be enough. The FDA may have required too little information on the label due to failure of the companies to fully disclose what they had learned about the links between SSRIs and violence. Furthermore, even if they acted based on full and complete information, the FDA may have required less stringent labeling than needed for the manufacturers to avoid state liability laws.

⁶³ See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 101 (2001).

⁶⁴ See *id.* at 45 (citing the Diagnostic and Statistical Manual of Mental Disorders IV (1994), which states that "Symptoms like those seen in a Manic Episode may also be precipitated by antidepressant treatment such as medication").

⁶⁵ *Id.* at 102.

⁶⁶ Peter R. Breggin, M.D., *GSK Updates the Paxil Label*, (viewed Feb. 24, 2002) <<http://www.breggin.com/paxilwithdrawalsuit.html>>.

D. Eli Lilly, Prozac, and Joseph Wesbecker

Any examination of the viability of lawsuits alleging a causal relationship between SSRIs and violent behavior must begin with the tragic story of Joseph Wesbecker. On September 14, 1989, Mr. Wesbecker entered the Louisville newspaper printing facility where he had once worked and killed eight people and wounded twelve others before killing himself.⁶⁷ Mr. Wesbecker had been taking Prozac for just less than a month prior to committing these acts.⁶⁸ Soon thereafter, a wave of lawsuits was brought against Eli Lilly, the manufacturer of Prozac.⁶⁹ These lawsuits alleged that Prozac had caused Mr. Wesbecker's violent behavior, and that Eli Lilly should pay for the wrongful deaths.⁷⁰ Of all of the plaintiffs similarly situated in the early 1990s, only one suit actually went to trial. Several plaintiffs⁷¹ in the Wesbecker matter combined their complaints and went to trial against Eli Lilly in the case of *Fentress v. Eli Lilly & Co.*⁷²

⁶⁷ See *Potter v. Eli Lilly & Co.*, 926 S.W.2d 449, 451 (Ky. 1996).

⁶⁸ See J. Stratton Shartel, *Decision to Eschew High-Tech Approach Pays Off in Prozac Case*, INSIDE LITIGATION, Feb. 1995, at 1, 2 (stating that the plaintiffs' attorneys charged that Wesbecker began taking Prozac on August 17, 1989).

⁶⁹ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>>. (stating that Eli Lilly & Co. was the target of more than 200 suits in the mid-1990s alleging that Prozac caused violent and suicidal feeling in some users).

⁷⁰ See J. Stratton Shartel, *Decision to Eschew High-Tech Approach Pays Off in Prozac Case*, INSIDE LITIGATION, Feb. 1995, at 1, 2.

⁷¹ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <http://www.lawyersweekly.com/prozac.cfm> (stating that the case "was filed on behalf of 28 victims of Joseph Wesbecker").

⁷² See J. Stratton Shartel, *Decision to Eschew High-Tech Approach Pays Off in Prozac Case*, INSIDE LITIGATION, Feb. 1995, at 1, 2 (citing this unpublished case as follows: *Fentress v. Eli Lilly & Co.*, No. 90 CI 033, Jefferson County Circuit Court, Louisville, KY., Judge John W. Potter. Case filed July 1990; verdict rendered December 12, 1994).

Although proving the scientific basis of a general link between Prozac use and violent or suicidal behavior was a significant obstacle faced by the plaintiffs in the Wesbecker cases, it was not the only or perhaps even the primary difficulty faced by the plaintiffs in this case. The additional problem was showing that Prozac actually caused Wesbecker individually to commit these acts. Since many Prozac users, including Wesbecker himself, suffer from severe depression, it is extremely difficult to convince a jury that the drug, rather than the underlying condition that led to the prescription of the drug, was the cause of the violent outburst.

Joseph Wesbecker had been struggling with mental health problems for some time before his shooting rampage.⁷³In addition, one of the more damaging pieces of evidence to the plaintiffs' case showed that he had made threats to commit violent acts against others at his workplace before he ever started taking Prozac.⁷⁴These threats were considered serious, as Wesbecker had even been known to once bring a loaded gun to work.⁷⁵He had attempted to commit suicide at least twelve times.⁷⁶Further weighing against the case that Prozac had caused Wesbecker's violence was that he had been accumulating a stockpile of guns for several months prior to the shooting.⁷⁷

⁷³See *id.* at 1 (stating that the evidence "revealed that Wesbecker had a history of mental instability"). See also Anthony Daniels, *Books: Did Prozac pull the trigger? Anthony Daniels considers a case of mass murder, drugs and litigation*, THE SUNDAY LONDON TELEGRAPH, Sept. 8, 1996, at 15 <<http://www.oralchelation.net/data/Lilly/data6.htm>> (quoting John Cornwell from his book *The Power to Harm: Mind, Medicine and Murder on Trial*: "for five years psychiatrists had treated his manic-depressive and schizoaffective disorders with more than a dozen psychoactive medications").

⁷⁴See J. Stratton Shartel, *Decision to Eschew High-Tech Approach Pays Off in Prozac Case*, INSIDE LITIGATION, Feb. 1995, at 1, 2 (stating that Wesbecker had "regularly talked about killing his bosses").

⁷⁵See *id.* at Figure 1 (presenting a timeline used by defense counsel in the case to show that Wesbecker had a history of violent actions and threats. Included in that timeline is an incident in which Wesbecker once brought a loaded gun to work and told a co-worker that he was going to kill their foreman).

⁷⁶See *id.* at 1.

⁷⁷See *id.*

Although Wesbecker had demonstrated violent tendencies, the plaintiffs emphasized that he had not acted on them until after he had begun taking Prozac (which, as noted above, was about a month before the fatal shootings).⁷⁸ The defense, in response, emphasized the fact that there had been intervening circumstances since he had begun taking Prozac that were more likely to have caused his action than the drug. One important change was that Wesbecker had been informed that his disability payments from Standard Gravure would be reduced from \$1,400 per month to \$300 per month effective October 1, 1989 due to the fact that the company did not regard mental illness as a handicap.⁷⁹ Additionally, Wesbecker's grandmother, who apparently was his closest and most loved family member, had died about a month before the shooting.⁸⁰ One final strategy used by the defense in the Wesbecker trial was demonstration of Wesbecker as a man whose violent manner spread to all parts of his life. They introduced his ex-wife as a witness. Not only did the ex-wife talk about Wesbecker's repeated threats against his bosses, but she also testified that he had once threatened to kill her eleven year-old daughter.⁸¹ All of these factors appeared to sway the jury, as the 9-3 decision⁸² was handed down with the result that Eli Lilly was not responsible for Wesbecker's

⁷⁸ See *id.* at 2 (stating that the plaintiffs alleged that Wesbecker had begun taking Prozac on August 17, 1989, and that the Prozac directly caused the shootings that occurred on September 14, 1989). See also Anthony Daniels, *Books: Did Prozac pull the trigger? Anthony Daniels considers a case of mass murder, drugs and litigation*, THE SUNDAY LONDON TELEGRAPH, Sept. 8, 1996, at 15 <<http://www.oralchelation.net/data/Lilly/data6.htm>> (citing John Cornwell from his book *The Power to Harm: Mind, Medicine and Murder on Trial* for the proposition that Wesbecker had been prescribed Prozac about a year before the shootings, but stopped taking it after two days because he did not like the effects of the drug. Wesbecker's psychiatrist tried Prozac again in August of 1989. Just two days before the shootings (Three days according to Dr. Breggin's *Anti-Depressant Fact Book* at 174, which otherwise affirms Cornwell's account of these events), the psychiatrist stated that he was disturbed by the agitation and volatile moods Prozac seemed to produce in Wesbecker. That psychiatrist did not discontinue the Prozac, however, as Wesbecker "insisted that it helped him").

⁷⁹ See J. Stratton Shartel, *Decision to Eschew High-Tech Approach Pays Off in Prozac Case*, INSIDE LITIGATION, Feb. 1995, at 1, 3.

⁸⁰ See *id.*

⁸¹ See *id.* at Figure 1 (quoting the statement of Wesbecker's ex-wife, Brenda Camp, who said that Wesbecker had told her "You know, it would be easy for me to blow your daughter's brains out, and then I wouldn't have to look at her. I wouldn't have to see her and I wouldn't have to be jealous of yours and her relationship").

⁸² See Peter R. Breggin, M.D., THE ANTIDEPRESSANT FACT BOOK 177 (2001) (noting that an 8-4 vote would have resulted in a hung jury, which in Dr. Breggin's words would have created a "public relations nightmare for Prozac").

behavior.⁸³ Because of the intense media publicity surrounding the trial, the verdict offered Eli Lilly a very valuable public confirmation of the safety of their primary product.⁸⁴ Several other suits were undoubtedly settled or not brought at all on the basis of this result.⁸⁵ Also, the verdict helped users and potential users of the drug feel comfortable with the safety of Prozac. Thus, the decision was a significant financial windfall for Eli Lilly, for whom Prozac was at one time one of the world's top selling drugs.⁸⁶ Although all of the evidence presented by the defense concerning Wesbecker's past behavior seemed to outweigh the scientific evidence brought by the plaintiffs, it soon was discovered that there may have been less than a full and complete presentation of evidence at the trial. During the latter stages of the trial, the parties argued at length to the judge concerning the admissibility of evidence that Eli Lilly had previously withheld information from the FDA concerning an unrelated drug. The plaintiffs sought to use this to show the jury that Eli Lilly had a pattern of revealing only the information it needed to get its drugs approved and to reap the profits from them, regardless of the safety. Judge Potter, who presided over the case, ruled for the plaintiffs on the matter. The plaintiffs, however, wrapped up their case the day after winning this motion without any mention of this evidence that they had fought so hard to be able to introduce to the jury.⁸⁷ Judge

⁸³ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>>.

⁸⁴ See May L. Harris, *Problems with Prozac: A Defective Product Responsible for Criminal Behavior?*, 10 J. CONTEMP. LEGAL ISSUES 359, 368 (1999) (quoting Eli Lilly CEO Randall Tobias following the Fentress verdict: "We have proven in a court of law, just as we have to more than seventy scientific and regulatory bodies all over the world, that Prozac is safe and effective. Our hearts go out to the victims of the terrible tragedy. But the members of the jury, after hearing the scientific and medical facts... came to the only logical conclusion – that Prozac had nothing to do with Joseph Wesbecker's actions").

⁸⁵ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>> (citing an April 22, 2000 article from the Indianapolis Star as stating that the Fentress verdict "prompted many plaintiffs' attorneys to drop their Prozac cases").

⁸⁶ See Lawrence Mondy, *Did Prozac Make Him Do It?*, TIME, (Nov. 28, 1994) <<http://www.time.com/time/magazine/archive/1994/941128/941128/behavior.box.html>> (stating that Prozac is the "most widely prescribed antidepressant." See also Anthony Daniels, *Books: Did Prozac pull the trigger? Anthony Daniels considers a case of mass murder, drugs and litigation*, THE SUNDAY LONDON TELEGRAPH, Sept. 8, 1996, at 15 <<http://www.oralchelation.net/data/Lilly/data6.htm>> (citing John Cornwell from his book *The Power to Harm: Mind, Medicine and Murder on Trial* as stating that Prozac contributed "more than one-fourth of Eli Lilly and Co.'s total 1995 sales of \$6.5 billion").

