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# THE RESOLUTION OF LEGAL IMPEDIMENTS TO THE MANUFACTURE AND ADMINISTRATION OF AN AIDS VACCINE

John P. Wilson\*

## I. INTRODUCTION

Fatalities from Acquired Immune Deficiency Syndrome (AIDS)<sup>1</sup> are increasing at an accelerating rate, and the loom-

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1. AIDS is the end condition of a viral infection. This opinion is held by the overwhelming majority of responsible scientists and others who are working in the field. However, there are more than two dozen cases worldwide that exhibit AIDS-like features yet exhibit no sign of the AIDS virus. David Perlman, *A Race to Explain Cases of AIDS Without HIV*, S.F. CHRON., June 24, 1992, at A20 (describing reports at the Eighth International Conference on AIDS in Amsterdam in July, 1992) [hereinafter Perlman, *A Race*]. So far, laboratory analysis has shown only that the causative organism, if it exists, is not related to any of the four known human retroviruses. *Id.* See also David Perlman, *People Who Have AIDS But Not HIV*, S.F. CHRON., July 20, 1992, at A1.

The AIDS agent is the Human Immunodeficiency Virus, or HIV. The HIV virus is transmitted primarily through sexual contact. Lisa M. Krieger, *Long-term Survivors Defy the Statistics*, S.F. CHRON., June 21, 1992, at A14. It may also be transmitted through needle-sharing by intravenous drug users, through infected blood used in transfusions, and by passage across the placental barrier from an infected mother to her fetus. Other modes of transmission, such as biting (which would inject the virus from saliva into a wound), may be possible but are highly unlikely. *Id.* Once a person has an HIV infection, the progression of the disease to AIDS appears to be relentless, although there are, to date, a few healthy, long-term survivors who coexist with the disease. *Id.* The rapidity of the onset of AIDS varies from individual to individual and may take many years. Perlman, *A Race*, *supra*, at A20.

ing shadow of a pandemic<sup>2</sup> of enormous magnitude is confronting every region of the world. There is no cure.

In the United States, there were 100,000 cases of AIDS reported in August 1989, eight years after the epidemic began.<sup>3</sup> In the next twenty-six months, another 100,000 cases were added to the toll.<sup>4</sup> Through March 1992, the national Center for Disease Control (CDC) reported that there were 218,000 cases of AIDS in the United States, and 139,000 people had died from the disease.<sup>5</sup>

Grim as these figures are, they pale in comparison to the dimensions of the worldwide pandemic. The Global AIDS Policy Coalition<sup>6</sup> has reported that nearly thirteen million people worldwide now have the HIV infection and that, by the end of the decade, the virus will infect at least thirty-

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2. An epidemic is the communication of a disease within a community, area, or region at one time. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, 762, (3d ed. 1986). In current usage by epidemiologists, a pandemic refers to the spread of a disease over a wide geographic area affecting an exceptionally high proportion of the population. *Id.* at 1629. See also David Perlman, *Report Predicts 38 Million Adult HIV Cases by Year 2000*, S.F. CHRON., June 4, 1992, at A20 [hereinafter Perlman, *Report*]. The influenza pandemic of 1918 is an example. *Id.* So is AIDS.

3. *AIDS Cases Grow at Accelerated Rate*, S.F. CHRON., Jan. 17, 1992, at A3.

4. *Id.*

5. Erik Eckholm, *AIDS, Fatally Steady in the U.S., Accelerates Worldwide*, N.Y. TIMES, June 28, 1992, at E5. The Center for Disease Control (CDC) roughly estimates that one million Americans are infected with HIV and that 40,000 to 80,000 are newly infected each year. *Id.* "AIDS and related infections are the leading cause of death among men ages 25 to 44 in 65 U.S. cities . . . [A]mong women of the same age, AIDS was the main cause of death in nine cities . . ." *Heavy AIDS Toll Among Baby Boomers*, S.F. CHRON., June 16, 1993 at A4. The CDC report notes "the rapidly increasing magnitude of the HIV epidemic" in this country and the changing composition of the victims. *AIDS Cases Grow at Accelerated Rate*, *supra* note 3, at A3. AIDS cases traceable to heterosexual transmission increased to 7% of the total (compared to 5% in the first 100,000 cases), and cases involving bisexual or homosexual men declined from 61% of the first 100,000 cases to 55% of the second 100,000. *Id.* Conversely, the number of women with the disease in each group increased from 9% to 12%. *Id.* The lifetime cost of treatment per patient has risen to \$102,000. Daniel Q. Haney, *Cost of Treating AIDS Patients Soars*, S.F. CHRON., July 23, 1992, at A11.

6. The Global AIDS Policy Coalition is comprised of an international team of AIDS experts drawn from 22 countries under the direction of Dr. Jonathan Mann of the International AIDS Center at Harvard University. Perlman, *Report*, *supra* note 2, at A2.

eight million adults and possibly as many as 110 million.<sup>7</sup> Across the globe, nearly two-and-one-half million people have already died of the disease.<sup>8</sup> Moreover, at least ten million children must be added to the total of infected persons by the year 2000.<sup>9</sup>

The magnitude of the pandemic has grown one hundred-fold since AIDS was first discovered in 1981.<sup>10</sup> The world is confronting a new, virulent, and lethal disease whose impact may rival the devastation caused by syphilis when it ravaged Europe in the early sixteenth century.

Without question there is desperate need for a treatment to impede the growth of, and eventually eradicate, the disease. The accelerating nature of the disaster makes efforts to this end imperative. Pharmaceutical companies in the United States and abroad are diligently searching for a means to combat the infection.<sup>11</sup> So far, however, no cure has been found, and it will be years, if ever, before an effective preventive vaccine can be devised, tested, and distributed.<sup>12</sup>

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7. *Id.* Sub-Saharan Africa is the most prevalent area, with over 6.5 million current cases of HIV infection, but the disease is spreading rapidly in Asia. Eckholm, *supra* note 5, at E5.

8. Perlman, *Report, supra* note 2, at A2.

9. *Id.* "In some African and Caribbean countries, 10% of the AIDS cases are in children under the age of five." Carol Levine, *Children in HIV/AIDS Clinical Trials: Still Vulnerable after All These Years*, 19 *LAW, MED. & HEALTH CARE* 231, 232 (1991) (citing UNICEF, *CHILDREN AND AIDS: AN IMPENDING CALAMITY* 1, 4-5 (1990)). In the United States, "AIDS is expected to move into the five leading causes of death in children in the next few years." *Id.* (citing SECRETARY'S WORK GROUP ON PEDIATRIC HIV INFECTION AND DISEASE, DEPARTMENT OF HEALTH AND HUMAN SERV., FINAL REPORT 1, 7 (1988)).

10. Perlman, *Report, supra* note 2, at A2. Unlike earlier years, when many American observers perceived AIDS as primarily an affliction restricted to homosexuals and intravenous drug users, there is now an appreciation that, in other parts of the world, AIDS overwhelmingly spreads through heterosexual contact. *Id.* Indeed, homosexual relations and intravenous drug use account for only 22% of all cases of HIV infection worldwide, whereas heterosexual relations account for 71%. *Id.* See also Eckholm, *supra* note 5, at E5. Women are the fastest-growing group of HIV-infected people and now constitute close to half of all cases. David Perlman, *Women Face Growing Risk from AIDS*, *S.F. CHRON.*, July 21, 1992, at A1. As noted earlier, this same trend is evident in the United States. See *supra* note 5 and accompanying text.

11. See Susan Okie, *AIDS Vaccine Test Planned—It May Be Misguided*, *S.F. CHRON.*, Jan. 4, 1992, at A5. See also Kellen F. Cloney, Note, *AIDS Vaccine Manufacturers v. Tort Regime: The Need for Alternatives*, 49 *WASH. & LEE L. REV.* 559, 561 (1992).

12. There are two possible kinds of vaccines. See David Perlman, *New Reports of Progress on Post-AIDS Therapies*, *S.F. CHRON.*, July 23, 1993, at A1 [hereinafter Perlman, *New Reports*]. One, a therapeutic vaccine, is designed to

Formidable obstacles lie in the path, yet a preventive vaccine, if it can be developed, would be a near-miraculous remedy for the afflicted populations of the world. Like smallpox, this dreadful scourge might then pass away.

This article addresses the legal impediments to the development and distribution of a preventive vaccine, focusing on both the perception of these impediments and their substantive reality. First, the article describes the detailed regulations of the Food and Drug Administration (FDA) with respect to the testing and approval of new drugs and vaccines. Next, the article provides a background description of the litigation that has beset the pharmaceutical industry in recent years. The article then discusses whether there is a litigation crisis that may dissuade drug companies from manufacturing and distributing an AIDS vaccine. The article also discusses the extent to which punitive damage verdicts in the product liability area impede innovation and the extent to which doctrinal developments in product liability law chill or encourage the distribution of drugs and vaccines. Four statutes that provide varying degrees of protection to vaccine manufacturers are described and analyzed. Lastly, recommendations for a federal statute are set forth that attempt to ensure fair compensation to those who are injured through administration of a vaccine while limiting the scope of liability.<sup>13</sup>

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stop the progression of a disease once an infection has already occurred. *Id.* Another, a preventive vaccine, is administered to stop infection from occurring at all. *Id.* Unless otherwise designated for the sake of clarity, this article uses the term "vaccine" to include both types.

13. In the United States, legal impediments to the development of a preventive vaccine are primarily in the form of suits based on a theory of product liability. As written, this article is not intended to slight the problems associated with the development of a therapeutic vaccine. However, most, if not all, of the issues related to the development of a preventive vaccine will apply—though obviously in a different context—to the development of a therapeutic vaccine. There are two major differences: (1) testing of a therapeutic vaccine will take place with consenting individuals who have already contracted an HIV infection, and (2) the time frame for determining the vaccine's efficacy will be relatively brief.

In the development of either kind of vaccine, the initial problem to be confronted is the variable nature of the virus itself, which mutates rapidly and exists in thousands of forms. *Vaccine Guards Monkeys from Simian AIDS*, S.F. CHRON., Jan. 24, 1992, at A12. See also Larry Gostin, *Vaccination for AIDS: Legal and Ethical Challenges From the Test Tube, to the Human Subject, Through to the Marketplace*, 2 AIDS & PUB. POL'Y J. 9, 10 (1987). There are seven distinct groups found in different regions of the world (although Africa contains six of the seven), and these groups vary genetically from each other

much more than do viruses that cause other diseases. Okie, *supra* note 11, at A5. Other reports indicate that there are five distinctly different varieties of the virus, based upon comparisons of the molecular structure of a major gene that carries the code for the interior of the virus. David Perlman, *New Variants of HIV Reported*, S.F. CHRON., July 21, 1992, at A7 [hereinafter Perlman, *New Variants*]. Most of the strains of the virus in North America and Europe are similar, but they differ genetically from strains found on other continents. *Id.*

As a result, a vaccine that may work in North America may not be effective in, for instance, Southeast Asia or Africa. Different vaccines, designed to neutralize different viral strains in different host countries, must be developed. Their objective will be to stimulate the production of antibodies to attack the virus directly or to develop an individual's cell immunity to viral attack. Gostin, *supra*, at 13. Unfortunately, the current tests to determine HIV infection depend upon the detection of antibodies to the disease in a person's blood, so it is clear that antibodies alone do not prevent the ultimate disease. However, they might if already present in a person prior to entry of the virus. *Id.* Traditional preventive vaccines are administered in this way (i.e., before a person contracts a disease), and they are ineffective if administered once the disease is present. *Id.*

As is the case with polio, an AIDS vaccine might consist of either a live or a killed virus. *Id.* A killed-virus vaccine is preferable, as it would not involve the potential introduction of infection into an otherwise healthy person. *Id.* Both approaches would involve the stimulation of neutralizing antibodies. *Id.* At the present time, however, the preventive AIDS vaccines being tested in the United States on animals involve killed viruses or genetically altered segments of the virus whose infectious nature has presumably been eliminated. Perlman, *New Reports*, *supra* note 12, at A1, A10. Several small-scale tests of therapeutic vaccines on human volunteers have also taken place, and limited success has been reported in tests of two preventive vaccines on healthy human subjects. David Pearlman, *Encouraging News on AIDS Vaccines*, S.F. CHRON., June 9, 1993, at A2. These vaccines use one or more protein molecules from the outer envelope or core of the virus to stimulate the body's immune system to produce antibodies to the virus. *Id.* So far, because segments of protein have been used in combination with a harmless, natural virus, these vaccines have been safe and have produced only mild side effects. *Id.* However, the trials have not proceeded for a time period long enough to determine whether the initial immune responses are significant. *Id.*

With respect to large-scale tests in human populations to determine the effectiveness of therapeutic vaccines, the World Health Organization has named Brazil, Rwanda, Thailand, and Uganda as the most likely countries for these trials because the infection is spreading rapidly in these areas. Okie, *supra* note 11, at A5. Thailand is the most likely site for the first large international test. *Id.* Vaccines developed and manufactured in the United States will be involved in these experimental programs. *Id.* However, major difficulties must be surmounted prior to these trials. *Id.* One difficulty involves the manufacture of a vaccine, whether based on a virus or a protein copied from a virus, that matches the viral strain or strains of HIV in the host country. *Id.* A vaccine designed to combat a particular viral strain (e.g., a vaccine that is effective against HIV infection in the United States) may be ineffective, or less effective, in another country. *Id.* See also *AIDS Virus in North Thailand Appears to Target Heterosexuals*, S.F. CHRON., July 23, 1992, at A10. Moreover, as there are multiple strains of the virus, it may be necessary to employ multiple vaccines in order to immunize a given population.

## II. DEVELOPMENT OF A VACCINE

In the rush to find a cure for AIDS, the risk, of course, is that the pressing imperative to develop a vaccine may overwhelm precautions. There has been a relative decline in the competitive performance of U.S. pharmaceutical concerns compared to foreign concerns. The U.S. share of world pharmaceutical exports fell from over thirty percent prior to 1960 to under fifteen percent by the early 1980s, although the U.S.-owned share of new drug introductions remained roughly stable.<sup>14</sup> Development of an effective AIDS vaccine will be a rich prize to the successful producer, and there is substantial competition to be the first. American companies cannot assume they will win the race.

However, scientists generally opt for slow, careful development of a new mode of treatment.<sup>15</sup> Arrayed against this point of view, persons at risk of contracting AIDS, particularly those who already have the virus but not the disease, want solutions now.<sup>16</sup> As previously indicated, the spread of the virus is increasing at an exponential rate, there is no known cure, and there is little hope that the behaviors that spread the disease can be readily or rapidly modified.<sup>17</sup> Aside from the pressure of competition, therefore, there is pressure from afflicted groups to speed up the approval process for any promising treatment and move quickly to human-subject trials without the usual delay, caution, and attention to risk that would normally attend the development of a new drug or vaccine.<sup>18</sup>

The ultimate goal, however, must not be treatment, but prevention of the infection at the outset. This is the traditional function of a vaccine.<sup>19</sup> Even though a truly effective preventive vaccine seems far away, when one is developed, it

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14. PHARMACEUTICAL PANEL, NATIONAL RESEARCH COUNCIL, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY: THE INFLUENCES OF TECHNOLOGY IN DETERMINING INTERNATIONAL INDUSTRIAL COMPETITIVE ADVANTAGE 1, 2-3 (1983).

15. See Gostin, *supra* note 13, at 15.

16. See Samuel Hellman & Deborah S. Hellman, *Of Mice But Not Men: Problems of the Randomized Clinical Trial*, 324 NEW ENG. J. MED. 1585, 1585-89 (May 30, 1991).

17. See *AIDS Cases Grow at Accelerated Rate*, *supra* note 3, at A3.

18. See Judith Miller, *Ethical Standards for Human Subject Research in Developing Countries*, IRB: A REV. OF HUM. SUBJECTS RES. (Hastings Center, Briarcliff Manor, N.Y.), May-June 1992, at 7, 8.

19. Gostin, *supra* note 13, at 10.

will make little sense to test it on low-risk groups, because sufficient data to evaluate efficacy will take a very long time to accumulate.<sup>20</sup> However, particular problems will arise if field trials take place in endemic areas and with high-risk groups, such as prostitutes. The researcher is morally obligated to advise research subjects of risk-minimizing behavior; to the extent that the subjects comply, they reduce their value to the experiment.<sup>21</sup> Obviously, the efficacy of a vaccine administered to prostitutes in an endemic area can be most readily ascertained if they continue to engage in risk-maximizing behavior and then either do or do not fall prey to the virus.

Even if initial trials take place in developing countries where the human immunodeficiency virus is highly prevalent and the need most urgent, there must also be experimentation on subjects in this country. Such research has begun. The multiple strains of the virus, and the multiple vaccines that may have to be developed to combat it, make this necessary.<sup>22</sup> The viral group in North America and Europe is not identical to groups elsewhere.<sup>23</sup> In this country also, there will be pressure to proceed quickly and to dispense with the formal procedures usually imposed in the development of new medical technologies.<sup>24</sup> These procedures are mandated by federal statute and interpreted in regulations promulgated by the FDA.<sup>25</sup> According to the recommendations proposed at the recent meeting of the Council of International Organizations of Medical Sciences, the ethical standards governing research in a host country should at least be equivalent to the standards in an initiating country.<sup>26</sup> Scientific merit would be assessed in the initiating country, and the host country would assume responsibility for the selection of subjects, ap-

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20. David J. Rothman, *Ethical and Social Issues in the Development of New Drugs and Vaccines*, 63 BULL. OF THE N.Y. ACAD. OF MED. 557, 565. (1987).

21. *Id.* at 567. See also Larry Gostin, *Ethical Principles for the Conduct of Human Subject Research: Population-Based Research and Ethics*, 19 LAW, MED. & HEALTH CARE 191, 193-95 (1991).

22. See Okie, *supra* note 11 at A5; see also Lisa M. Krieger, *AIDS Vaccine Speedup Urged*, S.F. EXAMINER, July 21, 1992, at A1, A15.

23. Perlman, *New Variants*, *supra* note 13, at A7.

24. See Gostin, *supra* note 13, at 15.

25. See *infra* text accompanying notes 28-42.

26. Miller, *supra* note 18, at 7; see *infra* notes 37-38 with respect to FDA requirements.



propriate consent, and feasibility of the study in light of the country's laws, culture, and local conditions.<sup>27</sup>

#### A. Food and Drug Administration Requirements

The procedures required by the FDA for its approval of a new drug or vaccine are elaborate, although the process has now been expedited in the case of drugs to treat and prolong the life of persons with AIDS.<sup>28</sup> In the first instance, an Institutional Review Board (a multidisciplinary committee located at institutions where research takes place) must approve and monitor a proposed clinical investigation to determine a drug or vaccine's safety and efficacy.<sup>29</sup> For a previously untested drug, this investigation is generally divided into three phases: (1) an initial phase, usually involving no more than twenty to eighty patients or volunteers to determine whether it is safe to proceed to the next phase, (2) a middle phase, usually involving several hundred subjects to evaluate effectiveness and short-term side effects, and (3) a final phase, often involving several hundred to several thousand subjects, to evaluate the overall risk-benefit ratio and to gather additional information about safety.<sup>30</sup>

Protocols, reviewed by the Institutional Review Board, are required for each phase.<sup>31</sup> The investigational new-drug application must contain adequate information about the pharmacological and toxicological effects of the drug in animals or *in vitro* to conclude that a clinical investigation will be reasonably safe.<sup>32</sup> Investigators must make sure that patients or volunteers are informed that the drug is being used for investigational purposes, and they must give their informed consent.<sup>33</sup>

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27. *Id.* at 7-8.

28. The FDA has sped approvals of AIDS drugs, but "[o]n the average, development of a new drug takes about a decade and costs \$231 million. In 1991, final FDA reviews alone had averaged 2½ years." Carolyn Lochhead, *FDA Assailed for Slow Testing of New Drugs*, S.F. CHRON., Oct. 26, 1992, at A1, A4. The cost should be reduced about 25% to account for tax savings derived from research and development expenses. Alex Barnum, *New Study on Drug Prices*, S.F. CHRON., Feb. 25, 1993, at D1.

29. 21 C.F.R. § 312.23(a)(1)(iv) (1992).

30. *Id.* § 312.21(a)-(c).

31. *Id.* § 312.23(a)(6)(i)-(ii).

32. *Id.* § 312.23(a)(8).

33. *Id.* § 312.53(c)(1)(vi)(d).

Once an investigation is underway, the sponsor must notify the FDA of any adverse experience associated with use of the investigational drug that is both serious and unexpected.<sup>34</sup> The FDA may request modification of, or terminate, an investigation if it finds that human subjects are being exposed to unreasonable risk of illness or injury, or that manufacturing methods or processes are inadequate to ensure subject safety.<sup>35</sup>

An application will be approved by the FDA if a drug (or vaccine) meets statutory standards for safety and effectiveness, manufacturing and controls, and labeling.<sup>36</sup> In addition, an application based on foreign clinical data meeting U.S. criteria for marketing approval may be approved<sup>37</sup> if the foreign data are applicable to the U.S. population, the studies have been conducted by clinical investigators of recognized competence, and the data are valid without an on-site inspection conducted by the FDA.<sup>38</sup> However, approval will be withheld if, among other criteria: a drug is unsafe under prescribed or recommended conditions; the methods used in manufacture, processing, packing and holding do not comply with good manufacturing practice; or the labeling is false or misleading.<sup>39</sup> A label, for example, must be prominently dis-

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34. *Id.* §§ 312.32(c), 312.50. In addition, annual reports are required that include information regarding frequent, adverse experiences and deaths. *Id.* § 312.33(b)(1), (b)(3). The investigator must also report any unanticipated problems involving human subjects to the Institutional Review Board. *Id.* § 312.66.

