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A Proposal for a Federal AIDS Immunization Policy

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A PROPOSAL FOR A FEDERAL AIDS IMMUNIZATION POLICY

CATHERINE M. POLIZZI¹

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I. INTRODUCTION

Since the discovery of the causative agent of AIDS in 1983,² a massive international research effort has been directed toward development of a vaccine to prevent this deadly infectious disease.³ Nearly ten years later, a vaccine has not yet been licensed. Progress toward the introduction of a vaccine has been hampered by several factors such as the complexity of the disease-causing organism, HIV,⁴ and the lack of a satisfactory animal model in which to conduct studies.⁵ In spite of these technical impediments, the contributions of numerous laboratories have produced at least some hope. Two vaccines are now entering Phase II clinical trials.⁶ Furthermore, there is

²F. Barre-Sinoussi et al., *Isolation of a T-Lymphotropic Virus from a Patient at Risk for AIDS*, 220 SCI. 868 (1983).

³See generally AIDS VACCINE RESEARCH AND CLINICAL TRIALS (Scott D. Putney & Dani P. Bolognesi eds., 1990) (discussing the qualities of HIV relevant to discovering a vaccine) [hereinafter AIDS VACCINE RESEARCH]; Wayne C. Koff and Daniel F. Hoth, *Development and Testing of AIDS Vaccines*, 241 SCI. 426 (1988) (discussing the problems inherent to discovering a vaccine for AIDS). There are two potential uses for an AIDS vaccine, both under active research and clinical testing: therapeutic, or vaccine administered to patients who are already sero-positive; and prophylactic, or vaccine administered to prevent HIV infection. This paper will concentrate on prophylactic use.

⁴See AIDS VACCINE RESEARCH, *supra* note 3, at 3-138.

⁵*Id.* at 279-380. Koff & Hoth, *supra* note 3, at 429.

⁶Jon Cohen, *Pediatric AIDS Vaccine Trials Set*, 258 SCI. 1568 (1992); *The Pink Sheet*, FOOD DRUG COSM. REP., Dec. 7, 1992, at TRADE & GOV'T MEM. 5-6. Phase II trials test

increasing optimism that a successful vaccine may be developed by the end of the decade.

Almost concurrent with the initiation of AIDS vaccine research, many observers expressed concern about the potentially negative impact of the liability of drug manufacturers on the development and distribution of an AIDS vaccine.⁷ This apprehension is not unfounded, particularly in the vaccine context. Beginning in the 1960's, manufacturers' liability costs and fears contributed to decreasing participation by manufacturers in the vaccine market.⁸ When the supply of one important childhood vaccine, DPT, became threatened,⁹ Congress responded by passing the National Childhood Vaccine Injury Act of 1986.¹⁰ The Act extended liability protection to vaccine manufacturers by creating the National Vaccine Injury Compensation Program. This Program established a federal no-fault system of compensation for victims of vaccine-related injury.¹¹ By removing primary allocation of responsibility for compensation from the tort system, manufacturers presumably had more incentive to stay in the market as well as develop new vaccines. In addition, victims would receive compensation more efficiently under the Program than from litigation.¹²

The legal system directly shapes innovation through its civil liability laws.¹³ From the manufacturer's point of view, the risk of liability is an important

primarily for safety and immune response, not efficacy. For technical information about the vaccines, consult the National Institute of Allergy and Infectious Diseases. As many as eight AIDS vaccines are in clinical trials, if therapeutic use is included. Barre-Sinoussi et al., *supra* note 2, at 868.

⁷See AMERICAN MEDICAL ASSOCIATION, *IMPACT OF PRODUCT LIABILITY ON THE DEVELOPMENT OF NEW MEDICAL TECHNOLOGY*, 12 (1988) [hereinafter *IMPACT OF PRODUCT LIABILITY*]; Richard Cooper, *The Makers of AIDS Vaccines Will Need Protection from Product Liability Suits*, MANHATTAN LAWYER, June 14, 1988 at 38; Koff and Hoth, *supra* note 2, at 431; Andrew Blum, *AIDS Research Faces Hurdle: Who's Liable?*, NAT'L L.J., July 29, 1991, at 3.

