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## AIDS VACCINE MANUFACTURERS V. TORT REGIME: THE NEED FOR ALTERNATIVES

Vaccines have contributed more to public health in this country and around the world than any other medical product, device, or procedure.<sup>1</sup>

Vaccines have effectively controlled or eradicated the once fatal and debilitating diseases of smallpox, diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio.<sup>2</sup> Yet, the imposition of strict product liability for adverse side-effects suffered by some vaccine users substantially deterred the development and manufacture of these vaccines and continues to hinder future access to them.<sup>3</sup> In the 1970s and early 1980s, twelve of the sixteen

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1. Peter Huber, *Will New Vaccine Statute Give Shot in Arm to Tort Reform?*, LEGAL TIMES, Mar. 9, 1987, at 9 (referring to importance of vaccines in combatting nationwide diseases and noting deterrent effect of tort liability). See generally Sharon Snider, *Childhood Vaccines*, FDA CONSUMER, Sept. 1990, at 19-26 (presenting historic overview of each childhood disease and vaccine).

2. See, e.g., EVE K. NICHOLS, NATIONAL ACADEMY OF SCIENCES, MOBILIZING AGAINST AIDS 223-24 (1989) [hereinafter MOBILIZING AGAINST AIDS] (noting that immunization by antiviral vaccines has controlled familiar diseases of measles, mumps and rubella); Victoria Bennett, *Health Law—Vaccine Injuries—Federal Law Prescribes for Alternatives to Tort Actions for Vaccine-related Injuries*, 11 U. ARK. LITTLE ROCK L.J. 749, 749 (1988-89) (noting that National Childhood Vaccination Programs' goal of reducing morbidity and mortality accompanying childhood diseases was successful); Gordon Ada, *Prospects for a Vaccine Against HIV*, 339 NATURE 331, 331 (1989) (noting that vaccines have controlled prior epidemics and that health officials can use vaccines to control current AIDS epidemic). Many vaccines designed to prevent or control viral infections are highly successful. *Id.* The use of vaccines against measles, mumps, rubella and polio viruses has reduced these diseases to minor public-health problems. *Id.* Vaccines are widely employed as public health measures in the United States and other industrialized countries and have had an enormous impact on morbidity and mortality. INSTITUTE OF MEDICINE, VACCINE SUPPLY & INNOVATION 18-19 (1985) [hereinafter VSI]; see also Snider, *supra* note 1, at 19-26 (describing effectiveness of vaccination programs in controlling childhood diseases and supporting finding with relevant infection statistics). For a list of the major achievements, including decreases in death and infection rates see *id.* at 18-19; Snider, *supra* note 1, at 19-26.

*Cf.* CAROLYN H. ASBURY, ORPHAN DRUGS 65 (1985) (noting that federal government played large role in development and distribution of vaccines for typhoid fever, cholera, anthrax, rabies, mumps, measles, rubella, and, most recently, hepatitis B, pneumococcal pneumonia and meningococcal infections).

3. See, e.g., Bennett, *supra* note 2, at 749 (stating that, during childhood disease crisis, litigation expenses and increasing liability insurance premiums drove vaccine manufacturers from the marketplace and forced those remaining to increase prices); Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J., 477, 477-79 (1990) (noting that threat of product liability lawsuits inhibited manufacturers of swine flu and childhood vaccines and that liability associated with vaccine-related injuries has marked effect of decreasing number of commercial manufacturers in business of vaccine development); VSI, *supra* note 2, at 15 (citing in-depth governmental study of tort liability's effect on vaccine production and availability). Withdrawals from the market due to vaccine-related injury liability concerns

American vaccine manufacturers simply dropped out of the market, seriously threatening vaccine supply.<sup>4</sup> In response, Congress enacted legislation to address the detrimental effect the tort liability system was having on vaccine innovation and access.<sup>5</sup> In order to avoid repeating history, we must learn from these past vaccine scenarios and attempt to structure an effective method to deal with the problems conventional tort liability places in the path of finding an answer to the Acquired Immunodeficiency Syndrome (AIDS) epidemic.<sup>6</sup>

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create a situation in which the United States is almost totally reliant on one manufacturer for polio and DPT vaccines (Lenderle), and on another for measles, mumps, and rubella vaccines (Merck, Sharp & Dohme). *Id.* Only one, or at most two, distributors supply each of the major pediatric vaccines, and even these situations are unstable. *Id.* Manufacturers state that decisions to discontinue are made because of extreme liability exposure, the high cost of litigation, and the difficulty of obtaining adequate insurance. *Id.* at 27. In addition to causing vaccine withdrawal from the market, imposition of tort liability has created a disincentive to investment in the development of new or improved immunizing agents. *Id.* at 15.

After an in-depth study of vaccine availability barriers and impediments through history, the Committee on Public-Private Sector Relations in Vaccine Innovation (on behalf of the Institute of Medicine) made several conclusions. *Id.* at 11. First, over the past two decades, pharmaceutical companies have been withdrawing from vaccine manufacturing and marketing areas in general. *Id.* Second, this withdrawal is primarily a result of manufacturers' concerns about litigation costs or difficulty in obtaining insurance coverage. *Id.* Third, these concerns of present or anticipated vaccine-related injury liability expenses are seen as an unreasonable burden in relation to the costs of product development and the income from sales. *Id.* at 11; see *infra* notes 249-52 and accompanying text (detailing Committee's findings and recommendations).

4. Snider, *supra* note 1, at 23.

5. See Hagan, *supra* note 3 (providing summary of federal and state vaccine compensation schemes). Manufacturers were immunized from small pox vaccination side-effects by the Vaccine Act of 1913 (repealed in 1922). VSI, *supra* note 2, at 15. In response to the wave of lawsuits surrounding the swine flu vaccine, Congress enacted P.L. 94-380 and assumed all liability on the behalf of the vaccine manufacturers. Bennett, *supra* note 2, at 750. The National Childhood Vaccine Injury Compensation Act of 1986 partially immunized manufacturers and created a system of no-fault compensation for persons suffering from vaccine-related injuries. 42 U.S.C. § 300aa-10 to -33 (Supp. 1986).

6. See AIDS AND THE LAW 26 (Harlon L. Dalton et al. eds., 1987) [hereinafter AIDS AND THE LAW] (suggesting that if AIDS vaccination reaches universal stage we would be faced afresh with all problems and issues which made swine flu immunization campaign of 1976 so difficult for public and for health officials); Richard Cooper, *For AIDS Inoculants, Ounce of Pre-emption Worth a Pound of Cure*, LEGAL TIMES, June 6, 1989, at 18 (acknowledging that researchers have made significant progress in overcoming some obstacles to useful vaccine, and so it is not too early to consider issues of products liability that will arise when and if vaccine becomes ready for mass use). Cooper, an AIDS commentator, analogizes the past vaccine scenarios with potential AIDS vaccines. *Id.* He notes that no vaccine can be perfect; it is reasonable to assume that an AIDS vaccine, like other vaccines, will produce some serious adverse effects in at least a statistically small number of vaccines. *Id.* The common-law rules of liability and the practical operation of the tort litigation system give manufacturers of vaccines even greater cause for concern than physicians treating patients or scientists conducting human research. *Id.* There is reason to expect that if an effective and safe vaccine were developed no manufacturer would market the vaccine until changes were made in the rules governing liability for injuries caused by the vaccine. *Id.* The precedent illustrating both the problem and a possible solution is swine flu. *Id.* After an outbreak of swine flu in the winter

AIDS is deemed the worst infectious disease in history.<sup>7</sup> The human immunodeficiency virus (HIV), responsible for transmitting AIDS, strikes all sectors of society, regardless of racial, economic, sexual, and age boundaries.<sup>8</sup> Fortunately, private industry has the ability to formulate, produce, and test an AIDS vaccine.<sup>9</sup> As of 1990, the National Institute of Allergic and Infectious Diseases reported at least thirty vaccines under development world-wide,<sup>10</sup> seven of which have already reached the human testing stage.<sup>11</sup> However, if the tort liability problems persist, these potential

of 1976, the federal government moved quickly to prevent an epidemic anticipated to begin the following fall. *Id.* At the urging of President Ford, Congress appropriated \$135 million to purchase the vaccine. *Id.* Vaccine manufacturers built up an inventory to 100 million doses but refused to release the doses when their insurance carriers declined to extend coverage to the vaccine. *Id.* To resolve the deadlock, Congress enacted P.L. 94-380. *Id.* Under this statute, the United States government assumed all liability on behalf of the vaccine manufacturers, the administrators of the immunization program, and the healthcare providers who would administer the shots. *Id.* Thus, the federal government assumed the burden of strict liability under state law and the burden of litigating unmeritorious claims. *Id.*

7. See, e.g., H.R. REP. No. 511, 101st Cong., 2d Sess. 693 (1990) (testimony of Stanley K. Monteith, M.D.) (stating that "[t]he insidious spread of AIDS has been likened to the Black Death of the 14th century."); Thomas J. Matthews & Dani P. Bolognesi, *AIDS Vaccines*, SCR. AM., Oct. 1988, at 120 (noting that prominent researchers remark that unless researchers develop effective vaccine, "this [past] decade in the shadow of AIDS will have been just a foretaste of the virus' ultimate impact on public health, behavior and the economy across the globe."); Anthony S. Fauci, *AIDS—Challenges to Basic and Clinical Biomedical Research*, ACAD. MED., Mar. 1989, at 115 (stating that scientists, physicians, and citizens of this nation have faced crises before, but in many ways AIDS is different and more complex); Frank M. Eldridge, *Formulating AIDS Policy*, 9 J. LEGAL MED. 519, 527 (1988) (stating that "[a]ll humanity will be effected by AIDS in some way."); *Great Expectations: Is the U.S. Doing Its Best to Beat AIDS?*, 23 FDA CONSUMER 36, 36 (1989) (noting that public fear surrounding polio in 1950s, at one point killing 55,000 a year, and tuberculosis, at one point killing 400,000 a year, is "pale compared with current public fear of AIDS."). Scientifically, the problems posed by AIDS are extraordinarily complicated, as is the nature of the virus that causes the disease. Fauci, *supra* at 118. AIDS is a fatal infectious disease for which there is no cure; it afflicts predominantly young, previously healthy persons in the prime of their lives. *Id.*

8. Michael Quam & Nancy Ford, *AIDS Policies and Practices in the United States*, in ACTION ON AIDS 25-28 (Barbara A. Misztal & David Moss eds., 1990). See *The HIV Challenge Continues*, HIV/AIDS PREVENTION NEWSL. (Center for Disease Control, Atlanta, Ga.), Feb. 1991, at 1-3 [hereinafter PREVENTION NEWSLETTER] (giving detailed statistical distribution of AIDS according to age, race, sex, and sexual orientation); DIVISION OF HIV/AIDS, CENTER FOR DISEASE CONTROL, HIV/AIDS SURVEILLANCE (Center for Disease Control, Atlanta, Ga.), Aug. 1991, at 8-12 [hereinafter HIV/AIDS SURVEILLANCE] (same); see also Geoffrey Cowley, *AIDS: The Next Ten Years*, NEWSWEEK, June 1990, at 20 (noting poor are not only ones suffering from HIV infection); Charles Hite, *AIDS in Women*, ROANOKE TIMES & WORLD NEWS, Oct. 1, 1991, at A1 (noting women account for nearly 10% of AIDS cases and numbers have increased steadily over past five years).

9. See CAL. HEALTH & SAFETY CODE § 199.45(d) (West 1990) (stating that industry has capability of conducting vaccine research, biological research, immunology, and genetic engineering of appropriate viral components needed to formulate, develop, produce and test AIDS vaccine); see also *infra* notes 33-38 and accompanying text (detailing current stage of AIDS vaccine research).

10. AIDS INFORMATION SOURCEBOOK 26 (H. Robert Malinowsky & Gerald J. Perry, eds. 3d ed. 1991).

11. 88 Medicines in Testing; 3 Approved in Past 12 Months, Bringing Total to 14, IN

AIDS vaccines may never reach the market. Federal legislation is the necessary solution to the detrimental effect that imposition of traditional tort liability has on the development, marketing, and price of an AIDS vaccine.<sup>12</sup>

### I. GENERAL BACKGROUND

The term "AIDS" designates the specific group of diseases and conditions that are indicative of the severe immunosuppression resulting from infection with HIV.<sup>13</sup> By August 1991 the total number of AIDS cases in the United States reached 186,895.<sup>14</sup> Some 1,500,000 United States citizens are infected with the HIV virus, and estimates predict that 365,000 Americans will develop AIDS by the end of 1992.<sup>15</sup> The world-wide picture is dimmer yet, with approximately eight to ten million people infected.<sup>16</sup> The most distressing statistic is the high mortality rate.<sup>17</sup> The average AIDS patient lives only eighteen months after diagnosis, and more than eighty-five percent die within three years.<sup>18</sup> AIDS is now the leading cause of death in New York City among young to middle-age men and women.<sup>19</sup> Currently there is no known cure for AIDS, and all scientific evidence indicates that individuals testing positive for the virus will eventually contract AIDS and die.<sup>20</sup> The above statistics indicate that AIDS is a frightening contagion that will challenge our medical, scientific, and legal communities for years to

DEVELOPMENT AIDS MEDICINES DRUGS AND VACCINES (Pharmaceutical Manufacturers Association, Washington, D.C.), Oct. 1991, at 1 [hereinafter *88 Medicines*]. Researchers are currently testing vaccines for effectiveness and safety in HIV negative, HIV positive, and AIDS-infected individuals. *Id.* at 7.

12. See *infra* p. 24 (proposing federal compensation and immunization scheme for AIDS vaccines).

13. HIV/AIDS SURVEILLANCE, *supra* note 8, at 1 (providing governmental definition of AIDS). For the medical description and definition of the Human Immunodeficiency Virus and the Acquired Immunodeficiency Syndrome, see MOBILIZING AGAINST AIDS, *supra* note 2, at 112-43.

14. HIV/AIDS SURVEILLANCE, *supra* note 8, at 5. Agency studies of AIDS reporting statistics suggest at least 90% reporting accuracy for infection rate numbers. PUBLIC HEALTH SERVICE, HEALTH UNITED STATES 1990, at 231 (1990).

15. AIDS AND THE COURTS at xvii (Clark C. Abt & Kathleen M. Hardy eds., 1990) (summarizing proceedings of 1989 five-day conference sponsored by State Justice Institute and National Institute of Justice, attended by over 250 state court judges, lawyers, doctors, professionals, government officials, and community representatives).

16. PREVENTION NEWSLETTER, *supra* note 8, at 1. The AIDS virus infects one-third of the population in parts of Africa. Cowley, *supra* note 8, at 20.

17. See QUAM & FORD, *supra* note 8, at 25 (noting that AIDS mortality rate is alarmingly high). AIDS mortality rates are extremely high, at approximately 90% for those diagnosed in 1983 or earlier. *Id.* The mortality rate in those diagnosed before 1985 is slightly lower—at more than 80%. Cooper, *supra* note 6, at 18. Experts have predicted approximately 365,000 AIDS cases and 263,000 AIDS-related deaths by 1992. QUAM & FORD, *supra* note 8, at 25 (citation omitted).

18. Margaret S. Rivas, *The California AIDS Initiative and the Food and Drug Administration: Working at Odds with Each Other?*, 46 FOOD DRUG COSM. L.J. 107, 108 (1991).

19. QUAM & FORD, *supra* note 8, at 25.

20. AIDS AND THE COURTS, *supra* note 15, at xii.

come.<sup>21</sup> Not surprisingly, health officials have propelled AIDS to the top of biomedical and public health agendas.<sup>22</sup>

## II. VACCINATION AS THE PREFERABLE MEDICAL APPROACH

Practitioners can use various medical approaches, including drug therapy and vaccination, to combat AIDS.<sup>23</sup> In 1991 the Pharmaceutical Manufacturers Association identified fourteen approved drugs, as well as eighty-eight drugs and vaccines in development for AIDS and AIDS-related conditions.<sup>24</sup> The major goal of existing drug therapies is to increase the quantity

21. THE MEANING OF AIDS: IMPLICATIONS FOR MEDICAL SCIENCE, CLINICAL PRACTICE, AND PUBLIC HEALTH POLICY 163 (Eric Juengst & Barbara A. Koenig eds., 1989) [hereinafter THE MEANING OF AIDS]. Projections for AIDS cases in the United States population are: Worst case scenario—15 million infected by 2002 and 2.8 million deaths; baseline scenario—6 million infected by 2002 and 1.5 million deaths; best case scenario—1.5 million infected and 1.0 million deaths. WILLIAM B. JOHNSTON & KEVIN R. HOPKINS, THE CATASTROPHE AHEAD 138, 142 (1990).

22. QUAM & FORD, *supra* note 8, at 25. See CAL. HEALTH & SAFETY CODE § 199.45(e) (West 1990) (noting that “[i]t is of the highest importance and in the public interest to maximize public protection by developing an AIDS vaccine.”); AIDS AND THE COURTS, *supra* note 15, at xi (stating that “AIDS is now the number-one public health priority in nation, and will continue to be so for years to come.”); see also THE MEANING OF AIDS, *supra* note 21, at 163 (acknowledging that AIDS “has generated an intense wave of vexing ethical, legal and public policy questions many of which permit no simple solutions, and evidence suggests that it will continue to do so for years to come.”).