35. *Id.* §§ 312.42(b), 312.44(b).

36. *Id.* § 314.105(c).

37. Foreign clinical studies can be accepted by the FDA for marketing approval if they are well designed, well conducted, performed by qualified investigators, and conducted in accordance with the ethical principles stated in the Declaration of Helsinki or the laws and regulations of the country in which the research was conducted, whichever affords greater protection to the research subject. *Id.* § 312.120(a), (c)(1). As with studies conducted in the United States in accordance with the regulations described herein, the Declaration of Helsinki mandates informed consent and forbids research where the importance of the objective (i.e., the benefit) is not in proportion to the inherent risk. *Id.* § 312.120(c)(4)(I)(9). Requirements with respect to investigational new drugs intended for expert are set forth in § 312.110(b).

38. *Id.* § 314.106(b) (1992). In the alternative, if the FDA concludes that an inspection is necessary, it may validate the data through an on-site inspection or through other appropriate means. *Id.*

39. *Id.* § 314.125(b)(3), (b)(6), (b)(13). FDA regulations contain detailed standards with respect to minimum good manufacturing practice, including such matters as building design, sanitation, packaging and labeling operations, inspection, and warehousing procedures. *Id.* §§ 211.42-.76. The regulations

played and must contain information about any special care that should be exercised or serious adverse reactions that have been encountered.<sup>40</sup>

Finally, no lot of any vaccine "shall be released by a manufacturer prior to completion of tests for conformity with standards applicable to such product."<sup>41</sup> A general safety test must be performed on biological products, including vaccines, that are intended for administration to human beings.<sup>42</sup>

### B. *Inhibitions on Marketing Once a Vaccine Has Been Developed*

Despite the elaborate testing and review procedures mandated by the FDA, the lure of profit, and the dictates of urgent medical necessity, pharmaceutical companies are understandably concerned about their exposure to liability. Their concerns are partly perceptual (i.e., based upon opinion and not necessarily upon fact), partly rooted in bitter experience, and partly an outgrowth of understandings and misunderstandings about legal doctrine. It is difficult to untangle these concerns, but they unquestionably substantially slow innovation and the marketing of new vaccines.

The following subsections discuss facets of this problem. The first deals with industry experience with the development and manufacture of vaccines,<sup>43</sup> and the second moves to perceptions about the litigation "explosion."<sup>44</sup> The third and fourth describe and analyze current trends with respect to punitive damages,<sup>45</sup> product liability law, and, to a lesser extent, the porous defense of compliance with regulatory standards.<sup>46</sup> A subsequent section describes legislation, either enacted or proposed, to limit liability,<sup>47</sup> and lastly, legislation that should be enacted to speed up the development and distribution of this critically important vaccine.<sup>48</sup>

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also set forth detailed criteria with respect to the directions accompanying a drug so that a layperson can use it safely for its intended purpose. *Id.* §§ 201.5-31.

40. *Id.* § 201.15.

41. *Id.* § 610.1.

42. *Id.* § 610.11.

43. *See infra* part II.B.1.

44. *See infra* part II.B.2.

45. *See infra* part II.B.3.

46. *See infra* part II.B.4.

47. *See infra* part III.B.

48. *See infra* part III.C.

### 1. *Industry Experience with Vaccine Development*

Vaccines have been a powerful tool in improving our well-being and longevity. Vaccines have been developed to control the following diseases: polio, whooping cough, measles, rubella, mumps, diphtheria, tetanus, influenza, pneumococcal and meningococcal infections, and hepatitis.<sup>49</sup> Four decades ago, polio was a dreaded disease that afflicted 57,000 Americans; in 1984, there were four cases.<sup>50</sup> In 1934, there were 265,000 cases of whooping cough and 7,500 deaths from the disease; in 1982, due to the pertussis component of the DPT vaccine, there were only 2,000 cases and four deaths.<sup>51</sup>

Yet, despite this spectacular accomplishment, the number of drug companies producing vaccines has declined sharply. "Between 1965 and 1985, the number of U.S. vaccine manufacturers shrank by more than half; . . . [a]nd only two major companies . . . were still investing heavily in vaccine research."<sup>52</sup> Within the 1980s, the number of firms producing vaccines for five serious childhood diseases declined from thirteen to three.<sup>53</sup>

Fear of liability was a major reason for this retreat.<sup>54</sup> Vaccines are infrequently administered to each recipient, sometimes only once in a lifetime. They require complex production and quality control processes but provide only a slight return on investment.<sup>55</sup> The profit per dose is low, and yet the perceived liability per dose is high.<sup>56</sup> In a strong, if flamboyant, attack, one scholar has asserted that blame for this perception must be assigned to the shift in tort law from negligence (with its corollary, the due care of the individual

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49. 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, 341 (Peter W. Huber & Robert E. Litan, eds., 1991).

50. RICHARD NEELY, *THE PRODUCT LIABILITY MESS: HOW BUSINESS CAN BE RESCUED FROM THE POLITICS OF STATE COURTS* 48 (1988).

51. *Id.*

52. PETER W. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 156 (1988).

53. W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship between Product Liability and Innovation*, in *TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE* 105, 111 (Peter H. Schuck ed., 1991).

54. See *id.* at 106; Lasagna, *supra* note 49, at 341; HUBER, *supra* note 52, at 155.

55. Lasagna, *supra* note 49, at 341.

56. Viscusi & Moore, *supra* note 53, at 111.

or company) to strict liability (with its emphasis upon alleged defects in the product itself).<sup>57</sup>

Certainly there are instances that critical commentators can cite to buttress their claim that modern tort law is a major culprit in drying up the number of vaccine manufacturers. Bendectin, a morning-sickness drug, was voluntarily withdrawn from the market after a flood of litigation, without apparent end, in which plaintiffs claimed it was a teratogen capable of producing congenital defects.<sup>58</sup> However, the evidence was, at best, ambiguous,<sup>59</sup> and the manufacturer, Merrell Dow, did not lose a single product liability case.<sup>60</sup> It gave up, however, because of adverse publicity and the \$18 million annual cost of legal fees and insurance that approximated the \$20 million in sales.<sup>61</sup>

In the case of swine flu, which was identified after four people contracted a severe form of influenza, pharmaceutical companies quickly developed a vaccine.<sup>62</sup> They failed, however, to obtain insurance from insurers who feared undue exposure to liability.<sup>63</sup> As a result, Congress passed a law insulating insurance companies from liability and establishing the Federal Treasury as the insurer.<sup>64</sup> Forty-five million people were inoculated.<sup>65</sup> By August, 1986, there were a total of 4,169 claims for damages filed against the government.<sup>66</sup> In 704 cases, cash settlements were sixty times original estimates, or \$86.3 million, and forty-one lawsuits seeking \$97.8 million in damages were still pending ten years after the program began.<sup>67</sup>

Even a few such instances make companies cautious. High development costs relative to profit, and the looming

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57. HUBER, *supra* note 52, at 157.

58. See Lasagna, *supra* note 49, at 337-41.

59. See HUBER, *supra* note 52, at 102 (stating that respectable scientific journals said the drug did not cause birth defects). In a recent case, while a well credentialed epidemiologist testified that no study had found Bendectin to be a human teratogen, others, equally credentialed, testified that based on animal and pharmacological studies, the drug can cause birth defects. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2787 (1993).

60. Viscusi & Moore, *supra* note 53, at 112.

61. *Id.*

62. See HUBER, *supra* note 52, at 133-34.

63. *Id.* at 133.

64. *Id.* at 134.

65. *Id.*

66. *Id.*

67. *Id.*

possibility of financial catastrophe due to the unpredictability of litigation, are persuasive forces making vaccine manufacturers increasingly reluctant to market new products.<sup>68</sup> With respect to an AIDS vaccine, liability might arise, not from the failure of the vaccine to prevent an HIV infection, but rather from a claim that it caused the infection or an adverse reaction or some other untoward result, such as birth defects in the infant of an inoculated, pregnant woman. Particularly in the case of an AIDS vaccine, which presumably will be administered to populations that have higher-than-normal exposure to the virus, there is the possibility of claims that the vaccine actually caused the disease rather than protected against it.<sup>69</sup> Current tests, in the early days of infection, cannot accurately determine the presence of antibodies to the virus.<sup>70</sup> An apparently healthy subject, who is actually infected, could be inoculated. The causation problem for the defense, which would attempt to prove that the subject's illness was caused by behavior and not the vaccine, could be significant.

In the case of other vaccines, the fear of liability or the cost of defending against unmeritorious suits has driven insurers out of the market or made insurance premiums prohibitively expensive.<sup>71</sup> Companies are forced to self-insure and to devote extra effort toward improving the safety of product design and the sufficiency of warnings against all conceivable hazards.<sup>72</sup> These measures may be as they should be, but the price of the product will invariably rise as a result.<sup>73</sup> Because most of the worldwide recipients of an

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68. See Gostin, *supra* note 13, at 12. See also Lasagna, *supra* note 49, at 342-43 (explaining that a few years ago, legal actions involving the diphtheria-tetanus-pertussis vaccine (DTP) involved claims many times the gross annual sales of the vaccine).

69. See Lasagna, *supra* note 49, at 345.

70. See Wendy K. Mariner & Robert C. Gallo, *Getting to Market: The Scientific and Legal Climate for Developing an AIDS Vaccine*, 15 *LAW, MED. & HEALTH CARE* 17, 19 (1987).

71. See Scott E. Harrington, *Liability Insurance: Volatility in Prices and in the Availability of Coverage*, in *TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE*, *supra* note 53, at 47, 64-65, 78; Gostin, *supra* note 13, at 12; Viscusi & Moore, *supra* note 53, at 112.

72. See Lasagna, *supra* note 49, at 343.

73. *Id.* at 335:

The fear of liability is responsible for much of the increased cost of vaccines over the past decade . . . . Before the liability crisis, back in 1982, the private-sector cost of immunizations for a two-year-old was \$20.17.

AIDS vaccine will be the poor,<sup>74</sup> the cost of the vaccine to them may be prohibitive. If they cannot pay, it is unclear that the countries in which they live will have the financial resources to pay for them.

Much of the evidence on whether tort liability (and the high cost of insurance) has dampened innovation is anecdotal, but "a common feature of this anecdotal evidence is the prominence in such accounts of the pharmaceutical industry in general and vaccines in particular."<sup>75</sup> And even if there is no proof of danger, there is a strong, widely held perception of it. Yet, there are voices, prompted by the dimensions of the public health emergency, that urge speed in the development of an AIDS vaccine.<sup>76</sup>

One respected commentator has stated that "the fears of manufacturers are more illusory than real"<sup>77</sup> and "[t]he actual chances that the industry would face liability from a carefully designed and marketed AIDS vaccine are slim."<sup>78</sup> This is not so certain. In view of the erratic nature of jury awards, manufacturers have good reason to be cautious. It appears that low liability costs have a positive, stimulative impact on innovation, but high liability costs tend to depress it.<sup>79</sup> The vaccine-producers' fears have genuine, realistic roots, although the interaction between liability and product design and distribution is highly complex. Another commentator has written that "[b]oth the industry-wide and pharmaceutical-specific trends are inconsistent with claims that liability fears have dampened innovative activities."<sup>80</sup> He adds, however, that "limited evidence from all sources suggests that the tort system has probably reduced innovation,

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Ten years later . . . the cost of a complete regimen of vaccinations had risen to \$188.19 . . .

*The Vaccine Scapegoat*, WALL ST. J., Feb. 23, 1993, at A18. This cost also included the added costs for two new vaccines. *Id.*

74. See David Perlman, *One More Problem for Third World*, S.F. CHRON., July 20, 1992, at A5; Eckholm, *supra* note 5, at E5.

75. Viscusi & Moore, *supra* note 53, at 111.

76. See, e.g., Gostin, *supra* note 13, at 10.

77. *Id.* at 13.

78. *Id.* at 12.

79. See Viscusi & Moore, *supra* note 53, at 122.

80. Robert E. Litan, *The Liability Explosion and American Trade Performance: Myths and Realities*, in TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE, *supra* note 53, at 126, 146.

although the magnitude of the negative effect is far from clear."<sup>81</sup>

## 2. *Perceptions About the Litigation "Explosion"*

It would not be surprising if the examples of Bendectin and the swine flu vaccine and litigation related to the DTP vaccine raised serious concerns among potential producers of an AIDS vaccine. In addition to these specific instances of legal difficulty, the perception prevails that, in the last twenty years, America has embarked on an orgy of litigation.<sup>82</sup> This widespread belief is shared by people in business and the lay public.<sup>83</sup> Undoubtedly, it affects business decisions. But how accurate is the perception, and are there particular problems related to product liability litigation involving drugs and vaccines?

### a. *The Litigation Explosion Exists*

It appears that people in the United States, Canada, and the United Kingdom increasingly refuse to accept risk, and its consequences, as a part of life and instead are prepared to shift responsibility to medical service providers and product manufacturers.<sup>84</sup> Business representatives claim that "companies have no choice but to avoid the courtroom by withdrawing products, keeping others off the market, and restricting the scope of research and development . . . ."<sup>85</sup> Lawyers are frequently blamed. With respect to asbestos and asbestos-related litigation, it has been said (as if law schools had no competing demands in the curriculum), that "[a] whole generation of lawyers has been schooled in asbestos liability theories that could possibly be turned against this or any similar substitute."<sup>86</sup>

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81. *Id.* at 148.

82. See, e.g., HUBER, *supra* note 52, at 9-10; DEBORAH R. HENSLER ET AL., RAND CORP., TRENDS IN TORT LITIGATION: THE STORY BEHIND THE STATISTICS 1 (1987); Richard J. Mahony & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 SCIENCE 1395, 1396 (1989) (the authors are, respectively, the CEO and Public Affairs Director of Monsanto); *VP Bites the Hand Feeding Him at ABA Confab*, THE RECORDER, Aug. 15 1991, at 6.

83. See Litan, *supra* note 80, at 144-45; HUBER, *supra* note 52, at 10.

84. See Michael J. Trebilcock et al., *Malpractice Liability: A Cross-Cultural Perspective*, in TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE, *supra* note 53, at 205, 216.

85. Mahoney & Littlejohn, *supra* note 82, at 1395.

86. *Id.*



Former Vice President Quayle added his voice to the attack. In a speech before the American Bar Association in August 1991, he asserted that in 1989 more than eighteen million civil suits were filed in the United States, one for every ten adults, and that in California it is estimated that one in ten jury awards include punitive damages "in amounts averaging more than 3 million."<sup>87</sup> The United States, he asserted, is the most litigious society in the world, home to seventy percent of the world's lawyers.<sup>88</sup> He claimed that the direct and indirect costs of litigation and insurance premiums to individuals and businesses exceed \$300 billion per year.<sup>89</sup>

This figure, by a circuitous route, apparently was borrowed in altered form from Peter W. Huber, one of the most vocal critics of the tort liability system.<sup>90</sup> Huber has stated:

The number of tort suits filed has increased steadily over two decades. . . . Cases where appliances, factory machinery, chemicals, automobiles, and other products are blamed for injuries increased fourfold between 1976 and 1986. More medical malpractice suits were filed in the decade ending in 1987 than in the entire previous history of American tort law.<sup>91</sup>

Case filings in federal courts, according to another critic of the system, increased from 51,063 in 1960 to 241,159 in 1983.<sup>92</sup>

Not only have filings increased, but so have the awards. Huber reports that there is now an increased probability that a suit will produce an award, and there has been a persistent and rapid growth in the average size of awards.<sup>93</sup> The average in all tort cases increased fivefold between the early 1960s and the early 1980s—from an inflation-adjusted \$50,000 to more than \$250,000.<sup>94</sup> In medical malpractice cases, inflation-adjusted awards have doubled approximately

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87. *VP Bites the Hand Feeding Him at ABA Confab*, *supra* note 82, at 6.

88. *Id.*

89. *Id.*

90. See HUBER, *supra* note 52, at 4. Huber's estimate, however, referred only to tort liability and totaled \$380 billion per year in direct and indirect costs. *Id.*

91. *Id.* at 9.

92. See NEELY, *supra* note 50, at 50.

93. HUBER, *supra* note 52, at 9.

94. *Id.* at 10.

every seven years.<sup>95</sup> There seems to be little dispute that the tort field, once a relatively settled and dormant area of the law, has become an unsettled and turbulent field that has generated substantial attention and controversy.<sup>96</sup>

The number of routine tort cases, however, has not increased dramatically relative to population growth. The explosion has come in the areas of medical malpractice and products liability. In some urban jurisdictions, between 1960 and 1984, the increase is more than tenfold.<sup>97</sup> Excluding cases involving asbestos, the Dalkon Shield, and Bendectin—problem areas that dominated the case load increase—it has been asserted that the number of products cases filed grew 338% from 1974 to 1986 (and then declined).<sup>98</sup> With respect to federal product liability cases,

the number of product liability lawsuits filed in the federal system . . . increased five-fold from 1975-1985 (from about 2,400 suits to about 12,500 suits); because other types of tort filings in the federal system have not increased at a similar rate, product liability cases now ac-

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95. *Id.* Another commentator has written: "Studies undertaken by the Rand Institute for Civil Justice show that the average personal injury verdict in cases involving serious personal injury at least tripled in after-inflation dollars between the early 1960s and the early 1980s." Gary T. Schwartz, *Product Liability and Medical Malpractice in Comparative Context*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION*, *supra* note 49, at 28, 47. Indeed, the size of some tort verdicts upheld on appeal seem staggering. *See, e.g.*, *Arnold v. Eastern*, 712 F.2d 899 (4th Cir. 1984), *cert. denied*, 464 U.S. 1040 (1984) (awarding \$3,027,500 for a hand injury); *Marks v. Mobil Oil*, 562 F.Supp. 759 (1983) (awarding, \$5,147,000 for loss of speech (excluding prejudgment interest)); *Hasson v. Ford*, 650 P.2d 1171 (Cal. 1982) (awarding \$9,850,000 for a fractured skull); *Robert & Co. v. Tigner*, 351 S.E.2d 82 (Ga. Ct. App. 1986), *cert. granted*, 354 S.E.2d 158 (1987) (awarding \$2,000,000 for a hip or pelvis fracture); *Clark v. Chicago*, 410 N.E.2d 1025 (Ill. App. Ct. 1980) (awarding \$1,102,000 for an assortment of bodily injuries; i.e., arm, leg, liver, and spleen); *Peterson v. Department*, 399 N.W. 2d 414 (Mich. Ct. App. 1986) (awarding \$7,256,905 for a neck injury).

96. *See generally* R.L. Raben, *Tort Law in Transition: Tracing the Patterns of Sociological Change*, 23 VAL. U. L. REV. 1 (1988-89).

97. Peter H. Schuck, *Introduction*, in *TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE*, *supra* note 53, at 17, 23. Mr. Schuck advises caution in assessing the data. *Id.* Many variables are involved, and studies of the problem use different methodologies, definitions and data sets. *Id.* "[T]he most basic factual elements of the debate . . . are exceedingly complex, technical and difficult to establish." *Id.* at 22.

98. *Id.* at 24. *See also* HENSLER et al., *supra* note 82, at 6-7 & fig. 2.1 (noting that the increase in personal injury lawsuits far outpaces population increases).

count for about 30 percent of all federal tort filings, compared to 9 percent in 1975.<sup>99</sup>

Product liability filings at the state court level, it is said, are "almost certainly" several times greater than at the federal level.<sup>100</sup>

Many causes for the increase have been cited. Their interaction and importance relative to each other are not clear.<sup>101</sup> Among them, however, "expansion of doctrine"<sup>102</sup> is often cited as the major reason for the growth in claims.<sup>103</sup> Mahoney and Littlejohn assert that huge punitive damage awards are "almost commonplace with multimillion-dollar awards occurring monthly."<sup>104</sup> With this incentive, plaintiffs' lawyers sue, even with weak cases, until they "hit the jackpot."<sup>105</sup> And "nothing stops different juries from awarding punitive damages in huge amounts against the same defendant for the same alleged conduct."<sup>106</sup>

These risks, whether real or exaggerated, prompt defendants to settle even weak claims. Settlement, in fact, constitutes the bulk of the litigation iceberg, concealed from view, about which little is known with certainty. There are those who charge that when punitive damages are claimed (an increasingly common phenomenon), settlements are much higher—from 60 to 150%—than they would be otherwise.<sup>107</sup> Statistics in California show "that more claims are being filed in court, but a larger proportion of the cases that are filed are

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99. DEBORAH R. HENSLER, RAND CORP., SUMMARY OF RESEARCH RESULTS ON PRODUCT LIABILITY 2-3 (1986)[hereinafter, HENSLER, SUMMARY].

100. Mahoney & Littlejohn, *supra* note 82, at 1396 (citing TERENCE DUNGWORTH, RAND CORP., PRODUCT LIABILITY AND THE BUSINESS SECTOR: LITIGATION TRENDS IN FEDERAL COURTS 20, 42 (1988)). However, caution should be exercised. Filings in federal courts constitute only a fraction of the total tort caseload. An estimated 95% of all tort cases are filed in state trial court systems, and most of these systems do not tabulate cases by type. As a result, whether the dramatic increase of products cases in the federal system was matched in the state courts is not known. HENSLER, SUMMARY, *supra* note 99, at 3. The data are incomplete.

101. See Schuck, *supra* note 97, at 25.

102. Expansion of doctrine is the shift from a negligence standard to strict liability and a greater willingness on the part of juries to award punitive damages. See generally Mahoney & Littlejohn, *supra* note 82, at 1396.

