

**R_x : TAKE TWO OF THESE AND SUE ME IN THE MORNING;
THE EMERGENCE OF LITIGATION REGARDING PSYCHOTROPIC
MEDICATION IN THE UNITED STATES AND EUROPE**

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I. INTRODUCTION

The specialization of our society has created, among countless other changes, expectations of perfection in the work of professionals, accompanied by a blind faith that these professionals will perfectly meet each and every one of our needs. We trust and expect doctors to improve our health, and scientists to develop safe and effective medicine to help in the process. To ensure the quality of our health care, we trust governmental regulatory agencies and, in the rare instances where our health care needs are not properly met, we expect the judicial system to compensate us for harms and inconveniences suffered.

But what if one's suffering is not eliminated through treatment or medication? And what if, as a result of the treatment or medication, one's suffering increases? What if, while taking this medication, one causes harm to another? The confusion surrounding these questions is compounded when the medication in question is one that alters the mental state of its users. We not only need to ask who is responsible for the adverse effects of the medication on its users, but also who is to blame when a user, in a state of mind influenced by the medication, commits an unlawful act.

In both the United States and abroad, these questions have surfaced in hundreds of courtrooms in which the medication involved was an immensely popular antidepressant drug called Prozac.¹ Prozac has been, and continues to be, raised in trial in both product liability suits against its manufacturer² and as a defense in criminal cases.³ This Note will examine the litigation surrounding Prozac in both the civil liability and criminal defense arenas in the United States and European countries alike. Part II provides an overview of the drug's history and of the controversy surrounding it. Part III examines product liability litigation actions against Prozac's manufacturer, compares such actions in the U. S. and Europe, and examines the liability of other responsible parties. Part IV discusses the use of Prozac as a criminal defense, and Part V analyzes current issues, recent

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1. See Jason Beattie, *Prozac, a Bitter Pill for Some*, BIRMINGHAM POST, Feb. 10, 2000, at 13.

2. See Jeff Swiatek, *Federal Suit in Hawaii Links Teen's Suicide to Prozac*, KNIGHT-RIDDER TRIB. BUS. NEWS, Jan. 7, 2000, at 2.

3. See A. Simpson, *Prozac is Not to Blame*, THE GUARDIAN, April 2, 2000, at 1.

developments, and future possibilities. Finally, Part VI concludes that the complicated issues raised by Prozac litigation are best resolved by allocating liability to the responsible party – often the user.

II. BACKGROUND

A. Prozac Facts and History

“Prozac” is the brand name for the antidepressant fluoxetine hydrochloride, developed by the pharmaceutical giant Eli Lilly & Co., and marketed by Dista Products.⁴ Bringing nearly three billion dollars each year to Lilly and constituting over one quarter of the manufacturer’s total sales,⁵ Prozac is the most widely prescribed antidepressant in the world and earns the second highest dollar volume of all drugs worldwide.⁶ In the fifteen years since its introduction, Prozac has been used by thirty-eight million people⁷ in ninety-nine countries.⁸ Physicians prescribe it to treat depression, anxiety attacks, bulimia, obsessive/compulsive disorders, premenstrual syndrome, and nicotine withdrawal.⁹

Prozac is classified as a selective serotonin reuptake inhibitor (SSRI).¹⁰ It achieves its antidepressant action by blocking the central nervous system’s reuptake of serotonin, a chemical that transmits impulses through the central nervous system to the brain.¹¹ By blocking serotonin reabsorption, SSRIs allow individual neurons to communicate with one another.¹² Prolonged treatment

4. See *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1479 (E.D. Okla. 1997); see also Amy Boardman, *Plaintiff’s Bar Anticipates Prozac Landslide; Wonder Drug Blamed in Suicide, Mass Murder*, TEXAS LAWYER, Mar. 11, 1991, at 8.

5. See *Eli Lilly’s President Promises Life After Prozac Without Need for Mergers*, CHEMICAL BUS. NEWS BASE 13, Jan. 15, 2001; see also Leah Garnett, *Debate About Effects of Prozac Continues as Drug Patent Nears Expiration*, KNIGHT-RIDDER TRIB. BUS. NEWS, May 7, 2000.

6. See Michael Jonathan Grinfeld, *Protecting Prozac*, CALIFORNIA LAWYER, Dec. 1998, at 36.

7. See Susan Kreimer, *Doctor Stirs Arguments over Prozac*, THE DES MOINES REGISTER, Aug. 19, 2000, at 1.

8. See Rebecca Fowler, *Is this the End of a Prozac Dream?*, DAILY MAIL, May 30, 2000, at 39.

9. See Kreimer, *supra* note 7 at 1; see also Michael Smith, *Drug That Still Fuels Debate*, THE SCOTSMAN, Jan. 18, 1999, at 11.

10. See May L. Harris, *Problems With Prozac: A Defective Product Responsible for Criminal Behavior?*, J. CONTEMP. LEGAL ISSUES, 1999, at 362.

11. See Catherine M. Vale, *The Rise and Fall of Prozac: Products Liability Cases and the “Prozac Defense” in Criminal Litigation*, 12 ST. LOUIS U. PUB. L. REV. 525, 527-28 (1993).

12. See *id.* at 528.

causes changes in brain tissue, which aid in the antidepressant action of the drug.¹³

Unlike the other classes of antidepressants - monoamine oxidase inhibitors (MAOIs) and tricyclics - SSRIs have a low side effect profile.¹⁴ The MAOIs and tricyclics interfere with the uptake of the neurotransmitter norepinephrine as well as serotonin,¹⁵ and as a result these drugs have higher levels of toxicity than do SSRIs.¹⁶ Prozac became the antidepressant of choice as a result of its low side effect profile and lack of toxicity in overdose.¹⁷ Even an extreme overdose of Prozac will very rarely be fatal,¹⁸ which makes the drug especially attractive for the treatment of depression.

Lilly's "wonder drug" has been proven to work in sixty percent of patients who receive it¹⁹ by alleviating or eliminating depression.²⁰ Many Prozac users believe the drug saved their lives or made them new people.²¹ However, not all users are quite so enthusiastic about Prozac's ability to work miracles.

Most notable among those reluctant to herald the value of this drug are the families of the estimated 50,000 patients who have committed suicide while taking Prozac²² and the survivors of victims killed by Prozac users. The three Payne brothers of Waderbridge, Cornwall, certainly did not expect to join this select group of mourners.²³ Initially, the use of Prozac appeared to help alleviate the depression their father, Reginald Payne, had been suffering.²⁴ Eleven days into his treatment with the drug, however, Reginald suffocated his wife Sally and then threw himself off a cliff near their retirement home.²⁵ The suit being brought against Lilly by the late couple's three sons is the first of its kind in the British courts,²⁶ but it is far from being the first legal action against the pharmaceutical manufacturer alleging that Prozac use can have fatal results.

13. *Id.*

14. *See Harris, supra note 10, at 362.*

15. *See id.* at 363.

16. *See id.* at 362.

17. *See Kreimer, supra note 7, at 2; see also Erica Goode, The Prozac Controversy, PORTLAND OREGONIAN, Aug. 20, 2000, at L13 (Living Today).*

18. *See They Told Us It Was Safe, MAIL AND GUARDIAN (Johannesburg), Nov. 5, 1999.*

19. *See Vale, supra note 11.*

20. *See id.; see also Harris, supra note 10, at 360.*

21. *See Fowler, supra note 8, at 39.*

22. *See Garnett, supra note 5.*

23. *Did 140 People Die because they took Prozac?, THE EXPRESS, April 2, 2000.*

24. Robert Verkaik, *The Paynes Expected a Peaceful Retirement. It Ended in Violent Death. But was Prozac to Blame?*, THE INDEPENDENT (London), Dec. 4, 2000, at 3.