Federal expenditures indicate the level of importance the AIDS epidemic has reached within the government. AIDS AND THE COURTS, *supra* note 15, at xiv. Fiscal funding for 1982 to 1988 was over \$1.5 billion, and the federal government spent \$2.8 billion in 1990 alone. *Id.* at xiii-xiv. Federal spending for AIDS research and treatment has climbed to \$1.6 billion in just nine years. Cowley, *supra* note 8, at 20.

23. See 88 Medicines, *supra* note 11, at 2-7 (listing and giving research stage of all treatment options, including antivirals, cytokines, immunomodulators, anti-infectives, and vaccines). The pressure to develop and evaluate experimental drugs to treat HIV infection continues to mount. Fauci, *supra* note 7, at 115. There continues to exist a sense of urgency to see the discovery, testing, and wide-scale availability of safe and effective drugs to fight HIV infection and AIDS. *Id.*

24. 88 Medicines, *supra* note 11, at 1. A “drug” is a product used for curing, preventing, or treating the effects of a disease. ABA AIDS COORDINATING COMM., AIDS: THE LEGAL ISSUES DISCUSSION DRAFT OF THE AMERICAN BAR ASSOCIATION AIDS COORDINATING COMMITTEE 135 (1988) [hereinafter ABA AIDS COORDINATING COMM.] (citing 21 U.S.C. § 321(g)(1) (1972)). The Food and Drug Administration (FDA) has given full marketing approval to azidothymidine (AZT), ganciclovir, pentamidine, trimetrexate, and dideoxyinosine (DDI). See Marilyn Chase, *Distribution Drill: Bristol-Myers Guides a New AIDS Drug in Marketing Minefield*, WALL ST. J., Oct. 10, 1991, at A1 (noting FDA approval of DDI); Gina Kolata, *F.D.A. Gives Quick Approval to Two Drugs to Treat AIDS*, N.Y. TIMES, June 27, 1989, at A1 (noting FDA approval of AZT, ganciclovir, pentamidine and trimetrexate). The first approved drug, AZT, was authorized for investigational treatment use in September 1986 and approved for application to the critically ill in 1987. JOHNSTON & HOPKINS, *supra* note 21, at 111. AZT operates to prevent infection of healthy cells by interfering with the HIV replication process, thereby slowing the progression of the disease. *Id.* Yet AZT’s severe toxicity has stopped many patients from taking the drug. *Id.* at 112. Thus, scientists and patients recognize that AZT, while somewhat successful, is not the final answer for the AIDS epidemic. MOBILIZING AGAINST

and quality of life: in other words, to delay mortality and to reduce morbidity.<sup>25</sup> While prolonging life and easing pain are important, a preventive or curative approach is clearly preferable and, thus, development of an AIDS vaccine is a highly desirable goal.<sup>26</sup>

A "vaccine" is a biological agent derived from a living organism, as compared to chemically derived drugs, used for human immunization against a virus.<sup>27</sup> Because a vaccine prepares the body to kill or block the functioning of the HIV, vaccination prevents the tearing down of the body's immune system in the first instance.<sup>28</sup> Thus, the major goal of an AIDS vaccine is

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AIDS, *supra* note 2, at 190. In 1989 the FDA announced that it would allow wider availability of the experimental aerosol drug, pentamidine, which helps prevent a life-threatening pneumonia often attacking AIDS victims. Rivas, *supra* note 18, at 108. Early testing indicates that the most recently approved AIDS drug, DDI, slows the multiplication of the virus in the body. Philip J. Hilt, *F.D.A., in Big Shift, Will Permit Use of Experimental AIDS Drug*, *TIMES*, Sept. 19, 1991, at A1; see Chase, *supra*, at A1 (noting DDI's introduction by Bristol-Squibb). Unfortunately, DDI has severe side-effects, including inflammation of the pancreas and some nerve damage, and its high death rate in the initial give-away program has been publicized. *Id.*

25. Douglas D. Richman, *Public Access to Experimental Drug Therapy: AIDS Raises Yet Another Conflict Between Freedom of the Individual and Welfare of the Individual and Public*, 159 *J. INFECTIOUS DISEASES* 412, 413 (1989). See JOHNSTON & HOPKINS, *supra* note 21, at 115 (explaining that current AIDS drugs neither prevent infection nor cure it but only act to slow down progression of disease). Several problems exist with therapeutic drugs that prevent these drugs from solving the AIDS crisis, regardless of the promise that AZT or other therapies have indicated. For instance, these drugs can neither prevent infection nor cure it. *Id.* Therapeutic drugs act only to slow down the speed with which infected persons progress to AIDS or die. *Id.* Ganciclovir, pentamidine, and trimetrexate treat the opportunistic disease, not the HIV infection itself. Kolata, *supra* note 24, at A1. Only two drugs, DDI and AZT, work directly against the AIDS virus; the rest simply treat the numerous opportunistic diseases and conditions indicative of the acquired immune deficiency syndrome. 88 *Medicines, supra* note 11, at 1. Yet both AZT and DDI have serious side-effects that make the drugs very unpromising solutions. Chase, *supra* note 24, at A1. For an in-depth explanation of the inadequacies of drug therapies in treating AIDS, see JOHNSTON & HOPKINS, *supra* note 21, at 115-18; Lawrence K. Altman, *Experts on AIDS, Citing New Data, Push for Testing*, *N.Y. TIMES*, Apr. 24, 1989, at A1. Both authors explain that the new drug approaches are not cures for fatal disease, but are expected to add months of extra life for those people infected. JOHNSTON & HOPKINS, *supra* at 115-18; Altman, *supra* note 21, at A1.

26. See CAL. HEALTH & SAFETY CODE §199.45(b) (West 1990) (stating that "[t]he best hope of stemming the spread of the AIDS virus among the general public is the development of an AIDS vaccine to develop an immunity to exposure."); JOHNSON & HOPKINS, *supra* note 21, at 118 (arguing that vaccines represent highest hopes of AIDS researchers). A vaccine would not necessarily prevent the infection from taking place, but with effective vaccination, antibodies against HIV would successfully prevent the virus from establishing itself in the body. *Id.* Commentators note that while the prospect of injecting healthy people with the living virus is understandably frightening, live-attenuated vaccines have previously proved the most effective means of establishing immunity. Shannon Brownlee, *Plotting a Fresh Attack in the War on AIDS*, *U.S. NEWS & WORLD REPORT*, Dec. 30, 1992, at 62.

27. See ABA AIDS COORDINATING COMM., *supra* note 24, at 135 (citing 42 U.S.C. § 231(g)(1)).

28. See *id.* (noting advantages of vaccine). Unlike current drug therapies, which seek to control the virus once it has already invaded the body and become entrenched in thousands

to block the progression of the HIV infection into AIDS.<sup>29</sup> An effective vaccine will virtually eliminate the risk of contracting AIDS, just as general vaccination has eliminated the risk of contracting polio and smallpox.<sup>30</sup> In fact, developing AIDS vaccines "hold the potential of rendering HIV infection no more a worry to most people than polio is today."<sup>31</sup>

Public support of vaccine development has been overwhelming, producing a vehement push for faster research and results.<sup>32</sup> There has been notable progress toward development of an AIDS vaccine.<sup>33</sup> Human testing of experimental AIDS vaccines began in 1987,<sup>34</sup> and by 1991 the Food and

of cells, an effective vaccine would stop the virus before it could penetrate the human immune system. JOHNSTON & HOPKINS, *supra* note 21, at 118; *see also* VSI, *supra* note 2, at v (explaining that vaccines are elegant solution to infectious disease because body's own protective mechanisms are primed by specific interventions to thwart invasion or multiplication of pathogen). The immunization process is one of the "genuinely decisive technologies of modern medicine—it is effective, relatively inexpensive, relatively simple, and relatively easy to deliver. *Id.*

29. JOHNSTON AND HOPKINS, *supra* note 21, at 118; *see supra* note 28 and accompanying text (explaining advantage of vaccination over drug therapy).

30. CAL. HEALTH & SAFETY CODE § 199.45(c) (West 1990).

31. JOHNSTON & HOPKINS, *supra* note 21, at 121.

32. *See* GEORGE GALLUP, JR., THE GALLUP POLL 104, 209, 230, 263 (1989). Public support for continued AIDS research efforts is evidenced by recent polls. *Id.* The 1989 and 1990 Gallup Poll found the following answers to survey questions: 1) Likely that scientists will develop vaccine for AIDS in next tens years? 72% Yes; 2) Should federal budget for AIDS research be increased? 1989—52%, 1990—59% Yes; 3) The government is not doing enough about the problem of AIDS? 53% agree. *Id.*

33. *See* JOHNSTON & HOPKINS, *supra* note 21, at 119-27 (explaining numerous researchers' progress and noting that after three years of research, scientists working on possible AIDS vaccine concepts have compiled more data on AIDS than during entire forty years in which they have been studying polio); AIDS INFORMATION SOURCEBOOK, *supra* note 10, at 20 (noting that Dr. Salk, prominent AIDS vaccine researcher and developer of polio vaccine, who reports great progress AIDS vaccine); Anthony S. Fauci, *Development and Evaluation of a Vaccine for Human Immunodeficiency Virus (HIV) Infection*, 110 ANNALS INTERNAL MED. 373, 373-84 (1989) [hereinafter *Development of Vaccine*] (explaining early obstacles to development of AIDS vaccine and evaluating existing attempts to formulate vaccine); Ada, *supra* note 2, at 331, 339 (re-evaluating prospects of AIDS vaccine after initial optimism and concluding that there existed encouraging findings for effective vaccine based on gp160—a surface antigen of HIV virus). *But see* JOHN LANGONE, AIDS: THE FACTS 148-52 (1988) (explaining several formidable obstacles for vaccine development and noting that even if this bleak outlook is overcome, vaccine will not be available for some time to come); MOBILIZING AGAINST AIDS, *supra* note 2, at 234 (surveying problems in vaccine development and emphasizing trial vaccine's failure to effect immunization in chimpanzees). One author points out that scientists and reporters have not made it very clear that current human trials, those up to 1989, are safety trials and do not themselves signal the advent of an effective vaccine. *Id.* at 227. Nevertheless, the first experimental AIDS vaccines will soon be ready for large-scale human testing for effectiveness, and currently health officials are planning vaccine trials in several developing countries. Susan Okie, *A Hitch in AIDS Vaccine Trials?: Research is Complicated by Differing Strains of HIV Virus*, WASH. POST, Dec. 31, 1991, (Health), at Z14. It will take three to five years after the first vaccine shows any effect before a vaccine is made that can protect 80 to 90% of the population. *Id.*

34. AIDS AND THE COURTS, *supra* note 15, at xii. For a chronology of scientific events



Drug Administration (FDA) had granted permission for clinical testing to a total of seven experimental vaccines.<sup>35</sup> Nevertheless, as scientific capabilities advance,<sup>36</sup> legal complexities continue to stand in the way of an end to the AIDS epidemic.<sup>37</sup>

### III. TRADITIONAL TORT THEORY HINDERS THE DEVELOPMENT OF AN AIDS VACCINE

The imposition of tort liability for pharmaceutical drug and vaccine side-effects hinders development of an AIDS vaccine.<sup>38</sup> An AIDS vaccine is

in AIDS research, see AIDS INFORMATION SOURCEBOOK, *supra* note 10, at 3-29. For a detailed discussion of specific results of experimental trials and new developments in vaccine research, see JOHNSTON AND HOPKINS, *supra* note 21, at 118-127; LANGONE, *supra* note 33, at 188-202.

35. *88 Medicines*, *supra* note 11, at 1. See AIDS INFORMATION SOURCEBOOK, *supra* note 34, at 3-29 (giving chronology of scientific events in AIDS treatment research). Danial Zagury conducted the first human trial of an AIDS vaccine at the Peirre and Marie Curie University in Paris. MOBILIZING AGAINST AIDS, *supra* note 2, at 227. Zagury demonstrated that vaccine gp160 recombinant virus could induce both antibody-mediated and cell-mediated immunity against HIV. *Id.* The vaccine did not produce any side-effects beyond localized soreness normally associated with a good immune response. *Id.* These trials do not provide any evidence about vaccine efficacy in humans but simply answer questions about safety and preliminary information. *Id.* Researchers at National Institute of Allergy and Infectious Disease (NIAID) also have had successful responses with no adverse side-effects in early human trials. JOHNSTON & HOPKINS, *supra* note 21, at 120.

36. See AIDS AND THE COURTS, *supra* note 15, at xiv (remarking that more scientific advances were made in less time for AIDS than for any other complex disease in history of medicine); *Development of Vaccine*, *supra* note 33, at 373 (remarking that level of scientific advancement and speed with which AIDS research were achieved was extraordinary); *supra* notes 33-35 and accompanying text (detailing scientific research on AIDS drugs and vaccines).

37. See, e.g., CAL. HEALTH & SAFETY CODE § 199.45(h) (West 1990) (noting utilization of this new vaccination approach to the AIDS epidemic may be forestalled by problems that have recently deterred development of vaccines); AIDS AND THE LAW, *supra* note 6, at 26 (arguing that if sound vaccine is developed, pragmatic barriers to testing, licensing and marketing would be staggering); JOHNSTON AND HOPKINS, *supra* note 21, at 127 (recognizing that even if effective vaccines are developed, liability problems might foreclose or greatly limit their distribution); Robert T. Schooley, *The Quest for an AIDS Vaccine, in THE AIDS EPIDEMIC: PRIVATE RIGHTS AND THE PUBLIC INTEREST*, 135, 135-44 (Padraig O'Malley ed., 1989) (noting that sufficient information is now known about life cycle of virus and its structural components to formulate vaccine; however, successful vaccine development program depends both on technological advances and on political will to create climate in which vaccination can safely take place); VSI, *supra* note 2, at v (explaining problems current legal system creates for vaccine manufacturers). The process of vaccine innovation, including basic research, development, testing, production, and marketing involves many organizations in the public and private sector. *Id.* Yet, the availability of vaccines for public use depends entirely on the willingness of commercial manufacturers to undertake production. *Id.* Unfortunately, numerous studies over the past 20 years indicate that market incentives fail to draw manufacturers into the vaccine area, especially in the wake of increased liability litigation. *Id.* See generally *infra* part III (describing in detail tort liability problem in detail).

38. See, e.g., LANGONE, *supra* note 34, at 199 (describing deterrent effect of potential tort liability on AIDS vaccine development); MOBILIZING AGAINST AIDS, *supra* note 2, at 230 (stating that "for more than decade United States has been struggling to develop just approach to issues of liability for vaccine-related injury and of compensation for those who are injured");

extremely expensive to produce and test—at least thirty to fifty million dollars each.<sup>39</sup> To this baseline cost manufacturers must add the threat of liability for a wide array of lawsuits involving vaccine-induced injury, both during clinical trials and general use.<sup>40</sup>

For over a decade there have been extensive lobbying efforts for tort reform, fueled by the burden that strict product liability places on manufacturers,<sup>41</sup> particularly pharmaceutical manufacturers.<sup>42</sup> Courts have made

Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, U. CHI. L. REV. 943 (1988) (explaining economic effects of tort liability on vaccine manufacturers), reviewed in *Product Liability Law and AIDS Vaccine Development*, BIO LAW § 3-8 (1988) (summarizing recent McKenna article); *supra* notes 3-6, 37 and accompanying text (describing and giving specific examples of the tort liability problem in the pharmaceutical context); *infra* notes 40, 44 (same).

39. JOHNSTON & HOPKINS, *supra* note 21, at 126; LANGONE, *supra* note 33, at 199; see Huber, *supra* note 1, at 10 (noting that vaccines are expensive to develop and manufacture; whereas, profit margins on vaccine sales have been historically quite low).

40. JOHNSTON & HOPKINS, *supra* note 21, at 126; LANGONE, *supra* note 33, at 199-200. Once a manufacturer gets a vaccine on the market, the contemporary tort system has the power to destroy not only the product, but also the entire company. Huber, *supra* note 1, at 10.

41. See George J. Annas, *Faith (Healing), Hope, and Charity at the FDA: the Politics of AIDS Drug Trials*, in AIDS AND THE HEALTH CARE SYSTEM 193 (Lawrence O. Gostin ed., 1990) (noting that drug companies will continue to lobby Congress and public to limit their liability for harm caused by dangerous drugs by eliminating possibility of punitive damages when FDA standards have been followed or by limiting liability for harm caused by vaccines); William M. Sage, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 989 (1988) (stating that “[t]he law of product liability increasingly compensates purchasers injured by their purchases.”); *Product Liability, Experts Differ Over Effects Strict Liability on Innovation*, Daily Report For Executives, (BNA) No. 160, Aug. 18, 1988, available in LEXIS, Nexis Library [hereinafter *Product Liability*] (stating that in 1987 survey of 101 high-level corporate executives 62% agreed that innovation and experimentation has been constrained, and 91% of those said liability system was major cause). See generally Linda Lipsen, *The Evolution of Products Liability as a Federal Policy Issue*, in TORT LAW AND THE PUBLIC INTEREST 247-300 (Peter H. Shuck ed., 1991) (evaluating state tort law reform and suggesting potential federal product liability reform legislation); W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY 1-13 (1991) (diagnosing liability crisis and suggesting proposals for reform).

