

April 2006

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Aisling V. O'Sullivan

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### Recommended Citation

Aisling V. O'Sullivan, *Walking a Fine Line: Are SSRIs Really Depression Wonder Drugs or Threats to Patient Safety?*, 26 Pace L. Rev. 549 (2006)

DOI: <https://doi.org/10.58948/2331-3528.1163>

Available at: <https://digitalcommons.pace.edu/plr/vol26/iss2/7>

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# Walking A Fine Line: Are SSRIs Really Depression Wonder Drugs or Threats to Patient Safety?

Aisling V. O'Sullivan\*

## Introduction

In June 2001, the District Court of Wyoming decided *Estate of Tobin v. SmithKline Beecham Pharmaceuticals*.<sup>1</sup> In *Tobin*, Donald Schell, shot and killed his wife, daughter, granddaughter, and himself while on the antidepressant Paxil.<sup>2</sup> The jury found that Paxil was a proximate cause of the deaths.<sup>3</sup> This was a landmark case because it was the first time a jury granted a verdict for plaintiffs in a selective serotonin reuptake inhibitor (SSRI) antidepressant case.<sup>4</sup> Prior to *Tobin*, hundreds of similar cases against manufacturers of antidepressants were dismissed or settled.<sup>5</sup> In fact, before *Tobin* only two other cases against antidepressant manufacturers actually went to trial, both of which resulted in verdicts for the defendants.<sup>6</sup>

This casenote examines the controversy that led up to the Food and Drug Administration (FDA) requiring blackbox warnings on all SSRI antidepressants alerting patients that suicidal and/or violent tendencies could develop from ingesting the drugs. This note will analyze the

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\* J.D. Candidate 2006, Pace University School of Law; B.A. Political Science, 2003, Fordham University. The author would like to thank the Pace Law Review staff for their editing assistance, and Cara Molloy for her invaluable comments on earlier drafts and her friendship. The author is extremely grateful to her father, Patrick, for inspiring her to attend law school, and her mother, Veronica, for her boundless love and encouragement. Finally, the author is grateful to her boyfriend, Ryan, for his love and patience the last three years and for his remarkable ability to always make her laugh.

1. 164 F. Supp. 2d 1278 (D. Wyo. 2001).

2. *Id.* at 1280.

3. Verdict Form, *Estate of Tobin*, 164 F. Supp. 2d 1278 (D. Wyo. 2001), available at <http://www.healyprozac.com/Trials/Tobin/Transcripts/6-6%Verdict.pdf> (specifically, the jury found the defendant SmithKline Beecham was 80% responsible for the plaintiffs' injuries and that Donald Schell was 20% at fault).

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

5. *Id.*

6. *Id.*

impact the *Tobin* decision had on this particular area of products liability litigation and examine post *Tobin* cases to see whether this radical decision impacted other courts. Finally, this note will examine the future implications the new FDA requirements regarding warning labels on SSRI drugs will have on current litigation for patients, doctors, and drug manufacturers.

Part I of this article briefly defines SSRI drugs, how they treat depression and how the popularity of these drugs rose in such a short period of time. Part II of this article examines the initial studies linking suicide and violence with SSRIs, discusses the only two cases to go to trial before *Tobin*, and examines the “learned intermediary defense,” which many manufacturers used as their defense in past litigation. Part III discusses *Tobin* and whether the decision impacted subsequent cases. Part IV discusses the new FDA warnings, examines the effect the warnings will have on pending litigation in this area, outlines potential tactics plaintiffs can take from *Tobin*, and analyzes how plaintiffs can combine these tactics with the new FDA warnings in order to obtain successful verdicts. Finally, Part V of the article reviews the potential dilemmas facing the medical field, pharmaceutical companies, and users (whose lives are improved by taking SSRIs) if plaintiffs are successful in this area of products liability litigation.

### I. Wonder Drugs: The Development of Selective Serotonin Reuptake Inhibitors

Antidepressants, belonging to a class of drugs called selective serotonin reuptake inhibitors (SSRIs), include Prozac (Fluoxetine), Zoloft (Sertraline), Paxil (Paroxetine), Luvox (Fluvoxamine), and Celexa (Citalopram).<sup>7</sup> SSRIs work to block the absorption of serotonin, which is a neurotransmitter that controls moods, into brain cells.<sup>8</sup> By blocking the absorption of serotonin, SSRIs allow individual neurons to communicate with one another providing for more efficient transmission of electrical signals to the brain, in turn promoting a feeling of well-being in patients.<sup>9</sup>

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7. Andrew E. Falsetti, *Fluoxetine-Induced Suicidal Ideation: An Examination of the Medical Literature, Case Law, and the Legal Liability of Drug Manufacturers*, 57 FOOD & DRUG L.J. 273, 274 (2002).

8. Sara Hoffman Jurand, *Lawsuits Over Antidepressants Claim the Drug is Worse than the Disease*, TRIAL, Mar. 2003, at 14.

9. *Id.*; see also Angela M. Walker, *R<sub>x</sub>: Take Two of These and Call Me in the Morning; The Emergence of Litigation Regarding Psychotropic Medication in the United States and Europe*, 19 ARIZ. J. INT'L & COMP. L. 775, 776 (2002).

From both a physician and patient perspective, SSRIs are more desirable than other classes of antidepressants due to their “low side effect profile and lack of toxicity in overdose.”<sup>10</sup> This latter characteristic is especially desirable for the treatment of depression.<sup>11</sup> Even in the most extreme overdose cases, SSRIs are rarely fatal.<sup>12</sup>

Prozac was the first SSRI approved by the FDA in 1987.<sup>13</sup> Prozac became the world’s most prescribed antidepressant and was heralded by Newsweek as a “wonder drug” for depression.<sup>14</sup> By 1997, Prozac was the fifth most prescribed drug in the United States, and its success spawned an influx of new SSRIs into the antidepressant market.<sup>15</sup> However, many family members of SSRI victims, who had suffered through what they thought of as an SSRI related death, argued that the drugs should not be treated as “wonder drugs.”<sup>16</sup> These family members believed SSRIs had severe side effects that could cause suicidal and violent behavior in patients that never before showed such tendencies.<sup>17</sup> Akathisia can be a side effect of Prozac, Zoloft, and Paxil.<sup>18</sup> Akathisia “is a neurological phenomenon characterized by intense internal restlessness, agitation, aggression, and suicide attempts.”<sup>19</sup> Patients have described akathisia as producing a desire to “jump out of their skin.”<sup>20</sup> Harvard psychologist Dr. Jonathan Cole testified in a 2000 wrongful death case that, “[t]he SSRI drugs, as a class, clearly have the potential to cause, and in reasonable medical probability or certainty do cause, akathisia in some patients . . . [which could] trigger or contribute to violent or suicidal behavior.”<sup>21</sup>

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10. Walker, *supra* note 9, at 776.

11. *Id.*

12. *Id.*

13. Falsetti, *supra* note 7, at 273.

14. May L. Harris, *Problems with Prozac: A Defective Product Responsible for Criminal Behavior?*, 10 J.CONTEMP. LEGAL ISSUES 359, 360 (1999).

