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# Prozac: Another Drug Wrongfully Attacked - What Can Be Done to Stop the Legal System From Driving Good Drugs Off the Market, While Protecting State and Federal Interests

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# **PROZAC: ANOTHER DRUG WRONGFULLY ATTACKED - WHAT CAN BE DONE TO STOP THE LEGAL SYSTEM FROM DRIVING GOOD DRUGS OFF THE MARKET, WHILE PROTECTING STATE AND FEDERAL INTERESTS**

## INTRODUCTION

In America today a person can be gravely ill, go to the doctor, and then learn that the only medicine that can help is either prohibitively expensive or is no longer on the market because the drug company could not afford any more law suits. The legal system drives wonderful scientific and medical breakthroughs off the market, or makes them far too expensive for someone in grave need. That person also could take a prescribed medication, and be the unfortunate person to suffer an injury caused by the medicine itself. For that person, there may be no compensation for injury from the side effect because the reaction was expected and no one was at fault. For either of these scenarios, there is no fault, but there is immeasurable harm to either the company developing and manufacturing worthwhile drugs, or to the victim of an expected but unavoidable adverse reaction.

This Comment will examine the U.S. Food and Drug Administration (FDA) as a regulatory agency, and the status of pharmaceutical products liability. The Comment will describe Prozac, an antidepressant drug currently caught in the products liability dilemma; its compliance with FDA regulations; and opposition to the drug since FDA approval. The Comment will then review American problems with pharmaceutical products liability, and solutions that other commentators have proposed. Finally, the Comment will propose that Congress erect barriers to filing claims against manufacturers for drugs that meet or exceed a higher level of FDA approval, like Bendectin<sup>1</sup> and Prozac<sup>2</sup>, through a special preemption process; and that Congress establish a system to compensate victims of expected, yet unavoidable, adverse drug reactions from those drugs meeting a higher standard.

## BACKGROUND

### *The Prozac Controversy*

In January of 1988 the Dista Products Company, a division of Eli Lilly and

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<sup>1</sup> Kuhlik & Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 FOOD DRUG COSM. L.J. 693, 702 n.58 (1990) (FDA independent expert panel conclusion that there is no increased risk of birth defects from Bendectin, a drug for morning sickness during pregnancy).

<sup>2</sup> Antidepressants Update, FDA Talk Paper, Oct. 18, 1991 (FDA Psychopharmacological Drugs Advisory Committee unanimously agreed that Prozac, an antidepressant drug, does not cause suicidal or violent behavior).

Company, introduced the drug Prozac (fluoxetine hydrochloride) into the American market for the treatment of depression.<sup>3</sup> Physicians and patients hailed its arrival as a wonder drug.<sup>4</sup> In July 1990, Rhonda Hala filed a \$150 million lawsuit against Eli Lilly alleging that Prozac caused her to repeatedly attempt suicide.<sup>5</sup> The day after Ms. Hala filed suit, Eli Lilly stock dropped three and seven-eighths points on the New York Stock Exchange.<sup>6</sup>

A variety of legal attacks against Prozac rapidly escalated.<sup>7</sup> Plaintiffs have alleged what has become known as the "Prozac defense" as an explanation for violent acts, homicide,<sup>8</sup> and even prostitution due to nymphomania.<sup>9</sup> Recently, a man denied employment as Santa Claus because of his use of Prozac named Macy's Department Store in a \$3.25 million discrimination suit.<sup>10</sup> Attacks on Prozac have also come from the Church of Scientology, Ralph Nader's Health Research Group, and lawyers attempting to profit from the suits.<sup>11</sup>

Dr. Jack Gorman, head of biological studies at Columbia University's College of Physicians and Surgeons, worries that the publicity will "scare people away from a good drug."<sup>12</sup> Dr. Gorman also noted that one lawsuit will breed more lawsuits, and that "people are going to try to make a fortune out of this."<sup>13</sup> Dr. Gorman's fear is turning into reality.<sup>14</sup> Dr. Gorman's predictions have become

<sup>3</sup> DISTA PROD. CO., ELI LILLY AND CO., PROZAC (fluoxetine hydrochloride) COMPREHENSIVE MONOGRAPH (1991), at 2 [hereinafter DISTA PROD. CO.].

<sup>4</sup> See, e.g., Cowley et al., *The Promise of Prozac*, NEWSWEEK, March 26, 1990, at 38; Grady, *Wonder Drug, Killer Drug: The Furor Over Prozac Won't Go Away*, AMERICAN HEALTH, October 1990, at 61; *New Drugs Boost Lilly*, USA TODAY, Nov. 22, 1989, at 3B (far fewer and less dangerous side effects than with drugs existing on the market, and an almost impossibility of using the drug itself as an agent for suicide).

<sup>5</sup> Hala v. Eli Lilly & Co., 90-14689 (Sup. Ct., Suffolk Co., N.Y. 1990). See also Grady, *supra* note 4, at 60.

<sup>6</sup> *Eli Lilly Falls 3 7/8 on News of Lawsuit*, USA TODAY, July 19, 1990, at 3B.

<sup>7</sup> Blodgett, *Eli Lilly Drug Targeted: Suits Allege Antidepressant Prozac Can Spark Suicide, Violent Behavior*, A.B.A. J., November 1990, at 24.

<sup>8</sup> E.g., *Wesbecker v. Eli Lilly & Co.*, 90-CI-007445 (Cir. Ct., Jefferson Co., Ky. 1990) (killed eight people, wounded twelve, and shot self); *Bulfin v. Eli Lilly & Co.*, 90 L 13926 (Cir. Ct., Cook Co., Ill. 1990) (killed one person and injured two others). See also Sargeant, *Prozac on Trial*, TRIAL, May 1991, at 101; Marcus, *Murder Trials Introduce Prozac Defense*, WALL ST. J., Feb. 7, 1991, at B1.

<sup>9</sup> Higham, *Drug Made Woman Slave to Her Desires, Attorney Says*, AKRON BEACON J., Sept. 7, 1991, at A3.

<sup>10</sup> Karel, *Santa's Suit Could Cost Macy's Much More Than It Bargained For*, PSYCHIATRIC NEWS, Jan. 3, 1992, at 4.

<sup>11</sup> *Review & Outlook: The Prozac Posse*, WALL ST. J., Sept. 27, 1991, at A10 [hereinafter *Prozac Posse*].

<sup>12</sup> Quoted in Grady, *supra* note 4, at 62.

<sup>13</sup> *Id.*

<sup>14</sup> See, Blum, *High Stakes: Wonder Drugs are Focus of Criminal, Civil Actions; Patients Sue Makers of Psychotropic Drugs*, NAT'L L.J., Oct. 22, 1990, at 1; Moses, *Prozac Suits Expected to Continue*

the "American way" regarding how the legal system handles drug safety, and other instrumentalities that are of great public benefit.<sup>15</sup>

The pharmaceutical products liability issue has become a public policy issue<sup>16</sup> which needs to be finally decided. Innocent drug companies that are forced to incur the high cost of defending a products liability action have been forced to remove beneficial drugs from the market. Many drugs that are still on the market are prohibitively expensive to consumers because the companies pass the costs of litigation along to consumers. Occasionally, expected but unavoidable side effects injure consumers of drugs who are not compensated because a court cannot hold the manufacturer liable. The policy dilemma is one of public versus private benefit or loss.