42. *Product Liability Reform Act: Hearings on S. 1400 Before the Subcomm. on the Consumer*, 101st Cong., 2d Sess. 611 (1990) (statement on behalf of Johnson & Johnson and pharmaceutical industry) (arguing that nowhere have changes in law of product liability had greater effect than in health care industry). This Johnson and Johnson statement cited the 1988 report of the Board of Trustees of the American Medical Association, remarking,

Product liability is having a profound negative impact on the development of new medical technologies. Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.

*Id.*

The increase of tort litigation involving pharmaceuticals, in particular, has spawned bitter and frustrated statements. Roger S. Fine, *A Personal Perspective from the “Manufacturer”*, 55 BROOK. L. REV. 899, 899 (1989). A president of a large pharmaceutical company recently

liability easier to prove and have upheld unprecedented damage awards.<sup>43</sup> The effect of such liability on vaccines and other pharmaceuticals jeopardizes their development and marketing, escalates the price of existing products, and forces manufacturers to remove necessary pharmaceuticals from the market, causing supply shortages.<sup>44</sup>

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remarked,

If discovering and selling products that enhance and prolong human life is a special interest, it is one of which we are proud. And the last time I looked, it was an interest that society wanted us to pursue. Therefore, when we are accused of being responsible for killing or injuring a fellow human being, and we know that it's not true, we resent it personally and deeply.

*Id.* at 900.

43. Sage, *supra* note 41, at 989.

44. See Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 773 (1990) (arguing that dual regulation of pharmaceuticals by tort system and FDA jeopardizes development and marketing of medications, escalates costs of health care, and undermines objectives of the FDA); see also *supra* notes 3-6, 37, 38 and accompanying text (detailing resultant effect of tort liability on pharmaceutical manufacturers).

Numerous historical scenarios within the vaccine context evidence the problem the tort system creates for manufacturers and the public. See Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side-effects: Keeping Dubious Lawsuits from Driving Good Drugs Off the Market*, 40 CASE WEST. RES. L. REV. 413, 413 (1989-90) (stating that "[b]eneficial drugs, approved by the United States Food and Drug Administration, have been forced off the market by the current legal standards for imposing a duty on drug manufacturers to warn of adverse side-effects from their drugs.'). Denemark explains that high damage awards exert a regulatory effect on drug manufacturers. *Id.* at 415. Potential liability drives drug companies to withdraw products from the market, and discourages research into new drugs to be used by individuals likely to sue and receive large damage awards. *Id.* Even more alarming for the manufacturer is the fact that the FDA's decision that a drug is safe, effective, and more beneficial than harmful can be nullified by the regulatory effect of private tort actions. *Id.* This climate of second guessing of FDA approval by juries has created a climate of uncertainty for the pharmaceutical industry. *Product Liability Reform Act: Hearings on S. 1400 Before the Subcomm. on the Consumer*, 101st Cong., 2d Sess. 611 (1990) (statement on behalf of Johnson & Johnson and pharmaceutical industry). The pharmaceutical manufacturer has no reliable means for predicting the future viability of a drug once it reaches the market. *Id.* This climate of uncertainty has had an adverse impact upon the public in the form of higher prices and fewer choices in the marketplace. *Id.*

In the medical device context, recent complications involving intrauterine devices (IUD) led to potential liability one thousand times greater than the profit from the product and forced the maker of one such device, the Dalkon Shield, into bankruptcy. Sage, *supra* note 41, at 990 & n.5. Searle Laboratories reported spending \$1.5 million in 1985 to defend itself against four suits over its IUD—each of which the company won. *Product Liability Reform Act: Hearings on S.1400 Before the Subcomm. on Commerce, Science, and Transportation*, 101st Cong., 2d Sess. 283 (1990) (testimony by Harry Featherstone on behalf of National Association of Manufacturers). After weighing the product's potential sales value of \$11 million a year against the future litigation costs, the company decided to discontinue the product. *Id.*

Recently, despite FDA approval of the drug Benedictin and its detailed warning information, as well as a strong scientific consensus that it is not a teratogen, the regulatory power of private tort actions forced the Benedictin from the market. Denemark, *supra*, at 428. Benedictin was the only drug available to treat morning sickness. *Product Liability Reform*

It is easy to understand why an AIDS vaccine manufacturer would be concerned about product liability. Commentators have already analogized the AIDS situation to that of the childhood disease, and swine flu vaccines.<sup>45</sup> In the aftermath of the swine flu immunization disaster in 1976-77, drug companies still face billions of dollars of outstanding lawsuits.<sup>46</sup> Because of the diverse complications that could result from an AIDS vaccine, manufacturers confront a possible financial exposure many times greater than in earlier vaccine scenarios.<sup>47</sup> Furthermore, FDA's expedited approval process has intensified manufacturers' liability concerns, because less is known about the possible risks of a vaccine at this early stage, and a manufacturer must incorporate potential liability concerns into decisions about which products to develop and bring to market.<sup>48</sup> The unavailability of liability insurance

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*Act: Hearings on S.1400 Before the Subcomm. on Commerce, Science, and Transportation, supra*, at 612 (statement of George S. Frazza on behalf of Johnson & Johnson and pharmaceutical industry). In 1985, Benedictin's manufacturer, Merrell Dow, faced multiple suits alleging that the drug caused birth defects. *Id.* After years of scientific study, the FDA and the world-wide scientific community, have never found any credible evidence that Benedictin causes birth defects. *Id.* Nonetheless, Merrell Dow was forced to take it off the market "solely because of the threat of liability." *Id.*

Clearly, the specter of tort liability forced many manufacturers of childhood vaccines out of the marketplace, leaving a large sector of the public with the risk of preventable diseases. 136 CONG. REC. S16,661 (daily ed. Oct. 25, 1990) (Sen. Heintz statement made in support of creation of uniform federal rules for product liability). For example, Lederle Laboratories, the sole producer of the DPT vaccine, raised its price per dose from \$2.80 to \$11.40 in 1987 to pay the costs of increased law suits. *Product Liability Reform Act: Hearings on S.1400 Before the Subcommittee on Commerce, Science, and Transportation*, 101st Cong., 2d Sess. 281 (1990) (testimony by Harry Featherstone on behalf of the National Association of Manufacturers). Lederle Labs is now the sole United States manufacturer of the DPT vaccine for polio, and Merck & Co. is now the only producer of the combined measles, mumps, and rubella vaccine—all others have left the field due to the threat of product liability lawsuits. *Id.* The resultant effect has been an increase in these once nearly eradicated infectious diseases. Snider, *supra* note 1, at 25.

The precise effects of tort liability on vaccine innovation and availability has been given thorough consideration in the past. See VSI, *supra* note 2, at 85-122 (giving thorough history of effect of tort liability on vaccines development and production in United States). In 1985 a national commission was created to review the problems of development, production and marketing of vaccines to combat infectious disease in general. *Id.* at v. This effort was in response to the access and supply problems surrounding the swine flu and childhood vaccines in the 1970s and 1980s. *Id.* The commission researched and analyzed tort theory's treatment of and effect upon vaccines in the United States. *Id.* at 27-65, 85-122. The commission concluded that the handling of vaccine-related injury liability by the courts has left manufacturers apprehensive and uncertain about the extent of their responsibilities. *Id.* at 155. These apprehensions act as a deterrent to vaccine production and thereby threaten the public health by limiting the supply of therapies to prevent infectious disease. *Id.*

45. See *supra* note 6 and accompanying text (detailing the analogy between the AIDS situation and the swine flu vaccine).

46. See *supra* note 6 and accompanying text (explaining the details of the swine flu vaccination program and resulting liability problems).

47. JOHNSTON & HOPKINS, *supra* note 21, at 126.

48. See *supra* note 40 and accompanying text (stating that potential liability litigation costs are factored into product cost). Representatives of small and medium sized companies

adds to the concern of vaccine manufacturers.<sup>49</sup> Insurance companies are already denying coverage to HIV vaccine researchers and manufacturers and experts predict that the unavailability of liability insurance will delay the marketing of any future FDA-approved vaccines.<sup>50</sup>

George Frazza, general counsel of Johnson & Johnson, states that strict liability encourages timidity on the part of manufacturers because of the uncertainty of what may be found to be a defect. According to Frazza, if his company came up with an AIDS vaccine, he would advise withholding it until Congress passes protective legislation.<sup>51</sup> Many other commentators have noted that even if an HIV vaccine were available, no one would manufacture it due to the cost of product liability suits.<sup>52</sup> A brief overview demonstrates the liability problem conventional tort theory causes pharmaceutical manufacturers.

#### IV. PHARMACEUTICAL MANUFACTURERS' LIABILITY FOR ADVERSE SIDE-EFFECTS

Society depends on state tort law to discourage individuals from subjecting others to unreasonable risks and to compensate those injured by unreasonably risky behavior.<sup>53</sup>

Under strict product liability theory, a manufacturer can be held liable without fault for a "defective" product. Restatement (Second) of Torts section 402 recognizes three ways in which a product can be "defective": (1) a manufacturing defect or flaw in production; (2) a design defect, revealed by the existence of safer alternative constructions; and (3) a warning defect, consisting of inadequate warnings or a total failure to warn of the risks related to the proper design of the product.<sup>54</sup> Most states have adopted the Restatement (Second) of Torts section 402 in some form.<sup>55</sup>

suggest that the push for expanded access to AIDS drugs and vaccines could increase the perception of liability for some therapy candidates, thereby making them less attractive to potential sponsors. EVE NICHOLS, INSTITUTE OF MEDICINE, EXPANDING ACCESS TO INVESTIGATIONAL THERAPIES FOR HIV INFECTION AND AIDS 50 (1991) (summary of roundtable conference held by Institute of Medicine in 1991).

49. See *infra* note 50 and accompanying text (explaining liability insurance problem facing AIDS drug and vaccine manufacturers).

50. ABA AIDS COORDINATING COMM., *supra* note 24, at 147 (citing *Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic* 47-48 (June 24, 1988)). The insurability of vaccines and drugs is controversial in part because of the lack of actual data. *Id.* at n.68. Insurability questions may inhibit biotechnological production of vaccines. *Id.*; James T. O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 HOUS. L. REV. 451, 464 (1987).

51. *Product Liability*, *supra* note 41.

52. Rivas, *supra* note 18, at 123. See *supra* note 37 (commenting on practical and economic barriers that will face future AIDS vaccines).

53. See Note, *supra* note 44, at 780 (examining ability of tort system to effectuate these purposes within context of FDA-approved medications).

54. RESTATEMENT (SECOND) OF TORTS § 402A (1965). The Restatement language describes the liability of a seller of defective products in the following manner,

Because vaccine manufacturers are subject to the tort laws of all fifty states, their liability is difficult to predict.<sup>56</sup> Universally, however, courts have found manufacturers of pharmaceutical products, including vaccines, liable when their products result in adverse side-effects.<sup>57</sup> Design defect and failure to warn theories are the most common basis for these liability claims.<sup>58</sup> Damage awards are often extreme and exert a strong regulatory effect on manufacturers' decisions concerning whether to develop or market a vaccine.<sup>59</sup> Interestingly, tort theory addresses both the economic problem that strict liability creates for pharmaceutical manufacturers and the inherent differences between pharmaceuticals and other consumer products.<sup>60</sup> That

402A. *Special Liability of Seller of Product for Physical Harm to User or Consumer*

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

- (a) the seller is engaged in the business of selling such a product, and
- (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

- (a) the seller has exercised all possible care in the preparation and sale of his product, and
- (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

*Id.*; see also *Brown v. Superior Court*, 751 P.2d 470, 473-75 (Cal. 1988) (explaining history of strict liability for defective products under Restatement 402A and noting three types of defect: design defect, manufacturing defect, and warning defect), *cert. denied*, 485 U.S. 942 (1988); *Savina v. Sterling Drug, Inc.* 795 P.2d 915, 923 (Kan. 1990) (noting that there are three types of product defects: manufacturing flaws, design defects, and inadequate warnings regarding product use).

A manufacturing defect occurs when a product falls below the manufacturers' own standards, *i.e.*, when an abnormality makes the product more dangerous than intended. See PAGE W. KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99(1), at 695 (5th ed. 1984). A design defect occurs when the product meets the manufacturers' own standards, but is more dangerous than the ordinary consumer would expect when using it in an intended or reasonably foreseeable manner, or if the benefits of the design do not outweigh its risks. See *id.* § 99(3), at 698. Even a flawlessly manufactured and designed product may be considered unreasonably dangerous if the manufacturer or seller fails to warn or adequately warn, of a risk or hazard associated with the product's use. See *id.* § 99(2), at 697-98.

55. *Brown*, 751 P.2d at 474 (citing KEETON, *supra* § 99, at 694 (5th ed. 1984)).

56. Joseph Early, *Can Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis?*, JURIMETRICS J., Spring 1990, at 356.

57. See Note, *supra* note 44, at 777-78 (noting that despite extensive FDA regulatory scheme and potential exclusion under Restatement's comment k, pharmaceutical manufacturers are still found strictly liable).

58. Early, *supra* note 56, at 356.

59. See Sage, *supra* note 41, at 989-90 nn.3-6 (arguing that courts have made liability easier to prove and have upheld unprecedented damage awards).

60. *Id.* at 990-91 & nn.7-8. A significant concern is that the rationale behind product liability does not apply well to an AIDS vaccine. The rationale behind imposition of liability without fault is threefold: First, the manufacturer is in the best position to anticipate and guard against the risks; second, the manufacturer can distribute the cost among the public; and third, it is in the public interest to discourage marketing of defective products. *Brown v.*

attempt has resulted in a complicated mass of exceptions to pure strict

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Superior Court, 751 P.2d 470, 474 (Cal. 1988), *cert. denied*, 485 U.S. 942 (1988). These policies do not appear to justify liability without fault in the HIV vaccine context. First, medical products are different from other goods because they are products which necessarily interact with the human body in order to be effective. *See Sage, supra* note 41, at 990 (noting that medical products, particularly drugs available exclusively by prescription, are different from other goods because they must intimately interact with consumer's body). Thus, the chemistry of the patient may contribute as much to the risk of an adverse side effect as does the chemistry of the vaccine. *Id.*; *see Cooper, supra* note 6, at 19 (arguing that it is reasonable to assume that AIDS vaccine, like other vaccines, will produce some serious adverse side-effects in at least statistically small number of vaccinees). The California Supreme Court recently noted perhaps the most important distinction between prescription drugs and other products—prescription drugs are needed to reduce pain and save lives, and prevent harm to at least some users is unavoidable. *Brown*, 751 P.2d at 478. Additionally it is often noted that individuals have a fundamental freedom of choice to make medical decisions that is especially acute during chronic illness. *See Richman, supra* note 25, at 412 (noting that with thousands of HIV-infected people facing prospect of fatal illness there is understandable impatience with any restrictions in making effective therapeutic measures quickly and widely available); Martin Delaney, *The Case for Patient Access to Experimental Therapy*, 261 JAMA 2444, 2444 (1989) (stating that for HIV victims with life-threatening illness it seems inhumane for government to deny access to treatments that might offer hope, however slim that hope might be). *But see Fauci, supra* note 7, at 116-17 (stating that balance must be struck between rigorous demands of scientific method involved in conducting proper clinical trials and rights of patients suffering from life-threatening disease to gain access to potentially effective new therapies at earliest feasible time).

Some commentators note that the societal interest in discouraging "unreasonable risk" is ill-placed in the AIDS context. Deanna Hodgkin, *Desperate to Live*, INSIGHT, Sept. 16, 1991, at 11, 17 (noting that many AIDS activists insist on primacy of free choice). John Greenberg, treatment advisor of ACT UP New York, has stated that "[s]uppressing information and treatments may deprive us of something that works." *Id.* If the chronically ill have a uniquely fundamental right to free choice in medical treatment the rationale underlying product liability breaks down. Yet another AIDS activist, Grace Powers Monaco, recognizes that free choice is not entirely free. *Id.* (noting statements of Monaco). Monaco notes that patients have the right to choose, but that freedom of choice means freedom of informed choice. *Id.* This patient freedom does not mean freedom to choose erroneously by being confined only to the hype in brochures and promotional anecdotes put out by promoters of unproven and untested therapies. *Id.* "Medical ethicists say that patients should be free to choose any treatment, or no treatment at all, 'so long as they are capable of understanding a treatment and making a decision.'" *Id.* (noting statement of Mary Faith Marshall, assistant professor at Center for Biomedical Ethics at University of Virginia concerning chronically ill person's access to medical treatments). The decision does not have to be a rational one, but it does have to be based on the patient's value system. *Id.* Marshall says health providers and manufacturers should disclose the risks, benefits and side-effects for each potential drug or treatment, as well as alternatives to treatment. *Id.* Additionally, the existence of competing societal interests play into any availability-of-treatment decision. Some commentators worry that the vaccine manufacturers' profit motive will result in the marketing of unsafe or unproven treatments. *Id.* Others, as noted above, emphasize the right to choice of the chronically ill individual. Scientists insist that drug access must be closely regulated to ensure the systematic collection of the scientific data necessary to determine treatment safety and efficacy. *Id.* Thus, the decision to obtain experimental or new drugs in life threatening situations is both a very personal and an institutional decision. *See Fauci, supra* note 7 (discussing both sides of debate over informed choice and treatment access for critically ill individuals). W

product liability.<sup>61</sup> The exceptions include: (1) exemption from liability for "unavoidably unsafe products" under the Restatement's comment k to section 402A; (2) judicial or statutory establishment of a duty to warn standard; (3) the learned intermediary doctrine, and; (4) the government standards defense.