25. *Id.*

26. *Id.*

B. The Link Between Prozac and Violence

Even before Prozac was introduced to the market, Lilly has been subject to accusations that its antidepressant medication causes more harm than it prevents. In 1985 the Bundes Gesundheit Amt (BGA; the German licensing authority equivalent to the Food and Drug Administration in the United States) refused to license Prozac for prescription in Germany based on the results of Lilly's own pre-marketing trials.²⁷ In those trials, sixteen patients attempted suicide, two successfully.²⁸ The BGA demanded that Prozac's packaging include a warning that a risk of suicide existed if patients did not take a sedative along with Prozac treatment.²⁹ It was not until seven years later, when Lilly finally included the suicide warning on the packages of Prozac to be sold in Germany, that the BGA allowed prescription of the drug.³⁰

The purported link between Prozac and suicide sparked a number of studies attempting to determine a causal connection between the use of Prozac and suicidal ideation and violent behavior. Although the results of these studies vary substantially, an abundance of research supports a finding that Prozac does in fact lead to suicidal and violent behavior. Even Lilly's own testing of its antidepressant points in this direction.³¹ Of the 5,600 U.S. patients included in Lilly's pre-marketing trials of Prozac, 10 to 15% experienced anxiety, 1% exhibited mania, and another 1% reported incidents of delusions, hostility, and paranoia.³² The company's internal documents also reveal that the trials produced reports of psychosis, severe depression, agitation, and akathisia.³³ (Akathisia, a feeling of mental restlessness or mania, can lead to an inability to concentrate or loss of inhibitions,³⁴ and has been recognized as leading to suicidal and homicidal feelings when caused by antipsychotic drug use.³⁵)

Boston scientist Herschel Jick found that in the United Kingdom, 187 of every 100,000 patients taking Prozac for depression commit suicide.³⁶ A comparison of Jick's data with published statistics that only 30 per 100,000 depressed people not taking antidepressant medication commit suicide³⁷ suggests that 157 of these suicides are caused by Prozac. Perhaps even more detrimental to

27. See MAIL & GUARDIAN, *supra* note 18.

28. See *id.*

29. See *id.*

30. See *id.*

31. See *id.*

32. Vale, *supra* note 11, at 529.

33. MAIL & GUARDIAN, *supra* note 18.

34. Anthony Browne, *Spiral of Violence Blamed on Prozac*, THE OBSERVER (London), May 12, 2000, at 15.

35. *Id.*

36. MAIL & GUARDIAN, *supra* note 18.

37. *Id.*

Lilly is a Wales study conducted by Dr. David Healy.³⁸ The first examination of Prozac using healthy rather than clinically depressed subjects, Healy's research revealed that one in ten adults who take Prozac can become belligerent and pose a risk to themselves and others.³⁹ Healy also concluded that between five and ten percent of healthy patients can be affected by akathisia.⁴⁰ Healy's findings deliver a severe blow to Lilly, which has defended itself against anti-Prozac accusations by asserting that it is the patient's depression that leads to suicide, and not Prozac.⁴¹ Many researchers support the company's position, insisting that it is impossible to separate the effects of an antidepressant drug from the effects of depression itself.⁴² Such an argument does not hold up quite as well when the users are in fact not depressed.

Despite any contrary findings, Lilly insists that there is no link or causal connection between Prozac and suicide or violence.⁴³ It finds support in a 1997 study conducted by Dr. Emil Coccaro, which suggests that Prozac use reduces aggressive behavior.⁴⁴ The United States Food and Drug Administration (FDA) likewise looks past any conflicting evidence and agrees with Lilly that no credible evidence exists linking the use of antidepressant drugs, including Prozac, to suicide or violent behavior.⁴⁵ In 1991, an advisory committee, established by the FDA for the purpose of investigating the accusations against Prozac, found no persuasive evidence that the drug causes an increase in its users' suicidal acts or feelings.⁴⁶

Not only are these accusations about Prozac untrue, according to Dr. Scott Richards, medical director of adult psychiatry at Iowa Lutheran Hospital, but they discourage the use of Prozac by many people who could benefit from taking the antidepressant.⁴⁷ Dr. Richards believes Prozac has been responsible for saving millions of lives by preventing suicide.⁴⁸ Most psychiatrists and researchers who have had experience with the drug agree, heralding it as useful and sometimes lifesaving in treating a variety of psychiatric disorders.⁴⁹

38. See Browne, *supra* note 34, at 15.

39. See *id.*

40. *Id.*

41. See Fowler, *supra* note 8; see also Grinfeld, *supra* note 6, at 36.

42. See Goode, *supra* note 17.

43. Deborah Orr, *What is the Truth About Prozac?*, THE INDEPENDENT (London), May 23, 2000, at 5.

44. See Simpson, *supra* note 3.

45. *Id.*

46. Goode, *supra* note 17.

47. See Kreimer, *supra* note 7.

48. See *id.*

49. Goode, *supra* note 17.

III. PRODUCT LIABILITY LITIGATION AGAINST ELI LILLY & CO.

A. Theories of Recovery in United States Courts

American plaintiffs in product liability lawsuits generally present four theories of recovery: (1) strict liability in contract for breach of warranty, express or implied; (2) negligence liability in contract for breach of warranty, express or implied; (3) negligence liability in tort for physical harm to persons and tangible things; and (4) strict liability in tort for physical harm to persons and tangible things.⁵⁰ A majority of courts limit plaintiffs in product liability actions against pharmaceutical manufacturers to employing the negligence theories of recovery.⁵¹ These courts have upheld Lilly's claim that Prozac is an unavoidably unsafe product, as are most therapeutic drugs, and therefore strict liability claims are invalid.⁵² Comment k to Section 402A of the Restatement (Second) of Torts states that manufacturers should not be held liable for injuries caused by unavoidably unsafe products.⁵³ Plaintiffs who claim they have been harmed by Prozac therefore must demonstrate that Lilly was negligent in failing to warn or adequately warn of Prozac's dangerous side effects.⁵⁴ In doing so, it is the plaintiffs' duty to adduce evidence that Lilly knew, or should have known, of the risk of which it failed to warn.⁵⁵

In product liability litigation, plaintiffs employ the above theories to support allegations that the product in question suffers from a design defect, a manufacturer's defect, or was marketed with inadequate warnings.⁵⁶ In the majority of courts that have agreed that comment k protects drug manufacturers from strict liability, a plaintiff may not allege that Prozac was defectively designed.⁵⁷ In a court that decides the issue of unavoidably unsafe products on a case-by-case basis rather than applying the blanket exception to all pharmaceuticals, however, a plaintiff may employ the design defect theory to allege that although Prozac was manufactured according to specifications, it

50. Vale, *supra* note 11, at 541.

51. Harris, *supra* note 10, at 370-71; *see also* Vale, *supra* note 11, at 541-42 (Because Lilly revised its Prozac literature in May 1990 to inform physicians of the purported association between the drug and violent behavior, plaintiffs are precluded from bringing strict liability claims); *see also* Brown v. Superior Court, 751 P.2d 470, 482-83 (Cal. 1988) ("[A] manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prescribed and accompanied by warnings.")

52. *See* Harris, *supra* note 10, at 370.

53. *See* RESTATEMENT (SECOND) OF TORTS § 402 A, cmt. k (1995); *see also* Todd P. Myers, *Halcion Made Me Do It: New Liability and a New Defense-Fear and Loathing in the Halcion Paper Chase*, 62 U. CIN. L. REV. 603, 613 (1993).

54. *See* Harris, *supra* note 10, at 369.

55. *See id.*

56. *See* Myers, *supra* note 53, at 614.

57. *Id.*

nonetheless is unreasonably dangerous for its intended use.⁵⁸ When determining on a case-by-case basis whether to apply comment k, the court must balance the risks and benefits of a drug at the time of its distribution.⁵⁹ In making such a balancing analysis, the court bases its decision on a four-prong test: (1) the feasibility of an alternative design; (2) at the time of the drug's manufacture; (3) which was commercially available; and (4) which would not destroy the drug's effectiveness.⁶⁰

A manufacturing defect occurs when a limited number of units in a product line deviate from the manufacturer's design or specifications.⁶¹ In response to an allegation that a product contains a manufacturing defect, the court must use the consumer expectation test to determine whether the product meets general expectations of safety.⁶² Although this is an easier test to meet than that for design defects, a plaintiff is unlikely to succeed using a manufacturing defect claim against Lilly because as an industry, pharmaceutical manufacturers have maintained an excellent record of minimizing manufacturing defects in their products.⁶³

The Prozac plaintiff's best bet is a failure to warn claim. A manufacturer's duty to warn attaches as soon as a side effect becomes known; thus, Lilly is responsible for warning patients of all known and foreseeable dangers associated with Prozac.⁶⁴ Prescription drug manufacturers do not warn patients of the risks directly, but instead they are charged with warning physicians of the risks associated with a prescription drug, and the physicians then act as learned intermediaries between the manufacturer and the patient.⁶⁵ Thus, once Lilly warns prescribing physicians of the purported risks of Prozac, the duty to warn transfers to the physicians so long as they have received all necessary information.⁶⁶ To be considered accurate, Lilly's warning to physicians must properly instruct physicians on how to use and prescribe Prozac, must give a fair appraisal of the scope and extent of any danger associated with the drug, and must be obviously displayed.⁶⁷ A court will find inadequate any warning that has been unduly delayed, reluctant in tone, or lacking in a sense of urgency.⁶⁸ A manufacturer's duty does not end with the initial warning. Lilly has a duty to keep up with all scientific data regarding Prozac, and must warn of any

58. *See id.* at 615.

