

# PHARMACEUTICAL PRODUCT LIABILITY MAY BE HAZARDOUS TO YOUR HEALTH: A NO-FAULT ALTERNATIVE TO CONCURRENT REGULATION

GREGORY C. JACKSON, M.D.

## INTRODUCTION

On June 19, 1988, Ilo Grundberg killed her eighty-three year-old mother with eight shots from a handgun while the victim held a cheerful birthday card.<sup>1</sup> Ms. Grundberg was charged with second degree murder,<sup>2</sup> but prosecutors asked the court to dismiss the case when psychiatric evaluations determined that Ms. Grundberg had been involuntarily intoxicated with the prescription sedative Halcion.<sup>3</sup> Ms. Grundberg filed a \$21 million lawsuit against Halcion's manufacturer, The Upjohn Company, alleging that Halcion was a defective drug and that Upjohn failed to warn her of the severe and sometimes fatal adverse reactions<sup>4</sup> that could result from ingesting the drug. In fact, Upjohn's label for Halcion did contain a warning that "paradoxical reactions," which include violent behavior, had been reported following the use of therapeutic doses of Halcion,<sup>5</sup>

---

1. See Geoffrey Cowley, *Sweet Dreams or Nightmare?*, NEWSWEEK, Aug. 19, 1991, at 44 (reporting incident as part of article examining evidence that prescription drug Halcion may predispose recipients to aggressive behavior).

2. *Id.*

3. *Id.*; see also WAYNE R. LAFAVE & AUSTIN W. SCOTT, JR., CRIMINAL LAW § 4.10(f), at 394 (2d ed. 1986) (defining "involuntary" intoxication as intoxication resulting from ingestion of mistaken substance; substance taken under duress; substance taken pursuant to medical advice; or pathological intoxication where person knows he or she is taking substance but is unaware of reaction he or she may have to substance). Halcion, known generically as triazolam, is a sedative-hypnotic among the structural class of medications known as benzodiazepines. PHYSICIANS' DESK REFERENCE 2340 (46th ed. 1992).

4. PHYSICIANS' DESK REFERENCE 2340-41 (46th ed. 1992).

5. See PHYSICIANS' DESK REFERENCE 1843 (40th ed. 1986) (warning of paradoxical reactions following therapeutic doses of Halcion and cautioning against drug's use in patients with signs or symptoms of depression); see also R.C.W. Hall & S. Zisook, *Paradoxical Reactions to Benzodiazepines*, 11 BRIT. J. CLINICAL PHARMACOLOGY 99S, 103S (1981) (concluding that paradoxical reactions are very rare and idiosyncratic with no associated clinical indicators). Reported paradoxical reactions to the usual sedative effect of benzodiazepines at the time of the

and the company might have reasonably relied on this warning to relieve it of liability.<sup>6</sup> Instead, Upjohn settled Ms. Grundberg's claim out of court for a reputed multi-million dollar amount.<sup>7</sup>

A significant problem for people who suffer adverse drug reactions such as Ms. Grundberg's is the unavailability of a reasonable means of compensating their unexpected and often devastating injuries.<sup>8</sup> Adverse drug reactions are a significant source of morbidity and mortality in this country, causing three to six percent of all medical admissions<sup>9</sup> and as many as 160,000 deaths per year.<sup>10</sup> Such injuries tend to go uncompensated without a lengthy adversarial process, however, that is generally only available in cases like Ms. Grundberg's where the injuries are serious and the product manufacturer wealthy.<sup>11</sup>

The problem confronting Upjohn and other pharmaceutical manufacturers regarding adverse drug reaction claims is the growing cost and unpredictability of product liability in the face of increasing costs for bringing drugs to market.<sup>12</sup> Pharmaceutical manufacturers are required by law to provide rigorous evidence that their products are both safe and effective as a prerequisite to marketing.<sup>13</sup> These same manufacturers, however, may later face lawsuits sounding in negligence or strict liability for the inadequacy of labels that were previously approved as essential elements of their products' safety and efficacy.<sup>14</sup> This paradoxical result comes at a time when the

---

Grundberg shooting included bizarre uninhibited behavior, euphoria, restlessness, hallucinations, hostility, rage, paranoia, and suicidal ideation. Stewart C. Harvey, *Hypnotics and Sedatives*, in GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 339, 349-50 (Alfred G. Gilman et al. eds., 7th ed. 1985).

6. See generally Lane D. Bauer & Laura D. Stith, *The Duty to Warn*, in PRODUCTS LIABILITY PHARMACEUTICAL DRUG CASES §§ 4.07-4.20 (Donald E. Vinson & Alexander H. Slaughter eds., 1988) (analyzing issues of adequacy of pharmaceutical warnings).

7. See Liz Hunt, *Data on Sleeping Pill's Effects Were Incomplete, Upjohn Says*, WASH. POST, Aug. 28, 1991, at A2 (noting reported settlement between Ms. Grundberg and Upjohn of millions of dollars, but that settlement stipulates all documents relevant to case remain confidential).

8. See *infra* notes 235-37 and accompanying text (documenting inadequacy of tort law compensatory function).

9. Brian L. Strom, *Pharmacoepidemiology: Current Status, Prospects, and Problems*, 113 ANNALS OF INTERNAL MED. 179, 179 (1990) (citing D.M. DAVIES, TEXTBOOK OF ADVERSE DRUG REACTIONS 4 (3d ed. 1985)).

10. See *id.* (citing Samuel Shapiro et al., *Fatal Drug Reactions Among Medical Inpatients*, 216 JAMA 467, 467-72 (1971)).

11. See Richard L. Abel, *A Critique of Torts*, 37 UCLA L. REV. 785, 796 (1990) (discussing legal and financial obstacles that stand in way of tort victim's recovery, and mentioning specifically that if tortfeasor lacks resources, judgment for plaintiff is "empty remedy").

12. See *infra* notes 214-17 and accompanying text (describing costs of new drug development).

13. See 21 U.S.C. § 355(b) (1988) (mandating that manufacturers include full reports concerning drug's safety and effectiveness when filing new drug application).

14. See *infra* notes 88-94 and accompanying text (describing mandatory pharmaceutical labeling process and its extensive regulation by FDA); cf. FOOD AND DRUG LAW INSTITUTE:

United States Food and Drug Administration (FDA), under a determined new commissioner,<sup>15</sup> is more aggressively enforcing current safety standards while Congress actively seeks to provide more powerful enforcement tools.<sup>16</sup>

The problem facing health care consumers with respect to the pharmaceutical industry is a chilling of new drug development and an actual loss of some existing therapies without an appreciable increase in safety.<sup>17</sup> For example, the United Kingdom recently removed Halcion from the market as a result of concern about reactions such as those suffered by Ms. Grundberg,<sup>18</sup> despite the fact that the drug is the most widely used prescription treatment for insomnia in the world.<sup>19</sup> After analyzing the available data, the FDA has refused to do the same in the United States<sup>20</sup> in part because Halcion has clear advantages over other drugs in its class<sup>21</sup> and in part because reactions such as those exhibited by Ms. Grundberg

---

FOOD AND DRUG LAW 164-81 (Richard M. Cooper ed., 1991) (describing food labeling requirements of FDA).

15. See Malcolm Gladwell, *FDA Chief Relishes Label of Lawman*, WASH. POST, Oct. 24, 1991, at A1 (crediting Dr. David Kessler, FDA's new commissioner, also known as "Eliot Knessler" for his Eliot Ness-like pursuit of nation's biggest food and drug firms, with revitalizing agency).

16. See *New Enforcement Tools Would Be "Helpful," but FDA Not Waiting*, 53 F-D-C REP. ("The Pink Sheet"), Aug. 12, 1991, at 7 (quoting Commissioner Kessler as stating that FDA will not wait for congressional action before vigorously enforcing drug safety and efficacy laws); *FDA Enforcement Draft Bill Would Provide Administrative, Judicial Recall Power as Well as Civil Fines: Draft Bill Reflects Commissioner Kessler's "Wish List,"* 53 F-D-C REP. ("The Pink Sheet"), Mar. 25, 1991, at 2 (noting that proposed H.R. 2597, 102d Cong., 1st Sess. (1991) is consistent with Kessler's belief that FDA needs greater enforcement powers).

17. See Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 334, 334-48 (Peter W. Huber & Robert E. Litan eds., 1991) (describing adverse effects of product liability on pharmaceutical research and development and focusing specifically on loss of Bendectin, drug used for treatment of morning sickness, loss of childhood vaccines development, and delays in development of orphan drugs, drugs used for treating rare disorders); *infra* notes 49-61 and accompanying text (discussing treatment gap created by loss of Bendectin and chilling effect of product liability on development of orphan drugs).

18. See Liz Hunt & Glenn Frankel, *Britain Takes Halcion Sleeping Pills Off the Market*, WASH. POST, Oct. 3, 1991, at A3 (reporting review of data that showed Halcion caused much higher incidence of depression and memory loss than similar drugs).

19. See Geoffrey Cowley, *Sweet Dreams or Nightmare?*, NEWSWEEK, Aug. 19, 1991, at 48 (reporting that annual Halcion prescriptions exceed other popular sleeping pills by millions).

20. See Malcolm Gladwell, *Why the FDA Cleared Halcion*, WASH. POST, June 2, 1992, at Z7 (noting that higher association of adverse reactions with Halcion were due largely to use of dose now believed to be well above what is ideal and safe).

21. See Mitchell B. Balter & E.H. Uhlenhuth, *The Beneficial and Adverse Effects of Hypnotics*, 52 J. CLINICAL PSYCHIATRY 16, 22 (1991) (finding that triazolam has improved effect on residual sedation and daytime functioning over other hypnotic drugs such as flurazepam and temazepam, but higher finding of anterograde amnesia, which is inability to recall events occurring after use of drug). But see Andrew J. Heritch et al., *A Case of Psychosis and Delirium Following Withdrawal from Triazolam*, 48 J. CLINICAL PSYCHIATRY 168, 168 (1987) (noting incidence of withdrawal symptoms from triazolam, which may include psychotic behavior, makes triazolam worse choice for treating insomnia than other hypnotics).

are exceedingly rare and not unique to Halcion.<sup>22</sup>

As a consequence of these concerns, the issue of product liability is receiving close scrutiny by Congress.<sup>23</sup> In the most recent in a long line of uniform product liability acts, Congress is currently considering Senate bill 640, which would create an absolute defense to punitive damages claims for drugs approved by the FDA.<sup>24</sup> Although the Senate failed to approve the bill in the 1992 session,<sup>25</sup> the bill enjoys wide support in the Senate, and Senators vow to go forward with the bill early in the next session.<sup>26</sup> Also, the President's Council on Competitiveness chaired by Vice President Quayle recently recommended significant limits on punitive damages along with other measures that would significantly hinder the pursuit of product liability claims.<sup>27</sup>

---

22. See David Greenblatt, *Current Status of Benzodiazepines (Part II)*, 309 NEW ENG. J. MED. 410, 414 (1983) (noting rarity of paradoxical reactions such as florid psychoses that are seen primarily during abrupt withdrawal from high doses of benzodiazepines).

23. See Gary Lee, *Corporate Lobby Tries to Create 'Big Mo' on Product Liability Bill*, WASH. POST, July 29, 1991, at A9 (citing increase in congressional support for limitations on product liability despite 10 years of failure to enact restrictions on such liability).

There is some evidence, however, that the need for such legislation may be waning. See Theodore Eisenberg & James A. Henderson, Jr., *Inside the Quiet Revolution in Products Liability*, 39 UCLA L. REV. 731, 741 (1992) (documenting decrease in plaintiff success rates in product liability cases filed in federal courts). Excluding the massive and unsuccessful Bendectin litigation, the authors found that at the federal district court level, the plaintiff success rate fell from 41% to 31% between 1979 and 1989 in product liability cases that report a judgment for plaintiff or defendant. *Id.* These declining plaintiff success rates, explicit lawmaking in product liability cases at both the trial and appellate levels, and declining product liability filings lead the authors to posit that a pro-defendant revolution began in the early 1980s and continued at least through 1989. *Id.* at 743-44.

24. See S. 640, 102d Cong., 1st Sess. § 303(c)(1) (1991) (prohibiting punitive damages, absent misrepresentation, against manufacturers of products approved as safe and effective by FDA); see also 138 CONG. REC. S13,149 (daily ed. Sept. 10, 1992) (statement of Sen. Thurmond) (speaking in support of product liability bill and noting that proponents of bill have been trying to enact product liability legislation since 1980). But see *Product Liability Government Standards Defense Proposal*, 53 F-D-C REP. ("The Pink Sheet"), Sept. 23, 1991, at 6 (quoting Professor Michael Rustad as stating that Senate bill 640 would have little impact on pharmaceutical manufacturers because punitive damages cases invariably involve fraud or withholding of information, that is, misrepresentation, that bill excludes from protection). At least three other bills with similar co-sponsorship would preempt state regulation of pharmaceuticals, at least with respect to punitive damages. See H.R. 3030, 102d Cong., 1st Sess. § 6(d)(1)(A) (1991) (prohibiting awards of punitive damages against manufacturers of drugs and devices approved by FDA); H.R. 2701, 102d Cong., 1st Sess. § 3(i) (1991) (limiting scope of punitive damages awards against professionals); H.R. 2700, 102d Cong., 1st Sess. § 8(e)(1)(A) (1991) (forbidding punitive damages awards against manufacturers of drugs subject to premarket approval).

25. See 138 CONG. REC. S13,155 (daily ed. Sept. 10, 1992) (reporting that Senate voted 58 to 38 to close debate on bill, thereby coming up two votes short of required minimum of 60 votes to close debate prior to voting on bill).

26. See *id.* at S13,155-56 (statement of Sen. Rockefeller) (proclaiming that "a very clear majority of the Senate" supports Senate bill 640 and assuring colleagues that he plans to go forward with bill early next session); *id.* at S13,156 (statement of Sen. Kasten) (noting that majority of Senate supports bill and stating that he is prepared to move forward with legislation early next session).

27. See PRESIDENT'S COUNCIL ON COMPETITIVENESS, AGENDA FOR CIVIL JUSTICE REFORM IN

Application of common law product liability precepts to pharmaceutical manufacturers assigns the burden of a risk to the product's creator, who is invariably the party best able to avoid the risk.<sup>28</sup> Manufacturers, in turn, spread the risk of injury among the public as a cost of doing business.<sup>29</sup> There is evidence, however, that pharmaceutical product liability has a chilling effect on the development of health care products<sup>30</sup> without reasonably compensating those injured by such products or significantly enhancing drug safety over that achieved through pervasive federal regulation.<sup>31</sup>

This Comment will examine the state of pharmaceutical product liability and address the conflicts arising in the current system of concurrent pharmaceutical regulation by both the FDA and state common law liability systems. The Comment analyzes alternatives to this concurrent regulation that may in some combination deal more efficiently with both the needs of the industry for a predictable liability system and the needs of consumers for drug safety and injury compensation. Part I briefly reviews the evidence of product liability's direct effect on drug development, availability, and cost. Part II examines the history of concurrent regulation of pharmaceuticals by the FDA and the states through the common law of

---

AMERICA 1, 11-13 (Aug. 1991) (outlining reform of discovery and expert evidence rules with recommendations for voluntary dispute resolution, changes in trial procedures, altered use of federal judicial resources, and "eliminating litigation over poorly drafted legislation"). Acting on this initiative, President Bush has signed an Executive order that includes a "loser pays" provision for certain contract disputes and other suits brought by the Federal Government. Exec. Order No. 12,778, 3 C.F.R. 359, 362 (1991); see John E. Yang, *Lawyer Guidelines Aim to Cut Costs, Delays*, WASH. POST, Oct. 24, 1991, at A21 (quoting President Bush stating fear of lawsuits has restricted access to health care, kept products off market, and increased consumer prices). In his State of the Union Address, President Bush called for the passage of the 1990 product liability reform bill. See Address Before a Joint Session of the Congress on the State of the Union, 26 WEEKLY COMP. PRES. DOC. 146, 148 (Jan. 31, 1990) (citing product liability reform as "the will of the people"); *supra* note 25 (providing citation and salient features of 1990 product liability bill).