⁸INSTITUTE OF MEDICINE, *VACCINE SUPPLY AND INNOVATION* 46 (1985).

⁹See SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE, 99th CONG. 2D SESS., *REPORT ON CHILDHOOD IMMUNIZATIONS* 68-70 (Comm. Print 1986).

¹⁰42 U.S.C. §§ 300aa-1 -33 (1988 & Supp. 1989).

¹¹See Wendy K. Mariner, *Report for Recommendation 91-4: Innovation and Challenge: The First Year of the National Vaccine Injury Compensation Program*, in ADMIN. CONF. U.S. 409, 425-39 (1991).

¹²*Id.*

¹³See generally *IMPACT OF PRODUCT LIABILITY*, *supra* note 7; Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 SCI. 1395 (1989) (arguing that there has been a proliferation of products liability lawsuits, which in turn has diminished the incentive to create new products and engage in scientific research.). The legal system has traditionally provided incentives for technological innovation through patent protection, which confers a 17 year monopoly on the claimed invention. 35 U.S.C. § 154 (1988). See generally ROBERT PATRICK MERGES,

aspect of the market that enters into decision-making.¹⁴ In its focus on providing disincentives to manufacturers for making unsafe products, the tort-based product liability system has created an additional, disturbing disincentive. Companies are increasingly reluctant to develop and manufacture products that, although saving many lives, may nonetheless unavoidably injure a few consumers.¹⁵ Drug companies must confront the potential for product liability as well. Perceived liability is thus intimately related to incentives to develop and produce vaccines. The potential risk of liability is especially acute when a company's exposure is uncertain, as with an experimental vaccine for AIDS. The impact of potential liability may become crucial in the AIDS context. In the AIDS vaccine market, a relatively small biotechnology manufacturer may be unable to obtain liability insurance even though it has developed a new vaccine designed to prevent this widespread, fatal disease.¹⁶

Many observers have proposed a federal, no-fault compensation scheme for injuries caused by an AIDS vaccine as a partial or total replacement of the tort system.¹⁷ The possibility that the perceived risk of liability is hampering AIDS vaccine research has spurred proposals of AIDS-specific legislation. Two states, California¹⁸ and Connecticut,¹⁹ have recently enacted laws extending liability protection to manufacturers of AIDS vaccines.²⁰ Recently, federal legislation

PATENT LAW AND POLICY (1992) (a textbook on patent law). Such market protection is especially important for the pharmaceutical and biotechnology industries, where development costs are high and there are many product failures for every single product success.

¹⁴Liability costs reduce the return on R & D investment, which in turn is the determinative factor in embarking on an R & D project. Vaccine manufacturers may become even more acutely sensitive to the impact of liability, as the current administration's assault on excess profits and the threat of price controls renders the investment return forecast even more uncertain. See Jon Cohen, *Childhood Vaccines: The R & D Factor*, 259 SCI. 1528 (1993).

¹⁵See generally IMPACT OF PRODUCT LIABILITY, *supra* note 7; Mahoney & Littlejohn, *supra* note 13, at 1395.

¹⁶Dan L. Burk and Barbara A. Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 829-30 (1994). See also Joseph Earley, *Can Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis?*, 30 JURIMETRICS J. 351, 351 n.5 (1990).

¹⁷See, e.g., KEYSTONE CENTER, KEYSTONE AIDS VACCINE LIABILITY PROJECT, FINAL REPORT (1990) [hereinafter KEYSTONE]; H. William Smith III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207, 209 (1992).

¹⁸CAL. HEALTH & SAFETY CODE § 199.50 (West Supp. 1995).

¹⁹CONN. GEN. STAT. ANN. § 19a-591b (West Supp. 1994).