103. See *id.* See also Schwartz, *supra* note 95, at 47.

104. Mahoney & Littlejohn, *supra* note 82, at 1396. But see *infra* text accompanying notes 239-248.

105. See Mahoney & Littlejohn, *supra* note 82, at 1396.

106. *Id.*

107. *Id.* In fact, no one knows. Lasagna, *supra* note 49, at 335.

settled by the parties without court intervention."<sup>108</sup> Presumably, as jury verdicts change, the amounts involved in these settlements will also change as defendants assess their chances.<sup>109</sup> However, to avoid the possibility of a future plaintiff using a prior, generous settlement as precedent, defendants often insist on secrecy with respect to all documents and information about a case as a condition of settlement.<sup>110</sup>

The impact of these developments has fallen with particular severity on the pharmaceutical industry. Between 1981 and 1986, for non-Dalkon Shield and non-Bendectin defendants, there was a doubling of the number of product liability lawsuits filed, and in the latter half of the 1980s "the number of punitive damage awards in all pharmaceutical product liability cases was fifteen times greater than in the entire decade of the 1970s."<sup>111</sup> With respect to vaccines, juries have imposed sizable damage awards despite proper manufacture and warning of the risk.<sup>112</sup> According to the American Medical Association, "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance."<sup>113</sup> In particular, "[c]urrent legal interpretation of product liability law, especially the doctrine of strict liability, diminishes the incentives of a manufacturer to research, develop and produce vaccines."<sup>114</sup> "Over the last 10 years the number of liability suits filed against vaccine manufacturers has increased significantly . . . ."<sup>115</sup> "As a consequence of the increasing number of suits, court awards, and out-of-court settlements, the manufacturers have been forced to devote an ever larger percentage of the revenue from vaccine sales to

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108. DEBORAH R. HENSLER, *RAND CORP., TRENDS IN CALIFORNIA TORT LIABILITY LITIGATION* 3-4 & tbl. 2 (1987).

109. See MARK A. PETERSON, *RAND CORP., A SUMMARY OF RESEARCH RESULTS: TRENDS AND PATTERNS IN CIVIL JURY VERDICTS* 1 (1986).

110. See Ralph Nader & Joan Claybrook, *Preserving a Pillar of our Democracy: Tort System Protects the Injured*, *TRIAL*, Dec. 1991, at 45, 46.

111. Mahoney & Littlejohn, *supra* note 82, at 1397.

112. See John K. Iglehart, *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 1316 *NEW ENG. J. MED.* 1286, 1286 (1987). See also *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974) (holding that inadequate warning resulted in a \$200,000 award).

113. ALAN R. NELSON, *AMERICAN MEDICAL ASS'N, IMPACT OF PRODUCT LIABILITY ON THE DEVELOPMENT OF NEW MEDICAL TECHNOLOGIES* 1 (1988).

114. *Id.* at 2.

115. *Id.* at 7.

costs of insurance and of defending against potential liability."<sup>116</sup>

There is no question that general liability premiums have risen markedly—from \$6.5 billion in 1984 to approximately \$20 billion by the end of the 1980s.<sup>117</sup> An expansion in claim costs (derived from expanded tort liability doctrines) and a significant reduction in insurance industry operating income during 1984-1985 (due to a drop in interest rates) fueled this rapid growth.<sup>118</sup> Protection against liability, however, is not a dominant component of product costs generally.<sup>119</sup> Two-thirds of all companies with at least \$100 million in sales charge one percent or less for insurance in their final prices, and for another eleven percent, liability insurance accounts for only two to three percent of the final price.<sup>120</sup> The impact falls on innovative technologies, where there is no accumulation of actuarial experience; in particular, liability insurance may account for a significant proportion of the price of a vaccine.<sup>121</sup>

#### b. *The Litigation Explosion Is a Myth*

The Vice President was mistaken. The United States is not home to seventy percent of the world's lawyers; it is home to twenty-five to thirty-five percent, roughly the U.S. proportion of the world's gross national product.<sup>122</sup> The cost of the American legal system is not \$300 billion a year, as the Vice President stated; using an erroneous calculation, he took this figure from Peter Huber, "who, it is fair to say, made it up."<sup>123</sup>

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116. Iglehart, *supra* note 112, at 1286.

117. *Id.*

118. Harrington, *supra* note 71 at 47, 54-55. Mr. Harrington notes that premium volatility and the availability of coverage was also "likely to have been aggravated by cyclical influences that are not fully understood." *Id.* at 55. Another author states that we "don't know the exact extent to which liability law rather than insurance company misjudgment has been responsible for the so-called 'insurance crisis.'" NEELY, *supra* note 50, at 172.

119. See Viscusi & Moore, *supra* note 53, at 125.

120. Joan Claybrook, *Products Liability: Serving All Americans*, TRIAL, Oct. 1990, at 27, 31.

121. Mahoney & Littlejohn, *supra* note 82, at 1397.

122. Marc Galanter, *Counting Counsel: Dan Quayle and Other Lawyer-Bashers Build their Case Against the Legal System on Wrong Numbers*, THE RECORDER, Feb. 25, 1992, at 8.

123. *Id.* at 8. But see Walter Olson, *Slowing the Recovery: Too Many Lawsuits*, SAN DIEGO UNION TRIB., May 3, 1992, at C1. Mr. Olson sets forth ways in which costs can be tabulated and concludes that Quayle's "figure may be too

According to Joan Claybrook, in an article citing the Rand Institute of Civil Justice study "Costs and Compensation Paid in Tort Litigation," the total nationwide expenditure for tort suits in state and federal courts of general jurisdiction in 1985 was between \$29 and \$36 billion dollars.<sup>124</sup> This estimate includes product liability suits and \$4.3 to \$5.3 billion in insurance company costs.<sup>125</sup> She concludes that this is "less than what consumers spend on cigarettes each year and half what they spend on alcohol."<sup>126</sup>

A decade ago, manufacturers and sellers, with the help of the insurance industry, launched a campaign to promote "the myth of a litigation crisis in the United States that is unparalleled in world history."<sup>127</sup> The critics of the critics assert that there is no litigation crisis, no explosion of product liability cases, no expansion of tort theory unfairly advantaging plaintiffs, and no surge in excessive awards.<sup>128</sup> The charge that these developments have occurred, they say, is based upon the increase in the number of cases filed in the federal court system, but only five percent of the cases are filed there.<sup>129</sup>

There is, in fact, "a stable curve of lawsuits and verdicts comparable to the growth of population and inflation."<sup>130</sup> From 1981 to 1986, product liability filings in the federal courts increased by only four percent annually if mass tort cases (asbestos, Dalkon Shield, and Bendectin) are excluded.<sup>131</sup> This increase is less than the six percent annual

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high—or quite possibly, too low. Which is one definition of a reasonable guess." *Id.* at C6.

124. Claybrook, *supra* note 120, at 28. While the figure must include direct payments for compensatory and punitive damages and insurance costs, it is not clear whether it includes the indirect costs of items such as settlement, lawyers' fees, and productive time lost to litigation. *Id.* These indirect costs could be high. *Id.*

125. *Id.*

126. *Id.*

127. Nader & Claybrook, *supra* note 110, at 45.

128. *Id.* at 48. See also Linda Lipsen, *The Evolution of Products Liability as a Federal Policy Issue*, in *TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE*, *supra* note 53, at 247, 255; NEELY, *supra* note 50, at 172, in which the author states that "the average jury award in product liability cases between 1975 and 1984 rose only slightly faster than inflation." *Id.*

129. See Nader & Claybrook, *supra* note 110, at 48.

130. *Id.* at 45.

131. *Id.* at 48. See also Claybrook, *supra* note 120, at 29.

increase for *all civil filings* (many of which were Social Security disability claims appeals following a change in the rules by the Reagan administration) and the five percent annual increase in personal expenditures for goods.<sup>132</sup> Moreover, according to a study by the National Center for State Courts, from 1978 to 1984 the total number of *tort filings* increased nine percent while the U.S. population increased eight percent.<sup>133</sup>

With respect to awards, the critics of the critics maintain that compensatory damages are strongly correlated in amount to the severity of injury, and punitive damages in turn are strongly correlated with compensatory damages.<sup>134</sup> The burden on corporate defendants is not excessive, and the scare talk about enormous punitive damage awards is largely unfounded. In products cases, punitive damages are, in fact, rarely awarded and often reduced on appeal, although from time to time juries have imposed significant civil penalties for truly unconscionable conduct.<sup>135</sup>

Indeed, the argument goes, if there is a problem, it is that only a tiny fraction of the people injured each year by defective products actually resort to the legal system for redress.<sup>136</sup> Yet, in terms of deterrence and prevention, the system performs a critically important role. Product suits are the single most important factor affecting design decisions, forcing manufacturers to improve quality and ensuring that warnings are clear and explicit. This result is acknowledged by industry representatives.<sup>137</sup> Research has not been deterred. Within the pharmaceutical industry, where product liability suits are prevalent, expenditures for research and

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132. Nader & Claybrook, *supra* note 110, at 48. See also Claybrook, *supra* note 120, at 29.

133. Nader & Claybrook, *supra* note 110, at 48. See also Claybrook *supra* note 120, at 29; *The Manufactured Crisis: Liability Insurance Companies Have Created a Crisis and Dumped it on You*, CONSUMER REP., Aug. 1986, at 544, 546.

134. Nader & Claybrook, *supra* note 110, at 48.

135. See MICHAEL RUSTAD, ROSCOE POUND FOUND., DEMYSTIFYING PUNITIVE DAMAGES IN PRODUCTS LIABILITY CASES: A SURVEY OF A QUARTER CENTURY OF TRIAL VERDICTS 23-27, 30 (1991). See also *infra* text accompanying notes 239-248.

136. Claybrook, *supra* note 120, at 27 ("[I]n 1985, 143,000 Americans died from product-related injuries, 57 million were injured and 2.3 million were hospitalized. The economic cost in 1988 was \$180 billion dollars.").

137. See Nader & Claybrook, *supra* note 110, at 46; Claybrook, *supra* note 120, at 27.

development have more than doubled.<sup>138</sup> An advertisement in the March 1, 1990, *Washington Post* proclaimed that Pharmaceutical Manufacturing Association companies are now the principal source of research and development in biomedicine, supplanting the National Institutes of Health.<sup>139</sup>

c. *The Reality of the "Litigation Explosion"*

What are we to make of this welter of conflicting claims? It may well be that both sides are right—that in hurling statistics at the opposing camp, each protagonist is describing different parts of a highly complex phenomenon.<sup>140</sup> It matters whether all torts are being described, or only products-related torts, or automobile personal injury torts, or mass toxic torts, or medical malpractice torts, and so on. It also matters whether the field of study is the federal system or the state systems and whether scrutiny is directed toward filings, settlements, trial verdicts, or awards following appeal. There is no single tort system, and because so many cases are brought in state courts (where statistical information is inadequate) or are settled in secrecy, there is a dearth of systemic, empirical information.

It does seem clear that, at least in the federal courts, there was a growth in products-related cases and an increase in punitive damages. But the crisis, if there ever was one, crested in the middle of the last decade, and since then the situation has been increasingly favorable for defendants.<sup>141</sup> The number of product liability cases filed has been shrinking. Putting aside asbestos-related litigation, filings in federal courts have fallen from 8,268 in 1985 to 5,236 in 1991, a decline of thirty-six percent, without any reason to believe there has been an offsetting increase in state courts.<sup>142</sup> In addition, the number of punitive damage awards in non-asbestos product liability cases has declined sharply since the mid-1980s, and the number of claims per \$100,000 in product liability premiums dropped from 32.9 in 1984 to 17.1 in 1988, a decline of forty-eight percent.<sup>143</sup>

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138. Claybrook, *supra* note 120, at 30.

139. *Id.*

140. See HENSLER, *supra* note 82, at 30.

141. See Schuck, *supra* note 97, at 29.

142. See Galanter, *supra* note 122, at 9.

143. *Id.* See also RUSTAD, *supra* note 135, at 24-25.



Manufacturers may breathe easier, it would seem. It is not clear, however, that pharmaceutical companies engaged in developing and marketing vaccines ought to feel any sense of relief. They have been particularly attractive targets.<sup>144</sup> Product liability law may be doing its job in other areas—compensating victims and deterring unsafe products from reaching the market—without dealing adequately with the peculiar vulnerabilities of vaccine manufacturers. Perception, as much as reality, will dictate decisions to proceed with testing and distribution of an AIDS vaccine. In this sense, has the crisis really passed? Several researchers working on the development of an AIDS vaccine predict that, under present legal conditions, if a vaccine were available today, no one would produce it. “Worries about product-liability lawsuits could stop any company from marketing a vaccine unless government assumes much or all of the risk.”<sup>145</sup>

### 3. *Punitive Damages*

Perception may be as important as reality in the punitive damages area as well. People in the business community share a widespread belief that punitive damages are out of control.<sup>146</sup> It does not appear that recent decisions by the Supreme Court will abate these fears with respect to the generality of cases,<sup>147</sup> but the concern about huge numbers of runaway verdicts is essentially groundless with respect to products cases—the cases of most concern to vaccine manufacturers.<sup>148</sup>

In this section, after discussing the contours of the problem in general and relevant Supreme Court decisions, the article summarizes recent research with respect to punitive damage awards involving only product liability cases.

Punitive damages have a long pedigree. They were first awarded in this country in 1784.<sup>149</sup> Yet retired Supreme

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144. See RUSTAD, *supra* note 135, at 30 (“[Forty-two] percent of punitive damage awards involving medical products and drug cases were in the top quartile of awards for all products. This is the highest category.”).

145. Stuart Gannes, *The Race for an AIDS Vaccine*, FORTUNE, Dec. 21, 1987, at 115, 118. See also R.M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 943 (1988).

146. See, e.g., Mahoney & Littlejohn, *supra* note 82, at 1396.

147. See *infra* text accompanying notes 188-238.

148. See *infra* text accompanying notes 240-248.

149. See *Genay v. Norris*, 1 S.C.L. (1 Bay) 6 (1784).

Court Justice Louis Powell has said that they should be abolished.<sup>150</sup> Traditionally, they are awarded on a finding that the defendant acted with malice. This imprecise term is variously described as acting oppressively,<sup>151</sup> wickedly,<sup>152</sup> with an evil motive,<sup>153</sup> with criminal indifference or spite,<sup>154</sup> or with such a conscious and deliberate disregard of the interests of others that the conduct may be called willful or wanton.<sup>155</sup> Punitive damages are, in a sense, a holdover from the ancient days when there was little or no distinction between tort and criminal law. As such, they exist as a civil penalty for behavior that may be criminal or that falls in a gray area between civil and criminal wrongdoing, and they serve functions that also undergird the policies of the criminal law.<sup>156</sup>

The principal purpose of punitive damages is "to punish the person doing the wrongful act and to discourage him and others from similar conduct in the future"<sup>157</sup>—that is to say, specific and general deterrence. In making the individualized penalty assessment, several factors may be taken into account. In the words of the Restatement of Torts:

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150. Donald B. Benedicts, *The Reasonable Man*, A.B.A. J., Oct. 1990, at 69, 75. Powell said, "The only standard is that there must have been malice. And nobody knows exactly what malice is." *Id.*

151. See Jeffery W. Grass, *The Penal Dimensions of Punitive Damages*, 12 HASTINGS CONST. L.Q. 241, 276 (1985).

152. See *id.* See also RESTATEMENT (SECOND) OF TORTS § 908(2) (1979).

153. See Grass, *supra* note 151, at 276.

154. See *id.* at 270; W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 2, at 9-10 (5th ed. 1984).

155. KEETON et al., *supra* note 154, § 2, at 9-10. See also *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 388 (Cal. Ct. App. 1981) (describing corporate conduct as "reprehensible in the extreme," exhibiting "a conscious and callous disregard of public safety"); Grass, *supra* note 151, at 276.

156. Grass, *supra* note 151, at 278, 282. For example, because the penalty is personal, it does not survive the tortfeasor's death. *Id.* at 266. Moreover, in many jurisdictions, it may not be shifted to an insurer. *Id.* at 283-84. Similarly, municipalities may not be liable for punitive damages in actions under 42 U.S.C. § 1983, because doing so would shift the burden to the taxpaying public. KEETON et al., *supra* note 154, at 12. See also generally *City of Newport v. Facts Concerts, Inc.*, 453 U.S. 247 (1981).

157. RESTATEMENT (SECOND) OF TORTS § 623A cmt. a (1977). Punitive damages are "commonly understood to be damages awarded to punish defendants for torts committed with fraud, actual malice, violence or oppression." *Molzof v. United States*, 112 S. Ct. 711, 715 (1992). See also, e.g., MARK PETERSON ET AL., RAND CORP., PUNITIVE DAMAGES: EMPIRICAL FINDINGS 2 (1987). But see Stephen Daniels & Joanne Martin, *Myth and Reality in Punitive Damages*, 75 MINN. L. REV. 1, 8-9 (1990) (stating that deterrence is ineffective).

Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant.<sup>158</sup>

In addition, an occasional court decision has mentioned that punitive damages may be used to compensate for wounded feelings or a plaintiff's expenses—including attorneys fees—in bringing a suit.<sup>159</sup>

In furtherance of the purposes to punish and deter, juries have traditionally been given broad latitude.<sup>160</sup> Thus, in *Kirkbride v. Lisbon Contractors Inc.*,<sup>161</sup> the Pennsylvania Supreme Court upheld an award of \$7,000 compensatory and \$70,000 punitive damages.<sup>162</sup> Citing the Restatement, the court concluded that the focus should be upon the seriousness of the acts committed and the wealth of the defendant, not

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158. RESTATEMENT (SECOND) OF TORTS § 908(2) (1979). These standards have been criticized. If incorporated into an instruction for the jury, Justice Brennan has said that they may be little better than no guidance at all. *Browning-Ferris Indus. of Vermont, Inc. v. Kelso Disposal, Inc.*, 492 U.S. 257, 281 (1989) (Brennan, J., concurring). Of the 46 states that permit common law punitive damages actions, 37 permit evidence of a defendant's wealth to be introduced. See RUSTAD, *supra* note 135, at 38.

159. See KEETON et al., *supra* note 154, at 9. Even though there is no logical relationship between the malice of the defendant and a plaintiff's counsel fees, nine states regularly allow juries to consider these fees in assessing punitive damages. See *St. Luke Evangelical Lutheran Church, Inc. v. Smith*, 568 A.2d 35, 40 (Md. 1990). Six other states deny consideration of attorneys fees as an element of punitive damages. *Id.* at 41. Two states, once evidence sufficient to award punitive damages is found, permit the award of attorney's fees as additional compensatory or special damages. *Id.* at 40-41. Presumably, without being explicit, the remaining states follow the American Rule; i.e., each side pays its own attorneys fees. Although contrary to the American rule, awarding reasonable attorneys fees can be seen as a further way to punish wrongful conduct and to protect plaintiffs against wealthy, corporate defendants who may otherwise be tempted to wear down opposition by running up the costs of discovery and trial. *Id.* See RESTATEMENT (SECOND) OF TORTS § 914 (1979) (supporting the concept of allowing a jury to consider a plaintiff's expenses in bringing a lawsuit as an element of punitive damages).

160. See Jane Draper, Annotation, *Excessiveness or Inadequacy of Punitive Damages Awarded in Personal Injury or Death Cases*, 12 A.L.R. 5th 195, 273 (1993).

161. 555 A.2d 800 (Penn. 1989).

162. *Id.* at 804. For an example of an unusually wide discrepancy between the amounts awarded for compensatory and punitive damages, see *infra* text accompanying notes 217-238.

proportionality between compensatory and punitive damages.<sup>163</sup> If a defendant is wealthy, a proportionate award might be too small to achieve a deterrent effect.<sup>164</sup> In short, if a civil fine is to achieve its purpose, it must "sting."

Unfortunately, the standards that govern this determination are cast in very general terms, and most appellate courts, reviewing a jury award, have looked only to see whether it shocked the conscience or was governed by passion or prejudice.<sup>165</sup> These terms invite a near-standardless review of a near-standardless determination. The situation may have been tolerable when, even thirty years ago, punitive damages were rarely demanded or awarded, but that is not the case today. It is said that punitive damages are now sought as a matter of course in virtually all damage actions.<sup>166</sup> Additionally, critics have maintained that the amounts awarded have exploded. Until 1959, the highest punitive award affirmed by a California appellate court was \$10,000; in the decades of the 1960s and 1970s the highest awards were, respectively, \$250,000 and \$740,000; by 1988, California appellate courts had approved awards of \$14 and \$15 million.<sup>167</sup> These are amounts approved on appeal.<sup>168</sup> The fright factor for a defendant at the trial level can be even more substantial, although initial awards may be modified at the appellate level.<sup>169</sup> In 1984, punitive damages were as-

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163. *Kirkbride*, 555 A.2d at 802.

164. *Id.* at 803.

165. *See Adams v. Murakami*, 813 P.2d 1348 (Cal. 1991) (en banc); *see also* Grass, *supra* note 151, at 310.

166. *See Rosener v. Sears Roebuck and Co.*, 168 Cal. Rptr. 237, 249-50 (1980) (Elkington, J., concurring).

167. *See Mahoney & Littlejohn, supra* note 82, at 1396. However, most cases show only a slight increase in the size of the award during the last twenty years; a small proportion of the total number of awards show a significant increase, and the few large awards are responsible for most of the total dollars awarded. PETERSON et al., *supra* note 157, at 42. *See also* Daniels & Martin, *supra* note 157, at 62.

168. *See Mahoney & Littlejohn, supra* note 82, at 1396 (citing *Hearings on Punitive Damages Before the Minnesota Injury Compensation Study Commission* 12 (Jan. 25, 1989) (testimony of T. B. Olson on Behalf of the Minnesota Civil Justice Coalition)).