⁸⁷ See *Potter v. Eli Lilly & Co.*, 926 S.W.2d 449, 452 (Ky. 1996) (stating that plaintiffs had sought to allow introduction of evidence that Eli Lilly had been charged criminally for failing to report deaths from the use of Oralflex, another drug

Potter then suspected the possibility of a secret settlement, which both parties denied when Judge Potter took them aside to inquire about this strange turn of events.⁸⁸The case was soon thereafter sent to the jury, which returned to the court a decision against the plaintiffs. Following the expiration of the time limitation for appeals to be filed, Judge Potter filed his own motion to hold a formal hearing with the parties to find why the final reported verdict should not be changed from “dismissed with prejudice” to “dismissed with prejudice as settled” based on his belief that the evidence indicated that a settlement had actually been reached in this case.⁸⁹Both parties to the Fentress case appealed this action by Judge Potter,⁹⁰and although the Court of Appeals determined that Judge Potter could not make such a change absent fraud by the parties,⁹¹that determination was reversed by the Supreme Court of Kentucky, who ultimately agreed with Judge Potter and upheld the validity of his decision.⁹²Finally, Judge Potter’s suspicions resulted in an official change of the verdict in 1997 to “dismissed as settled.”⁹³ Despite the fact that Judge Potter had found that the trial had been less than zealously litigated, the media attention had long since moved away from this matter, and as such the new verdict was not publicized in nearly the same magnitude as the original verdict.⁹⁴Eli Lilly had effectively paid for a jury verdict to establish precedent in favor of Prozac. While the manufactured by Eli Lilly, to the FDA. The court stated that this issue was “extensively argued” and that “the adversarial encounter took more than a day from the trial”).

⁸⁸*See id.* at 452.

⁸⁹*See id.* at 451 (providing the following timeline for the course of events: Jury verdict reached on December 12, 1994; Judge Potter enters the judgment on January 25, 1995; Appeal time expired on February 24, 1995; Judge Potter files motion seeking to amend the verdict on April 19, 1995).

⁹⁰*See id.* at 452.

⁹¹*See id.*

⁹²*See id.* at 455.

⁹³Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>>.

⁹⁴*See* Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 178 (2001) (stating that “Although the mass media had covered the original fake victory by Eli Lilly & Co., only the British news agency, Reuters, made any mention of the reversal against the drug company”).

precedent does not stand, the public impression of the safety of Prozac that was created by the widespread publicity of the first Wesbecker verdict remains.

Following the original December 1994 Fentress verdict, all of the suits against Eli Lilly and the other SSRI manufacturers were dismissed or settled.⁹⁵ The reasons for this high rate of settlement are fairly easy to ascertain. Understandably, the drug makers do not enjoy the prospect of the great amount of negative publicity a trial might bring. Additionally, it is always difficult to successfully defend claims when the plaintiffs have such strong sympathy in their favor due to there being actual wounded victims or family members of dead victims. These factors, combined with the fact that the plaintiffs' medical evidence is at least somewhat compelling, makes it much less risky for the drug makers to settle the cases quietly. Recent years, however, have seen a return to the courtroom, with juries reaching decisions on two matters contesting substantially the same issue as in the Wesbecker case.

E. The Forsyth Case and the Sepracor Patent

The first notable return to the courtroom again featured Eli Lilly as the defendant and Prozac as the alleged "culprit". *Forsyth v. Eli Lilly*, as with virtually all of the cases brought against the antidepressant drug manufacturers, tells a gruesome tale of violence. In this case, William Forsyth stabbed his wife fifteen times in their bedroom before impaling himself on another knife.⁹⁶ Their children brought wrongful death suits against Eli Lilly.⁹⁷ As with the Wesbecker case, the *Forsyth* case defendants argued that the events in Forsyth's life caused him to act violently rather than his prescription of Prozac. The Eli Lilly attorneys painted him as a man who was suffering from major depression and whose marriage was failing. This extremely

⁹⁵ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>> (stating that only two cases regarding Prozac have made it to trial. Those cases are the Fentress case involving the Joseph Wesbecker shootings and the case of *Forsyth v. Eli Lilly & Co.*).

⁹⁶ See May L. Harris, *Problems with Prozac: A Defective Product Responsible for Criminal Behavior?*, 10 J. CONTEMP. LEGAL ISSUES 359 (1999).

⁹⁷ See *id.*

traumatic life event was the cause of his actions, according to the defense, just as similar circumstances result in violent behavior each year with those who are not using SSRIs.⁹⁸ The plaintiffs, on the other hand, emphasized that three physicians had examined Forsyth in the months before his violent episode, with each of them failing to detect any suicidal thoughts.⁹⁹ They tried to paint the introduction of Prozac, which Forsyth began taking ten days before the murder-suicide, as the catalyst for his shocking behavior.¹⁰⁰ On April 7, 1999, the Hawaii jury in Forsyth ruled unanimously for Eli Lilly, finding that Prozac was not the cause of Forsyth's actions.¹⁰¹ Unlike in Fentress, Eli Lilly actually obtained a valid precedent, as there was no allegation of hidden settlement (although the plaintiffs filed an appeal based on the fact that three jurors later said that they disagreed with the verdict¹⁰²). As with Fentress, however, controversy has arisen following this decision that has cast doubt on the status of the outcome.

Due to the nearing expiration of the Prozac patent, Eli Lilly had been working to introduce a "new Prozac". The new version was to come from another drug manufacturer named Sepracor, who had developed a supposed improved version of Prozac. Eli Lilly acquired exclusive rights to patent 5,708,035 from Sepracor in December 1998 by paying Sepracor \$20 million, along with another \$70 million in milestone payments based on the drug's progress through clinical trials and a percentage of sales¹⁰³ (Eli Lilly subsequently terminated the licensing and development agreement with Sepracor, apparently due to heart irregularities

⁹⁸ See *id.* at 359-60 (quoting Eli Lilly attorney Andrew See: "This case is about a good drug and a very bad, powerful disease").

⁹⁹ See *id.* at 360.

¹⁰⁰ See *id.* at 359 (quoting plaintiffs' attorney Andy Vickery: "This is a case about drug-induced violence. Bill was taking Prozac for ten days and did something totally out of character").

¹⁰¹ See Vickery & Waldner, press release, *Suit Alleges Second Prozac Verdict Also Tainted*, (June 8, 2000) <www.justiceseekers.com>. Vickery & Waldner represented the plaintiffs in Forsyth v. Eli Lilly.

¹⁰² See *id.*

¹⁰³ See Mitchell Zuckoff, *Prozac data was kept from trial, suit says*, BOSTON GLOBE, (June 8, 2000) <<http://www.connix.com/~narpa/prozac.data.suppressed.htm>>.

found in association with high dosages of the drug in clinical testing, in October 2000).¹⁰⁴ It is notable that Eli Lilly purchased the rights to this patent from Sepracor months before the beginning of arguments in the Forsyth v. Eli Lilly case.¹⁰⁵

The significance of this newly acquired patent is that the language used in the patent filing by Sepracor to describe the new drug indicates that the effects of Prozac that Eli Lilly had always denied may in fact have been known to exist. The Sepracor patent lists among the advantages of the new drug as compared to the old Prozac that the new Prozac will decrease existing side effects, including “inner restlessness (akathisia)”.¹⁰⁶ This was obviously an important revelation for the plaintiffs in cases against Eli Lilly, as one of the centerpieces of their legal argument was that Prozac caused akathisia, which in turn caused violent behavior.¹⁰⁷ The information about the new Prozac patent wording did not come to the attention of the plaintiffs until more than a year after the verdict was rendered in Forsyth, when a Boston Globe article revealed the incriminating wording of the new patent.¹⁰⁸ As a result of this discovery, the plaintiffs’ lawyers in the Forsyth case have filed an appeal seeking a new trial based upon what they called fraud by the defense attorneys.¹⁰⁹ They allege that the in-house attorneys for Eli Lilly, including a patent attorney named Doug

¹⁰⁴ See *Sepracor falls on Lilly’s decision to drop Prozac*, BOSTON BUSINESS JOURNAL, (October 19, 2000) <http://www.bizjournals.com/boston/stories/2000/10/16/daily10.html>.

¹⁰⁵ See *Forsyth v. Eli Lilly & Co.*, Case No. CV00-00401 SPK, Independent Action to Set Aside Judgment for Fraud on the Court, paragraph 14, (June 7, 2000) <<http://www.baumhedlundlaw.com/media/fraudcomplaint.html>>. This fraud complaint was obtained from the website of Baum, Hedlund, Aristei, Guilford & Schiavo, who is one of the firms representing the plaintiffs in this matter.

¹⁰⁶ *Id.* at paragraph 20.

¹⁰⁷ See *id.* at paragraph 24 (describing that one of the specific points of contention at trial was whether akathisia could be exhibited by mere inner restlessness or whether external manifestations were also necessary. Eli Lilly’s attorneys argued that external manifestations were required, and that Forsyth had not exhibited such signs. The Sepracor patent’s description of akathisia as “inner restlessness” without mention of any external signs was seen by the plaintiffs’ lawyers as an admission by Eli Lilly upon purchasing the Sepracor patent that inner restlessness was in fact the lone requirement for demonstrating akathisia).

¹⁰⁸ See *id.* at paragraph 30 (noting that a May 7, 2000 article in the Boston Globe entitled “Prozac Revisited” brought the matter to their attention).

¹⁰⁹ See *id.*

Norman, would have known about the Sepracor patent language linking the old Prozac to akathisia and suicidal thoughts.¹¹⁰ Despite this knowledge, according to the complaint, they sat silently while the defense argued that Prozac did not cause akathisia or suicidal thoughts.¹¹¹ According to the plaintiffs, 9th circuit precedent¹¹² prohibits in-house lawyers, due to their role as “officers of the court”, to remain silent “while trial counsel withholds critical evidence and creates erroneous impressions”.¹¹³ Regardless of the success of the attempt to get a new trial in Forsyth, this Sepracor patent information will likely be used in future suits against Eli Lilly. Andy Vickery, the most visible plaintiffs’ attorney in these matters, believes that the new information will sway jurors to the plaintiffs’ position that the drug company knew the side effects existed, and thus should have warned of these effects.¹¹⁴ In addition, he feels that expert witnesses used by the plaintiffs will have increased credibility as a result of the Sepracor patent disclosure.¹¹⁵ Another attorney in the Forsyth case, Karen A. Barth, has said that she sees the purchase of the new patent as a clear admission by Eli Lilly of their knowledge of the dangerous effects of Prozac. “If Lilly denies this”, says Barth, “they’ve paid \$90 million for an invalid patent. (For a patent of a new product to be accepted, it must be something new and useful. The “useful” part of this patent is reduced side effects.)”¹¹⁶ While it is

¹¹⁰ See *id.* at paragraphs 21, 25.