28. See *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring) (claiming that manufacturer is best situated to afford protection against consumer injuries). Justice Traynor's position that responsibility for product injuries should be fixed with the one best able to afford protection against a risk, regardless of negligence, was also adopted in *Greenman v. Yuba Power Products Inc.*, 377 P.2d 897, 900-01 (Cal. 1963).

29. See *Escola*, 150 P.2d at 441 (endorsing cost-spreading function of strict liability).

30. See *Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 115 (1986) (reporting finding of Dr. Martin H. Smith, president, American Academy of Pediatrics, that liability concerns have constraining effect on research and development of vaccines); AMERICAN MED. ASS'N, PROCEEDINGS OF THE HOUSE OF DELEGATES, 137TH ANNUAL MEETING 79 (1988) [hereinafter AMA PROCEEDINGS] (finding that product liability for pharmaceutical manufacturers has profound negative impact in that it tends to inhibit development of innovative products).

31. See Judith P. Swazey, *Prescription Drug Safety and Product Liability*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 291, 293 (Peter W. Huber & Robert E. Litan eds., 1991) (noting marginal effect of liability laws and legislation on safety when compared with federal regulation and role of physicians as learned intermediaries who provide instructions on safe drug usage to patients when prescribing medications).

product liability. Part III surveys model alternatives to concurrent regulation. These alternatives include judicial preemption and no-fault compensation for drug-induced injuries and are exemplified by the systems currently operating in Sweden through the Swedish Pharmaceutical Insurance and in the United States through the National Childhood Vaccine Injury Act of 1986. Part IV analyzes the efficiency of concurrent regulation and examines the effectiveness of product liability as a mechanism to deter risks and compensate those injured. Part V recommends preempting state causes of action against pharmaceutical manufacturers as an initial remedy in exchange for an industry-funded, no-fault system of drug injury compensation. This Comment concludes that the concurrent system of drug regulation is costly and provides neither a significant increase in safety nor an efficient means of compensating persons injured by adverse drug reactions. The adoption of a no-fault system of drug injury compensation addresses these inefficiencies by meeting the needs of pharmaceutical manufacturers for a predictable system of liability, as well as consumer needs for safety, access to health care developments, and drug injury compensation.

## I. A BRIEF HISTORY OF PHARMACEUTICAL PRODUCT LIABILITY

Evidence of the direct effect of pharmaceutical product liability on drug development is not comprehensive. Research expenditures for contraception and fertility, for example, fell ninety percent from a peak in expenditures in 1973.<sup>32</sup> Twelve of thirteen companies once active in this area terminated research and development within the last twenty years.<sup>33</sup> A recent study by the National Research Council and the Institute of Medicine cited product liability as a principle factor inhibiting the development of new contraceptives.<sup>34</sup>

Similarly, despite the profound benefit of childhood vaccines on public health, the number of vaccine manufacturers has declined

---

32. See PETER W. HUBER, *LIABILITY, THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 155 (1988) (discussing status of birth control research and noting that chemical formula for steroid oral contraceptives has not changed since 1976, nor have any new contraceptive chemical entities been introduced since 1968).

33. AMA PROCEEDINGS, *supra* note 30, at 86.

34. See NATIONAL RESEARCH COUNCIL & INST. OF MEDICINE, *DEVELOPING NEW CONTRACEPTIVES—OBSTACLES AND OPPORTUNITIES* 141 (1990) (citing unpredictable nature of litigation and failure of courts to give sufficient emphasis to compliance with FDA regulations as significant disincentives for research). As a result, American manufacturers' preeminence in the area of fertility research and development has all but disappeared. See HUBER, *supra* note 32, at 155 (quoting pharmaceutical company president stating that no one in his or her "right mind" would work on products for pregnant women because of enormous liability risks such work engenders).

significantly.<sup>35</sup> For some vaccines only a single supplier remains.<sup>36</sup> There is little doubt that this decline in vaccine availability is due to the overwhelming burden of product liability.<sup>37</sup> As an illustration of this burden, in one instance a punitive damages claim against a former vaccine manufacturer totaled more than 200 times the annual revenue generated by the vaccine.<sup>38</sup>

In addition, product liability has had a predictable effect on the cost of available vaccines, as well as on research into new vaccines. For example, the cost per dose of the diphtheria-tetanus-pertussis vaccine (DTP) increased from 11¢ in 1982 to \$11.40 in 1986.<sup>39</sup> Eight dollars of this price went for liability insurance.<sup>40</sup> While the National Childhood Vaccine Injury Act of 1986 (Act)<sup>41</sup> establishes a no-fault system of compensation for injuries suffered as a result of certain vaccine usage, not all vaccines are covered.<sup>42</sup> Moreover, the

---

35. See H.R. REP. NO. 908, 99th Cong., 2d Sess., pt. 1, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344-45 (noting that decline in number of vaccine manufacturers has caused decline of immunization against some preventable diseases coupled with increase of disease incidence).

36. *Id.* at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6348 (noting that only one manufacturer of measles, mumps, and rubella (MMR) vaccine and two manufacturers of diphtheria-tetanus-pertussis (DTP) vaccine remain actively engaged in production of these vaccines).

37. See INSTITUTE OF MED., VACCINE SUPPLY AND INNOVATION 2, 11 (1985) (finding that liability concerns threaten investment in development of vaccines). Vaccines are uniquely susceptible to adverse effects of liability for a number of reasons: (1) vaccines can cause birth defects and these cases tend to foster large awards; (2) unlike drugs, vaccines require extremely complex and specialized production facilities; (3) production of individual lots of vaccines can take six to twelve months, which leads to inventory and cashflow problems on the part of the manufacturer; (4) vaccines are administered in a limited number of doses, and the success of a vaccine can have a downward effect on demand; (5) the largest foreign markets are often third world countries with limited resources for such purchases; and (6) vaccine experts needed for litigation are relatively few, and those arguably most competent, those with the Centers for Disease Control (CDC) or the FDA, are generally not available because federal policy prevents government employees from testifying in disputes between private parties. See Lasagna, *supra* note 17, at 341-43 (examining above-listed disincentives as well as additional discouragement produced by product liability on vaccine development).

38. See HUBER, *supra* note 32, at 166-67 (noting that as recently as 1986, manufacturer of whooping cough vaccine was named as defendant in new lawsuit each week and faced over \$2 billion in damage claims). One dose in 310,000 of DTP, the vaccine used to immunize children against whooping cough, causes permanent damage because the diphtheria portion of the vaccine includes a crude preparation of whole bacteria. See Gina Kolata, *Litigation Causes Huge Price Increases in Childhood Vaccines*, 232 SCIENCE 1339, 1339 (1986) (noting that up to 20 million doses of DTP are sold in United States each year).

39. Kolata, *supra* note 38, at 1339. From 1984 to 1986, the mean price paid by the CDC to stockpile vaccines for emergent needs rose from \$2 per dose to \$12 per dose. See Robert M. McKenna, Comment, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 955 (1988) (analyzing possibility of similar price stress on development of vaccine for human immunodeficiency virus (HIV)).

40. Kolata, *supra* note 38, at 1339.

41. 42 U.S.C. §§ 300aa-1 to -34 (1988).

42. See *infra* notes 154-76 and accompanying text (discussing mechanics of National Childhood Vaccine Injury Act). Legislation modeled on the National Childhood Vaccine Injury Act is pending that would establish a trust fund to cover adverse reactions involving injury, illness, disability, or death after receiving a vaccine for HIV. H.R. 5893, 102d Cong., 2d Sess. (1992). Injured persons could not file suits against manufacturers before exhausting

Act does not affect claims made before October 1, 1988.<sup>43</sup>

A number of commentators have indicated that liability concerns threaten the development of a vaccine for the human immunodeficiency virus (HIV),<sup>44</sup> the infectious agent responsible for the acquired immune deficiency syndrome epidemic currently threatening the lives of more than one million persons.<sup>45</sup> Product liability has already demonstrably slowed the development of a vaccine for HIV.<sup>46</sup> At least one major pharmaceutical manufacturer has halted promising research and development into a vaccine for HIV, and others have postponed clinical trials pending changes in the legal climate.<sup>47</sup> The cost of such a delay is impossible to calculate, but with expenditures for the HIV epidemic measured in billions of dollars,<sup>48</sup> any delay will add significantly to the social costs of liability.

---

remedies under the act. *Id.* § 2151(a)(2)(A). Manufacturers could not be held liable for unavoidable side effects or for injuries solely due to the manufacturer's failure to provide direct warnings to the injured party. *Id.* § 2162(c). A covered vaccine would be presumed to be accompanied by proper directions and warnings if its manufacturer shows that it complied with all requirements under the Federal Food, Drug, and Cosmetic Act and § 351 of the Public Health Service Act. *Id.* § 2162(b)(2).

43. See 42 U.S.C. §§ 300aa-300ll (1988) (stipulating requirements for claims of compensation).

44. See, e.g., Deborah M. Barnes, *Will an AIDS Vaccine Bankrupt the Company That Makes It?*, 233 *SCIENCE* 1035, 1035 (1986) (noting that pharmaceutical companies may be less willing to invest money in production of AIDS vaccine in legal climate wherein lawsuits against manufacturers are richly rewarded); Donald P. Francis & John C. Petricciani, *The Prospects for and Pathways Toward a Vaccine for AIDS*, 313 *NEW ENG. J. MED.* 1586, 1586-87 (1985) (recognizing liability concerns as major reason why companies are reluctant to invest large amounts of money in development of AIDS vaccine); Alison J. Arnold, Comment, *Developing, Testing, and Marketing an AIDS Vaccine: Legal Concerns for Manufacturers*, 139 *U. PA. L. REV.* 1077, 1084 (1991) (enumerating unsolved social, ethical, and legal problems confronting HIV vaccine development); Peter Huber, *AIDS and Lawyers*, *NEW REPUBLIC*, May 5, 1986, at 14 (predicting that no manufacturer would produce readily available AIDS vaccine given current legal climate). *But see* McKenna, *supra* note 39, at 963-64 (arguing that although pharmaceutical companies face many obstacles in developing HIV vaccine, legal liability is not one of them).

45. See *Estimates of HIV Prevalence and Projected AIDS Cases: Summary of a Workshop, October 31 - November 1, 1989*, 39 *MORBIDITY & MORTALITY WEEKLY REP.* 110, 110 (1990) (estimating that one million persons in United States are currently infected with HIV); see also Sophia W. Chang et al., *The New AIDS Case Definition; Implications for San Francisco*, 267 *JAMA* 973, 973-75 (1992) (stating that national projections based on 1987 definition of AIDS disease estimate there will be between 139,000 and 188,000 people living with AIDS in 1992, whereas additional 169,000 to 440,000 HIV-infected individuals are projected to classify under new AIDS diagnosis); *Mortality Attributable to HIV Infection/AIDS—United States*, 265 *JAMA* 848, 848-49 (1991) (estimating that 165,000 to 215,000 persons will die of AIDS during 1991-92).

46. See Jon Cohen, *Is Liability Slowing AIDS Vaccine?*, 256 *SCIENCE* 168, 168 (1992) (quoting AIDS division chief at National Institute of Allergy and Infectious Disease who voiced opinion that liability concerns are slowing progress in vaccine research). For example, while vaccines may be useful in preventing transmission of the AIDS virus to the fetus of an infected mother, use of the vaccine during pregnancy can cause birth defects. *Id.* at 170. Moreover, in the absence of a national healthcare system in this country, HIV-infected people often have little or no access to sufficient health care. *Id.* at 169. As a result, the prospect of a jury award for an injury might add an incentive to seek a legal remedy. *Id.*

47. See *id.* (noting Oncogen's halt in HIV vaccine development and MicroGeneSys' postponement of tests in HIV-infected pregnant women due to liability concerns).

48. See *Mortality Attributable to HIV Infection/AIDS—United States*, *supra* note 45, at 848-49



Access to individual drugs has also suffered as a result of product liability. The principle example of this phenomenon is the case of Bendectin, the only drug marketed in the United States for the treatment of nausea and vomiting associated with pregnancy.<sup>49</sup> Bendectin was voluntarily removed from the U.S. market in 1983 as a result of multi-million dollar claims that it caused birth defects in children carried by women who were prescribed the drug during pregnancy.<sup>50</sup> Despite over thirty million exposures in utero, expert opinion was sharply divided on this issue although the preponderance of evidence indicated that Bendectin was not a significant teratogen.<sup>51</sup> The FDA and most courts were unequivocal in finding no increased risk of birth defects associated with Bendectin.<sup>52</sup> Nevertheless, no drug is currently on the market for the treatment of nausea and vomiting during pregnancy, nor is any active research currently underway in this area.<sup>53</sup>

More recently, product liability has proven to be a significant disincentive in the development of orphan drugs, drugs that are used to treat rare diseases.<sup>54</sup> The intention of the Orphan Drug Act of 1983 was to encourage the development and availability of products used in the treatment of rare disorders by increasing monetary in-

---

(stating that in 1989 insurers paid out more than \$1 billion for reimbursement of AIDS-related claims).

49. See generally Lasagna, *supra* note 17, at 337-41 (examining history of Bendectin's demise).

50. Lasagna, *supra* note 17, at 338.

51. See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 318-19 (1992) (noting that none of 39 epidemiological studies clearly concluded Bendectin was teratogen). Six studies reported at least one significant correlation between Bendectin and some adverse effect, while 33 studies either drew no conclusion or found no statistical relationship. *Id.* at 340.

52. See *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1350 (6th Cir. 1992) (finding insufficient evidence to conclude Bendectin caused plaintiff's birth defect), *petition for cert. filed*, 60 U.S.L.W. 3860 (U.S. June 9, 1992) (No. 91-1987); *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 803 (D.D.C. 1986) (citing and following independent FDA advisory panel finding nothing to implicate Bendectin exposure as cause of increased incidence of birth defects), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); *Lynch v. Merrell Nat'l Lab.*, 646 F. Supp. 856, 867 (D. Mass. 1986) (concluding that plaintiff's evidence was insufficient to support conclusion that Bendectin caused her birth defect), *aff'd*, 830 F.2d 1190 (1st Cir. 1987).

53. See AMA PROCEEDINGS, *supra* note 30, at 88 (citing conclusion of American College of Obstetricians and Gynecologists that Bendectin's loss is "significant therapeutic gap" resulting in nutritional deficiencies in some women because their pregnancy-induced vomiting is untreated). Even members of the plaintiff's bar concede that Bendectin was driven from the market by unjustified litigation. See Michael A. Pretl & Heather A. Osborne, *Trends in U.S. Drug Product Liability—The Plaintiff's Perspective*, in *PRODUCT LIABILITY INSURANCE AND THE PHARMACEUTICAL INDUSTRY: AN ANGLO-AMERICAN COMPARISON* 109, 114 (Geraint G. Howells ed., 1990) (noting evidence that suggests Bendectin does not cause higher incidence of fetal deformities than incidence of birth defects in newborn population as whole).

54. See Carolyn H. Asbury, *The Orphan Drug Act: The First 7 Years*, 265 JAMA 893, 893 (1991) (noting that before 1983 Orphan Drug Act was enacted, few drugs to treat rare or "orphan" diseases had been developed).

centives for such research.<sup>55</sup> Congress recognized that on average, orphan drugs would cause more adverse reactions in patients than would non-orphan products.<sup>56</sup> Congress also recognized that orphan drugs present unique problems in determining safety and efficacy because very few persons qualify to participate in clinical trials for the drugs.<sup>57</sup> Nevertheless, no provision was made in the statute for protecting these drugs from liability.<sup>58</sup> While the forty-two orphan products developed between 1983 and 1989 constitute a significant increase in rare disease treatments, nearly one-fifth have already been the target of liability claims.<sup>59</sup> Not surprisingly, therefore, a recent survey of manufacturers identified product liability as a major disincentive to the development of orphan drugs.<sup>60</sup> The Public Health Service also concluded that liability concerns have led to serious delays in the development of orphan drugs and to increases in insurance costs.<sup>61</sup>

Product liability, however, has arguably had a beneficial effect on the safety of health care products. The Dalkon Shield, an intrauterine contraceptive device marketed by A.H. Robbins Company, was driven from the market by liability exposure when it was found to cause an increased incidence of pelvic inflammatory disease and sterility in women using the device.<sup>62</sup> Similarly, Accutane (isotretinoin) was first marketed in 1982 to treat severe cystic acne with the

---

55. See 21 U.S.C. § 360ee (1988) (permitting sponsors of orphan drug development to obtain grants to defray qualified clinical testing expenses); *id.* § 360cc (providing exclusive seven-year marketing rights for unpatentable types of orphan drugs).