169. Recently the Texas "King of Torts," Joe Jamail, won a \$550 million judgment against MiniScribe Corporation from a Galveston jury, \$530 million of it in punitive damages. *Quayle vs. Jamail*, WALL ST. J., Feb. 12, 1992, at A22. Studies show "that less than five percent of civil actions result in punitive awards—and many of these are altered on appeal." Harvey Pitt & Karl Groskaufmanis, *The Punitive Damages Decision: The Roulette Wheel Still*

essed in ten percent of *all tort* cases in Los Angeles in amounts ranging from \$25.00 to \$64 million.<sup>170</sup>

These results can occur because lay juries, "selected essentially at random," can impose "unfocused penalties solely for the purpose of punishment and some undefined deterrence."<sup>171</sup> Punitive awards are entirely within the jury's discretion, and a defendant can be subject to them in multiple lawsuits by different plaintiffs in the same or different jurisdictions.<sup>172</sup> Some plaintiffs may lose or settle for modest amounts; others may receive freakish windfalls.<sup>173</sup> The awards are given "full faith and credit."<sup>174</sup> A defendant can be held liable by a preponderance of the evidence, and a jury's sense of wrongdoing can be inflamed by hearing testimony of wealth—particularly in the case of a large, corporate defendant being sued by an individual plaintiff who has suffered horrible injuries—before a verdict of guilt is reached.<sup>175</sup> Furthermore, substantial punitive damages can be awarded on a showing of only nominal compensatory damages.<sup>176</sup> Most jurisdictions do not provide guidelines to focus a jury's determination.<sup>177</sup>

This situation, extensively publicized by a few large awards, has created an uproar of criticism from corporate

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*Turns*, THE RECORDER, Mar. 28, 1991, at 4. See also PETERSON et al., *supra* note 157, at 42. In a notable case involving the polio vaccine, a jury awarded an \$8 million punitive damage verdict against Lederle Laboratories, even though the FDA had approved the warning concerning its use. See *Johnson v. American Cynamid Co.*, 718 P.2d 1318, 1320 (Kan. 1986). The lay jury decided that the company should have marketed a different vaccine despite reputable opinion that the vaccine in controversy was preferable. *Id.* at 1320-22. In spite of these facts in the company's favor, the award was set aside by only a four-to-three verdict of the Kansas Supreme Court. *Id.* at 1320, 1327, 1334.

170. See Grass, *supra* note 151, at 300 n.474 (citation omitted).

171. *Silkwood v. Kerr McGee Corp.*, 464 U.S. 238, 283 (1984).

172. See Grass, *supra* note 151, at 263, 313.

173. See, e.g., *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711 (1993). See also Grass, *supra* note 151, at 265 and *infra* text accompanying notes 217-238.

174. See Grass, *supra* note 151, at 313.

175. *Id.* at 264 n.173.

176. *Id.* at 265. In certain circumstances, no compensatory damages need be shown at all. See, e.g., *General Motors Corp. v. Johnston*, 592 So. 2d 1054 (Ala. 1992).

177. See Grass, *supra* note 151, at 265. Justice O'Connor set forth factors to guide a proportionality analysis in *Browning-Ferris Industries of Vermont, Inc. v. Kelso Disposal, Inc.*, 492 U.S. 257, 300-01 (1989).

America and has prompted measures of reform.<sup>178</sup> In a number of states, procedures have been adopted to blunt the worst inequities while preserving punitive damages as a tool to promote socially responsible behavior.<sup>179</sup> Five states either totally or partially prohibit them.<sup>180</sup> Seven states place an outer limit on the amount that may be recovered, and in five others, full compliance with FDA product approval regulations is a defense.<sup>181</sup> At least one state requires proof of punitive damages beyond a reasonable doubt,<sup>182</sup> and others require proof by clear and convincing evidence.<sup>183</sup> Ten other states employ bifurcated trials so that evidence of wealth is not heard by a jury until liability has been established.<sup>184</sup> Others will not permit multiple punitive damage awards for the same tort.<sup>185</sup> Seven states require that punitive awards be applied to a public purpose (the statutes of Colorado and Georgia were overturned).<sup>186</sup>

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178. See Mahoney & Littlejohn, *supra* note 82, at 1396, 1398; Grass, *supra* note 151, at 286-287; Lipsen, *supra* note 128, at 248.

179. See Lasagna, *supra* note 49, at 356; Mahoney & Littlejohn, *supra* note 82, at 1397-98.

180. See *St. Luke Evangelical Lutheran Church, Inc. v. Smith*, 568 A.2d 35, 42 (Md. 1990). Massachusetts and New Hampshire do not permit common law punitive damages actions. *Id.* In Connecticut, punitive damages are limited to litigation expenses less taxable costs. *Id.* at 43 (citing *Triangle Sheet Metal Works, Inc. v. Silver*, 222 A.2d 220 (1966)).

181. See Lasagna, *supra* note 49, at 356; Mahoney & Littlejohn, *supra* note 82, at 1398.

182. See COLO. REV. STAT. § 13-25-127(2) (1984).

183. Arizona, Maine, Indiana, Minnesota, and Oregon require proof by clear and convincing evidence. See *Linthicum v. Nationwide Life Ins. Co.*, 723 P.2d 675 (Ariz. 1986); *Tuttle v. Raymond*, 494 A.2d 1353 (Me. 1985); *Travelers Indemn. Co. v. Armstrong*, 422 N.E. 2d 349 (Ind. 1982); MINN. STAT. § 30.925 (1981); OR. REV. STAT. § 52-49-20 (1981). See also Pitt & Groskaufmanis, *supra* note 169, at 4.

184. These include Georgia, Missouri, Utah, Connecticut, New Jersey, Maryland, Nevada, California, Montana, and Kansas. See Mahoney & Littlejohn, *supra* note 82, at 1398; Grass, *supra* note 151, at 286; MODEL PRODUCT LIABILITY ACT § 12(c) (1983) (allowing trial judge to determine amount of punitive damages after liability established).

185. See Grass, *supra* note 151, at 287.

186. See Debra C. Moss, *The Punitive Thunderbolt*, A.B.A. J., May 1993, at 88, 91. See also *McBride v. General Motors Corp.*, 737 F.Supp. 1563 (M.D.Ga. 1990) (holding that Georgia statute U.C.G.A. § 51-12-5.1 granting state 75% of punitive damages in product liability cases was unconstitutional as denial of equal protection and due process clauses of the Georgia and Federal Constitutions); *Kirk v. Denver Pub. Co.*, 818 P.2d 262 (1991) (holding that Colorado statute, C.R.S.A. § 13-21-102, allocating one-third of all reasonable exemplary damages to the state general fund was an unconstitutional taking of private property without just compensation). *But see* *Gordon v. Florida*, 608 So.2d 800

Neutral commentators have also voiced their concern, pointing out that the purpose of punitive damages falls within the ambit of the criminal law and should therefore trigger the necessity for constitutionally required protections.<sup>187</sup> This argument reached the Supreme Court. In *Bankers Life & Casualty Co. v. Crenshaw*,<sup>188</sup> members of the Court expressed concern about a punitive damages scheme where an award would be set aside only if it was manifestly and grossly excessive or exhibited passion or prejudice sufficient to shock the conscience.<sup>189</sup> Justices Scalia and O'Connor, concurring, objected to the lack of an objective standard, which seemed "inconsistent with due process."<sup>190</sup>

A year later, in *Browning-Ferris Industries of Vermont, Inc. v. Kelso Disposal, Inc.*,<sup>191</sup> five Justices reiterated much the same theme while putting off consideration of the due process question until the issue was properly presented at a lower level.<sup>192</sup> With respect to the specific issue raised on appeal, the Court refused to apply the Excessive Fines Clause of the Eighth Amendment in a case, such as the one before it, where the government had not prosecuted the case or had a stake in the outcome.<sup>193</sup> In her separate opinion, Justice O'Connor, noting that the Vermont jury had awarded Kelso \$51,000 in compensatory damages (later trebled) and over \$6 million in punitive damages, at a ratio of 117:1, made the following observation:

Awards of punitive damages are skyrocketing. As recently as a decade ago, the largest award of punitive damages affirmed by an appellate court in a products liability case was \$250,000. . . Since then, awards more than 30 times as high have been sustained on appeal. . . The threat of such enormous awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have

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(Fla. 1992) (holding that Florida statute is constitutional in giving 60% of punitive damages awarded in personal injury and wrongful death actions to the state).

187. See generally Grass, *supra* note 151.

188. 486 U.S. 71 (1988).

189. See *Bankers Life & Casualty Co. v. Crenshaw*, 483 So. 2d 254, 278 (Miss. 1985).

190. *Bankers Life*, 486 U.S. at 88.

191. 492 U.S. 257 (1989).

192. *Id.* at 277.

193. *Id.* at 275.

decided it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market.<sup>194</sup>

The due process issue was addressed but not decided two years later in *Pacific Mutual Life Insurance Co. v. Haslip*.<sup>195</sup> *Haslip* was an insurance fraud case in which an agent had misappropriated premiums, and medical insurance had been canceled unbeknownst to the insured.<sup>196</sup> The plaintiff, who incurred unreimbursed medical bills in the amount of \$3,800, brought suit against the agent and Pacific Mutual Insurance Company.<sup>197</sup> A jury held the company liable under a theory of respondeat superior and rendered a general verdict of \$1,040,000, of which \$840,000 of which was punitive damages.<sup>198</sup> After unsuccessful review by the trial court and the Alabama Supreme Court,<sup>199</sup> Pacific Mutual petitioned the Supreme Court, arguing that its due process rights had been violated because it had been held liable under respondeat superior and had punitive damages assessed against it without specific standards to guide the jury.<sup>200</sup> A large number of manufacturers and insurers intervened as amici in support of Pacific Mutual.<sup>201</sup>

The company lost.<sup>202</sup> Justice O'Connor was the sole dissenter.<sup>203</sup> In an opinion by Justice Blackmun, the court pointed out that the practice of awarding punitive damages was well accepted before the adoption of the Fourteenth Amendment.<sup>204</sup> Nevertheless, the court also made clear that

it would be just as inappropriate to say that, because punitive damages have been recognized for so long, their imposition is never unconstitutional . . . We note once again our concern about punitive damages that 'run wild'. . . One must concede that unlimited jury discretion - or unlimited judicial discretion for that matter - in the fixing of

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194. *Id.* at 282 (O'Connor, J., concurring in part and dissenting in part).

195. 499 U.S. 1 (1991).

196. *Id.* at 5.

197. *Id.*

198. *Id.* at 7.

199. *Id.*

200. *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 7 (1991).

201. *Id.* at 8, n.4.

202. *Id.* at 24.

203. *Id.* at 42 (O'Connor, J., concurring in part and dissenting in part).

204. *Id.* at 15-16.



punitive damages may invite extreme results that jar one's constitutional sensibilities.<sup>205</sup>

Persuasive to the court was the fact that, in the Alabama scheme, there were reasonably clear jury instructions and meaningful judicial review.<sup>206</sup> The jury was told that punitive damages were entirely discretionary; that they were intended to punish and deter; and that they should reflect, and be proportionate to, the character and degree of the wrong.<sup>207</sup> On review, the excessiveness of a punitive verdict was tested according to seven "detailed substantive standards" to ensure that the amount of punitive damages was reasonable and rational from the standpoint of punishment and deterrence.<sup>208</sup>

Justice Blackmun made two additional potentially important observations with respect to the constitutional aspects of the case. He rejected the argument that a standard of proof higher than "preponderance of the evidence" is required to satisfy due process when the preponderance standard is "buttressed . . . [by] procedural and substantive protections" such as those that exist in Alabama.<sup>209</sup> More importantly, he also pointed out that the punitive award, at approximately four times the amount of compensatory damages, may be "close" to the boundary separating constitutional from unconstitutional punishments.<sup>210</sup>

Following its decision, the Court granted certiorari petitions in twelve pending punitive damages cases, vacated

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205. *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991).

206. *Id.* at 22.

207. *Id.* at 19.

208. *Id.* at 20-21 (1991). In reviewing a punitive damages award, the trial court must weigh culpability, the need to deter similar conduct, and the impact on the parties and innocent third parties. *Id.* at 20. The state supreme court may consider: (1) whether there is a reasonable relationship between the damages awarded and the harm inflicted; (2) the wrongfulness of the conduct and awareness of it; (3) whether the defendant had profited from it; (4) defendant's financial condition; (5) the costs of litigation; (6) any criminal sanctions imposed for purposes of mitigation; and (7) other mitigating civil awards. *Id.* at 20-21. In her dissenting opinion, Justice O'Connor argued nevertheless that greater procedural protections are necessary to shield defendants from the bias and prejudice of juries. *Id.* at 42-43 (O'Connor, J., concurring in part and dissenting in part).

209. *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 23 n.11 (1991).

210. *Id.* at 23-24. "We cannot say that the common law method for assessing punitive damages is so inherently unfair as to deny due process and be per se unconstitutional." *Id.* at 17. Nevertheless, "general concerns of reasonableness and adequate guidance from the court when the case is tried to a jury properly enter into the constitutional calculus." *Id.* at 18.

their judgments, and remanded them for further consideration in light of the *Haslip* opinion.<sup>211</sup> In one of these cases, *Wollersheim v. Church of Scientology*,<sup>212</sup> the California Second District Court of Appeal noted that out of twenty decisions decided after *Haslip* (as of April 20, 1992), seventeen upheld their state's processes for determining punitive damages (although two found the awards before them excessive), and only three concluded that their jurisdictions' procedures were in some way defective.<sup>213</sup> In two of the cases in which the punitive damages awards were upheld,<sup>214</sup> the standard for review was "excessiveness" without further articulated guidelines.<sup>215</sup>

It appears that *Haslip* has not precipitated a major change in punitive damages law by state courts and legisla-

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211. See *Clayton Brokerage Co. v. Jordan*, 111 S. Ct. 1298 (1991); *Reserve Life Ins. Co. v. EichenSeer*, 111 S. Ct. 1298 (1991); *Hospital Auth. v. Jones*, 111 S. Ct. 1298 (1991); *Church of Scientology v. Wollersheim*, 111 S. Ct. 1298 (1991); *International Soc'y for Krishna Consciousness v. George*, 111 S. Ct. 1299 (1991); *Pacific Lighting Corp. v. MGW, Inc.*, 111 S. Ct. 1299 (1991); *Portec, Inc. v. Post Office*, 111 S. Ct. 1299 (1991); *Intercontinental Life Ins. Co. v. Lindblom*, 111 S. Ct. 1575 (1991); *AMCA Int'l Fin. Co. v. Hilgedick*, 111 S. Ct. 1614 (1991); *Southern Life and Health Ins. Co. v. Turner*, 111 S. Ct. 1678 (1991); *Trans-america Occidental Life Ins. Co. v. Koire*, 111 S. Ct. 2253 (1991); *Fleming Land-fill, Inc. v. Garnes*, 111 S. Ct. 2882 (1991).

212. 6 Cal. Rptr. 2d 532 (Ct. App. 1992).

213. *Id.* at 537 n.4. In *Adams v. Murakami*, 813 P.2d 1348 (Cal. 1991), the California Supreme Court concluded that a plaintiff must introduce evidence of a defendant's financial condition to obtain punitive damages and that "in light of *Haslip*, the absence of such evidence raises doubt as to the constitutionality of a punitive damage award." *Id.* at 1356. The Court also observed that the state's "passion and prejudice" standard of review "appears to be similar to those as to which the high court noted its concern." *Id.* at 1356-57, n.9. That standard may pass constitutional muster, however, because California requires "clear and convincing evidence that the defendant has been guilty of oppression, fraud or malice." CAL. CIV. CODE § 3294(a) (West Supp. 1993). Moreover, in determining whether a punitive damages award is excessive, an appellate court may consider the reprehensibility of the defendant's conduct, the relationship of the award to compensatory damages, and the award's deterrent effect in light of the defendant's financial condition. See *Neal v. Farmers Ins. Exch.*, 582 P.2d 980, 990 (Cal. 1978). Similarly, the Eighth Circuit Court of Appeals, guided by *Haslip*, upheld the "shocks the conscience" or "passion or prejudice" standards of review in Arkansas because the Arkansas Supreme Court had set forth specific areas of inquiry to test these standards. See *Robertson Oil Co. v. Phillips Petroleum Co.*, 979 F.2d 1301 (8th Cir. 1992), *vacated to be heard en banc*.

214. See *Wolf v. Goodyear Tire and Rubber Co.*, 808 S.W.2d 868 (Mo. Ct. App. 1991); *Coyne v. Allstate Insurance Co.*, 771 F. Supp. 673 (E.D. Pa. 1991).

215. See *Coyne*, 771 F.Supp. at 679-81.

tures.<sup>216</sup> And in its most recent decision, *TXO Production Corp. v. Alliance Resources Corp.*,<sup>217</sup> the Supreme Court appears to have retreated from the position that an award of punitive damages more than four times compensatory damages might trigger a due process violation.<sup>218</sup> *TXO* seemed an ideal case to test this proposition. A West Virginia jury had awarded the plaintiff \$10,000,000 in punitive damages and \$19,000 in compensatory damages at a ratio of 526 to 1.<sup>219</sup> The West Virginia Supreme Court, in an opinion by Justice Richard Neely, held that an award of punitive damages five times compensatory damages should be applied for "really stupid" defendants,<sup>220</sup> but "when a defendant is not just stupid but really mean, punitive damages must be greater in order to deter future evil acts by the defendant."<sup>221</sup> Finding that the defendant had engaged in a "pattern and practice of fraud, trickery and deceit," the court upheld the award.<sup>222</sup>

The United States Supreme Court affirmed in a six-to-three ruling.<sup>223</sup> A plurality opinion by Justice Stevens focused not on the disparity between compensatory and punitive damages, but rather on the difference between the award of punitive damages and the amount of money potentially at stake in terms of reduced or eliminated royalty payments.<sup>224</sup> According to the plurality, the relationship between compensatory and punitive damages is only one of "a host of facts

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216. Many state legislatures and courts already impose restrictions that exceed the constitutional requirements of *Haslip*. See *Johnson v. Hugo's Skateway*, 949 F.2d 1338, 1350-51 (4th Cir. 1990) (rejecting the scheme in Virginia that provided for overturning an award that "is so excessive as to shock the conscience of the court, or to create the impression that the jury was influenced by passion or prejudice").

217. 113 S. Ct. 2711 (1993).

218. See *id.* at 2711.

219. *Id.*

220. *TXO Production Corp. v. Alliance Resources Corp.*, 419 S.E.2d 870, 889 (W. Va. 1992), *aff'd*, 113 S. Ct. 2711 (1993).

221. *Id.*

222. *Id.* at 890.

223. *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2714 (1993).

224. *Id.* at 2721-22. Echoing this approach in his concurring opinion, Justice Scalia commented that in *Haslip* the Court said a four-to-one ratio between punitive damages and actual damages may raise a question of constitutional impropriety, but "today we decide that a 10-to-1 ratio between punitive damages and the potential harm of petitioner's conduct passes muster." *Id.* at 2727 (Scalia, J., concurring).

and circumstances” to be considered in each particular case, and the basic concern must be the reasonableness of an award in light of these factors and whether it is so grossly excessive that it violates the substantive component of the Due Process Clause.<sup>225</sup> Such was not the case, in the view of the plurality, nor was there a violation of procedural due process. Despite Justice Neely’s colorful language, the Court held that there had been careful and thorough appellate review.<sup>226</sup>

Once again in dissent, Justice O’Connor stated that the Court had “held out the promise that punitive damages awards would receive sufficient constitutional scrutiny to restore fairness in what is rapidly becoming an arbitrary and oppressive system.”<sup>227</sup> That promise, she said, was false.<sup>228</sup> Noting that the upward trajectory of these awards continues unabated,<sup>229</sup> she sharply criticized the plurality’s reliance on the “potential harm” theory as “an after-the-fact rationalization invented by appellate counsel who could not otherwise explain this disproportionate award.”<sup>230</sup> In her view, the plurality opinion failed to offer adequate instructions to guide lower courts.<sup>231</sup> While she did not dispute that the wealth of a defendant is a legitimate factor for a jury to consider,<sup>232</sup> she objected strongly to the emphasis placed by trial counsel on the corporate defendant’s extraordinary resources and out-of-

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225. *Id.* at 2721. If compensatory damages are unusually large or unusually small, the ratio of punitive to compensatory damages is not necessarily a good measure of whether the award is excessive. See PETERSON et al., *supra* note 157, at 59. In *Austin v. United States*, 113 S. Ct. 2801 (1993), a case decided shortly after *TXO*, the Court held that a civil forfeiture to the government in a drug case could be disproportionate for purposes of the excessive fines clause of the Eighth Amendment. *Id.* at 2801. The Court pointed out that *Austin* involved a fine payable to the government rather than damages payable to a private party. *Id.* at 2804. Cf. *Browning-Ferris Industries, Inc. v. Kelso Disposal, Inc.*, 492 U.S. 257 (1989), in which the Court held that the Eighth Amendment does not limit the amount of punitive damages awarded to a *private party* “when the government neither has prosecuted the action nor has any right to receive a share of the damages.” *Id.* at 264.

226. *TXO*, 113 S. Ct. at 2724.

227. *Id.* at 2728 (O’Connor, J., dissenting).

228. *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2728 (1993).

229. *Id.* at 2742.

230. *Id.* at 2736.

231. *Id.* at 2731-32.