*A. Protection for Manufacturers under Restatement (Second) Section 402A, comment k*

Comment k to the Restatement (Second) of Torts section 402A recognizes an exception to strict liability for "unavoidably unsafe products."<sup>62</sup>

This provision protects manufacturers whose products are enormously beneficial to society yet are incapable of being made completely risk free for their intended use.<sup>63</sup> Such products are not considered "defective" if properly prepared and accompanied by adequate warnings.<sup>64</sup> The overwhelming majority of jurisdictions adopt comment k.<sup>65</sup> However, an examination of relevant cases demonstrates that state courts are not consistent in their application of the comment k exemption to pharmaceutical products.<sup>66</sup>

Some state courts have extended the comment k exception to all prescription drugs, holding that the drugs are by definition "unavoidably unsafe

61. Sage, *supra* note 41, at 990-91.

62. Comment k of the Restatement (Second) provides:

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 same is true of many other drugs, vaccines, and the like, many of which for this very reason can not legally be sold except to physicians, or . . . prescription. It is also true of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically cognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, 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.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1964) (italics in original).

63. *Id.*

64. *Id.* See *supra* notes 62-63 and accompanying text (discussing manufacturers' strict liability under comment k exception); *infra* notes 81, 87 and accompanying text (discussing manufacturers' strict liability for failure to warn or inadequate warnings).

65. Brown v. Superior Court, 751 P.2d 470, 476 (Cal. 1988) (citing jurisdictions that have adopted comment k), *cert. denied*, 485 U.S. 942 (1988).

66. See *infra* text accompanying notes 67-71 (discussing conflicting applications of comment k). For an excellent discussion of the historical application of comment k within the pharmaceutical context, see George H. King, *A Prescription for Applying Strict Liability: Not all Drugs Deserve Comment k Immunization*, 21 ARIZ. ST. L.J. 809 (1989).



products'' within the Restatement's description.<sup>67</sup> The California Supreme Court recently examined the rationale behind this blanket approach in *Brown v. Superior Court*.<sup>68</sup> The court noted that requiring a case-by-case determination of comment k applicability would impede significant advances in scientific knowledge and discourage the development of new drugs to combat disease.<sup>69</sup> The court concluded that to keep prescription drugs both available and affordable, a court must assure the manufacturer that it will not hold them strictly liable.<sup>70</sup>

Most courts, however, have refused to apply comment k to every pharmaceutical drug and still proceed on a case-by-case basis.<sup>71</sup> This ap-

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67. See *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1335 (C.D. Cal. 1987) (finding comment k automatically applies to design defect strict liability claims, but allowed plaintiff to pursue a claim of strict liability for manufacturing defects, because comment k is not a shield from those claims); *Brown*, 751 P.2d at 471 (holding that comment k applies to all manufacturers of prescription drugs); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (holding that FDA-approved drugs are as matter of law unavoidably unsafe within comment k description); *Collins v. Ortho Pharmaceutical Corp.*, 231 Cal. Rptr. 396, 404 (1988) (same).

68. *Brown*, 751 P.2d at 473-77. In *Brown* the Supreme Court of California reviewed the policy underlying comment k's strict liability exemption and comment k's past application by other courts. *Id.* The court concluded that comment k should exempt all manufacturers of prescription drugs from strict liability arising form claims alleging the defective design of their products. *Id.* at 477. The court noted that a case by case determination of comment k applicability would impede significant advances in scientific knowledge, and discourage the development of new and improved drugs to combat disease. *Id.* at 479-82. To keep prescription drugs both available and affordable, a manufacturer must be certain that it will not be held strictly liable. *Id.* at 478-79, 81.

69. *Id.* at 482; see *supra* note 68 (discussing rationale behind strict product liability and comment k exception); *infra* note 70 (same).

70. *Brown*, 751 P.2d at 482. The *Brown* court stressed three public policies mitigating against imposition of strict liability for prescription drugs. *Id.* at 479-80 First, drug manufacturers might stop producing valuable drugs because of lost profits resulting from lawsuits or the inability to secure adequate insurance. *Id.* at 479-80. Second, consumers have a vested interest in prompt availability of new pharmaceutical products, and imposing strict liability for design defects might cause manufacturers to delay placing new products on the market even after those products receive FDA approval. *Id.* at 479. Finally, the added expense of insuring against strict liability and additional research programs might cause the cost of medication to increase to the extent that the medication would no longer be affordable to consumers. *Id.*

71. *Reyes v. Wyeth Labs*, 498 F.2d 1264 (5th Cir. 1974) (acknowledging that vaccine was "unavoidably unsafe" and then utilizing balancing approach to determine whether vaccine was "so unsafe that marketing it at all [was] 'unreasonably dangerous per se'"), *cert. denied*, 419 U.S. 1096 (1974); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988) (citing *Toner*, where court denied summary judgement and held that manufacturer must prove that product is unavoidably unsafe based on resolution of material issues of fact); *Patten v. Lederle Lab.*, 676 F. Supp 233, 236 (D. Utah 1987) (predicting that Utah would adopt comment k); *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991) (adopting comment k under interpretation of Iowa case law and deciding to apply exception on case-by-case basis); *Toner v. Lederle Lab.*, 732 P.2d 297 (Idaho 1987) (holding courts must decide applicability of comment k on case-by-case basis), *cert. denied*, 485 U.S. 942 (1988); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924 (Kan. 1990) (holding that courts should make application of unavoidably unsafe products exception to strict liability on case-by-case determination); *Johnson*

proach does little to ease the manufacturers' liability concerns because there is no guarantee that the trier of fact will find a particular vaccine "unavoidably unsafe".<sup>72</sup> Moreover, even if the trier eventually finds the exemption applicable, the manufacturer has expended time and money on the initial litigation.<sup>73</sup> These factors play into the manufacturers' considerations of product cost and profitability.<sup>74</sup> The confusion existing in several states

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v. American Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986) (appearing to hold that the court should determine application of comment k on a case-by-case basis); Niemiera v. Schneider, 555 A.2d 1112, 1116 (N.J. 1989) (noting that New Jersey recently adopted case-by-case basis for applying comment k to pharmaceuticals); Pollard v. Ashbury, 793 S.W.2d 394, 400 (Mo. App. 1990) (holding that comment k is affirmative defense and courts should determine its applicability on case-by-case basis); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781 (R.I. 1988) (specifically rejecting *Brown* and holding that comment k protection extends to prescription drugs on case-by-case basis); Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984) (holding comment k applicable only if manufacturer places drug in question on market without adequate testing because of exigent circumstances). In *Toner*, plaintiff's three-month-old child was paralyzed by defendant's vaccine. 732 P.2d at 299. The Supreme Court of Idaho held that vaccines are not unavoidably unsafe products per se under comment k and that courts should decide the application of comment k on a case-by-case basis. *Id.* at 309. The court also held that Lederle could be found negligent for having marketed the only pertussis vaccine licensed by the FDA, instead of developing and obtaining FDA approval for a fractionated-cell vaccine, although the FDA had previously withdrawn approval of another firm's fractionated-cell vaccine. *Id.* at 312. Richard Cooper, an AIDS commentator, notes that the potential consequences of the *Toner* decision, which the Supreme Court has decline to review, are staggering. Cooper, *supra* note 6, at 19. Another frightening design defect case for manufacturers is *Johnson v. American Cyanamid Co.*, where the jury awarded \$2 million compensatory damages and \$8 million punitive damages on the theory that the Sabin polio vaccine was defectively designed because the Sabin vaccine was less safe than the Salk vaccine. 718 P.2d 1318, 1320. The Supreme Court of Kansas reversed in a 4-3 decision. *Id.* at 1326. The Supreme Court granted immunity to the polio vaccine manufacturer because the product was "unavoidably unsafe" and a "useful and desirable product, attended with a known but apparently reasonable risk." *Id.* at 1323. Yet it is unclear that the *Johnson* court meant for comment k to apply to all vaccine manufacturers. *Id.* at 1322-24.

See also *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) (holding comment k does not absolve drug manufacturers, here oral contraceptive manufacturer, in all instances from design defect strict liability theory, and allowing recovery on defective design theory); *Feldman v. Lederle Lab.*, 479 A.2d 374, 380 (N.J. 1984) (holding that while "generally the principal of strict liability is applicable to manufacturers of prescription drugs. . . [w]e do not agree that the protective shield of comment k immunizes all" of them).

72. See *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991) (noting problems with case-by-case determination of comment k application). According to the *Grundberg* court, in determining whether a product is "unavoidably unsafe" a jury may consider: (1) Whether, when distributed, the product was intended to confer an exceptionally important benefit that made the products availability highly desirable; (2) whether the then-existing risk posed by the product both was substantial and unavoidable; and (3) whether the interest in availability outweighs the interest in promoting enhanced accountability through strict liability design defect review. *Id.* at 93 & n.6. This case-by-case determination results in a "mini-trial" which is unworkable because of the procedures impact on the development and marketing of new drugs. *Brown*, 751 P.2d at 481; *Grundberg*, 813 P.2d at 95.

73. See *Brown*, 751 P.2d at 481-82 (arguing high litigation costs result when courts proceed in case-by-case basis).

74. See *supra* notes 3-6 (describing how tort liability deterred development and access to

regarding who—judge or jury—should decide the applicability of comment k increases litigation unpredictability even further.<sup>75</sup> Jury decisions can be particularly quixotic, and the ensuing inconsistencies leave manufacturers in a quandry.<sup>76</sup> Even more threatening for a manufacturer in states that use a case-by-case approach is that FDA approval does not ensure against liability.<sup>77</sup> Thus, the fact that the FDA completed a risk and benefit analysis during the approval stage does not mean that the trier of fact must find the pharmaceutical “unavoidably unsafe.”<sup>78</sup> Rather, FDA approval is merely one factor the factfinder considers when making this determination.<sup>79</sup>

In summary, comment k exemption from liability could effectuate the desired result of consistency and predictability required to remove a portion of the tort liability specter for manufacturers, but only if a blanket approach is adopted in all states. This is far from the existing situation. More importantly, commentators have stated that such a blanket approach is not a desirable solution because it is an inflexible rule that ignores the differences between various drugs.<sup>80</sup> Yet, even if a vaccine fits within the “unavoidably

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vaccines in the past); *supra* note 40 (stating that manufacturers add potential litigation costs into product price); *supra* note 44 (noting that liability effects pharmaceutical development, marketing and supply).

75. See King, *supra* note 66, at 819-20 (explaining that courts differ as to whether judge or jury should balance the risks and benefits in determining the applicability of unavoidably unsafe exception).

76. *Id.*

77. See Toner v. Lederle Lab., 732 P.2d 297, 308-09 (Idaho 1987) (arguing extensive risk benefit analysis preformed by FDA before approving prescription drug should foreclose reassessment under comment k, nonetheless, case-by-case application of comment k by many courts allows jury to override FDA's determination of safety despite inherent risks), *cert. denied*, 485 U.S. 942 (1988); Mazur v. Merck & Co, 742 F. Supp. 239, 247 (E.D. Pa. 1990) (holding that manufacturers must meet state tort law requirements, in addition to satisfying initial FDA requirements). The Mazur court noted that mere compliance with the FDA's suggestion, regulation, or order does not override state tort law pertaining to drug manufacturers' liability. *Id.* Rather, compliance with FDA regulations may establish that manufacturer met appropriate minimum standards of due care, but such compliance does not necessarily absolve manufacturer of all liability. *Id.*; see also King, *supra* note 66, at 810, 817-18 (discussing effect of FDA's decision to approve prescription drug on applicability of comment k).

78. See Toner, 732 P.2d at 305-09 (giving in-depth overview of factors trier of fact must balance in determining whether vaccine is “unavoidably unsafe” under comment k); see also *supra* note 77 (discussing effect of FDA approval on state tort law requirements).

79. See Feldman v. Lederle Labs., 479 A.2d 374, 383 (N.J. 1984) (noting that FDA's risk-utility analysis would not supplant risk-utility analysis required in judicial process); Mazur, 742 F. Supp. at 247 (noting that FDA approval establishes only a minimum level of safety which state tort law may override).

80. See King, *supra* note 66, at 829 (arguing that middle ground consisting of judicially or legislatively created “presumptions and truncated analysis” fashioned in manner like Childhood Vaccine Act is best solution to inadequacies of tort system). King argues that such legislative enactments do not completely foreclose strict liability for plaintiffs injured by vaccines, but establish presumptions to aid the trier of fact. *Id.* at 830-31. These presumptions are rebuttable, allowing for flexibility when circumstances require special treatment. *Id.* at 831. An additional advantage is that a legislative approach only affects one class of prescription drugs, vaccines, unlike the Brown court's solution of a blanket exemption for prescription drugs adopted pursuant to the Restatement's “unavoidably unsafe” exemption. *Id.*

unsafe" exception under comment k, individuals suffering adverse side-effects can still sue the manufacturer based on theories of design defect, inadequate warning, and negligence.<sup>81</sup> Thus, even a blanket approach to comment k for prescription drugs and vaccines does not foreclose the manufacturers' litigation fears.

### *B. Design Defects and Failure to Adequately Warn Liability Theories*

While allegations of design defects are unusual in vaccine cases,<sup>82</sup> the implications of the recent *Toner v. Lederle Laboratories*<sup>83</sup> opinion are frightening.<sup>84</sup> In *Toner*, the Supreme Court of Idaho recognized a pharmaceutical company's potential liability under a design defect theory for failure to promote and produce a different vaccine.<sup>85</sup> A three-month-old baby was paralyzed after vaccination with Lederle's DPT vaccine. The court held that it could find Lederle negligent for having marketed the vaccine, notably the only pertussis vaccine approved by the FDA, instead of developing and obtaining FDA approval for a fractionated cell vaccine, for which the FDA had previously withdrawn approval.<sup>86</sup> While negligence actions are beyond the scope of this article, the court's acknowledgement of potential design defectiveness under these circumstances was both surprising and frightening.

Under Restatement section 402A a manufacturer is liable for an inadequate warning even if the vaccine is deemed "unavoidably unsafe."<sup>87</sup> This

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81. See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (same); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (noting that by its terms, comment k does not except product from strict liability where plaintiff alleges manufacturing flaw or inadequate warning), *cert. denied*, 419 U.S. 1096 (1974); *Toner*, 732 P.2d at 305 (same); *Brown v. Superior Court*, 751 P.2d 470, 481 (Cal. 1988), *cert. denied*, 485 U.S. 942 (1988) (same); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924 (Kan. 1990) (same); *Feldman v. Lederle Labs.*, 479 A.2d 374, 384 (N.J. 1984) (same); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 780 (R.I. 1988) (same); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 89 (Utah 1991) (same). Thus, most courts hold that establishing that the drug was properly prepared and accompanied by adequate warnings of its dangerous propensities and inherent risks is a prerequisite to the comment k exemption.

82. Vaccine injury cases proceeding under a design defect theory include: *Petty v. United States*, 740 F.2d 1428 (8th Cir. 1984); *Reyes*, 498 F.2d at 1264; *Williams v. Lederle Lab.*, 591 F. Supp. 381 (S.D. Ohio 1984); *Dunn v. Lederle Lab.*, 328 N.W.2d 576 (Mich. Ct. App. 1982).

83. 732 P.2d 297 (1987), *cert. denied*, 485 U.S. 942 (1988).

84. *Cooper*, *supra* note 6, at 19 (noting staggering potential consequences of *Toner* decision, which Supreme Court has declined to review).

85. *Brown*, 732 P.2d at 297.

86. *Id.* at 309-10 (stating that authorities universally agree that where product is deemed unavoidably unsafe, plaintiff is deprived of strict liability cause of action, but may proceed under negligence cause of action).

87. See, e.g., *Petty v. United States*, 740 F.2d 1428, 1439 (8th Cir. 1984) (holding that swine flu vaccine was unavoidably dangerous product under comment k, but because warnings were inadequate, manufacturer was held strictly liable); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1335-6 (C.D. Cal. 1987) (holding that even though comment k applied to DPT

type of defect is by far the most common basis for liability.<sup>88</sup> The problem posed for national manufacturers is that state courts use a wide array of standards to determine the appropriate timing and adequacy of the warning required. Normally, a manufacturer must warn of known or knowable risks at the time of drug marketing.<sup>89</sup> Yet some courts have found a duty to warn when the danger of a side effect is "apparent,"<sup>90</sup> or even when there is only a hint of danger.<sup>91</sup>

In reviewing the adequacy of a warning, the trier of fact may take into account the circumstances surrounding the communication of the warning.<sup>92</sup> Courts have held that a jury is free to conclude that the language of the warning should have included data on incidence, should have been clearer or stronger, and that specific points should have been explained at greater length or been given greater emphasis.<sup>93</sup> Moreover, when a hard-sell promotional campaign encourages vaccination, the jury may rely on the campaign to conclude that the literal text of the warning was diluted because of the emotion surrounding distribution.<sup>94</sup> Thus the hype and promotion certain to surround the introduction of an AIDS vaccine will require manufacturers to give extremely potent warnings to meet the adequacy standard. Even more worrisome is that while the jury may consider FDA requirements for labeling, it is not bound by them in its inadequacy determination.<sup>95</sup> Even if the FDA has required, approved or actually drafted

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vaccine, inquiry would not be limited to failure to warn theory); *Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984) (noting even if prescription drug were unavoidably unsafe, comment k immunity would not eliminate strict liability for failure to provide a proper warning); see *supra* note 81 and accompanying text (discussing establishment of adequate warnings and design as prerequisites to "unavoidably unsafe" exemption).