56. See H.R. REP. No. 840, 97th Cong., 2d Sess. 7 (1982) (citing findings of 1980 survey performed by U.S. House of Representatives Subcommittee on Health and Environment that orphan drugs cause more severe side effects than drugs for common diseases).

57. See *id.* (noting that such inherent difficulties make these drugs unprofitable to develop).

58. See 21 U.S.C. §§ 360aa-360ee (1988) (failing to shield orphan drug manufacturers from common law product liability claims); Asbury, *supra* note 54, at 894 (noting that Act made no attempt to address common law treatment of liability).

59. See Asbury, *supra* note 54, at 894 (noting that new products were intended for treatment of wide range of rare diseases, including human immunodeficiency virus, various cancers, and Parkinson's disease).

60. See Asbury, *supra* note 54, at 893 (noting product liability as one of three major disincentives limiting commercial interest in orphan drug products). Orphan drugs may be more vulnerable to liability claims because the reduced number of patients with an orphan disorder provides fewer opportunities to detect adverse reactions during clinical trials. *Id.* at 894.

61. See NATIONAL COMM'N ON ORPHAN DISEASES, REPORT OF THE NATIONAL COMMISSION ON ORPHAN DISEASES xvi (1989) (noting that liability concerns serve to deter treatment of persons with rare diseases, delay development of drugs, and increase insurance costs). The Commission recommended legislative resolution of product liability issues and urged special relief for orphan products threatened by liability. *Id.* at 104.

62. See Pretl & Osborne, *supra* note 53, at 113 (arguing that liability's adverse effect on early oral contraceptives research resulted in hasty development of intrauterine devices that were unsafe when marketed). Before removing the Dalkon Shield from the market in 1974, A.H. Robbins Company defended more than 13,000 lawsuits representing over 300,000 individual Dalkon Shield claims and made payments of nearly \$3 billion to these plaintiffs. *Id.*

knowledge that it was teratogenic in animals and, as a result, it was marketed with a specific warning that it should not be used by women at any time before or during pregnancy.<sup>63</sup> When birth defects resulting from Accutane use were reported in the medical literature, Hoffmann-La Roche, the drug's manufacturer, acting out of fear for its liability exposure and on the recommendation of an FDA advisory committee, sought to affirmatively reduce the risk that pregnant women would use the drug. The company added a pregnancy prevention kit to its Accutane product that included an instructional video tape for physicians, information for patients, an informed consent form, and a true-false test to be completed by the patient to ensure physicians could be satisfied that patients understood the risk.<sup>64</sup>

Do the benefits of pharmaceutical product liability justify the apparent social costs of lost therapies or research forgone? The remainder of this Comment examines this question in the context of the current regulatory safeguards for prescription drug marketing and the common law compensatory mechanisms for adverse drug reactions.

## II. THE CONCURRENT REGULATION OF PHARMACEUTICALS

Decisions regarding whether to develop and market a drug are based in part on a balancing of the perceived profitability of a drug against the costs of bringing the drug to market.<sup>65</sup> Both the FDA and state common law exert regulatory demands that impose costs on drug manufacturers. The portion of costs traceable to satisfying the demands of the FDA can reasonably be estimated, while the costs of product liability cannot.<sup>66</sup> This section reviews the demands of the FDA and of state common law, which may complement or contradict one another.

### A. Federal Regulation

The history of the FDA reflects an increasingly pervasive involve-

---

63. See Swazey, *supra* note 31, at 312-13 (noting that Accutane received approval from FDA despite agency's recognition that drug may cause fetal abnormalities).

64. See Swazey, *supra* note 31, at 313 (discussing efforts of Hoffman-La Roche to make use of Accutane safer).

65. See Lasagna, *supra* note 17, at 336-37 (detailing incentives and disincentives to pharmaceutical development and explaining that costs of research plus significant risks of potential damage claims play significant role in manufacturer's economically based decision whether to market particular drug).

66. See, e.g., Lasagna, *supra* note 17, at 337 (describing unpredictability of litigation as unknown quantity that may threaten company's existence); see also *infra* note 215 and accompanying text (providing average cost of bringing drug to market in compliance with FDA regulations).

ment in every aspect of drug approval and postapproval surveillance.<sup>67</sup> The FDA is entrusted with ensuring the safety and effectiveness of all drugs and medical devices on the market.<sup>68</sup> The agency draws on its own expertise and enforcement powers<sup>69</sup> as well as on those of outside medical authorities.<sup>70</sup> Regulation extends from preapproval testing of new drugs to drug manufacturing, labeling, advertising, and postapproval surveillance of adverse drug reactions.<sup>71</sup> Such pervasive regulation has led to significant criticism of the FDA, including charges that the agency contributes to unnecessary delay in the marketing of new chemical entities.<sup>72</sup> However, faced with the possibility of erring by allowing an unduly dangerous drug to enter the market or of delaying the availability of an effective medication, the FDA has consistently tended to emphasize safety in attempting to strike an appropriate balance.<sup>73</sup>

---

67. See generally FOOD AND DRUG LAW INSTITUTE, *supra* note 14, at 1-163 (detailing history of FDA as one developing in response to tragic injuries and increasing demand for federal protection of public health). In 1962, for example, Congress significantly tightened federal control over the pharmaceutical industry by amending the Food, Drug, and Cosmetic Act. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.). The amendments added the requirement that pharmaceutical companies follow good manufacturing practices, *id.* § 101, 76 Stat. at 780-81 (codified as amended at 21 U.S.C. § 360(F) (1988)), provided for government inspection of manufacturing plants, *id.* § 201, 76 Stat. at 792-93 (codified as amended at 21 U.S.C. § 374 (1988)), added the requirement that the government weigh drug effectiveness with drug safety, *id.* § 102, 76 Stat. at 781-82 (codified as amended at 21 U.S.C. § 360d(a) (1988)), and added the requirement that pharmaceutical companies conduct adequate and well-controlled studies of the drug's effects on humans. *Id.* § 103, 76 Stat. at 782-83 (codified as amended at 21 U.S.C. § 360c (1988)). See generally Louis Lasagna, *Congress, the FDA, and New Drug Development: Before and After 1962*, 32 PERSPECTIVES IN BIOLOGY & MED., 322, 330-31 (1989) (detailing history and substantive points of amendments).

68. See 21 U.S.C. § 360(c)(b) (1988) (describing preapproval provisions for pharmaceuticals regarding appointment of review panels concerning studies on humans); see also David Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281, 283 (1989) (examining preapproval process and noting that FDA regulates composition and function of institutional review boards that monitor research involving human subjects).

69. See 21 U.S.C. §§ 301-360 (1988) (defining prohibited acts, penalties, and requirements of food and drug approval).

70. See Fredrick H. Degnan, *An Introduction to FDA Advisory Committees*, 45 FOOD DRUG COSM. L.J. 709, 714-16 (1990) (noting that 38 standing committees, including committees of physicians, nurses, epidemiologists, and pharmacologists, have become integral parts of FDA decisionmaking process).

71. See 21 C.F.R. §§ 200-226 (1991) (regulating scope of labeling, advertising, and sound manufacturing practices). Federal regulation is so pervasive in the pharmaceutical industry that courts have found it sufficiently analogous to liquor and firearms regulation as to hold that warrantless searches of pharmaceutical companies are not unreasonable under the Fourth Amendment. See *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 537 (8th Cir. 1981) (holding that drug manufacturers' capacity to cause harm is so great that they fall into carefully defined class of exceptions to search warrant requirement), *cert. denied*, 455 U.S. 1016 (1982).

72. See THE COMPTROLLER GENERAL, REPORT TO THE SUBCOMMITTEE ON SCIENCE, RESEARCH, AND TECHNOLOGY, FDA DRUG APPROVAL—A LENGTHY PROCESS THAT DELAYS THE AVAILABILITY OF IMPORTANT NEW DRUGS, at 12-29 (1980) (detailing factors contributing to lengthy drug approval process).

73. See Milton Friedman, *Frustrating Drug Advancement*, NEWSWEEK, Jan. 8, 1973, at 49

Drugs must be tested in animals, subject to sound laboratory practices, and must show evidence of safety before any human testing may begin.<sup>74</sup> Animal and other chemical and manufacturing data is compiled and reported in an application or Notice of Claimed Investigational Exemption for a New Drug (IND),<sup>75</sup> which must include: (1) sufficient data indicating the drug is reasonably safe for humans;<sup>76</sup> (2) detailed protocols for human trials showing testing in humans is reasonably safe;<sup>77</sup> (3) details of the drug's chemistry and processes of manufacture;<sup>78</sup> and (4) identification of proposed investigators and evidence of their qualifications to perform clinical trials.<sup>79</sup> Only after this material is reviewed and sanctioned by the FDA may clinical trials begin.

Preapproval human trials are conducted in three phases and are subject to FDA proposed and final standards known as current "Good Clinical Practice" regulations and clinical guidelines.<sup>80</sup> Phase I clinical trials, designed to document a drug's safety, are conducted in small numbers of healthy adults and are of short duration.<sup>81</sup> Phase II clinical trials are conducted in as many as several hundred persons who have the medical condition that the drug under review is designed to treat.<sup>82</sup> Phase III trials, which require detailed protocols and evaluation by investigators, include

---

(noting that history of tragedies like thalidomide led FDA to choose conservative approach to drug approval).

74. See 21 U.S.C. § 355(i)(1) (1988) (describing acceptable laboratory practices for nonclinical testing, including those tests performed on animals). The Secretary of Health and Human Services is directed by 21 U.S.C. § 355(i) (1988) to promulgate regulations protecting public health during investigational new drug safety and efficacy testing.

75. See 21 C.F.R. § 312.3 (1991) (defining IND as investigational new drug application, synonymous with "Notice of Claimed Investigational Exemption for a New Drug").

76. *Id.* § 312.23(a)(5)(i)-(v).

77. *Id.* § 312.23(a)(6).

78. *Id.* § 312.23(a)(7).

79. *Id.* § 312.23(a)(6)(b).

80. See NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW 64-65 (Mark Mathieu ed., 1987) [hereinafter NEW DRUG DEVELOPMENT] (describing FDA's publication, "General Considerations for the Clinical Evaluation of Drugs," as outlining elements in clinical testing to meet FDA requirements).

81. See 21 C.F.R. § 312.21(a) (1991) (providing that studies may be conducted on patients or volunteers and typically include groups of 20 to 80 subjects); see also NEW DRUG DEVELOPMENT, *supra* note 80, at 66 (describing these short-term "clinical pharmacology" studies as determinative of further human study by establishing metabolism, pharmacologic action, and early side effects data).

82. See 21 C.F.R. § 312.21(b) (1991) (stating that Phase II trials include evaluating effectiveness of drugs on specific medical conditions); see also NEW DRUG DEVELOPMENT, *supra* note 80, at 71-72 (contrasting Phase I short-term human trials with Phase II studies, which are usually of longer duration and are designed to measure drugs' efficacy as well as safety). The FDA will often require an "end-of-phase 2" meeting to evaluate all data gathered to that point before permitting a manufacturer to proceed to Phase III clinical trials. See 21 C.F.R. § 312.47(b) (1991) (authorizing FDA to conduct such meetings to minimize wasteful expenditures and assist in design of later studies).

thousands of effected persons and are conducted over a period of years in order to more comprehensively analyze the target drug's safety, efficacy, and dosage.<sup>83</sup>

Only after this process is completed may a manufacturer apply for FDA approval of a drug, which is done through a New Drug Application (NDA).<sup>84</sup> This document is a comprehensive collection of all data available on a drug at the time of the application and includes samples of the drug and proposed labeling for the drug.<sup>85</sup> If further information is required for the FDA to accurately evaluate a new drug's performance, the agency will not hesitate to request it.<sup>86</sup> If the FDA finds insufficient data supporting a drug's clinical safety and effectiveness or deficiencies in manufacturing, processing, or labeling of the drug, the agency must deny approval of the application.<sup>87</sup>

Central to the determination of a drug's safety and often dispositive on the issue of a manufacturer's liability is the sufficiency of the drug's labeling.<sup>88</sup> While a manufacturer may desire to include every conceivable adverse reaction on a drug's label to protect itself from liability, warnings are limited to describing the results of scientific testing.<sup>89</sup> To ensure that a label does not obscure essential information among a sea of warnings included only because of liability con-

---

83. See 21 C.F.R. § 312.21(c) (1991) (providing that Phase III trials are intended to gather additional information on effectiveness and safety of drugs); see also NEW DRUG DEVELOPMENT, *supra* note 80, at 98-104 (setting forth requirements of Phase III studies and noting FDA's focus on them as pivotal to drug's approval). All proposed studies must be reviewed not only by the FDA but also by an investigational review board (IRB). See 46 Fed. Reg. 8942, 8977 (1981) (comments to adopted rule) (rule codified as amended at 21 C.F.R. § 56.109 (1991)) (detailing FDA regulation of IRBs). An IRB must verify the scientific integrity of the study it oversees and ensure that the testing does not expose participants to inappropriate risks. See Kessler, *supra* note 68, at 283 (noting that FDA holds IRB responsible for ethical conduction of research).

84. See 21 U.S.C. § 355(a) (1988) (mandating pharmaceutical manufacturers' use of NDAs to introduce any new drugs into interstate commerce).

85. See 21 C.F.R. § 314.50 (1991) (detailing requirements of NDA).

86. See Nancy Mattison & Barbara W. Richard, *Postapproval Research Requested by the FDA at the Time of NCE Approval, 1970-1984*, 21 DRUG INFO. J. 309, 313 (1987) (graphically depicting increasing trend of postapproval research as condition of new drug marketing).

87. See 21 C.F.R. § 314.125(b)(1)-(16) (1991) (detailing 16 reasons for denying approval of NDA, including failure to perform adequate tests to show whether or not drug is safe for use).

88. See 50 Fed. Reg. 7452, 7470 (1985) (comments to adopted rule) (rule codified as amended at 21 C.F.R. § 314.70 (1991)) (stating that drug's label is standard by which FDA determines drug is safe and effective). The FDA draws on the extensive experience of clinical investigators, practicing physicians, and independent advisory panels in determining a label's contents. See 44 Fed. Reg. 37,434, 37,437 (1979) (comments to adopted rule) (rule codified as amended at 21 C.F.R. §§ 201.57, 201.100 (1991)) (detailing sources that FDA consults to obtain complete and accurate explanation of drug label).

89. See 39 Fed. Reg. 33,229, 33,231 (1974) (comments to proposed rule) (rule codified as amended at 21 C.F.R. § 1.21 (1991)) (stating FDA will prescribe warning on drug label only when there is significant medical evidence of possible health hazard).

cerns, regulations specifically preclude manufacturers from warning consumers of unknown or theoretical adverse reactions that their drug might cause.<sup>90</sup> Indeed, labels may not even reflect differences of opinion with respect to potential dangers of the drugs.<sup>91</sup>

Postapproval changes in labeling are subject to a similarly rigorous review process.<sup>92</sup> Technically, a manufacturer may change a label at any time to enhance the safety of a drug.<sup>93</sup> In practice, however, manufacturers may not change a label without approval of the FDA.<sup>94</sup>

Regulation also extends to drug advertising.<sup>95</sup> Advertising that presents unsubstantiated information such as claims of safety or effectiveness superior to that of another product,<sup>96</sup> or references

---

90. See 21 C.F.R. § 201.57(d) (1991) (stipulating that warnings shall be only of known hazards, not theoretical hazards); 44 Fed. Reg. 37,434, 37,446-47 (1979) (comments to adopted rule) (rule codified as amended at 21 C.F.R. §§ 201.57, 201.100 (1991)) (citing FDA Commissioner's belief that including theoretical hazards as contraindications in drug labeling would cause that important section of labeling to lose its significance).