232. *Id.* at 2737.

state status.<sup>233</sup> In view of her concern that jury decision-making can be swayed by "arbitrariness, caprice, passion, bias, and even malice,"<sup>234</sup> she was further distressed by the cursory review conducted by the West Virginia trial and appellate courts—a process of review, in her opinion, clearly inconsistent with due process and the Court's decision in *Haslip*.<sup>235</sup>

For pharmaceutical companies, the *TXO* decision must surely be a disappointment.<sup>236</sup> However, the case was a commercial dispute between two corporations, and the jury's verdict was based upon the intentional tort of slander of title.<sup>237</sup> As Justice Kennedy stated, "a case involving vicarious liability, negligence, or strict liability might present different issues."<sup>238</sup> A complaint brought against a manufacturer for injury or death caused by a vaccine will likely be a product liability action grounded in negligence or, possibly, in strict liability. In this more limited context, the available evidence suggests that, as a practical matter, the concern about runaway punitive damages awards is not well founded.<sup>239</sup>

The United States Product Safety Commission has estimated that an estimated 29,000 Americans are involved annually in product-related deaths, and an additional 33 million more are the victims of product-related injuries.<sup>240</sup> Yet, after exhaustive research, Professor Michael Rustad of Suffolk University Law School determined that there had been only 355 punitive damage awards in trial verdicts in product

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233. *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2736 (1993).

234. *Id.* at 2728.

235. *Id.* at 2740-41.

236. Continuing enormous punitive damage awards are an additional concern. For example, an Atlanta trial court jury recently awarded parents of a decedent \$101 million in punitive damages and \$4.2 million in compensatory damages. See *State of Georgia v. Moseley*, 436 S.E.2d 632 (Ga. 1993).

237. *TXO Production Corp. v. Alliance Resources Corp.*, 419 S.E.2d 870, 879-80 (W. Va. 1992), *aff'd*, 113 S. Ct. 2711 (1993).

238. *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2726 (1993) (Kennedy, J., concurring). With respect to the claimed basis of liability, at least in California and Cook County, Illinois, the highest number of awards are generally for intentional tort, breach of contract, and fraud; the awards are far fewer when a claim is based on strict liability, negligence, or breach of warranty. See PETERSON et al., *supra* note 157, at 46-47.

239. See RUSTAD, *supra* note 135, at vi. See also Daniels & Martin, *supra* note 157, at 38.

240. See RUSTAD, *supra* note 135, at 23.

liability lawsuits during the period between 1965 and 1990.<sup>241</sup> The number of cases in which punitive damages were awarded has risen steadily from 7 in the 1965-1970 period to 151 in the 1986-1990 period, but the rate of increase has slowed, and if asbestos-related cases are removed from the tabulation, the rate actually decreased during the latter period.<sup>242</sup>

According to Professor Rustad, the rarity of awards is "staggering."<sup>243</sup> The overwhelming number of U.S. manufacturers never have a punitive damage award levied against them, and those that do are guilty of serious misconduct.<sup>244</sup> Even when punitive damages are awarded, however, post-trial reductions are common, and no punitive damages are collected in 38.1% of the cases.<sup>245</sup> Moreover, median punitive damage awards are close in amount to median compensatory damages, exceeding them by ten times or more in only thirteen percent of the cases.<sup>246</sup> Professor Rustad concludes that punitive damage awards have not skyrocketed, as claimed, and have not hindered—but in fact, have facilitated—product innovation.<sup>247</sup> He concludes further that, in the vast majority of the rare number of cases in which they are imposed, such damages are "richly deserved."<sup>248</sup>

#### 4. *Strict Product Liability*

In strict product liability, as elsewhere, the perception of reality seems at least as important as reality itself. It is frequently asserted that the strict liability standard is one of the primary agents in dampening innovation and inspiring the

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241. *Id.* However, Professor Rustad points out that the actual number of awards in product liability litigation is unknown due to the lack of a comprehensive reporting system. *Id.* at 2.

242. *Id.*

243. *Id.* at 24.

244. *Id.* at 7.

245. *Id.* at 31, 46.

246. *Id.* at 29, 32, 44, 47.

247. *Id.* at 38-39. One unhappy caveat should be noted, however. Medical products were the third-highest product category (after asbestos and vehicles) in terms of number of punitive damages verdicts. *Id.* at 26. And medical products, including drug cases, were the highest product category in the top quartile of punitive damages awards. *Id.* at 30. Unfortunately, it takes only a few high verdicts to send shock waves through an industry.

248. *Id.* at 48. See also Daniels & Martin, *supra* note 157, at 43, 63. There is no evidence of a nationwide problem, and the claim that juries routinely award punitive damages in large amounts should be viewed with skepticism.

growth of products-related lawsuits.<sup>249</sup> Whether or not this is so with respect to most products, however, it does not appear that strict liability for failure to warn of dangers that were neither known nor knowable is the applicable standard in the case of drugs.<sup>250</sup> The criticism, in consequence, should not apply to an AIDS vaccine. Before discussing the cases that reach this result, the origin of the doctrine and the various tests that have been adopted to define it will be briefly described.<sup>251</sup>

In early products cases, if a manufacturer sold a product to a local retailer and if a consumer bought the product from the retailer and was injured by a hidden defect in it, which entity was liable? Was it the retailer, which might have limited assets and no insurance, or the manufacturer? The customer, it was argued, did not buy directly from the manufacturer (i.e., did not have privity) for purposes of a suit against it in either contract or tort.<sup>252</sup> This situation left consumers without adequate redress for injuries. To right the balance, over a period of years the defense of privity was overthrown.<sup>253</sup> The defense died in contract actions for breach of an express or implied warranty of merchantability and in tort actions grounded in negligence.<sup>254</sup> Consumers obtained the right to sue manufacturers directly for injuries sustained from use of a defective product, and, to avoid contract-based disclaimers and limitations on damages, the preferred route became negligence.<sup>255</sup>

That still left a major problem. The plaintiff had to prove that what the manufacturer had done was unreasonable—a sometimes formidable undertaking—and likewise often had to marshal the resources and staying power to combat the opposing resources and staying power of a major corporation

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249. See Viscusi & Moore, *supra* note 53, at 106.

250. See *infra* text accompanying note 337.

251. See *infra* text accompanying notes 252-273.

252. See, e.g., *Losec v. Clutc*, 51 N.Y. 494 (1873); KEETON et al., *supra* note 154, § 96, at 681; Schwartz, *supra* note 95, at 30.

253. See KEETON et al., *supra* note 154, at 690-94. See also generally William L. Prosser, *The Assault Upon the Citadel*, 69 YALE L.J. 1099 (1960); William L. Prosser, *The Fall of the Citadel*, 50 MINN. L.REV. 791 (1966).

254. See, e.g., *McPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916); *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960); *Berg v. General Motors Corp.*, 555 P.2d 818 (Wash. 1976).

255. See KEETON et al., *supra* note 154, at 682-83, 692-93; Schwartz, *supra* note 95, at 30.

that typically raised procedural issues or argued a lack of defect or causation.<sup>256</sup> The idea that one should be liable only if at fault (in some way) is deeply ingrained.<sup>257</sup> Nevertheless, it was difficult to accept the spectacle of a large, wealthy corporation escaping liability in the face of an injured—perhaps dreadfully injured—individual whose impaired, mangled, or deformed state resulted from the use of a product manufactured by that corporation.<sup>258</sup> The argument was therefore advanced that a manufacturer should act as an insurer, because the benefit of producing for and selling to a mass market implied a corollary obligation to reimburse those injured by its products.<sup>259</sup> The manufacturer, it was assumed, could factor the expense of occasional injury into the cost of doing business.<sup>260</sup>

Thus, to greatly oversimplify matters, evolved the notion of strict liability for product defects, a notion borrowed from strict liability for breach of contract (the implied warranty of merchantability).<sup>261</sup> In this new context, it served both a loss-distributive and a deterrent function.<sup>262</sup> In all likelihood, it has also had a positive impact on the quality of American products relative to the rest of the world, although the result is regrettably not evident in comparative health and safety statistics.<sup>263</sup>

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256. See, e.g., *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); KEETON et al., *supra* note 154, at 695-96; Schwartz, *supra* note 95, at 32.

257. See KEETON et al., *supra* note 154, at 608-09, 615.

258. *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 445 (Cal. 1944) (Traynor, J., concurring).

259. See HUBER, *supra* note 52, at 6. Huber, referring to them as the Founding Fathers, names Deans William Prosser and John Wade and California Supreme Court Justice Roger Traynor as the most influential early advocates of strict liability in product cases. *Id.*

260. See *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897, 903 (Cal. 1963); KEETON et al., *supra* note 154, at 693.

261. See RESTATEMENT (SECOND) OF TORTS, §§ 519-520 (1977). Strict liability for defective products was first proposed by Justice Traynor in a concurring opinion in *Escola*, 150 P.2d at 436. The California Supreme Court adopted the doctrine eighteen years later in *Greenman*, 377 P.2d at 897. "One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm caused to the ultimate user or consumer . . . [even if] the seller has exercised all possible care in the preparation and sale of the product." RESTATEMENT (SECOND) OF TORTS § 402(A) (1965). Some form of strict liability has been adopted by nearly all states. KEETON et al., *supra* note 154, at 694.

262. KEETON et al., *supra* note 154, at 693.

263. See Peter W. Huber & Robert E. Litan, *The Liability Maze*, The Brookings Institution, (1991). However, for a contrary point of view supporting the



Unlike negligence, where the inquiry is directed toward conduct (i.e., whether a manufacturer acted unreasonably in light of known or constructively known risks), strict liability focuses on the product, and knowledge of risk is imputed at the time of injury.<sup>264</sup> There are three kinds of product defects. First, strict liability will be imposed when there is a manufacturing defect (e.g., when out of 10,000 items, one is produced that contains a defect that causes injury).<sup>265</sup> It will also be imposed for a design defect; that is, a failure in the design of a product so that every item produced is capable of causing injury.<sup>266</sup> Tests have evolved to determine when strict liability for design defect should apply. One, less popular today, is a "consumer expectation" test; in this test, a product will be considered defective, and a manufacturer held liable, when the danger in a design is beyond the expectations of an ordinary consumer who uses the product in an intended or reasonably foreseeable manner.<sup>267</sup> Another test, currently the most popular, is a risk-benefit evaluation of the product's design to determine whether the risk in a challenged design outweighs its potential benefit.<sup>268</sup> To this latter test, companies have asserted a "state-of-the-art" defense. They argue, given technological capability at the time of manufacture, that certain future risks could not have been anticipated<sup>269</sup> or, if anticipated, could have not been eliminated.

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favorable impact of product liability law on safety, see generally Claybrook, *supra* note 120, at 30. See also generally Nader & Claybrook, *supra* note 110, at 46.

264. See *Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988).

265. See *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426 (Minn. 1971); *Moraca v. Ford Motor Co.*, 332 A.2d 599 (N.J. 1975).

266. See *Leichtamer v. American Motors Co.*, 424 N.E.2d 568 (Ohio 1981); *KEETON et al.*, *supra* note 154, at 698-702; *Schwartz*, *supra* note 95, at 31-32.

267. RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965).

268. See *Barker v. Lull Eng'g Co.*, 573 P.2d 443 (Cal. 1978); *Knitz v. Minster Machine Co.*, 432 N.E.2d 814 (Ohio 1982).

269. See, e.g., *Phillips v. Cameron Tool Corp.*, 950 F.2d 488 (7th Cir. 1991) (deciding to apply technological capability standard). But see *Beshada v. John-Manville Prod. Corp.*, 447 A.2d 539 (N.J. 1982) (refusing to apply state-of-the-art defense in strict liability case), *modified*, *Feldman v. Lederle Lab.*, 479 A.2d 374 (1984). For other cases refusing to apply a state-of-the-art defense in strict liability cases, see *Halphen v. Johns-Mansville Sales Corp.*, 788 F.2d 274 (5th Cir. 1986); *Petty v. United States*, 740 F.2d 1428 (8th Cir., 1984); *Dart v. Wiebe Mfg. Inc.*, 709 P.2d 876 (Ariz. 1985); *Johnson v. Raybestos-Manhattan, Inc.*, 740 P.2d 548 (Haw. 1987); *Simmons v. Monarch Machine Tool Co.*, 596 N.E.2d 318 (Mass. 1992); *Elmore v. Owens-Illinois, Inc.*, 673 S.W.2d 434 (Mo. 1984). Knowledge or knowability, however, is required in a majority of states, and only

When a product is beneficial yet may be dangerous if misused, or is unavoidably dangerous to the occasional consumer even with proper use, it must be accompanied by a warning of the hazards to be expected.<sup>270</sup> The adequacy of a warning is determined by whether it covers risks that were known or reasonably should have been known, is reasonably detailed in terms of substance, and is reasonably clear in style.<sup>271</sup> This is the language of negligence. It has been argued that the risk-benefit balancing for design defect is also cast in the language of negligence, so that the strict liability determination for design defect and failure to warn appears to be ultimately grounded in a negligence standard.<sup>272</sup> However, by calling the standard strict liability, the inquiry can be focused in a highly aggressive way on whether the product design, or the warning, is reasonable in light of the nature of the product and the potential hazards arising from its antici-

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a small minority have rejected this requirement. See *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 554 n.10 (Cal. 1991) (citing cases in Louisiana, Missouri, Pennsylvania, and Washington); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska, 1992).

270. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k of the Restatement reads:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous . . . . The seller of [drugs and vaccines] . . . with the qualification that they are properly prepared and marketed, and proper warning is given, . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.*

271. See, e.g., *Anderson*, 810 P.2d at 554 n.10 (citing cases in Louisiana, Missouri, Pennsylvania, and Washington); *Bloxom v. Bloxom*, 512 So. 2d 839 (La. 1989).

272. See Schwartz, *supra* note 95, at 32-33 (noting that the key difference does not lie in a distinction between strict liability and negligence, but rather in the willingness of courts to apply the design defect balancing test in "a free-wheeling and aggressive way . . . indeed, many recent courts have been willing to explicitly acknowledge that in design and warning cases negligence remains the actual standard of the manufacturer's liability"). See also *Anderson*, 810 P.2d at 549 (taking a position between strict liability and negligence). See also generally Sheila N. Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593 (1980).

pated use that were known, or should have been known, at the time of manufacture.<sup>273</sup>

This aggressive pursuit of liability has driven many commercial firms from the development and manufacture of vaccines, despite a market worth an estimated \$500-600 million a year.<sup>274</sup> A principal reason for the exodus is the prohibitive cost associated with vaccine manufacture due to litigation expenses that have driven insurance premiums so high that many vaccines are no longer economically feasible to manufacture.<sup>275</sup> Unlike the case of other industries, which encountered the problem earlier, this development did not occur until after serious suits began in the late 1970s. Until then, most courts were reluctant to repeat the difficult balancing of risks and benefits associated with the use of drugs, vaccines, and medical devices that had already been conducted by the FDA.<sup>276</sup> However, design defect litigation eventually swept up the pharmaceutical industry along with the others.

Because vaccine manufacturers are subject to the tort laws of all fifty states, and because each jurisdiction views the responsibility of drug manufacturers differently, with some tending toward a strict liability standard, it is extremely difficult for pharmaceutical companies to estimate future liability.<sup>277</sup> Understandably, they have become apprehensive about entering new markets and cautious about remaining in old ones. In the past, plaintiffs injured by vaccine products have proceeded under four theories of recovery frequently used in any product liability litigation: negligence, breach of express or implied warranty, strict liability in terms

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273. Employing a "strict liability for defects" standard has an important bearing on the liability of entities that pass the product from the manufacturer en route to the consumer. Once the product is labeled defective, all such later entities become liable. However, the language of Comment k, with respect to vaccines, is cast in terms of negligence for both design defects and warnings. See *supra* note 270. "Comment k has been adopted in the overwhelming majority of jurisdictions that have considered the matter." *Brown v. Superior Court*, 751 P.2d 470, 476 (Cal. 1988).

274. See, e.g., HUBER, *supra* note 52, at 153; Viscusi & Moore, *supra* note 53, at 111.

275. See John Abelson, *Product Liability in a Litigious Society*, 240 SCIENCE 1589 (1988). See also Mahoney & Littlejohn, *supra* note 82, at 1395 (citation omitted).

276. See HUBER, *supra* note 52, at 39.

277. See Joseph Earley, *Can Biotechnology Immunize Vaccine Manufacturers From the Products Liability Crisis?*, 30 JURIMETRICS J., 351, 356 (1990).

of design defect, and failure to warn.<sup>278</sup> Due to rigorous testing and review, however, a vaccine would rarely be improperly prepared.<sup>279</sup> Rather, as with many drugs, the problem for drug manufacturers is that vaccines are unavoidably dangerous.<sup>280</sup> Some people may be injured by their use, and those people cannot be ascertained in advance.<sup>281</sup> They may contract the very diseases the vaccines are intended to prevent, because the vaccines are too potent or not potent enough, or they may incur serious side effects.<sup>282</sup> Yet, for most people, the vaccines may provide an enormous benefit.

As previously mentioned, the solution has been to require a detailed warning of the risks that may be encountered so that each person inoculated with a vaccine will first give his or her informed consent.<sup>283</sup> It is in respect to the adequacy of the warning, therefore, that the most troublesome litigation has occurred.<sup>284</sup> A review of some leading cases is instructive.

In *Davis v. Wyeth Laboratories, Inc.*,<sup>285</sup> the plaintiff was inoculated at a mass immunization clinic with the Sabin oral polio vaccine.<sup>286</sup> He became permanently paralyzed from the waist down.<sup>287</sup> Along with two other manufacturers, Wyeth had been licensed to produce the vaccine after testing on 700,000 to 1,000,000 people, and the federal government rigorously tested each lot of the vaccine to be used.<sup>288</sup> Neverthe-

278. See KEETON et al., *supra* note 154, at 694. See also RUSTAD, *supra* note 135, at 28 (stating that in product liability cases, 80% of plaintiffs plead strict liability, 7% plead negligence, 33 1/3% plead breach of warranty, and 20% plead misrepresentation, fraud, deceit, or intentional tort).

279. See *supra* text accompanying notes 28-42.

280. See generally Okraner C. Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 TOLEDO L. REV. 799, 817 (1988).

281. See James A. Newhard, *Immunity from AIDS Awaits Immunity for Vaccine Manufacturers: How Products Liability Law May Affect the Development of an AIDS Vaccine*, 19 TOLEDO L. REV. 885, 887-88 (1987). In most cases, it is impossible to predict, before a vaccination injection, whether a specific individual's immune system would, or would not, be able to produce the specific antigens needed to fight a virus. *Id.* Thus, drug manufacturers may find themselves subject to suit for just such an occurrence. *Id.* at 888.

282. *Id.* See also Early, *supra* note 277, at 355-56.

283. See *supra* text accompanying notes 37, 40, 270-271.

284. See *infra* text accompanying notes 285-339.

285. 399 F.2d 121 (9th Cir. 1968).

286. *Id.* at 122.

287. *Id.*

288. *Id.* at 122-23.

less, the court noted that there was a small but definite risk for adult recipients of the vaccine. A fact sheet published by Wyeth represented that the vaccine was completely safe, and the pharmacist in charge of the clinic was not apprised of the risk.<sup>289</sup> The bottles of the vaccine did contain a warning from the Surgeon General, but these bottles were never seen by the ultimate consumers, nor was there a "learned intermediary" to make the risk-benefit assessment.<sup>290</sup> The court held that there was a failure to warn the plaintiff, denying him the opportunity to exercise a voluntary, informed choice, which exposed the vendor to strict liability in tort.<sup>291</sup>

A troubling aspect of this case and others that followed is the conclusion that the inadequate warning was the proximate cause of the plaintiff's injury.<sup>292</sup> The court apparently presumed that the plaintiff would have refused the vaccination had the risks, estimated at the time at one in one million, been known to him.<sup>293</sup> The implication is that informed persons will never be voluntarily vaccinated if any risk is involved—an implication that would appear to undermine the social policy goal of reducing or eradicating communicable diseases.<sup>294</sup>

*Davis* was followed by another "failure to warn" case, *Reyes v. Wyeth Laboratories, Inc.*,<sup>295</sup> which also involved the Sabin oral polio vaccine.<sup>296</sup> In *Reyes*, an eight-month-old child was fed drops of the vaccine at a health clinic in Texas and was diagnosed with polio two weeks later.<sup>297</sup> The vaccine was administered by a nurse without a doctor being pres-

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289. *Id.* at 125.

290. *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 125, 130-31 (9th Cir. 1968). In the case of prescription drugs (which include vaccines), a warning to the physician administering them, rather than to the ultimate consumer, is sufficient and may be raised as a defense, because the physician makes an informed, individualized assessment of risk and benefit to the recipient. This is called the "learned intermediary" doctrine. There was no learned intermediary in *Davis*, where the vaccination took place in a mass inoculation clinic. *Id.* at 122. See also *Thomas v. Hoffman-La Roche, Inc.*, 949 F.2d 806, 811 (5th Cir., 1992); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195 (Alaska 1992); *McKenna*, *supra* note 145, at 957-58.

291. *Davis*, 399 F.2d at 126-27.

292. *Id.* at 129.

293. *Id.*

294. See generally *Earley*, *supra* note 277.

295. 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

296. *Id.*

297. *Id.* at 1270.

ent.<sup>298</sup> The child's mother had a seventh-grade education, spoke Spanish, and signed a release form that did not contain a warning and that she either did not read or lacked the ability to understand.<sup>299</sup> The nurse had read a package insert that came with the vaccine and that contained a warning, but she failed to convey the warning to Mrs. Reyes.<sup>300</sup> A jury found for the plaintiff despite the fact that the child might have contracted the disease from a polio epidemic that was raging in the county at the time.<sup>301</sup>

In affirming a jury verdict for the plaintiff, the Fifth Circuit Court of Appeals stated that unless administered by a physician, the warning must reach the consumer.<sup>302</sup> Wyeth had ample reason to foresee how the drug would be administered.<sup>303</sup> The court concluded that it had to assume that the mother would have responded to a warning; there was a basis for rational choice—a statistically foreseeable risk and an alternative in the form of the Salk killed polio vaccine.<sup>304</sup> Without a warning, all that was present in the case was a strict liability analysis based upon design defect.<sup>305</sup>

Three years later, the Fifth Circuit considered another appeal involving the Sabin oral polio vaccine in *Givens v. Lederle Laboratories*,<sup>306</sup> a case involving a mother who contracted polio and subsequent paralysis following the administration of the vaccine to her daughter.<sup>307</sup> Unlike the situation in *Reyes*, the vaccine was administered by a pediatrician in his office.<sup>308</sup> A warning in the package containing the doses of vaccine said the risk of contracting polio from the vaccine was one in three million and that persons in close contact with a recipient might become infected.<sup>309</sup> This warning was never conveyed to Ms. Givens.<sup>310</sup> According to

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298. *Id.*

299. *Id.*

300. *Reyes v. Wyeth Lab., Inc.*, 498 F.2d 1264, 1270 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

301. *Id.* at 1271.