59. *See id.*

60. *Id.*

61. *Id.* at 617.

62. *See id.* at 617.

63. *See* Martin J. MacNeill, *Strict Liability in the Manufacture of Pharmaceuticals: The Halcion Homicide*, 5 *BYU J. PUB. L.* 69, 83-84 (1991).

64. *See* Myers, *supra* note 53, at 618.

65. *Id.* at 619.

66. *See id.* at 620.

67. *See* Harris, *supra* note 10, at 372.

68. *See* Myers, *supra* note 53, at 621.

subsequently discovered side effects.⁶⁹

Despite the specific claim or theory of recovery employed, the burden of proof in any Prozac product liability suit falls on the plaintiff to show that the drug's utility is outweighed by its dangers.⁷⁰ This is a formidable challenge to a Prozac plaintiff, for Lilly can employ the "state of the art" defense, which is an assertion that Prozac conformed with the state of the art in antidepressant drug design at the time it was prescribed.⁷¹ Because studies have also revealed a link between suicidal ideation and the tricyclic and MAOI classes of antidepressants,⁷² Lilly will likely prevail with such a defense. In addition, Prozac's sixty percent success rate⁷³ supports a jury finding that the drug's benefits outweigh its risks.

B. Theories of Recovery in European Countries

In all Member States of the European Union, product liability laws and standards are governed by the Product Liability Directive 85/374.⁷⁴ Under Article 1 of the Directive, a producer is liable for damage caused by a defect in his product, and Article 4 states that to recover for such damage, "[T]he injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage."⁷⁵ Therefore, in order to prevail against Lilly in a product liability action brought in a European court, the Prozac user must show that Prozac was manufactured defectively, that he suffered some form of harm from the drug, and that harm was caused by the defect present in Prozac. Article 6(1) of the Directive specifically sets forth what constitutes a defect, stating "[A] product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation."⁷⁶

The Directive also sets forth defenses to product liability claims in Article 7.⁷⁷ A producer cannot be found liable if he can prove:

(a) that he did not put the product into circulation; or (b) that, having regard to the circumstances, it is probable that the defect

69. *See id.* at 622.

70. *See Harris, supra* note 10, at 377.

71. *See id.* at 378.

72. *See id.* at 377.

73. *See Vale, supra* note 11, at 525.

74. *See* Case 300/95, E.C. Commission v. United Kingdom (Re the Product Liability Directive), [1997] 3 C.M.L.R. 923.

75. Council Directive 85/374/EEC, arts. 1, 4, 1985 O.J. (L 210), 29.

76. Council Directive 85/374/EEC, art. 6(1), O.J. (L 210), 29.

77. *See* Re the Product Liability Directive, 3 C.M.L.R. at 926.

which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or (c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or (d) that the defect is due to compliance of the product with mandatory regulations issued by public authorities; or (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.⁷⁸

With the exception of Article 7(e), the state of the art defense,⁷⁹ all other defenses enumerated in the Directive are inapplicable to Lilly in product liability actions involving Prozac. The state of the art defense may prove useful, though, since Lilly could claim it is impossible to determine the exact effect a pharmaceutical drug will have on every single patient to whom it is prescribed. Therefore, if Prozac is in fact defective, the existence of the defect was not discoverable through the extensive testing and trials Lilly conducted before putting the drug on the market.⁸⁰ Nor has such a defect been discovered in the past thirteen years that Prozac has been prescribed to depressed patients.⁸¹ Of course European courts are likely to look to the over 200 product liability lawsuits brought against Lilly in America,⁸² and reject this defense on the grounds that the number of suits alleging that Prozac is defective negates Lilly's claim that no knowledge of a defect exists.

Instead, Lilly is more likely to resort to the defenses they have successfully relied upon in the U.S. cases, that Prozac is not in fact defective and the aggressive or suicidal behavior of a small percentage of those who take it is caused by the depression itself.⁸³ Applying these assertions to the Product Liability Directive, Lilly would presumably contend that plaintiffs cannot prove the existence of a defect or the necessary causal relationship.⁸⁴ To recover damages, a plaintiff bringing a product liability suit against Lilly in any Member State of the European Union will have the difficult task of distinguishing the cause

78. Council Directive 85/374/EEC, art. 7, 1985 O.J. (L 210), 29.

79. *See Re the Product Liability Directive*, 3 C.M.L.R. at 923.

80. *See Simpson, supra* note 3, at 1.

81. *See id.*

82. Swiatek, *supra* note 2.

83. *See Beattie, supra* note 1.

84. *See Re the Product Liability Directive*, 3 C.M.L.R. at 926.

of its user's violent behavior as being the antidepressant⁸⁵ rather than the effects of the disorder for which it is being taken.⁸⁶ Because the United Kingdom is a Member State of the European Union,⁸⁷ the plaintiffs in the first product liability action involving Prozac brought in Europe, which is scheduled for trial in the British High Court later this year,⁸⁸ will carry the burden of proving that Prozac, and not depression itself, is responsible for the devastating consequences suffered.

C. Physicians' Liability

Because the duty to warn patients transfers to the physician once a pharmaceutical manufacturer has warned a physician of the risks associated with a medication,⁸⁹ an analysis of Prozac product liability litigation requires an examination of the role of prescribing physicians. Experts in the field of depression urge physicians to administer Prozac carefully and closely monitor their patients who receive it.⁹⁰ The prescribing physicians should continuously monitor these patients for any changes in severity of depression, suicidal ideation, aggression, agitation, and akathisia.⁹¹

Lilly contends that any problems resulting from Prozac use arise because the drug has been misprescribed.⁹² That physicians have the capability to blatantly contravene a manufacturer's warnings when they prescribe drugs to their patients supports the company's claim.⁹³ Physicians themselves, in both the United States⁹⁴ and the United Kingdom,⁹⁵ admit that the practice of disregarding warnings from pharmaceutical companies occurs frequently. To hold Lilly liable for the negligence of prescribing physicians seems rather unjust, but in an unprecedented move, the pharmaceutical giant precluded itself from pointing its finger at the medical community.⁹⁶ On June 5, 1991, Lilly publicly announced

85. *See id.*

86. *See* Beattie, *supra* note 1 (Dr. Gillian Wainscott of Birmingham University states that aggression and disinhibition could be related to personal factors in depressed patients); *see also* Vale, *supra* note 11 (The FDA found that "assertions that Prozac leads depressed patients to obsess more about suicide than depressed patients not on the drug cannot be substantiated.").

87. *See* Re the Product Liability Directive, 3 C.M.L.R. at 923.

88. Verkaik, *supra* note 24.

89. *See* Myers, *supra* note 53, at 619.

90. Vale, *supra* note 11, at 535.

91. *Id.*

92. *See* Orr, *supra* note 43, at 5.

93. *Id.*

94. *See* Karen Goldberg Goff, *Medicines for the Mind*, WASH. TIMES, May 7, 2000, at D1; *see also* Orr, *supra* note 43, at 5.

95. Theodore Dalrymple, *Prescription for a Free Lunch*, THE GUARDIAN, April 18, 2000; *see also* Beattie, *supra* note 1, at 13.