88. Cooper, *supra* note 6, at 19.

89. KEETON, *supra* note 54, at 685; See, e.g., *Petty*, 740 F.2d at 1441 (finding warning inadequate because it failed to apprise plaintiff of known risk of serum sickness); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (noting manufacturers' duty is to warn of all potential dangers which it knew, or in exercise of reasonable care should have known to exist); *Brown v. Superior Court*, 751 P.2d 470, 471, 476 n.4 (Cal. 1988) (holding that manufacturers of drug were liable for failure to warn of dangers they knew or could have known at time drug was released), *cert. denied*, 485 U.S. 942 (1988). For an analysis of a manufacturers' duty to warn of possible known or knowable dangers see Carol A. Cheney, Comment, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees*, 85 Nw. U. L. REV. 562 (1991); James Britain, *Product Honesty is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 Nw. U. L. REV. 342 (1984).

90. See Denemark, *supra* note 44, at 443 (discussing court's use of "apparent standard" in duty to warn cases); see also *infra* notes 101-02 and accompanying text (describing apparent standard).

91. See Denemark, *supra* note 44, at 438 (noting some courts hold manufacturers to hint of danger standard).

92. Cooper, *supra* note 6, at 19.

93. *Id.*

94. *Id.*

95. *Id.*

the specific warning in question, a lay jury can still conclude that it was inadequate.<sup>96</sup> Thus, the latitude of the various state approaches to the adequacy of warning determination and the inconclusiveness of FDA-approval prevents manufacturers from predicting the adequacy of any particular warning.

### 1. Establishment of a Consistent National Standard for Warnings

State product liability law and federal regulatory law have been butting heads for several decades.<sup>97</sup> The effect of the dual system is that tort litigation often repeats de novo the risk and benefit analysis performed by the FDA during the pharmaceutical approval process. In the past the trier of fact has found a pharmaceutical manufacturer liable for an inadequate warning although the FDA mandated, verbatim, the warning at issue.<sup>98</sup> As a solution to these conflicting systems, several states have adopted product liability statutes that recognize compliance with governmental regulations or "state of the art" as valid defenses.<sup>99</sup> Other commentators have suggested pre-emption by federally enacted national standards, such as FDA-approval, as a possible solution.<sup>100</sup>

Yet another alternative is the establishment of a legal duty to warn based on the "apparent standard."<sup>101</sup> To be successful under the "apparent standard", a plaintiff must show that the risk of a certain side effect was "apparent"—that is, recognized by at least a respectable minority of experts.

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96. *Id.* For a detailed discussion of the conflict between state tort law and federal regulation, see Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 *FOOD DRUG COSM. L.J.* 171 (1986); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 245-48 (E.D. Pa. 1990) (denying manufacturers' motion for summary judgment on grounds that federal regulation of vaccine labels and package circulars does not preempt state law requirements).

97. Note, *supra* note 44, at 773; Walsh & Klein, *supra* note 96, at 171.

98. Note, *supra* note 44, at 779 & 779 n.39.

99. See ARIZ. REV. STAT. ANN. § 12-683(1) (West 1982) (providing that proof of compliance with state of art constitutes complete defense in any product liability defective design or fabrication action); ARK. CODE ANN. § 16-116-105 (Michie 1987) (providing that proof of compliance with governmental standard comprises evidence that product is not unreasonably dangerous in product liability action); COLO. REV. STAT. § 13-21-403(1)-(2) (1987) (providing that proof of compliance with either "state of the art" or governmental standard gives rise to rebuttable presumption of non-negligence and non-defectiveness in any product liability action); KY. REV. STAT. ANN. § 411.310(2) (Michie Bobbs-Merrill 1990 Supp.) (providing that compliance with state of the art gives rise to rebuttable presumption of non-negligence and non-defectiveness in any product liability action); TENN. CODE ANN. § 29-28-104 (Michie 1980) (providing that compliance with governmental standard gives rise to rebuttable presumption of non-negligence and non-defectiveness in any product liability action).

100. See King, *supra* note 66, at 830-31 (suggesting set of presumptions and truncated analysis prescribed by federal law); Note, *supra* note 44, at 785-93 (giving arguments proposing and opposing FDA-approval as pre-emptor of state tort claims); see also Denemark, *supra* note 44, at 15 (providing excellent summary of the proponents and opponents arguments of preemption based on FDA approval).

101. See Denemark, *supra* note 44, at 442, 448 (explaining use of apparent standard in product liability actions). Some courts have already adopted the "apparent standard." *Id.* at 444.

Thus, a manufacturer would be liable if its warning failed to relate to the consumer the current state of knowledge, which does not include warnings based on dubious scientific evidence.<sup>102</sup> But the establishment of a consistent warning standard does not end the manufacturers' problems, because manufacturers still face the dilemma of determining to whom the warning must be given.<sup>103</sup>

## 2. The "Learned Intermediary Doctrine"

Commentators suggest that legislation protecting potential AIDS vaccine manufacturers is not necessary because of the protection available under the "learned intermediary doctrine."<sup>104</sup> As a general rule, a manufacturer has no duty to warn ultimate users of known product-use dangers when a prescribing physician acts as an intermediary between the manufacturer and the user.<sup>105</sup> Under this rule, the manufacturer discharges its duty to warn the patient by warning a "learned intermediary"—usually the prescribing physician or health care provider.<sup>106</sup> The learned intermediary then transmits the relevant information to the patient.<sup>107</sup> The Restatement of Torts (Second) accepts the learned intermediary doctrine,<sup>108</sup> and most jurisdictions considering whether a drug manufacturer has a duty to warn individual patients have adopted this approach.<sup>109</sup>

However, commentators recently criticized the learned intermediary doctrine, contending that the doctrine incorrectly presumes that the physician will provide the appropriate risk information to patients.<sup>110</sup> In fact, patients frequently receive little or no information concerning the drugs their phy-

102. *Id.* at 449.

103. See *infra* notes 104-26 and accompanying text (discussing to whom manufacturer owes duty to warn).

104. McKenna, *supra* note 38, at 957, 962.

105. McKenna, *supra* note 38, at 957-63.

106. Cheney, *supra* note 89, at 571; McKenna, *supra* note 38, at 958.

107. Cheney, *supra* note 89, at 571; McKenna, *supra* note 38, at 958.

108. RESTATEMENT (SECOND) OF TORTS § 388(c) cmt. n (1965) states:

Giving to the third person through whom the chattel is supplied all the information necessary to its safe use is not in all cases sufficient to relieve the supplier from liability. It is merely a means by which this information is to be conveyed to those who are to use the chattel. The question remains whether this method gives a reasonable assurance that the information will reach those whose safety depends upon their having it. . . [I]t is obviously impossible to state in advance any set of rules which will automatically determine in all cases whether one supplying a chattel for the use of others through a third person has satisfied his duty to those who are to use the chattel by informing the third person of the dangerous character of the chattel, or of the precautions which must be exercised in using it in order to make its use safe.

*Id.*

109. Cheney, *supra* note 89, at 572 n.135. See *id.* (listing specific court cases adopting learned intermediary doctrine).

110. Margaret Gilhooly, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 674-76 (1986).

sicians prescribe.<sup>111</sup> Two recent cases cast further doubt on the continued validity of the learned intermediary doctrine in the pharmaceutical context.<sup>112</sup> Practitioners note that *MacDonald v. Ortho Pharmaceutical Corp.*<sup>113</sup> and *In re Certified Questions*<sup>114</sup> suggest that the learned intermediary doctrine could be limited in the future, with a case-by-case analysis replacing the previous certainty and predictability provided by the rule.<sup>115</sup>

Even assuming the doctrine survives this recent attack, it is doubtful that the learned intermediary doctrine will apply to AIDS vaccine manufacturers for two reasons. First, the rationale behind the doctrine is not logically applicable to AIDS therapies.<sup>116</sup> The learned intermediary rule embodies the practical circumstances surrounding the distribution of prescription drugs.<sup>117</sup> Thus the rule exempting manufacturers from a direct warning to the vaccinee is based on several assumptions: The physician is in a better position to inform the patient of the dangers involved with the vaccination; the physician will exercise informed judgement gained through independent learning, experience with the individual patient, and the manufacturers' warning to him of the associated risks; and, most importantly, the physician will in fact communicate the warnings to the patient, whereas the manufacturer could not do so because of the sheer numbers involved.<sup>118</sup> A court may easily conclude that these assumptions simply are not valid in the AIDS vaccination context. First, a vaccine administrator, whether physician or nurse, will not necessarily know enough about the risks associated with a new AIDS vaccine to substitute his warning for that of the manufacturer.<sup>119</sup> Commentators already note that physicians prescribing AIDS drugs are not very well-informed, especially in the context of the FDA's expedited access program.<sup>120</sup> In addition, many ethicists argue that when

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111. *See id.* (noting that surveys indicate that substantial proportions of patients claimed to have received no information on drug risks); David B. Brushwood & Larry M. Simonsmeier, *Drug Information for Patients: Duties of the Manufacturer, Pharmacist, Physician, and Hospital*, 7 J. LEGAL MED. 279, 279 (1986) (noting numerous studies that indicate quality and quantity of information about drugs provided patients is inadequate).

112. Walsh & Klein, *supra* note 96, at 189.

113. 475 N.E.2d 65, *cert denied*, 106 S.Ct. 250 (1985).

114. 358 N.W.2d 873 (1984).

115. Walsh & Klein, *supra* note 96, at 192.

116. McKenna, *supra* note 38, at 959.

117. *Mazur v. Merck & Co.*, 742 F. Supp. 239, 252 (E.D. Pa. 1990).

118. *See Cheney, supra* note 89, at 573-76 (stating and critiquing basic rationales typically asserted in support of learned intermediary doctrine); *see also, Mazur*, 742 F. Supp. at 252 (discussing the learned intermediary doctrine's application in vaccination context). In *Mazur* the court explained that application of learned intermediary rule has depended on "extent of the medical professional's involvement in the decision to administer the drug." *Id.* The doctrine has been found to apply in situations where the medical professional exercises his "individual medical judgement bottomed on a knowledge of both patient and palliative." *Id.* at 252.

119. *See O'Reilly, supra* note 50, at 479-81 & n.107 (arguing that learned intermediary doctrine is applicable only in situations where learned intermediary understands risks in sufficient detail).

120. *See supra* note 48 and accompanying text (noting expanded access creates increased liability concerns for manufacturers).



dealing with a critical illness, it is crucial that the patient—not the prescribing physician—make the final decision regarding the risk involved.<sup>121</sup> This would be impossible if the doctor cannot thoroughly explain the risks of vaccination or simply fails to inform the patient.<sup>122</sup>

Second, and most importantly, the learned intermediary doctrine is not typically applicable in mass immunization contexts, where the courts have noted an exception to the doctrine for two reasons: First, vaccination occurs without an individualized balancing by a physician of the risks of vaccination; and second, there is no close communication between the physician and the patient during which the physician informs the patient of the vaccination risks and dangers.<sup>123</sup> According to the learned intermediary doctrine the manufacturers' warning must reach the patient for the substitute warning logic to make sense.<sup>124</sup> Under mass immunization precedent it is not sufficient that the warning reach the public-health officials who design and administer the immunization program.<sup>125</sup> Thus, the rationale behind the exemption breaks down in the mass vaccination context. Because the long-term goal of an AIDS vaccine is mass immunization, the learned intermediary doctrine is of little probable protection for a manufacturer.<sup>126</sup>

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121. See *supra* note 60 (giving in-depth discussion of conflicting results of quick and easy drug access).

122. See Gilhooley, *supra* note 110, at 637, 670, 674-75 (noting that physicians rarely explain anything at all about risk of treatments they prescribe, thus warnings never reach patient); see also *supra* note 111 and accompanying text (stating that patients receive little or no information about risks from their physicians).

123. Cheney, *supra* note 89, at 587. Courts have carved out two exceptions to the learned intermediary doctrine: oral contraceptives and vaccines. *Id.* at 586 Both exceptions were created because of specific characteristics not typical of prescription drugs generally. *Id.* In the vaccination context the manufacturer knows or has reason to know that the physician will not be intimately involved with any particular patient, thus the manufacturer retains the duty to warn the patient, who is the ultimate user. *Id.* at 587 (citing Barbara P. Flannagan, Comment, *Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405, 414 (1986)). But see *Mazur v. Merck & Co.*, 742 F. Supp. 239, 253 (E.D. Pa. 1990) (noting that all vaccine cases recognize theoretical validity of "mass immunization exception" to learned intermediary rule, but very few find situations where its application is warranted). Often commentators and courts state that the only exception to the learned intermediary doctrine is in cases involving mass immunization programs, where (1) the treatment decision is generally made by patient outside of traditional physician-patient relationship; and (2) medication is given in assembly line fashion. *Petty v. United States*, 740 F.2d 1428, 1428 (8th Cir. 1984); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974); Walsh & Klein, *supra* note 96, at 189.

124. Cooper, *supra* note 6, at 19.

125. *Id.* The first court to adopt this view thought it easy for the manufacturer to reach the ultimate patients. *Davis v. Wyeth Labs.*, 399 F.2d 121, 121 (9th Cir. 1968). Yet, manufacturers operating under Murphy's law and contemplating all the foul-ups that can occur trying to communicate warnings to many vaccines, might take a different view. Cooper, *supra* note 6, at 19.

126. See *Mazur*, 742 F. Supp. at 252-54 (holding learned intermediary doctrine did not apply to manufacturer where physician was not present and never made an individualized

### C. The "Government Contract Defense"

The government contract defense is a relatively recent development that may protect manufacturers in mass vaccination litigation.<sup>127</sup> Under this theory, a company that has complied with the FDA requirements for approval has a legal defense to a negligence claim.<sup>128</sup> This mechanism would prevent judges or juries from second-guessing the conclusions of the regulatory agency.<sup>129</sup> The defense contains two large pitfalls regarding application in an adverse side-effect case: the defense does not provide protection from strict product liability, and the protection from negligence allegations may not extend to unapproved products—that is, those still in the testing stage.<sup>130</sup>

## V. SOLUTIONS

For more than a decade the United States legal system has been struggling to develop a just approach to the issue of liability for vaccine-related injury.<sup>131</sup> The application of traditional tort theory to manufacturers greatly hinders the development and marketing of vaccines because of the difficulty in complying with the variety of state standards,<sup>132</sup> the unpredict-

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assessment of MMR II vaccination risks for 300,000 elementary school students). Even in vaccination cases where the court has held the learned intermediary doctrine suffices to relieve a manufacture of his duty to warn the vaccinee directly, a physician who weighed the risks and benefits of the drug for each patient was required, as opposed to pure mass vaccination by a nurse or administrator. *See Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989) (holding that learned intermediary doctrine applied to DPT vaccination where "physician almost invariably sees the patient before the vaccination is given" and physician weighs risk and benefits for "each patient"); *Mazur*, 742 F. Supp. at 252 (noting that in many, but not all, vaccine cases learned intermediary rule has been applied, since physician or physician's aid, administered vaccine); *see also Samuels v. American Cyanamid Co.*, 495 N.Y.S.2d 1006 (1985) (holding that pharmaceutical company had duty to warn recipient of vaccines when company knew vaccines were ordinarily given without "meaningful" balancing of risks and benefits by "informed" intermediary). Thus the mass immunization level AIDS vaccination would not be protected because there would not be a learned intermediary performing an individualized balancing of risks, both because of the complexity of the new AIDS vaccine and the large immunization numbers.

127. Cooper, *supra* note 6, at 18. In general the government contract defense applies where the defendant supplied an article to the government pursuant to specifications, and the government knew as much as the defendant about the hazards of the article. *Id.*

128. *Id.*

129. Nichols, *supra* note 48, at 51. Under this theory, a company that has complied with the FDA requirements for approval has a legal defense to a negligence claim. This mechanism would prevent judges or juries from second guessing the conclusions of the FDA. *Id.* The future of such a defense is now before the Supreme Court on certiorari in *Grumman Aerospace Corp. v. Shaw*, No. 85-1529.

130. Nichols, *supra* note 48, at 51.

131. MOBILIZING AGAINST AIDS, *supra* note 2, at 230.

132. *See supra* note 56 and accompanying text (explaining that manufacturers are subject to tort law of fifty states).

ability of the protections within the tort system,<sup>133</sup> the large damage awards,<sup>134</sup> and the incompatibility of strict product liability with governmental regulation.<sup>135</sup> The government must decide whether the HIV epidemic represents a special case, and, if so, how to structure a workable system for allocating responsibility for the adverse side-effects that inevitably will occur.<sup>136</sup> The available approaches include: (1) Mass immunization statutes; (2) product liability reform legislation; and, (3) legislation immunizing manufacturers and setting up compensation funds for injured vaccinees.<sup>137</sup>

Several states have enacted legislation altering either, or both, an injured vaccinees' compensation options or a manufacturers' responsibility in strict liability. In fact, most of the legislative response to the AIDS epidemic has occurred at the state level.<sup>138</sup> States have passed more than 170 laws dealing with the disease.<sup>139</sup> Yet, only five of these laws address the vaccine liability problem.<sup>140</sup> Federal legislation, on the other hand, has not dealt with product liability issues at all, but covers five other basic areas including: (1) research, (2) education, (3) testing and counseling, (4) non-discrimination civil rights, and (5) financing.<sup>141</sup> Congress recently authorized the FDA to accelerate

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133. See *supra* notes 60-61 and accompanying text (explaining exceptions within tort theory).