302. *Id.* at 1276.

303. *Id.*

304. *Id.* at 1282.

305. *Reyes v. Wyeth Lab., Inc.*, 498 F.2d 1264, 1282 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

306. 556 F.2d 1341 (5th Cir. 1977).

307. *Id.* at 1343.

308. *Id.*

309. *Id.*

310. *Id.*

the court, the "learned intermediary doctrine"<sup>311</sup> did not apply because the vaccine administration took place in an atmosphere resembling a small county health clinic, as in *Reyes*, and not by prescription in a doctor's office.<sup>312</sup> Under the circumstances, the defendant was responsible for getting the warning directly to the consumer, particularly as there was a failure to impress on the physician the real risk involved.<sup>313</sup>

However, in a Kansas case,<sup>314</sup> where a father contracted polio after his daughter received the Sabin oral polio vaccine from a physician, the Kansas Supreme Court reversed a jury verdict for the plaintiff against the defendant company for \$2 million actual damages and \$8 million punitive damages.<sup>315</sup> The jury had reached its verdict despite the facts that the federal government supplied the seed strains of the virus to the company, closely supervised the manufacture of the vaccine, and approved the warning.<sup>316</sup> The plaintiff sought to impose strict liability based upon design defect, arguing that the risk-free Salk, rather than the Sabin, vaccine should have been used, despite near unanimous approval of the Sabin vaccine in the medical community.<sup>317</sup> The Kansas Supreme Court disagreed, holding that there was no manufacturing or design defect, that the warning to the physician (as "learned intermediary") was adequate,<sup>318</sup> and that in determining the adequacy of a warning, the test is reasonableness, not strict liability.<sup>319</sup> In effect, the court asserted that negligence and

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311. See *supra* note 290 and accompanying text.

312. *Givens v. Lederle Lab.*, 556 F.2d 1341, 1345 (5th Cir. 1977).

313. *Id.*

314. *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986).

315. *Id.* at 1320, 1327.

316. *Id.* at 1320-22.

317. *Id.* at 1321, 1326.

318. Unlike the *Davis*, *Reyes*, and *Givens* cases, *American Cyanamid* involved *adequacy* of warning, not failure to warn. *Id.*

319. *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986). In his dissenting opinion, Justice Prager states:

[T]he cases generally agree that an adequate warning in mass inoculation cases requires that vaccinees be directly informed in clear and simple terms by the drug manufacturer of (1) the reasonably foreseeable risk inherent in the product; (2) reasonable available alternative products and the reasonably foreseeable risks posed by such alternatives; and perhaps—in appropriate cases—(3) the reasonably foreseeable results of remaining untreated.

*Id.* at 1328 (Prager, J., dissenting).

strict liability in warning cases are functional equivalents and that, in consequence, the plaintiff had to show that the defendant was negligent.<sup>320</sup>

In reaching its conclusion, the court cited a prior California case, *Kearl v. Lederle Laboratories*.<sup>321</sup> Yet another tragic case involving the Sabin oral polio vaccine, *Kearl* involved an infant who became paralyzed after receiving the vaccine.<sup>322</sup> The infant's mother had signed a consent form to which an information sheet with a warning was attached.<sup>323</sup> The warning informed the vaccinee that one in every four million vaccinations result in permanent paralysis or possibly death; it further stated that there was a less effective, killed polio vaccine (the Salk vaccine) with no known risk of causing paralysis.<sup>324</sup> The plaintiff's case was based upon two theories of liability: strict-liability design defect and inadequate warning.<sup>325</sup> The trial court instructed the jury on design defect, and the jury found the defendant Lederle liable for \$800,000 in damages.<sup>326</sup>

Reversing, the California Appeals Court held that the trial court should first have determined whether the product was unavoidably dangerous.<sup>327</sup> If it was, the manufacturer of the product would be exempt from strict-liability design defect analysis and would, instead, be judged on the basis of negligence.<sup>328</sup> Such a finding would not preclude prosecution of a case based on strict liability for manufacturing defect.<sup>329</sup> The court further held that, because in all warning cases "the

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320. *Id.* at 1324-25.

321. 218 Cal. Rptr. 453 (Cal. Ct. App. 1985).

322. *Id.* at 456.

323. *Id.*

324. *Id.*

325. *Id.* at 458-68.

326. *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 457 (Cal. Ct. App. 1985).

327. *Id.* at 463-65.

328. *Id.* at 463-64. In making the determination, a court should consider whether:

(1) . . . the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both "substantial" and "unavoidable"; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review."

*Id.* at 464.

329. *Id.* at 465.



tests actually applied condition imposition of liability on the defendant's having actually or constructively known of the risk that triggers the warning,<sup>330</sup> the adequacy of the warning must also be judged on a reasonableness (i.e., negligence) standard even if a claim is advanced under the rubric of strict liability.<sup>331</sup> In this case, the warning was reasonable and therefore was upheld.<sup>332</sup>

In *Brown v. Superior Court*,<sup>333</sup> a case decided three years after *Kearl*, the California Supreme Court overruled that portion of *Kearl* that held that the negligence standard provided in Restatement of Torts Comment k<sup>334</sup> should be applied to a prescription drug only after a trial court determination that the drug is unavoidably dangerous.<sup>335</sup> Rather, the court determined that all prescription drugs are unavoidably dangerous and subject to a negligence standard.<sup>336</sup> The majority opinion stated:

in accord with almost all our sister states that have considered the issue, we hold that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.<sup>337</sup>

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330. *Id.* at 465-66. In strict liability, on the other hand, the focus is not on the reasonableness of conduct but on the product, and actual or constructive knowledge of risk is either ignored or imputed to the manufacturer.

331. *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 466 (Cal. Ct. App. 1985).

332. *Id.* at 467, 469.

333. 751 P.2d 470 (Cal. 1988).

334. *See supra* note 270.

335. *Brown*, 751 P.2d at 482.

336. *Id.* at 481-83.

337. *Id.* at 482-83. In a subsequent opinion, the California Supreme Court extended the rationale of *Brown* beyond the drug context and held that there must be knowledge or knowability before there can be strict liability for failure to warn. *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 557 (Cal. 1991). While noting that "[i]t may . . . be true that the 'warning defect' theory is 'rooted in negligence,'" the primary inquiry in strict liability is not the reasonableness of the manufacturer's conduct but only whether the defendant gave adequate warning "of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Id.* at 558. The distinction between negligence and strict liability is in practice, however, "without a substantial difference." *Id.* at 562 (Mosk, J., concurring in part and dissenting in part). *See also* *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377 (Cal. Ct. App. 1992) (holding that an action for breach of express or implied warranty is available to a plaintiff if manufacturer does not prove a danger is unknown or unknowable).

The court arrived at this holding for reasons of public policy. Strict liability would not further the important public interest in the development and availability of drugs at an affordable price. Drug manufacturers, fearful of large adverse monetary judgments and the expense of insurance, may be reluctant to undertake research programs or market risky drugs that might save lives and reduce suffering.<sup>338</sup> In reaching these conclusions, the court cited the experience of pharmaceutical companies with vaccines.<sup>339</sup>

For pharmaceutical companies, these decisions are somewhat positive. If a reasonably detailed warning adequately apprises a consumer in a clinic, or a doctor prescribing a prescription drug, of the risk, the manufacturer will be exempt from liability.<sup>340</sup> Moreover, in almost all states, the standard for measuring fault will be the reasonableness of the manufacturer's conduct in light of what was known, or should have been known, at the time of distribution.<sup>341</sup> Unless a manufacturing defect is involved, a strict-liability determination will not be made either for design defect or for failure to warn of unknown and unknowable hazards.<sup>342</sup>

However, the cases present troubling issues sub silentio. Suits have been brought and juries have returned huge verdicts, including large punitive damages awards, even though some were reversed on appeal.<sup>343</sup> Moreover, the "learned intermediary" doctrine has been narrowly construed.<sup>344</sup> Ultimately, AIDS vaccines may be administered in mass inoculation clinics by nurses and public health workers.<sup>345</sup> If a warning becomes too detailed, encompassing all possible risks, and if it must be comprehended by consumers who are

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338. *Brown v. Superior Court*, 751 P.2d 470, 478-79 (Cal. 1988).

339. *Id.* at 479-80 (citing Gina Kolata, *Litigation Causes Huge Price Increases in Childhood Vaccines*, 232 *SCIENCE* 1339 (1986)). In the case of the DTP vaccine, liability exposure and the resulting difficulty in obtaining insurance has driven all but two manufacturers from the market. *Id.* at 479. Justice Mosk stated that "the cost of each dose rose a hundredfold from 11 cents in 1982 to \$11.40 in 1986, \$8 of which was for an insurance reserve." *Id.* The price increase roughly paralleled an increase in the number of lawsuits from one in 1978 to 219 in 1985. *Id.*

340. *Id.* at 477-78.

341. *Id.* at 482-83.

342. *Id.*

343. *See supra* note 216.

344. *See, e.g., Davis v. Wyeth Lab.*, 399 F.2d 121 (9th Cir. 1968).

345. *See McKenna, supra* note 145, at 952.

uneducated, there is a risk that it will be neither understood nor read. The possibilities of abuse and liability are genuine.

Noteworthy, also, is the fact that prior FDA approval of both the manufacturing process for the Sabin oral polio vaccine and the warning that accompanied distribution did not kill these cases at the stage of summary judgment.<sup>346</sup> Although compliance with public regulations is some evidence that a design is non-defective, the court is the final arbiter of the manufacturer's duty.<sup>347</sup> Even complete conformity to standards written by Congress itself will not immunize a defendant manufacturer from liability.<sup>348</sup> Moreover, FDA studies that find no link between a drug and a defect will not necessarily preclude a substantial jury award.<sup>349</sup>

To be sure, most American jurisdictions recognize a "state-of-the-art" defense in design and warning cases.<sup>350</sup> In other words, a manufacturer cannot be held liable for a defect that was neither known nor, in the exercise of reasonable diligence, could have been known at the time of manufacture and distribution.<sup>351</sup> A jury, however, confronted with a badly injured or paralyzed plaintiff is still left with discretion to determine whether the defect was reasonably scientifically knowable, although it was in fact not known.<sup>352</sup> If it makes this determination, the manufacturer will be liable.<sup>353</sup> And if suit is brought years after distribution, so that the manufacturer of a particular dose of vaccine cannot be identified and individual culpability ascertained, all manufacturers produc-

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346. See, e.g., *Davis*, 399 F.2d at 121; *Reyes*, 498 F.2d at 1264, *cert. denied*, 419 U.S. 1096 (1974).

347. *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 458 (Cal. Ct. App. 1985).

348. See *HUBER*, *supra* note 52, at 47-49. "The manufacturer of a birth control pill paid \$2.75 million in punitive damages for an allegedly defective chemical formulation, despite complete compliance with all applicable FDA regulations." *Id.* at 49 (citing *Ortho Pharmaceutical Corp. v. Wooderson*, 681 P.2d 1038 (Kan. 1984), *cert. denied*, 469 U.S. 965 (1984)); *Ramirez v. Plough, Inc.*, 12 Cal. Rptr. 2d 423, 425 (Cal. Ct. App. 1992). *But see Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322 (Or. 1978) (holding that the case should not go to jury due to prior approval of engine by FAA).

349. See *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986) (awarding \$4.7 million for birth defect following use of spermicide), *reh'g denied*, 795 F.2d 89 (1986). "An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not sufficient for state tort law purposes." *Id.* at 746.

350. See *Schwartz*, *supra* note 95, at 43.

351. *Brown v. Superior Court*, 751 P.2d 470, 483 (Cal. 1988).

352. *Id.* at 481-83.

353. *Id.* at 481.

ing the same vaccine with identical levels of risk may be held liable according to their share of the product market.<sup>354</sup>

### III. LEGISLATION AND PROPOSALS

#### A. *The Problems That Need to Be Addressed*

If a preventive vaccine is developed, it is not clear to whom it would be administered. Among other things, that will depend upon the cost of the vaccine and the extent of the pandemic.<sup>355</sup> In countries where the disease is spreading rapidly through both heterosexual and homosexual contacts, all members of society may be candidates for inoculation. In this country where, to date, HIV transmission still appears to be confined largely to specific groups, the demand for the vaccine, at least in the first instance, may be limited to the members of those groups. Nevertheless, even if the target population is restricted, large numbers of people will be involved. Their need for a vaccine is acute.

The foremost hindrance to making a vaccine available is the enormous scientific difficulty associated with developing one.<sup>356</sup> A close second in this country, however, is the liability concerns of United States drug manufacturers.<sup>357</sup> They operate within a matrix of legal rules that are imposed by fifty states and the federal government. In the last ten to fifteen years, these rules have resulted in an increase in suits against vaccine manufacturers and a corresponding decrease in the incentive to develop and produce a new vaccine.<sup>358</sup> The international competition to develop an AIDS vaccine is intense. Yet, despite superficial similarity, the American tort system places a brake on United States drug companies by

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354. *Id.* See also *Sindell v. Abbott Lab.*, 607 P.2d 924 (Cal. 1980), *cert. denied*, 449 U.S. 912 (1980); *Hymowitz v. Eli Lilly*, 539 N.E.2d 1069 (N.Y. 1989), *cert. denied*, 493 U.S. 944 (1989).

355. See *supra* text accompanying notes 3-10, 13.

356. See *supra* note 13.

357. These concerns are exacerbated by the extremely high cost of developing a vaccine, estimated to be \$50 million or more. See *Cloney, supra* note 11, at 567.

358. See NELSON, *supra* note 113, at 2, 7. See also *Iglehart, supra* note 112, at 1286 and *supra* text accompanying notes 52-53.

generating many more lawsuits and higher damage awards than do the systems in Europe and Japan.<sup>359</sup>

A way must be found to speed a vaccine to market by reducing the liability concerns of American manufacturers. Uniform legislation in all states might achieve this goal, but its enactment is unlikely. The most feasible alternative is a federal statute. There are those who argue, however, that no legislation to protect AIDS vaccine manufacturers is necessary.<sup>360</sup> This argument appears to be based upon several assumptions. First, the epidemiology of AIDS makes mass immunization unnecessary, and thus a preventive vaccine need only be administered to so-called high-risk groups. Since distribution will therefore be limited and, in any event, the vaccine "will be too expensive and scarce to administer indiscriminately," it will probably "be prescribed by a physician who will have an especially active role in the vaccination decision." Also, because any AIDS vaccine to be developed will be based upon new genetic engineering techniques, it should be very safe.<sup>361</sup> Under the circumstances, it is contended, manufacturers should be amply protected from liability by the "learned intermediary" doctrine, by the inherent safety of the product, and by existing standards of liability for warning defects.<sup>362</sup>

These arguments are unrealistic for several reasons. To begin with, even if the disease is still largely confined in this country to certain cities and groups, it is now present in every state and is also spreading to women through heterosexual contact.<sup>363</sup> The threat is heightened in the face of a virus that mutates rapidly.<sup>364</sup> Therefore, immunization against the HIV virus cannot be limited indefinitely to high-risk groups but must, to the extent possible, also be readily available to others in the population.

In view of this plausible eventuality, it is unlikely that a physician will monitor the inoculation of every potential vaccinee, even in this country. Supervision by a physician may

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359. See Peter W. Huber & Robert E. Litan, *Overview*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION*, *supra* note 49, at 22-23; Schwartz, *supra* note 95, at 68-75.

360. See, e.g., McKenna, *supra* note 145, at 944.

361. *Id.* at 949, 961.

362. *Id.* at 948-61.

363. See *supra* notes 5, 10.

364. See *supra* note 13.

be the practice at the outset with specific, targeted groups, but this practice probably would not continue for very long.<sup>365</sup> In all likelihood, mass immunization through clinics will gradually become standard practice, and inoculations by nurses or other allied health care workers will become the norm.

In addition, it is unrealistic to assume that the vaccine will be so safe that liability concerns should be irrelevant. It is true that a vaccine made from a fragment of the viral coating should indeed be safer than a live or killed whole-virus vaccine.<sup>366</sup> But any drug, administered to large numbers of different kinds of people, has some statistical chance of causing injury or death.<sup>367</sup> As two commentators have pointed out, because the HIV virus has certain genetic components in common with other viruses that cause cancer, there is a risk of a vaccinee developing cancer at some point after vaccination even with an attenuated-virus vaccine.<sup>368</sup> "Regardless of the care with which an AIDS vaccine is designed," they say, "adverse reactions are inevitable."<sup>369</sup>

Nor is it sufficient to assert that, because about eleven vaccines are in early-stage trials, seven of which are being tested by the National Institute of Allergy and Infectious Diseases,<sup>370</sup> at least some manufacturers must believe that the statutory and/or common law protections that are currently available justify the costs of research and the risks associated with vaccine development. Research and testing are at a stage prior to marketing, distribution, and administration. The General Counsel of Johnson and Johnson has said that if his company developed an AIDS vaccine, he would not recom-

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365. For example, clinics were the site of the vaccinations in *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 123 (1988) ("[in] the absence of a doctor, the administration of the vaccine for the . . . clinic was delegated to a pharmacist") and, in *Reyes v. Wyeth Lab., Inc.*, 498 F.2d 1264, 1270 (1974) ("The vaccine was administered . . . by a registered nurse; there were no doctors present.").

366. See *supra* note 13; McKenna, *supra* note 145, at 949, 961; Mariner & Gallo, *supra* note 70, at 18.

367. See Mariner & Gallo, *supra* note 70, at 21; Cloney, *supra* note 11, at 560 n.6 (citing Richard Cooper, *For AIDS Inoculants, Ounce of Prevention Worth a Pound of Cure*, LEGAL TIMES, June 6, 1989, at 18).

368. Mariner & Gallo, *supra* note 70, at 18.

369. *Id.* at 23.

370. In *Gloomy AIDS Picture, Patches of Blue Emerge in Understanding, Awareness*, Biotechnology Newswatch, Aug. 17, 1992, available in LEXIS, Nexis Library.

mend that it be marketed until Congress passed protective legislation.<sup>371</sup>

Even though the "products liability crisis" may have eased, it damaged the pharmaceutical industry.<sup>372</sup> In addition, although the Supreme Court may have imposed rough limits on the award of punitive damages, and states have also taken steps to curb excesses in this area, large exemplary awards are still possible.<sup>373</sup> Juries, moreover, are sympathetic to injured plaintiffs, whether a strict-liability or a negligence standard is applied, so that drug manufacturers have good reason to be cautious. It is certainly arguable that federal legislation covering products liability in general would be unnecessary, unwise, and contrary to principles of federalism, but there is precedent, given the swine flu and childhood vaccines, that carving out federal protection for particular products is justified.<sup>374</sup> The urgent need to develop an AIDS vaccine appears to be a situation where such legislation is warranted.

In order to determine the parameters and objectives of such legislation, this article presents an overview of legislation affecting availability and use of other vaccines.<sup>375</sup> To assist in effectively reviewing this material, the following objectives of the proposed federal statute provide baseline guidance.<sup>376</sup>

The federal statute must provide adequate redress to persons injured by the administration of a vaccine. It must impose suitable rules to deter improper corporate conduct.<sup>377</sup> Finally, it must set forth standards and procedures that fairly adjudicate liability yet limit damage awards to reasonable amounts.<sup>378</sup> The statute should, at a minimum address the following factors: (1) the duty of care, (2) the nature of the fact-finder, (3) punitive damages, (4) compensatory damages, (5) defenses, and (6) the standard of review on appeal.

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371. *Cloney, supra* note 11, at 570.

372. *See supra* text accompanying notes 49-67.

373. *See supra* part II.B.3.

374. *See infra* parts III.B.1-2; *Cloney, supra* note 11, at 562.

375. *See infra* parts III.B.1-4.

376. *See infra* text accompanying notes 377-383.

377. For example, slipshod methods in manufacturing processes should be deterred.

378. In addressing these objectives, Congress may deal with aspects of the American tort system (e.g., contingent fees) that differentiate it from other legal systems. These concerns are not the focus of this article.

### 1. *The Duty of Care*

The duty of care was treated in the preceding section.<sup>379</sup> In order to limit manufacturer liability, should the standard be negligence rather than some variant of strict liability? Should a defendant be permitted to plead conformity with the requirements of regulatory agencies, in particular the FDA, as a complete defense?<sup>380</sup> In the alternative, should a manufacturer be completely absolved of liability in the event of injury with the entire burden assumed by the government, possibly with the government having a right of redress against a manufacturer in a case of gross or wanton negligence?

### 2. *The Nature of the Fact-Finder*

It is sometimes argued that the lottery-like quality of American tort law is caused by the use of lay juries.<sup>381</sup> Perhaps a judge alone, or a panel of government-appointed medical experts, should determine liability.

### 3. *Punitive Damages*

The punitive damages factor also has been treated in a preceding section.<sup>382</sup> Although these damages are awarded in only a small proportion of cases and are frequently reduced on appeal, the enormous amounts occasionally awarded are a major concern to any manufacturer contemplating the introduction of a new product.<sup>383</sup> Should the amount be capped and given only on a finding of gross negligence by clear and convincing evidence rather than a preponderance of the evidence? Should a trial be bifurcated with evidence to support

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379. See *supra* text accompanying notes 340-342.