91. See 21 C.F.R. § 1.21(c)(1) (1991) (prohibiting inclusion on labels of differing opinions regarding contraindications, precautions, adverse reactions, and other product hazards). Permitting conflicting opinions would destroy the usefulness of drug labels by obscuring essential information among differing views, with limited space to adequately address the weight of any given opinion. See 39 Fed. Reg. 33,229, 33,232 (1974) (comments to proposed rule) (rule codified as amended at 21 C.F.R. § 1.21 (1991)) (noting that few statements on drug labels do not evoke some controversy among medical professionals). These regulations reflect the policy of avoiding an overload of information in which trivial or rare reactions would dilute the importance of critical warnings. See Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 237-38 (1986) (noting that physicians frequently have little time to refer to labeling and therefore information should be limited to what is reasonably required for physician to make treatment decisions). Some courts have acknowledged this label-diluting problem. See, e.g., *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) (noting danger of inundating physicians with every conceivable risk includes risk of diluting notice of serious adverse reactions); *Dunn v. Lederle Lab.*, 328 N.W.2d 576, 581 (Mich. Ct. App. 1982) (recognizing that warnings must be selective to be effective and that excessive warnings might dissuade physicians from reading them).

92. See 21 C.F.R. § 314.70 (1991) (detailing procedures for supplementing or changing approved application); 50 Fed. Reg. 7452, 7470 (1985) (comments to adopted rule) (rule codified as amended at 21 C.F.R. § 314.70 (1991)) (stating that more than any other change, label changes effect FDA's previous conclusions concerning safety and efficacy).

93. See 21 C.F.R. § 314.70(c)(2)(i)-(iv) (1991) (permitting label changes to enhance safety).

94. See Cooper, *supra* note 91, at 236 (noting that neither FDA nor manufacturers envision that labels may be changed without approval of FDA). With the pervasive scope of FDA oversight of the drug approval process, manufacturers must work closely with the agency. Manufacturers are therefore very reluctant to be perceived as acting unilaterally. *Id.* Moreover, any label change is costly and must be approved by the FDA eventually. *Id.* The risk always exists that the agency will find the change unsupported by sufficient evidence and require that it be removed from the label. *Id.*

95. See 21 U.S.C. § 352(n) (1988) (requiring that advertisements quantitatively report each ingredient contained in drug and describe side effects, contraindications, and effectiveness of drug). FDA regulations similarly require that advertisements include descriptions of side effects, warnings, precautions, and information concerning effectiveness of drugs. 21 C.F.R. § 202.1(e)(1) (1991).

96. See 21 C.F.R. § 202.1(e)(6)(ii) (1991) (defining drug effectiveness comparisons in ad-

favorable test results while disregarding concurrent or more recent unfavorable data,<sup>97</sup> may render a drug "misbranded" and subject to seizure.<sup>98</sup>

Investigational obligations often do not terminate upon approval of an NDA.<sup>99</sup> According to one study, additional research into a drug's long-term effects has become an FDA condition of approval in one-third to one-half of drugs reviewed.<sup>100</sup> While such research is expensive<sup>101</sup> and frequently does not result in labeling changes,<sup>102</sup> the practice is indicative of the FDA's insistence on objective, long-term review of drug safety.<sup>103</sup>

Nevertheless, even the most comprehensive preapproval testing will not uncover all adverse events that a new drug might engender.<sup>104</sup> To keep the FDA abreast of these events, manufacturers are required to report serious and unexpected adverse drug reactions to the agency within fifteen working days of the reaction.<sup>105</sup> Annual

---

vertising without substantial support as misleading and violative of Federal Food, Drug, and Cosmetic Act).

97. *See id.* § 202.1(e)(6)(viii) (defining as misleading any advertisement that refers to favorable data while ignoring concurrent or more recent unfavorable data regarding drug's performance).

98. *See* 21 U.S.C. § 334(a) (1988) (authorizing seizure of drugs that are "misbranded" through deceptive advertising practices). Courts have held that even when warnings are adequate by themselves, a manufacturer may still be held liable for drug-induced injury if overpromotion obscures the warning. *See, e.g.,* *Yarrow v. Sterling Drug, Inc.*, 203 F. Supp. 159, 163 (D.S.D. 1967) (holding manufacturer liable where doctor was inundated by overwhelming amount of literature regarding product safety and warnings); *Love v. Wolf*, 38 Cal. Rptr. 183, 195-96 (Cal. Ct. App. 1984) (noting that manufacturer may be liable for overpromotion of adequate warnings, unless there exists intervening cause of harm to patient); *Stevens v. Parke Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (finding excessive promotion may have effect of persuading physician to disregard warning).

99. *See generally* Mattison & Richard, *supra* note 86, at 309 (examining FDA's conditioning of marketing approval on additional studies ranging from testing in special populations to refining dosages).

100. *See id.* at 323 (noting that postapproval studies are now standard FDA practice and not exceptional requirement). Mandatory postapproval research reflects the FDA's balancing of public needs for access to effective new therapies against the continuing need for assessing the safety of such therapies. *See id.* at 309 (describing FDA's approval of levodopa for treatment of Parkinson's disease as compromise, because it occurred on condition that manufacturer conduct postapproval studies of long-term effects of chronic use, which enabled clearly effective drug to become available two to three years earlier than otherwise would have been possible).

101. *See id.* at 318 (showing range of median costs of postapproval studies examined to be between \$60,000 and \$530,000).

102. *See id.* at 323 (finding that two-thirds of postapproval drug studies examined resulted in data not different enough from NDA data to warrant label change).

103. *See supra* notes 73-83 and accompanying text (discussing FDA's emphasis on drug safety and objective criterion on which FDA evaluates new drugs).

104. *See* U.S. GEN. ACCOUNTING OFFICE, *FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976-1985* 3 (1990) (reporting that more than half of drugs approved by FDA between 1976 and 1985 had serious postapproval risks, as evidenced by label changes or removal from market after postapproval study period).

105. *See* 21 C.F.R. § 314.80(a), (c)(1) (1991) (requiring reporting of overdoses or any other reaction that is fatal, life-threatening, permanently disabling, or results in congenital



reports must be submitted detailing any information that might affect safety, effectiveness, or labeling of the drug.<sup>106</sup> The FDA is authorized to withdraw approval of an NDA for a manufacturer's failure to make any required reports.<sup>107</sup> Approval may also be withdrawn if the FDA determines at any time that the drug is unsafe.<sup>108</sup> Indeed, failure to comply may subject a manufacturer to civil and criminal penalties.<sup>109</sup>

Moreover, the FDA has aggressively used its existing enforcement powers<sup>110</sup> while Congress has actively sought to provide additional enforcement authority.<sup>111</sup> Enforcement activities such as drug seizures for mislabeling are increasingly common as a result of the FDA's general campaign to more forcefully assert its role as protector of public safety.<sup>112</sup> Though criticized in the past as underfunded, ill-equipped, and incapable of effectively performing its

---

anomaly or cancer). Other adverse reactions must be reported every quarter for the first three years after approval and annually thereafter. *Id.* § 314.80(c)(2). Furthermore, manufacturers are required to disclose data regarding adverse reactions occurring outside the United States. See Ellen J. Flannery, *Reporting Foreign ADRs and ADRs in Phase IV Studies, and the Significance of Causality Assessment*, 46 *FOOD DRUG COSM. L.J.* 43, 50-51 (1991) (noting that FDA's requirement of reporting any serious adverse drug experiences without regard to causality includes reporting of any foreign data).

106. See 21 C.F.R. § 314.81(b)(2) (1991) (specifying contents of mandatory annual postmarketing reports). These annual reports must include any alterations in product manufacturing, labeling, or chemistry and any new clinical or animal test data available on a drug, whether or not the test data was produced by the manufacturer. *Id.*

107. *Id.* § 314.81(d).

108. See 21 U.S.C. § 355(e) (1988) (authorizing rescinding of NDA approval upon finding that drug is unsafe).

109. See *id.* §§ 331-334 (defining prohibited acts that subject pharmaceutical manufacturers to injunction proceedings, criminal penalties, and drug seizures).

110. See Lena Williams, *F.D.A. Steps Up Effort to Control Vitamin Claims*, N.Y. *TIMES*, Aug. 9, 1992, at A1 (recounting raid by bulletproof vest-clad FDA agents on clinic that illegally provided "vitamin-mineral concoctions" for injection). But see Nancy L. Buc, *FDA Enforcement 1991: Some Questions*, 47 *FOOD & DRUG L.J.* 149, 149-50 (1992) (questioning whether FDA's aggressive law enforcement is efficient, fair, and wise). The FDA's present enforcement powers include the power to seek injunctions, criminal indictments, and to seize products. See 21 U.S.C. § 372 (1988) (detailing powers and authority of FDA enforcement personnel).

111. See 137 *CONG. REC.* S18,706-07 (daily ed. Nov. 27, 1991) (statement of Sen. Kennedy) (introducing legislation to enhance FDA enforcement authority and noting that despite regulation of 25¢ of every dollar spent in this country, FDA simply does not have necessary means to enforce law).

112. See Liz Hunt, *FDA Seizes \$5 Million Worth of Collagen Products*, WASH. *POST*, Aug. 17, 1991, at A14 (describing medical device seizure for manufacturer's inadvertent failure to include one line of print on package insert as part of "tougher line" at FDA). Much of the change in the FDA's enforcement activities has been accredited to the recent appointment of Dr. David Kessler, a physician and attorney who previously taught food and drug law at Columbia University School of Law, as the new commissioner of the FDA. See Herbert Burkholtz, *A Shot in the Arm For the F.D.A.*, N.Y. *TIMES MAG.*, June 30, 1991, at 15, 17 (noting that Kessler, upon taking office, immediately sought increased administrative and judicial authority to order product recalls). Dr. Kessler's aggressive enforcement of food and drug laws has reportedly revitalized an agency whose low morale had seriously compromised its effectiveness. See Malcolm Gladwell, *FDA Chief Relishes Label of Lawman*, WASH. *POST*, Oct. 24, 1991, at A1 (describing new enthusiasm throughout FDA created by Kessler's sense of purpose).

public-protection mandate,<sup>113</sup> the FDA has recently been granted significant funding increases by Congress.<sup>114</sup> More importantly, Congress is seeking to enhance the FDA's enforcement powers.<sup>115</sup> Senate bill 2135, the new FDA enforcement bill, would for the first time grant the FDA administrative recall authority,<sup>116</sup> seizure and embargo authority,<sup>117</sup> subpoena power,<sup>118</sup> and would permit civil money penalties for drug safety and efficacy violations.<sup>119</sup>

### B. Common Law Regulation

Regulation of an industry is the coercive power to dictate corporate behavior. A number of courts have recognized that state common law exerts such regulatory authority.<sup>120</sup> Compliance with federal regulation, however, may have no effect on common law regulatory demands, and in fact the two often conflict.<sup>121</sup>

---

113. See U.S. DEP'T OF HEALTH AND HUMAN SERV., FINAL REPORT OF THE ADVISORY COMMITTEE ON THE FOOD AND DRUG ADMINISTRATION 15 (1991) (depicting dramatic disparity between resources and responsibilities at FDA and examining recent legislation that has left FDA incapable of fulfilling its statutory obligations); John K. Iglehart, *The Food and Drug Administration and Its Problems*, 325 NEW ENG. J. MED. 217, 217 (1991) (delineating FDA's ineffectiveness as result of Reagan administration's deregulation policy during 1980s and of congressional enactment of 32 new FDA-related laws without providing adequate funds to implement them). The FDA has also been the object of severe criticism for lax oversight. See *FDA's Regulation of the New Drug Versed: Hearings Before a Subcomm. of the House Comm. on Gov't Operations*, 100th Cong., 2d Sess. 2 (1988) (statement of Rep. Weiss) (reporting that FDA was brought before Congress three times in two years for failure to recognize manufacturer's gross violation of legal reporting requirements); *FDA's Regulation of Zomax: Hearings Before a Subcomm. of the House Comm. on Gov't Operations*, 98th Cong., 1st Sess. 2 (1983) (statement of Rep. Weiss) (faulting FDA for failure to require manufacturer to include warning of life-threatening reactions, despite knowledge of such reactions by FDA for over one year, and for permitting drug to enter market without further testing despite animal data that indicated drug may cause cancer).

114. See Iglehart, *supra* note 113, at 217-19 (documenting FDA's significant budgetary increases for fiscal year 1991 and noting additional increases scheduled for 1992). The 1992 increases, however, include significant contribution of "user fees," which are charges to the regulated industries. *Id.* These fees have not been approved by Congress. *Id.*

115. See S. 2135, 102d Cong., 1st Sess. (1991) (providing enforcement tools currently granted to other regulatory agencies). Industry opposition to new enforcement powers for FDA is, however, considerable. See *Senate Enforcement Bill Contains "Loophole" in Subpoena Authority Provision Allowing FDA Access to Confidential Information, PMA's Mossinghoff Testifies*, 54 F-D-C REP. ("The Pink Sheet"), May 25, 1992, at 5 (noting that Pharmaceutical Manufacturer's Association remains strongly opposed to enforcement bill and believes, for example, that civil penalties should be available only for repeated or significant violations).

116. S. 2135, 102d Cong., 1st Sess. § 2 (1991).

117. *Id.* § 4.

118. *Id.* § 5.

119. *Id.* § 6. The House version would provide similar enforcement tools. H.R. 3642, 102d Cong., 1st Sess. (1991).

120. See *DeLuryea v. Winthrop Lab.*, 697 F.2d 222, 228 (8th Cir. 1983) (assuming that product liability, as state common law mechanism, exerts regulatory effect by motivating manufacturer through economic self-interest to make safer products); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (noting that state product liability common law exacts high degree of care from manufacturers and that compliance with federal laws and regulations will not absolve manufacturers from such common law liability).

121. See *Salmon*, 520 F.2d at 1362 (holding that manufacturer's compliance with federal

The scientifically derived evidence that manufacturers must provide the FDA to establish the safety and efficacy of a drug may provide precious little protection from product liability claims.<sup>122</sup> Indeed, while courts have held that the failure to comply with FDA regulations constitutes negligence per se,<sup>123</sup> courts have also held that a showing of compliance is only relevant to the issues of defectiveness or unreasonable danger and does not absolve the manufacturer from liability.<sup>124</sup> This imbalance stems from the well-known adage that there is no such thing as a government standards defense.<sup>125</sup> Such standards represent merely a floor of safety below which a defendant's product may not fall.<sup>126</sup> Both the FDA and manufacturers, however, regard regulatory oversight as a compre-

---

drug laws and regulations does not absolve manufacturer of liability for failure to effectively and adequately warn consumers of drug's inherent dangers); *see also* *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988) (noting that preemption of state law does not immediately follow from federal regulation and explaining that when Congress does not expressly state its intent, there is strong presumption against preemption, especially with state regulation of health and safety matters).

122. *See* *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981) (finding that compliance with federal regulation does not preclude manufacturer's liability); *Salmon*, 520 F.2d at 1362 (holding that compliance with federal laws and regulations cannot indemnify manufacturer); *see also* Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (1987) (concluding that FDA regulation affords only modest protection from liability, while evidence of noncompliance may virtually establish liability).

123. *See, e.g.*, *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (regarding, as negligence per se, violation of Federal Food, Drug, and Cosmetic Act that was proximate cause of injury); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 964-65 (E.D. Wisc. 1981) (holding violation of statute designed to protect class of persons to be negligence per se when violation results in harm to person in that class); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 409 (Cal. Ct. App. 1967) (establishing negligence from failure to comply with adverse reaction reporting regulations). As defined by the American Law Institute: "The unexcused violation of . . . an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable [manufacturer], is negligence in itself." RESTATEMENT (SECOND) OF TORTS § 288B(1) (1965).