²⁰The laws differ in their focus: California protects vaccine manufacturers of an FDA-approved vaccine, while Connecticut protects the clinical testing phase. Helen Holt Blake, Note, *The AIDS Vaccine: Legislation to Limit Manufacturer Liability*, 27 TULSA L.J., 757, 766-67 (1992).

was proposed that closely mirrors the existing National Childhood Vaccine Injury Act.²¹

In considering special AIDS legislation to alleviate the liability burden, legislatures have focused almost exclusively on the research and development (R & D) phase. Focusing on the R & D phase reflects a concern for maximizing the research effort toward AIDS vaccine development.²² An even greater concern is the impact of potential liability on manufacturers of a licensed AIDS vaccine, which is ready for distribution throughout the country. The AIDS context represents an unprecedented convergence of elements: (1) a widespread, deadly epidemic of huge economic impact; (2) a highly politically-charged atmosphere; and (3) heavy participation by a strategically important, young biotechnology industry. The inherent uncertainty and complexity of AIDS precludes simplistic replication of pre-existing vaccine legislation. To the extent that the AIDS context is unique and inherently uncertain, an effective federal compensation scheme must respond to the singular problems posed by the introduction of a licensed AIDS vaccine. Although the licensing of an AIDS vaccine is still some years away, the enormity of the public health problem created by AIDS compels a serious examination of a federal compensation scheme as a possible solution to the liability problem.

This paper will examine the creation of a federal AIDS compensation scheme for victims of injuries caused by vaccines which are distributed as part of a national immunization program. As a preliminary inquiry, I will examine the impact of perceived liability on potential manufacturers to determine whether the risk of liability for manufacturers decreases the possibility that a successful AIDS vaccine will be introduced into the market. I will then discuss whether, given the present laws and economic incentives surrounding the vaccine industry, a federal compensation scheme for an AIDS vaccine is necessary. After analyzing the unique problems of AIDS and its implications for the design of a compensation scheme, I will present one model for a compensation scheme. The model is premised upon the distinctive difficulties of the introduction of a licensed AIDS vaccine in the mass immunization context. The need for implementation of an active post-market surveillance system will be addressed. Finally, I will discuss the possible costs of such a program, emphasizing the impact of the chosen immunization strategy on the extent of liability.

²¹138 CONG. REC. H8130-04 (daily ed. Aug. 12, 1992). *See also*, Jon Cohen, *Liability Bill Introduced in Congress*, 257 SCI. 1035 (1992) (providing a brief overview of the Bill's limitations on punitive and compensatory damages).

²²This is also because the mass immunization context is seen as inherently even more unpredictable than the R & D phase. *See, e.g.*, KEYSTONE, *supra* note 17, at 17.

II. LIABILITY—THREAT OR EXCUSE?

A major premise underlying the implementation of a compensation scheme for the AIDS vaccine is that the threat of manufacturer liability could hamper the development of an AIDS vaccine. In addition, the threat of liability would negatively affect market participation by potential vaccine manufacturers.²³ A number of other considerations purportedly enter into the R & D decision. Yet the risk of liability is the most important factor cited by manufacturers in explaining their hesitancy or refusal to enter the AIDS vaccine research effort. Since the threat of liability is so central an issue in implementing a federal compensation scheme for the AIDS vaccine,²⁴ it is appropriate to at least reconsider this premise.

*A. Basis and Evidence for the Negative Impact of Liability in the
AIDS Vaccine Context*

The threat of liability in the vaccine industry has historical underpinnings. Beginning in the late 1960's, a series of large damage awards for injuries caused by childhood vaccines created an uncertain market environment for all vaccine manufacturers. The manufacturers believed the cost of liability would drive them out of the market.²⁵ Between 1968 and 1977, more than half of the vaccine manufacturers in the U.S. did indeed withdraw from production.²⁶ When the supply of DPT, a major childhood vaccine, became threatened,²⁷ political pressure mounted on Congress to mitigate this situation by alleviating some of the liability burden. The response was the National Childhood Vaccine Act of 1986.²⁸

The federal government discovered the potentially staggering cost of liability in administering a vaccine when it passed the Swine Flu Act of 1976.²⁹ In anticipation of a swine flu epidemic, the federal government had undertaken an ambitious vaccination strategy and assumed all liability for injury in order

²³See Jon Cohen, *Is Liability Slowing AIDS Vaccines?* 256 SCI. 168 (1992). The severe toll of liability costs on drugs, vaccines, and other lifesaving products is well-documented and has elicited legislative proposals and other solutions recommending tort reform. Mahoney & Littlejohn, *supra* note 13, at 1397-98.