380. See HUBER, *supra* note 52, at 47-49. In *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985), *cert. denied*, 474 U.S. 920 (1985), after finding no federal preemption, the court determined that compliance with FDA regulations, though admissible to demonstrate lack of negligence, was not conclusive on the issue. *Id.* at 70-71. Similarly, in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984), the federal appeals court stated that mere compliance with federal regulatory requirements does not preclude liability. *Id.* at 1542.

381. See Huber & Litan, *supra* note 359, at 22-23; Schwartz, *supra* note 95, at 64, 73.

382. See *supra* part II.B.3.

383. See Stephen D. Sugarman, *The Need to Reform Personal Injury Law Leaving Scientific Disputes to Scientists*, 248 SCIENCE 823, 825 (1990). In tort actions for personal injuries, punitive damages are not available in France, Germany, and Japan. Schwartz, *supra* note 95, at 72.



punitive damages permitted only in a separate proceeding after liability is determined? Should conformity with agency standards be a defense?

#### 4. *Compensatory Damages*

Like punitive damages, should these also be capped with a specific maximum, such as \$250,000, permitted for pain and suffering? If a higher standard of proof is imposed for punitive damages, should a preponderance of the evidence suffice in the case of compensatory damages?

#### 5. *Defenses*

As previously mentioned, to encourage manufacturers to produce an AIDS vaccine, it is arguable that compliance with the standards of a regulatory agency should be a defense. Should it also be permissible to plead contributory or comparative negligence? Further, should consent be a bar to liability if there has been sufficient warning?

#### 6. *The Standard of Review on Appeal*

If a panel of experts is used for the initial determination of liability, should judicial review be based on the same standard as review of an administrative agency determination (i.e., upheld unless clearly erroneous)? Or should review be *de novo*?

### B. *Other Legislative Approaches*

Legislation to ensure the availability and use of other vaccines and mollify the liability concerns of pharmaceutical companies has been crafted by Congress in the recent past.<sup>384</sup> Moreover, legislation has been enacted in California to address these same concerns in the specific context of AIDS.<sup>385</sup> In addition, Congress has considered, but so far not adopted, legislation that would modify the product liability rules of most concern to manufacturers.<sup>386</sup> All of these will be described briefly to determine whether they contain provisions that might be incorporated into federal legislation dealing

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384. See *infra* parts III.B.1-2.

385. See *infra* part III.B.3.

386. See *infra* part III.B.4.

with liability issues in the manufacture and dissemination of an AIDS vaccine.

1. *National Swine Flu Immunization Program of 1976*

Following an outbreak of swine flu in the winter of 1976, Congress appropriated \$135 million to purchase swine flu vaccine in order to ensure its distribution.<sup>387</sup> However, drug manufacturers would not release their substantial inventory of the vaccine because their insurance carriers refused to grant coverage.<sup>388</sup> The situation was regarded as so serious that Congress enacted legislation, the National Swine Flu Immunization Program of 1976.<sup>389</sup> In this legislation, Congress provided an exclusive remedy for injured claimants against the United States; suits by persons alleging personal injury or death were barred against agencies, organizations, and individuals that manufactured, distributed, or administered the vaccine.<sup>390</sup> The legislation stated, in pertinent part:

the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty.<sup>391</sup>

However, if the United States were found guilty on a negligence theory, the government could recover damages from the negligent program participant.<sup>392</sup> A two-year statute of limitations was imposed from the time of administration of the vaccine.<sup>393</sup>

The government undertook to prepare a consent form that would provide adequate warning, but the form did not

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387. See Cloney, *supra* note 11, at 561 n.6.

388. *Id.* See also *Unthank v. United States*, 732 F.2d 1517, 1518 (10th Cir., 1984).

389. Public Health Service Act, Pub. L. No. 94-380, 90 Stat. 1113 (1976) (codified at 42 U.S.C. § 247b(j)-(l) (1976)). If the situation recurs, manufacturers of an AIDS vaccine will in all likelihood keep it from the market unless there is protective legislation. See Earley, *supra* note 277, at 369. See also Malcolm Gladwell, *Firms Seeking an AIDS Vaccine Ask Protection: If Serum is Discovered, They Say, Threats of Lawsuits Could Block Distribution*, L. A. TIMES, Nov. 29, 1988, at 7.

390. 42 U.S.C. § 247b(k)(1)(A)(i)-(ii) (1976).

391. *Id.* § 247b(k)(2)(A)(i).

392. *Id.* § 247b(k)(7).

393. *Id.* § 247b(k)(2)(A)(iii).

include the unanticipated risk of contracting Guillain-Barre syndrome, a paralytic condition, from the vaccine.<sup>394</sup> After only two months, a large number of cases of this syndrome compelled the discontinuation of the inoculation program.<sup>395</sup> Settlements and adverse judgments have exceeded \$100 million dollars. No reimbursement from a participating manufacturer has been sought.<sup>396</sup>

## 2. *The National Childhood Vaccine Injury Act*

Following a conclusion by the Committee on Public-Private Sector Relations in Vaccine Innovation that "the common law tort system is not able to provide predictable, rapid and equitable compensation for vaccine-related injuries because each claim requires an extended, costly and complex adjudication procedure that results in unpredictable outcomes,"<sup>397</sup> the National Childhood Vaccine Injury Act of 1986 was enacted.<sup>398</sup> This statute aimed to provide "optimal prevention of human infectious diseases through immunization" and "optimal prevention against adverse reactions" by, inter alia, encouraging cooperation between government and non-government entities in research and development of vaccines, providing efforts to encourage public acceptance of vaccines, educating the public with respect to adverse reactions and contraindications of the vaccines, and establishing a National Vaccine Advisory Committee to study and recommend ways to encourage the availability of safe and effective vaccines.<sup>399</sup> The immunization of almost all children against a wide range of pediatric illnesses was required, and a no-fault program was created for victims suffering from adverse reactions to

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394. See Cloney, *supra* note 11, at 597.

395. *Id.*

396. *Id.* at 597-98. See also HUBER, *supra* note 52, at 102. It should be noted, however, that the vaccine may, in fact, not have caused Guillain-Barre Syndrome. Helen H. Blake, Note, *The AIDS Vaccine: Legislation to Limit Manufacturer's Liability*, 27 TULSA L.J. 757, 770 (1992). The incidence among the population receiving the vaccine was the same as the incident rate in the general population. *Id.*

397. Edwin J. Jacob, *Of Causation in Science and Law: Consequences of the Erosion of Safeguards*, 40 BUS. LAW. 1229, 1241 (1985).

398. National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3755, (1986) (codified at 42 U.S.C. § 300aa-1 to aa-34 (1988)). See also Mary B. Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988).

399. See 42 U.S.C. § 300aa-2, aa-5 (1988).

DTP and other vaccines typically used in a childhood immunization program.<sup>400</sup>

A no-fault program—the first federal program of its kind with respect to vaccines—is embodied in the National Vaccine Injury Compensation Program that was established as part of the Act.<sup>401</sup> In general, its purpose is to discourage litigation against manufacturers by providing more certain, if potentially less generous, compensation from the federal government.<sup>402</sup> Under the Compensation Program, a vaccine manufacturer cannot be sued in state or federal court for more than \$1,000 for damages arising from a vaccine-related injury or death unless a petition has first been filed under the program for compensation.<sup>403</sup> The legislation includes a Vaccine Injury Table that itemizes injuries, disabilities, illnesses, conditions and deaths associated with each vaccine that is covered under the Program.<sup>404</sup> Causation is presumed for these events if they occur within the time specified in the Vaccine Injury Table.<sup>405</sup> However, a petition may also document (a) an illness or disability not set forth in the Vaccine Injury Table but that was caused by a named vaccine, and (b) symptoms of an illness or disability that did not occur within the time period set forth in the Table but that were caused by a named vaccine.<sup>406</sup> In these instances, a petitioner must prove causation by a preponderance of the evidence.<sup>407</sup>

The petition is filed with the United States Court of Federal Claims; and a Special Master makes the initial findings of fact and conclusions of law, then issues a decision as to whether compensation should be awarded.<sup>408</sup> Upon motion, these findings and conclusions may then be reviewed by the Claims Court, which may uphold the Master's decision, remand, or issue its own findings of fact and conclusions of law, if it determines that the Special Master's decision is arbi-

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400. *Id.* § 300aa-13 to 14.

401. *Id.* § 300aa-10(a).

402. *Id.* § 300aa-11(a)(2)(A).

403. *Id.*

404. *Id.* § 300aa-14(a). This Table includes the time period in which the first symptom or manifestation of each condition must occur after vaccine administration in order to be eligible for compensation. *Id.*

405. See *Hines v. Secretary of the Dep't. of Health and Human Servs.*, 940 F.2d 1518, 1524 (Fed. Cir. 1991).

406. 42 U.S.C. § 300aa-11(C)(1)(c)(ii)(I) to (II) (1988).

407. See *Hines*, 940 F.2d at 1525.

408. 42 U.S.C. § 300aa-12(a), (c) (1988).

trary, capricious, an abuse of discretion, or otherwise not in accordance with law.<sup>409</sup> A de novo review of the resulting judgment may be had in the United States Court of Appeals for the Federal Circuit.<sup>410</sup> This court may examine the Special Master's decision again.<sup>411</sup>

To recover, a plaintiff must show by a preponderance of the evidence that he or she received a vaccine set forth in the Vaccine Injury Table within the jurisdiction of the United States and that there is not a preponderance of evidence that the illness, disability, or death was due to factors unrelated to the administration of the vaccine.<sup>412</sup> Compensation may include reasonable past and future medical expenses, and past and future expenses incurred for rehabilitation, special education, vocational training, counseling, emotional and behavioral therapy, and custodial care.<sup>413</sup> Compensation for actual and anticipated loss of earnings is permitted, as are reasonable attorneys' fees and other costs.<sup>414</sup> A \$250,000 cap is imposed for pain and suffering or for death benefits.<sup>415</sup> Punitive damages are prohibited, but they may be awarded if a manufacturer fraudulently withholds information during approval proceedings, intentionally withholds information respecting safety and efficacy after approval, or engages in criminal or

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409. *Id.* § 300aa-12(e).

410. *Id.* § 300aa-12(f), aa-32. See *Hines v. Secretary of the Dep't. of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (holding that the court of appeals should review Claim Court's decision to determine whether or not Special Master acted arbitrarily in its decision).

411. The "arbitrary and capricious" standard is a highly deferential form of review. *Hines*, 940 F.2d at 1528. The focus is on the agency's decision-making rather than on the actual decision, and a decision will be upheld if a Special Master has considered all relevant evidence, drawn plausible inferences, and articulated a rational basis for the decision. *Id.* (citing *United States v. Garner*, 767 F.2d 104, 116 (5th Cir. 1985)). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id.*

412. 42 U.S.C. § 300aa-13(a)(1) (1988).

413. *Id.* § 300aa-15(a)(1)(A)-(B). However, the Program mandates that compensation shall not be made to the extent that other sources of compensation can be obtained either under state programs or through health insurance. *Id.* In addition, no health insurance provider is permitted to make payment of its benefits to a claimant secondary to payment under the Program. *Id.* § 300aa-15(h).

414. *Id.* § 300aa-15(a)(3)(A)-(B), aa-15(e)(1)(A)-(B).

415. *Id.* § 300aa-15(a)(2), (4).

illegal activity relating to the safety and effectiveness of a vaccine.<sup>416</sup>

The procedural mechanisms for compensation require that, upon judgment, the applicant for compensation file an election either to receive the compensation awarded (or not awarded) or to file a civil action for damages for injury.<sup>417</sup> If the applicant elects to accept the judgment, he or she may not subsequently bring an action against the vaccine manufacturer for the vaccine-related injury or death.<sup>418</sup> Payment is made from a Vaccine Injury Compensation Trust Fund,<sup>419</sup> which is subrogated to all rights of the petitioner up to an amount no greater than the compensation paid.<sup>420</sup> The Trust Fund is funded from a tax, not large in amount, on each dose of vaccine sold.<sup>421</sup> If awards exceed a certain number during specified time intervals (up to six hundred during a four-year period), the Secretary may refuse to accept further petitions, and injured claimants must thereupon seek a remedy through legal action.<sup>422</sup>

If a civil action is commenced, state law applies.<sup>423</sup> However, no vaccine manufacturer is liable for injury or death resulting from unavoidable side effects where the vaccine was properly prepared and accompanied by proper directions and warnings (defined as manufacturer compliance in material respects with all appropriate FDA requirements).<sup>424</sup> An exception to this immunity arises where the injured party can show conduct entitling a petitioner to punitive damages<sup>425</sup> or can show by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with the FDA regulations.<sup>426</sup> In addition, in what appears to be an extension of the "learned intermediary"

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416. *Id.* § 300aa-15(d)(1), -23(d)(2).

417. *Id.* § 300aa-21(a)(1) (1988).

418. *Id.*

419. *Id.* § 300aa-15(i)(1); 26 U.S.C. § 9510(d)(1) (1988).

420. 42 U.S.C. § 300aa-17(a) (1988).

421. 26 U.S.C. § 4131(a)-(b) (1988).

422. 42 U.S.C. § 300aa-34(b)(1)-(2) (1988).

423. *Id.* § 300aa-22(a). The action could be commenced for negligence, failure to warn a physician under strict liability, or breach of express or implied warranties. *Id.*

424. *Id.* § 300aa-22(b)(1)-(2). This provision appears to codify Comment k of the Restatement. See RESTATEMENT (SECOND) OF TORTS § 401 cmt. k (1965).

425. 42 U.S.C. § 300aa-23(d)(2) (1988).

426. *Id.* § 300aa-22(b)(2)(B).

doctrine to mass immunizations, the Program also grants immunity to manufacturers who fail to provide a direct warning to an injured party with respect to the potential dangers that may result from administration of a vaccine.<sup>427</sup> If a trial takes place, it must be divided into three stages to assess liability, general damages, and, where permitted, punitive damages.<sup>428</sup>

As of January 1991, no claimant had declined an award of compensation under the Program.<sup>429</sup> The purpose of the statute—to provide reimbursement to injured claimants while avoiding the hazards and delay of litigation—appears to have been met. Nevertheless, awards as of January 1991 totaled \$74 million, and it is not clear that the Program will have enough money in the Vaccine Injury Compensation Trust Fund to compensate the victims of the increased number of meritorious claims that have recently been filed.<sup>430</sup>

### 3. *The California AIDS Statute*

Many states have enacted legislation dealing with AIDS in areas such as education, blood screening, confidentiality, and insurance.<sup>431</sup> Only California, it appears, has enacted legislation that deals with compensating members of the general public, not research subjects, who may be injured or killed as a result of receiving an AIDS vaccine.<sup>432</sup> The legislature, in its findings and declarations, noted the rapidly spreading epidemic, the critical need for a vaccine, and the unwillingness of pharmaceutical companies “to become involved in vaccine research, development and manufacturing because of uncertain profitability and perceived and actual

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427. *Id.* § 300aa-22(c).

428. *Id.* § 300aa-23(a)-(d).

429. *See* Cloney, *supra* note 11, at 596. Moreover, lawsuits against DPT manufacturers have declined sharply, from 255 in 1986 to 47 in 1990. *Id.*

430. *Id.*

431. *See* Larry O. Gostin, *Public Health Strategies for Confronting AIDS: Legislative and Regulatory Policy in The United States*, 261 JAMA 1621, 1622-23 (March 1989). Connecticut and Massachusetts have passed statutes that address liability arising from the administration of vaccines, the former with respect to injuries to research subjects, and the latter, at least arguably, with respect to an AIDS fund for vaccinees injured during experimental treatment. *See* 1991 CONN. PUB. ACT §§ 19a-590 to 19a-591c (1991); MASS. ANN. LAWS ch. 10, § 35K (Law. Co-op. 1991) (effective Jan. 1, 1991 to June 30, 1995); MASS. ANN. LAWS ch. 111, § 2E (Law. Co-op. 1990).

432. *See* CAL. HEALTH & SAFETY CODE §§ 199.45(r), .50 (Deering 1990).

marketplace risks and disincentives."<sup>433</sup> Moreover, the legislature, observing that any serious obstacles to the development of a vaccine should be removed, declared that it is "in the public interest to assure fair compensation, if necessary at public expense, to any innocent victim who may be injured by an AIDS vaccine."<sup>434</sup>

To further this laudable objective, the California legislature established an AIDS Vaccine Victims Compensation Fund to pay to any person whose injury is proximately caused by administration of a vaccine all direct medical costs, loss of earnings caused by the injury, and damages for pain and suffering up to \$550,000.<sup>435</sup> Claims against the fund are expressly limited by the amount of money in the fund, which derives from a surcharge on the sale of each unit of a vaccine.<sup>436</sup> Applications for payment of damages are made to the State Board of Control, and in the event of a disallowance in whole or part, a victim may obtain a hearing before the Board or a hearing examiner and, subsequently, judicial review (with the court exercising independent judgment).<sup>437</sup>

There are significant limitations. No payment will be made to the extent that damages are attributable to the comparative negligence of the victim or arise from a vaccination administered during a clinical trial.<sup>438</sup> Of most significance, no payment will be made if a manufacturer has been found liable in a court of law, and the fund is subrogated to any claim an injured person may make against a manufacturer.<sup>439</sup>

Originally, the statute was written so that manufacturers were insulated from strict product liability for damages proximately caused by design or warning defects or breach of implied warranty if, upon motion and hearing, a trial judge determined that the vaccine causing injury was unavoidably dangerous.<sup>440</sup> The three criteria set forth in *Kearl v. Lederle*

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433. *Id.* § 199.45(a),(b),(l).

434. *Id.* § 199.45(p),(r).

435. *Id.* §§ 199.47(d)(1)-(3), .50(b)(3).

436. *Id.* § 199.50(o)-(p).

437. *Id.* § 199.50(d)-(i).

438. *Id.* § 199.50(c)(1), (c)(3). It should be noted that manufacturers may suffer the greatest exposure to liability from injuries that result from clinical trials.

439. *Id.* § 199.50(c)(2), (k).

440. See Kelly G. McIntyre, *Review of 1986 California Legislation: Health and Welfare; Acquired Immune Deficiency Syndrome—Manufacturer Liability*,



*Laboratories*<sup>441</sup> were incorporated into the statute.<sup>442</sup> However, in 1988, the same year the California Supreme Court, in *Brown v. Superior Court*,<sup>443</sup> overruled the "unavoidably dangerous" portion of *Kearl*, the protection afforded by the statute was eliminated.<sup>444</sup> The statute does not bar concurrent claims against the fund and against manufacturers,<sup>445</sup> and victims may receive compensation, therefore, from either entity, although no payment (supplementary or otherwise) shall be made by the state if a manufacturer is liable.<sup>446</sup> The surviving incentive to manufacturers in the statute is a state guarantee to purchase up to 500,000 units of an FDA-approved vaccine at no more than twenty dollars per dosage.<sup>447</sup>

#### 4. *Product Liability Fairness Act*

With the strong endorsement of American business, bills to create uniform federal legislation with respect to product liability have been introduced every year since 1982 without reaching the Senate or House floor for a vote.<sup>448</sup> Over this period of time, in an effort to obtain bipartisan support, many of the original strict limits on manufacturer liability were either watered down or eliminated.<sup>449</sup> Yet the attempt to move the most recent bill<sup>450</sup> toward a floor vote in the Senate

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18 PAC. L.J. 663, 665 & n.14 (1987) (citing CAL. HEALTH & SAFETY CODE § 199.49(a)(2)). Recovery based upon negligence, manufacturing defect, and breach of express warranty was not precluded. See *id.* at 665. Section 199.49 was later repealed by the California Legislature. 1988 Cal. Stat. 1955 § 3.

441. 218 Cal. Repr. 453 (1985). For a discussion of *Kearl*, see *supra* text accompanying notes 321-330.

442. See McIntyre, *supra* note 440, at 664 & n.8 (citing CAL. HEALTH & SAFETY CODE § 199.49(c)).

443. 751 P.2d 470 (1988). For a discussion of *Brown*, see *supra* text accompanying notes 333-339.

444. 1988 Cal. Stat. 1555 § 3.

445. See CAL. HEALTH & SAFETY CODE § 199.50(c)(2), (m) (Deering 1990).

446. *Id.* § 199.50(c)(2).

447. *Id.* § 199.51.

448. See Kenneth Jost, *Rewriting the Rules for Products Liability*, THE RECORDER, Apr. 27, 1992, at 5, 15.

449. See S. 640, 102d Cong., 1st Sess. § 103(b)(1991); see also Robert A. Goodman, Note, *Proposed Federal Standards for Product Liability*, 30 HARV. J. ON LEGIS. 296, 303-4 (1993).

450. See S. 640, 102d Cong., 1st Sess. (1991). Its close counterpart in the House of Representatives was the Fairness in Product Liability Act of 1991, H.R. 3030, 102d Cong., 2d Sess. (1991).

was defeated on September 10, 1992.<sup>451</sup> It was opposed by Democrats and some Republicans, in significant measure due to concern that a federal statute should not encroach on an area traditionally left to the states, particularly when state courts and legislatures have already instituted significant changes in product liability law in the last decade.<sup>452</sup>

Absent from the bill were a cap on punitive damages, a general defense against liability for complying with government standards, and a defense for products that are inherently dangerous.<sup>453</sup> However, the portions of the bill directed to manufacturers of drugs and medical devices provided that no punitive damages could be awarded where the drug or device (1) was subject to pre-market approval by the FDA, or (2) was generally recognized as safe and effective under conditions established by the FDA.<sup>454</sup> Otherwise, punitive damages could be awarded only in a bifurcated proceeding at the election of the defendant if compensatory damages were also awarded.<sup>455</sup> Also required was a showing by clear and convincing evidence that the harm suffered was the result of conduct manifesting a manufacturer's or product seller's conscious, flagrant indifference to the safety of those persons who might be harmed by the product.<sup>456</sup> Failure to exercise reasonable care was not in itself considered to be such conduct.<sup>457</sup> The bill also encouraged parties in product liability disputes to first engage in alternate dispute resolution before proceeding to trial.<sup>458</sup> In an effort to mimic the loser-pay-all English system and thereby discourage litigation, it provided that plaintiffs or defendants would have to pay opposing counsel fees if they rejected settlement offers that, from their respective viewpoints, were equal to or better than the award of damages at trial.<sup>459</sup> A two-year statute of limitations, except for capital goods, was imposed to run from the time a

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451. See S. 640, 102d Cong., 1st Sess. § 103(b) (1991). See also Robert A. Goodman, Note, *Proposed Federal Standards for Product Liability*, 30 HARV. J. ON LEGIS. 296, 303-04 (1993).