### *The Pharmaceutical Public Policy Dilemma*

The 1960's witnessed the first successful lawsuits against vaccine manufacturers.<sup>17</sup> Before those cases, the Supreme Court upheld governmental programs requiring vaccination against smallpox; for example, against individual injury claims.<sup>18</sup> The Supreme Court considered the benefit to the public from the smallpox vaccination program to be enormous.<sup>19</sup> However, during the 1960's a shift occurred in the emphasis from public safety to individual rights.<sup>20</sup> As a result, individuals alleging injury from vaccinations became very successful in the courtroom.<sup>21</sup>

Insurance companies eventually stopped covering manufacturer's losses due to tort liability.<sup>22</sup> In 1984, only one manufacturer remained for nineteen vaccines.<sup>23</sup> The prices of these vaccines doubled so that the manufacturer could

*Although No Link Was Found to Violence*, WALL ST. J., Sept. 24, 1991, at B5.

<sup>15</sup> See Cochran, *Plaintiffs' Creative Approaches to Prove Who or What Caused Injury*, 57 DEF. COUNS. J. 452, 452 (1990); Henderson & Eisenberg, *The Quiet Revolution in Products Liability: An Empirical Study of Legal Change*, 37 UCLA L. REV. 479, 480-81 (1990).

<sup>16</sup> Blum, *Drug Maker Mounts an Attack: Effort to Shore Up Prozac*, NAT'L L.J., June 17, 1991, at 3 (quoting Victor Schwartz of Crowell & Moring, Washington, D.C.).

<sup>17</sup> Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 286-87 (1985) (the first successful suit was *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) (failure to warn of one in a million risk of contracting polio from the vaccine)).

<sup>18</sup> *Id.* at 286 ("[medical experts] generally have considered the risk of such an injury [from improper vaccination] too small to be seriously weighed against the benefits. . .") (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 23-24 (1905)).

<sup>19</sup> *Id.* (citing Henderson, *A Victory for All Mankind*, WORLD HEALTH, May 1980, at 3 (announcing the eradication of smallpox)).

<sup>20</sup> *Id.* at 287.

<sup>21</sup> *Id.* (the Swine Flu Vaccination program alone had \$2.95 billion in claims against it).

<sup>22</sup> *Id.* at 287-89.

<sup>23</sup> *Id.* at 289.

cover the tort liability risk.<sup>24</sup> Today, ninety-five percent of the price of childhood vaccines is attributable to insurance to cover the costs of tort litigation.<sup>25</sup>

In 1986, Congress passed the no-fault National Vaccine Injury Compensation Program to combat high vaccine prices and a dwindling number of manufacturers.<sup>26</sup> The program covers claims related to injuries from polio, DPT and measles-mumps-rubella vaccines.<sup>27</sup> Congress and the President have recently tried to create ways to fund the nearly broke program.<sup>28</sup> If the government does not find funding, this country could easily face the risk of nonimmunization of its children against preventable fatal diseases.<sup>29</sup> The costs could either be exorbitant, or there could be a complete lack of essential vaccines because manufacturers would cease to produce them due to liability problems.

Litigation against Merrell Dow, manufacturer of Bendectin, is another example of the tort system gone awry.<sup>30</sup> This example exemplifies the future for Prozac and other drugs if the liability problem remains unsolved. Bendectin is the only drug currently approved<sup>31</sup> by the U.S. Food and Drug Administration for a pregnant woman's morning sickness.<sup>32</sup> The medical community hailed Bendectin for its benefits to maternal health.<sup>33</sup> Yet in 1983, the manufacturer ceased production and distribution of the drug because litigation became prohibitively expensive.<sup>34</sup>

Other examples of drugs and drug products withdrawn from the market due

<sup>24</sup> *Id.*

<sup>25</sup> Rubenstein, *Punitive Damages*, NAT'L REV., Nov. 4, 1991, at 16.

<sup>26</sup> Glazer, *Vaccine Victims: No-Fault Federal Program Compensates for Injuries*, WASH. POST, Jan. 29, 1991, at Z9.

<sup>27</sup> *Id.*

<sup>28</sup> Squires, *U.S. Immunization Campaign Struggles; Problems Include High Vaccine Costs, Poor Access, and Parental Indifference*, WASH. POST, Oct. 22, 1991, at Z6.

<sup>29</sup> *Id.*

<sup>30</sup> See 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, 426-29 (1990); Huber, *supra* note 17, at 333 n.196; Kuhlik & Kingham, *supra* note 1, at 702-703; Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 774-75 (1990) [hereinafter *Question of Competence*].

<sup>31</sup> Kuhlik & Kingham, *supra* note 1, at 702 n.58 (FDA adopted its Fertility and Maternal Health Drugs Advisory Committee conclusion, in 1980, that there is no increased risk of birth defects from Bendectin, and the FDA has not changed its position since).

<sup>32</sup> *Question of Competence*, *supra* note 30, at 774.

<sup>33</sup> Denemark, *supra* note 30, at 426 (severe morning sickness can result in the need for an abortion or in maternal death).

<sup>34</sup> *Id.* at n.88 (citing *Richardson v. Richardson-Merrill, Inc.*, 857 F.2d 823, 824 (D.C. Cir. 1988) (for example, one trial alone involved over 1500 cases consolidated in the Southern District of Ohio alleging birth defects caused by Bendectin)).

to excess liability abound.<sup>35</sup> One must wonder at the number of "miracle drugs" that have not been discovered or produced because of the fear of litigation and its corresponding costs.

## THE U.S. FOOD AND DRUG ADMINISTRATION

### *The FDA and the Approval Process*

The U.S. Food and Drug Administration is the federal agency responsible for assuring the public that all drugs available through a physician or over the counter are safe and effective.<sup>36</sup> The FDA derives its authority from the 1938 Federal Food, Drug and Cosmetic Act (FDCA)<sup>37</sup> and subsequent amendments that improved the regulatory system.<sup>38</sup> The FDA's authority includes approving all drugs for human use before a drug is on the market, and enforcing compliance with the FDCA through its regulatory powers after a drug is on the market.<sup>39</sup>

The approval process starts when the proponent of a new drug, typically a manufacturer, submits an investigational new drug application (IND) to the FDA, requesting approval to proceed to clinical studies on humans.<sup>40</sup> The IND presents the results of the proponent's completed laboratory and animal testing.<sup>41</sup> The FDA then has thirty days to either request more information or require changes. If the FDA does not respond, the proponent is free to begin clinical trials.<sup>42</sup>

Clinical trials are time-consuming processes which can take from two to ten years.<sup>43</sup> Clinical trials include three phases: (1) testing on a few healthy

<sup>35</sup> E.g., Denemark, *supra* note 30, at 426 (contraceptive spermicidal jelly); Huber, *supra* note 17, at 321 (Dalkon Shield IUD); Kuhlik & Kingham, *supra* note 1, at 703 (anti-coagulant drug Coumadin greatly threatened); *Question of Competence*, *supra* note 30, at 774 (eyelid muscle spasm drug Oculinum).

<sup>36</sup> Farley, *Benefit vs. Risk: How FDA Approves New Drugs*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 27, 30 (FDA Consumer Special Report, 1988).

<sup>37</sup> 21 U.S.C. §§ 301-392 (1991).

<sup>38</sup> Farley, *supra* note 36, at 30 (Durham-Humphrey Amendment in 1951 required labeling for prescription drugs; Kefauver-Harris Amendments of 1962 increased FDA control over drugs by adding "effectiveness" to the "safety" already regulated).

<sup>39</sup> Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994, 994 n.1 (1977).

<sup>40</sup> Farley, *supra* note 36, at 27.

<sup>41</sup> Cohn, *The Beginnings: Laboratory and Animal Studies*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 8, 11 (FDA Consumer Special Report, 1988).

<sup>42</sup> Farley, *supra* note 36, at 27.