124. *See, e.g.*, *Mazer v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990) (holding compliance with FDA requirements not necessarily indemnifying manufacturer from negligence liability on defectiveness issue); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1491 (D. Kan. 1987) (finding compliance with FDA regulations not conclusive on liability issue with dangerous vaccine); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass. 1985) (finding compliance with FDA requirements admissible to demonstrate lack of negligence but not conclusive on issue).

125. *See* RESTATEMENT (SECOND) OF TORTS § 288C (1965) (stating that compliance with government standards does not prevent finding of negligence); Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 39 (1991) (noting that jury is traditionally permitted to consider compliance with government standards merely as factor in determining negligence liability).

126. *See* *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 997 (D.N.D. 1966) (holding without discussion that FDA regulations are minimal safety requirements), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (noting without inquiry that warnings required by regulatory agencies may be only minimal in nature); *Feldman v. Lederle Lab.*, 479 A.2d 374, 391 (N.J. 1984) (holding FDA regulations are minimal standards with no effect on manufacturer's duty to warn of dangers about which it knew or should have known); *Bristol-Meyers Co. v. Gonzales*, 548 S.W.2d 416, 423 (Tex. Civ. App. 1976) (refusing to find FDA regulation as providing more than minimum standard of safety).

hensive determination of safety, viewing regulations in general and labeling in particular as central to the determination that a drug is safe and effective.<sup>127</sup> In fact, the FDA regards as its mandate the requirement that drug labeling be fully adequate to convey all necessary information to a physician.<sup>128</sup> Moreover, it seems unreasonable to suggest that Congress, by extending to the FDA ever-wider mandates to ensure safety through controlled clinical trials and enhanced policing power, intended merely to establish a floor of safety.<sup>129</sup>

Nevertheless, courts permit juries to decide whether the risks of drug-induced injury are outweighed by benefits to patient health.<sup>130</sup> Even though manufacturers and the FDA are required to determine that a drug's utility outweighs its risks,<sup>131</sup> juries are allowed to perform their own risk-benefit analyses on a case-by-case basis.<sup>132</sup> This occurs despite the fact that NDAs may be many thousands of pages

---

127. See Cooper, *supra* note 91, at 237 (observing that product liability exerts strong incentive on manufacturer to issue warnings that are adequate); Scarlett, *supra* note 125, at 33 (describing FDA's perception that label is centrally important document as reason for protracted, careful review process). But see Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334 (1985) (noting that agencies are actually quite happy to have product liability as "safety valve" for focusing hostility on manufacturers when harm to consumers does occur).

128. See 40 Fed. Reg. 15,392, 15,392 (1975) (comments to proposed rule) (rule codified as amended at 21 C.F.R. §§ 201.56, 202.1 (1991)) (noting that primary purpose of FDA labeling regulations is to adequately provide physicians with all information needed for safe and effective patient care); see also Scarlett, *supra* note 125, at 40 (rejecting notion that labeling requirements are meant to be minimal safeguards, given careful NDA review process and mandatory disclosure of adverse drug reaction data).

129. See Lasagna, *supra* note 67, at 324 (noting that 1962 amendments to Federal Food, Drug, and Cosmetic Act were based in principle part on need to assure public that only drugs of high quality would be permitted on market); see also *supra* notes 115-19 and accompanying text (discussing House bill 2597, which proposes to increase FDA's enforcement powers).

130. See *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) (allowing jury to consider social utility and desirability of pharmaceutical product along with product's risks in determining if product is unreasonably dangerous); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (finding summary judgment inappropriate when jury could find that benefit from use of "valuable, life saving" antibiotic was not commensurate with risk of blood disorder specifically warned of in antibiotic's label).

131. See 21 C.F.R. § 314.50(d)(5)(viii) (1991) (requiring integrated summary of drug risks and benefits and discussion of why benefits exceed risks under conditions stated in labeling).

132. See, e.g., *Hurley v. Lederle Lab.*, 851 F.2d 1536, 1540 (5th Cir. 1988) (upholding jury's role in risk-utility analysis because absence of product liability may increase uncertainty of vaccine's quality, thereby discouraging its use); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1115-16 (4th Cir.) (holding that reasonableness of warning is question of fact for jury and that neither treating physician's view nor compliance with federal regulation is conclusive on question of adequacy), *cert. denied*, 488 U.S. 908 (1988); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 659 (1st Cir. 1981) (permitting jury to weigh risks and benefits of high-dose contraceptive and its low-dose alternative); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1273 (5th Cir.) (affirming two-step analysis to determine if vaccine is so unsafe that marketing it at all is unreasonably dangerous per se, and if not, whether introduced into commerce without sufficient safeguards, product is unreasonably dangerous as marketed), *cert. denied*, 419 U.S. 1096 (1974); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985) (noting that warning adequacy is substantial issue of material fact for jury to consider).

in length and may engage multiple scientific disciplines,<sup>133</sup> and that a trial may focus the bright light of hindsight on a relatively small collection of negative data.<sup>134</sup>

This case-by-case approach has produced findings directly at odds with FDA determinations. The most striking examples include jury determinations that the FDA's authority over labeling provided inadequate protection to consumers.<sup>135</sup> Warnings have been found inadequate despite the fact that the FDA mandated the precise wording of the warnings as part of a uniform class labeling requirement.<sup>136</sup> And even when the FDA expressly rejected a warning change requested by a manufacturer because the alteration was not supported by sufficient scientific evidence, juries have still found manufacturers liable.<sup>137</sup> Some courts permit juries to find liability even when a risk has not been conclusively established.<sup>138</sup> This

---

133. See Gibbs & Mackler, *supra* note 122, at 223-25 & n.193 (observing that NDAs often include extensive chemistry, pharmacology, toxicology, and clinical data and noting that NDA summary alone may be over two hundred pages).

134. See Gibbs & Mackler, *supra* note 122, at 225 (questioning reasonableness of expecting jury to evaluate risk-benefit ratios of providing drug to physicians, who use their own expertise to choose among alternative therapies in light of vast amounts of relevant data covered in NDAs).

135. See *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91-92 (2d Cir. 1980) (finding warning to doctor inadequate despite adequacy of product label warning); *Stephens*, 602 F. Supp. at 381 (refusing to hold FDA-approved warning provided to medical profession adequate as matter of law and determining that warning adequacy is question for jury); *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan.) (holding that jury may find warning to doctor inadequate despite FDA determination that possibility of harm, which did occur, was insufficient to warrant warning in product label), *cert. denied*, 469 U.S. 965 (1984).

136. See *Brachy*, 642 F.2d at 658-59 (holding required uniform labeling not conclusive of warning's adequacy when single scientific study might persuade jury that label was inadequate); *McGewen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534 (Or. 1974) (finding that reasonable manufacturer would have communicated additional warning despite fact that FDA already required inclusion of authorized package insert with product).

137. See *Wooderson*, 681 P.2d at 1057 (rejecting argument that court should defer to FDA's determination, which rejected warning label because evidence of causation was unconvincing); *Feldman v. Lederle Lab.*, 479 A.2d 374, 378-79 (N.J. 1984) (upholding liability despite FDA denial of request to include warning that Declomycin caused discoloration in teeth of infants even after repeated attempts by manufacturer to include warning); see also *Upjohn To Challenge \$127.6 Million Verdict, Says Trial Court Wrongly Excluded Evidence*, 19 Prod. Safety & Liab. Rep. (BNA) No. 43, 1169 (Oct. 25, 1991) (noting that physician used medication for unapproved use and that FDA had refused to permit warning against such use).

138. See *Feldman*, 479 A.2d at 378-79 (allowing manufacturer to be held liable for failure to adequately warn in spite of FDA conclusion that evidence of substantial risk is not present); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 837 (Ohio 1981) (stating that jury may decide evidence of danger is associated with drug even though manufacturer is unconvinced that drug is dangerous); see also Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 193 (1986) (stating that liability finding when risk is not sufficiently substantiated under federal law is equivalent to liability finding for unknown risk). But see *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 232 (D.S.D. 1983) (refusing to extend liability to manufacturer who neither knew nor should have known of drug's adverse reaction potential); *Griggs v. Combe, Inc.*, 456 So. 2d 790, 792 (Ala. 1984) (holding that no legal theory could justify recovery when danger could not be known through reasonable human foresight and manufacturer neither knew nor should have known drug could cause injury); *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 97 (Mo. Ct. App. 1969)

is a direct affront to the public policy of providing physicians with warnings that reasonably reflect the current state of scientific observation.<sup>139</sup>

Manufacturers are thus caught between independent arbiters of drug safety. Both the FDA and the court system have extensive coercive power that is little affected by the other. Common sense might dictate that when conflicting regulatory demands are present, the expertise of an independent agency should bear significant or even presumptive weight.<sup>140</sup> Unfortunately, such is not the case. Alternatives to this concurrent regulation are the subject of the remainder of this Comment.

### III. MODEL ALTERNATIVES TO CONCURRENT REGULATION

#### A. *Judicial Preemption*

A number of commentators have argued that under the Supremacy Clause,<sup>141</sup> federal regulation preempts state common law liability with respect to pharmaceuticals.<sup>142</sup> Such analyses take

---

(refusing to hold manufacturer liable for injury of which it neither knew nor had means to know, because plaintiff's injury was first reported instance of adverse reaction). Judges have even gone so far as to suggest that manufacturers should bypass the FDA entirely and warn physicians directly of suspected adverse reactions that do not meet the FDA's requirement of sufficiently substantiated evidence of causation. See *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1169-70 n.20 (Cal. 1984) (Bird, C.J., dissenting) (noting that manufacturers could use advertising, promotional literature, letters to medical profession, and sales personnel to communicate risks). This view, however, is probably incorrect because regulations subject virtually all of a manufacturer's communications with the medical community to labeling restrictions under the Federal Food, Drug, and Cosmetic Act. See 21 C.F.R. § 202.1(k)(2) (1991) (providing that brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion pictures, film strips, lantern slides, sound recordings, exhibits, literature, and other materials describing drugs to medical community are treated as "labeling" and thus are regulated by Federal Food, Drug, and Cosmetic Act).

139. See *supra* notes 122-29 and accompanying text (discussing role of warnings in providing public with complete safety information).

140. See Pennington Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 119-20 (1988) (noting persistent attempts of states to regulate from courtroom and recommending that determinations by FDA, independent governmental agency, be given precedence under federal preemption doctrine).

141. See U.S. CONST. art. VI, cl. 2 (stating that federal law "shall be the supreme Law of the Land").

142. See, e.g., Huber, *supra* note 127, at 288-89 (describing chilling effect of liability on drug production and advocating federal preemption to decrease tort liability); Landen, *supra* note 140, at 119-20 (arguing that both Supremacy Clause and common sense support conclusion that state tort actions for defective drug designs and labeling are federally preempted); Michael R. Taylor, *Federal Preemption and Food and Drug Regulation: The Practical, Modern Meaning of an Ancient Doctrine*, 38 FOOD DRUG COSM. L.J. 306, 314-17 (1983) (finding very narrow scope of preemptive function of drug regulation); Jennie Clarke, Comment, *Federal Preemption: A Vaccine Manufacturer's Defense*, 56 U. MO. K.C. L. REV. 515, 543 (1988) (concluding that additional regulation of pertussis vaccine beyond usual FDA approval and criminal penalties for sale of any other DTP vaccine is clear evidence of preemption of state tort causes of action); John F. Del Giorno, Comment, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL

issue with the case-by-case risk-utility analyses engaged in by lay juries that occur despite the existence of comprehensive federal regulation.<sup>143</sup> From such regulation, congressional intention to preempt state common law causes of action might be inferred.<sup>144</sup> While some courts have approached this result by exempting prescription drugs from exposure to strict liability,<sup>145</sup> adoption of a federal preemption analysis in the absence of clear guidance from Congress has been avoided.<sup>146</sup>

This reluctance stems from a perception that the aims of federal regulation and state common law are so different as to not interfere with one another. That is, the state has an interest in providing

---

L. REV. 629, 656 (1989) (concluding that judicial recognition of federal preemption is only antidote to conflicting demands on drug manufacturers); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 792-93 (1990) (urging judiciary to defer to institutional expertise of FDA by means of Supremacy Clause).

143. See Walsh & Klein, *supra* note 138, at 193 (arguing that lay jury is simply not competent to find that expert advisors to FDA erred in evaluation of scientific evidence supporting warning adequacy). Adjudicative regulation reaches its extreme when juries conclude that a drug should never have been marketed. See *Feldman v. Lederle Lab.*, 479 A.2d 374, 374-83 (N.J. 1984) (refusing to permit FDA risk-utility analysis to supplant that of judicial process).

144. See *Hurley v. Lederle Lab.*, 651 F. Supp. 993, 998-1001 (E.D. Tex. 1986) (holding that while preemption is not expressly found in Federal Food, Drug, and Cosmetic Act, comprehensive regulation and vital federal interest in uniformity of drug labeling establish pre-emptive inference when state common law causes of action are found to undermine federal objective), *rev'd on other grounds*, 851 F.2d 1536 (5th Cir. 1988).

145. See *Grundberg v. Upjohn Co.*, No. 90-0573, 1991 Utah LEXIS 44, at \*2 (May 14, 1991) (recognizing FDA approval as basis for exempting prescription drug from strict product liability); *Brown v. Superior Court*, 751 P.2d 470, 480 (Cal. 1988) (limiting scope of product liability to design defects and analyzing failure to warn of reasonably knowable dangers under negligence standard). In *Brown*, the California Supreme Court found that public interest in the development, availability, and reasonable pricing of drugs outweighed consumer interest in strict liability principles. *Brown*, 751 P.2d at 477. The court extended the protection of comment k of section 402A of the *Restatement (Second) of Torts* to all prescription drugs as a matter of law. *Id.* Comment k provides an exception to strict liability for products that are incapable of being made safe for their intended use, provided that their utility outweighs their apparent risks and proper warnings are given. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (exempting unavoidably unsafe products accompanied by adequate warning from strict liability exposure). Other courts, however, have declined to extend comment k protection to prescription drugs. See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064, 1068-69 (8th Cir. 1989) (noting that drafters of comment k considered and rejected extension of strict liability exemption to all prescription drugs); *Martinkovic v. Wyeth Lab.*, 669 F. Supp. 212, 216-17 (N.D. Ill. 1987) (holding medical literature discussing safer alternatives to vaccine sufficient to counter manufacturer's argument that its drug was unavoidably unsafe); *Toner v. Lederle Lab.*, 732 P.2d 297, 306-08 (Idaho 1987) (determining that particular drug's benefits must clearly outweigh its risks for comment k to apply, and finding that such exemption obviously does not apply to all drugs).

146. See *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1988) (finding decisive fact that defendant can point to no statutory language or legislative history lending credence to conclusion of congressional intention to preempt state tort law); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1491 (D. Kan. 1987) (requiring clear notice of congressional intention to preempt states from protecting citizens through judicial process because federal regulations traditionally set minimum standards); *Feldman v. Lederle Lab.*, 592 A.2d 1176, 1191-92 (N.J. 1991) (*Feldman II*) (holding that no federal preemption may attach when federal law does not clearly require drug manufacturer to obtain prior approval from FDA before warning of known or knowable danger), *cert. denied*, 60 U.S.L.W. 3878 (U.S. June 29, 1992).

compensation for drug-induced injuries using the police powers of the common law.<sup>147</sup> The federal government, on the other hand, has a national interest in ensuring that drugs are safe before they reach the public.<sup>148</sup> In light of these differing interests, courts have refused to protect manufacturers from common law liability without a replacement remedy for plaintiffs' drug-induced injuries.<sup>149</sup>

### B. No-Fault Compensation for Drug—Induced Injuries

#### 1. National Childhood Vaccine Injury Act

In 1986, Congress recognized for the first time that product liability for vaccines was a matter of national concern.<sup>150</sup> Responding to the fact that liability for vaccine-related injuries was driving manu-

---

147. See *Feldman v. Lederle Lab.*, 479 A.2d 374, 391 (N.J. 1984) (recognizing state interests in protecting public and compensating injured persons and noting that such compensation interest is especially strong when there is little risk that common law interferes with effective regulation).