96. *See* Vale, *supra* note 11, at 542.

that it would retain legal counsel for physicians involved in malpractice lawsuits arising from prescribing Prozac and pay the cost of defending any litigation as well as any judgments from lawsuits challenging the use of Prozac.⁹⁷

No other pharmaceutical company on record has ever made such an offer to the medical profession.⁹⁸ Lilly's landmark statement elicits two conflicting interpretations. From one perspective, Lilly is confident enough in its antidepressant drug to believe it will never lose a lawsuit; thus it will never be required to cover the cost of a verdict against a prescribing physician. Or conversely, Lilly knows that the plaintiffs' claims have at least some degree of validity; thus it needs to offer an extra incentive to persuade physicians to prescribe the drug to their patients. Of course, Lilly contends that there is no causal relationship between Prozac and violent behavior. Its offer, according to the pharmaceutical company, is simply one of several measures taken to combat the "unfounded concern" that has arisen regarding Prozac.⁹⁹ Despite the motivation or reasoning behind the offer, its effect is to eliminate prescribing physicians from the list of possible defendants that could possibly be held accountable in a Prozac product liability action.¹⁰⁰

D. Governmental Regulation

1. Regulation in the United States

In assessing a product liability claim regarding Prozac, one must examine the role of the government agency that regulates the licensing, marketing, and distribution of the drug. Before any drug is made available to the public in the United States, the Food and Drug Administration (FDA) must approve its use.¹⁰¹ The FDA subjects pharmaceutical drugs to an extensive pre-approval testing process that is the most rigorous of any consumer product.¹⁰² To obtain approval to prescribe Prozac, therefore, Lilly must have proven to the FDA that the drug is in fact safe for consumer use.¹⁰³ Notably, the pre-approval trials of Prozac were the most extensive of any FDA-approved drug to date.¹⁰⁴ Lilly's application for Prozac's approval consisted of more than one million pages, ten times than that of

97. *See id.*

98. *See* Daniel Wise, *Eli Lilly to Pay Legal Expenses, Awards to Doctors in Prozac Suits*, N.Y.L.J., Jun. 6, 1991, at 1; *see also* Vale, *supra* note 11, at 542.

99. Wise, *supra* note 98, at 1.

100. *See* Vale, *supra* note 11, at 542.

101. *See* Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs off the Market*, 40 CASE W. RES. L. REV. 413, 414 (1990).

102. *Id.* at 417.

103. *See id.*

104. *See* Vale, *supra* note 11, at 542.

an average new drug application.¹⁰⁵ And while the FDA only requires pharmaceutical manufacturers to conduct three investigational studies, Lilly conducted twenty-five for Prozac.¹⁰⁶

2. Regulation in Europe

Some European governing agencies place more stringent restrictions on pharmaceutical medication than does the FDA. For instance, before Sweden would approve Prozac for prescription in that country, it required Lilly to include a warning that the risk of suicide from taking Prozac may initially increase.¹⁰⁷ Similarly, the German licensing authority Bundes Gesundheit Amt (BGA) refused to grant a license to Prozac until Lilly included in its product literature a warning that a risk of suicide existed if the patient did not take a sedative simultaneously with Prozac.¹⁰⁸

The FDA's British equivalent, the Medicines Control Agency (MCA), joins the FDA in concluding that no association exists between the use of Prozac and suicidal or violent behavior.¹⁰⁹ Perhaps it is not surprising, then, that neither the United States nor the United Kingdom have an official reporting system for adverse side effects of prescription drugs.¹¹⁰ The FDA MedWatch system allows physicians to report such adverse effects on a voluntary basis,¹¹¹ but the National Institute of Health warns that a voluntary reporting system is insufficient to track common adverse behavioral effects.¹¹² Likewise, the Yellow Card reporting system used in the United Kingdom, which requests doctors to voluntarily report adverse conditions caused by new drugs to the MCA, has received similar criticism.¹¹³ The MCA estimates that only a small fraction of adverse reactions are actually reported, as doctors usually find themselves too busy to fill out the Yellow Cards.¹¹⁴

Although the information reported to the MCA is not confidential, it has never been widely disseminated, and in fact many medical experts have been denied access to it.¹¹⁵ Inspection of the Yellow Card reports involving Prozac

105. See Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 172 (1998).

106. *Id.*

107. See Harris, *supra* note 10, at 375.

108. See MAIL & GUARDIAN, *supra* note 18.

109. See Beattie, *supra* note 1, at 13.

110. See Garnett, *supra* note 5; see also Fowler, *supra* note 8, at 39.

111. *Safety and Efficacy Concerns*, MEDICAL UTILIZATION MANAGEMENT, May 13, 1999.

112. *Id.*

113. Fowler, *supra* note 8, at 39.

114. THE EXPRESS, *supra* note 23.

115. *Id.*

reveals that over 100 patients have complained of feeling suicidal while on the antidepressant, another 57 had attempted suicide, and an additional 170 exhibited aggressive behavior.¹¹⁶ Patients have reported agitation, anxiety, delusion, and hallucinations as side effects of Prozac as well.¹¹⁷ Given these numbers, the lack of access is rather disturbing in regard to physicians' ability to adequately inform their patients of the risks associated with the drug.

The most questionable practice of these governing agencies is the FDA's policy of prohibiting manufacturers from warning of adverse reactions when differences of opinions exist in the medical community regarding such reactions.¹¹⁸ The FDA may impose this restriction to prevent pharmaceutical manufacturers from listing every possible side effect, thus completely absolving itself from any future liability.¹¹⁹ Although somewhat logical from a legal standpoint, this policy may detrimentally prevent public knowledge of serious side effects simply because not all evidence regarding the effects is in exact agreement.

E. History of Past Cases

1. Fentress v. Eli Lilly & Co.

On September 16, 1989, Joseph R. Wesbecker entered his place of employment, the Standard Gravure Printing Plant in Louisville, Kentucky.¹²⁰ He opened fire with an AK-47 assault rifle and killed eight people, injured twelve others, and then killed himself.¹²¹ Wesbecker had been taking Prozac, and a group of victims and victims' families filed suit against Lilly, claiming that Prozac caused Wesbecker's shooting spree and that Lilly was marketing Prozac with the knowledge that it could cause people to commit harm to others.¹²²

This lawsuit became the first legal action blaming Prozac for violent behavior to reach the trial stage.¹²³ The issue presented was whether Prozac is unreasonably dangerous, and whether it caused Wesbecker to injure and kill his victims. Lilly held its position that Prozac does not cause violent behavior in its users, and defended the suit with evidence that Wesbecker began making preparations for murder before taking the antidepressant.¹²⁴ He had purchased \$3,500 in weapons and ammunition, and had talked to others about killing his

116. *Id.*

117. *Id.*

118. *See Harris, supra* note 10, at 372-73.

119. *See id.* at 373.

120. *Vale, supra* note 11, at 540.

121. *Id.*

122. *See id.* at 541.

123. *See Kentucky Jurors Find Prozac Maker Not Liable in Murder Case*, LIABILITY WEEK, Jan. 2, 1995.

124. *Id.*

bosses prior to beginning treatment with Prozac.¹²⁵ Wesbecker's history of mental illness was fatal to the plaintiffs' case, and the jury returned a nine-to-three verdict in favor of Lilly in just five hours.¹²⁶

As the first of the Prozac lawsuits to go trial, *Fentress* set the stage for all others to follow, establishing the precedent that a user is responsible for his own actions while taking psychotropic medication. The *Fentress* verdict, however, contains one caveat: the user is responsible for his own actions when the actions are consistent with his behavior prior to taking the medication. *Fentress* does not address the possibility that, while taking psychotropic medication, one may act in a way inconsistent with his previous normal behavior. This 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.

2. Forsyth v. Eli Lilly & Co.

In the only other Prozac lawsuit to have come to trial, Lilly again prevailed despite a lack of previous violent behavior on the part of the Prozac user.¹²⁷ In 1993, William Forsyth killed his wife by stabbing her fifteen times and committed suicide by impaling himself on a kitchen knife.¹²⁸ Forsyth was a successful retired businessman with no previous suicidal or homicidal tendencies, and had been taking Prozac for two weeks when he took the lives of his wife and himself.¹²⁹

Hundreds of wrongful death cases involving Prozac and naming Lilly as a defendant have been either dropped, dismissed, or settled out of court.¹³⁰ Lilly has yet to come out on the losing side of a product liability lawsuit, and the rate at which such cases are filed is on the decline,¹³¹ but the facts and circumstances of each new case can pose a threat to the seemingly invincible pharmaceutical giant.

125. *Id.*

126. See Grinfeld, *supra* note 6, at 38.

127. See Swiatek, *supra* note 2; see also John O'Brien, *Suit Blames Drug for Murder Suicide: The Family of a Skaneateles Man Sues His Doctor and the Company That Make Prozac*, THE POST STANDARD (Syracuse, NY), Nov. 4, 2000, at B3.