¹¹¹ See *id.* at paragraph 23 (alleging a lack of action by Mr. Norman and other trial counsel of Eli Lilly). See also Mitchell Zuckoff, *Prozac data was kept from trial, suit says*, BOSTON GLOBE, (June 8, 2000) <<http://www.connix.com/~narpa/prozac.data.suppressed.htm>> (noting that top Eli Lilly scientist Dr. Gary Tollefson testified at trial “that there is absolutely no medically sound evidence of an association between any antidepressant medicine, including Prozac, and the induction of suicidal ideation or violence”).

¹¹² See *Pumphrey v. K.W. Thompson Tool Co.*, 62 F.3d 1128 (9th Cir. 1995).

¹¹³ Vickery & Waldner, press release, *Suit Alleges Second Prozac Verdict Also Tainted*, (June 8, 2000) <www.justiceseekers.com>.

¹¹⁴ See Christa Zevitas, *New Prozac Patent Could Change the Tide of Litigation*, (visited Feb. 22, 2002) <<http://www.lawyersweekly.com/prozac.cfm>>.

¹¹⁵ See *id.*

¹¹⁶ Baum, Hedlund, Aristei, Guilford & Downey, press release, *Prozac Maker, Eli Lilly and Company, Committed Fraud on Hawaii Court by Concealing Crucial Evidence at Trial, Family in Newly Filed Lawsuit Allege*, (June 8, 2000) <www.baumhedlundlaw.com/media/pressreleasefraud.html>.

understandable that plaintiffs' attorneys would trumpet the value of this information, it is notable that they are not the only experts who feel the Sepracor patent is crucial. Author, psychiatrist, and Harvard Medical School instructor Dr. Joseph Glenmullen, who has written about the dangers of Prozac in his controversial book entitled "Prozac Backlash", stated that "To me the new patent can be compared to the tobacco papers. It's a pharmaceutical company document that acknowledges this dangerous side effect which has been downplayed by Eli Lilly and other pharmaceutical companies for a decade."¹¹⁷ It is certainly not clear how great of an impact this will have on suits against Eli Lilly, but it will provide plaintiffs at least a temporary boost of energy in their zeal to fight the drug maker. As usual, Eli Lilly will most likely continue to counter by settling most suits and by using what has thus far been a successful defense that combines blaming the actor's underlying mental illness, pointing to intervening circumstances in the actor's life, and relying on FDA approval as an indication of the safety of their product. As to the specific allegations regarding the Sepracor patent, Eli Lilly has responded by saying that Sepracor was an entirely separate company from Eli Lilly and that Eli Lilly did not have to find all of the side effects listed in the Sepracor patent to be medically or scientifically proven in order to find value in other aspects of the new drug.¹¹⁸

F. The Tobin Case

Having reviewed the two cases against Eli Lilly that reached jury verdicts (albeit under strange circumstances), I will now turn to the most publicized recent case to reach a jury. The latest case is that of Tobin v. SmithKline Beecham Pharmaceuticals, which is yet another horrific tale in which the plaintiffs assert that

¹¹⁷Mitchell Zuckoff, *Prozac data was kept from trial, suit says*, BOSTON GLOBE, (June 8, 2000) <<http://www.connix.com/~narpa/prozac.data.suppressed.htm>> (quoting Dr. Glenmullen).

¹¹⁸See Editorial, *The prozac question*, BOSTON GLOBE, June 13, 2000, at A26 (stating that "the patent's message should also be conveyed to a jury in a second trial of the... case").

an SSRI was the catalyst. The crime in this case occurred on February 13, 1998, when Donald Schell, a Wyoming man, killed his wife, as well as his visiting daughter and nine-month-old granddaughter, before turning the gun on himself.¹¹⁹ Schell had been taking Paxil for only two days before the murders¹²⁰, and had taken Prozac in the past (but stopped taking Prozac because of hallucinations caused by that drug).¹²¹ Timothy Tobin (Schell's son-in-law), the husband and father, respectively, of the murdered daughter and granddaughter, brought the wrongful death suit along with the sister of Schell's murdered wife, Neva Kay Hardy.¹²² While the arguments were essentially the same as in the Eli Lilly cases, Andy Vickery, who again was the plaintiffs' attorney, employed a somewhat different approach in the Tobin case. This time, he made sure that he "didn't let the defense try the case on an either/or basis: Was it depression or was it Paxil?"¹²³ Instead, he conceded that depression may be a risk factor for suicide and violent behavior, but asked the jury to find that Paxil "was a biological trigger that was a concurrent cause of the tragedy."¹²⁴ Another difference between the Tobin case and the previous ones against Eli Lilly was that while there was some documentation of Eli Lilly studies linking Prozac to suicide and violence, they may not have been as harmful to Eli Lilly as the documents discovered by the plaintiffs pertaining to SmithKline Beecham (SmithKline Beecham is now known as GlaxoSmithKline and will be referred to for the remainder of this paper as "SmithKline" given that the new ownership of the company is irrelevant to the substance of this paper) and Paxil. The plaintiffs in Tobin found internal company documents showing that company-requested studies had produced

¹¹⁹ See Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil010606.html>>.

¹²⁰ See Janet L. Holt, *Documents from Paxil Case May Aid Plaintiffs Harmed by Antidepressants*, TRIAL, September, 2001, at 84.

¹²¹ See Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil010606.html>> (citing Andy Vickery as source).

¹²² See *id.*

¹²³ Janet L. Holt, *Documents from Paxil Case May Aid Plaintiffs Harmed by Antidepressants*, TRIAL, September, 2001, at 84.

¹²⁴ *Id.*

evidence that hundreds of volunteers had adverse reactions to Paxil, including attempted suicide.¹²⁵ Vickery said that his strategy in Tobin was to use this evidence to argue that the defendant should have known of the risk, and therefore should have conducted clinical trials to further test for the possibility of a link between Paxil and the adverse reactions reported among volunteers.¹²⁶ Not surprisingly, Vickery suggested that the drug companies do such tests only to the extent necessary to get FDA approval and thus to make the maximum profits from the product without regard to ensuring maximum consumer safety.¹²⁷ Although Vickery's change in strategy and the addition of more evidence of pre-existing knowledge of SmithKline may have been the most tangible differences from the other cases, there were other significant differences between the Potter and Forsyth cases and the Tobin case. The most notable difference may have been the human element of the facts in the Tobin case. The defense strategy in the other cases had been, at least partially, to claim that there were recent circumstances in the life of the killer that were more likely to have caused the violent outburst than the antidepressant. Although Mr. Schell had been through the recent deaths of his brother and father-in-law, and SmithKline tried to use these events as likely causes of Mr. Schell's outburst¹²⁸, those events seem less serious than the ones experienced in the Eli Lilly cases. Wesbecker had lost his closest family member, and had reason to be angry with his workplace due to his reduction in benefits. Forsyth was said to have a failing marriage, which is often the cause of murder-suicides. But the problems Mr. Schell was experiencing did not seem to fit the crime he committed. There seemed to be no indication, before he took Paxil, that this kind of behavior would occur. In fact, Timothy Tobin himself has stated

¹²⁵ See *id.* at 86.

¹²⁶ See *id.*

¹²⁷ See *id.* (quoting Andy Vickery as saying that "Drug companies test exhaustively for things they can market", while noting that they should be as diligent in testing for risks).

¹²⁸ See Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil010606.html>> (stating that defense attorney Charles Preuss cited the death of Schell's father-in-law and brother, as well as problems at work regarding a threatened lawsuit, as among the contributing factors to his violent outburst).

that Mr. Schell was a caring, loving, and non-violent man and that the family was especially closely knit, particularly after the birth of the granddaughter (the family's first grandchild).¹²⁹ While there can be no certainty as to how significant a role this played in the jury's decision, the link between the killer's life events and the subsequent murders was far less apparent in this case than it had been in the two cases against Eli Lilly.

On June 6, 2001, the jury in the Tobin case found SmithKline 80% liable for Schell's actions¹³⁰, holding that "Paxil can cause some individuals to commit homicide and/or suicide".¹³¹ The court then awarded an \$8 million judgment based on the decision of the jury.¹³² Appeals by the defense are still pending, although the U.S. District Court of Wyoming denied SmithKline's request for judgment as a matter of law as well as its request for a new trial.¹³³ As expected, SmithKline did not believe the verdict was a true indication of the safety of Paxil. SmithKline attorney Charles Preuss still held after the case that "Paxil is a very effective medication in helping depression, and our only regret is that Mr. Schell did not have Paxil for a longer period of time."¹³⁴ "It's plain from the facts, science, and common sense," Preuss said in his closing arguments, "Don Schell's escalating depression caused this."¹³⁵ SmithKline Senior Vice-President David Wheadon appeared on the Today show following the Tobin decision, where he acknowledged that some patients have

¹²⁹ See *Four people dead is four too many*, THE GUARDIAN, (Aug. 9, 2001) <http://www.guardian.co.uk/health/story/0,3605,534058,00.html>.

¹³⁰ See Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil010606.html>> (noting that Donald Schell was found liable for 20% of the fault in the case).

¹³¹ *Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F. Supp. 2d 1278 (D. Wyo. 2001) (quoting the first of the necessary elements of proof given as jury instructions in the case).

¹³² See *Paxil's maker hit with \$8 million judgment*, HOUSTON CHRONICLE, (June 7, 2001) <<http://www.chron.com/cs/CDA/story.hts/nation/934893>>.

¹³³ See *Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F. Supp. 2d 1278 (D. Wyo. 2001).

¹³⁴ *Paxil's maker hit with \$8 million judgment*, HOUSTON CHRONICLE, (June 7, 2001) <<http://www.chron.com/cs/CDA/story.hts/nation/934893>>.

¹³⁵ Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil0106>>.

acted violently after taking Paxil, but that scientific data has not shown Paxil to be the cause.¹³⁶ Vickery countered, however, with what has always been his main contention. “Since 1990, SmithKline knew there was a small group at risk, and Don Schell was one of those vulnerable people”, Vickery stated.¹³⁷ So what are the questions that should be raised or conclusions that should be drawn from these three cases? First, it seems probable that the Tobin verdict will stimulate further suits against the drug makers. Since the hundreds of suits that were filed against Eli Lilly in the early 1990’s following Wesbecker’s shootings, the amount of suits filed have diminished substantially.¹³⁸ The new precedent established in Tobin may convince more plaintiffs, and perhaps more importantly more plaintiffs’ attorneys, to take their shots against the big pharmaceutical companies.¹³⁹ A second notable point following these cases is that Eli Lilly still appears to be untouchable. While their tactics have been questioned, the bottom line is that they have not had a losing verdict. This is despite the fact that most of the cases filed were against the maker of the popular Prozac.¹⁴⁰ Although it is probably true that the right plaintiff could score a victory against Eli Lilly, and those plaintiffs have probably existed, Eli Lilly has managed to keep them from having their cases heard before a jury. As such, Eli Lilly and Prozac appear to be likely, after more than ten years of cases alleging a link between Prozac and violent behavior, to escape broad sanctions in this area absent some yet to be

¹³⁶ See *Paxil’s maker hit with \$8 million judgment*, HOUSTON CHRONICLE, (June 7, 2001) <<http://www.chron.com/cs/CDA/story.hts/nation/934893>>.