148. See *supra* notes 67-73 and accompanying text (addressing FDA's responsibility to monitor drug safety and efficacy).

149. See, e.g., *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1176-77 (5th Cir. 1988) (noting that courts may find preemption only where Congress has left no room for supplementary state regulation), *rev'g* 651 F. Supp. 993, 999 (E.D. Tex. 1986) (inferring preemption of common law liability, which impinges on FDA's determination of safety and efficacy, because determination is sole function of FDA); *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743, 745-46 (D.N.M. 1987) (finding that remedy of compensating injuries need not be forfeited by state that accepts drug into its market); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1489-91 (D. Kan. 1987) (finding strong presumption that Congress did not intend to displace state law in absence of express preemption and refusing to extend immunity from liability to pharmaceutical manufacturer despite compliance with FDA regulations); *Wack v. Lederle Lab.*, 666 F. Supp. 123, 127-28 (N.D. Ohio 1987) (refusing to immunize manufacturer and deprive injured plaintiff of civil remedy when federal alternative not provided by Congress); *Feldman*, 479 A.2d at 380, 383 (finding no justification for immunizing all prescription drug manufacturers from strict liability); *accord Patten v. Lederle Lab.*, 655 F. Supp. 745, 748 (D. Utah 1987) (finding no congressional intent to preclude access to common law remedy even after promulgation of National Childhood Vaccine Injury Act, which was designed to provide no-fault compensation for vaccine related injuries).

In 1976, Congress amended the Federal Food, Drug, and Cosmetic Act to provide federal preemption of state causes of action against medical devices. See *Medical Device Amendments of 1976*, Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k (1988)) (forbidding any state from enforcing any requirement "which relates to the safety or effectiveness of the device"). The requirements under these amendments for tampon and breast implant labeling have had a preemptive effect over product liability actions, yet courts have not addressed the fact that plaintiffs have consequently been denied a remedy. See *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 245 (5th Cir. 1989) (noting that causes of action for defective manufacture, labeling, and warning may be preempted where FDA regulations specifically apply); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1062 & n.2 (D. Minn. 1989) (finding that 17 of 18 courts found preemption applied in device labeling requirements for tampons); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 15 (D. Conn. 1989) (holding failure to warn of breast implant leakage not actionable under state common law when implants were in compliance with medical device amendments); see also John 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, 573-76 (1990) (examining preemptive function of Medical Device Amendments).

150. See H.R. REP. NO. 908, *supra* note 35, at 4-7, *reprinted in* 1986 U.S.C.C.A.N. at 6344-48 (recognizing negative effects of product litigation on vaccine industry).



facturers out of the market<sup>151</sup> and that children injured by vaccines were having to resort to tort relief for compensation,<sup>152</sup> Congress provided an innovative solution.<sup>153</sup> The National Childhood Vaccine Injury Program,<sup>154</sup> created as part of the National Childhood Vaccine Injury Act of 1986,<sup>155</sup> provides a no-fault system of compensation for injuries caused by any of seven childhood vaccines.<sup>156</sup> Recognizing that those injured by childhood vaccines were immunized largely for the benefit of public health, Congress set out to provide a reliable source of compensation for vaccine-associated injuries that specifically eliminated the need for the costly and lengthy uncertainty of common law adjudication.<sup>157</sup>

Petitions under the Act are heard in the United States Claims Court, which determines eligibility and award amounts for compensable injuries.<sup>158</sup> To avoid delay and controversy over causation issues, the Act describes in a Vaccine Injury Table a number of injuries for which compensation eligibility is presumed.<sup>159</sup> A special master is appointed to assist in obtaining evidence and to prepare findings of fact and proposed conclusions of law that are presented to the court.<sup>160</sup> In determining award eligibility and compensation,

---

151. See *supra* notes 34-37 and accompanying text (describing liability burden forcing vaccine manufacturers to exit marketplace).

152. See *infra* note 157 and accompanying text (noting that Congress sought to eliminate need for children injured by vaccines to seek compensation through costly and lengthy litigation).

153. See H.R. REP. NO. 908, *supra* note 35, at 4-7, reprinted in 1986 U.S.C.C.A.N. at 6344-48 (describing Congress' attempt to remedy crisis in vaccine availability and improve injury compensation by establishment of no-fault compensation program).

154. See 42 U.S.C. § 300aa-10 (1988) (establishing National Vaccine Injury Compensation Program).

155. Pub. L. No. 99-660, 100 Stat. 3755 (codified at 42 U.S.C. §§ 300aa-1 to -34 (1988)).

156. See generally Alan R. Hinman, *The National Vaccine Program and the National Vaccine Injury Compensation Program*, 44 FOOD DRUG COSM. L.J. 633, 633-36 (1989) (describing general purposes of program, goals and duties of National Vaccine Advisory Committee, and requirements of providers of immunizations under program). The vaccines covered include: diphtheria and tetanus toxoids (DT); measles, mumps, and rubella (MMR); diphtheria, tetanus, and pertussis (DTP); poliomyelitis, and any combination thereof. 42 U.S.C. § 300aa-14 (1988).

157. See H.R. REP. NO. 908, *supra* note 35, at 7, reprinted in 1986 U.S.C.C.A.N. at 6348 (outlining dual objectives of National Childhood Vaccine Injury Act of providing expeditious method of compensating children injured by vaccines and establishing predictable determinations of manufacturer liability).

158. 42 U.S.C. §§ 300aa-12 to -13 (1988) (giving United States Court of Claims jurisdiction to hear petitions, determine eligibility, and grant compensation under National Childhood Vaccine Injury Act); see CL. CT. R. app. J, at 59 (detailing rules including review of claim for completeness, assessment of validity of claim, and development of proposed settlement).

159. See 42 U.S.C. § 300aa-14 (1988) (presenting Vaccine Injury Table and describing revision procedures for Table). Death and injuries including seizures, convulsions, paralysis, brain damage, and shock-collapse caused by the administration of specific vaccines warrant compensation under the Act. *Id.*

160. 42 U.S.C. § 300aa-12(c) (1988) (detailing duties and requirements of special master designated by United States Claims Court).

the sole issue before the court is whether, by a preponderance of the evidence, the injury was vaccine related.<sup>161</sup> The Act provides that the injured party shall be compensated from a trust fund,<sup>162</sup> which is financed by an excise tax imposed on each dose of covered vaccines.<sup>163</sup> Compensation includes nonreimbursable medical expenses, rehabilitation, lost wages, and a pain and suffering award that may not exceed \$250,000.<sup>164</sup>

While not entirely preempting a common law remedy, Congress significantly limited such recourse by enacting this statute. First and most important, in return for a more certain and efficient dispute resolution process, petitioners must exhaust all remedies provided through the Act before bringing any action in tort.<sup>165</sup> Accepting compensation under the Act or failing to file a tort claim within ninety days of a judgment under the Act precludes any further claim against a manufacturer.<sup>166</sup> Second, the Act adopts comment k of section 402A of the *Restatement (Second) of Torts*<sup>167</sup> by stating that a vaccine is an unavoidably unsafe product and that no liability should attach when a vaccine is properly prepared and accompanied by an adequate warning.<sup>168</sup> The Act creates an explicit presumption that a vaccine is accompanied by proper direction and warning if the manufacturer shows it complied with all requirements imposed by the FDA.<sup>169</sup> Third, manufacturers may not be held liable for failing to warn users directly, rather than through a learned intermediary.<sup>170</sup> This provision specifically overrules a number of decisions that require a direct warning for vaccines.<sup>171</sup> Finally, compliance

---

161. See *id.* § 300aa-13 (stipulating determination procedures for compensation eligibility).

162. *Id.* § 300aa-15(i).

163. See 26 U.S.C. §§ 4131-4132 (1988) (imposing tax on "taxable vaccines," which include vaccines for diphtheria, tetanus pertussis, measles, mumps, rubella, and polio).

164. 42 U.S.C. § 300aa-15(a) (1988).

165. See *id.* § 300aa-11(a) (barring civil action for eligible persons until remedies under Act are exhausted); *id.* § 300aa-21(a) (describing petitioner qualifications and petition content). The American Medical Association had further argued for establishing a no-fault compensation system as the exclusive remedy for claimants so as to avoid the financial stress on manufacturer research costs and development. See William A. Check, *AMA Offers Recommendations for Vaccine Injury Compensation*, 252 JAMA 2937, 2939 (1984) (detailing position of AMA's ad hoc committee on vaccine injury that only exclusive remedy could meet goal of continued vaccine availability, vaccine development, and participation of health workers in vaccine programs).

166. 42 U.S.C. § 300aa-21(a) (1988).

167. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

168. 42 U.S.C. § 300aa-22(b) (1988).

169. *Id.* Only a clear and convincing showing that a manufacturer engaged in fraudulent conduct or intentionally withheld information can overcome this presumption. See H.R. REP. NO. 908, *supra* note 35, at 26, *reprinted in* 1986 U.S.C.C.A.N. at 6367 (noting that only "substantial wrongdoing" on part of manufacturer should result in liability).

170. 42 U.S.C. § 300aa-22(c) (1988).

171. See *Givens v. Lederle Lab.*, 556 F.2d 1341, 1345 (5th Cir. 1977) (finding that manu-

with FDA regulations protects manufacturers from punitive damages absent conscious withholding of safety data.<sup>172</sup>

In addition to limiting liability, however, Congress also affirmatively sought to enhance patient information and vaccine safety through adverse drug reaction reporting.<sup>173</sup> For the first time for any pharmaceutical, the Act mandates that health care providers of vaccines must report all occurrences of adverse events of the types listed in the Vaccine Injury Table.<sup>174</sup> Moreover, the Act requires vaccine providers to inform parents of specified information concerning the benefits and risks of childhood vaccines.<sup>175</sup> This information must include the frequency and severity of both the disease to be prevented and the adverse reactions caused by the vaccine.<sup>176</sup>

## 2. *The Swedish Pharmaceutical Insurance*

While the United States has relied largely on private causes of action with fault-based insurance coverage to compensate drug-induced injuries,<sup>177</sup> a number of other nations have provided for a no-

---

factorer has affirmative duty to warn user directly when vaccine administered under conditions of small county health clinic); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1267 (5th Cir.) (requiring direct patient warning when manufacturer knew or had reason to know vaccine would not be administered by physician), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that manufacturer must warn patient directly when manufacturer knows or should have known vaccine would not be administered by physician).

172. See 42 U.S.C. § 300aa-23(d)(2) (1988) (stating that punitive damages will be allowed if information was withheld prior to approval of vaccine, subsequent to approval of vaccine, or if manufacturer engaged in criminal or illegal activity relating to safety and effectiveness of vaccine).

173. See H.R. REP. NO. 908, *supra* note 35, at 4, *reprinted in* 1986 U.S.C.C.A.N. at 6344-45 (discussing how manufacturers must keep detailed records regarding vaccines, while reporting any potential problems to federal agencies within 24 hour period of discovery of problem). The House Report also details the requirements for development and distribution of parent information materials, recalling of hazardous vaccines, and performance of studies on the sufficiency of warnings and labels. *Id.*

174. See 42 U.S.C. § 300aa-25(b) (1988) (mandating reporting of any event listed specifically in Vaccine Injury Table that occurs within seven days of vaccine administration). The National Vaccine Program uses both vaccine-specific adverse reaction forms and the FDA's Adverse Drug Experience Form (Form 1639) to manage communication between state health departments and the Centers for Disease Control. See *Hinman, supra* note 156, at 635-36 (explaining system of reporting and noting that such reporting will lead to unitary system of surveillance).

175. See 42 U.S.C. § 300aa-25(a), (c) (1988) (mandating distribution of vaccine information materials to legal representative of child receiving any vaccine listed in Vaccine Injury Table).

176. *Id.* The information form, projected to be as long as 3500 words per vaccine, is likely to create workload problems in clinics, particularly in those that serve parents with limited reading skills whose infants receive more than one inoculation during a visit. See *Hinman, supra* note 156, at 636 (expressing concern that such paperwork may deter some physicians from providing needed services, forcing children into more crowded facilities).

177. See Henry Grabowski, *Product Liability in Pharmaceuticals: Comments on Chapters Eight and Nine*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 360,

fault insurance system of redressing at least some of these harms.<sup>178</sup> Generally funded by the pharmaceutical industry or private insurance, such systems compensate persons without the lengthy process or expense of tort law.<sup>179</sup> The Swedish Pharmaceutical Insurance is one model.<sup>180</sup>

In establishing the Swedish Pharmaceutical Insurance in July 1978, the Swedes concluded that the costs of legally establishing the elements of negligence or strict liability were higher than the costs incurred in a system of injury compensation lacking determinations of fault.<sup>181</sup> The system attempts to provide an efficient institutional

---

361 (Peter W. Huber & Robert E. Litons eds., 1991) (noting how United States, unlike other countries, relies on tort litigation and regulation for consumer protection).

178. See Diana Brahams, *No Fault Compensation Finnish Style*, THE LANCET, Sept. 24, 1988, at 733, 733-36 (describing Finnish system, which provides no-fault compensation for pain and suffering, loss of amenities, and lost earnings that exceed other benefits). Drug importers and manufacturers fund the Finnish system, which provides prompt compensation for injuries caused by drugs. *Id.* at 733. However, no compensation is provided for medically justifiable treatment where no equally effective procedure is available. *Id.* at 734; see also PHARMACEUTICAL ADMINISTRATION IN JAPAN, RELIEF SYSTEM FOR SUFFERERS FROM ADVERSE DRUG REACTIONS 87-94 (Pharmaceutical Affairs Bureau Ministry of Health and Welfare [Japan] ed., 4th ed. 1988) [hereinafter PHARMACEUTICAL ADMINISTRATION IN JAPAN] (delineating no-fault drug injury compensation system funded by industry and subsidized with additional charges imposed on manufacturer of injuring drug in individual cases); *infra* notes 181-97 and accompanying text (discussing Swedish system). In contrast to that in Finland and Sweden, relief under the Japanese system does not depend on whether the severity of the injury or the adverse reaction was known. PHARMACEUTICAL ADMINISTRATION IN JAPAN, *supra*, at 87.

New Zealand provides a comprehensive, no-fault personal injury compensation system aimed at restoring injured persons to fullest physical, mental, social, and economic capacity. See Michael Whincup, *Accident Compensation in New Zealand*, in PRODUCT LIABILITY INSURANCE AND THE PHARMACEUTICAL INDUSTRY: AN ANGLO-AMERICAN COMPARISON 203, 205-13 (Geraint G. Howells ed., 1990) (examining compensatory mechanism focusing on injury rather than causation providing universal comprehensive entitlement for all accidents to obviate anxiety, waste, and frustration of English system). The system is funded by a levy on employers (57%), the self-employed (12%), motor vehicle licenses (14%), and the government (17%). *Id.* at 207. In a departure from the scheme's focus on injury rather than causation, drug-induced injuries are compensated only if the side effect goes beyond what could reasonably be expected by a physician as likely to arise from a prescribed treatment. *Id.* at 211.

Germany, on the other hand, has adopted a statutory scheme that mandates the purchase of insurance and provides for liability based on strict liability for defects in development, production, or labeling. See Geraint G. Howells, *Drug Product Liability in West Germany and Sweden*, in PRODUCT LIABILITY INSURANCE AND THE PHARMACEUTICAL INDUSTRY: AN ANGLO-AMERICAN COMPARISON, *supra*, at 190-96 (finding liability restricted to "harmful effects which go beyond a measure defensible according to the findings of medical science" as equivalent to standard where the "therapeutic value outweighs the harmful effects" of drug). Salient features of the scheme are the concept of defectiveness and statutory limit on liability. *Id.* at 192.

Although most forms of insurance are essentially "no-fault," the term is commonly used in a narrower sense to describe insurance designed to replace the present system of negligence law and liability insurance. ROBERT E. KUTON, INSURANCE LAW § 4.10, at 246 (1971).