15. Jurand, *supra* note 8, at 14.

16. Walker, *supra* note 9, at 776.

17. Jurand, *supra* note 8, at 14.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

## II. The First Study Linking SSRIs to Violence, Early Defense Strategies and Pre-*Tobin* Litigation

### *A. The First Study to Examine a Link Between SSRIs and Violent Behavior*

Harvard psychiatrist Martin H. Teicher's 1990 report on Prozac was one of the first reports addressing how SSRIs could cause suicidal or homicidal tendencies.<sup>22</sup> Teicher studied six depressed patients, who prior to their first dosage of Prozac did not exhibit suicidal or violent behavior.<sup>23</sup> Teicher was amazed at the results of the study.<sup>24</sup> All of his patients developed violent tendencies after twenty six days of taking Prozac.<sup>25</sup> Teicher explained that "[t]wo patients . . . tried to conceal their suicidal feelings and impulses and to continue [Prozac] treatment, believing that the drug would eventually enable them to successfully kill themselves!"<sup>26</sup> Teicher further explained surprising outcomes of the study as follows:

Two patients fantasized, for the first time, about killing themselves with a gun . . . , and one patient . . . actually placed a loaded gun to her head. One patient . . . needed to be physically restrained to prevent self-mutilation . . . . [Another patient], who had no prior suicidal thoughts, fantasized about killing himself in a gas explosion or a car crash.<sup>27</sup>

At that time, Teicher's article was criticized by many other commentators for its small case sample size and the high doses of the drug fluoxetine given to the patients.<sup>28</sup> Today, many scientific studies and commentators agree with Teicher's results and support the

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22. *Id.*; see also John Alan Cohan, *Psychiatric Ethics and Emerging Issues of Psychopharmacology in the Treatment of Depression*, 20 J. CONTEMP. HEALTH L. & POL'Y 115, 141 (2003) (citations omitted).

23. Cohan, *supra* note 22, at 141.

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.* at 141-42.

28. See Harris, *supra* note 14, at 362 n.33 (citing Maurizio Fava & Jerrold F. Rosenbaum, *Suicidality and Fluoxetine: Is There a Relationship?*, 52 J. CLINICAL PSYCHIATRY 108, 108-09 (1991) (which criticized Teicher for reporting an incidence rate that by their estimation was "vastly distorted"); Richard A. Miller, *Discussion of Fluoxetine and Suicidal Tendencies*, 147 AM. J. PSYCHIATRY 1571 (1990) (which questioned the high doses of fluoxetine reported by Teicher and speculated that an increase in observed suicidal preoccupation was due to severe akathisia)).

proposition that SSRIs can cause suicidal ideation and homicidal behavior.<sup>29</sup>

*B. SSRI Manufacturers' Use of the "Learned Intermediary Defense" and an Examination of Pre-Tobin Litigation*

The two principal cases tried before *Tobin*, were *Fentress v. Eli Lilly & Company*<sup>30</sup> and *Forsyth v. Eli Lilly & Company*.<sup>31</sup> In these early cases, SSRI manufacturers usually employed a "learned intermediary defense" against claims of inadequate warnings for potential side effects, like suicide or violent behavior, on their drug labels.<sup>32</sup> In 1997, the Restatement (Third) of Torts: Products Liability, promulgated the defense providing that "a prescription drug or medical device is not reasonably safe . . . if risks of harm are not provided to . . . prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings."<sup>33</sup> The Kentucky Supreme Court acknowledged three basic rationales behind this defense in *Larkin v. Pfizer Inc.*,<sup>34</sup> stating:

The first and best rationale is that the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient. . . . The second rationale for the rule is that manufacturers lack effective means to communicate directly with each patient. . . . [And] [t]he third rationale for the rule is that imposing a duty to warn upon the manufacturer would unduly interfere with the physician-patient relationship.<sup>35</sup>

More generally, SSRI manufacturers have employed an overarching defense by claiming that most patients taking SSRIs suffer from clinical

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29. Cohan, *supra* note 22, at 142 n.144 (citing Eric W. Fine, M.D., *Selective Serotonin Reuptake Inhibitors (SSRIs) and Cases of Alleged Related Violence*, 23 AM. J. FORENSIC PSYCHIATRY 5 (2003) (which noted that cases involving Prozac-induced suicide and homicide cannot be ignored)).

30. See Walker, *supra* note 9, at 786; see also World Almanac Video, *Landmark Consumer Rights Trials: Prozac on Trial: Fentress v. Eli Lilly*, 1, 2 (2001), available at [http://www.choicesvideo.net/guidebooks/WAV/LanCon\\_prozac.pdf](http://www.choicesvideo.net/guidebooks/WAV/LanCon_prozac.pdf).

31. *Forsyth v. Eli Lilly & Co.*, 904 F. Supp. 1153 (D. Haw. 1995).

32. Andy Vickery, *Changing Times for the Learned Intermediary Defense*, TRIAL, Sept. 2004, at 82.

33. *Id.*; see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (1998).

34. *Larkin v. Pfizer Inc.*, 153 S.W.3d 758 (Ky. 2004).

35. *Id.* at 763-64 (citations omitted).

depression and therefore, already possess suicidal or violent tendencies.<sup>36</sup> To counter manufacturers' claims, families of victims and patients have filed products liability suits against SSRI manufacturers for failure to warn about the risk of increased suicidal or violent behavior.<sup>37</sup> Also, family members have called for the FDA to clamp down on the drug makers and require warning labels on the drug bottles.<sup>38</sup> Over the years, these lawsuits have ended in settlements or summary judgments in favor of manufacturers.<sup>39</sup> Summary judgments were common because plaintiffs lacked evidence to establish that the maker of the SSRI knew or potentially knew that the antidepressant was dangerous.<sup>40</sup>

The first lawsuit claiming that Prozac specifically caused violent behavior was the 1987 case, *Fentress v. Eli Lilly & Company*.<sup>41</sup> In *Fentress*, Joseph R. Wesbecker shot and killed eight people, injured twelve others and then committed suicide at his workplace.<sup>42</sup> Wesbecker had been taking Prozac prior to the shootings.<sup>43</sup> The jury found for Eli Lilly.<sup>44</sup> The *Fentress* verdict suggested that "the user [was] responsible for his own actions when the actions [were] consistent with [the user's] behavior prior to taking the medication."<sup>45</sup> Therefore, the *Fentress* decision does not address whether

while taking psychotropic medication, one may act in a way inconsistent with [their] previous normal behavior . . . [and] [t]his verdict leaves the door wide open for cases in which a Prozac user, who had never exhibited signs of violence before treatment with the drug, begins to act violently while taking Prozac.<sup>46</sup>

In *Forsyth v. Eli Lilly & Company*, William Forsyth killed his wife and then himself.<sup>47</sup> The verdict was for Eli Lilly even though Forsyth killed his wife and then himself after being on Prozac for only two

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36. Jurand, *supra* note 8, at 14.

37. Holt, *supra* note 4, at 86.

38. *Id.*

39. *Id.* at 84.

40. *Id.*

41. Walker, *supra* note 9, at 786; see generally World Almanac Video, *Landmark Consumer Rights Trials: Prozac on Trial* *Fentress v. Eli Lilly* 1, 2 (2001), available at [http://www.choicesvideo.net/guidebooks/WAV/LanCon\\_prozac.pdf](http://www.choicesvideo.net/guidebooks/WAV/LanCon_prozac.pdf).