¹³⁷ Associated Press, *Paxil Maker Ordered to Pay \$8 Million*, (June 6, 2001) <<http://www.abcnews.go.com/sections/living/dailynews/paxil0106>>.

¹³⁸ See Claudine Chamberlain, *Prozac Prosecution Rests* (visited Feb. 24, 2002) <<http://www.abcnews.go.com/sections/living/InYourHead/allinyourhead.45.html>> (quoting Andy Vickery, at some date prior to the Tobin case: “With the exception of me, I don’t know anybody who’s taking on new cases against these drug companies. It’s a monumental effort”).

¹³⁹ See Janet L. Holt, *Documents from Paxil Case May Aid Plaintiffs Harmed by Antidepressants*, TRIAL, September, 2001, at 84 (citing Andy Vickery’s belief that the Tobin result will lead to more cases. Also quoting Los Angeles attorney George “Skip” Murgatroyd: “the Tobin victory will make it easier for attorneys bringing antidepressant cases, primarily because company documents showing that Paxil could cause serious side effects were made public”).

¹⁴⁰ See Claudine Chamberlain, *Prozac Prosecution Rests*, (visited Feb. 24, 2002) <<http://www.abcnews.go.com/sections/living/InYourHead/allinyourhead.45.html>> (stating that “Eli Lilly alone has faced more than 160 civil lawsuits blaming Prozac for violence”).

found smoking gun (it has yet to be determined whether the Sepracor patent will be that smoking gun).

Another major question that arose following the Tobin verdict was the direct impact that decision would have on future suits. Andy Vickery speculated about this potential, saying that collateral estoppel may allow courts to rule across the board against SmithKline on pending Paxil litigation of substantially the same matter.¹⁴¹ Vickery's hope for a broad impact is based on the non-specific jury instruction in Tobin that Paxil can cause some individuals to commit homicide and/or suicide.¹⁴² Vickery got his chance to test out this collateral estoppel theory in *Coburn v. SmithKline Beecham Corp.*,¹⁴³ a Utah case. In that case, in which a Paxil user had committed suicide, Vickery made a motion for partial summary judgment on the grounds that collateral estoppel based on the result in Tobin rendered any argument in the case unnecessary.¹⁴⁴ The Coburn court rejected Vickery's attempt at collateral estoppel rather forcefully, listing several reasons why the Tobin verdict does not apply to Coburn.¹⁴⁵ Many of these reasons would also mandate that collateral estoppel not apply to most other cases brought against SmithKline. The first problem with collateral estoppel was one of "issue identity", which is a problem with the fact that it is not clear what the basis for the Tobin jury's decision was.¹⁴⁶ The plaintiffs in Tobin offered up several theories for recovery, and the jury was not asked to specify under which of those theories it was deciding for the plaintiff.¹⁴⁷ Instead, as noted above, the jury only said that Paxil can cause some individuals to commit suicide and/or homicide.¹⁴⁸ Another

¹⁴¹ See Janet L. Holt, *Documents from Paxil Case May Aid Plaintiffs Harmed by Antidepressants*, TRIAL, September, 2001, at 84, 86.

¹⁴² See *id.*

¹⁴³ *Coburn v. SmithKline Beecham Corp.*, 174 F.Supp. 2d 1235 (D. Utah 2001).

¹⁴⁴ See *id.*

¹⁴⁵ See *id.*

¹⁴⁶ *Id.* at 1238.

¹⁴⁷ See *id.*

¹⁴⁸ See *id.* (making clear that the Tobin jury did not specify which theory of the plaintiffs it accepted in awarding them the verdict. The factual differences between the cases make it necessary for a jury to determine whether Coburn was suffering from any of the potential Paxil-related causes of violent or suicidal behavior).

unidentified issue concerns the fact that only some people are vulnerable to the effects that apparently bothered Schell. Since the population of people in that group is undefined, the court refused to simply assume that Mr. Coburn should be included in that group based on the fact that he committed suicide while taking Paxil. Since there must be an examination of the specific facts of the case in order to determine whether Mr. Coburn is in the vulnerable subpopulation, the court decided that a jury was in the best position to make the determination.¹⁴⁹ A final ambiguity cited by the court was that the plaintiff had not shown that Utah applied the same tort liability standards as Wyoming.¹⁵⁰ Thus, even if the jury's reasoning was known, it would not be possible to use collateral estoppel unless the grounds for liability were the same in both states. Yet another problem with applying collateral estoppel is that the standard for a violation of the duty to warn is that the manufacturer knew or should have known about the fact for which a warning should have been given.¹⁵¹ In this case, Mr. Coburn was taking Paxil in November 1996.¹⁵² This was prior to 1998, when Schell shot his family and himself. Because of the earlier date, the court would not assume that SmithKline knew or should have known in 1996 what they knew or should have known in 1998.¹⁵³ In a related reason, the court determined that scientific evidence as it existed at the time of the Tobin trial could be different for the Coburn trial due to new studies or new interpretations of existing studies.¹⁵⁴ Another reason for denying the motion concerned a separate case pending against Pfizer, the makers of Zoloft. In *Miller v. Pfizer*,

¹⁴⁹ *See id.* (stating that, while Schell was found to be in some "vulnerable subpopulation" of Paxil users, the jury in that case did not define that subpopulation. As such, the Tobin result may not be applicable to Coburn since he may not have been affected by the drug in the way that Schell was).

¹⁵⁰ *See id.* at 1238-39.

¹⁵¹ *See id.* at 1239.

¹⁵² *See id.*

¹⁵³ *See id.*

¹⁵⁴ *See id.*

Inc.¹⁵⁵, the court's independent experts found that plaintiff expert witness Dr. Healy's opinions had not been accepted in the relevant scientific community.¹⁵⁶ As a result of this, the Coburn court refused to apply collateral estoppel from the Tobin case since Dr. Healy's testimony as an expert witness was an essential part of the plaintiffs' case in Tobin.¹⁵⁷ Instead, they decided that Utah would have to make a determination as to Dr. Healy's usefulness.

The Coburn court also reasoned that other similar cases had been decided in the direction of the defense, including Forsyth.¹⁵⁸ Also, the court noted that the defendants in the Smith v. Pfizer, Inc.¹⁵⁹ case won by summary judgment. Given these decisions and the fact that much of the evidence used by the plaintiffs is applicable to all SSRIs,¹⁶⁰ the court further reasoned that the case at hand was one of substantial factual question that could not be resolved simply based on the Tobin outcome.¹⁶¹ Finally, the court found it "contrary to public policy to allow a single jury verdict to brand an entire product defective throughout the country, particularly when there exists a significant and ongoing debate in the scientific and medical community about the issues involved in this and other SSRI cases".¹⁶² The court then goes on to note that the plaintiff may have been particularly sympathetic in the Tobin case, and that the Wyoming jury may have been acting out against a drug that generates over \$6 million per day for the manufacturer.¹⁶³ So the

¹⁵⁵ *Id.* (citing as follows: Miller v. Pfizer, Inc., United States District Court for the District of Kansas, No. 99-2326-KHV).

¹⁵⁶ *See id.*

¹⁵⁷ *See id.* at 1240.

¹⁵⁸ *See id.*

¹⁵⁹ *Id.* (citing as follows: Smith, 2001 WL 968369).

¹⁶⁰ *See id.* (noting also that defendant will continue to argue that SSRIs should not be considered together scientifically and legally).

¹⁶¹ *See id.* at 1240 (stating that "these inconsistent verdicts against other manufacturers of SSRI medications militate against applying collateral estoppel in this case").

¹⁶² *Id.* at 1241.

¹⁶³ *See id.* at 1241.

Coburn court very clearly ruled that collateral estoppel was inapplicable, and it could be expected based on the Coburn analysis that most other courts would rule the same way. As such, any further cases against the SSRI manufacturers will likely have to be decided based on the specific facts of the particular case. While the Tobin case may make a winning verdict seem like a less daunting prospect, the fact is that the difficulty in actually getting the case to a jury tends to favor settlement. While settlement may be in the best interest of judicial efficiency, it certainly does not help to answer the important underlying question of whether SSRIs do create dangers above and beyond what users, doctors, the FDA, and society at large would consider acceptable.

G. Concluding Remarks on the SSRI Link to Violent Behavior

The link between violent or suicidal behavior and SSRIs has produced a decade-long process of litigation that has yielded virtually no precedent and no firm scientific answers. That may not suggest that it still does not have the potential to result in huge liability for the drug producers, as there have been important developments in that area in the last two years.¹⁶⁴ Until the evidence against them becomes more compelling, however, the drug companies are unlikely to suffer the same fate as the tobacco companies.

III. SSRI Withdrawal Effects

While the threat of litigation for the link between SSRIs and suicide and violence may seem controllable to the drug manufacturers, there may be another storm of liability on the horizon that could prove (due

¹⁶⁴Namely the Tobin case and the Sepracor patent issue.

to the sheer number of plaintiffs who could bring suits) even more dangerous than the wrongful death and injury cases. A recent and fast-growing trend involves allegations by users of SSRIs that those drugs have resulted in a withdrawal syndrome, in which those who have used them suffer various side effects when they stop taking the medication. These side effects can be quite serious, and for the most part there is no warning given about the possibility of these withdrawal effects. Although the package insert for Paxil does include a mention of a withdrawal syndrome, it is reported in a way that makes side effects seem relatively rare.¹⁶⁵ Those who believe this insert is not enough argue that patients (and prescribing doctors) are not given a clear enough picture of just how difficult it may be to stop taking the drug and how long that process may take.

Among the additions to the warning, according to critics, should be the more serious effects that are commonly reported, including electroshock sensations felt within the heads of those trying to quit the drugs.¹⁶⁶ The manufacturers are clearly reluctant to provide such a warning, as that would tend to indicate that the drugs are addictive, which could scare off some doctors and/or consumers from prescribing and/or using the drugs.

Lawsuits have already been started by those who claim to be suffering from the withdrawal syndrome, both in the form of class actions and in groups seeking injunctions against the marketing and sale of the drugs until the label has been changed to warn of the potential withdrawal effects.¹⁶⁷ **A. Science of the Withdrawal Syndrome**

¹⁶⁵The new label for Paxil, found at www.fda.gov/medwatch/SAFETY/2001/dec01.html and announced by the FDA on December 14, 2001, includes a warning related to the discontinuation of Paxil. The most commonly reported side effect, according to the label, is dizziness, which was found to occur in 7.1% of those who discontinued the drug on the tapered method of discontinuation suggested on the label.

¹⁶⁶The December 14, 2001 label change, at www.fda.gov/medwatch/SAFETY/2001/dec01.html, does note that side effects such as electric shock sensations have been reported, but it says that such events may not have a causal relationship to Paxil.