128. Harris, *supra* note 10, at 359.

129. See Verkaik, *supra* note 24, at 3; see also Grinfeld, *supra* note 6, at 36.

130. See MAIL & GUARDIAN, *supra* note 18; see also Jeff Swiatek, *Eli Lilly Not Fearful of Liability Suits From Use of Prozac for Severe PMS*, KNIGHT-RIDDER TRIB. BUS. NEWS, Jul. 12, 2000; Swiatek, *supra* note 2.

131. See Swiatek, *supra* note 2.

F. Pending Cases and their Significance

1. Hala v. Eli Lilly & Co.

Today, ten Prozac-related lawsuits against Lilly are pending in U.S. courts¹³² and one in the United Kingdom.¹³³ In one such U.S. suit, filed in July of 1990, Rhonda Hala of Long Island, New York, claims that although she has no history of depression or suicidal tendencies, while taking Prozac she experienced sporadic episodes of suicidal ideation for eighteen months.¹³⁴ She attempted suicide six times and mutilated herself 150 times while taking the antidepressant.¹³⁵ Currently awaiting decision in the United States Supreme Court (as of February 14, 2002), this case is of great importance to Lilly not only because of its monetary value (Hala is seeking \$150 million)¹³⁶ but also because, unlike Joseph Wesbecker, Hala has no history of violence. She claims that she first experienced suicidal thoughts after a few weeks of taking Prozac, and her episodes of sporadic violence and suicidal ideation ended when her psychiatrist discontinued the prescription.¹³⁷

The Hala decision will have a profound effect on Lilly, the future of Prozac, and the entire psychotropic drug industry.¹³⁸ A ruling in favor of the plaintiff would verify Prozac's capability to alter and, in some cases, drastically change the behavior and personality of some users. It would establish Lilly's legal liability for the suffering of Prozac users and invite legal action from any patient who experienced adverse side effects while on Prozac. A verdict for Lilly, on the other hand, would absolve pharmaceutical manufacturers from responsibility for the side effects of their drugs, suggesting that the benefits derived from the drugs outweigh the potential harm that they may cause in a percentage of users.

2. The Reginald Payne Case

Great Britain's first Prozac product liability lawsuit is currently (as of February 14, 2002) before the British High Court.¹³⁹ Not only is this action, filed

132. See *Indianapolis Pharmaceutical Firm Faces Additional Lawsuits Linked to Prozac*, THE INDIANAPOLIS STAR AND NEWS, Aug. 5, 2000.

133. Verkaik, *supra* note 24, at 3.

134. See Vale, *supra* note 11, at 539.

135. *Id.*

136. *Id.*

137. See *id.*

138. Rhonda Hala had no history of depression or suicidal tendencies. See Boardman, *supra* note 4. Therefore, a plaintiff's verdict would suggest Prozac, and possibly other psychotropic drugs, are capable of turning users violent.

139. Verkaik, *supra* note 24.

by the three surviving sons of Reginald and Sally Payne, remarkable as the first such lawsuit against Lilly filed in Great Britain, but the facts of the case are shockingly similar to those of *Forsyth v. Lilly*.¹⁴⁰ Like William Forsyth, Reginald Payne had been on his eleventh day of Prozac treatment when he took his life and that of his wife.¹⁴¹ Like Forsyth, Payne had even been showing signs of improvement for the first few days on the antidepressant, but after a week of treatment his depression began to worsen.¹⁴² Furthermore, like the Forsyths' children, the Payne brothers insist that their father had never before shown signs of violence or aggression, and blame Prozac for changing his behavior.¹⁴³

Although the Forsyths were unsuccessful in recovering from Lilly, the Paynes will still rely on evidence presented and admissions made during the course of the *Forsyth* trial.¹⁴⁴ Among such evidence is an internal memo in which a Lilly employee expressed concern over the company's future if Prozac were to be brought to trial in the United Kingdom.¹⁴⁵ The Paynes will also introduce the in-court admission of one of Lilly's own expert witnesses that Prozac can cause akathisia.¹⁴⁶

Graham Ross, the solicitor representing the Payne family, will allege that Lilly was negligent in failing to warn of the risk of side effects associated with Prozac.¹⁴⁷ He claims that Prozac can produce a condition of mind in some patients that can lead to acts of violence that would not otherwise have occurred,¹⁴⁸ and that Reginald Payne's homicidal and suicidal behavior is an incident of such Prozac-induced violence.¹⁴⁹ Although the drug may only have this violent effect on a small percentage of patients, according to Ross the damage is so devastating that the manufacturer undeniably owes doctors and patients an honest acknowledgment of the risk.¹⁵⁰ Ross believes Lilly should be more concerned with its duty to Prozac users rather than defending its commercial interests, and bases the Paynes' claim on Lilly's legal obligation to disclose to doctors and patients its knowledge of the antidepressant's deadly effects.¹⁵¹

Unquestionably, a verdict for the Paynes would have a profound effect on the future of Prozac use and subsequent product liability actions in the United Kingdom. The Government's Medicines Control Agency (MCA) reports that since it licensed Prozac for sale in Britain ten years ago, the drug has been

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. Verkaik, *supra* note 24.

146. *Id.*

147. *Id.*

148. *Id.*

149. THE EXPRESS, *supra* note 23.

150. Verkaik, *supra* note 24.

151. *Id.*

involved in 140 deaths in the country.¹⁵² The MCA's data reveal that an additional 12,000 adverse reactions, including 45 suicides, 7 unexplained sudden deaths and 44 deaths from heart failure, are also linked to Prozac use.¹⁵³ Because of the voluntariness of the MCA's reporting system, these recorded figures may be only the "tip of the iceberg,"¹⁵⁴ with the real number of Prozac-related deaths in Britain being much higher. The concern expressed by Lilly in the internal memo to be introduced at trial by the Paynes, that "Lilly can go down the tubes if we lose Prozac, and just one event in the UK can cost us that,"¹⁵⁵ is no surprise.

IV. THE USE OF PROZAC AS A CRIMINAL DEFENSE

A. Theory of the Prozac Defense

Product liability litigation is not the only legal arena in which litigants have alleged the causal connection between Prozac and violent behavior. In at least seventy-seven cases to date, criminal defendants have argued that their use of Prozac caused them to commit violent crimes they would not have ordinarily committed.¹⁵⁶ Thus far, no criminal defendant has escaped culpability based on such a defense when Prozac is the drug in question,¹⁵⁷ but courts have reversed convictions of defendants claiming intoxication induced by other psychotropic drugs.¹⁵⁸ The possibility that courts may someday apply the holdings in the Halcion decisions¹⁵⁹ warrants an analysis of the defense theories available to criminal defendants taking Prozac.

1. Insanity

The theory behind the insanity defense is that a defendant who acted without criminal intent or was unable to exercise free will should not be considered blameworthy, and thus cannot be punished for his actions.¹⁶⁰ Most U.S. courts utilize the M'Naghten rule, although there is no universally recognized test for insanity.¹⁶¹ The M'Naghten rule states that a defendant is insane if he has (1) a mental disease or defect; (2) a defect of reason caused by such disease or

152. THE EXPRESS, *supra* note 23.

153. *Id.*

154. *Id.*

155. Verkaik, *supra* note 24.

156. *See* Simpson, *supra* note 3.

157. *Id.*

158. *See* Myers, *supra* note 53, at 605.

159. *See id.*

160. *See id.* at 630.

161. *See id.* at 631.

defect; and (3) a lack of knowledge about the consequences, legality, or morality of his actions.¹⁶²

A defendant attempting to use the “Prozac Defense” is not asserting that he is in fact insane, but rather that he suffered from temporary insanity due to the drug use.¹⁶³ Generally, however, courts have held that voluntary drug use does not cause temporary insanity to exculpate a defendant from criminal responsibility.¹⁶⁴ The issue then becomes whether Prozac-induced intoxication is voluntary or involuntary intoxication when the drug is used as prescribed by a physician.¹⁶⁵

2. Voluntary Intoxication

Voluntary intoxication is caused by substances, knowingly introduced into the defendant’s body, the tendency of which to cause intoxication the defendant knows or ought to know.¹⁶⁶ To successfully use this defense, the defendant must show that, because of the intoxicating substance, he was incapable of forming the intent that is a required element of the crime with which he is being charged.¹⁶⁷ Of course, this requires proof that the defendant was under the influence of the substance in question at the time he committed the crime.¹⁶⁸ Therefore, a criminal defendant utilizing the “Prozac Defense” must show that at the very time the crime occurred, he was in fact taking Prozac. Defendants find limited relief in the voluntary intoxication defense, however, because it will only provide relief for specific intent crimes, such as first-degree murder.¹⁶⁹ Even in specific intent crimes, if a defendant succeeds with the voluntary intoxication defense he may receive a conviction of a lesser crime.¹⁷⁰ Only on a rare occasion will such a defendant be acquitted altogether.¹⁷¹ Voluntary intoxication also provides no defense to general intent crimes, such as second degree murder, or absolute liability crimes like driving under the influence of drugs.¹⁷² In addition, not all jurisdictions allow the voluntary intoxication defense.¹⁷³ Although it is a more applicable defense than insanity, because of these limitations voluntary

162. *Id.*

163. *See* Harris, *supra* note 10, at 380.