42. Walker, *supra* note 9, at 786.

43. *Id.*

44. *Id.*

45. *Id.* at 788.

46. *Id.*

47. *Forsyth v. Eli Lilly & Co.*, 904 F. Supp. 1153, 1155 (D. Haw. 1995).

weeks.<sup>48</sup> Before the verdict in *Forsyth*, the plaintiffs still hoped they could win at trial if they presented evidence that a user had no previous violent or suicidal tendency, which would imply that the SSRI caused the violence. This argument was suggested in *Fentress*, but the *Forsyth* verdict seemed to close the door on any chance for the plaintiffs to win using that argument. Again, Eli Lilly's attorney claimed the victim's depression caused the killings, not Prozac, stating "[t]he case is about a good drug and a very bad, powerful disease."<sup>49</sup>

A turning point for plaintiffs bringing suits against SSRI manufacturers came when the United States District Court of Wyoming decided *Estate of Tobin v. SmithKline Beecham Pharmaceuticals*. The jury found for the plaintiffs, specifically holding that Paxil could cause some users to commit suicide and/or homicide.<sup>50</sup>

### III. Examining the Case of *Tobin v. SmithKline Beecham*

#### A. *Tobin v. SmithKline Beecham: The Factual Background and Opposing Theories*

In *Tobin*, the plaintiffs presented several products liability claims; specifically, negligent failure to warn, negligent misrepresentation, and negligent failure to test and investigate.<sup>51</sup> As a matter of law, the court dismissed the plaintiffs' claim for negligent misrepresentation.<sup>52</sup>

Plaintiffs alleged at trial that Donald Schell, shot and killed his wife, his daughter, his granddaughter, and himself, as a result of taking Paxil.<sup>53</sup> At the time of the shootings, Donald Schell had been taking Paxil for two days and ingested only two doses of the drug.<sup>54</sup> Schell had fought with at least five bouts of depression and in the past had not followed the advice of three psychiatrists about his medication.<sup>55</sup> At trial, the plaintiffs' attorneys argued that the defendant failed to provide adequate warning

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48. *Id.* at 1155, 1161.

49. Harris, *supra* note 14, at 360.

50. See Verdict Form, *supra* note 3.

51. *Estate of Tobin v. SmithKline Beecham Pharms.*, 164 F. Supp. 2d 1278, 1280 (D. Wyo. 2001).

52. *Id.* ("the [c]ourt dismissed as a matter of law the plaintiffs' claim for negligent misrepresentation under § 402B of the Restatement of Torts.").

53. *Id.*

54. Falsetti, *supra* note 7, at 287.

55. *Id.*



labels about possible violent reactions or suicide attempts from ingesting the drug.<sup>56</sup> Also, the plaintiffs argued that SmithKline Beecham did not adequately test Paxil to determine if it caused violence and/or suicide.<sup>57</sup> Therefore, they argued, the company misled the public, its customers, and doctors.<sup>58</sup> The plaintiffs' theory was that Schell was dealing with akathisia, which led to his violent reaction towards his family and himself.<sup>59</sup> The defense, on the other hand, argued Schell's ingestion of one tablet of Paxil daily for two days did not cause him to commit murder and suicide, but that his violent reaction was caused by his clinical depression.<sup>60</sup>

*B. Arguments at Trial, the Battle Over Expert Testimony, and the Verdict*

To prove their theory, the defense had a three part strategy: (1) to use scientific evidence to show that SSRIs help millions of people; (2) to emphasize that depression is a dangerous disease that can cause abnormal behavior including violence and suicide; and (3) to show that Schell had previous violent or suicidal tendencies.<sup>61</sup> To counter the defense's scientific evidence and experts, plaintiffs' lawyers intended to use their own experts to testify that SSRIs can make patients violent and/or suicidal.<sup>62</sup> During trial, the defense made a motion to exclude or limit the testimony of plaintiffs' experts, Dr. Healy and Dr. Maltsburger.<sup>63</sup> The court denied the motion concluding that the plaintiffs demonstrated the reliability and the relevance of the proposed testimony of Dr. Healy and Dr. Maltsburger.<sup>64</sup>

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56. Falsetti, *supra* note 7, at 287.

57. *Id.*; see also *Estate of Tobin*, 164 F. Supp. 2d at 1280.

58. See Cohan, *supra* note 22, at 154.

59. Falsetti, *supra* note 7, at 287; see also *Estate of Tobin*, 164 F. Supp. 2d at 1284.

60. Cohan, *supra* note 22, at 154.

61. Falsetti, *supra* note 7, at 287.

62. *Id.*

63. *Estate of Tobin v. SmithKline Beecham Pharms.*, No. 00-CV-0025-Bea (D. Wyo. May 8, 2001) (order denying defendant's motion to exclude or limit the testimony of plaintiffs' witnesses), available at <http://www.justiceseekers.com/files/NLPP00000/042.pdf> [hereinafter *Tobin Order*]. The defense argued that the court should exclude or severely limit the testimony of Dr. Healy and Dr. Maltsburger for three reasons: (1) that the doctors are not properly qualified to offer expert testimony under FRE Rule 702; (2) that the proposed opinion testimony of the doctors is not reliable since research involving SSRIs other than Paxil cannot be used to establish the effects of Paxil; and (3) the doctors' methodologies are unreliable because they have not been published and they are driven by litigation. *Id.* at 5, 6.

64. *Id.* at 3, 4.

At trial, the plaintiffs' attorneys offered Dr. Healy's expert testimony to prove the theory that Paxil can generally cause suicidal ideation. The plaintiffs used Dr. Healy's testimony to establish that Paxil can cause some patients to become homicidal or suicidal, "by inducing either: (1) extreme anguish, akathisia, or agitation; (2) psychotic decompensation; or (3) emotional blunting."<sup>65</sup> Dr. Healy testified that SSRIs can "produce a state of affairs which make an individual who may not have been likely to commit suicide before taking the pill, more likely to do so while on a course of treatment."<sup>66</sup> Furthermore, Dr. Healy testified that, "Paxil is an SSRI that [in his] experience can produce these problems. There are a number of studies in the literature supporting this position. There is also an extensive literature on SSRIs in respect to these possibilities."<sup>67</sup> Dr. Healy based his conclusions of general causation on "his own clinical experience, his review of healthy volunteer data gathered by the defendant, and published scientific works."<sup>68</sup> Finally, Dr. Healy testified to specific causation, stating, "I believe that if Mr. Schell didn't have the Paxil that he had been given that he would be alive today and so would his family."<sup>69</sup> Dr. Healy based his statements on his review of Schell's medical records and Schell's anxiety problems when he was on Prozac.<sup>70</sup>

Dr. Malsburger testified at trial to prove that Schell's use of Paxil caused the killings and his suicide.<sup>71</sup> The most compelling part of his testimony concerned the dangerous consequences that can develop from prescribing SSRIs to patients who already demonstrate akathisia symptoms.<sup>72</sup> Dr. Malsburger testified as follows:

When a patient has a hypomanic history (Mr. Schell appears to have had none) or already exhibits akathisia symptoms (Mr. Schell did), SSRI compounds should not be prescribed because they have the potential to make the anxiety much worse, indeed, to make it unbearable. There are credible reports of patients becoming suicidal and homicidal when thrown into intolerable states of anguish by prescription of these drugs. . . . Already anxious, his mind speeding, and sleepless, when given an SSRI in 1998,

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65. *Id.* at 3.