¹⁶⁷See Baum, Hedlund, Aristei, Guilford & Shiavo, press release, *17 individuals file first (non-class action) lawsuit seeking damages against Smithkline Beecham for severe withdrawal reactions from the antidepressant, Paxil*, (Jan. 25, 2002)

The withdrawal syndrome, unlike other alleged consequences of taking SSRIs, differs based on the particular SSRI that was used. The half-life of each drug varies, with Paxil having the shortest half-life.¹⁶⁸ The SSRIs with the shortest half-lives leave the user's blood the most quickly and thus are most likely to cause quick and extreme withdrawal symptoms.¹⁶⁹ Prozac has the longest half-life of the SSRIs, which means that the users are less likely to experience withdrawal effects since the Prozac exits the system over a period of weeks.¹⁷⁰ Even with the longer half-life, Dr. Robert Hedaya¹⁷¹ says that "withdrawal symptoms take longer to hit, but that doesn't mean you won't experience them in four or five weeks."¹⁷² Nevertheless, Eli Lilly does appear again to be shielded from liability in this area, at least when compared to the other SSRI manufacturers. In fact, one website had a question and answer session with a doctor who advised a potential sufferer of Paxil withdrawal syndrome that "many authorities recommend switching to Prozac first because it doesn't have the withdrawal symptoms because it slowly leaves the body."¹⁷³ On the other end of the spectrum, and the subject of virtually all of the talk about SSRI withdrawal, is Paxil. Paxil has the shortest half-life in the group, and many users have reported severe effects upon stopping their regular doses of the medication.¹⁷⁴

<http://www.bhagd.com/media/ssri/paxil/Paxil-17-release.htm>. This release, in addition to providing the information in the title of the press release, also notes that they filed the first class action against SmithKline Beecham related to Paxil withdrawal on August 24, 2001, and that additional class action lawsuits have been initiated since that date.

¹⁶⁸ See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 129 (2001).

¹⁶⁹ See *A Painful Withdrawal: Unedited, Uncorrected Transcript of ABC-TV 20-20 Program*, (Aug. 25, 2000) <www.socialaudit.org.uk/5106-990.html>.

¹⁷⁰ See *id.*

¹⁷¹ Psychopharmacologist, Georgetown University professor, and author of "The Antidepressant Survival Guide".

¹⁷² *Getting Off Antidepressants: Withdrawal Side Effects of SSRIs Emerging*, 20/20, (August 25, 2000) <www.escapinghades.com/antidepressants.html>.

¹⁷³ Dr. Heller, *Is It Paxil Withdrawal?*, (visited Feb. 24, 2002) <<http://www.biologicalunhappiness.com/AskDoc/PaxilWdr.htm>>. The advice that Prozac does not have significant withdrawal symptoms directly conflicts with Dr. Breggin. See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 129 (Perseus Publishing 2001) (stating that "people do experience withdrawal reactions from Prozac, usually starting several days or weeks after terminating the drug").

¹⁷⁴ As evidenced by various lawsuits relating to Paxil withdrawal, television specials devoted to the topic, and multiple websites devoted to establishing a sense of community among those claiming to suffer from Paxil withdrawal syndrome.

B. SSRI Withdrawal, Television, and the Internet

One of the real phenomena that makes what is often referred to as Paxil withdrawal special is that the individuals who suffer from the effects, who would normally be isolated and have no way of knowing that others were experiencing similar side effects, are coming together on the internet. There are several web sites where past Paxil users testify to the problems they have had with the drug.¹⁷⁵ Many of the contributors to these sites express that they felt they were alone in suffering the side effects of Paxil withdrawal before finding others similarly situated on the internet. An example of this was seen by a national audience when ABC's "20/20" ran a segment on its August 25, 2000 program on the topic of Paxil withdrawal.¹⁷⁶ That special has become a major point of emphasis among those who claim to be experiencing withdrawal effects, as they felt that it helped to publicize and legitimize their suffering.

The segment featured moderator Connie Chung leading a discussion of several former Paxil users who claimed to have suffered from terrible post-use effects of Paxil.¹⁷⁷ Dr. Nancy Snyderman acted as the medical expert in the panel discussion.¹⁷⁸ Melissa Hall, who was one of the panelists on the program, said that she turned to the internet as a last resort when she could not find any doctors who seemed to understand the problems she was experiencing after stopping her regimen of Paxil.¹⁷⁹ When she finally typed "Paxil withdrawal" into an internet search engine, she said she found "hundreds of sites of people having the same exact symptoms" that she had been experiencing.¹⁸⁰ Panelist Shari Loback had a similar experience. Upon finding that there

¹⁷⁵Including: <http://www.quitpaxil.org/>; <http://www.paxilprogress.org/>; <http://paxil.bizland.com/jbuzzw.htm>; and <http://anxietyhelp.org/directory/meds/>.

¹⁷⁶A transcript of the "20/20" program was obtained on-line. *A Painful Withdrawal: Unedited, Uncorrected Transcript of ABC-TV 20-20 Program*, (Aug. 25, 2000) <www.socialaudit.org.uk/5106-990.html>.

¹⁷⁷*See id.*

¹⁷⁸*See id.*

¹⁷⁹*See id.*

¹⁸⁰*Id.*

were many others experiencing the same side effects, she said she thought “Oh, my God. This is me and nobody ever knew it. Nobody ever suggested that it was the Paxil.”¹⁸¹

While the specific stories found on the internet vary, those who tell their stories with Paxil withdrawal troubles paint a similar picture of having their daily lives interrupted by the severity of the symptoms. Tanya is a typical example. On a Harvard University forum, she wrote that after quitting Paxil (which she was taking in an effort to alleviate her migraine headaches) cold turkey, she “experienced the WORST dizziness” and that her “whole world is constantly spinning.”¹⁸² Furthermore, demonstrative of the dangers of the more serious side effects, she claims that she “got into a car accident Friday, and have not driven since.”¹⁸³ Adding to Tanya’s frustration was the fact that her doctor told her that the Paxil stoppage had nothing to do with her illness and that she probably just had a virus.¹⁸⁴ While that doctor’s assessment may have been correct, the total disregard for her problems left her dumbfounded, and she stated that she was considering a move back to England “just to have the support of my family while seeking care.”¹⁸⁵ **C.**

Does Paxil Withdrawal Really Exist?

Whether an actual withdrawal syndrome exists is debatable, at least to the extent that many of the sufferers claim. Just as the link between SSRIs and violence and suicide remains unproved, so too does the extent of the withdrawal effects of these drugs. Dr. Nancy Snyderman, however, indicated that she had spoken

¹⁸¹ *Id.*

¹⁸² Tanya, *Paxil withdrawal? help pls!*, (Nov. 9, 1999) <http://neuro-www.mgh.harvard.edu/forum_2/HeadacheF/11.9.993.41MPaxilwithdra.htm>

¹⁸³ *Id.*

¹⁸⁴ *See id.*

¹⁸⁵ *Id.*

“with over 50 people who say they suffered from similar problems,”¹⁸⁶and these numbers multiply quickly upon taking a quick survey of the internet sites devoted to those who claim to be part of this group of sufferers. The problems Dr. Snyderman mentioned were “headaches, nausea, electric-shock sensations, and confusion.”¹⁸⁷While the headaches and nausea may seem trivial and not likely to trigger widespread tort liability for the manufacturers, that may not be accurate. These symptoms have reportedly been so severe as to render it impossible for those suffering the symptoms from conducting their daily activities such as going to work. Melissa Hall, for example, said that she “didn’t work for two months” and that she “just laid on my couch waiting for the dizziness and nausea and everything to go away.”¹⁸⁸“There’s no question” the withdrawal difficulties are real, says Dr. Hedaya.¹⁸⁹ Another source that believes in the Paxil withdrawal syndrome is the World Health Organization (WHO). The WHO has stated that “Paxil has the highest incidence rate of withdrawal adverse experiences of any antidepressant drug in the world.”¹⁹⁰Although it is not clear how many of the total users suffer some withdrawal effects, the estimates and studies range as high as 85% of people taking all SSRI antidepressants.¹⁹¹This is in comparison to the 1-2% number that SmithKline’s spokesman had claimed for Paxil,¹⁹²and the 7% figure on the current Paxil label.¹⁹³While the exact percentage is debated, in each case it is a statistically significant number of users who suffer upon

¹⁸⁶A *Painful Withdrawal: Unedited, Uncorrected Transcript of ABC-TV 20-20 Program*, (Aug. 25, 2000) <www.socialaudit.org.uk/5106-990.html>.

¹⁸⁷*Id.*

¹⁸⁸*Id.*

¹⁸⁹*Id.*

¹⁹⁰*Paxil Side Effects Lawsuits*, (visited Feb. 24, 2002) <www.paxil-side-effects-lawsuits.com/pages/withdrawals.html>.

¹⁹¹*See id.*

¹⁹²Alison Tonks, *Withdrawal from paroxetine can be severe, warns FDA*, BRITISH MEDICAL JOURNAL, (Feb. 2, 2002) <<http://bmj.com/cgi/content/full/324/7332/260>> (stating that a company spokesman for GlaxoSmithKline had called withdrawal symptoms for Paxil “very rare” and noted that they occur in only two out of every 1,000 patients).

¹⁹³From www.fda.gov/medwatch/SAFETY/2001/dec01.html.

stopping their doses.

A related problem with the understatement of withdrawal effects and the failure to have them legitimized is that it makes an already vulnerable population of depressed people feel crazy. Dr. Snyderman suggests that experts call this feeling among depressed people a “dangerous state of mind”.¹⁹⁴ Those who deny the existence of a widespread syndrome, at least in a more serious form, discredit much of the evidence by calling it anecdotal.¹⁹⁵ In scientific circles, this is critical, as the methods and processes of trained scientists are thought to be the only way to produce a reliable and useful result. Perhaps because many of the critics of SSRIs use anecdotal evidence, the advocates for reform generally suggest that there be further testing and study required by the FDA based on all of the reported problems rather than an outright present ban of the drugs.

Dr. David Wheadon of SmithKline says that to the extent the problems do occur, they are not severe and do not last long.¹⁹⁶ Retreating to one of the most successful and frequently used pharmaceutical company strategies, he also raises the point that people may be confusing withdrawal symptoms for what may in fact be a return of the problem that originally led one to begin taking the antidepressant.¹⁹⁷ This is a win-win argument for the company, as it deflects the possibility of a withdrawal syndrome while at the same time suggesting that the former user should perhaps begin to take the drug again to make the symptoms come to a

¹⁹⁴ *A Painful Withdrawal: Unedited, Uncorrected Transcript of ABC-TV 20-20 Program*, (Aug. 25, 2000) <www.socialaudit.org.uk/5106-990.html>.

¹⁹⁵ See Craig Offman, *Prozac indignation: How a little-known Harvard clinician needled sleeping giant Eli Lilly*, (May 17, 2000) <www.salon.com/health/feature/2000/05/17/backlash/> (quoting Eli Lilly marketing and communications associate Laura Miller, in commenting about Dr. Glenmullens' *Prozac Backlash*: “It’s full of anecdotes that will frighten people off their medication. It’s a disservice to all patients”).

¹⁹⁶ See Alison Tonks, *Withdrawal from paroxetine can be severe, warns FDA*, BRITISH MEDICAL JOURNAL, (Feb. 2, 2002) <<http://bmj.com/cgi/content/full/324/7332/260>>.