164. *See* Myers, *supra* note 53, at 633.

165. *See id.* at 634.

166. MODEL PENAL CODE § 2.08(5)(b) (2000).

167. *See* Myers, *supra* note 53, at 636.

168. *See id.* at 635.

169. *Id.*

170. *See* Martin J. Bidwill & David L. Katz, *Injecting New Life into an Old Defense: Anabolic Steroid-Induced Psychosis as a Paradigm of Involuntary Intoxication*, 7 U. MIAMI ENT. & SPORTS L. REV. 1, 35 (1989).

171. *See id.*

172. Myers, *supra* note 53, at 636.

173. *See id.*

intoxication will only provide limited relief to a very small number of criminal defendants who take Prozac.

3. Involuntary Intoxication

By contrast, involuntary intoxication is a complete defense in jurisdictions that follow the M’Naghten Rule.¹⁷⁴ A successful involuntary intoxication defense requires proof of three elements: (1) that the defendant was intoxicated; (2) that the intoxication was involuntarily created; and (3) that as a result of the involuntary intoxication, the defendant’s mental state met the jurisdiction’s test for insanity.¹⁷⁵ Invoking this defense is not a simple task for defendants who seek to blame Prozac for their crimes. The first element, intoxication, is the easiest to prove because as a psychotropic drug, Prozac’s purpose is to alter the user’s mental state. However, to show that such intoxication was involuntary even though the user knowingly ingested the medication presents a bit of a challenge. Courts have determined that intoxication from drug or alcohol consumption may be involuntary when any of the four following conditions are met: (1) the intoxication was coerced or the result of duress; (2) the intoxication was pathological; (3) the intoxication resulted from a drug taken pursuant to a doctor’s advice; or (4) the intoxication was the result of an innocent mistake by the defendant.¹⁷⁶

Most courts strictly construe the coerced intoxication requirement, denying relief absent a showing that the defendant was physically forced to ingest drugs or alcohol.¹⁷⁷ Unless a criminal defendant can prove that someone else forced him to swallow Prozac prior to the commission of the crime, and that he is among the small percentage of Prozac users who suffer adverse reactions to the drug, claiming coerced intoxication would be futile.

Pathological intoxication, on the other hand, has potential for use as a successful defense where the defendant is a Prozac user. The test for pathological intoxication is met when the defendant suffers a reaction to the medication that is grossly excessive in degree, and the defendant did not know of his special susceptibility to the medication.¹⁷⁸ If the defendant can show he suffered a psychotic reaction from Prozac that was grossly excessive in respect to the reaction he expected to experience, he must then prove that, because of the reaction, his mental capacities were impaired to the extent necessary to meet the insanity defense standard.¹⁷⁹ In a claim of pathological intoxication, Prozac must have caused the defendant’s reaction, not a combination of Prozac and another

174. *Id.* at 638.

175. *Id.*

176. *See* Bidwill & Katz, *supra* note 170, at 39.

177. *See* Myers, *supra* note 53, at 639.

178. MODEL PENAL CODE § 2.08(5)(c) (2000).

179. *See* Myers, *supra* note 53, at 642-43.

intoxicant.¹⁸⁰ Although courts have been reluctant to uphold the pathological intoxication defense in cases involving prescription medication,¹⁸¹ the particular facts and circumstances surrounding the cases in which criminal defendants have used Prozac suggest that defendants could successfully employ a pathological intoxication defense.

A defendant can also claim involuntary intoxication when ingestion of a medically prescribed drug caused his intoxication.¹⁸² As long as a patient takes the medication according to his physician's instructions, any resulting intoxication may be deemed involuntary because the patient is entitled to assume that his physician would not prescribe such a dosage that would result in the intoxication.¹⁸³ Courts will allow a defendant to claim involuntary intoxication from ingestion of Prozac as medically prescribed so long as the defendant had no reason to know that Prozac would have such an intoxicating effect.¹⁸⁴ Because Lilly does not warn of the purported violent side effects associated with Prozac use,¹⁸⁵ a defendant can easily meet this requirement absent evidence that he nonetheless knew of the possibility of Prozac-induced violence. Prozac must also be the sole cause of the defendant's intoxication at the time of the alleged criminal act.¹⁸⁶ Therefore, the defendant must prove he was under the influence of Prozac and not any other substance. Finally, as with the other involuntary intoxication defenses, the defendant must be temporarily insane due to the intoxication caused by Prozac.¹⁸⁷ Although the temporary insanity requirement varies among jurisdictions and can be difficult to meet, involuntary intoxication from a medically prescribed drug presents a Prozac user's best shot at defending himself against criminal charges.

By employing the defense of involuntary intoxication by mistake of fact, a defendant claims that he ingested a particular drug while innocently believing it to be some other lawful substance.¹⁸⁸ This defense has not been, and is not likely to ever be, used where the drug ingested is Prozac because of the extremely slim probability that the defendant not only mistook Prozac for another substance, but also was one of the few people susceptible to the rare violent reactions of Prozac.¹⁸⁹ Even if a defendant were to meet both of these unique circumstances, he would still have the difficult task of proving he was temporarily insane at the time of the alleged crime as a result of ingesting Prozac.¹⁹⁰ A defense based on

180. *See id.* at 643.

181. *Id.*

182. *See id.*

183. *Id.*

184. *See id.* at 644.

185. *See* MAIL & GUARDIAN, *supra* note 18.

186. *See* Myers, *supra* note 53, at 644.

187. *See id.*

188. *See* Bidwill & Katz, *supra* note 170, at 47.

189. *See* Myers, *supra* note 53, at 646.

190. *Id.* at 645.

ingestion of a medically prescribed drug in accordance with a doctor's prescription is clearly the most applicable and potentially successful of the four involuntary intoxication claims for a Prozac-using criminal defendant.

B. History of Past Cases

1. State of Connecticut v. Christopher DeAngelo

On December 2, 1997, twenty-eight year old insurance agent Christopher DeAngelo robbed the First Union Bank of Derby, Connecticut.¹⁹¹ At his trial, defense attorney John R. Williams argued that DeAngelo suffered from temporary insanity caused by his ingestion of Prozac and another tranquilizer called Xanax.¹⁹² Three psychiatrists, including one hired by the state prosecutors, introduced evidence in support of DeAngelo's defense that his mental state was impaired by an adverse reaction to the combination of the two medications.¹⁹³ Psychiatric expert Peter Breggin testified that had DeAngelo not taken Prozac and Xanax, "he would almost certainly never have committed these crimes."¹⁹⁴ DeAngelo's physician had in fact prescribed both of the drugs, and DeAngelo voluntarily ingested them in accordance with his prescription.¹⁹⁵ The amount of Prozac prescribed to DeAngelo, however, was sixty milligrams,¹⁹⁶ which is three times the average dosage of the antidepressant.¹⁹⁷

Superior Court Judge Richard E. Arnold announced his decision on February 24, 2000. In the first ruling in which the so-called "Prozac Defense" has aided in the acquittal of a criminal defendant and the only such decision to date,¹⁹⁸ Judge Arnold found that DeAngelo "lacked substantial capacity as a result of mental disease or defect to appreciate the wrongfulness of his conduct, or to control his conduct within the requirements of the law."¹⁹⁹ Assistant State's Attorney Kevin Doyle, who prosecuted the case, believes that the acquittal should not be viewed as a Prozac defense.²⁰⁰ Instead, according to Doyle, it was

191. *State of Connecticut v. Christopher DeAngelo*, 26 CONN. L. RPTR. 461, 465 (Super. Ct. 2000).