452. S. 640, 102d Cong., 1st Sess. (1991).

453. *Id.*

454. *Id.* § 303(c)(1)(A)-(B). This defense is not available to any defendant who has committed fraud during the approval or review process. *Id.*

455. *Id.* § 303(a), (d).

456. *Id.*

457. *Id.* § 303(a).

458. *Id.* § 202.

459. *Id.* § 201(e)-(f).

plaintiff discovered or should have discovered the harm and its related cause.<sup>460</sup>

Arguably, uniform federal standards respecting product liability are both inappropriate and unworkable. But to the extent there is a product liability crisis, this legislation might have improved American competitiveness by easing the liability fears of manufacturers. On the other hand, consumer advocates, and the plaintiffs' bar, concerned that federal legislation would unfairly favor manufacturers at the expense of injured consumers, pointed out that the data do not support the claim that such a crisis exists.<sup>461</sup> Moreover, in the last decade, forty-one states have enacted product liability reform measures that, in many cases, address the concerns of manufacturers.<sup>462</sup> For these reasons and circumstances, federal legislation was felt to be either unnecessary or harmful.<sup>463</sup>

In all likelihood, the forum for debate has now shifted to the American Law Institute, the organization that spurred the development of product liability law when it promulgated Section 402A of the Restatement (Second) of Torts in 1965. In what is planned as a four- or five-year project, the Institute is planning to draft a new restatement on product liability law.<sup>464</sup> Its non-binding but authoritative statement

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460. *Id.* § 304(a)-(b).

461. See Lipsen, *supra* note 128, at 254; see also *supra* text accompanying notes 122-139.

462. See Jost, *supra* note 448, at 15. Twenty-five states have changed the common law treatment of punitive damages, eleven have permitted a defense for complying with "state of the art," nine allow compliance with government standards as a defense, and seventeen have placed limits on pain and suffering damages. Lipsen, *supra* note 128, at 248-49. In California, a seller will not be liable if a product is a common consumer product, is inherently unsafe, and is known to be unsafe by the ordinary consumer. CAL. CIVIL CODE § 1714.45 (Deering Supp. 1993). This provision, however, does not apply to prescription drugs, and the California Supreme Court made no mention of the statute in *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988). See D.O. Aitken, *The Product Liability Provision of the Civil Liability Reform Act of 1987: An Evaluation of Its Impact and Scope*, 62 S. CAL. L. REV. 1449, 1481-83 (1989).

463. For example, the American Bar Association opposed federal product liability reform in the 1990 Senate hearings and proposed a compensation scheme in place of uniform tort reform in cases where the claims in terms of number and liability damages threaten the solvency of a significant number of manufacturers and the numbers of such claims have been a burden on courts. *Product Liability Reform Act, 1990: Hearings on S. 1400 Before the Subcomm. on the Consumer*, 101st Cong., 2d Sess., 583-84 (1990) (statement of Robert B. McKay, Chairman of the Action Commission to Improve the Tort Liability System and James Serota, Chairman of the Committee Section of Antitrust and Law).

464. See Jost, *supra* note 448, at 5.

should channel developments in this area of the law for years to come.

### C. Proposed Legislation

In summary, any legislation that attempts to address the liability concerns of AIDS vaccine manufacturers must limit manufacturer liability for non-negligent, harmful side effects caused by the vaccine, yet at the same time, ensure prompt and reasonable compensation to all vaccinees for their injuries, and deter improper corporate conduct.<sup>465</sup> Conceivably, national health insurance might pay the medical costs of injured vaccinees, but, in all likelihood, such insurance will not modify tort liability for general damages or other special damages arising from drug-related injuries.<sup>466</sup> Moreover, if private insurance companies are retained in the final scheme that is enacted, as seems likely for the time being, they will surely balk at the prospect of creating reserve funds to deal with non-imminent and unknown injuries arising from administration of an AIDS vaccine.<sup>467</sup> A separate government program will be required, one that involves a compensation fund for this restricted purpose.

The National Swine Flu Immunization Program<sup>468</sup> offers a flawed approach toward the achievement of these objectives, because government assumption of risk for non-negligent injuries without adequate limitations on liability make it far too open-ended in cost. An AIDS vaccine may produce

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465. See generally part III.B.2.

466. On October 27, 1993, President Clinton delivered his 240,000 word proposal for universal health insurance to Congress. Robert Pear, *Congress Is Given Clinton Proposal for Health Care*, N.Y. TIMES, Oct. 28, 1993, at A1. He demanded passage of a reform act by the end of 1994. *Id.* Representatives of both parties predict that the proposal will be substantially revised. *Id.* The American Medical Association is attempting to activate physicians to lobby Congress for significant changes. Robert Pear, *Doctors Rebel Over Health Plan in Major Challenge to President*, N.Y. TIMES, Sept. 30, 1993, at A1. Thus, at this point, it is not possible to predict accurately what the content of the final legislative package will be.

467. Industry analysts predict that over 500 health insurers will be driven from the field when a final plan is implemented. Peter Kerr, *Insurers Fear They'd Be the Big Losers in a World of Managed Health Care*, N.Y. TIMES, Oct. 1, 1993, at A11. Nevertheless, several of the largest insurers, particularly those that have already invested in managed care networks, should survive. *Id.* Financial incentives will push consumers toward the less-expensive managed care plans. *Id.*

468. See *supra* notes 387-396 and accompanying text.

an unanticipated symptom—as may have been the case with Guillain-Barre syndrome in the administration of the swine flu vaccine—and it would be an embarrassing denouement to repeat a hasty termination of an inoculation program due to liability costs. Similarly, the California AIDS statute suffers from inherent flaws.<sup>469</sup> In addition to the exclusion of those in clinical trials, it eliminates state liability in cases where liability against a manufacturer has been proven in a court of law, and no restrictions are placed on the scope of that liability.<sup>470</sup> Manufacturers may prevail, as in the Bendectin catastrophe, yet still incur enormous legal costs. Moreover, a model that involves a multiplicity of state statutes would be unsatisfactory in light of the perceived danger. While in many instances the piecemeal development of law in the separate states permits each state to craft its own solutions to particular needs, uniform national legislation is still the preferred route when dealing with a crisis of national—indeed, international—dimensions.<sup>471</sup>

Unlike the previously mentioned statutes, both the National Childhood Vaccine Injury Act<sup>472</sup> and the failed Product Liability Fairness Act<sup>473</sup> contain provisions that may be models sufficient for the task. The former, in particular, is a useful example, because it is directed toward resolving many of the same issues, in the context of other vaccines, that are present in connection with the manufacture and distribution

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469. See *supra* notes 431-447 and accompanying text.

470. See CAL. HEALTH & SAFETY CODE § 199.50(c)(2)-(3) (Deering 1990).

471. Whether such legislation would preempt state law will depend upon the extent to which it so thoroughly occupies the field that it is reasonable to infer that Congress left no room for the states to supplement it. See *Pennsylvania v. Nelson*, 350 U.S. 497, 502-05 (1956). Matters beyond the reach of the statute may not be preempted. See *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2617-18 (1992) (holding that amended §§ 1331-1340 of the 1965 Federal Cigarette Labeling and Advertising Act preempted claims based on failure to warn but not on express warranty, intentional fraud, or conspiracy). Most courts have refused to hold that the National Childhood Vaccine Injury Act bars suits under state law, and indeed the statute by its express terms appears to make such suits possible. See *Abbot v. American Cyanamid*, 844 F.2d 1108, 1116-17 (4th Cir. 1988) (Wilkins, J., concurring); *Graham v. Wyeth Lab.*, 666 F.Supp. 1483, 1491 (D. Kan. 1987). See also Peggy J. Naile, Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 685-700 (1989).

472. Pub. L. 99-660, 100 Stat. 3755, (1986) (codified at 42 U.S.C. §§ 300aa-1 to -34 (1988)).

473. S. 640, 102d Cong., 1st Sess. (1991).

of an AIDS vaccine.<sup>474</sup> Indeed, as a general statutory scheme, one might argue simply for an amendment of the National Childhood Vaccine Injury Act to include injuries arising from an AIDS vaccine; the Vaccine Injury Table could be expanded to encompass particular harms from an AIDS vaccine for which compensation would be allowed, and periods of limitation could be established in which to file for compensation due to these harms.<sup>475</sup> As is the case with the other vaccines covered by the statute, manufacturers would be afforded substantial protection because they could not be sued unless a prior claim for compensation had first been filed under the Act; injured vaccinees would receive prompt compensation, and damage awards would be reasonable but limited.

While this approach is certainly commendable, there are drawbacks. For one, AIDS may merit a separate statute simply because of the growing size of the problem and a resultant concern that an amendment would swallow the original. It may be wise to keep the other vaccines, with their separate funding needs, as distinct entities. Moreover, it is not clear how easily any problems associated with an AIDS vaccine would fit into the Vaccine Injury Table, even though the general approach of the statute is sound. The only means available for identifying those injuries that might be caused by vaccination will be through data collected during clinical trials, but such data will be limited in both time and scope. It will be virtually impossible to collect data on all potential side effects of a vaccine for every age group, racial or ethnic group, or group that might be hypersensitive to vaccination. Thus, the basic scheme of the Vaccine Injury Table—to presume causation for known, potential injuries that occur within specific time periods—will be difficult or impossible to attain. Of

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474. See *supra* text accompanying notes 397-430.

475. Causation would be presumed if the statutory criteria were satisfied. As in the National Childhood Vaccine Injury Act, non-specified harms, or specified harms arising after the period of limitation, would have to be proven by a preponderance of the evidence. See *supra* text accompanying notes 406-407. There is, however, an obvious problem in the context of an AIDS vaccine when adverse reactions may not be discovered during clinical trials and in fact may not occur until years after inoculation. See Blake, *supra* note 395, at 771. The presence of HIV antibodies, without more, will not guarantee that a vaccine has been effective, because these antibodies are present in those who eventually succumb to AIDS; indeed, there is a danger that knowledge of their presence may encourage unwarranted, risk-taking behavior.

course, recipients of an AIDS vaccination (either during clinical trials or thereafter) could receive compensation, essentially upon filing a claim, for those injuries that, on the basis of information obtained during clinical trials, are known to be proximately caused by vaccination. But for most injuries, until a body of information is available, causation would have to be proven, as is currently the case under the Vaccine Injury Table for non-named injuries or injuries that arise after the applicable period of limitation.<sup>476</sup>

In other respects, the approach of the National Childhood Vaccine Injury Act could be followed. A victim would be required first to make a claim for compensation from a fund established by the federal government (discussed below), and an award from this fund would be based upon the fact of injury and not the manufacturer's behavior. Only after the receipt of compensation, or the denial thereof, would a state claim be permitted against a manufacturer, and an election at that point (to accept the judgment or file a civil action) would be required. In the application for compensation from the government, an injured vaccinee would have to prove injury and, presumably, causation by a preponderance of the evidence and, as is the case under the National Childhood Vaccine Injury Act, that there is not a preponderance of evidence that the illness or disability is unrelated to the administration of the vaccine.<sup>477</sup>

Most cases should terminate at the conclusion of the process to obtain compensation from the government, because most claimants will accept a known result in preference to the hazards of litigation. The possibility of suit—and, in some instances, the actuality—will serve as a deterrent to improper manufacturer conduct. However, should the injured vaccinee elect to file an action against a manufacturer based upon fault, the statute should proscribe strict liability except where there has been a failure to warn of known or

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476. See *supra* text accompanying notes 406-407. Until a reliable body of information is obtained, it is not possible to state what the applicable statute of limitation should be for an unknown, but proximately caused, injury. While the presence of HIV occurs soon after infection, other manifestations of illness (presumably controlled by the vaccine) may not arise for years. See Blake, *supra* note 395, at 771. Thus, if a period of limitation is imposed, its outer limit should be generous.

477. See 42 U.S.C. § 300aa-13(a)(1)(B) (1988).

knowable risks.<sup>478</sup> Thus, an award of compensatory damages should in most cases be restricted to a finding of negligence, by a preponderance of the evidence, in the manufacture or distribution of the vaccine. Although manufacturers need and deserve protection from unwarranted suits, they should pay "fair damages" if they fail to take reasonable care,<sup>479</sup> which should be defined as compliance in all material respects with specific and detailed FDA guidelines regarding both the production process and the information to be included in a warning. These guidelines, set forth earlier in detail, are meticulous as to the safeguards applied to the testing, manufacture, and labeling of new drugs and vaccines.<sup>480</sup> "The formal federal licensing of a new drug, medical device, [or] vaccine . . . should be viewed as the momentous matter it really is—not as a routine and irrelevant pleasantry to be forgotten as soon as the first tort plaintiff walks into the courthouse."<sup>481</sup>

Arguably, a warning should be issued to the vaccine recipient directly, thereby precluding application of the "learned intermediary" doctrine. Such direct warning to the recipient would be needed since, in a mass immunization program, nurses and other health workers, but not physicians, would likely be responsible for vaccine administration. A proper warning should set forth known and suspected side effects and state that, to a certain extent, vaccines in general are considered unavoidably unsafe. If it is known that certain people (e.g., by age group or ethnicity) are at higher risk of injury, this information should be included. The warning might also provide information as to the risks of not being vaccinated, as well as the consequences of contracting AIDS. Finally, a consent form reciting the limits on claims for injury and the procedures to be followed to be eligible for compensation should be signed by every vaccinee.

Punitive damages—perhaps the greatest fear of drug manufacturers, despite persuasive evidence that they are awarded sparingly in product liability suits and are overwhelmingly restricted to cases of egregious misconduct<sup>482</sup>—

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478. See *supra* text accompanying notes 333-337.

479. See *Gostin, supra* note 13, at 14.

480. See *supra* text accompanying notes 28-42.

481. HUBER, *supra* note 52, at 215.

482. See *supra* text accompanying notes 241-248.



should be limited, and compliance with agency standards should be a defense. These damages should be awarded only upon clear and convincing evidence of malfeasance.<sup>483</sup> In addition, to further protect manufacturers, trial of these matters should take place in a bifurcated proceeding, as is the case in many states, after determination of liability and compensatory damages.<sup>484</sup> A cap on the amount of punitive damages for a particular episode of malfeasance, arguably well in excess of a million dollars given the financial strength of many drug companies and the behavior required to trigger liability, should be imposed, with the award paid into a government compensation fund.<sup>485</sup> If the cap is not reached in one proceeding, punitive damages could continue to be assessed in subsequent proceedings until the cap is attained.

Similarly, limits should be imposed on the amount to be recovered as compensatory damages from the government compensation fund. Reasonable past and present medical expenses, costs of rehabilitation, special education and the like, lost earnings, and reasonable attorneys' fees should be covered. Of most importance, there should be a cap on damages for pain and suffering; the limit of \$250,000 in the National Childhood Vaccine Injury Act is a reasonable compromise,<sup>486</sup> and the same figure should suffice as a death benefit. The fund should be subrogated to all rights of an injured vaccinee, up to the amount paid, if the government elects to proceed against a manufacturer,<sup>487</sup> and an offset should be allowed for contributory or comparative negligence.

While lay juries may naturally be employed as the factfinder in a state civil action, their presence should be avoided in the petition to the government. The evidentiary burdens imposed by a jury, and the presumptive lack of any expertise in a body drawn at random from the community, militate against a jury's effectiveness. Instead, administrative judges,

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483. The National Childhood Vaccine Injury Act prohibits a fraudulent withholding of relevant information from the FDA, either before or after a vaccine's approval, or criminal or illegal activity relating to the vaccine's safety and efficacy. 42 U.S.C. § 300aa-23(d)(2) (1988).

484. A bifurcated proceeding was also proposed in the Product Liability Fairness Act. See S. 640, 102d Cong., 1st Sess. § 303(a), (d) (1991).

485. If Congress preempts the field, it seems likely that equal protection problems will be avoided. See *supra* note 186.

486. 42 U.S.C. § 300aa-15(a) (1988).

487. See *id.* § 300aa-17(a).

masters,<sup>488</sup> or panels of scientific and medical experts could be established to evaluate claims. The National Childhood Vaccine Injury Act calls for the use of masters,<sup>489</sup> but in an emerging area where proof of injury caused by the vaccination may be difficult, a panel of experts would be preferable. Once a body of knowledge is available, the less cumbersome use of masters can be employed. For the same reason, upon review by the Claims Court and the United States Court of Appeals for the Federal Circuit, the decisions of the panel should be upheld unless found "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law."<sup>490</sup> Instead of de novo review, the focus should be on the rationality of the panel's decision-making process rather than on the actual decision that is reached. This is, as the *Hines* Court stated, "a highly deferential standard of review," with the focus on whether all relevant evidence has been considered, plausible inferences have been drawn, and a rational basis for the decision has been articulated.<sup>491</sup>

Lastly, the financing of the government compensation fund should be considered. There are a variety of sources that could be used to provide money. The federal government could allot money to the fund from general revenues, but then the fund would be subject annually to the competing demands of other worthy causes.<sup>492</sup> Alternatively, a tax in the form of a surcharge could be imposed on the sale of each unit of vaccine; unless the government becomes a purchaser, however, in many instances vaccine recipients will be too poor to afford the cost, and distribution to them will be gratis and tax-free. As a variation, drug companies might be required to deposit a fixed amount into the fund for each unit of vaccine distributed, and the federal government, from general revenues if necessary, would become an insurer of last resort if claims on the fund exhausted the amount contributed to it.

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488. See *id.* § 300aa-12(c) to (d).

489. See *supra* notes 408-411 and accompanying text.

490. 28 U.S.C. § 1295(a)(3) (1988). See also 42 U.S.C. § 300aa-12(e) (1988).

491. *Hines v. Secretary of the Dep't. of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

492. Another alternative would be to mandate that each state contribute to the fund in an amount proportionate to the number of citizens in that state who are vaccinated. The source of the state contribution could be through a general sales tax increase or the like.

The price of the vaccine would necessarily rise to all purchasers to cover the unreimbursed cost of distribution to the poor.

For vaccines included under the National Childhood Vaccine Injury Act, a tax is imposed for each unit of vaccine that is sold by a manufacturer, producer, or importer.<sup>493</sup> There is precedent, therefore, for that approach, and it may operate effectively with respect to an AIDS vaccine. But the National Childhood Vaccine Injury Act also suspends operation of its compensation scheme if the total number of awards in a given period exceed the number listed.<sup>494</sup> In this eventuality, claimants are free to initiate suits against manufacturers without first applying for compensation from the fund, and protection to the manufacturers ceases.<sup>495</sup> This is an undesirable possibility, particularly when potential injuries from an AIDS vaccine, although in all likelihood quite limited, are unknown in scope and severity. The government must be prepared to underwrite the fund if it becomes insolvent, or the advantages of a statute safeguarding manufacturers, yet providing prompt and reasonable compensation in the event of injury, may be seriously compromised.

#### IV. CONCLUSION

The crisis precipitated by the onslaught of the Human Immunodeficiency Virus continues unabated.<sup>496</sup> While the need for a vaccine is acute in areas of rampant infection in other parts of the world, there is also an urgent need for a vaccine in this country.<sup>497</sup> Drug companies—some with experimental vaccines already in clinical trials—are working to develop effective preventive or therapeutic vaccines.<sup>498</sup> However, the possibility of tort litigation for any injury resulting from vaccine administration will impede the manufacture and distribution of a final product.<sup>499</sup>

There is a widespread impression within the business community that the country has been subject in recent years to an orgy of litigation.<sup>500</sup> Upon examination, however, the

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493. 26 U.S.C. § 4131(a) (1988).

494. 42 U.S.C. § 300aa-34 (1988).

495. *Id.* § 300aa-34(b)(1).

496. *See supra* text accompanying notes 2-10.

497. *See supra* text accompanying notes 3-5.

498. *See supra* text accompanying notes 11-13.

499. *See supra* part II.B.1.

500. *See supra* text accompanying notes 82-121.

evidence for this proposition is ambiguous, but there seems little doubt that, within the last decade-and-a-half, pharmaceutical companies experienced a number of damaging lawsuits, many related to vaccines.<sup>501</sup> Their concern, therefore, is realistic. Moreover, even though there appears to be an emerging trend toward limiting punitive damages<sup>502</sup> and even though almost all courts impose a negligence standard, rather than strict liability for unknown or unknowable defects in the case of unavoidably unsafe products such as vaccines,<sup>503</sup> the fear of tort liability and large damage awards remains.

If an effective vaccine is to be brought to market, a way must be found to limit manufacturer concerns about liability yet provide timely and adequate compensation to injured vaccinees. Federal legislation is the best way to achieve this goal. The National Childhood Vaccine Injury Act can serve as a useful model.<sup>504</sup>

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501. See *supra* text accompanying notes 52-57, 75-81.

502. See *supra* part II.B.3.

503. See *supra* part II.B.4; see notes 336-37.

504. See *supra* part III.B.2.