²⁴The other major rationale is providing fair compensation to victims who sustain vaccine-related injuries.

²⁵H.R. REP. NO. 99-908, 99th Cong., 2d Sess., reprinted in 1986 U.S.C.C.A.N., 6347-48.

²⁶INSTITUTE OF MEDICINE, *supra* note 8, at 46. Some vaccines, such as measles, mumps, and rubella, have only one manufacturer, raising fears that the sole supplier of a critical vaccine may withdraw from that market altogether. *Id.* at 29.

²⁷See REPORT ON CHILDHOOD IMMUNIZATIONS, *supra* note 9.

²⁸See *supra* note 10.

²⁹National Swine Flu Immunization Program of 1976, 42 U.S.C. § 247 b(j)-(l) (1976), amended by Pub.L.No. 95-626, 92 Stat 3574 (1978).

to guarantee vaccine supply from otherwise reluctant manufacturers.³⁰ The result was an avalanche of litigation involving millions of dollars worth of settlements—an ironic reward for attempting to prevent an epidemic that failed to materialize.³¹

Recent reports have cited the threat of liability as having already exerted an impeding effect on the progress of AIDS vaccine research.³² Large established pharmaceutical companies, traditionally leaders in R & D, are noticeably absent from the AIDS vaccine effort.³³ The participation instead by biotechnology companies raises the additional concern that these relatively small firms would be even less able to withstand liability costs than the large pharmaceutical companies.³⁴ One large pharmaceutical concern recently withdrew from a collaborative NIH trial, citing its potential liability as the main reason for its refusal to participate.³⁵ Another firm offered to "donate" its vaccine to the federal government for testing in return for complete immunity from liability.³⁶ The message from the manufacturers is clear: liability concerns are a crucial issue in the development and distribution of an AIDS vaccine. As clinical trials progress and licensure becomes imminent, pressure will undoubtedly mount on Congress to provide some kind of liability protection in order for the AIDS vaccine to be sold.

B. Signs That Liability is a Factor of Lessening Concern

Just as there are indications that the fear of liability may be negatively influencing R & D efforts towards finding an AIDS vaccine, there are also indications that liability may be a factor of lessening, albeit lingering, concern. One sign is the extent of R & D participation in the AIDS vaccine effort. In spite of their vocal concern over the threat of liability, over ten U.S. companies are actively engaged in AIDS vaccine development.³⁷ It seems unlikely that so

³⁰RICHARD E. NEUSTADT & HARVEY V. FINEBERG, M.D., *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* 57-62 (1978) [hereinafter *SWINE FLU*].

³¹Smith, *supra* note 17, at 222.

³²Cohen, *supra* note 21.

³³Laurie Garret, *The Waiting Game in AIDS Research: Giant Drug Companies are Watching the Little Guys in the Quest for a Vaccine*, *NEWSDAY*, September 18, 1990, at 5.

³⁴Burk & Boczar, *supra* note 16, at 829-30.

³⁵Paul Cotton, *Infants, Science May Lose as Liability is Blamed for Company Pullout from HIV Prevention Trial*, 268 *JAMA* 1987 (1992). Abbott Laboratories wanted complete indemnification before it would participate in the trials. *Id.*

³⁶See *The Pink Sheet: Bristol-Myers Squibb's HIVAC-1e Vaccine*, *FOOD DRUG COSM. REP.*, Sept. 28, 1992 at 7.

³⁷Some of the participants: Genentech; Biocene (a joint venture between Ciba-Geigy and Chiron); Oncogen (a subsidiary of Bristol-Meyers); Immune Response; Viral Technologies (a joint venture between Cel-Sci and Alpha Biomedicals); Progenics; Viagene; MicroGeneSys. Ongoing, active research into development of other vaccines

many companies would engage in such extensive research for a product that may never reach or remain on the market due to liability concerns.