¹⁹⁷ See *A Painful Withdrawal: Unedited, Uncorrected Transcript of ABC-TV 20-20 Program*, (Aug. 25, 2000) <www.socialaudit.org.uk/5106-990.html>.

stop! When asked by Dr. Snyderman about the fact that the supposed withdrawal symptoms are symptoms that the patient had never previously experienced, Dr. Wheadon responded that “when that illness recurs”, you are not guaranteed to “have the same sort of symptoms.”¹⁹⁸ This, despite being true, does not address such symptoms as feelings of electroshock, which have never been known to be a sign of depression or other illnesses Paxil is used to treat.

The previously mentioned “20/20” panelist, Melissa Hall, made the ironic point that one of the reasons she started taking Paxil was that her doctor told her that there were few side effects from starting the drug.¹⁹⁹ This is a clear indication of what critics say is wrong with the current state of affairs. They argue that the drug companies know that many of these withdrawal effects are serious and legitimate, and that by not providing an appropriate warning to doctors and consumers they are unnecessarily subjecting the patients to painful and discomforting effects of quitting the drug.²⁰⁰

D. Has the Medical Community Responded to Possible Withdrawal

The belief that many doctors do not understand the potential effects of discontinuing SSRI use has been confirmed by at least one study. The Journal of Clinical Psychiatry reported that “as many as 70% of general practitioners and 30% of psychiatrists do not know about the side effects of ending serotonin-boosting drugs.”²⁰¹ This problem is exacerbated by the fact that there is an even further problem with getting the doctor’s knowledge relayed to the patient. The same Journal of Clinical Psychiatry report found that of those doctors who did know about the SSRI side effects, “only 20% of psychiatrists and 17% of general practitioners caution their patients about the proper way to slowly lower the levels of these drugs to come

¹⁹⁸ *Id.*

¹⁹⁹ *See id.*

²⁰⁰ *See* Joseph Glenmullen, M.D., PROZAC BACKLASH 61 (2001).

²⁰¹ Robin Eisner, *Falling Off Prozac*, (May 24, 2001) <<http://abcnews.go.com/sections/living/DailyNews/ssri000524.html>>.

off them.”²⁰² Thus, only about 5.1% of patients of general practitioners and 14% of patients of psychiatrists are counseled on the proper way to stop taking these drugs. This is the type of gap that activists in the area are trying to correct through mass publicity, lawsuits, new labels, and doctor education. “Getting off these drugs properly is an issue that is underappreciated,” says Dr. Alexander Bodkin, who is the director of the clinical psychopharmacology research program at Harvard Medical School affiliate McLean Hospital in Belmont, Massachusetts.²⁰³ ***E. A New Paxil Label***

The latest piece of news in this area is a positive development for those who have contended all along that there is a serious withdrawal syndrome. That development is a new label that was approved for Paxil as part of approving the drug for use in the treatment of post-traumatic stress disorder.²⁰⁴ The new label includes recognition of a more severe problem with discontinuation²⁰⁵ of Paxil than had been previously admitted by the company, although the warning does stop short of stating that there is a causal link between the drug’s discontinuation and the symptoms.²⁰⁶ The bulk of the new label deals with the importance of a gradual reduction in dosage as opposed to an abrupt discontinuation of the medication.²⁰⁷ The label also indicates that resuming treatment with the previously prescribed dose may be considered if the patient shows intolerable symptoms of the discontinuation program.²⁰⁸ After this, the recommendation is to once again attempt to

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ See Baum, Hedlund, Aristei, Guilford & Shiavo, press release, *17 individuals file first (non-class action) lawsuit seeking damages against Smithkline Beecham for severe withdrawal reactions from the antidepressant, Paxil*, (Jan. 25, 2002) <http://www.bhagd.com/media/ssri/paxil/Paxil-17-release.htm>.

²⁰⁵ “Discontinuation” is preferred to “withdrawal” by the drug makers due to the fact that “withdrawal” is associated more with addictive drugs. See Peter R. Breggin, M.D., *GSK Updates the Paxil Label*, (viewed Feb. 24, 2002) <http://www.breggin.com/paxilwithdrawalsuit.html>.

²⁰⁶ From www.fda.gov/medwatch/SAFETY/2001/dec01.html (stating that “During Paxil marketing, there have been spontaneous reports of similar adverse events, which may have no causal relationship to the drug, upon the discontinuation of Paxil (particularly when abrupt)”).

²⁰⁷ From www.fda.gov/medwatch/SAFETY/2001/dec01.html (stating that “A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible”).

²⁰⁸ From www.fda.gov/medwatch/SAFETY/2001/dec01.html (stating that “If intolerable symptoms occur following a decrease

taper the patient off of the drug at an ever more gradual rate.²⁰⁹ As a result of this new label, one of the first class-actions suits against SmithKline was voluntarily dismissed.²¹⁰ One of the lawyers who brought the suit, Don Farber, told Dr. Breggin that “it is highly likely that the suit influenced both the drug company and the FDA to strengthen the label in regard to Paxil withdrawal effects.”²¹¹ This is a demonstration of the effectiveness of lawsuits in motivating the drug companies to take steps to protect and inform the consuming public.

Some critics, including Dr. Breggin, believe the amended label does not go far enough in warning consumers and doctors of the dangers of withdrawing from Paxil and other drugs. Dr. Breggin says that use of the term “discontinuation” rather than “withdrawal” allows the drug maker to obscure “the potential severity of these symptoms and their tendency to force patients to continue taking the drug.”²¹² He goes on to say that the new Paxil label is “grossly inadequate in regard to the range, intensity, and persistence of Paxil withdrawal reactions, including the danger of aggressive, violent, or suicidal behavior, and an overall worsening of the patient’s medical condition.”²¹³

An additional noteworthy item is that the British Medical Journal’s online edition reported that the Inter-

in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered”).

²⁰⁹From www.fda.gov/medwatch/SAFETY/2001/dec01.html (stating that “Subsequently, the physician may continue decreasing the dose but at a more gradual rate”).

²¹⁰See Peter R. Breggin, M.D., *GSK Updates the Paxil Label*, (viewed Feb. 24, 2002) <http://www.breggin.com/paxilwithdrawalsuit.html>.

²¹¹*Id.*

²¹²*Id.*

²¹³*Id.*

national Federation of Pharmaceutical Manufacturers Association recently “declared the company guilty of misleading the public about paroxetine (the chemical name for Paxil) on US television.”²¹⁴The Association’s consideration of this issue came as a result of a complaint filed by Charles Medawar, who is the head of a consumer research group named Social Audit.²¹⁵The misleading information that the Association refers to is the statement of SmithKline’s Dr. Wheadon, who said, as noted above, that the withdrawal symptoms are only found in one or two of 1,000 people who stop taking the drug.²¹⁶After considering the statements made by Dr. Wheadon, the Association ruled that they were promotional and wrong.²¹⁷In fact, the new FDA label shows that clinical studies found that 7.1% of patients suffered dizziness as part of the aftereffects of a program in which the drug was discontinued gradually before being abruptly stopped at 20mg/day.²¹⁸

F. Judicial Awareness of SSRI Withdrawal Effects

Although there have been no cases brought to a decision on the issue of SSRI withdrawal, there is an indication that at least one court has already accepted the view that such a problem exists. In McClure v. Walgreen Co.²¹⁹, the court held that Walgreen’s incorrectly filled a Pepcid (antacid) prescription with Paxil.²²⁰After being informed of the error, Walgreen’s did not inform the patient of any Paxil withdrawal effects.²²¹The patient was then hurt twelve days after discontinuing the Paxil, in a fall that was attributed

²¹⁴Alison Tonks, *Withdrawal from paroxetine can be severe, warns FDA*, BRITISH MEDICAL JOURNAL, (Feb. 2, 2002) <<http://bmj.com/cgi/content/full/324/7332/260>>.

²¹⁵*See id.*

²¹⁶*See id.*

²¹⁷*See id.*

²¹⁸From www.fda.gov/medwatch/SAFETY/2001/dec01.html.

²¹⁹McClure v. Walgreen Co., 613 N.W.2d 225 (Iowa, 2000).

²²⁰*See id.* at 229.

²²¹*See id.* at 231 (stating that “contrary to pharmacy standards and its own policy manual, Walgreen neglected to warn Shari or her family of such adverse side effects”).

by doctors to dizziness brought on by Paxil withdrawal.²²² “What made Walgreen’s conduct particularly egregious”, stated the decision of the court, “was its failure to warn Shari or her doctors of the serious side effects associated with Paxil and the abrupt discontinuance of the drug.”²²³ Although the purpose of this case was not to debate side effects of the discontinuance of Paxil use,²²⁴ the court’s assumption that these effects exist may further add to what seems to be a common belief among past users that this is an unquestionable fact. While far from establishing as fact the existence of a Paxil withdrawal syndrome, the McClure court does bolster the critics of the drug by assuming what is argued to some degree by SmithKline.

Among the recent lawsuits that have been recently publicized is one that was filed on January 25, 2002 by 17 people who claim to have suffered from the Paxil withdrawal effects.²²⁵ The attorneys representing the plaintiffs claim that this is the first non-class action lawsuit of this kind, and that “class action lawsuits have been cropping up across the country related to Paxil withdrawal ever since” their first such suit was filed against SmithKline on August 24, 2001.²²⁶ The strategy of the firm bringing this new suit seems to be to stress the stability and normalcy of the individual plaintiffs, which was a problem in the cases trying to link SSRIs to violent and suicidal behavior. Among the plaintiffs in the new case are a research doctor and a pharmacist.²²⁷ In addition, having medically educated people claim that they were unaware of this syndrome will add to the plaintiffs’ case that the previously used warning was not enough to indicate the true severity of the withdrawal problems.

²²² See *id.* at 229 (stating that “On September 9, 1997... she fell again because of dizziness” and “Medical testimony attributed this fall to symptoms of a withdrawal syndrome associated with the abrupt discontinuance of Paxil”).

²²³ *Id.* at 231.

²²⁴ See *id.* The opinion at no point mentions any argument by the defendant that the Paxil withdrawal symptoms are a fiction.

²²⁵ See Baum, Hedlund, Aristei, Guilford & Shiavo, press release, *17 individuals file first (non-class action) lawsuit seeking damages against Smithkline Beecham for severe withdrawal reactions from the antidepressant, Paxil*, (Jan. 25, 2002) <http://www.bhagd.com/media/ssri/paxil/Paxil-17-release.htm>.

²²⁶ *Id.*

²²⁷ See *id.*

G. Concluding Remarks on SSRI Withdrawal

As with the link to suicide and violence, one of the major issues with withdrawal syndrome is the need for more research. The companies have little incentive to do this research, as they are reliant on the revenues generated by these antidepressants. Dr. Peter Haddad, consultant psychiatrist at Mental Health Service NHS Trust in Salford, England, believes that these types of problems should be addressed before any approvals of new antidepressant drugs.²²⁸ “This is a seriously under-researched area”, Dr. Haddad has said.²²⁹ “There’s no good evidence to help doctors get the dosing right as patients come off treatment. It’s still a matter of trial and error.”²³⁰ This observation is an important one, as the ability to administer effective health-care should be one of the main objectives of the regulatory authorities. In a case such as this one, where negative effects of a drug become known as at least reasonably possible based on anecdotal evidence, the FDA should have the authority to order further testing to keep the drug on the market. A reasonable time could be given to conduct these tests, and the drug companies would have plenty of incentive to conduct the tests given their reliance on the revenue from these drugs. Short of this solution, the types of problems discussed by current and past SSRI users, as well as some health-care providers and scientists, will continue to occur, as doctors have no reason to suspect that they should administer drugs such as these SSRIs differently than other types of drugs they prescribe.