66. *Id.*

67. *Id.*

68. *Estate of Tobin v. SmithKline Beecham Pharms.*, 164 F. Supp. 2d 1278, 1283 (D. Wyo. 2001).

69. *Id.* at 1284.

70. *Id.*

71. *See Tobin Motion*, *supra* note 63, at 4.

72. *Id.*

[Schell] quickly became violent and killed his family and himself. . . . In this case, I can identify only one factor which triggered the murders and subsequent suicide; Paxil . . . . Though we lack details of what exactly Mr. Schell's mental state was on that fatal night, it is clear to me that it was Paxil that drove him out of control.<sup>73</sup>

The plaintiffs presented evidence that another SSRI manufacturer had knowledge that its products could cause violent and suicidal tendencies in users. The plaintiffs introduced evidence that Eli Lilly, the makers of Prozac, had initially included a statement in Prozac's packaging warning, "mania and psychosis may be precipitated in susceptible patients by antidepressant therapy."<sup>74</sup> However, Eli Lilly did not include the warning in the final packaging for Prozac.<sup>75</sup> Also, Eli Lilly failed to inform the FDA that Germany's Bundes Gesundheits Amt (Germany's version of the FDA) had required a label that warned users of an increased risk of suicide on Prozac before the agency would approve the drug for distribution in Germany.<sup>76</sup>

Finally, the plaintiffs' attorneys introduced internal company documents from SmithKline Beecham establishing the company's awareness that a small number of patients could become agitated or violent due to ingestion of Paxil.<sup>77</sup> In addition, a former SmithKline Beecham employee testified that Paxil should be "titrated" (the patient should be started on a low dose and increased over time).<sup>78</sup> Finally, plaintiffs' attorneys argued that Schell's doctor, Dr. Patel, would have followed a warning label and explained to Schell the possible side effects of taking Paxil.<sup>79</sup> Dr. Patel testified that, "[I] would have liked to have had this information before prescribing Paxil for [Schell] and that it would have affected [my] treatment decisions."<sup>80</sup> In closing, the plaintiffs' attorneys left the jury to answer, "whether or not the depression was exacerbated or triggered by [Paxil and] . . . flipped it into something far worse than ordinary depression."<sup>81</sup>

The jury deliberated for five hours and came back with a verdict for

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73. *Id.*

74. Jurand, *supra* note 8, at 16.

75. *Id.*

76. *Id.*; see also Sara Hoffman Jurand, *New Data Show Paxil May Increase Suicide Risk in Children*, TRIAL, Oct. 2003, at 75, 75-77.

77. Falsetti, *supra* note 7, at 287.

78. Vickery, *supra* note 32, at 85.

79. *Id.*

80. *Id.*

81. Falsetti, *supra* note 7, at 287.

the plaintiffs, finding SmithKline Beecham 80% liable for the killings and the suicide and Schell 20% at fault.<sup>82</sup> The court entered a judgment in excess of seven million dollars for the plaintiffs.<sup>83</sup> After the verdict, SmithKline Beecham claimed that "it was clear from the facts, science and common sense . . . [that] escalating depression caused this."<sup>84</sup> The company also argued that only two doses of Paxil could not have lead to Schell's violent reaction.<sup>85</sup>

Subsequently, SmithKline Beecham filed a motion for judgment as a matter of law, or in the alternative, for a new trial.<sup>86</sup> SmithKline Beecham contended there was no reliable scientific evidence to support the conclusions that Paxil can cause suicide and homicide.<sup>87</sup> Also, the defense argued there was no evidence that the absence of warnings proximately caused the murders and suicide in this case.<sup>88</sup> The court ordered that the judgment stand.<sup>89</sup> Specifically, the court concluded both of the plaintiffs' experts were qualified and based their conclusions on sound scientific analysis.<sup>90</sup> The court ruled that Dr. Patel's testimony was sufficient to allow a reasonable jury to conclude that if Paxil contained a warning label about homicide and suicide, he may not have prescribed the drug or would have monitored Schell differently.<sup>91</sup> Therefore, it was reasonable for the jury to conclude that the defendant's product contained an inadequate or improper warning.<sup>92</sup>

Commentators predicted that this case would have severe legal ramifications for the other SSRI manufacturers since all of these drugs have similar side effects. Thus, other SSRI antidepressants could be "implicated by association."<sup>93</sup> Judge Brennan, who delivered the opinion of the district court, emphasized that "[t]he list of side effects for all of the drugs in the class overlaps heavily . . . . The general designation of these drugs as SSRIs . . . refers to a common understanding that broadly

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82. See Verdict Form, *supra* note 3, at 2.

83. *Id.* at 3.

84. Falsetti, *supra* note 7, at 287.

85. *Id.*

86. Estate of Tobin v. SmithKline Beecham Pharms., 164 F. Supp. 2d 1278, 1280 (D. Wyo. 2001).

87. *Id.* at 1280.

88. *Id.* at 1281.

89. *Id.* at 1290.

90. *Id.* at 1283-87.

91. *Id.* at 1287.

92. *Id.*

93. Cohan, *supra* note 22, at 154.

speaking the drugs are similar- there may be differences but there is broad overlap.”<sup>94</sup> Attorney George Murgatroyd, who has handled several cases dealing with Paxil, was quoted after the *Tobin* decision stating that “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.”<sup>95</sup> However, many courts were reluctant to follow the *Tobin* decision.<sup>96</sup> The reluctance stemmed from the lack of general consensus among the FDA and the medical community about suicidal and homicidal tendencies as potential side effects of SSRIs.<sup>97</sup>

*C. The Reluctance of Courts to Follow Tobin: An Analysis of Three Subsequent and Similar Cases*

*Smith v. Pfizer* was decided three days after *Tobin* was affirmed.<sup>98</sup> In this case, the decedent, Daryl Dempsay, stabbed his wife and two children, and then committed suicide.<sup>99</sup> The plaintiffs’ claims against Pfizer were for failure to test and to warn, and marketing defects and misrepresentations.<sup>100</sup> The decedent’s wife claimed that her husband’s ingestion of Zoloft had caused his violent outbreak.<sup>101</sup> In response, the defense filed a motion for summary judgment alleging that plaintiffs failed to establish general causation, inadequate testing or warnings, and wanted to exclude testimony from plaintiffs’ expert witness.<sup>102</sup> Specifically, the defense attacked the plaintiffs’ only expert witness, Dr. Maltsberger, claiming that he was not qualified to give his opinion on a potential causal link between Zoloft, akathisia, and violent behavior.<sup>103</sup>

The plaintiffs tried to counter the defense’s attack on general causation by presenting the testimony from *Tobin*, and explaining that Dr. Maltsberger was allowed to testify as an expert witness in that

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94. *Id.* at 156.