134. See *supra* note 43 and accompanying text (describing large damage awards in pharmaceutical cases).

135. See *supra* notes 77-79 and accompanying text (describing conflict between federal regulatory system and state tort law).

136. See *MOBILIZING AGAINST AIDS*, *supra* note 2, at 231 (advocating alternative solution to treatment by traditional tort theory).

137. See *NICHOLS*, *supra* note 48, at 50-51 (stating summarized solutions proposed at the 1988 "Roundtable for the Development of Drugs & Vaccines Against AIDS", which include: Modification of state tort law doctrine to eliminate strict product liability for pharmaceutical products, and federal standardization of state product liability decisions); *McKenna*, *supra* note 38, at 943 (stating proposed measures to protect AIDS vaccine manufacturers, including federal or state assumption of liability for injuries caused by privately manufactured vaccines and statutory modification of prevailing common law strict liability for design and warning defects); *Sage*, *supra* note 41, at 1025 (concluding that "[f]or prescription drugs, which are nationally marketed and regulated by FDA, the lack of a uniform federal product liability statute, the unpredictability of jury verdicts, and the expense and risk of developing new drugs threatens the availability and innovation of important treatments.").

138. *Rivas*, *supra* note 18, at 110 (citing *GEORGE WASHINGTON UNIV., THE INTERGOVERNMENTAL HEALTH POLICY PROJECT, A REVIEW OF STATE AND LOCAL GOVERNMENT INITIATIVES AFFECTING AIDS 1* (1985)).

139. *Barry O. Gostin, Public Health Strategies for Confronting AIDS: Legislative and Regulatory Policy in the United States*, 261 *JAMA* 1621, 1621 (1989). See generally, *QUAM & FORD*, *supra* note 8, at 1-36 (providing overview of State AIDS legislation). The typical progression has been for a state to create a task force or study commission to examine various aspects of AIDS, then after a period of review, the legislature drafts appropriate legislation. *QUAM & FORD*, *supra* note 8, at 32. See *Rivas*, *supra* note 18, at 110 n.38, for a listing of state task forces.

140. See *infra* pp. 13-16 (discussing state AIDS legislation).

141. *AIDS AND THE COURTS*, *supra* note 15, at 327. See *id.* at 327-34, for an overview of federal legislation in these areas and *id.* at 335-41 for an overview of state AIDS legislation on testing, reporting, confidentiality, knowing transmission, and treatment financing. The most

the approval process for clinical trials and marketing of AIDS-related treatments, thus enabling quicker access.<sup>142</sup> However, technology is useless if manufacturers are not willing to produce the enormous quantities of drugs or vaccines required.<sup>143</sup> Even more discouraging is that the new expanded access is likely to deter vaccine development because of the manufacturers' increased perception of risk regarding product liability suits.<sup>144</sup> So far, the federal government has declined to address the obstacle of tort liability; thus, the prospect of strict liability for adverse side-effects confronts manufacturers seeking to develop and market vaccines.<sup>145</sup>

### A. Current State Legislation

Several states passed legislation dealing with a manufacturers' liability for AIDS drugs and vaccines.<sup>146</sup> Three states created a general fund which is used to compensate AIDS vaccine-injured individuals without requiring them to resort to tort litigation.<sup>147</sup> Two state's statutes go further than a mere compensation fund and actually immunize manufacturers from strict product liability suits for AIDS drug or vaccine-related injuries.<sup>148</sup>

In 1983 California became the first state to pass laws establishing policies for responding to AIDS,<sup>149</sup> and in 1986 took specific action to remove the impediments to the quick development of an AIDS vaccine by passing the first AIDS immunization legislation.<sup>150</sup> The California AIDS Vaccine Statute immunizes manufacturers from product liability suits and sets up a special

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recent state AIDS legislation can be obtained from Lisa Bowleg, AIDS Policy Center, The George Washington University Intergovernmental Health Policy Project, Washington, D.C.

142. 21 C.F.R. § 312.34 (1988). The life-threatening circumstances facing AIDS patients creates a demand for major revisions in protocol and acceleration in processes for approving new experimental medical treatments. Brad Stone, *How AIDS Has Changed FDA*, 24 FDA CONSUMER No. 1, 14, 14-16 (1990). In October 1988 the FDA announced its new policy providing quicker access to experimental drugs for patients with life-threatening illness like AIDS. *Id.* at 15-16.

143. See *supra* notes 51-52 and accompanying text (noting manufacturers will not produce HIV vaccine unless immunized from liability); *supra* note 37 (discussing legal complexities facing manufacturers of potential AIDS vaccines).

144. See NICHOLS, *supra* note 48, at 45 (arguing that earlier access necessarily means less knowledge of risk, thus increases liability potential for manufacturers).

145. See *supra* pp. 12-13 (discussing pharmaceutical manufacturers' tort liability problems). Three states have responded by enacting legislation directly addressing the need for an alternative to traditional tort liability for manufacturers of AIDS drugs and vaccines. See *supra* pp. 13-16 (discussing state AIDS legislation).

146. CAL. HEALTH & SAFETY CODE § 199.47-.52 (West 1988 & Supp. 1992) (AIDS compensation fund); 1991 CONN. PUB. ACT 349 (informed consent & immunization for research testing).

147. See *infra* pp. 13-15 (detailing state AIDS legislation).

148. See *infra* pp. 13-15 (detailing state AIDS legislation).

149. Rivas, *supra* note 18, at 112.

150. CAL. HEALTH & SAFETY CODE §§ 199.45-.51 (1986) (amended 1988). See Rivas, *supra* note 18, at 112 (detailing California's legislative response to AIDS epidemic).

fund from which victims of adverse side-effects can be compensated.<sup>151</sup> The Act encourages development of an HIV vaccine through a two-tiered approach: by providing compensation for victims, and by removing the discouraging specter of a product liability suit.<sup>152</sup> The original statute provided limited protection for the manufacturers of an FDA-approved vaccines by exempting the manufacturers from strict liability suits for design or warning defects.<sup>153</sup> Thus, the Act had loopholes because it did not foreclose all strict products liability suits. Furthermore, the Act both originally and in its current form exempts clinical trials, one of the most risky periods for manufacturers, from the immunization provision completely.<sup>154</sup>

In 1988 California repealed the provision of the Act providing limited liability for manufacturers of an AIDS vaccine.<sup>155</sup> The 1988 revisions attempted to encourage vaccine manufacturers by leaving in place the AIDS Compensation Fund and by ensuring a profitable market for AIDS vaccines through state-guaranteed purchasing.<sup>156</sup> A surcharge on the sale of state or federal approved AIDS vaccine finances the fund that compensates injured vaccinees.<sup>157</sup> Financing the fund by a product tax, which manufacturers are sure to incorporate into product cost, adds to the current problem of exorbitant AIDS drug prices.<sup>158</sup> Moreover, with the immunity provision repealed the Act allows plaintiffs the option of tort lawsuits, thus, manufacturers are in no way assured vaccine-injured individuals will resort to the compensation fund.<sup>159</sup>

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151. CAL. HEALTH & SAFETY CODE §§ 199.49-.51 (1986) (amended 1988 & 1990). Section 199.49 immunizes manufacturers from strict product liability in most circumstances. (repealed and replaced by Stat.1988, ch. 1555, § 3 (1988)). Section 199.50 sets up the "AIDS Vaccine Victims Compensation Fund." [

152. See Rivas, *supra* note 18, at 122 (stating that California insulated manufacturers from uncertain liability in effort to encourage development of HIV vaccine).

153. CAL. HEALTH & SAFETY CODE § 199.49 (West 1986) (repealed and replaced 1988). Section 199.49 prohibited compensation from the fund if (1) the victim was "comparatively negligent", (2) the "manufacturer had been found liable. . .in a court", for negligence or a legal basis other than section 199.45 strict liability, or (3) if vaccinations were administered during a clinical trial. *Id.*

154. *Id.* § 199.50(c)(3).

155. CAL. HEALTH & SAFETY CODE §199.49, *repealed by* 1988 Cal. Stat. 1555 § 3. The immunity provisions had not yet been utilized in court and no reasons were given for the repeal. Rivas, *supra* note 18, at 122.

156. CAL. HEALTH & SAFETY CODE § 199.50-.51 (West Supp. 1992). The purpose of the state-guaranteed purchase of FDA or state-approved AIDS vaccines was dual: First, governmental purchase of the vaccine ensures that at least 175,000 HIV-infected individuals can afford vaccination; and, second, the ensured purchase guarantees manufacturers a worthwhile return on their investment. *Id.* § 199.51(a).

157. CAL. HEALTH & SAFETY CODE § 199.50(o) (West 1990 & Supp. 1992). The surcharge, not to exceed \$10 per unit of vaccine, will be levied on the sale of each unit of vaccine sold, delivered, administered or dispensed in California. *Id.*

158. See *infra* note 214 and accompanying text (noting federal proposal by Keystone group rejected California's funding scheme). A taxing funding mechanism poses practical problems in addition to increasing product cost because initially there will be a lack of money in the fund—because the Act puts a cap of ten dollars per unit on the vaccine tax. *Id.*

159. CAL. HEALTH & SAFETY CODE § 199.50(m).

In 1991 Connecticut enacted the second AIDS vaccine liability law.<sup>160</sup> The Connecticut statute provides immunity to manufacturers, researchers, and research institutions for vaccine-related injuries on research subjects as long as written informed consent is obtained prior to vaccination.<sup>161</sup> A major drawback for future application of the law is that it only addresses liability in research settings.<sup>162</sup>

In 1991 Massachusetts created the "Massachusetts AIDS Fund."<sup>163</sup> The commissioner of public health controls the fund which is financed by public and private appropriations, gifts, grants and donations.<sup>164</sup> The state health commissioner, with the advice and guidance of an advisory board, can use the moneys for "research treatment, experimental treatment, and education relating to the acquired immune deficiency syndrome."<sup>165</sup> The definition of "experimental treatment" includes treatments not yet approved for general use by a federal agency.<sup>166</sup> The term "research" includes scientific study through community-based efforts to determine the effectiveness of drug and nondrug therapies in combatting the HIV infection.<sup>167</sup> Thus, while the fund does not specifically intend to compensate injured vaccinees, it could foreseeably be used to do so.<sup>168</sup>

Changes in product liability laws can also decrease a manufacturers' liability concerns. Most states have enacted product liability reform legislation in an attempt to curb litigation and high product cost.<sup>169</sup> Such

160. 1991 CONN. PUB. ACT 349.

161. *Id.* See AIDS Policy Center, *State Laws Related to Liability for AIDS Vaccines* (The George Washington University Intergovernmental Health Policy Project, Washington, D.C.), Nov. 5, 1991 (summarizing Connecticut statutory provision). The Connecticut act does not extend immunity where a researcher was grossly negligent, reckless, or failed to comply with the law. *Id.*

162. 1991 CONN. PUB. ACT 349.

163. MASS. ANN. LAWS ch. 10, § 35J (Law. Co-op. 1991) (effective Jan. 1, 1991 and expires July 1, 1995).

164. MASS. ANN. LAWS ch. 10, § 35J (Law. Co-op. 1991). Under an accompanying law individuals are encouraged to contribute their state tax refunds to the Massachusetts AIDS Fund. MASS. ANN. LAWS ch. 62, § 6G (Law. Co-op. 1991).

165. MASS. ANN. LAWS ch. 10, § 35J (Law. Co-op. 1991). The fund can be used to further the purposes as set out in chapter 111 sections 2D and E. *Id.*

166. MASS. ANN. LAWS ch. 111, § 2D (Law. Co-op. 1991).

167. MASS. ANN. LAWS ch. 111, § 2D (Law. Co-op. 1991).

168. See HAW. REV. STAT § 325-6 (1985) (creating a similar fund to finance preventable disease). In 1986 Hawaii created an "Epidemic Control Fund" which could be used to compensate injured vaccinees. *Id.* Under the Hawaii program the department of health may apply the resources of the fund toward controlling, suppressing, or preventing the spread of any communicable or preventable disease. *Id.* The fund is not specifically directed toward AIDS, but could foreseeably be used to compensate injured vaccinees.

169. See generally, Glenn Blackman & Richard Zeckhauser, *State Tort Reform Legislation: Assessing Our Control of Risks*, TORT LAW AND THE PUBLIC INTEREST 272, 272-99 (Pete H. Shuck, ed., 1991) (discussing need for tort reform and states' various reform efforts thus far); Joseph Sanders & Craig Joyce, "Off to the Races": *The 1980s Tort Crisis and the Law Reform Process*, 27 Hous. L. REV. 207 (same). See Blackman & Zeckhauser, *supra* at 295-98 for specific product liability reform provisions of each state.

legislation varies greatly in subject matter and scope, but typically provides for qualified immunity; limited liability for manufacturers of "inherently unsafe" products, chemicals, pharmaceuticals, or drugs; and caps or prohibits entirely punitive damages.<sup>170</sup> These statutes may help curb the problems associated with AIDS vaccines and tort liability. For instance, California's Civil Liability Reform Act of 1987 contained a section that substantially altered the state's product liability law.<sup>171</sup> This provision may have great national significance because California is a leader in the development of product liability law.<sup>172</sup> The provision affords medical device and drug manufacturers protection from punitive damage awards provided they meet certain government standards—or "state of the art" defense—and do not intentionally withhold or misrepresent information about the product's safety.<sup>173</sup>

Another legislative option is mass immunization statutes. Mass immunization laws protect those administering vaccines under broadscale immunization programs. For example, a Maryland law protects persons administering a drug or vaccine from liability when the administration is part of a state approved immunization project.<sup>174</sup> Such statutes could be

170. See Sanders & Joyce, *supra* note 169, at 220-22 (discussing state tort reform provisions); Blackmon & Zeckhauser, *supra* note 169, at 272-300 (same).

171. Darren O'Leary Aitken, Note, *The Products Liability Provision of the Civil Liability Reform Act of 1987: An Evaluation of Its Impact and Scope*, 62 S. CAL. L. REV. 1449 (1989) (discussing effect of CAL. CIV. CODE § 1714.45 (West Supp. 1991) on product liability law).

172. Aitken, *supra* note 171, at 1449.

173. *Id.* at 1449 n.4. The complete text of CAL. CIV. CODE § 1714.45 (West Supp. 1991) reads:

- (a) In a product liability action, a manufacturer or seller shall not be liable if:
  - 2(1) The product is inherently unsafe and the product is known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community; and
  - 2(2) The product is a common consumer product intended for personal consumption, such as sugar, castor oil, alcohol, tobacco, and butter, as identified in comment i to Section 402A of the Restatement (Second) of Torts.
- (b) For purposes of this section, the term "product liability action" means any action for injury or death caused by a product, except that the term does not include an action based on a manufacturing defect or breach or an express warranty.
- (c) This section is intended to be declarative of and does not alter or amend existing California law, including *Cronin v. J.B.E. Olsen Corp.*, (1972) 8 Cal. 3d 121 and shall apply to all product liability actions pending on, or commenced after, January 1, 1988.

*Id.*

174. The text of Maryland's mass immunization statute reads,

(a) Nonliability of persons administering.—person lawfully administering a drug or vaccine shall have the immunity from liability described under § 5-372 (b) of the Courts and Judicial Proceedings Article.

(b) Immunization projects; nonliability of participants.—If the Secretary or a designee of the Secretary finds that a proposed immunization project would conform to good medical and public health practice and gives written approval for the project to be administered in this State, a physician, nurse, or person participating in the project shall have the immunity from liability described under § 5-372 (c) of the Courts and

expanded to cover the manufacturer of the FDA-approved vaccine. However, strong debate exists on whether an HIV vaccine will be used to vaccinate the whole population or just high risk groups, thus such statutes may be of limited utility.<sup>175</sup>

Clearly, states have been much more involved in the development of AIDS legislation and policies than has the federal government.<sup>176</sup> While these state resolutions are praiseworthy for their active role, AIDS presents a national emergency that federal officials must deal with by national policy.<sup>177</sup> In June 1987, the National Conference of State Legislatures adopted a broad policy requesting increased federal efforts to prevent the spread of AIDS.<sup>178</sup> A national consensus, as opposed to individual treatment by the states, will effectively provide the uniform treatment of manufacturers required to solve the problem.<sup>179</sup> Yet at the close of the first decade of the AIDS epidemic, the United States had neither a national AIDS policy nor a coordinated strategy for combatting this public health threat.<sup>180</sup>

### B. Possible Federal Legislation

There are three types of federal legislation that would encourage the development and marketing of an AIDS vaccine: (1) federal Product liability reform; (2) specific federal AIDS legislation; or (3) a national vaccine

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#### Judicial Proceedings Article.

MD. HEALTH-GEN. CODE ANN. § 18-401 (1990) (emphasis omitted).