179. See Brahams, *supra* note 178, at 733 (explaining mechanics of no-fault system in Finland and noting that Finland's inquisitorial legal system deterred plaintiffs with its extraordinary slowness and poor chance of success). Interestingly, the Finnish Bar Association supported the no-fault system as being in the best interest of patients. Brahams, *supra* note 178, at 733.

180. See Brahams, *supra* note 178, at 733 (concluding that Swedish Pharmaceutical Insurance is efficient, effective, and vastly superior to fault-based liability systems).

181. See Carl Oldertz, *The Swedish Pharmaceutical Insurance—Construction and Rules*, in DETEC-

risk-utility analysis outside of an adversarial system.<sup>182</sup>

The system is not based on a statute, but rather was established by a voluntary agreement between the pharmaceutical industry and a consortium of insurance companies.<sup>183</sup> Funding of the system occurs entirely through levies on the industry.<sup>184</sup> Making a claim is exceptionally simple, requiring only that a form be filled out with the aid of a patient's physician rather than an attorney.<sup>185</sup> The form is submitted to the insurer and is reviewed, along with all pertinent medical records, first by the insurer's medical assessor and then by physicians who are employed as part-time advisors to the scheme.<sup>186</sup> A "preponderant probability" standard is utilized by reviewers to determine whether a drug caused an injury.<sup>187</sup> Questions of principle or disputes in indemnification are, if requested by an injured individual or an insurer, referred to The Drug Injury Committee, which will issue a statement on its findings with respect to the right to receive compensation.<sup>188</sup> If a dispute persists following the committee's findings, final determinations are decided by arbitrators in

---

TION AND PREVENTION OF ADVERSE DRUG REACTIONS 259, 261 (Harry Boström & Nils Ljungstedt eds., 1984) (noting that only attorneys gain from protracted litigation and uncertain outcomes of fault-based system).

182. See *id.* at 259, 261-62 (concluding that voluntary nature of scheme allows for faster changes in implementation than legislated system and cuts administrative costs and that use of arbitration boards for dispute resolution permits faster case handling than court system).

183. See Harry Boström & Pentti Ajo, *Pharmaceutical Insurance in Sweden and Finland*, in TRENDS IN PRODUCT LIABILITY LAW AND NO-FAULT COMPENSATION FOR DRUG-INDUCED INJURIES 9, 9 (Sheila R. Shulman & Louis Lasagna eds., 1990) (stating that in 1978 pharmaceutical industry manufacturers and importers, along with number of insurance companies, agreed to create scheme to complement existing system of patient insurance for injuries occurring in course of medical treatment). Although the system was created voluntarily, it was spurred by threat of legislation. See Howells, *supra* note 178, at 197 (describing how proposed legislation in Sweden providing for strict liability for drugs prompted voluntary insurance agreement).

184. See Boström & Ajo, *supra* note 183, at 9 (noting that participation in scheme is condition of manufacture, import, or sale of drugs in Sweden).

185. See Diana Brahams, *The Swedish Medical Insurance Schemes*, THE LANCET, Jan. 2/9, 1988, at 43, 46 (mentioning that lawyer may assist with claim but that this is not usual or necessary). As an added benefit, this system of injury communication enhances the patient-physician relationship. See Boström & Ajo, *supra* note 183, at 9 (explaining that preparation of claim is collaborative effort between patient and physician).

186. See Brahams, *supra* note 185, at 46 (noting that advisory physicians do not decide compensation amounts but rather provide opinions on causation and expected length of disabilities).

187. See Boström & Ajo, *supra* note 183, at 9 (explaining standard of review under Swedish system for determining injury causation). If it is known that a particular drug will cause injuries of a certain type, liability is often accepted, subject to guidelines of reasonably accepted risks, if it cannot be shown that there is another reason that is at least as probable. See Oldertz, *supra* note 181, at 265. A close temporal relationship between the taking of a drug and an injury is also strongly supportive of a claim. *Id.* at 265-66.

188. See Oldertz, *supra* note 181, at 270 (noting eight-member committee includes representatives for interests of patient, policyholder, medical science, medical authority, and also includes chairperson appointed by government who has deciding vote).

accordance with the Swedish Arbitration Act.<sup>189</sup>

To be compensated, a claimant must sustain a significant disability measured by bodily injury and/or time away from work.<sup>190</sup> The seriousness of the claimant's illness is an essential element in determining whether compensation is awarded; the more serious the condition, the greater risk an individual is expected to assume.<sup>191</sup> Recovery is minimal by American standards, providing a maximum of \$69,500, with an average indemnification of \$12,000.<sup>192</sup> These awards are nonetheless generally adequate because the program is only one of a wide network of medical insurance plans.<sup>193</sup>

Accepting compensation subrogates all other remedies to the insurance consortium, which has agreed not to pursue indemnification from individual manufacturers.<sup>194</sup> Recovery under the plan is therefore not strictly no-fault, inasmuch as inquiry into the injury is not merely focused on determining causation.<sup>195</sup> In fact, a very specific

---

189. See *id.* (noting that even if plaintiff loses case before arbitrator, insurer must pay arbitrator's remuneration if reasonable cause existed for dispute review).

190. See Boström & Ajo, *supra* note 183, at 9 (explaining that claimant must suffer inability to work for continuous period of 14 days, bodily impairment lasting similar period, permanent bodily injury, or death before claimant or claimant's heirs may obtain compensation). Known adverse reactions or reactions that should reasonably be accepted as a consequence of using a particular drug, however, are not indemnified unless the injury has significantly impaired a person's ability to work. *Id.* Elements in this determination include: (1) the nature and severity of the disease for which a drug was used; (2) the general health of the claimant; (3) the severity of the adverse drug reaction; and (4) the foreseeability of the adverse reaction. *Id.*

191. See Boström & Ajo, *supra* note 183, at 11 (noting that primary reasons for denying coverage include failure to establish causal connection, minor nature of injury, reaction is reasonably expected, or reaction is reasonable given the serious state of patient's condition). A reasonable guideline for compensation imposes a restriction that a drug injury has to be at least as great as the injury that would have been suffered had the drug not been used. See Oldertz, *supra* note 181, at 267 (questioning whether this principle ought to be used to reduce compensation by amount commensurate with injury that would have been suffered had disorder not been treated).

192. See Boström & Ajo, *supra* note 183, at 11 (reporting that limitations on recovery include caps on individual awards and total benefits and reductions in recoveries resulting from exceeding maximum yearly fund).

193. See Boström & Ajo, *supra* note 183, at 11 (observing that 70% of all benefits under Swedish Pharmaceutical Insurance are used to compensate pain and suffering and that lost wages, medical treatment, and nursing care are covered by other national programs). Indeed, some have argued that access to a universal health care system would significantly reduce the use of legal remedies for drug injuries. See Jon Cohen, *Is Liability Slowing AIDS Vaccines?*, 256 SCIENCE 168, 169 (1992) (noting that while nationalized health care may not be solution to vaccine liability, there is no reason to give pharmaceutical manufacturers special legal status that might not result in more or better vaccines).

194. See Boström & Ajo, *supra* note 183, at 13 (describing relationship between manufacturers and insurance companies under Swedish Pharmaceutical Insurance program); see also ROBERT E. KEETON & ALAN I. WIDISS, *INSURANCE LAW: A GUIDE TO FUNDAMENTAL PRINCIPLES, LEGAL DOCTRINES, AND COMMERCIAL PRACTICES* § 3.10(a) (1988) (defining subrogation as equitable doctrine facilitating adjustment of rights to avoid unjust enrichment by substituting one person or entity in place of another in regard to claim or right that second person or entity has against third party).

195. See Brahams, *supra* note 185, at 44 (commenting that "no-fault" is inaccurate because

risk-utility analysis is performed before compensation is awarded.<sup>196</sup> As a result, decisions take on a measure of uniformity over time and provide both manufacturers and consumers with a degree of certainty of rights and responsibilities that is not possible at common law.<sup>197</sup>

#### IV. EFFICIENCY ANALYSIS OF PHARMACEUTICAL PRODUCT LIABILITY

The costs of pharmaceutical product liability consist of direct expenditures for defending liability claims<sup>198</sup> and indirect costs to consumers reflected in the chilling of research,<sup>199</sup> the elevated price of drugs,<sup>200</sup> and the simple unavailability of particular therapies.<sup>201</sup> Such costs are reasonable only if product liability enhances product safety beyond that which federal regulation provides and/or if product liability efficiently spreads the risk of drug-induced injuries by compensating those injured. Unfortunately, product liability has not brought about either of these benefits.<sup>202</sup>

Any analysis of the costs and benefits of pharmaceutical product liability suffers from a serious paucity of relevant data. Beyond the specific examples noted in Part I,<sup>203</sup> very little quantitative data exists to document the actual costs or benefits to consumers of product liability litigation.<sup>204</sup> Individual manufacturers are understandably unwilling to discuss the expense of in-house counsel, outside attorneys, trial preparation, settlements, and judgments.<sup>205</sup>

---

scheme provides compensation without apportioning blame for unanticipated reactions or events arising from medical treatment in which error was causal factor).

196. See Boström & Ajo, *supra* note 183, at 9 (stating that inquiry focuses on several considerations such as nature and severity of treated disease, general health of patient, severity of reaction, and foreseeability of reaction).

197. Cf. Lasagna, *supra* note 17, at 337 (arguing that product liability litigation is unpredictable, and risks associated with liability are impossible to quantify).

198. See Lasagna, *supra* note 17, at 337 (explaining that costs of litigation include legal advice and services, compensatory damages, and possible punitive damages).

199. See Lasagna, *supra* note 17, at 336-37 (noting that costs of drug research coupled with liability risks adversely affect pharmaceutical development).

200. See *supra* notes 39-40 and accompanying text (mentioning effects of product liability on vaccine costs).

201. See *supra* notes 18-22, 49-53 and accompanying text (discussing current unavailability of drugs such as Halcion and Bendectin as result of product liability claims).

202. See *supra* note 31 and accompanying text and *infra* notes 235-37 and accompanying text (positing that product liability does not significantly enhance drug safety over that provided by federal regulation and describing how system fails to compensate drug-induced injuries adequately).

203. See *supra* notes 39-40 and accompanying text (examining drug costs with respect to vaccine development).

204. See Lasagna, *supra* note 17, at 335 (noting inadequacies of tracking court settlements and paucity of data on liability costs to pharmaceutical industry).

205. See Lasagna, *supra* note 17, at 335 (observing that out of court settlements are common and that publicizing their size would encourage new suits or increase future settlement demands).

Jury awards are often reduced,<sup>206</sup> and settlements are frequently sealed.<sup>207</sup> Moreover, liability expenditures cannot be accurately distinguished from other legal costs.<sup>208</sup>

In addition, indirect assessments of the costs and benefits of product liability are not wholly adequate. One recent study of insurance expenditures found that for those pharmaceutical companies studied, losses were nearly double the amount of premiums paid,<sup>209</sup> and these losses represented an increase of more than 250% between 1980 and 1984.<sup>210</sup> The authors reported that relatively few pharmaceutical companies were represented in their study and that the study period was one of considerable competition within the insurance industry, however.<sup>211</sup> Another study found a strong upward trend in federal product liability filings against the pharmaceutical industry.<sup>212</sup> The study revealed, though, that only five companies accounted for seventy-two percent of the filings and that two of these five, A.H. Robbins and Merrell Dow, accounted for sixty percent of filings owing to the Dalkon Shield and Bendectin disputes, respectively.<sup>213</sup>

The costs of product liability, however large, add to the already extraordinary costs and risks of new drug development.<sup>214</sup> Research and development of a new chemical entity now takes, on average, over twelve years and costs, on average, over \$230 million,

---

206. See Swazey, *supra* note 31, at 297 (relating senior pharmaceutical company attorney's remarks that "nuisance money" is "real hassle" because companies are forced to settle by threat of runaway juries even though jury awards are often reduced on appeal).

207. See Diana Brahams, *Secrecy and Product Liability Litigation*, THE LANCET, Sept. 22, 1990, at 737, 737 (stating that sealing of files as part of settlement deal is commonplace in United States).

208. See Lasagna, *supra* note 17, at 335 (discussing difficulty in distinguishing between percentage of costs attributable to product liability and to other routine legal needs).

209. W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation*, in THE LIABILITY MAZE, *supra* note 17, at 97 (Table 3-8) (assessing data compiled from Insurance Service Office for product liability coverage between 1980-1984).

210. Viscusi & Moore, *supra* note 209, at 97.

211. Viscusi & Moore, *supra* note 209, at 85.

212. See TERENCE DUNGWORTH, THE RAND CORP., PRODUCT LIABILITY AND THE BUSINESS SECTOR: LITIGATION TRENDS IN FEDERAL COURT, 38-42 (1988) (identifying and evaluating trends in product liability claims brought against major pharmaceutical manufacturers between 1974 and 1986).

213. Dungworth, *supra* note 212, at 40-41; see also Eisenberg & Henderson, *supra* note 23, at 801 (finding drop in plaintiff success rate in pharmaceutical product liability suits from 48% to 38% between 1979 and 1989 in federal court cases with published opinions).

214. See Joseph A. DiMasi, *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107, 121-26 (1991) (examining research and development costs of 12 United States-owned pharmaceutical firms). The requirement for increased preapproval patient exposures, heightened complexity and scope of research required, and adoption of expensive new technologies have added to costs. *Id.* at 133. As the American population ages, manufacturers have also begun to focus on treatments of chronic and degenerative disorders, which require longer and more costly development. *Id.* at 132-33.



twice the cost of ten years ago.<sup>215</sup> For every 10,000 chemical entities examined, twenty enter animal studies and ten of these enter human trials, but only one gains FDA approval.<sup>216</sup> Furthermore, estimating the additional postapproval cost of liability is nearly impossible given that adverse reactions may not appear during preapproval testing.<sup>217</sup>

Critics of tort reform might point to equally impressive profits made by the pharmaceutical industry as an indication that whatever the cost of liability, the industry is more than able to absorb the risk of liability under the current system. These profits are growing at a time when drug prices are increasing faster than other medical expenses.<sup>218</sup> A recent staff report of the Senate Special Committee on Aging documented a number of startling statistics, which included: (1) during the first six months of 1991, the annualized general inflation rate was 3.3%, while the annualized prescription drug inflation rate was 11.2%;<sup>219</sup> (2) the drug industry has an average annual profit margin of 15.5%, which is more than three times the annual profit margin of the average Fortune 500 company;<sup>220</sup> (3) the average American pays 62% more for prescription drugs than the average Canadian citizen and 54% more than the average European citizen;<sup>221</sup> and (4) drug manufacturers will spend over one billion

---

215. DiMasi, *supra* note 214, at 125-26 (measuring costs in 1987 dollars). Of the compounds that survive preclinical testing and continue through human drug trials, only 23% are ultimately approved by the FDA. *Id.*

216. See P. Roy Vagelos, *Are Prescription Drug Prices High?*, 252 *SCIENCE* 1080, 1082 (1991) (providing odds for getting pharmaceutical to market and noting that statistics do not reflect increased difficulties concerning new technologies and more complex diseases). Research and development costs, while high in absolute terms, pale in comparison to the benefits derived from monies saved as a result of morbidity and mortality prevented. See Craig C. White et al., *Benefits, Risks and Costs of Immunization for Measles, Mumps and Rubella*, 75 *AM. J. PUB. HEALTH* 739, 739-40 (1985) (noting that vaccination programs prevented approximately 1.5 million rubella cases, 2.1 million mumps cases, and 3.3 million measles cases). The bill for the nation's measles, mumps, and rubella vaccination programs in 1983 came to \$100 million, while the cost of treating these disorders would have been \$1.4 billion. See *id.* at 741 (Table 2) (compiling statistical data on vaccination programs from 1983).

217. See ALFRED GILMAN, GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 64 (8th ed. 1990) (observing that one-half of both useful and adverse effects of drugs are not recognized during clinical trials and are later reported by practicing physicians).