95. Holt, *supra* note 4, at 84.

96. See *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308 (D. Vt. 2002); see also *Smith v. Pfizer Inc.*, No. 98-4156-CM, 2001 WL 968369 (D. Kan. 2001); *Cloud v. Pfizer Inc.*, 198 F. Supp. 2d 1118 (D. Ariz. 2001).

97. See *Blanchard*, 207 F. Supp. 2d at 318-22.

98. *Smith*, 2001 WL 968369 at \*1.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.* at \*9.

103. *Id.* at \*6, \*7.

case.<sup>104</sup> However, the *Smith* court distinguished *Tobin* explaining that the *Tobin* court allowed expert testimony relating to general causation based on the plaintiffs' other expert, Dr. Healy, and not from Dr. Maltsberger.<sup>105</sup> The *Smith* court explained that Dr. Healy was qualified to give an opinion on a connection between Zolof and violence to establish general causation.<sup>106</sup> The *Smith* court concluded that Dr. Maltsberger was not qualified to testify on general causation, but allowed Dr. Maltsberger to testify on specific causation.<sup>107</sup> Since the plaintiffs had no other expert witnesses at trial to testify to general causation, the court granted the defense's motion for summary judgment.<sup>108</sup>

The case *Cloud v. Pfizer* was decided three months after *Tobin*.<sup>109</sup> The decedent, Darren Baskins, committed suicide in August of 1997.<sup>110</sup> Baskins had originally been prescribed Zolof for minor depression in February of 1996.<sup>111</sup> Baskins and his wife were having marital problems and his wife had threatened to leave him prior to his hospitalization in August 1997.<sup>112</sup> Evidence showed that the week before Baskins' death his mood had altered and a counselor had diagnosed him as suicidal.<sup>113</sup> Baskins was admitted into a hospital before his death and the medical staff testified at trial that Baskins was not displaying akathisia.<sup>114</sup> Three days after being released from the hospital, Baskins hung himself at his home.<sup>115</sup> Baskins' widow brought a products liability and negligence action against Pfizer, the manufacturer of Zolof, for alleged failure to warn and/or provide proper instructions regarding the potential side-effect of suicide.<sup>116</sup>

At trial, Pfizer made a motion to exclude the expert testimony of plaintiffs' witness, Dr. Edwin E. Johnstone.<sup>117</sup> Surprisingly, the plaintiffs used Dr. Johnstone even though he testified that the articles upon which

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104. *Id.* at \*8.

105. *Id.*

106. *Id.*

107. *Id.* at \*9.

108. *Id.* at \*12.

109. *Cloud v. Pfizer*, 198 F. Supp. 2d 1118, 1118 (D. Ariz. 2001).

110. *Id.* at 1121.

111. *Id.* at 1121, 1127.

112. *Id.* at 1127.

113. *Id.*

114. *Id.* at 1128.

115. *Id.*

116. *Id.* at 1121.

117. *Id.* at 1128.

he relied on for general causation were only “strongly suggestive” of the fact that Zoloft causes suicide.<sup>118</sup> Pfizer argued that Dr. Johnstone’s testimony should be excluded because he failed to satisfy both the reliability and fitness requirements under the *Daubert v. Merrell Dow Pharmaceuticals* test.<sup>119</sup> The *Cloud* court decided that Dr. Johnstone’s testimony should be excluded from the trial and as a result granted summary judgment in favor of Pfizer.<sup>120</sup> The *Cloud* court noted that Dr. Johnstone had no clinical experience with any patient committing suicide while on Zoloft, had not published articles, given any testimony, or communicated to scientific organizations that SSRIs cause suicide.<sup>121</sup> The *Cloud* court explained that Dr. Johnstone was not qualified to testify about a general causal link between Zoloft and suicide because he relied upon Dr. Healy’s analysis of Pfizer in clinical trials and not his own study.<sup>122</sup> Also, the *Cloud* court ruled Dr. Johnstone was not qualified to testify on specific causation because the doctor came to his conclusions that Zoloft caused Baskins’ suicide before the doctor reviewed all of Baskins’ medical records.<sup>123</sup> Also, the *Cloud* court noted that Dr. Johnstone failed to fully explore other potential causes of Baskins’ suicide including his alcohol use, family problems, and the diet pill ephedrine.<sup>124</sup>

Finally, *Blanchard v. Eli Lilly & Company* followed the pattern of the other post-*Tobin* decisions discussed above by granted Eli Lilly’s motion for summary judgment.<sup>125</sup> In this case, the decedent Elvira Espinoza shot and killed her two children and then herself.<sup>126</sup> At the time of her death, the decedent was taking Prozac, which she had been prescribed some years prior for depression.<sup>127</sup> The decedent’s dosage for Prozac had been increased before her death, but she was also known to adjust her own dosage randomly.<sup>128</sup> The plaintiffs, decedent’s parents and ex-husband, brought a products liability case against Eli Lilly, claiming that the decedent’s ingestion of Prozac caused her to kill her

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118. *Id.* at 1133.

119. *Id.* at 1128; *see also* *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

120. *Cloud*, 198 F. Supp. 2d at 1139.

121. *Id.* at 1131.

122. *Id.* at 1134.

123. *Id.* at 1135-36.

124. *Id.* at 1136.

125. *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 311 (D. Vt. 2002).

126. *Id.*

127. *Id.*

128. *Id.*

children and herself.<sup>129</sup> There was evidence at trial that the decedent was diagnosed with major depression and dependent personality disorder.<sup>130</sup> She also had several major stress factors in her life including: (1) the breakup of her marriage; (2) poverty; (3) single motherhood; (4) her belief that her ex-husband had abandoned their children; (5) her children's behavioral problems; (6) the threat of losing custody; (7) her own academic problems in nursing school; (8) dissatisfaction with her appearance; (9) and absence of a love life.<sup>131</sup>

The plaintiffs relied on testimony from Dr. Maltzberger to establish their products liability claims.<sup>132</sup> The doctor reviewed extensive material about the decedent's life, and concluded that Prozac was a contributing cause of decedent's death, but he did not specifically address a causal connection between the decedent's ingestion of Prozac and the deaths of her children.<sup>133</sup> Eli Lilly argued that the doctor's testimony failed to establish general and specific causation and moved for summary judgment.<sup>134</sup> The court concluded that the doctor's testimony failed to meet the *Daubert* standard.<sup>135</sup> The plaintiffs failed to elicit testimony from the doctor that his opinion of a link between SSRIs and suicide, led to a conclusion that in the decedent's case, Prozac caused her violent behavior.<sup>136</sup> However, the court stressed, "that it is not holding that Dr. Maltzberger's methods cannot provide a reliable basis for an expert opinion on causation, but that in this particular case the information upon which Dr. Maltzberger based his opinion could not reliably determine the cause of this particular double homicide-suicide."<sup>137</sup> Also, there was no evidence that the decedent was suffering from akathisia symptoms and the plaintiffs failed to show that the doctor had any data (from his clinical experience or other scientific literature) that SSRIs trigger suicidal thoughts or violence in people who are not at the same time experiencing akathisia, mania, hypomania, or disinhibition.<sup>138</sup>

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129. *Id.* at 311.

130. *Id.* at 312.

131. *Id.*

132. *Id.* at 313.