192. See Colin Poitras, *Judge Accepts Prozac Defense: Bank Robbery Suspect Acquitted in Ruling*, THE HARTFORD COURANT, Feb. 25, 2000 at A1.

193. See *id.*

194. *Id.*

195. *State of Connecticut*, 26 CONN. L. RPTR. at 467.

196. See Poitras, *supra* note 192.

197. See Vale, *supra* note 11 at 528.

198. See Browne, *supra* note 34; see also *State of Connecticut*, 26 CONN. L. RPTR. at 470.

199. See *State of Connecticut*, 26 CONN. L. RPTR. at 470.

200. Jeff Swiatek, *Successful Prozac Defense is Thought To Be The First*, KNIGHT-RIDDER TRIB. BUS. NEWS, Mar. 1, 2000.

DeAngelo's involuntary intoxication as a result of being overmedicated that led to the unusual ruling.²⁰¹ The State of Connecticut also stressed that DeAngelo is not walking free after Judge Arnold's decision, but rather that he was committed to the state Department of Mental Health and Addiction Services for further evaluation.²⁰²

Although this case has drawn a great deal of public attention as the first case in which Prozac was involved in a successful criminal defense,²⁰³ the *DeAngelo* ruling is not likely to be applicable to many future cases, if any at all. The unique factors affecting Christopher DeAngelo's mental state - his unusually high prescription of Prozac, his simultaneous use of Xanax, his spotless criminal record prior to the robbery, and his family history of bipolar disorder²⁰⁴ - narrow the holding considerably. Wide acceptance of the "Prozac Defense" following this case is highly unlikely, especially when almost eighty other defendants have failed to win an acquittal by blaming the drug.²⁰⁵

2. The Louise Wheldon Case

European courts have not differed significantly in their treatment of the Prozac defense. As in the United States, no criminal defendant has been able to completely escape culpability by claiming ingestion of Prozac caused him to commit the crimes with which he is charged.²⁰⁶ As in the *DeAngelo* case, however, such a defense may soon prove capable of securing the defendant a reduced sentence.²⁰⁷

The High Court of Edinburgh, Scotland, as of February 14, 2002, is determining the sentence of Louise Wheldon, a thirty-four year old Claremont Court, Edinburgh, woman who is charged with attempted murder after stabbing a man outside of a pub on October 19, 1999.²⁰⁸ Wheldon had been taking Prozac for four years, and claims that she was never warned about the side effects of the

201. See Poitras, *supra* note 192.

202. See *id.* (On June 20, 2000, the court sentenced DeAngelo to serve ten years at the Whiting Unit, Connecticut's maximum-security psychiatric hospital, after hearing the results of such evaluation.); see also *Excuses: Twinkies to Prozac*, HARTFORD COURANT, Mar. 3, 2000, at A14.

203. See Swiatek, *supra* note 200; see also Browne, *supra* note 34.

204. See *id.*; see also Poitras, *supra* note 192.

205. See Simpson, *supra* note 3.

206. Christopher DeAngelo is the only defendant to have used the Prozac defense successfully both in the United States and abroad. See Browne, *supra* note 34, at 15; see also Simpson, *supra* note 3, at 1.

207. See Stephen Deal, *Mother Calls for Prozac Warning After Stab Frenzy*, EVENING NEWS (Edinburgh), Jun. 15, 2000, at 17.

208. See *id.*

antidepressant.²⁰⁹ She was unaware that Prozac should not be mixed with alcohol, that for some users it can be addictive, or that it purportedly may cause violent behavior.²¹⁰ Like Christopher DeAngelo, Louise Wheldon has no prior history of violent behavior, and she also claims to have suffered from an adverse reaction caused by the combination of Prozac and another substance (alcohol).²¹¹

A psychiatrist testifying on behalf of Louise Wheldon asked the court to consider the fact that violent behavior is a known potential side effect of Prozac, and that Wheldon was unaware of this effect when she took the drug.²¹² Although a prison sentence is normally automatic for a defendant found guilty of attempted murder, the judge presiding over this case has publicly stated that she is prepared to consider community service as an alternative.²¹³ If Wheldon does receive the lighter sentence, however, it is important to recognize that, just as in *DeAngelo*, the specific facts of this particular case would prevent it from being applicable to all other uses of the Prozac defense. The complete absence of any warning of side effects, the unknown reaction with alcohol, and the possibility that Wheldon's attack on her victim was provoked²¹⁴ all suggest that even if the judge grants a reduced sentence in light of the defendant's Prozac use, a landslide of similar rulings in Europe is tremendously unlikely.

V. ANALYSIS AND DISCUSSION

A. Recent Developments and Future Issues

To say that the litigation surrounding Prozac both in the civil and criminal areas has had an enormous impact on its manufacturer would be a gross understatement. Not only has Lilly already spent over \$50 million just to settle the product liability claims brought against it,²¹⁵ but the repercussions of all the negativity and accusations regarding Prozac are reflected in the August 2000 U.S. federal appeals court ruling that Lilly could not retain its protective patent on the antidepressant.²¹⁶ The patent on Prozac was due to expire in February 2001, but supplementary patents, if granted, would have protected the drug until 2004.²¹⁷ Lilly is in the process of appealing the ruling, which essentially shaved three years

209. *See id.*

210. *Id.*

211. *See id.*

212. *See id.*

213. *Id.*

214. *See id.*

215. Swiatek, *supra* note 2.

216. *See Eli Lilly's President Promises Life After Prozac Without the Need for Mergers*, CHIMIE HEBDO, Jan. 15, 2001.

217. *See Six-Month Extension for Prozac Patent*, BIOTECHNOLOGY BUSINESS NEWS, Dec. 4, 2000.

off Prozac's corner on the antidepressant market.²¹⁸ It is desperate to retain patent protection for Prozac because the development and marketing of generic versions of the drug is estimated to slice Lilly's Prozac profits in half.²¹⁹

The pharmaceutical company gained a small victory in December 2000 when it was granted a six-month extension on the patent, scheduling it to expire in August 2001 instead of February.²²⁰ This extension was given so that Lilly could acquire data on the use of Prozac for treatment of depression in children and young adults.²²¹ Since August 2001, however, a number of competing antidepressants have entered the market,²²² and for the first time Prozac's success appears near a decline.²²³

Despite this threat of competition, Lilly contends that it has not become more willing to settle the product liability lawsuits brought against it, and will still vigorously defend Prozac against any civil action.²²⁴ According to Lilly spokesman Edward A. West, the patent situation has no bearing on the company's legal defense strategy.²²⁵ When Lilly has previously settled product liability suits, says West, the decision to settle was made only because it would have been more costly to let the case go to trial.²²⁶

The most recent settlement took place in October 2000.²²⁷ Insisting that this settlement in no part admits any fault on the part of Prozac and Lilly, the company claims it "made business sense" to settle and have the case dismissed from U.S. District Court in Hawaii.²²⁸ As with all other Prozac lawsuits Lilly has settled, it refused to disclose the amount of money paid to the family of a seventeen-year-old Hawaiian boy who hung himself a week after starting to take Prozac for his depression.²²⁹ (Lilly has settled over thirty civil liability suits to date.)²³⁰

Currently Lilly is wrapping up the development of a new form of Prozac to be put on the market once the patent for the existing version of the drug expires.²³¹ The new pill is called R-fluoxetine, and its label claims it will not

218. *See id.*

219. *See id.*

220. *See id.*

221. *Id.*

222. *See* Phil Galewitz, *Prozac's Reign as Top Antidepressant Ending*, C-Health, Mar. 6, 2000, at http://www.slam.ca/Health0003/06_prozac.html (last visited Jan. 28, 2002).

223. *See* CHIMIE HEBDO, *supra* note 216.

224. *See* Swiatek, *Indianapolis-Based Eli Lilly Settles Prozac Wrongful-Death Lawsuit*, KNIGHT-RIDDER TRIB. BUS. NEWS, Nov. 1, 2000.

225. *Id.*

226. *Id.*

227. *See id.*

228. *See id.*

229. *See id.*; *see also* Grinfeld, *supra* note 6, at 40.

230. *Id.*; *see also* Vale, *supra* note 11, 542.