175. MOBILIZING AGAINST AIDS, *supra* note 2, at 232-34 (discussing the advantages and disadvantages of pre-exposure and postexposure vaccination). It remains unclear whether an AIDS vaccine will be used to vaccinate the population in general and thus the utility of the mass immunization statutes is uncertain. *Id.*

176. Taunya L. Banks, *AIDS and Government: A Plan of Action?*, 87 MICH. L. REV. 1321, 1333-34 (1989); *see supra* notes 138-42 and accompanying text (discussing scope of state and federal legislation dealing with AIDS epidemic).

177. *See Rivas, supra* note 18, at 110 (remarking this is not situation where each state can be left to deal with issues individually); Harold L. Hirsh, *AIDS Updated: A Review—Part I*, 31 TRAUMA 85, 86 (1989) (arguing that because of enormity and complexity of AIDS problem it is critical that United States develop realistic AIDS policy); AIDS DRUGS: WHERE ARE THEY?, H.R. REP. NO. 1092, 100th Cong., 2d Sess. 16 (1988) [hereinafter AIDS DRUGS] (noting national scope of crisis which necessitates federal response). During a crisis of the national scope and proportions of the AIDS epidemic, the federal government necessarily must become the primary policymaker and stimulus of action. *Id.* The Committee on Government Operations found that "the Federal Government has not provided that leadership." *Id.* at 17. The Committee recommended that the President declare AIDS a public health emergency and direct all relevant federal agencies to create long-term action plans to accomplish the goal of finding a cure. *Id.* at 33. Recently, Congress noted that given the growing dimensions of the crisis and the limited resources available, it is imperative that a national policy be developed jointly by the public and private sectors. H.R. REP. NO. 511, 101st Cong., 2d Sess. 156 (1990). Such a policy must seek, in a cost-effective way, to achieve fundamental national goals of prevention, treatment, and cure. *Id.* A coherent national approach is needed, not piecemeal solutions. *Id.*

178. Rivas, *supra* note 18, at 110 (citing *State Legislators Endorse Massive Federal AIDS Effort*, AIDS POL'Y & L., Aug. 12, 1987, at 4).

179. QUAM & FORD, *supra* note 8, at 44-45. *See supra* notes 177-78 and accompanying text (describing necessity of federal solution).

180. QUAM & FORD, *supra* note 8, at 44.



compensation and immunization system.<sup>181</sup> Federal legislation in any of these areas would remove the obstacles currently hindering the development and marketing of potential AIDS vaccines.

### 1. Product Liability Reform

For over a decade, lobbyists have been hounding Congress to pass a uniform product liability law.<sup>182</sup> Advocates of tort reform contend that juries grant excessive punitive damage awards to consumers which go far beyond fair compensation,<sup>183</sup> and that the patchwork of state laws discourages new product development.<sup>184</sup> In 1990, the Senate Commerce Committee approved a bill, the Product Liability Reform Act, designed to resolve some of the manufacturers' liability problems.<sup>185</sup> The bill would establish federal standards for product liability litigation and includes provisions that would pre-empt conflicting state product liability law, establish incentives for out-of-court settlements, place uniform time limitations on liability, and prohibit punitive damages against manufacturers and sellers of drugs and medical devices approved by the FDA.<sup>186</sup> The positive effect of the bill for pharmaceutical companies would be two-fold. First, the pre-emption of state tort law by uniform federal standards decreases the current uncertainty surrounding a manufacturers' liability exposure and makes compliance with standards possible.<sup>187</sup> Second, the prohibition against punitive damages

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181. See *infra* part V.B.1 (discussing product liability reform); *infra* part V.B.2 (discussing AIDS specific legislation); *infra* part V.B.3 (discussing national vaccine compensation system).

182. See *Issue: Product Liability*, 49 CONG. Q. 2235, 2235 (1991) (special report) (stating that "undaunted by more than a decade of congressional rebuffs on issue, manufacturers are again pushing for federal legislation to limit collections for injuries caused by faulty products"). But see Russ M. Herman, *Drug Industry Delusions*, TRIAL, Dec. 1989, at 7 (arguing that Product Liability Reform Act, Senate Bill S. 1400, and Product Liability Reform Act of 1989, House Bill H.R. 2700, are anti-consumer legislation supported only by large manufacturers). Herman states that such bills are the last step in insulating the drug industry from public and legal accountability for its products. *Id.* He further argues that FDA approval is completely inadequate to ensure consumers sufficient information on the drug and is tainted by political and administrative difficulties. *Id.*

183. See *Issue: Product Liability*, *supra* note 182, at 2235 (noting that in March 1991 Supreme Court gave issue of tort reform and recovery limitations back to Congress and individual states by holding that punitive damages are constitutional).

184. Section Notes, 49 CONG. Q. 2618, 2618 (1991).

185. *Issue: Product Liability*, *supra* note 182, at 2235. The Product Liability Reform Act was the topic of long-lasting hearings before the subcommittee on the Consumer in Spring of 1990. See *Product Liability Reform Act: Hearings on S. 1400 Before the Subcomm. on the Consumer*, 101st Cong., 2d Sess. (1990) [hereinafter *Product Liability Hearings*].

186. *Id.* at 11-36 (giving full text of bill's punitive damage provision).

187. See *id.* at 592 (statement of National Governors Association). The Association argued that differences in state liability laws have made it difficult for manufacturers to assess their own risks and have increased the costs and the general uncertainty about the nature of risks involved in product development. *Id.* The Association urged Congress to adopt a uniform product liability code to decrease these rising product liability costs. *Id.* at 13-14 (statement of George S. Frazza on behalf of Johnson & Johnson and the pharmaceutical industry). Frazza argued that there is no single standard by which a pharmaceutical manufacturers' product is judged and that ensuing damage awards are huge. *Id.* This climate of uncertainty causes higher prices and fewer choices in the marketplace damaging the citizens of this country. *Id.* at 611.

greatly reduces the cost of litigation for a pharmaceutical manufacturer.<sup>188</sup> Interestingly, the punitive damage provision would cover only FDA-approved products, and thus is a codification of the common-law government standards defense.<sup>189</sup> Despite its popularity, the Product Liability Reform Act never reached the Senate floor in 1990. Nevertheless, in early 1991 the bill was reintroduced in both the Senate and the House.<sup>190</sup> What will become of the renamed Product Liability Fairness Act during second session of 1991 Congress is still unclear.<sup>191</sup>

Notably, there are strong political forces opposing a uniform product liability law. The American Bar Association (ABA) clearly expressed its dislike of federal product liability reform during the 1990 Senate hearings.<sup>192</sup> The ABA finds state tort law both desirable and adequate, with the possible exception of mass torts.<sup>193</sup> In the mass tort context, which would be applicable to an AIDS vaccination scheme, the ABA favors a compensation system, as opposed to uniform tort reform.<sup>194</sup> The ABA's approach is consistent with the National Commission on Vaccine's approach of a compensation program for vaccine-related injuries.<sup>195</sup> Consumer groups criticize current product liability law proposals as anti-consumer legislation supported only by large manufacturers who are attempting to insulate the drug industry from public and legal accountability.<sup>196</sup>

## 2. AIDS-Specific Legislation

In 1987 the Reagan administration appointed an independent public advisory commission, the Presidential Commission on AIDS (Commission),

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188. *See id.* at 610-14 (noting the cost of tort suits and arguing for prohibition of punitive damages for FDA-approved drugs in tort actions).

189. *Id.* at 614 (statement of pharmaceutical industry in support of S.1400).

190. *Issue: Product Liability*, *supra* note 182, at 2235. House bill H.3030 was introduced on July 25, 1991, by J. Roy Rowland and was referred to the Energy, Commerce, and Judiciary, and Energy house committees. *Id.* Senate bill S.640 was introduced March 13 by Bob Kasten and was referred to the Commerce Consumer Subcommittee, which after hearings in mid-september approved the bill. *Id.*

191. The Senate Commerce, Science, and Transportation Committee approved the Product Liability Fairness Act on October 3, 1991. *See* Current Status of Senate Bills (CCH) ¶ 20,502 (Oct. 18, 1991). The House hearings are expected this fall, under the support of committee Chairman John D. Dingell, D-Mich. *Issue: Product Liability*, *supra* note 182, at 2235. But even supporters for the bill are doubtful because the bill, now S.640, does not set a uniform standard, as it does for products liability, for awarding punitive damages and thus even supporters of the bill express concern that this version would address only part of the current problem facing manufacturers. *Id.*

192. *Product Liability Hearings*, *supra* note 185, at 583 (statement of Robert B. McKay, chairman, Action Commission to Improve Tort Liability System).

193. *Id.* at 584.

194. *Id.*

195. *See infra* part V.B.3.b (discussing National Childhood Vaccine Injury Act).

196. Herman, *supra* note 182.

to investigate the epidemic and recommend policies and practices for the federal government.<sup>197</sup> More specifically, the President asked the Commission to recommend measures that he and the Secretary of Health and Human Services could take to protect the public from contracting HIV, to assist in finding a cure for AIDS, and to care for those who already have the disease.<sup>198</sup> A year later the Commission published a final report that was praised by many as "a blueprint for action that was scientifically sound, politically sensitive, and far-reaching in its critique of current efforts and calls for major reforms."<sup>199</sup> The report pointed out the necessity for liability protection for manufacturers who are attempting to develop an AIDS vaccine.<sup>200</sup> The National Commission on AIDS<sup>201</sup> continues the President's Commission program, but government officials have yet to take any action on the recommendation to develop liability protection.<sup>202</sup> One commentator notes that once again the federal health establishment is acting as a "many-headed bureaucratic system with no one in effective control."<sup>203</sup>

### 3. A National Vaccine Compensation System

While there appears to be no legislation planned for the immediate future, Congress has indicated interest in the subject and various senators have requested committees and outside institutions to develop proposals. The proposals for an AIDS vaccine liability bill include a novel scheme called the Keystone Center AIDS Vaccine Liability Project<sup>204</sup>, and a scheme

197. Exec. Order No. 12,601, 52 Fed. Reg. 24,129 (1987) (reports by Committee include: preliminary report-12/2/87; interim report-3/15/88; final report-6/24/88). The President asked the Commission to advise government officials on the medical, legal, ethical, social, and economic impact resulting from the spread of HIV. AIDS DRUGS, *supra* note 177, at 18 (citing Exec. Order No. 12,601); Kristine M. Gebbie, *The President's Commission on AIDS: What Did it Do?*, 79 AM. J. PUB. HEALTH 868, 868 (citing Presidential Commission, *The Final Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic 47* (Washington, D.C.: U.S. Govt. Printing Office, June 1988, which lists examination of policies for development of drugs as one of Commission's main goals).

198. *See id.* For a detailed overview of the Presidential Commissions on AIDS goals, recommendations, and accomplishments, see Banks, *supra* note 176.

199. QUAM & FORD, *supra* note 8, at 44. *See also* Gebbie, *supra* note 197, at 868 (explaining what President's Commission did and did not accomplish).

200. PRESIDENTIAL COMMISSION, *THE FINAL REPORT OF THE PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC 47* (Washington, D.C.: U.S. Govt. Printing Office, June 1988).

201. 42 U.S.C. § 300cc (1991).

202. *See* Gebbie, *supra* note 197, at 868-70 (discussing Commission's mandate, accomplishments, and short-comings). In 1988, Congress passed S. 1220 declaring AIDS a national emergency and authorizing funds for research and public information efforts, but aside from this legislation, Congress has not formulated a policy beyond the scope of appropriation. AIDS Page, FDA CONSUMER, Feb. 1989, at 2.

203. QUAM & FORD, *supra* note 8, at 29.

204. Keystone Center, *Keystone AIDS Vaccine Liability Project Final Report* (May 1990), reprinted in AIDS REFERENCE GUIDE ¶ 1321 (1990) [hereinafter *Keystone Proposal*] (study & proposal by non-profit group at request of Rep. John Dingell, chair of House Energy & Commerce Committee, for information contact Robert Stein of Blicker, Futterman & Stein, D.C.).

modeled after previously implemented state and federal schemes, such as the National Childhood Vaccine Injury Act of 1986,<sup>205</sup> the California Acquired Immunodeficiency Syndrome Vaccine Statute,<sup>206</sup> and the National Swine Flu Immunization Program of 1976.<sup>207</sup>

a. The Keystone Center AIDS Vaccine Liability Report

In 1990 a congressionally delegated group of individuals drafted the Keystone Center Proposal as a compensation system for clinical trials.<sup>208</sup> The scheme focuses on liability for injuries occurring in clinical trials of AIDS vaccines as opposed to general vaccination.<sup>209</sup> While the proposal is not designed to address a manufacturers' liability for FDA-approved or marketed vaccine injuries, some of the proposal's systems and attributes are transferrable to legislation that would protect manufacturers once a vaccine reaches the mass immunization context.

The Keystone proposal provides an exclusive administrative remedy for injury resulting from vaccination.<sup>210</sup> The basic structure of the system consists of: (1) A thorough prevaccination informed consent process;<sup>211</sup> (2) a hearing of any injury claims before a small expert panel who will determine causation and degree of disability;<sup>212</sup> (3) a determination as to the compensation levels depending on type and extent of injury,<sup>213</sup> and; (4) a limited appeal provision.<sup>214</sup>

The group rejected a common-pool fund approach to compensation because it was concerned that if manufacturers were made responsible for

205. 42 U.S.C. § 300aa-10 to -33 (1991).

206. CAL. HEALTH & SAFETY CODE §§ 199.45-.57 (West 1990 & Supp. 1992).

207. 42 U.S.C. § 247b(j)-(l) (1991).

208. *Keystone Proposal*, *supra* note 204, at 1.

209. *Id.*

210. *Id.* at 1, 5. There is an exception to the "exclusive" remedy for injury resulting from "unacceptable behavior" for which a tort remedy is still available. *Id.* at 5. The "unacceptable behavior" standard was set at a level to ensure preservation of the "deterrent effect of the existing tort system" on manufacturers in the new system. *Id.* Unacceptable behavior would include an "intentional violation of the law, conscious disregard for the rights or safety of others, or intentional conduct that was designed to deceive or conceal; and which was casually related to the injury in question." *Id.*

211. *Id.* at 2-4.

212. *Id.* at 4-5. The panel would be solely scientific experts in AIDS because of the causal relation problems inherent in vaccine injury cases, especially with a disease as new as AIDS. *Id.* Even more interestingly, the causation standard employed would give the benefit of the doubt to the claimant. *Id.* at 6.

213. *Id.* at 6. The proposal provided for payment of unreimbursed medical expenses, but was inconclusive as to allowances for economic losses and pain and suffering awards. *Id.* at 9. A lump sum was favored over periodic payments, and would consist of medical expenses, but the group did not reach consensus on coverage for other economic losses, or pain & suffering. *Id.* at 6-7. However, the Keystone group did note that the Childhood Vaccine Scheme has a cap of 250,000 economic losses and the California scheme provides up to \$250,000 for pain & suffering. *Id.* at 7-8.

214. *See id.* at 6 (providing provision for administrative appeal and limited formal judicial review).

injuries caused by a competitor's product vaccine development would be discouraged.<sup>215</sup> Instead, the group suggested a system in which each manufacturer is responsible for its own vaccinees up to a set amount, with a federal trust fund to pay awards exceeding that maximum.<sup>216</sup> There has been little commentary on the proposal, and the drafters recognize that the effectiveness of the system depends on many factors that can not be predicted until actual utilization of the scheme.<sup>217</sup>

b. The National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act (Act) of 1986 established the National Vaccine Injury Compensation Program to compensate individuals for injuries or death related to the childhood vaccines.<sup>218</sup> The program is the first federal no-fault system for handling claims arising from injuries caused by vaccines and could be used as a prototype for handling claims related to AIDS vaccines.<sup>219</sup> The compensation is less generous than that available in a tort action, but the low burden of proof and speed of award make the process attractive.<sup>220</sup> Petitions are filed within a specified time with the United States Court of Claims.<sup>221</sup> A Special Master makes the initial findings of fact and conclusion of law, which are then reviewed by the Claims Court.<sup>222</sup> To succeed, an injured party must establish by a preponderance of the evidence that the injury was one listed on the Vaccine Injury Table, that the first symptoms of injury occurred within the time period specified on the table, and that factors unrelated to vaccine administrations did not cause the injury.<sup>223</sup> A party is free to appeal the judgement to the United States Court of Appeals.<sup>224</sup>

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215. *See id.* at 8 (noting disadvantage of California's compensation system because funding mechanism consists of surcharge on manufacturers in common pooled format).

216. *Id.* at 8-9.

217. *Id.* at 9. The Keystone group noted that,

"Whether such a trade-off between manufacturers and injured volunteers] will reduce the likelihood of inappropriate deterrence to AIDS vaccine research will depend upon the risks perceived by vaccine developers as clinical trials approach, the levels of the proposed caps on awards, practical approaches to ensuring that insolvency and actual bankruptcies of small companies will not prevent the availability of funds for claims, and the exact extent of the role to be played by tort suits in the context of a claims program."

*Id.*

218. 42 U.S.C. § 300aa-10 to -33 (1991). The law aims at funnelling lawsuits out of the overburdened court system and into a simpler, federally funded compensation program, thereby lowering manufacturers' insurance costs and preserving vaccine supplies. Sarah Glazer, *Vaccine Victims: No-Fault Federal Program Compensates for Injuries*, WASH. POST, Jan. 29, 1991, at 9.