²²⁸ See Alison Tonks, *Withdrawal from paroxetine can be severe, warns FDA*, BRITISH MEDICAL JOURNAL, (Feb. 2, 2002) <<http://bmj.com/cgi/content/full/324/7332/260>>.

²²⁹ *Id.*

²³⁰ *Id.*

IV. Are SSRIs Over-Prescribed?

A final area that must be discussed involving SSRIs is one that has been the subject of substantial debate. The issue is whether the SSRIs are being over-prescribed. Many doctors today believe that far too many prescriptions are being written for SSRIs. “I feel we have a national health-care crisis,” Dr. Glenmullen observed.²³¹ “These antidepressants are being vastly over-prescribed, while their dangers are being ignored.”²³² These critics further claim that it is problematic that the drugs are being prescribed for far broader uses than those for which they were approved (off-label uses) by the FDA.²³³ A related and scary issue is that children are also receiving mass quantities of SSRIs despite the fact there has been little specific FDA approval for treatment of children.

While it is unquestioned that millions of people are taking SSRIs, the supporters of the drugs argue that their use is helping those millions of people live happier, more productive lives.²³⁴ The critics, however, believe that the profitability of the drugs is leading the industry to push them beyond their intended purposes and to people whose benefits from the drug could be exceeded by far by the possible problems that were discussed

²³¹Judith Blake, *Drugs and depression: How much is too much?*, SEATTLE TIMES, (Apr. 12, 2000) <<http://seattletimes.nwsourc.com/news/lifestyles/html98/proz12.20000412.html>>.

²³²*Id.*

²³³See Todd Zwillich, *SSRI Prescribing in Primary Care Draws Fire*, CLINICAL PSYCHIATRY NEWS, (visited Mar. 10, 2002) <http://www.drugawareness.org/Oldsite/admissions.html> (citing Stephen Crystal, Ph.D., who researches prescribing trends at Rutgers University, for the proposition that “research is beginning to show that large numbers of prescriptions for selective serotonin reuptake inhibitors (SSRIs) aren’t accompanied by a diagnosis of depression or any other mental condition”).

²³⁴See The National Institute of Mental Health, (visited Mar. 4, 2002) <www.nimh.nih.gov/publicat/numbers.cfm> (citing information that supports the advocates of increased diagnosis of mental illness. The NIMH cites a study that 22.1% of American adults “suffer from a diagnosable mental disorder in a given year.” The same study then shows that more than 9% of adults have some kind of depression disorder, and that women are almost twice as likely as men to have such a depression disorder in a given year).

in the prior parts of this paper.

A. Approved Uses for SSRIs

Although the approved uses do not limit the illnesses for which the antidepressants may be described, the growing list of approved problems for some of the SSRIs is, according to some, indicative of a desire by the manufacturers to use the drugs as panaceas. The most recent trend has been FDA approval of SSRIs for various anxiety disorders²³⁵, which critics claim are akin to shyness and should not be corrected with serious medication. The clear effect of approval for problems that could be considered commonplace is that the drug companies are able to target a wide segment of the population as potential users of their products. By broadening their consumer base, the drug companies are able to significantly expand their potential revenue.

B. Mental Health Professionals vs. Primary Care Physicians

A problem closely related to the prior point is that many of these antidepressants are being prescribed by primary care doctors rather than psychiatric doctors who could more appropriately determine the condition of the patient.²³⁶Part of this is due to the growth of HMOs, as the HMO primary care physician is pressured to refer as little as possible to specialists given the costliness of such specialists.²³⁷

Some experts believe that the participation of primary care physicians is not a problem, or at least that the benefits of primary care doctor participation outweigh any of the perceived problems. Although primary

²³⁵See *id.* (stating that a staggering 13.3% of Americans aged 18-54 suffer from some type of anxiety disorder in a given year. It lists “panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, generalized anxiety disorder, and phobias (including social phobia)” as examples of anxiety disorders).

²³⁶See Todd Zwillich, *SSRI Prescribing in Primary Care Draws Fire*, CLINICAL PSYCHIATRY NEWS, (visited Mar. 10, 2002) <http://www.drugawareness.org/Oldsite/admissions.html> (stating that “while an estimated 11 million psychiatrist appointments included an antidepressant prescription in 1994, more than 10 million other antidepressant prescriptions were written by primary care doctors”).

²³⁷See *id.*

care doctors are less experienced with psychological conditions than psychiatrists, they are gaining more experience with the drugs and their effects as a result of having so many patients using them.²³⁸ Additionally, the use of less costly primary care physicians is thought to provide access to these drugs to a much more diverse range of patients.²³⁹ “Those who are underserved by specialists are nonwhite and not wealthy. They are the ones who benefit most from primary care physician prescribing,” said psychiatrist Dr. Gregory Simon.²⁴⁰ This increase in availability can be viewed as a positive impact of increased primary care physician participation, assuming that the benefits of the drugs outweigh their social costs.²⁴¹

C. Other Side Effects of SSRIs

Although some of the problems associated with SSRIs have been widely disputed as discussed previously in this paper, there are some side effects that are admitted and acknowledged by the manufacturers (although just how often those side effects manifest is an oft-disputed point). An example of this is sexual dysfunction, which has been linked to the SSRIs and acknowledged by the manufacturers. In Dr. Glenmullen’s book, he holds that up to 60% of Prozac users experience sexual dysfunction.²⁴² While Eli Lilly admits to the effect, their estimate is in the 20-30% of users range.²⁴³ The inability of the drug companies to recognize and disclose the magnitude of side effects is magnified even more when looking at the fact that Eli Lilly’s labels still indicated only a 2-5% occurrence of sexual dysfunction as of 2000.²⁴⁴ As is demonstrated by this example,

²³⁸ See *id.*

²³⁹ See *id.*

²⁴⁰ *Id.*

²⁴¹ An assumption that is speculative given the conflicting opinions presented in this paper on the level of effectiveness of these drugs as compared to their potential harms.

²⁴² See Craig Offman, *Prozac indignation: How a little-known Harvard clinician needled sleeping giant Eli Lilly*, (May 17, 2000) <www.salon.com/health/feature/2000/05/17/backlash/>.

²⁴³ See *id.*

²⁴⁴ See *id.*

there will generally be more accurate information reported about the side effects of SSRIs after more time is allowed to study such effects. In the meantime, however, a large volume of the public (28 million Americans according to one study)²⁴⁵ is being exposed to a set of drugs that may have more far-reaching effects than originally thought.

While it is typically the case for any prescription medication that more will be known about the drug after the public uses it for years, the widespread prescription of the SSRI drugs is deemed by some to subject patients to an unnecessary risk of effects of drugs that they do not need. Dr. Glenmullen, unlike some of the other critics of the SSRIs, does not avoid prescribing them to his patients.²⁴⁶ Instead, he practices and preaches a more judicious method of treatment, in which such drugs are only prescribed for those who are suffering from more serious mental illnesses.²⁴⁷

Critics of the manufacturers suggest that the doctors are being under-informed about the risks of SSRIs, and are therefore passing out the drugs without requiring that the condition in question be serious enough to warrant the medicine. They claim that the ease of first time prescription and then the future ease of renewal is not consistent with the dangers of the prescribed medication.²⁴⁸ Dr. Breggin drives home the point that these drugs are too easily obtained by suggesting that the SSRIs have effects that mimic

²⁴⁵ See Nicholas Regush, *More Prozac Backlash: Drug Firm Attacks Prozac Book, But Lacks Long-Term Data*, (visited Feb. 27, 2002) <http://www.abcnews.go.com/sections/living/SecondOpinion/secondopinion_80.html>.

²⁴⁶ See Judith Blake, *Drugs and depression: How much is too much?*, SEATTLE TIMES, (Apr. 12, 2000) <<http://seattletimes.nwsourc.com/news/lifestyles/html98/proz12.20000412.html>>.

²⁴⁷ See Robin Eisner, *Falling Off Prozac*, (May 24, 2001) <<http://abcnews.go.com/sections/living/DailyNews/ssri000524.html>> (stating that “Glenmullen says today the serotonin boosters are being prescribed for more and more moderate conditions, but that they should be reserved for people who are truly debilitated by their mental illness”).

²⁴⁸ See Judith Blake, *Drugs and depression: How much is too much?*, SEATTLE TIMES, (Apr. 12, 2000) <http://seattletimes.nwsourc.com/news/lifestyles/html98/proz12.20000412.html> (noting a Glenmullen account of a patient “who received a six-month prescription for an antidepressant from an emergency-room doctor after her second visit for a panic attack”).

amphetamines or cocaine.²⁴⁹ If Dr. Breggin and others are right about the dangers of SSRIs, it is difficult to justify the prescription of such drugs for relatively minor problems such as shyness, headaches, or weight gain concerns. Many doctors still doubt these dangers, however, and prescribe the SSRIs for virtually any ailment, regardless of whether it is considered to be strictly a mental health problem. Dr. Donald Black, President of the American Academy of Clinical Psychology, is a believer in both the safety and effectiveness of the SSRIs and thus disputes the claims of SSRI critics. He has called them “remarkably safe and versatile,” and has even prescribed the antidepressants to help prevent patients from biting their fingernails.²⁵⁰

D. SSRIs for Children

Another criticized practice is the proliferation of SSRI prescriptions for children.²⁵¹ The FDA has not specifically approved most of the SSRIs for use in children, but rather gives a blanket approval for the drugs based on adult testing for safety and effectiveness.²⁵² Despite the fact that the most successful SSRIs are have not been specifically approved for children, doctors can prescribe them to children at their discretion.²⁵³ Critics believe this is a dangerous thing to do, as the labeling relates to adults, and because dosages cannot simply be cut by certain percentages based on body weight or some other measure to be used safely and effectively.²⁵⁴ The only real solution to this problem is for the drug companies to test the products on children in order to gain specific FDA approval²⁵⁵, which they have already done or are beginning to do for the most popular SSRIs. Until the specific approval, however, the companies will continue to quietly market the products for use in children. Evidence of this is found in the fact that most of the SSRIs are already

²⁴⁹See Peter R. Breggin, M.D., *THE ANTIDEPRESSANT FACT BOOK* 56 (2001).

²⁵⁰Judith Blake, *Drugs and depression: How much is too much?*, SEATTLE TIMES, (Apr. 12, 2000) <http://seattletimes.nwsource.com/news/lifestyles/html98/proz12.20000412.html>.

²⁵¹See Dr. Joseph Glenmullen, (May 24, 2000) <http://abcnews.go.com/sections/living/DailyNews/000524_prozac_glenmullen_chat.html> (stating that he was “very concerned about the huge number of children that are being prescribed these antidepressants”).