<sup>43</sup> Young, *The Reality Behind the Headlines*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 4, 5 (FDA Consumer Special Report, 1988).

volunteers; (2) randomized controlled trials<sup>44</sup> on up to several hundred volunteers; and, (3) testing on several hundred to thousands of volunteer patients who have the condition targeted by the drug.<sup>45</sup> The FDA and outside institutional review boards (IRBs) are heavily involved throughout the clinical trial process.<sup>46</sup>

When clinical trials are complete, the proponent submits a new drug application (NDA) to the FDA. The FDA then begins a review process that can take from two months to seven years to complete.<sup>47</sup> The review triggered by submission of the NDA is the FDA's most intense involvement during the entire process.<sup>48</sup> The FDA's task in this review is to comply with the FDCA mandate that there be "substantial evidence" that any drug approved is safe and effective for its intended use.<sup>49</sup> To do this, the FDA must decide if the benefits of the drug to the intended population sufficiently outweigh the risks.<sup>50</sup> The FDA extensively analyzes all available information to assure that the manufacturer used randomized clinical trials to eliminate bias and prevent fraud, and that the manufacturer used correct analytical models.<sup>51</sup>

The FDA's policy concerning drug approval reflects Congressional intent that a drug may only be approved if it is effective and if its label adequately describes the relative risks and benefits.<sup>52</sup> Historically, the FDA has been conservative in granting approvals.<sup>53</sup> The FDA has often waited years after other countries have approved the same drug.<sup>54</sup>

Once the drug has received FDA approval and the manufacturer has placed

<sup>44</sup> Flieger, *Testing in 'Real People'*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 13, 14 (FDA Consumer Special Report, 1988) (treatment groups receive the drug and matching control groups receive standard treatment or a placebo).

<sup>45</sup> *Id.* at 14-17.

<sup>46</sup> Thompson, *Protecting 'Human Guinea Pigs'*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 20, 20 (FDA Consumer Special Report, 1988) (IRBs are groups, regulated by the FDA and other federal agencies, at hospitals and research facilities that regularly review the research and ensure that volunteer participants in the studies are willing and informed); see also Farley, *supra* note 36, at 27.

<sup>47</sup> Young, *supra* note 43, at 5.

<sup>48</sup> See Farley, *supra* note 36, at 29; Denmark, *supra* note 30, at 417-18; Kuhlik & Kingham, *supra* note 1, at 693-94; *Question of Competence*, *supra* note 30, at 776-77.

<sup>49</sup> See 21 U.S.C. § 355(d) ("[S]ubstantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations by experts qualified . . . to evaluate the effectiveness of the drug involved. . . .").

<sup>50</sup> Kuhlik & Kingham, *supra* note 1, at 695-96.

<sup>51</sup> Paul Leber, M.D., Remarks at the Meeting of the FDA Psychopharmacologic Drugs Advisory Committee 19 (Oct. 10, 1985) (transcript available in FDA Freedom of Information Office).

<sup>52</sup> *Id.* at 24-25.

<sup>53</sup> Kuhlik & Kingham, *supra* note 1, at 696-97.

<sup>54</sup> *Id.*

the drug on the market, the FDA remains active through post-market surveillance.<sup>55</sup> To monitor approved drugs, the FDA requires all manufacturers to submit adverse drug reaction reports (ADRs).<sup>56</sup> The FDA also encourages physicians and other medical professionals to submit ADRs, but their participation is voluntary.<sup>57</sup> The ADRs provide the information needed by the FDA to initiate any post-market enforcement action.<sup>58</sup>

If a problem with a drug arises, the FDA has enforcement powers including injunctions, product seizures and criminal penalties.<sup>59</sup> When a problem initially arises, the FDA generally asks one of its thirty-eight standing advisory committees to consider the problem.<sup>60</sup>

### *FDA Advisory Committees*

In 1972 Congress passed the Federal Advisory Committee Act<sup>61</sup> to regulate the need for, public access to, and membership in committees that act in an advisory capacity to any governmental agency.<sup>62</sup> Congress felt a need for greater regulation so that special interests could not be advanced by members,<sup>63</sup> and public reliance on federal agencies could be enhanced.<sup>64</sup> Members of the FDA committees are outside experts, primarily physicians in the committee's particular specialized field.<sup>65</sup> An FDA medical officer serves as each committee's executive secretary, providing the link to the FDA.<sup>66</sup> In 1964 the FDA began using the committees for outside expert advice, to balance the evaluative process and to lend additional credibility to FDA decisions.<sup>67</sup>

There are primarily three reasons for convening a meeting of an advisory

<sup>55</sup> Farley, *supra* note 36, at 28.

<sup>56</sup> Ackerman, *Watching for Problems That Testing May Have Missed*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 51, 52 (FDA Consumer Special Report, 1988).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 51-52.

<sup>59</sup> Kuhlik & Kingham, *supra* note 1, at 694 n.4.

<sup>60</sup> See Farley, *Getting Outside Advice for the 'Close Calls'*, in FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 35, 37 (FDA Consumer Special Report, 1988); Degnan, *An Introduction to FDA Advisory Committees*, 45 FOOD DRUG COSM. L.J. 709, 715 (1990).

<sup>61</sup> 5 U.S.C. app. §§ 1-14 (1988).

<sup>62</sup> Degnan, *supra* note 60, at 710.

<sup>63</sup> *Id.* at 709-10.

<sup>64</sup> See *id.* at 709; Farley, *supra* note 60, at 35.

<sup>65</sup> Farley, *supra* note 60, at 35.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* See also Degnan, *supra* note 60, at 709.



committee.<sup>68</sup> First, the agency may be required or want to have an advisory committee review a product.<sup>69</sup> Second, a manufacturer may want an advisory committee to review the problem before any FDA action.<sup>70</sup> Third, the FDA may want the advisory committee's advice on either a "close call" decision, or a question of whether the benefits outweigh the risks, or a controversy about a particular product.<sup>71</sup> Although the conclusion of an advisory committee is not a final FDA decision, the FDA usually adopts the advisory committee's findings in reaching a decision.<sup>72</sup>

### *The Need for Such Pervasive Regulation*

There is no drug in existence that is absolutely safe.<sup>73</sup> The *Restatement (Second) of Torts*, § 402A, comment k, acknowledges that drugs are an obvious example of "unavoidably unsafe" products.<sup>74</sup> Nevertheless, to protect the public, someone must regulate drugs on the market to ensure that they are as safe and effective as possible. The government with its expert administrative agencies is the most effective entity to regulate drugs for public safety.<sup>75</sup> Courts are particularly inappropriate to handle public safety issues.<sup>76</sup> The purpose of the court system is primarily to redress individual wrongs, not to plan for and regulate the nation's public health and welfare.

A drug manufacturer is accountable to a dual system of regulation: the FDA and state tort law.<sup>77</sup> The very pervasive scheme of FDA regulation must seem frustrating to those involved in the regulatory process, and to the manufacturers. Even if a manufacturer complies fully with the mandates of the FDCA, they can still be held liable in tort for an adverse reaction about which they warned the patient.

## COMMON LAW PHARMACEUTICAL PRODUCTS LIABILITY

The law realizes that a drug may cause adverse reactions, even when

<sup>68</sup> Degnan, *supra* note 60, at 715.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> See Kuhlik & Kingham, *supra* note 1, at 694-95; *Question of Competence*, *supra* note 30, at 773.

<sup>74</sup> Kuhlik & Kingham, *supra* note 1, at 695.

<sup>75</sup> See, e.g., Huber, *supra* note 17, at 329.