219. Glazer, *supra* note 218, at 9.

220. Cooper, *supra* note 6, at 18.

221. 42 U.S.C. § 300aa-11 (1991).

222. 42 U.S.C. § 300aa-12 (1991). *See* Huber, *supra* note 1, at 10 (noting that this system can result in the district judge "doing the whole thing over again").

223. 42 U.S.C. § 300aa-13 (1991); Hagan, *supra* note 3, at 481.

224. 42 U.S.C. § 300aa-12, -32 (1991) (within 60 days).

The Act partially immunizes a vaccine manufacturer from civil liability.<sup>225</sup> A manufacturer is not liable if the injury results from side-effects which were unavoidable even though the vaccine was properly prepared and accompanied by proper directions and warnings—this is, a codification of the Restatement's comment k exception.<sup>226</sup> Most importantly, warnings that comply with FDA requirements are presumed to be adequate, unless the plaintiff can show fraud or intentional withholding of information from the FDA during pre and post approval of the vaccine.<sup>227</sup> Furthermore, manufacturers are not liable for failure to provide direct warnings to the vaccinee of the potential dangers.<sup>228</sup> The Act also allows for civil liability where a plaintiff shows by clear and convincing evidence that the manufacturer failed to exercise due care—a negligence-like standard.<sup>229</sup> In cases where civil liability is found a manufacturer is not generally subject to punitive damages.<sup>230</sup>

Compensation comes from a pool funded by revenues from a tax on vaccine sales.<sup>231</sup> Individuals filing for claims under the Act can receive expenses for medical care, rehabilitation, emotional therapy, residential and custodial care, and loss of earning capacity.<sup>232</sup> Compensation for pain and suffering is capped at \$250,000.<sup>233</sup> The Act also requires parents to read and sign a long, complicated consent form regarding the frequency and severity of potential risks before vaccination of the child.<sup>234</sup>

Disadvantages to this approach include the likelihood that funding of the compensation pool from a tax on the manufacturers will cause the companies to pass the cost on to consumers in the price of the vaccine.<sup>235</sup>

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225. See 42 U.S.C. § 300aa-22(a) (1991) (limiting vaccine manufacturers' liability for unavoidable side effects in product liability actions).

226. 42 U.S.C. § 300aa-22(b)(1) (1991).

227. 42 U.S.C. § 300aa-22(b)(2) (1991).

228. 42 U.S.C. § 300aa-22(c) (1991); Hagan, *supra* note 3, at 483; Huber, *supra* note 1, at 10. The duty to warn provision in effect overrules the contrary holdings in *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) and *Reyes v. Wyeth Laboratories, Inc.*, 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). Hagan, *supra* at 483. In other words, does away with the mass immunization exception limiting the application of the learned intermediary doctrine in the general immunization context. See *supra* notes 123-26 and accompanying text (discussing mass immunization exception).

229. 42 U.S.C. § 300aa-22(2)(B) (1991).

230. 42 U.S.C. § 300aa-23(d) (1991); Hagan, *supra* note 3, at 483; Huber, *supra* note 1, at 10.

231. 42 U.S.C. §§ 4131-4132 (Supp. 1988); Hagan, *supra* note 3, at 482. Compensation for vaccine administration prior to Oct. 1, 1988 will come from congressional appropriations. *Id.* at 482 n.33.

232. 42 U.S.C. § 300aa-15 (1991). Compensation comes in a lump sum for injuries related to vaccination after Oct. 1, 1988. Hagan, *supra* note 3, at 482.

233. 42 U.S.C. § 300aa-15(a)(4) (1991); Snider, *supra* note 1, at 23. Individuals injured before Oct. 1, 1988 are eligible for less than this, and \$250,000 is awarded in the case of death. *Id.*

234. 42 U.S.C. § 300aa-26 (1991).

235. See Bennett, *supra* note 2, at 768-70 (discussing potential problems with National Childhood Vaccine Injury Compensation Act).

Unfortunately the exorbitant price of AIDS treatments already has been a notable problem.<sup>236</sup> The biggest gap in the legislation is that an individual is free under the Act to give up the alternative compensation and pursue a traditional tort action if dissatisfied with the compensation determined under the statutorily created proceeding.<sup>237</sup> Yet, as of January 1991, the Court of Claims reports that no one has declined an award.<sup>238</sup>

The National Childhood Vaccine Injury Act has been in effect for almost seven years and by most measures, the program is a success.<sup>239</sup> Lawsuits against DPT manufacturers declined from their 1986 peak of 255 to 47 in 1990, vaccine prices have stabilized, and worries over supply have subsided.<sup>240</sup> As of May 21, 1990, 296 vaccine-related injury claims were filed.<sup>241</sup> The sixty-nine awards granted up to May 1990 totaled thirty-seven million dollars.<sup>242</sup> But the program has caused concern since the fall of 1990, when more than 3,000 new claims were filed.<sup>243</sup> Assuming half of these are meritable, the program will not have enough money to compensate all the injured vaccinees.<sup>244</sup> By January 1991, the total figure for awards paid out has already jumped to seventy-four million dollars.<sup>245</sup> The chairman of the Advisory Commission on Childhood Vaccines has remarked, "This is going to be . . . something Congress will have a tough time wrestling with."<sup>246</sup>

### c. The National Swine Flu Program

Another past federal program that could serve as a model for AIDS vaccine liability reform is the National Swine Flu Program.<sup>247</sup> During federal

236. See Chase, *supra* note 24, at A1 (discussing patients dissatisfaction with prices of current AIDS drug therapies).

237. 42 U.S.C. § 300aa-12 (1991). See Hagan, *supra* note 3, at 482 (noting that after judgement awarding or denying compensation in statutorily created proceeding, petitioner has 90 days to accept judgement or file civil action for damages); Huber, *supra* note 1, at 10 (noting injured plaintiff is free to reject findings and file action against manufacturer in state court under slightly restricted tort theory).

238. Glazer, *supra* note 218, at 9.

239. *Id.*

240. *Id.*

241. Snider, *supra* note 1, at 23. Of the 296 vaccine-related claims under the National Childhood Vaccine Program, 194 were for injuries and 102 were for deaths. *Id.*

242. *Id.* Nineteen of the 296 claims have been either dismissed or voluntarily withdrawn. *Id.*

243. Glazer, *supra* note 218, at 9.

244. *Id.*

245. *Id.*

246. *Id.* The newspaper article on the Childhood Vaccine Injury Act suggests solutions to the financing problems such as a cap on awards or restricting the kinds of injuries for which awards may be granted. *Id.* Although there are caps on certain categories of expenses the current law puts no limit on the overall injury award amount. *Id.* Awards for the pre-1988 injuries averaged about 1.2 million dollars, according to Human Health Services. According to Claims Court Chief Special Master, the program has paid out 74 million dollars in 145 cases thus far. *Id.*

247. National Swine Flu Immunization Program of 1976, Pub. L. No. 380, 90 Stat. 1113

efforts to prevent a possible swine flu pandemic in 1976, the federal government indemnified swine flu vaccine manufacturers from product liability by enacting the National Swine Flu Immunization Program.<sup>248</sup> This legislation barred suits for injuries or death allegedly caused by the swine flu vaccine against those who manufactured, distributed, or administered it.<sup>249</sup> This vaccine immunity act is entirely different from all others in that the exclusive remedy for an injured party is a suit against the United States. Thus, the government assumed liability for any action based on strict liability, negligence, or breach of warranty.<sup>250</sup> If recovery was ultimately obtained under a negligence theory, the government was free to recover from the manufacturer the amount paid out to the injured party.<sup>251</sup>

While such a structure certainly removes most of a manufacturers' liability worries, it is too lax. The manufacturer does not even have a duty to warn under such legislation.<sup>252</sup> Rather, in the swine flu context the government prepared a consent form that attempted to provide adequate warning about the possible adverse effects from swine flu immunization.<sup>253</sup> This system proved disastrous for the government because of the unavoidable delays when incorporating the manufacturers' new risk information into the government's consent form.<sup>254</sup> The system also resulted in a lack of incentive for the manufacturers to continue monitoring risks.<sup>255</sup> Only two months after the immunizations began they were abruptly discontinued due to a large number of cases of Guillain-Barre syndrome, a paralytic condition, resulting from the immunization.<sup>256</sup> The government's consent form did not include the risk of contracting the syndrome and, thus, the government was left with a number of extremely unfavorable lawsuits.<sup>257</sup> As of January 1989, the government had received 4179 claims and 1604 lawsuits alleging injury from the vaccine. The government has settled 1100 of these suits at a cost of about 79 million dollars, and judgements for plaintiffs in 105 lawsuits resulted in a cost of about 45 million dollars.<sup>258</sup> The government

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(1976) (current version at 42 U.S.C. § 247b(j)-1 (1991)). See Cooper, *supra* note 6, at 19 (stating "the only legislation. . . [which] would satisfy [AIDS] manufacturer or its insurers" is one modeled after the swine-flu legislation).

248. ASHBURY, *supra* note 2, at 69.

249. National Swine Flu Immunization Program of 1976, Pub. L. No. 380, § 4(i)(2)(A), 90 Stat. 1113, 1115 (1976) (current version at 42 U.S.C. § 247b(j)-1 (1991)); Hagan, *supra* note 3, at 478.

250. National Swine Flu Immunization Program of 1976, Pub. L. No. 380, § 4(i)(2)(A), 90 Stat. 1113, 1115 (1976) (current version at 42 U.S.C. § 247b(j)-1 (1991)); See ASHBURY, *supra* note 2, at 69 (noting federal government indemnified swine flu vaccine manufacturers from product liability suits).

251. ASBURY, *supra* note 2, at 72.

252. *Id.*

253. *Id.* at 72-73.

254. Hagan, *supra* note 3, at 479.

255. *Id.*

256. Hagan, *supra* note 3, at 478; ASHBURY, *supra* note 2, at 73.

257. Hagan, *supra* note 3, at 478.

258. *Id.*



has not sought reimbursement from any manufacturer that participated in the program.<sup>259</sup> It is unlikely that the federal government will ever open itself up to such enormous liability costs again.<sup>260</sup>

#### 4. Proposal for a Federal Compensation and Immunization System

In summary, support clearly exists for the federal government to alter an AIDS vaccine manufacturers' liability under traditional tort theory, either by enactment of a national product liability statute or by exempting manufacturers from product liability suits and creating a compensation scheme for injured vaccinees.<sup>261</sup> General Product liability reform is a massive undertaking with strong opposition from both the ABA and consumer groups.<sup>262</sup> The AIDS vaccine liability problem must be addressed immediately and specifically.<sup>263</sup> Thus, general tort reform is an inadequate solution. The best option is to create a federal compensation and immunization statute specifically tailored to the AIDS situation. The Institute of Medicine Committee on Public-Private Sector Relations in Vaccine Innovation's findings lend support to this solution.<sup>264</sup> In 1985 the Committee concluded 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>265</sup> It recommended a compensation approach that would attempt to balance the need to compensate the rare injured victim and the public health goal of preventing the spread of harmful disease through vaccination.<sup>266</sup> These recommendations led to the enactment of the National Childhood Vaccine Injury Act of 1986 designed to address the problem tort liability was causing childhood vaccine manufacturers.<sup>267</sup> The National Childhood Vaccine Act has been quite successful, both in compensating injured vaccinees quickly and inexpensively and in removing the liability worries that inhibit vaccine innovation, raise prices, and remove

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259. Hagan, *supra* note 3, at 479.

260. See ASHBURY, *supra* note 2, at 74 (noting that government will probably not fashion any future vaccine liability system on swine flu scenario).

261. See ABA COORDINATING COMMITTEE, *supra* note 24, at 147 (citing R. NEUSTADT AND H. FINEBERG, *THE SWINE FLU AFFAIR* (1987)) (discussing history of federal assumptions of liability when insurance carriers would not or could not accept risks for vaccine). Government programs to indemnify manufacturers of HIV vaccines may be developed in the event that obtaining liability insurance is a problem for future products. *Id.* at 147 (citing National Childhood Vaccine Injury Act).

262. See *supra* notes 182-196 and accompanying text (discussing product liability reform efforts).

263. See *infra* note 279 and accompanying text (noting pressing need for AIDS vaccine).

264. VSI, *supra* note 2, at v.

265. *Id.* at 155.

266. *Id.* at 1-13 (summarizing Committee findings and models for possible vaccine-related injury compensation and liability systems).

267. 42 U.S.C. §§ 300aa-10 to -33 (1991).

existing products from the market.<sup>268</sup> The inadequacy of the product liability system at handling the childhood vaccines is analogous to the AIDS vaccine situation, and thus, one expects similar success with an AIDS vaccine compensation scheme.

Yet, an AIDS vaccine compensation and immunization system should not be identical to the Childhood Vaccine Injury Act. Rather, it should consist of a compilation of effective features from each of the previously discussed models. An appropriate statute would include: Almost complete immunity from traditional product liability suits, a scientific administrative body to determine causation and degree of disability, a capped compensation fund financed by a vaccine tax with a government backup provision, and limited judicial review.

The high level of protection from liability available under an "unacceptable behavior standard," such as in the Keystone proposal,<sup>269</sup> provides better protection for the manufacturer than an "unavoidable side-effect" standard, as in the Childhood Vaccine Act, because it requires an injured vaccinee to meet much higher burden before a tort cause of action becomes available. A high standard satisfactorily quenches a manufacturers' litigation fears while leaving intact the deterrent effect of tort liability on negligent or malicious behavior by manufacturers.<sup>270</sup> An expert body is needed to hear the injury cases because the novelty and complexity of AIDS requires special causation considerations to make sure the injuries complained of result from vaccination and not one of the numerous conditions or side-diseases characteristic of the Syndrome itself.<sup>271</sup> A common-pool compensation fund is a better choice than Keystone's self-insuring model because it is not as complicated as a self-insuring fund. A self-insuring fund requires a bond-like deposit every time an individual is vaccinated—placing a huge burden on a manufacturer.<sup>272</sup> Thus, the manufacturer is responsible for the total money award to an individual suffering side-effects from its vaccine.<sup>273</sup>

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268. See *supra* notes 239-246 and accompanying text (discussing success of Childhood Vaccine Injury Act).

269. See *Keystone Proposal, supra* note 204, at 5-6 (discussing unacceptable behavior standard). The Keystone group explained that the "unacceptable behavior" standard could be met by "behavior which was an intentional violation of the law, conscious disregard for the rights or safety of others, or intentional conduct which was designed to deceive or conceal [the risks]." *Id.* at 5.

270. See *id.* (noting that it is important to preserve deterrent effect of existing tort system in any new system that is developed); *supra* note 237 and accompanying text (noting that leaving vaccinee option of rejecting compensation fund monies and resorting to tort litigation may be problematic and does not assure manufacturers much protection); *supra* note 159 (noting that under California statutory scheme plaintiffs are allowed option of tort lawsuits, thus, manufacturers are in no way assured vaccine-injured individuals will resort to compensation fund).

271. See *Keystone Proposal, supra* note 204, at 4, 6 (discussing causation burden in Keystone proposal); *supra* note 220 and accompanying text (noting advantage of low causation connection in childhood vaccine injury cases).

272. *Keystone Proposal, supra* note 204, at 8.

273. *Id.*

The common-pool approach requires a surcharge on each vaccine unit distributed, which then goes into a general fund.<sup>274</sup> The surcharge system proportionalizes the amount paid into the fund with the units of vaccine administered. A government back-up fund is necessary to prevent fund financing problems which may occur at the start of the fund and in times of increased injuries.<sup>275</sup> Compensation for the injured vaccinee should be limited to unreimbursed medical expenses, capped economic losses, and capped pain and suffering.<sup>276</sup> The compensation award should not include punitive damages.<sup>277</sup> Additionally, manufacturers should be required to coordinate with vaccine administrators in planning a thorough informed consent process. The consent process would inform potential vaccinees on an individual basis of the known benefits and risks and the array of unknowns surrounding the new AIDS vaccine.<sup>278</sup>

## VI. CONCLUSION

In order to stop the AIDS epidemic before it reaches catastrophic proportions a vaccine against the HIV infection must be available for manufacturing no later than the mid-1990s.<sup>279</sup> The existence of liability for adverse side-effects under traditional tort theory, even with built-in exceptions in the pharmaceutical context, is hindering both the development and production of potential vaccines. An alternative approach to handle the dual goal of compensation of injured plaintiffs and regulation of manufacturers' safety considerations is needed in order to promote vaccine development, production, and access. Carefully structured federal legislation limiting immunity for AIDS-vaccine manufacturers and creating a compensation fund can accomplish this goal.

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274. See *supra* notes 156-58 and accompanying text (discussing California statute's common-pool compensation fund).

275. See *supra* note 158 (explaining problem surcharge funding mechanism may create during start-up of fund); *supra* notes 243-46 and accompanying text (explaining current fear that overwhelming increase in petitions will drain fund and suggesting possible solutions of capping awards or using other government funds).

276. See *Keystone Proposal*, *supra* note 204, at 7-8 (discussing losses to be compensated by AIDS vaccine compensation and immunization system).

277. See *id.* at 8 (noting that in nonfault-based system punitive damages should not be awarded); *supra* note 188-89 and accompanying text (explaining why product liability reform bills prohibit punitive damages).

278. See *id.* at 2-4 (explaining necessity of thorough informed consent and describing possible methods).

279. JOHNSTON & HOPKINS, *supra* note 21, at 6.