133. *Id.* at 313 n.3.

134. *Id.* at 315.

135. *Id.* at 319-20.

136. *Id.* at 320.

137. *Id.*

138. *Id.*



*D. Justifying the Different Outcomes in Smith, Cloud, Blanchard, and Tobin*

The different outcomes in *Smith*, *Cloud* and *Blanchard* from *Tobin* can be explained by analyzing the medical histories of the decedents and the varied expert testimony given at each trial. In *Smith*, the decedent had been abused as a child, and had a long history of depression and drug and alcohol abuse.<sup>139</sup> In addition, the decedent (Dempsey) had been in jail on multiple occasions, and spent a total of five years in jail for offenses related to alcohol and drugs.<sup>140</sup> Finally, the decedent was also on a high dosage of the anxiety medication Xanax when he killed himself.<sup>141</sup> In *Tobin*, however, the decedent (Schell) did not have a violent past, had no obvious marital problems, and seemed to adore his children and grandchildren.<sup>142</sup> Also, Schell had a bad reaction to an SSRI in the past.<sup>143</sup> Finally, in *Tobin*, the plaintiffs' attorneys presented a stronger case against SmithKline Beecham than the case presented against Pfizer in *Smith*. In *Tobin*, the court heard the expert testimony of both Dr. Healy and Dr. Maltsberger, as opposed to just the testimony from Dr. Maltsberger in *Smith*. These differences between the two cases justify the ruling in favor of Pfizer in *Smith*, since there was overwhelming evidence in *Smith* that the decedent's depression was the cause of his violent behavior and not the SSRI.

The different result in *Cloud* can similarly be explained since the decedent (Baskins) had many additional stress factors that could have caused him to commit suicide. Again, there was no indication in *Tobin* that the decedent suffered from anything but minor depression. In *Smith*, *Cloud* and *Blanchard*, the decedents suffered from major depression and had other stress triggers in their lives, all of which could have caused their violent behavior.

Finally, in *Blanchard*, the court explained why the case was distinguishable from *Tobin*, requiring a verdict for Eli Lilly, even though Dr. Maltsberger was an expert witness in both.<sup>144</sup> The major difference in Dr. Maltsberger's testimony was that the doctor could not expressly

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139. *Smith v. Pfizer Inc.*, No. 98-4156-CM, 2001 WL 968369, \*2 (D. Kan. 2001).

140. *Id.*

141. *Id.*

142. Holt, *supra* note 4, at 84.

143. *Estate of Tobin v. SmithKline Beecham Pharms.*, 164 F. Supp. 2d 1278, 1284 (D. Wyo. 2001).

144. *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 321 n.6 (D. Vt. 2002).

state that Prozac caused the decedent Espinoza's violent behavior.<sup>145</sup> This is in contrast to Maltzberger's testimony in *Tobin*, where he specifically linked Paxil to Schell's violent behavior.<sup>146</sup>

#### IV. Emerging Developments for SSRI Drugs, the FDA Warnings, and Strategies for Litigation

##### *A. The FDA Steps In: Ordering Blackbox Warnings For All SSRI Drugs*

Prior to any public action taken by the FDA on SSRI drugs, the United Kingdom's Department of Health reviewed the potential link between suicide and SSRIs.<sup>147</sup> In late 2003, the United Kingdom's Department of Health publicly ordered that children younger than eighteen should not be prescribed SSRIs (except Prozac), because of the drugs' link to suicide.<sup>148</sup> In June 2003, the FDA privately began reviewing whether SSRI drugs raise the risk of suicide in children and teenagers.<sup>149</sup> The FDA solicited researchers from Columbia University to review different studies indicating a risk of increased suicidal tendencies when taking SSRI drugs.<sup>150</sup> The FDA asked the researchers to develop their own study to guide what actions the agency should take in this area.<sup>151</sup> In March, before the study was complete, the FDA announced that it was "asking" the manufacturers of ten antidepressants to put stronger suicide warnings on the package inserts of their drugs, "to encourage close observation for worsening depression or the emergence of suicidal thinking and behavior in both adult and pediatric patients being treated with [SSRIs]."<sup>152</sup>

The requested warnings would also advise and alert doctors to look

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145. *Id.* at 313 n.3.

146. *Tobin* Motion, *supra* note 63, at 4.

147. Injuryboard.com, *Antidepressants and Other Psychiatric Drugs*, <http://www.injuryboard.com/view.cfm/Topic=375> (last visited Mar. 29, 2006).

148. *Id.*

149. FDA Talk Paper, *FDA Issues Public Health Advisory on Cautions for Use of Antidepressants in Adults and Children*, Mar. 22, 2004, <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01283.html>.

150. FDA Talk Paper, *FDA Updates Its Review of Antidepressant Drugs in Children*, Aug. 20, 2004, <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01306.html>.

151. *Id.*

152. FDA, *Questions and Answers on Antidepressant Use in Children, Adolescents, and Adults*, [http://www.fda.gov/cder/drug/antidepressants/Q&A\\_antidepressants.htm](http://www.fda.gov/cder/drug/antidepressants/Q&A_antidepressants.htm) (last visited Mar. 29, 2006).

for symptoms associated with depression and suicide in their patients.<sup>153</sup> The FDA asked the manufacturers of ten SSRI drugs (including Prozac, Zoloft, Paxil, Luvox, Celexa, Lexapro, Wellbutrin, Effexor, Serzone, and Remeron) to place warnings on their inserts.<sup>154</sup> However, the FDA repeatedly cautioned that it had not established a causal link between increased suicidal tendencies and ingestion of SSRI drugs.<sup>155</sup> The agency explained it was still reviewing the possibility of a link and planned to hold a public meeting at the end of the summer to announce its final analysis.<sup>156</sup> Prior to the March announcement, the FDA was under a congressional investigation for prohibiting Dr. Andrew Mosholder from testifying before an FDA advisory panel.<sup>157</sup> Mosholder was an epidemiologist for the FDA and the first FDA official to find and discuss the link between suicide and SSRI drugs.<sup>158</sup>

In August 2004, the FDA released a "talk paper" updating the public and the medical community on their review of SSRI drugs, the Columbia study, and the progress made after the March announcement.<sup>159</sup> The FDA stated that since the March announcement seven manufacturers added the warning language to their products, and three other makers had agreed to adopt the language.<sup>160</sup> In addition, the Columbia study had presented "data suggestive of an increased risk of suicidality for some of these drugs, but there remain inconsistencies in the results, both across trials for individual drugs and across drugs."<sup>161</sup> The FDA concluded that because of these inconsistencies "an overall interpretation of these findings represents a substantial challenge."<sup>162</sup> The FDA was being cautious about announcing any finding since "as a public health agency, [we] must weigh the possibility of an increased risk of suicidality in young patients taking these drugs against the known risk of suicide in patients whose depression goes untreated."<sup>163</sup> The agency

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153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. CBSNews.com, *Antidepressant Warnings Weighed*, Sept. 13, 2004, <http://www.cbsnews.com/stories/2004/09/14/health/printable643433.shtml>.

158. *Id.*

159. FDA Talk Paper, *FDA Updates its Review of Antidepressant Drugs in Children*, Aug. 20, 2004, <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01306.html>.