231. *See* Kreimer, *supra* note 7.

cause side effects such as akathisia, suicidal thoughts, and self-mutilation.²³² Lilly's choice to include such information on the label for the new version of Prozac is rather startling. Although it may encourage consumption by patients who otherwise may have been dissuaded from taking the antidepressant by the negative publicity linking it to those very side effects, it also could be interpreted by Prozac's critics as an admission of guilt with regards to the original version of the drug. If the old Prozac did not cause serious side effects, as Lilly has always contended, then why is the company manufacturing a new form of the drug guaranteed not to lead to such effects? Examination of the patent for R-fluoxetine, which is predicted to be marketed by Lilly later in 2002,²³³ supplies critics with a wealth of ammunition. The patent states that this new version of Prozac will decrease the side effects of the existing version - the same side effects Lilly has repeatedly insisted Prozac does not cause.²³⁴

References to the admissions contained in the R-fluoxetine patent will undoubtedly surface in future product liability cases as plaintiffs seek to bolster their chances of recovery by using the patent in an attempt to prove Prozac does in fact cause violent behavior. A claim of negligence against Lilly is also strengthened by the patent's suggestion that the pharmaceutical manufacturer has been aware of the existence of such side effects but continued to market Prozac without warning consumers. Criminal defendants may also point to the patent as evidence that their unlawful behavior was caused by use of the original Prozac, which undisputedly is linked to serious negative side effects. And the new form of Prozac may very well bring about an entirely new wave of litigation. Although Lilly will market the new pill with the assertion that it has fewer side effects, it is impossible to predict what effects may surface once a large number of patients begin using the antidepressant for a prolonged period of time.²³⁵

B. The Power of the Market

While lawsuits involving Prozac have certainly generated a number of problems for Lilly, it appears that competing pharmaceutical companies are reaping the benefits of such litigation.²³⁶ These companies market new antidepressants, such as Zoloft, Paxil, and Celexa, with promises of fewer side effects than Prozac.²³⁷ These promises, whether true or simply a clever advertising campaign, seem to be working for pharmaceutical giant Pfizer.²³⁸ In January 2002, more physicians wrote new prescriptions for Pfizer's antidepressant

232. *See id.*

233. Garnett, *supra* note 5.

234. *Id.*

235. *Id.*

236. *See* Galewitz, *supra* note 222.

237. *Id.*

238. *See id.*

Zoloft than for Lilly's Prozac.²³⁹ While Prozac remains the leader in total prescriptions, the popularity of Zoloft and other competing drugs suggest its reign is in jeopardy.²⁴⁰

Prozac's diminishing corner on the antidepressant market may very well be a function of the natural product life cycle.²⁴¹ The power of negative publicity, however, is impossible to ignore. Although a variety of factors enter into a physician's decision regarding which medication to prescribe, or a patient's choice of which pill to take, the correlation between the growing number of Prozac lawsuits and the decline in Prozac sales can hardly be characterized as a coincidence. In addition, the allegations against Lilly provide its competitors ample ammunition with which to attack Prozac, and thus boost their own sales.²⁴²

Conversely, the rise in popularity of Zoloft and other antidepressants may signify the market's response to a faulty product. If the allegations against Prozac are in fact accurate, then theoretically, physicians will react by choosing to prescribe competing drugs instead. Regardless of the true cause of Zoloft's increased popularity, the new antidepressant is not immune to the accusations plaguing Prozac.²⁴³ Zoloft is already the subject of a number of lawsuits alleging the antidepressant causes violent behavior and/or suicide.²⁴⁴ Perhaps, not surprisingly, the claims and allegations against Pfizer are virtually identical to those against Lilly in the Prozac suits.²⁴⁵ Striking similarities must exist, either between Zoloft and Prozac, or among the people who use both drugs, namely, their inability to own up to their actions.

C. Pointing Fingers

Despite the staggering number of lawsuits, years of debate and study, and volumes of research, one question remains. Who is to blame? Who *is* responsible for the aggressive, violent, and suicidal behavior of Prozac users? Do we point the finger at Lilly, the drug's manufacturer, which put the controversial antidepressant on the market and profits immensely from its commercial success? Or perhaps we look to the physicians, who have a duty to their patients to disclose all risks and side effects associated with the medication they prescribe. But we cannot overlook the government agencies such as the Food and Drug Administration and its European counterparts, charged with protecting the public from such adverse effects by approving only those drugs that are safe for use.

In this difficult task of allocating liability among a number of potentially

239. *Id.*

240. *See id.*

241. *Id.*

242. *See id.*

243. *See, e.g., Foster v. Pfizer*, 2000 WL 33170897 (2000).

244. *See Motus v. Pfizer*, 127 F. Supp. 2d 1085 (2000).

245. *See Foster*, 2000 WL 33170897 at 1; *see also Motus*, 127 F. Supp. 2d at 1087.

responsible parties, the party that is arguably the most responsible is often left out of the equation. In the rush to find someone to blame, and to prove another guilty of some wrongdoing no matter how far removed from the actual harm at issue, the one actor who actually committed the harm is ignored. The concept of taking responsibility for one's own actions is forgotten as injured victims and grieving families scramble for compensation from a giant pharmaceutical manufacturer, occasionally placing culpability on the government and the medical profession as well, but never stopping to consider that the violent Prozac user may possess even the most minute degree of accountability for what he did.

The conclusion arrived at by FDA research scientists, simply that drugs have side effects and the decision to take medication always involves the weighing of benefit against risk,²⁴⁶ best sets forth the appropriate standard for assessing Prozac claims. Of course this requires that any patient contemplating the use of Prozac must be able to make an informed decision whether to take the drug, and to do so, he or she relies on the complete disclosure by Lilly of all side effects associated with Prozac. The decision is also dependent on the prescribing physician's conveying to the patient any information regarding the side effects he or she may experience. Thus when an informed choice is made to take Prozac, the user is acknowledging the existence of any and all known adverse effects and accepting the responsibility of his behavior despite the possibility of these effects.

VIII. CONCLUSION

The first fifteen years of Prozac's existence have been characterized by immense commercial success, an abundance of litigation, and incessant controversy. Eli Lilly & Co.'s involvement in legal action for the purpose of defending its popular antidepressant is nothing new. Recent developments and events, however, suggest Lilly's undefeated status may be in jeopardy. The first criminal acquittal in which the defense involved the use of Prozac, the emergence of product liability litigation outside the United States, the expiration of Prozac's protective patent and the evidence it has uncovered, all indicate significant changes in legal issues involving the drug.

As an antidepressant and thus a member of the psychotropic drug family, Prozac's exact influence on the mental condition of its users is impossible to discern. Until we are able to completely understand how the human mind works, the legal questions surrounding Prozac and other psychotropic drugs will remain at issue. Because a complete understanding of the complexities that constitute the human neurological makeup is not likely to ever be fully achieved, the law must instead adapt to deal with these legal questions.

In allocating liability for the violent actions of depressed patients who use Prozac, it is important to identify the responsibilities of all involved parties.

246. Goode, *supra* note 17.

No party should be held accountable for any more or any less than compliance with its legal duties to others. Pharmaceutical manufacturers are responsible for marketing safe medication and making all information regarding their products available to those who may use them. Physicians are responsible for conveying the information that they receive from the manufacturers to their patients, and make the choice to prescribe based on that information and the condition of each individual patient. If the government has established an agency for the regulation of medication, then that agency has the responsibility to allow only medication deemed safe by its regulatory standards to be marketed and prescribed. The patient is responsible for making his own informed decision whether to use the prescribed drug.

But the responsibility of the user doesn't end with his decision to take the medication. He still must adhere to the responsibility of obeying the laws of the country in which he lives. The use of prescription psychotropic medication does not absolve a user of his responsibility not to hurt or kill himself or others. No separate body of law exists to govern only psychotropic drug users; they are bound by the same rules as anyone, and necessarily face the same consequences for failure to abide by these rules. Just as with the use of any product, external factors and circumstances may alter the allocation of liability, but the user cannot escape the obligation to behave lawfully.

By placing responsibility where it belongs – with the actor who failed to uphold his duty – courts can easily obtain the answers to the difficult questions brought about by psychotropic drugs and the consequences of their use can easily be obtained by placing liability where it truly belongs - with the actor who failed to uphold his duty. If each involved party performs the duties for which it is responsible, problems of product liability and criminal culpability would never arise, and litigation involving mind-altering medication would cease to exist. Everyone would be satisfied with the outcome. And of course for those who are truly unhappy with the results, there is always Prozac.