<sup>76</sup> *Id.*

<sup>77</sup> *Question of Competence*, *supra* note 30, at 777. See also Agar, *Labeling of Prescription Devices for the Food and Drug Administration and Product Liability: A Primer - Part II*, 45 FOOD DRUG COSM. L.J. 569, 569 (1990).

developed, manufactured and administered properly.<sup>78</sup> Therefore, common law requires that appropriate warnings about possible side effects accompany every drug.<sup>79</sup> Since the choice of a prescription drug and the information regarding its side effects are too technical for the patient,<sup>80</sup> the manufacturer must make appropriate warnings to the physician. Legally the physician is considered to be a "learned intermediary" between the manufacturer and the patient.<sup>81</sup> Regardless of the asserted legal theory,<sup>82</sup> the issue in most pharmaceutical products liability suits is whether the manufacturer provided adequate warning to the appropriate party.<sup>83</sup>

Even if a manufacturer has warned about a particular side effect, a court may still hold that manufacturer liable for an adverse reaction.<sup>84</sup> This is so even in spite of the *Restatement (Second) of Torts* directive that "[t]he seller of such products . . . is not to be held to strict liability for unfortunate. . . ."<sup>85</sup> Courts that follow such legal dogma use tort law as an instrument of social policy.<sup>86</sup> Tort law has long been recognized as an instrument for compensating injured parties and deterring socially unacceptable behavior.<sup>87</sup>

A plaintiff's verdict based on a design defect or inadequate warning should compensate the victim and induce the manufacturer to make a change in the design or the warning.<sup>88</sup> In reality, when the claim is that the drug has a design defect, a jury must weigh the drug's risks and benefits,<sup>89</sup> which is apart from the FDA's scientific risk/benefit analysis.<sup>90</sup> Moreover, when the claim is that the drug has an inadequate warning, the jury must analyze the warning apart from the

<sup>78</sup> Denemark, *supra* note 30, at 419.

<sup>79</sup> *Id.* See also RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

<sup>80</sup> Denemark, *supra* note 30, at 420-21.

<sup>81</sup> *Id.* (but some drugs, such as birth control pills, require warning to the patient); Agar, *supra* note 77, at 586-88.

<sup>82</sup> Denemark, *supra* note 30, at 421 (negligence, breach of duty to warn, breach of warranty, or strict liability).

<sup>83</sup> *Id.*

<sup>84</sup> See, e.g., *Feldman v. Wyeth Laboratories*, 97 N.J. 429, 441-42, 479 A.2d 374, 380 (1984) (does not agree with comment k); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1273 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974) (so unsafe that marketing is unreasonably dangerous per se); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (insufficient safeguards so unreasonably dangerous as marketed). See generally *Question of Competence*, *supra* note 30, at 777-78.

<sup>85</sup> RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

<sup>86</sup> See Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 171-72 (1986).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 172-73.

<sup>89</sup> See, e.g., *Hurley v. Lederle Laboratories*, 851 F.2d 1536, 1542 (5th Cir. 1988) (remanding for jury decision of design defect), *modified*, 863 F.2d 1173 (5th Cir. 1989).

extensive analysis the FDA used in determining the most significant warning information which must be on the drug's label.<sup>91</sup> The FDA prescribes every label; the manufacturer has virtually no control over its contents.<sup>92</sup>

When a company markets a drug, it is inevitable that some form of personal injury will occur and that the manufacturer will likely face many injury claims.<sup>93</sup> At the trial, jury members are asked whether the particular drug caused the injury, and if so whether the manufacturer adequately warned the public or the physician, or whether the manufacturer defectively designed the drug. Causation is always a question of fact for a jury.<sup>94</sup> In pharmaceutical product liability cases, there are complex and technical aspects of causation which are extremely difficult for a jury to resolve.<sup>95</sup> Juries are not pharmaceutical experts, they are people who are influenced by the sad facts of the case they are evaluating and who are trying to apply the law as explained to them. They are people who wish to see the individual plaintiff adequately compensated, and the drug manufacturer sufficiently punished.<sup>96</sup> To exacerbate the problem, a recent survey indicates that seventy percent of potential jurors would believe an individual's description of events over that of a corporation's description.<sup>97</sup>

Except in a relatively few cases,<sup>98</sup> a drug company found to have met the FDA's standards may be free from liability while the plaintiff remains uncompensated for injury. That injury may not be the fault of the plaintiff either; the injury was just an expected but unavoidable adverse reaction.

The courts vary in their response to expected but unavoidable adverse reactions to drugs. Some courts hold that the FDA's standards warrant preemption since the standards are so comprehensive.<sup>99</sup> Other courts hold that the FDA's regulations are minimum standards that remain subject to judicial review.<sup>100</sup> Even if a case does not reach trial, a manufacturer's legal costs of preparing a defense to many claims against one product can eventually make

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<sup>91</sup> See Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 234-38 (1986) (FDA experts weigh too much vs. too little prescription information so that a physician's treatment decisions can be the most rational).

<sup>92</sup> *Id.*

<sup>93</sup> Kuhlik & Kingham, *supra* note 1, at 697.

<sup>94</sup> *Id.* at 698.

<sup>95</sup> *Id.*

<sup>96</sup> See *id.* at 697-98.

<sup>97</sup> *Survey of Potential Jurors*, A.B.A. J., Feb. 1992, at 35 (citing The Metricus National Juror Opinion Survey conducted by Metricus, Inc., Palo Alto, Cal.) (5,030 jury-eligible Americans surveyed).

<sup>98</sup> E.g., *supra* notes 26 and 27 and accompanying text (National Vaccine Injury Compensation Program).

<sup>99</sup> Westerfield, *Federal Preemption and the FDA: What Does Congress Want?*, 58 U. CIN. L. REV. 263, 264 (1989).

<sup>100</sup> *Id.*  
http://ideaexchange.uakron.edu/akronlawreview/vol25/iss3/6

marketing that product prohibitively expensive. Although still on the market, the litigation surrounding Prozac is a good example. Of approximately 100 cases filed to date against the manufacturer, none have gone to trial.<sup>101</sup> Twenty-two cases have been voluntarily dismissed.<sup>102</sup> Additionally, no plaintiff has been compensated since Eli Lilly and Company will settle no claims.<sup>103</sup> Nonetheless, Eli Lilly has had to mount a rigorous and extremely costly campaign in defense of its drug. A manufacturer in such a situation must pass on the costs of litigation to the consumers. At the same time, the consumers need to have access to this drug. One day consumers may be in need of the drug, and need to be able to afford it. There would be little solace in knowing that the drug may no longer be available because a few people were unavoidably harmed.

## PROZAC

### *Depression*

Recently, one of the nation's experts in psychopharmacology stated that depression is a "major chronic, relapsing, debilitating illness, . . ." <sup>104</sup> An alteration in the central nervous system's chemistry often causes the illness.<sup>105</sup> Symptoms of depression include regularly sleeping too much or too little, a depressed mood, change in weight or appetite, agitation or slowness observable by others, excessive self-blame or feeling worthless, suicidal thoughts, indecisiveness or a lack of concentration, fatigue, and little interest or pleasure in daily activities.<sup>106</sup> At least five of these symptoms, including depressed mood or little interest or pleasure in daily activities, must be present nearly daily for a minimum of two weeks for a doctor to diagnosis major depression in a patient.<sup>107</sup> Depression is treatable with antidepressant drugs which restore the central nervous system's balance.<sup>108</sup>

Another prominent expert has pointed out that depression is not only a grave illness, but if left untreated, depression has a mortality rate of fifteen percent of

<sup>101</sup> Telephone interview with Kelly Weston, Corporate Communications, Eli Lilly & Co., Indianapolis, Ind. (June 2, 1992).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> Burton Goldstein, Remarks at the Meeting of the FDA Psychopharmacological Drugs Advisory Committee 51 (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).

<sup>105</sup> *Prozac Posse*, *supra* note 11, at A10.

<sup>106</sup> DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 222-23 (American Psychiatric Ass'n ed., 3d ed. 1987).

<sup>107</sup> *Id.*

its population as a result of suicide.<sup>109</sup> Depression is treatable, but not without an element of risk.<sup>110</sup> Several therapies are available, including medications and psychotherapy.<sup>111</sup> Each therapy has the possibility of side effects; some side effects are more serious than others.<sup>112</sup> Prozac is one of the most recently available medications for depression.