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

also indicated it would hold a public Advisory Committee meeting in September with the Psychopharmacologic Drugs and the Pediatric Advisory Committees about the study to discuss whether they should require strong warning labels on SSRI drugs.<sup>164</sup>

At the September hearing, Dr. Mosholder was finally allowed to testify about the link he found between suicide and SSRIs.<sup>165</sup> The FDA's director of neuropharmacological drug products, Dr. Russell Katz, explained why the FDA did not allow Dr. Mosholder to testify earlier.<sup>166</sup> Katz testified that there were errors in early studies, which were inconclusive on the safety of the drugs, and therefore, too dangerous for the agency to announce.<sup>167</sup> Also, 73 family members who lost loved ones taking SSRIs testified at the hearing.<sup>168</sup> The family members called for the FDA to order manufacturers to place strong warning labels on the outside of the drugs' packaging.<sup>169</sup> Coinciding with the FDA's September hearing, Congress continued to investigate whether the FDA was covering up any information on the links of suicide and SSRIs, and if the agency was silencing employees who were aware of the risks.<sup>170</sup>

The family members who testified at the September hearing got their wish in October of 2004, when the FDA ordered that all SSRI antidepressant drugs carry a black box warning on the outside of the packaging, which is the agency's strongest safety alert.<sup>171</sup> The warning will alert users and doctors that there is a link between ingesting the drugs and increased suicidal thoughts and behavior among teens and children who are prescribed the drugs.<sup>172</sup> The FDA also will create a medication guide for patients that will alert them of the risk, since the black box warnings are often only seen by doctors.<sup>173</sup> The guide will alert parents about the warning signs for suicidal symptoms in their children that could come within the first month of use or a change in

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164. FDA Talk Paper, *FDA Updates its Review of Antidepressant Drugs in Children*, Aug. 20, 2004, <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01306.html>.

165. CBSNEWS.com, *Antidepressant Warnings Weighed*, Sept. 13, 2004, <http://www.cbsnews.com/stories/2004/09/14/health/printable643433.html>.

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

171. CBSNEWS.com, *FDA Orders Antidepressant Warning*, Oct. 15, 2004, <http://www.cbsnews.com/stories/2004/08/04/health/printable63409.shtml>.

172. *Id.*

173. *Id.*

dosage.<sup>174</sup> The warning signs “include worsening depression, agitation, irritability, and unusual changes in behavior.”<sup>175</sup> Dr. Lester Crawford, the acting FDA commissioner, spoke about the balance the agency was trying to strike with warnings about the drugs against the benefit of treating children with SSRIs.<sup>176</sup> Crawford stated that the “[FDA] continues to believe, however, that these drugs provide significant benefits for pediatric patients when used appropriately” and the new warning label alerts patients to the “risk of suicidality and encourages prescribers to balance this risk with clinical need.”<sup>177</sup> At the announcement for the black box warnings, the FDA released a finding from the Columbia University study, which found that 2-3% of children using SSRI drugs had increased suicidal thoughts.<sup>178</sup>

*B. Outlining Tactics for Litigation: Can Plaintiffs Succeed by Combining Strategies from Tobin, the New FDA Warnings, and Released Documents From SSRI Makers?*

With mandatory black box warnings on suicidal and violent tendencies as side effects of SSRIs and developing allegations that some SSRI makers had prior knowledge of these dangers, there is new hope for plaintiffs seeking judgments against SSRI manufacturers.<sup>179</sup> This new hope gained momentum when New York Attorney General Eliot Spitzer filed a lawsuit, after the FDA blackbox announcement, alleging that GlaxoSmithKline, the makers of Paxil, committed fraud by withholding “negative information and misrepresenting data on prescribing its antidepressant Paxil to children.”<sup>180</sup> The suit also alleged that Glaxo “suppressed four studies that failed to demonstrate the drug was effective in treating children and adolescents and that suggested a

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174. *Id.*

175. *Id.*

176. *Id.*

177. MSN.com, *New Warning Label Ordered for Antidepressants*, Oct. 15, 2004, <http://www.msnbc.msn.com/id/6254504/print/1/displaymode/1098/>.

178. CBSNEWS.com, *FDA Orders Antidepressant Warning*, Oct. 15, 2004, <http://www.cbsnews.com/stories/2004/08/04/health/printable634089.shtml>.

179. Reuters, *Glaxo Faces Lawsuits From U.S. Parents Over Paxil*, available at <http://www.antidepressantsfacts.com/2004-09-06-GSK-lawsuits-US-parents-paxil.htm> (last visited Mar. 29, 2006).

180. CBSNEWS.com, *NY State Sues Drug Giant*, June 3, 2004, <http://www.cbsnews.com/stories/2004/08/26/health/printable638707.shtml>.

possible increase in suicidal thinking and acts.”<sup>181</sup> Also, the suit alleged that an internal document from 1999 showed that Glaxo intended to “manage the dissemination of data in order to minimize any potential negative commercial impact.”<sup>182</sup> Glaxo initially denied any wrongdoing,<sup>183</sup> but then agreed to settle the lawsuit with the State of New York.<sup>184</sup> Glaxo agreed to a scheduled release of internal negative data on the safety and effectiveness of Paxil and agreed to pay \$2.5 million to New York State.<sup>185</sup> The negative data will be posted on Glaxo’s website by the end of 2005 and will include summaries of all of Glaxo’s medical studies on Paxil since December 2000.<sup>186</sup> Glaxo’s spokesperson Nancy Pekarek stated, “[Glaxo is] choosing to settle this basically to avoid the high cost and time of protracted litigation.” Spitzer’s health care bureau chief responded to the settlement by stating, “[t]he immediate impact is sending a signal to the other pharmaceutical manufacturers that this is the new standard with regard to disclosure of clinical studies. We will continue to do that until we feel this industry as a whole has stopped this practice.”<sup>187</sup> In response to this settlement, many families with similar claims filed lawsuits against GlaxoSmithKline.<sup>188</sup> The suits are alleging that Glaxo suppressed data that showed the drug increased suicidal tendencies in young people.<sup>189</sup>

Eli Lilly has also been accused of suppressing negative data.<sup>190</sup> As early as fifteen years ago, Eli Lilly possessed data showing users of Prozac were far more likely to attempt suicide and show hostility than were patients on other SSRI drugs.<sup>191</sup> The report shows that Eli Lilly was attempting to minimize public awareness of these negative affects.<sup>192</sup> The document included the following: (1) 3.7% of patients attempted

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181. *Id.*

182. *Id.*

183. *Id.*

184. CBSNEWS.com, *Glaxo Settles Paxil Lawsuit*, Aug. 24, 2004, <http://www.cbsnews.com/stories/2004/06/03/health/printable620815.shtml>.

185. *Id.*

186. *Id.*

187. *Id.*

188. Reuters, *Glaxo Faces Lawsuits From U.S. Parents Over Paxil*, available at <http://www.antidepressantsfacts.com/2004-09-06-GSK-lawsuits-US-parents-paxil.htm> (last visited Mar. 29, 2006).

189. *Id.*

190. Tom Watkins, *Papers Indicate Firm Knew Possible Prozac Suicide Risk*, Jan. 3, 2005, <http://www.cnn.com/2005/HEALTH/01/03/prozac.documents/>.