218. See Gina Kolata, *Why Drugs Cost More in U.S.*, *N.Y. TIMES*, May 24, 1991, at D1 (reporting economists' claims that drug companies, even foreign ones, charge Americans disproportionate share of companies' research costs). According to industry representatives, however, high prices are the cost of a preeminent drug industry. *Id.* at D3; see also Vagelos, *supra* note 216, at 1081 (noting increased research and development costs, increased preapproval requirements, and resulting diminished period of patent protection as among elements causing increased drug prices).

219. STAFF OF SENATE SPECIAL COMM. ON AGING, 102D CONG., 1ST SESS., THE DRUG MANUFACTURING INDUSTRY: A PRESCRIPTION FOR PROFITS 28-29 (Comm. Print 1991).

220. *Id.* at 39.

221. *Id.* at 13.

dollars more on marketing and advertising than on research.<sup>222</sup> Such profits may merely reflect the fiduciary duty of a manufacturer's directors and officers to the manufacturer's stockholders.<sup>223</sup> The argument that drug profits are excessive takes little notice of the chilling effect that product liability has on pharmaceutical research and development. The issue, rather, is whether product liability deters unacceptable risks and sufficiently compensates those injured by adverse drug reactions to warrant its continued negative impacts on drug development and availability.

There is little evidence to support an adequate risk-deterrent function under negligence theory when a manufacturer cannot know before marketing a drug what a jury will find a company knew or should have known about the harm that drug might cause.<sup>224</sup> Additionally, assessing causation of adverse drug reactions is extremely difficult and expensive.<sup>225</sup> The presentation of often complex scientific issues of causation through the testimony of competing expert witnesses can create considerable unpredictability at trial.<sup>226</sup> This is especially problematic when such experts express opinions of dubi-

---

222. *Id.* at 10. Moreover, the drug industry currently receives a \$2 billion nonresearch and development-oriented tax credit, *id.* at 17, giving it 264% more in tax credits per employee than it pays in wages. *Id.* at 18. At current inflation trends, an average \$20 prescription purchased in 1980 will increase by 600% to \$120.88 by the year 2000. *Id.* at 8.

223. See Vagelos, *supra* note 216, at 1081 (arguing for alternative perspective on pharmaceutical industry's high profitability).

224. See *supra* notes 135-38 and accompanying text (discussing jury determination of adequacy of manufacturer labeling and minimal protective effect provided manufacturers through compliance with FDA regulations).

225. See Claudio A. Naranjo et al., *Idiosyncratic Adverse Drug Reactions: Challenges to Clinical Pharmacologists*, in *IDIOSYNCRATIC ADVERSE DRUG REACTIONS: IMPACT ON DRUG DEVELOPMENT AND CLINICAL USE AFTER MARKETING 1-7* (Claudio A. Naranjo & Judith K. Jones eds., 1990) (discussing reasons why adverse drug reactions are not detectable in standard premarketing and postmarketing studies and consequently require special procedures for their detection, assessment, and verification).

226. See *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 266-67 (N.D. Ga. 1985) (describing judge's close attention to demeanor and tone in determining credibility of expert testimony), *modified*, 788 F.2d 741 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986); see also Huber, *supra* note 127, at 333 (noting that Ph.D. holder can be found to swear to almost any "expert" opinion); Peter Huber, *Junk Science in the Courtroom*, *FORBES*, July 8, 1991, at 68, 71 [hereinafter Huber, *Junk Science*] (noting that since 1975 both federal and state courts have been more tolerant of scientific testimony). The *Wells* case resulted in a \$5.1 million judgment for the plaintiff primarily on the strength of unpublished and inconclusive studies associating birth defects with spermicidal jelly. See *Wells*, 615 F. Supp. at 294 (relying on unpublished 1976 Oechsli study, 1977 Smith study, and 1975 Population Reports article entitled "Vaginal Contraceptives—A Time for Reappraisal?"); see also Huber, *Junk Science*, *supra*, at 70 (arguing that judgment against Ortho Pharmaceutical Corp. was based largely on strength of "grossly inaccurate" study).

ous scientific validity<sup>227</sup> not readily understandable by a lay jury.<sup>228</sup> A report of the Attorney General's Tort Policy Working Group found considerable abuse of expert testimony in drug liability cases.<sup>229</sup> Moreover, even if a causal relationship is determined at trial, the jury is often no better qualified to calculate damages reasonably than it was to resolve scientific disputes.<sup>230</sup>

Strict liability theory imposes a risk-deterrent effect by encouraging manufacturers to invest in product safety.<sup>231</sup> This rationale, however, is less compelling in the case of pharmaceuticals that have extensive social utility but are inherently risky because of the varied reactions they may induce in individual human physiologies.<sup>232</sup> Strict liability may drive certain products off the market and deter research despite aggregate health benefits that are greater than the risks of injury.<sup>233</sup> Most importantly, exposing pharmaceutical manufacturers to strict liability fails to take into account the FDA's assessment of social utility. Strict liability thus creates excessive administrative or transactional costs in the form of litigation expenses, with little or no improvement in safety as measured by those actually injured.<sup>234</sup>

---

227. See Robert L. Brent, *The Irresponsible Expert Witness: A Failure of Biomedical Graduate Education and Professional Accountability*, 70 PEDIATRICS 754, 755 (1982) (maintaining that some experts are willing to express opinions in courtroom that they would not voice in scientific forum). Dr. Brent suggests the quality of expert testimony would improve if depositions were exposed to peer review. *Id.* at 761.

228. See Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Defense to Medical Practice Guidelines*, 77 CAL. L. REV. 1483, 1496 (1989) (noting that medical expert testimony is often too complex for juries to understand).

229. See REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY 62-63 (1986) (finding personality and demeanor of expert witnesses were often more critical in determination of issues than "decades of evolving scientific and medical investigations and thought"); see also Marc S. Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 395 (1990) (delineating major societal implications of abuse of expert testimony in pharmaceutical product liability cases).

230. See Note, *supra* note 142, at 781 n.44 (observing that tendency for overcompensation in such situations is great because jury sympathizes with injured plaintiffs and perceives defendant manufacturing companies to have "deep-pockets").

231. See Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 745-47 (1990) (noting courts' belief that product sellers will lack incentive to promote safety absent forced responsibility for product-related injuries).

232. See, e.g., Bruce S. Bochner & Lawrence M. Lichtenstein, *Anaphylaxis*, 324 NEW ENG. J. MED. 1785, 1786 (1991) (stating that no known epidemiologic characteristic exists that reliably identifies those at risk for serious drug sensitivity, other than previous exposure).

233. See Huber, *supra* note 127, at 304-05 (finding that consumers as whole benefit by absorbing small risk of individual significant adverse reactions when loss of drug entirely would deprive many more consumers of drug's considerable utility).

234. See GUIDO CALABRESI, *THE COST OF ACCIDENTS* 102-03 (1970) (arguing that it may be cheaper to achieve societal goals through direct means rather than through indirect means such as imposing tort liability); Ausness, *supra* note 231, at 753 (arguing that FDA's licensing process may ensure pharmaceuticals are properly evaluated and any additional costs brought by strict liability would exceed any marginal benefits gained therefrom).

The tort system fails even more completely as a means of compensating injuries.<sup>235</sup> The initial difficulty of getting into the legal system includes, by itself, the rather formidable obstacles of recognizing the causal relationship between an injury and a drug, identifying legal privileges, and gaining access to competent counsel.<sup>236</sup> A vast majority of drug-induced injuries go uncompensated as a result of the rigors of the tort system.<sup>237</sup>

Empirical data from the study of medical negligence demonstrates the inadequate compensatory mechanism of the common law.<sup>238</sup> The Harvard University School of Public Health examined over 31,000 medical records in fifty-one hospitals in New York in 1984.<sup>239</sup> Of the patients who suffered adverse events due to medical personnel negligence, less than three percent filed claims.<sup>240</sup> More importantly, the study concluded that the cost of compensating all injured patients for medical expenses, lost wages, fringe benefits, and lost household production was considerably less than the \$1 billion paid in malpractice costs in 1984.<sup>241</sup> Indeed, this coverage could include all iatrogenic injuries of greater than six months whether or not they were caused by negligence.<sup>242</sup> There is no evidence to suggest that the common law is any better at compensating

---

235. See Note, *supra* note 142, at 783-85 (observing that excessive inefficiencies of tort law result in inadequate compensations and overdeterrence); see also A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, 325 NEW ENG. J. MED. 245, 249 (1991) (noting reasons why few patients pursue tortious medical claims).

236. See Note, *supra* note 142, at 784 (finding that such hurdles make recovery highly unlikely for majority of injured persons).

237. See Abel, *supra* note 11, at 796-97 (citing numerous studies documenting infrequent recovery for tortious injury).

238. See Localio et al., *supra* note 235, at 248, 250 (concluding that evidence shows that civil justice system rarely compensates negligently injured patients and usually fails to identify substandard health care providers, much less hold them responsible, inasmuch as so few negligently injured patients find their way into system).

239. HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK 2-3 (1990) [hereinafter HARVARD STUDY, PATIENTS, DOCTORS, AND LAWYERS].

240. See Localio et al., *supra* note 235, at 247-48 (Figure 1) (reporting that out of 27,179 adverse events due to negligence, only 415 (2%) resulted in malpractice claims). Over half of the more seriously injured patients were under the age of 70, resulting in significant losses in earnings. *Id.* (finding number of persons under age of 70 negligently injured to be 2,834). The authors questioned whether it is possible for the malpractice system to have a beneficial effect on medical care if so few with legitimate claims actually find their way into court. *Id.* at 249.

241. See HARVARD STUDY, PATIENTS, DOCTORS, AND LAWYERS, *supra* note 239, at 11-7 (noting cost of compensating all such injuries was only slightly more than malpractice premiums alone).

242. *Id.* Subsequent examination of a no-fault system of injury compensation has found the system to be more efficient than the common law. See Randall R. Bovbjerg et al., *Obstetrics and Malpractice: Evidence on the Performance of a Selective No-Fault System*, 265 JAMA 2836, 2842-43 (1991) (concluding that accelerated compensation system using adverse event probabilities would more quickly compensate injured patients at less cost than current liability-based system while serving to develop useful medical data).

drug-induced injuries than it is at compensating those injured by medical malpractice.<sup>243</sup> A more efficient remedy is a no-fault insurance scheme.

## V. RECOMMENDATIONS

An American no-fault insurance system would draw on the models set forth by the National Childhood Vaccine Injury Act<sup>244</sup> and the Swedish Pharmaceutical Insurance program.<sup>245</sup> The system would require all manufacturers to participate and would be funded by the industry through an excise tax on medications sold across the United States.<sup>246</sup> This would shield the American taxpayer from directly funding the system and would allocate risk to members of the industry in some proportion to their market share of drug sales.

The system would be administered through the Department of Health and Human Services (HHS), which would establish a review board and procedures for determining eligibility for relief and means of compensation.<sup>247</sup> Review boards would oversee inquisitory rather than adversarial proceedings, and determinations would focus solely on causation and claim eligibility.<sup>248</sup>

Eligibility would be based on a reasonableness standard that would take into account the seriousness of an injury and the seriousness of a patient's condition.<sup>249</sup> Moreover, eligibility standards would reflect the need to compensate serious injuries regardless of foreseeability.<sup>250</sup> Causation would be accepted if the drug is found

---

243. See HUBER, *supra* note 32, at 225-26 (finding administrative costs of judicial system are always more costly than purchase of relevant insurance by all exposed to injury).

244. See *supra* notes 154-76 and accompanying text (discussing National Childhood Vaccine Injury Act).

245. See *supra* notes 178-97 and accompanying text (examining Swedish Pharmaceutical Insurance).

246. See *supra* notes 218-22 and accompanying text (detailing considerable profits within industry that would permit coverage of both compensation and administrative costs).

247. Cf. *supra* note 186 and accompanying text (detailing use of independent insurance reviewers in Swedish Pharmaceutical Insurance System); *supra* note 158 and accompanying text (noting use of United States Claims Court for arbitrating claims under National Childhood Vaccine Injury Act). Placement of the scheme within HHS would enhance the program's public health function by providing a means by which adverse drug reactions could be readily detected.

248. Cf. *supra* note 158 (describing fact-finding focus in determining compensation eligibility under National Childhood Vaccine Injury Act to encourage claimants to seek remedy under Act).

249. Cf. *supra* note 190 (outlining Swedish calculus of reasonable compensation). Denying compensation to persons suffering reactions that were reasonable in light of the seriousness of their condition furthers the principle that manufacturers are not absolute insurers of their products. Patients would still be expected to accept some risk as a condition of treatment.

250. Cf. Brahams, *supra* note 185, at 44 (noting that under Swedish system compensation of serious injury is not limited by unforeseeable nature of injury). Compensating unforeseen injuries would have the effect of encouraging the reporting of unforeseen reactions. Not compensating reasonably foreseeable injuries would retain the incentive among manufacturers to

more likely than not to have caused the injury.<sup>251</sup> This standard would be based on a reasonable medical certainty, as assessed by experts in medicine and pharmacology. Compensation levels would provide reasonable coverage of medical expenses, lost wages, and rehabilitation.<sup>252</sup> The ultimate aim of the regulations would be to provide an enhanced opportunity for compensation over that provided by the common law.<sup>253</sup>

A remedy in tort would be available only after exhaustion of all administrative procedures under the program.<sup>254</sup> Accepting compensation under the scheme would preempt any remedy at common law.<sup>255</sup> Compensation at common law would be available only upon a showing by clear and convincing evidence that a manufacturer willfully failed to comply with federal regulations or withheld safety information.<sup>256</sup>

### CONCLUSION

It is time to stop pleading with the judiciary to take uniform notice of scientific expertise, and it is time to take lawyers out of the process of determining public safety.<sup>257</sup> Unfettered drug development and drug injury compensation are social goods that should be pursued without resorting to an adversarial legal system. The regula-

---

continually evaluate the safety profile of their products. Compensating serious injuries whether or not they were foreseeable promotes the compensatory function of strict liability without the administrative costs of the common law.

251. *Cf. supra* note 161 and accompanying text (noting that Congress adopted preponderance of evidence standard for eligibility under National Childhood Vaccine Injury Program); *supra* note 187 and accompanying text (describing preponderant probability standard under Swedish Pharmaceutical Insurance).

252. *Cf. supra* notes 164, 191 and accompanying text (detailing compensation schemes under Swedish system and National Childhood Vaccine Injury Act).

253. *Cf. supra* note 165 and accompanying text (examining explicit congressional intent to encourage remedies provided under National Childhood Vaccine Injury Act).

254. *Cf. supra* note 165 and accompanying text (explaining deterrent mechanism under National Childhood Vaccine Injury Act against seeking remedy at common law). Retaining a tort remedy in some fashion would maintain some vestige of its deterrent effect.

255. *Cf. supra* notes 166-94 and accompanying text (noting that acceptance of compensation under Swedish system and National Childhood Vaccine Injury Act precludes remedy at common law).

256. *Cf. supra* note 169 and accompanying text (discussing Congress' explicit adoption under National Childhood Vaccine Injury Act of comment k and presumption that drug warning is adequate if approved by FDA).

257. See Howard A. Denmark, *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, 446 (1990) (recommending that courts extend great weight to peer-reviewed scientific observation as decisionmaking tool in complex causation litigation involving drugs). *But see* Victor E. Schwartz & Liberty Mahshigian, *Issues in Tort Reform: National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 396 (1987) (finding no-fault system of National Childhood Vaccine Injury Act applicable to very narrow product with relatively few adverse events that are well defined as triggers for compensation, and inapplicable to majority of drugs).

tory demands of the common law simply do not provide a risk deterrent function that is more comprehensive than the federal regulatory system currently in place. Moreover, the compensatory function of the common law is wholly inadequate, providing precious few injured persons a sufficient remedy.

A no-fault system of drug injury compensation would provide a more efficient means of compensating persons injured by adverse drug reactions, enhance public safety by linking compensation under the scheme to the current adverse drug reaction reporting system, and provide manufacturers with predictability as to the extent of liability. Congress should take the initiative and establish a compensation system without fault for adverse drug reactions as an affirmative alternative to the common law.