### *Prozac - The Drug*

Prozac is an inhibitor of the uptake of serotonin into nerve endings of the central nervous system.<sup>113</sup> Prozac is different from previous drugs for depression in that previous drugs did not selectively inhibit serotonin.<sup>114</sup> The other commonly available antidepressants are tricyclics and monoamine oxidase inhibitors (MAOIs). Side effects for these antidepressants include dry mouth, dizziness, constipation, blurred vision, cardiac effects, and weight gain.<sup>115</sup> These side effects often are difficult for the physician to monitor and control.<sup>116</sup> Prozac's common side effects include nausea, anxiety/nervousness, insomnia, drowsiness, and headache; side effects that are easier to control.<sup>117</sup> Prozac has also proven effective for weight loss,<sup>118</sup> pre-menstrual syndrome (PMS) and obsessive compulsive disorder.<sup>119</sup>

Perhaps the greatest reason for Prozac's popularity among physicians treating depression is that it is almost impossible for a patient to use the drug itself to commit suicide.<sup>120</sup> In fact, Prozac is less dangerous overall than cyclic or MAOI antidepressants, but Prozac is particularly less dangerous to patients who may try to use an overdose to commit suicide.<sup>121</sup>

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<sup>109</sup> Carolyn Rabinowitz, Remarks at the Meeting of the FDA Psychopharmacological Drugs Advisory Committee 90 (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office) (Dr. Rabinowitz is the senior deputy medical director of the American Psychiatric Association).

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> DISTA PROD. CO., *supra* note 3, at 2.

<sup>114</sup> Cowley, *supra* note 4, at 39.

<sup>115</sup> DISTA PROD. CO., *supra* note 3, at 18-20.

<sup>116</sup> See Guze & Freedman, *Psychiatry*, 265 J. AM. MED. ASS'N 3164, 3165 (1991); DISTA PROD. CO., *supra* note 3, at 18; Cowley, *supra* note 4, at 39-40.

<sup>117</sup> DISTA PROD. CO., *supra* note 3, at 18-20.

<sup>118</sup> *Id.* at 19.

<sup>119</sup> Stephen M. Pariser, M.D., Address to Akron, Ohio area primary care physicians regarding management of the depressed patient (Dec. 5, 1991) (slide transcript available in Dept. of Psychiatry, Ohio State Univ.).

<sup>120</sup> DISTA PROD. CO., *supra* note 3, at 24 (since the introduction of Prozac only one death attributable to the drug itself); see also Cowley, *supra* note 5, at 40 (far less risk of overdose).

*FDA Approval of Prozac*

Dr. David Wong of Lilly Research Laboratories discovered Prozac in July of 1972.<sup>122</sup> Before FDA approval, Lilly conducted clinical trials over a ten year period on more than 3,000 patients with depression.<sup>123</sup> Overall, there were more than 11,000 participants in the clinical trials for Prozac, with more than 6,000 patients treated with the drug.<sup>124</sup>

Eli Lilly submitted the NDA to the FDA in September of 1983.<sup>125</sup> FDA analysis took more than four years to complete.<sup>126</sup> The FDA gave final approval of Prozac in December of 1987.<sup>127</sup> During the FDA analysis phase, the Psychopharmacologic Drugs Advisory Committee met at the request of the FDA, in October of 1985, to provide outside expert advice before approval.<sup>128</sup> After intense probing of Eli Lilly's clinical trials and conclusions, the committee voted unanimously that the drug had antidepressant efficacy and appeared safe given the claimed use.<sup>129</sup>

The FDA approved Prozac in December of 1987. Lilly first marketed the drug in January of 1988.<sup>130</sup> As of August of 1990 over two million patients had been treated with the drug.<sup>131</sup> By September 1991, Prozac had been given to more than four million patients.<sup>132</sup> In July of 1990 the first lawsuit against Eli Lilly was filed.<sup>133</sup> To date, there have been approximately 100 cases arising out of the use of Prozac which have been filed against the manufacturer.<sup>134</sup>

<sup>122</sup> W. Leigh Thompson, M.D., Ph.D., Remarks at the Meeting of the FDA Psychopharmacologic Advisory Committee 61 (Oct. 10, 1985) (transcript available in FDA Freedom of Information Office).

<sup>123</sup> *Id.*

<sup>124</sup> Letter from Charles M. Beasley, M.D., Clinical Investigation and Regulatory Affairs Division, Dista Products Company, to Edward K. Katz, M.D., Chief Clinical Officer, County of Summit Alcohol, Drug Addiction and Mental Health Services Board, Cuyahoga Falls, Ohio (Aug. 24, 1990) (on file with author).

<sup>125</sup> Thompson, *supra* note 122, at 132.

<sup>126</sup> Thomas Laughren, M.D., Remarks at the Meeting of the FDA Psychopharmacological Drugs Advisory Committee 134 (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).

<sup>127</sup> *Id.*

<sup>128</sup> Leber, *supra* note 51, at 134 (asking if fluoxetine is a reasonable antidepressant, and what the experts would want to know before approval).

<sup>129</sup> Thomas Detre, M.D., Chairman, Remarks at the Meeting of the FDA Psychopharmacologic Drug Advisory Committee 167 (Oct. 10, 1985) (transcript available in FDA Freedom of Information Office).

<sup>130</sup> See *supra* note 3 and accompanying text.

<sup>131</sup> Detre, *supra* note 129, at 167.

<sup>132</sup> Burton, *Panel Finds No Credible Evidence to Tie Prozac to Suicides and Violent Behavior*, WALL ST. J., Sept. 23, 1991, at B5.

<sup>133</sup> See *supra* note 5 and accompanying text.

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<sup>134</sup> Weston, *supra* note 101.

### *Opposition to Prozac*

Publicity about Prozac and its alleged side effects has been overwhelming. Defendants in criminal trials have alleged that Prozac caused their actions.<sup>135</sup> Prozac has even been blamed for the suicides of prominent citizens.<sup>136</sup> Highly active and controversial groups, such as the Church of Scientology and Ralph Nader's Health Research Group, have made Prozac a target.<sup>137</sup> Numerous scientific articles have been written about Prozac, particularly after a report in the *American Journal of Psychiatry* that the drug might cause suicidal preoccupation.<sup>138</sup>

The Church of Scientology's effort has been through the Citizen's Commission on Human Rights (CCHR),<sup>139</sup> a group largely committed to eliminating psychiatry in general.<sup>140</sup> The Church of Scientology is a religious cult that, according to the Cult Awareness Network's Director, is "quite likely the most ruthless, the most classically terroristic, the most litigious and the most lucrative cult the country has ever seen."<sup>141</sup> CCHR's activity against Prozac has been extensive, including mass mailings, appearances on television and radio talk shows, lobbying,<sup>142</sup> and referrals of prospective plaintiffs to sympathetic attorneys.<sup>143</sup> The *Wall Street Journal* has found Ralph Nader's Health Research Group to be a suspect organization because of a lack of scientific proof for the allegations against Prozac.<sup>144</sup> The *Journal* also suspects the group's motives because the group will not reveal its funding sources.<sup>145</sup>

In February 1990, Dr. Martin Teicher opined that Prozac might cause preoccupation with suicide.<sup>146</sup> He based his findings on only six patients treated with fluoxetine, four of whom were also taking other medications.<sup>147</sup> Dr. Teicher did not recommend that the drug not be used at all, but rather he merely

<sup>135</sup> See, e.g., Marcus, *supra* note 8, at B1; Grady, *supra* note 4, at 60-61.

<sup>136</sup> Blum, *supra* note 14, at 1 (singer Del Shannon and activist Abbie Hoffman).

<sup>137</sup> *Prozac Posse*, *supra* note 11, at A10.

<sup>138</sup> Teicher et al., *Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment*, 147 AM. J. PSYCHIATRY 207, 207 (1990).