191. *Id.*

192. *Id.*

suicide while on Prozac (a rate more than twelve times cited for any of the other four commonly used SSRIs), (2) 2.3% of the users suffered psychotic depression while on the drug (more than double the next highest rate of patients using another antidepressant), (3) 1.6% of patients reported incidents of hostility (more than double the rate for the other top four manufacturers), and (4) 0.8% of users of Prozac reported causing an intentional injury (eight times the rate than other SSRIs).<sup>193</sup> Also, it was documented that Prozac may produce nervousness, anxiety, agitation, or insomnia in 19% of users and sedation in 13% of users.<sup>194</sup>

The authors of this report suggested ways to explain this data, explaining that “several suggestions may be helpful in presenting this information to physicians . . . including emphasizing that more patients on another class of antidepressants stopped taking their drugs than did those on Prozac.”<sup>195</sup> This report purportedly reappeared after being reported missing during the *Fentress* case.<sup>196</sup> Eli Lilly posted a statement on its website stating “[t]o our knowledge, there has never been any allegation of missing documents from the Wesbecker [*Fentress*] trial or any other trial involving Lilly.”<sup>197</sup> Subsequently, the FDA received the report and is currently reviewing it.<sup>198</sup> Representative Maurice Hinchey, whose office released the report, stated, “[t]he case demonstrates the need for Congress to mandate the complete disclosure of all clinical studies for FDA-approved drugs so that patients and their doctors, not the drug companies, decide whether benefits of taking a certain medicine outweigh the risks.”<sup>199</sup> The author of the Eli Lilly report, Dr. Charles Beasley, responded by stating “the data were reviewed extensively at the time, but we did not believe this data, for a number of reasons, were terribly useful or informative in terms of suggesting anything about a causal link between the drug and the adverse effects being reported.”<sup>200</sup>

Plaintiffs can now combine the released internal documents and the new black box warnings with the strategies employed by the *Tobin* attorneys, all of which might increase the rate of success against SSRI manufacturers. Andy Vickery, the *Tobin* lead attorney, credits two

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193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.*

200. CNN.com, *Documents: Prozac Use Reports More Likely To List Suicide*, Jan. 4, 2005, <http://www.cnn.com/2005/HEALTH/01/04/prozac.documents/>.

strategies for his success.<sup>201</sup> First, Vickery did not let the case be narrowed down by the defense to whether Paxil caused the killings or depression.<sup>202</sup> Secondly, Vickery credits the ultimate success of his case to his discovery of negative internal GlaxoSmithKline documents, which he used to show the company's knowledge of harmful side effects.<sup>203</sup> Vickery's first strategy was a success since he conceded that depression places people at risk for suicide, but argued that scientific testimony from experts would show that there could have been "a biological trigger that was a concurrent cause of the tragedy."<sup>204</sup> The mandatory black box warnings could change the minds of those who are still skeptical that an antidepressant drug and not depression was the cause of violent and suicidal behavior.

Vickery also argued that Glaxo was aware of Paxil's potential for causing extreme reactions and the company should have conducted more testing before releasing it to the public.<sup>205</sup> Vickery's claim was supported by internal documents from Glaxo of studies that showed hundreds of volunteers had negative reactions to Paxil, including attempted suicide.<sup>206</sup> If potential plaintiffs follow the strategy employed by Vickery, and use the black box warnings and released internal documents as evidence, they should be increasingly successful because there is even more evidence against manufacturers than was available in the *Tobin* case.

#### V. Conclusion: Future Dilemmas and Implications from SSRI Litigation

In light of the many new lawsuits involving SSRI drugs, the medical community and the pharmaceutical industry will face several dilemmas in the future. First, doctors will have to adjust how they treat and monitor their patients taking SSRI drugs. They will have to alert patients and parents of the black box warnings on the drugs and advise them on how to watch for warning signs of suicide in their children. Even before the black box warnings were ordered, some statistics showed that physicians had already begun to decrease prescriptions of SSRI drugs to

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201. Holt, *supra* note 4, at 85.

202. *Id.*

203. *Id.* at 86.

204. *Id.* at 84.

205. *Id.* at 86.

206. *Id.* at 86.



teens and children.<sup>207</sup> One such study, released by Medco Health Solutions, a leading pharmacy benefit manager, surveyed the impact that the FDA's October 2003 Public Health Advisory had on physicians.<sup>208</sup> Medco's survey revealed that there was nearly a 12% decrease in the number of children and teen patients on an SSRI drug in the second quarter of 2004 and an overall 5% decrease in the entire state of Illinois.<sup>209</sup> The chief medical officer of Medco stated:

The research shows that physicians and parents in Chicago and across the state are beginning to respond to the growing evidence that antidepressants need to be used with caution when treating children for depression. While antidepressants have very effectively treated many children suffering from depression, studies show that greater caution is needed when treating pediatric and teen depression with medication, and it is clear that physicians are heeding these warnings.<sup>210</sup>

Although the black box warnings are only for children and teens, adult prescriptions could be targeted next since the exposure of the documents showing manufacturers' knowledge of a link between suicide and all patients. This will certainly effect the overall way physicians monitor *all* patients on SSRIs.

Secondly, the pharmaceutical industry will be financially impacted if they have to continue to settle and/or litigate claims by patients. In addition, although SSRI drugs are still a billion dollar market, it is probable that the recent negative press will impact sales and the reputation of these companies.

Finally, although all of the measures that were taken to alert the public on the potential ill effects of using an SSRI drug were a tremendous triumph for patients' rights, this victory has to be balanced by the fact that these drugs have been an effective depression treatment.<sup>211</sup> The negative press creates hysteria for some users who become concerned that they are in danger. The challenge facing the FDA and other researchers is to plan how to present the data collected to the public in order to not create panic for users, who might stop their

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207. PRNewswire-FirstCall, *Chicago Responds to FDA Warning on Pediatric Antidepressants with Significant Reduction in Use*, <http://phx.corporateir.net/phoenix.zhtml?c=131268&p=irol-newsArticle-print+ID=622556> (last visited Mar. 29, 2006).

208. *Id.*

209. *Id.*

210. *Id.*

211. See generally MSN.com, *New Warning Label Ordered for Antidepressants*, Oct. 15, 2004, <http://www.msnbc.msn.com/id/6254504/print/1/displaymode/1098/>.

medication or tamper with their dosages.<sup>212</sup> A conscious effort is needed by those disseminating the data on the side effects to promote the importance of allowing a physician to monitor a patient's use of drugs and allowing only a physician to take a patient off of a drug. This emerging area of products liability litigation will be very tricky. If a patient who should be on an antidepressant drug, stops taking it because of the warnings and hurts themselves or someone else, courts may place liability with doctors for failure to monitor their patients effectively. These are just some of the many conflicts that can potentially arise in the future in this emerging area of the law. Because of the potential for fatal consequences, the government must provide adequate funding for literature and training for physicians, parents, and patients on how to best monitor and treat depression. These steps are essential so that patients and their loved ones can be assured that neither the depression they suffer from, nor the SSRI drugs prescribed to help cure them, will take their lives.

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212. *Id.*