²⁵²See Leticia M. Diaz, Esq., *Regulating the Administration of Mood-Altering Drugs to Juveniles: Are We Legally Drugging Our Children?*, 25 SETON HALL LEGIS. J. 83, 97 (2001) (presenting a chart showing that Zoloft and Luvox are approved for children with respect to obsessive compulsive disorder).

²⁵³See Elyse Tanouye, *Pharmaceuticals: Antidepressant Makers Study Kids' Market*, THE WALL STREET JOURNAL, Apr. 4, 1997, at B1.

²⁵⁴See Leticia M. Diaz, Esq., *Regulating the Administration of Mood-Altering Drugs to Juveniles: Are We Legally Drugging Our Children?*, 25 SETON HALL LEGIS. J. 83, 100 (2001).

²⁵⁵See *id.* at 104.

offered in forms that are more palatable to children, including a minty flavored Prozac.²⁵⁶ While there is nothing illegal or possibly even unethical about such marketing toward prescription for children, the dangers are unknown and critics believe specific testing is in the best interest of this vulnerable population.

Critics also suggest that SSRIs that have not been specifically tested for pediatric use present a special problem because parents often are not aware that the drugs have not been tested on or approved for children. “Parents are in a very difficult situation of having to make the best judgment with their physicians, without data,” says Peter Jensen, an official at the National Institutes of Health.²⁵⁷ Nonetheless, about 580,000 children received prescriptions for Prozac, Paxil, or Zoloft in 1996, according to IMS America Ltd., a research firm.²⁵⁸ Another firm, Scott-Levin Inc. says that children account for about 4% of all prescriptions for antidepressants.²⁵⁹ These large numbers are part of a larger problem seen by Dr. Glenmullen, who has stated that “children are the tip of the iceberg” and that “I think it’s just a reflection of the irrational way they’re being prescribed across the board that we’re seeing them so commonly prescribed to children.”²⁶⁰

While this may be cause for concern, many people assume, perhaps rationally, that the FDA would not allow the practice of prescribing medications to children and adults if they had reason to believe that there was a greater risk of dangers to children than adults from taking the drugs. Thus, in this case the companies may appropriately be able to cite the FDA policy as a justification for the way they promote the drug to be useful for children and adults. It is unquestioned that the FDA knows the drugs are being widely prescribed to children in practice. Dr. Thomas Laughren, FDA team leader for psychiatric drug products, admitted

²⁵⁶ See Elyse Tanouye, *Pharmaceuticals: Antidepressant Makers Study Kids’ Market*, THE WALL STREET JOURNAL, Apr. 4, 1997, at B1.

²⁵⁷ *Id.*

²⁵⁸ *See id.*

²⁵⁹ *See id.*

²⁶⁰ Dr. Joseph Glenmullen, (May 24, 2000) <http://abcnews.go.com/sections/living/DailyNews/000524-prozac_glenmullen_chat.html>.

“if we approve a drug for depression in adults, we know it be applied in kids.”²⁶¹ The FDA, therefore, has urged the companies to conduct testing on children given that this class of drugs is already being so widely prescribed to youths.²⁶² The companies are responding to this, and are seeking approval in many cases for the SSRIs for use in children.²⁶³ In the meantime, their primary defense to the critics of the widespread treatment of children with SSRIs is that the drugs are serving an important need by helping some of the millions of children in America who are thought to suffer from depression and obsessive-compulsive disorder.

Some have worried that the dangers of the drugs, particularly with respect to prescribing them to children, have manifested themselves in several of the mass school shootings that have been well-publicized in recent years. In several of those cases, one or more of the shooters was taking an SSRI.²⁶⁴ The most famous of those cases is Eric Harris, one of the two shooters at Columbine High School in Littleton, Colorado. Harris was taking Luvox at the time of the shootings,²⁶⁵ which is actually FDA approved for children up to the age of 17 for the treatment of obsessive-compulsive disorder.²⁶⁶ Although the scientific proof in linking children’s violent behavior to the SSRIs is no more compelling than the link between adult violent behavior and SSRIs that was discussed above, the high-profile nature of these publicized homicidal students who turn out to have taken an SSRI provides additional worry for the drug companies.

E. Concluding Remarks on the Possible Over-Prescription of SSRIs

²⁶¹Leticia M. Diaz, Esq., *Regulating the Administration of Mood-Altering Drugs to Juveniles: Are We Legally Drugging Our Children?*, 25 SETON HALL LEGIS. J. 83, 99 (2001).

²⁶²*See id.* at 100.

²⁶³*See* Elyse Tanouye, *Pharmaceuticals: Antidepressant Makers Study Kids’ Market*, THE WALL STREET JOURNAL, Apr. 4, 1997, at B1.

²⁶⁴*See* Leticia M. Diaz, Esq., *Regulating the Administration of Mood-Altering Drugs to Juveniles: Are We Legally Drugging Our Children?*, 25 SETON HALL LEGIS. J. 83, 90-91 (2001) (stating that eighteen-year-old high school senior Eric Harris killed 13 people after having taken Luvox, and that 15-year-old Oregon high school student Kip Kinkel was taking Ritalin and Prozac before killing his parents and two students).

²⁶⁵*See id.* at 85.

²⁶⁶*See id.* at n.11.

From a liability standpoint, it seems that the increasingly widespread prescription of SSRIs puts the drug companies on the same footing as with the other areas discussed in this paper. They seem to be faced with liability only if eventual plaintiffs are able to show that there was a detrimental effect of the drug that the company knew or should have known about, and then did not warn either the doctor or possibly the consumer of the detrimental effect. Therefore, doctrinally there is no reason for the drug companies to not extend the marketing and eventual sale of their product to as large a market as possible. Where the trouble might occur, however, is with two areas.

First, those who are taking the medication for less serious mental health problems, or even for problems totally unrelated to the approved purposes, may eventually be able to bring claims more easily using some type of balancing analysis in which the lesser need for medication could require a lower standard in finding liability against the drug company where the drug turns out to have effects that far outweighed the original problem. The second possible liability problem for manufacturers is that the broad use of SSRIs for children may subject the drug companies to liability more easily given jury sympathies in cases involving children and given that children (who will someday be adults who may have been affected by the drugs) cannot properly evaluate for themselves the effects of the drugs.

While no such cases have been brought simply based on having a certain status among the group of SSRI users, it is on the outskirts of possibilities. Undoubtedly the drug companies have assessed this risk and weighed it against the increased revenue from extending the product to a broad user base. If there are, as has been suggested, 28 million Americans taking these drugs, however, and if there eventually is a conclusive finding that the effects are on the more serious side of the spectrum of possibilities, there will be a liability

and public health disaster that could rival and exceed some of the greatest ones in U.S. history (i.e. smoking, asbestos, breast implants, etc.). It must be stressed that what is unique in this last situation (the potential problem of over-prescription) is that the drugs are believed by many to possess very serious harms, while the problems for which the drugs are being diagnosed are often not at a corresponding level of seriousness. The drug company shield from liability, in which some risk is allowed given the existence of a greater health benefit to some segment of the population, may not apply when the prescriptions are being given to cure nail biting and other minor problems.

V. Conclusions

The drug companies have largely been able to avoid liability related to the SSRIs, particularly the publicized types of liability that occur beyond the realm of settlement. Given that the primary means for imposing liability have been and will continue to be a failure to warn and the related failure to further test the drugs upon knowledge that some problem may exist, it will be difficult for plaintiffs to be more successful against the companies absent some sort of smoking gun. That smoking gun would likely need to be internal documents showing that the companies knew or should have known of some danger and did not act to address that danger.

The wording on the Sepracor patent, while certainly not helpful to Eli Lilly, likely falls short of the necessary smoking gun. While Eli Lilly surely knew of the wording when acquiring the rights to the patent, they will continue to base their side on the fact that it was Sepracor, not Eli Lilly, who wrote that description. Eli Lilly can most likely point out that the drug was patentable and novel for reasons other than the claimed differences from Prozac in serious side effects. Thus, this single piece of information will probably not produce as great a change as the plaintiffs attorneys and other drug company critics would hope.

The Tobin decision, while serving as an important confidence-builder for plaintiffs attorneys, will probably not have the kind of precedential value that will greatly increase the chances for plaintiff victory in future

cases. The fact-specific nature of these cases, along with the fact that there has been no judicial unanimity in this matter, will prevent future plaintiffs from being assured of future success based on the single outcome of Tobin.

It is more difficult to speculate as to the possible liability for the alleged withdrawal syndrome. While the sufferers do have side effects that cause pain and suffering and financial loss, the magnitude of each individual case is far less than in the wrongful death situations. This is combined, however, with a drastically higher number of possible plaintiffs. It seems that the fact that a much greater percentage of users suffer from withdrawal problems than become suicidal or violent would make it more likely for the drug companies to have discovered this problem during its initial testing of the products. While their samples may not have yielded an accurate percentage, it is very probable that some knowledge of the problem would have developed if the problem is currently as great as some claim. Thus, if there is conclusive evidence of the existence of the withdrawal syndrome occurring on a broad scale, there may be an opening for plaintiffs to claim that the drug company did know or should have known about the problem and should be liable for failing to act upon that knowledge.

The opinion that the drugs are over-prescribed presents a greater total liability potential, but the existence of liability hinges on the same problems of proof that are blocking liability for violent behavior and a withdrawal syndrome. One possible difference in this area may be that it diminishes the drug companies' argument that the affected person was predisposed to his or her behavior before having taken the drug. Although it may be true that Joseph Wesbecker had shown violent tendencies before ever having taken Prozac, that kind of evidence will be much more difficult to produce for a user who suffers from effects of an SSRI after having taken the drug for a minor issue such as weight loss.

The debate over this area is a vibrant one. Both sides do present what looks like compelling evidence, both scientific and otherwise. The stakes are high, both from a public health and an industry liability standpoint.

Given these things, I would be in favor of a move by the FDA to launch a thorough investigation into these drugs. This is also the approach favored by Nicholas Regush, who produces medical features for ABC News. He speculated that the government may need to “do long-term studies on the impacts of these drugs as the pharmaceutical companies have little incentive at this point to do it because the drugs have been on the market for seven years.”²⁶⁷ If nothing else, an FDA sponsored review of the drugs by an independent group of scientists would appease those who claim that the companies and the FDA are hiding behind faulty tests that were rigged by the companies to help them obtain a favorable outcome with the FDA.

There is a substantial amount of mistrust of the drug companies by a significant part of the public with respect to these drugs, and that problem could be corrected by a thorough, independent study. The role of the FDA is in large part to protect consumers, and the evidence warrants that the FDA take steps to ensure consumer safety. With the large and growing number of people who have taken or are currently taking SSRIs, this project should be given extremely high priority. If it turns out that the problems are at the higher end of the range of possibilities, the long-term effects could be disastrous. If the studies proved inconclusive or if the greater problems were not found, the public and the drug companies could breathe a deep sigh of relief and the doctors could again feel confident in their ability to control the known effects in their own best medical judgment.

²⁶⁷Nicholas Regush, *More Prozac Backlash: Drug Firm Attacks Prozac Book, But Lacks Long-Term Data*, (visited Feb. 27, 2002) <<http://www.abcnews.go.com/sections/living/SecondOpinion/secondopinion.80.html>>.