<sup>139</sup> Sanford Block, CCHR's Executive Director, did not respond to this author's letter or telephone calls requesting information.

<sup>140</sup> Behar, *The Thriving Cult of Greed and Power*, TIME, May 6, 1991, at 53.

<sup>141</sup> *Id.* at 51.

<sup>142</sup> *Id.* at 53.

<sup>143</sup> *Prozac Posse*, *supra* note 11, at A10.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> Teicher, *supra* note 138, at 207.

advocated cautious use of Prozac and attentive practitioners.<sup>148</sup> Nonetheless, Dr. Teicher's article sparked controversy in the scientific community. Scientific publications have been prolific since Dr. Teicher's article, with most of the articles politely refuting Dr. Teicher's findings.<sup>149</sup>

Eli Lilly responded to the attacks on Prozac with a vigorous campaign in support of the drug.<sup>150</sup> In an untraditional public strategy, Eli Lilly has actively helped lawyers faced with the "Prozac defense."<sup>151</sup> Eli Lilly has sent out information to doctors, shareholders, pharmacists, and the media<sup>152</sup> and has even offered to pay the legal fees of any non-negligent physician sued as a result of prescribing Prozac.<sup>153</sup> High profile members of the media have also helped Eli Lilly through their sympathetic national coverage.<sup>154</sup>

The FDA has also been very active in the Prozac controversy. Ralph Nader's Health Research Group filed a petition asking the FDA to require relabeling of Prozac to reflect a suicide warning.<sup>155</sup> The CCHR filed a petition to have the FDA withdraw approval of the drug.<sup>156</sup> On September 20, 1991 the FDA convened its Psychopharmacological Drugs Advisory Committee.<sup>157</sup> There were nine outside members of the committee, helped by six consultants including Dr. Teicher and other physicians and researchers who had been active in studying

<sup>148</sup> *Id.*

<sup>149</sup> See, e.g., Beasley, et al., *Fluoxetine and Suicide: A Meta-Analysis of Controlled Trials of Treatment for Depression*, 303 BRIT. MED. J. 685 (1991) (fluoxetine not associated with increased risks of suicidal acts or thoughts among depressed patients); Fava & Rosenbaum, *Suicidality and Fluoxetine: Is There a Relationship?*, 52 J. CLINICAL PSYCHIATRY 108 (1991) (knowing of the Teicher article before publication, these researchers quickly surveyed 27 not-yet-biased psychiatrists as to treatment of 1,017 depressed outpatients and found no significant suicidal results from fluoxetine); Mann & Kapur, *The Emergence of Suicidal Ideation and Behavior During Antidepressant Pharmacotherapy*, 48 ARCH. GEN. PSYCHIATRY 1027 (1991) (study in response to Teicher article that concluded that there should be a close doctor/patient relationship so the clinician can decide if symptoms are result of the depression, the environment, or the treatment).

<sup>150</sup> Blum, *supra* note 16, at 3.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> See Snyder, *Prozac Maker Offers Doctors Legal Help*, USA TODAY, June 5, 1991, at 1D; Preuss, *Prozac: Jumping on the Lilly Pad; Company to Doctors: Don't Be Intimidated By Smear Campaign*, LEGAL TIMES, Sept. 2, 1991, at 25.

<sup>154</sup> See *Good Morning America: Medical Myths* (ABC television broadcast, Feb. 21, 1991) (myth that Prozac increases risk of suicide); *Prozac's Critics Hurt Mentally Ill*, USA TODAY, June 11, 1991, at 11A (pro-Prozac interview of Eli Lilly representative); *Prozac Posse*, *supra* note 11, at A10 (pro-Prozac); *60 Minutes: Prozac* (CBS television broadcast, Oct. 27, 1991) (pro-Prozac; anti-Scientologists).

<sup>155</sup> *Prozac Posse*, *supra* note 11, at A10.

<sup>156</sup> Letter from Carl C. Peck, M.D., Director, FDA Center for Drug Evaluation and Research, to Sanford Block, CCHR Executive Director 1 (July 26, 1991) (denying the request) (on file with author).

<sup>157</sup> Meeting of the FDA Psychopharmacological Drugs Advisory Committee (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).



fluoxetine.<sup>158</sup> The committee unanimously decided that Prozac, and the other antidepressants, do not cause the emergence or intensification of suicidality or other violent behaviors.<sup>159</sup> The committee also decided, in a six to three vote, that no labeling changes should be made.<sup>160</sup> The committee meeting generated much publicity<sup>161</sup> which seemed to abate some of the legal activity.<sup>162</sup>

The legal controversy over Prozac has not stopped. Although some plaintiffs voluntarily dismissed their cases against the manufacturer,<sup>163</sup> there are others still in existence<sup>164</sup> and Eli Lilly's costs of defense continue to mount.

### THE PROBLEM REDEFINED

The controversy is two fold. First, a manufacturer that has more than complied with the pervasive FDA regulations is also liable under state common law to an individual plaintiff for an unavoidable injury. Juries cannot ignore the sight of injured plaintiffs in the courtrooms. Occasionally, the drug at issue caused their injuries, but often the cause was unavoidable or even caused by the plaintiff himself through noncompliance with the physician's orders. The personal injury attorneys are fighting for these victims, but often to the detriment of the overall public good. Even when a company is not considered at fault, as is currently happening to Eli Lilly and Company with the Prozac controversy, the manufacturer still faces the high costs of defending multiple lawsuits.

Second, the true victim of an expected but unavoidable adverse drug reaction may not be compensated. Just as it is inequitable for a manufacturer to be held liable for a non-negligent and unintentional act, failure to compensate the victim for injury that he did not bring upon himself is also inequitable.

#### *The Manufacturer and Solutions*

Potential solutions to these problems include preemption, elimination of punitive damage awards, and review and strict adherence to the rules of civil and evidentiary procedure. After a thorough scholarly analysis of public versus private risk taking, one commentator concluded that an answer may lie in fewer

<sup>158</sup> *Id.* at 2.

<sup>159</sup> *Id.* at 294.

<sup>160</sup> *Id.* at 331.

<sup>161</sup> *E.g.*, Burton, *supra* note 132, at B5; *No Credible Evidence Connects Antidepressants to Suicide and Violent Actions, Experts Conclude*, PSYCHIATRIC TIMES, November, 1991, at 54.

<sup>162</sup> Weston, *supra* note 101.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*; see also Moses, *supra* note 14, at B5.

lawyers.<sup>165</sup> He noted that "life has grown safer not because of the legal system, but despite it."<sup>166</sup>

## 1. Preemption

Commentators often advocate federal preemption over state civil claims as a solution to the pharmaceutical products liability problem.<sup>167</sup> Under the preemption doctrine, if the federal government has acted in a particular area of the law, a state may not take contradictory action in the same legal area.<sup>168</sup> Preemption may be expressly stated, which Congress has not done for pharmaceutical products liability, or implied through a series of legally established rules.<sup>169</sup> Courts vary as to the applicability of preemption depending on their interpretation of FDA regulations and the preemption rules.<sup>170</sup>

One argument for preemption arises out of the belief that the FDA is the best avenue to evaluate public risk.<sup>171</sup> However, assurances of greater public input need to be built in to the FDA regulations.<sup>172</sup> Another argument advocates narrowly viewing the preemption doctrine. In such instances, courts would evaluate activities of the FDA, not the manufacturer, regarding a drug.<sup>173</sup> As to labeling, commentators argue that the FDA must change its guidelines to remove any doubt that the FDA has sole regulatory power over label contents.<sup>174</sup> Finally, commentators argue that the courts must recognize that FDA regulations fulfill all requirements for implied preemption.<sup>175</sup> The courts must then strictly apply the traditional rules<sup>176</sup> and hold that manufacturers' compliance with FDA regulations preempts state common law. Opponents to preemp-

<sup>165</sup> Huber, *supra* note 17, at 336.

<sup>166</sup> *Id.*

<sup>167</sup> See, e.g., Comment, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629, 656 (1989) [hereinafter *Federal Preemption*] (preemption is the only answer); Huber, *supra* note 17, at 335 (courts should respect the risk/benefit analysis of the expert licensing agency); *Question of Competence*, *supra* note 30, at 792 (judiciary should defer to FDA).

<sup>168</sup> See Westerfield, *supra* note 99, at 264-69.

<sup>169</sup> *Id.* at 266-69 (preemption can be implied from the comprehensiveness of federal action, from a federal interest being dominant, or from direct conflict of federal and state laws).

<sup>170</sup> *Id.* at 264 (some courts view FDA standards as minimum, but others view FDA standards as so comprehensive that preemption is necessary).

<sup>171</sup> Merrill, *supra* note 39, at 1011-12.

<sup>172</sup> *Id.*

<sup>173</sup> *Question of Competence*, *supra* note 30, at 793.

<sup>174</sup> Cooper, *supra* note 91, at 238-39.

<sup>175</sup> *Federal Preemption*, *supra* note 167, at 656.

tion argue that injured individuals go uncompensated.<sup>177</sup> In their view, the courts add a safety incentive to manufacturers through the threat of an adverse holding.<sup>178</sup> However, without preemption drug manufacturers face enormous litigation expenses. In response to the elimination of preemption, drug companies would be forced to either pass on the cost to the consumer or remove effective drugs from the market.

## 2. Elimination of Punitive Damages

In addition to compensatory damages, courts may allow a jury to award punitive damages as a measure of social disapproval and an attempt to deter similar future harm.<sup>179</sup> Since pharmaceutical products liability cases involve highly technical issues that are difficult for a jury to evaluate, these cases are particularly susceptible to punitive damage awards.<sup>180</sup>

Awards of punitive damages contribute enormously to the overall drug liability problem due to the nature of drugs as unavoidably unsafe and the likelihood of multiple claims regarding one product.<sup>181</sup> Suggested reforms include: constitutional protections, state legislative enactments, and federal product liability legislation.<sup>182</sup> The first reform, constitutional protections, suggests that defendants should allege that there are constitutional barriers to the award of punitive damages.<sup>183</sup> Some of these defenses have already proven unsuccessful.<sup>184</sup> In the second area of reform, a few states have enacted legislative barriers to punitive awards, particularly for pharmaceutical companies that have complied with FDA regulations.<sup>185</sup> The third area of reform, federal legislation, would provide the greatest impact on the problem.<sup>186</sup> Federally mandated programs, like the vaccine injury program or one providing a defense to punitive damage awards, would apply to all jurisdictions through preemption.<sup>187</sup> Any one of these reforms, particularly federal legislation, would have an impact. Nonetheless, the manufacturer who did nothing wrong and complied fully with FDA regulations would still be liable under state common law.

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<sup>177</sup> Westerfield, *supra* note 99, at 283.

<sup>178</sup> Denemark, *supra* note 30, at 431.

<sup>179</sup> See Kuhlik & Kingham, *supra* note 1, at 697 n.21.

<sup>180</sup> *Id.* at 697-98.

<sup>181</sup> *Id.*

<sup>182</sup> *Id.* at 704-07.

<sup>183</sup> *Id.* at 704-05.

<sup>184</sup> *Id.*

<sup>185</sup> *Id.* at 705-06.

<sup>186</sup> *Id.* at 706-07.

### 3. Review of Procedural Rules

Many commentators have noted that courts inconsistently interpret the rules of civil and evidentiary procedure, particularly as the rules relate to expert witnesses.<sup>188</sup> This misinterpretation is often applied to the detriment of products liability litigation in general.<sup>189</sup> A paradoxical situation is created since experts are necessary to interpret and explain the technical issues that confront a jury, yet at the same time the jury must choose between competing experts to resolve the technical issues about which they know nothing.<sup>190</sup>

Federal Rule of Evidence 702 encourages the use of experts in assisting the trier of fact to understand the evidence or determine a fact in issue. There are problems though in relying on expert witnesses. The qualifications of some experts are questionable.<sup>191</sup> The opinions of some experts may be well apart from the generally accepted opinions in their scientific field.<sup>192</sup> Even worse, some experts may formulate their testimony to fit the needs of the retaining party.<sup>193</sup> Courts must evaluate an expert's qualifications in determining whether to allow testimony.<sup>194</sup> Federal Rule of Evidence 104(a) requires that a court determine an expert's qualifications. The rule provides that "[p]reliminary questions concerning the qualifications of a person to be a witness . . . shall be determined by the court."<sup>195</sup>

Courts must also follow additional procedural rules. For example, courts must apply Federal Rule of Civil Procedure 11, which sanctions attorneys who file frivolous suits.<sup>196</sup> Perhaps courts should consider applying Rule 11 more liberally so that attorneys would reconsider filing a claim based on weak or nonexistent law, and ensure that attorneys have a good faith argument for the extension, modification or reversal of existing law. Congress should also consider developing a rule for products liability actions that requires an expert's affidavit

<sup>188</sup> See, e.g., Denmark, *supra* note 30, at 423-26; Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 393-96 (1990).

<sup>189</sup> *Id.*

<sup>190</sup> Klein, *supra* note 188, at 441-42.

<sup>191</sup> Denmark, *supra* note 30, at 424.

<sup>192</sup> *Id.* See also Scott, *Junk Science Attempts to Create Medical and Scientific Causation*, 57 DEF. COUNS. J. 462, 462 (1990).

<sup>193</sup> Denmark, *supra* note 30, at 424.

<sup>194</sup> FED. R. EVID. 702 ("a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify . . .").

<sup>195</sup> FED. R. EVID. 104(a) (emphasis added).

<sup>196</sup> FED. R. CIV. P. 11 ("Every pleading . . . shall be signed by at least one attorney . . . [and] [t]he signature . . . constitutes a certificate by the signer . . . that to the best of the signer's knowledge . . . it is well-grounded in fact and is warranted by existing law or a good faith argument . . .").

stating that there is reasonable cause to commence the action.<sup>197</sup> Finally, courts should grant summary judgment motions in favor of a manufacturer that provided adequate and clear warnings in accordance with FDA guidelines concerning possible side effects,<sup>198</sup> even when a plaintiff has a qualifiable expert. Opponents argue that courts can prevent erroneous decisions by scrupulously applying the rules.<sup>199</sup> All of the rules are subject to interpretation, however. There are many courts in many jurisdictions with differing rules, as well as many judges and many juries. This multitude of players and factors manipulates laws which leave room for interpretation, so perhaps Congress must leave no room for interpretation in its statutes on pharmaceutical products liability.

#### 4. Is There an Equitable Answer?

In cases where the manufacturer is not at fault, it seems that most of the arguments for relieving the liability of a manufacturer lie in equity. In those cases, the manufacturer has done nothing negligent nor intentional to cause harm. When the manufacturer does act negligently or intentionally and harm results, the FDA has the power to punish the company and eliminate the product from the stream of commerce.<sup>200</sup> Those attorneys fighting for injured individuals are not satisfied with any of these answers since they feel that their clients are not compensated for their real injuries.

#### *The Victim and Solutions*

As in the vaccination situation, drugs can harm a person even when it is not the person's fault. Perhaps the reason that Congress and others have not seriously considered previously proposed solutions, such as preemption, is because of the resulting problem: the uncompensated victim. State courts do not take their roles of protecting their citizen's health and safety lightly.<sup>201</sup> Although there is a strong argument for the federal government preempting state laws, there is an equally strong argument for the state's police powers in protecting citizens in the absence of express federal preemption.<sup>202</sup> Any solution that considers the

<sup>197</sup> This type of rule applies to medical malpractice claims in Ohio. OHIO REV. CODE ANN. § 2307.42(C) (Baldwin 1991).

<sup>198</sup> Denmark, *supra* note 30, at 423.

<sup>199</sup> Klein, *supra* note 188, at 442.

<sup>200</sup> 21 U.S.C. § 331 (prohibited acts) (primarily adulteration, misbranding, and mislabeling); 21 U.S.C. § 332 (injunction proceedings) (district court jurisdiction to restrain violations of § 331); 21 U.S.C. § 333 (penalties) (generally less than one year imprisonment and/or less than \$1,000, unless multiple violations); 21 U.S.C. § 334 (product seizure) (primarily adulteration, misbranding, and mislabeling).

<sup>201</sup> Westerfield, *supra* note 99, at 270 (to protect the health and safety of its citizens a state may establish regulations on manufacturers, and regulate through the common law).

victim includes maintaining civil litigation in pharmaceutical products liability, but this does not deal with the manufacturer problem. The answer appears to be that the federal government should also be involved,<sup>203</sup> to force a blending of federal and state interests that considers all parties in the dilemma.

### A SOLUTION TO THE WHOLE PROBLEM

Because of this federal/state dilemma, a solution must be found that will better satisfy all concerned. Congress must act to assure that manufacturers are not unjustly held liable, and yet see that victims of a product are compensated.

#### *Special Preemption*

Some drugs, such as Prozac and Bendectin, have not only met the standards of FDA review, but FDA advisory committees have also found that their safety and efficacy are such that they do not cause the harms alleged. Drugs meeting either this higher level of approval by the scientific community or the additional standards that could be developed by the FDA<sup>204</sup> should be preempted from civil tort suits. Manufacturers would probably choose to meet this higher standard. Thus, the manufacturers would in effect be competing for the privilege of special preemption since it would be the manufacturer bearing the costs involved in meeting the standard. Admittedly the consumer would ultimately pay for the longer or more extensive FDA review, but this cost would surely be lower than litigation costs. The manufacturer would have to meet a higher burden of proof before the FDA would allow the manufacturer to put the drug on the market, but that higher burden would pay off by eliminating the threat of civil litigation. The economic reality is that without some kind of express preemption, necessary drugs will become prohibitively expensive for the average citizen in need, or will not be available when needed.

Opponents may argue that companies occasionally deal dishonestly with the FDA. Specifically, opponents argue that a drug meeting an even higher standard of approval may still be harmful,<sup>205</sup> but available due to dishonest nondisclosure of information. Currently, critics of the Upjohn Company, makers of Halcion, a best-selling sleeping pill, allege that the company has concealed information for twenty years that the drug causes serious adverse psychiatric reactions.<sup>206</sup> Up-

<sup>203</sup> Huber, *supra* note 17, at 330 (injured wish to be compensated and a "compassionate, generous society should surely respond").

<sup>204</sup> Additional standards might include a greater number of clinical trials, or a longer clinical trial period, to create a higher benefit to a lower risk expectation.

<sup>205</sup> Denemark, *supra* note 30, at 430 (a manufacturer withheld adverse reactions from the FDA).

<sup>206</sup> Kolata, *Critics Say Drug Firm Hid Adverse Data*, AKRON BEACON J., Jan. 20, 1992, at A1, Col. 6 (Britain has banned the drug, and the company settled in a suit alleging that the drug caused a psychosis that caused the plaintiff to murder her mother).

john has responded by suing members of the media and a Scottish psychiatrist who is the leading critic of the drug.<sup>207</sup> Perhaps this whole controversy could have been avoided if Upjohn had sought a higher standard of approval for Halcion. Additionally, if the FDA's post-marketing surveillance was better funded and the FDA had greater leeway in assessing sanctions against manufacturers that intentionally withheld information, the FDA would have already dealt with the alleged problems. To answer the argument that civil law penalties are far greater incentives than "inconsequential maximum fine[s],"<sup>208</sup> Congress should authorize the FDA to level much more severe penalties on non-compliant manufacturers. Any funds obtained from stronger federal sanctions against intentional misrepresentation could be put to good use in a program to compensate victims of adverse reactions.

### *Federal Victim Compensation Program*

The federal government should apply what it learned from the vaccination cases, and develop a "no fault" program to compensate victims of adverse drug reactions from specially preempted drugs. The drug must be proven to be the causative agent, and not the illness or other factors such as patient non-compliance with a physician's orders, or a physician's malpractice. The manufacturers could supply some funds, in a manner similar to worker's compensation. After all, they would no longer be liable in civil courts for exorbitant damages. Similar to worker's compensation programs, the victim compensation program would provide the exclusive remedy. Recovery might be lower, but recovery would be guaranteed and the process would be much faster than the civil law process.

At the rate that pharmaceutical products liability is going, many drugs that are currently available to help so many in need will eventually no longer be there. Manufacturers will either cease to develop and market needed pharmaceuticals because of the difficulties in liability protection, or those drugs will no longer be within public reach because of their high cost.

### A REMINDER OF PHYSICIAN RESPONSIBILITY

At the meeting of the FDA Psychopharmacological Drugs Advisory Committee in September of 1991, the committee allowed fifty people to make presentations.<sup>209</sup> People alleging harm from Prozac made many of the presentations. They told very moving stories. In response to those comments,

<sup>207</sup> *Upjohn Co. Sues Over U.K. Stories*, AKRON BEACON J., Jan. 25, 1992, at B12, Col. 1.

<sup>208</sup> Denmark, *supra* note 30, at 430 (the company that withheld adverse reaction information from the FDA lost between \$45 and \$55 million as a result of civil litigation).

<sup>209</sup> Michael Bernstein, Remarks at the Meeting of the FDA Psychopharmacological Drugs Advisory Committee (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).

Michael Stanley, Ph.D., of the Department of Psychiatry at Columbia University, stated that "in many of the cases that I heard this morning, I was frankly very appalled by the lack of clinical care that some of the patients received, whether they were getting Prozac or anything. It just seemed to me a very bad level of care. . . ." <sup>210</sup> Dr. Daniel Casey, Chairman of the committee of the VA Medical Center and Oregon Health Sciences University in Portland, Oregon, agreed with Dr. Stanley about the care that some of the people who reported adverse reactions to Prozac were receiving. <sup>211</sup> Under the "learned intermediary" doctrine the physician is held to be the one competent to understand the drug labels and rationally prescribe medicine. The physician is responsible for the care received by the patient, through medications or other form of treatment. Physicians need to remember their responsibilities in prescribing drugs, advising patients about possible side effects, and advising patients concerning what to do in the event a side effect does occur.

#### CONCLUSION

The pharmaceutical drug products liability dilemma in this country has reached epic proportions. Are worthwhile drugs that help many people, like Prozac, going to be allowed to be driven off the market because a few expected reactions occur? A solution must be found to the conflict between public and private interests and between state and federal interests.

The federal government should take action to solve the problem, since action from the federal sector, as opposed to the state or private sectors, will be most effective. To create incentives for manufacturers to meet higher standards, Congress should mandate federal preemption for drugs meeting a higher standard of safety and efficacy. To protect the victim's interest in recovery and to keep costs down for the public, Congress should establish a program to compensate victims of side effects from those preempted drugs. Without such Congressional action, needed drugs will no longer be available. The drugs will either be totally out of financial reach, or not be there at all.

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<sup>210</sup> Michael Stanley, Remarks at the Meeting of the FDA Psychopharmacologic Drugs Advisory Committee 319 (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).

<sup>211</sup> Daniel Casey, Remarks at the Meeting of the FDA Psychopharmacologic Drugs Advisory Committee 319 (Sept. 20, 1991) (transcript available in FDA Freedom of Information Office).