Moreover, the recent stance of courts toward vaccine manufacturers seems to have changed in favor of manufacturers. Market protection for crucial, life-saving products such as vaccines has evidently become increasingly important to the judiciary.³⁸ A recent Court of Appeals decision holding that a vaccine manufacturer had discharged its duty to warn was viewed as "a significant victory for vaccine manufacturers."³⁹ Similarly, courts have refused to impose strict liability on manufacturers of blood products for public policy reasons.⁴⁰

Implicit in these decisions is an increasing awareness of the importance of market-based protection for manufacturers of life-saving products, a factor largely ignored in earlier cases. It is important to remember that the seminal—and most devastating—court decision concerning vaccine liability occurred nearly thirty years ago.⁴¹ Arguably, the judicial attitude toward product liability for vaccines has changed since then.⁴² Furthermore, the seemingly precarious circumstance of a sole manufacturer of a given vaccine has not yet yielded to a complete withdrawal from the market by other companies, as has been often feared.⁴³ Nor has the disastrous liability track record of the DPT vaccine been repeated. It is quite possible that the concern over AIDS will produce some concomitant degree of reasonable immunity conferred by the judiciary based on public health policy.

In conclusion, in view of the extent of AIDS vaccine R & D and the evolving judicial attitude toward product liability for vaccines, the risk of liability may not be as ominous a factor as previously supposed. While an in-depth analysis of the effect of perceived liability on the decision to market the AIDS vaccine

also attests that liability is a factor of lessening concern. See *infra* note 65 and accompanying text.

³⁸See generally Mahoney & Littlejohn, *supra* note 13, at 1397-98 (noting trend toward reform of granting extensive punitive damage awards).

³⁹*Mazur v. Merck & Co., Inc.*, 964 F.2d 1348 (3d Cir. 1992), *cert. denied*, 113 S. Ct. 463 (1992) (holding that a vaccine manufacturer fulfilled its duty to warn by contractually obligating the Centers for Disease Control to warn vaccinees directly). See *Appeals Court Rules for Vaccine Maker in Suit over Warning*, LIABILITY WEEK, June 1, 1992, Vol. 7, No. 21.

⁴⁰E.g., *Rogers v. Miles Laboratories*, 802 P.2d 1346, 1352 (Wash. 1991).

⁴¹*Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding vaccine manufacturer strictly liable for failure to provide adequate warning). See Smith, *supra* note 17, at 214.

⁴²Certainly, Congress' passage of the National Childhood Vaccine Injury Act reflects an increasing awareness of the importance of liability protection for vaccine manufacturers.

⁴³See *supra* notes 24-26 and accompanying text.

is beyond the scope of this paper,⁴⁴ it may be observed that the extent to which the threat of liability has stymied progress toward development of an AIDS vaccine is far from clear.⁴⁵

Clearly, other factors must have entered into the decision to pursue the time-consuming, expensive, and risky prospect of developing a successful AIDS vaccine. One obvious possible incentive is the potential size of the AIDS vaccine market, which could be substantial. Another incentive is an increasingly positive track record of biotechnologically engineered sub unit vaccines, such as that for hepatitis b.⁴⁶

It is also possible that the extent of R & D could alternatively reflect the implicit belief that the urgency surrounding AIDS will compel an altered liability structure. Ironically, the development of an AIDS vaccine could well provide its own leverage to force Congress to grant specialized liability protection. A successful vaccine, once licensed, may be placed on the shelf by its makers until the federal government acts to confer immunity.⁴⁷

Even if liability costs are having only an uncertain impact in the development of an AIDS vaccine, the case for implementing a federal no-fault compensation scheme is not necessarily defeated. AIDS is a costly, devastating disease. The mere possibility of a disincentive to vaccine production created by the existing liability structure is itself reason enough to at least examine proposals to remove such an obstacle. Furthermore, participation by the strategically important, but relatively immature, biotechnology industry may provide independent grounds for liability protection.⁴⁸ Finally, a federal vaccine liability law that compensates victims without faulting manufacturers reinforces an emphasis on regulatory control as the primary deterrence against unsafe vaccines. Regulatory control produces a move away from punishing manufacturers for marketing a vaccine that the federal government has licensed as safe.⁴⁹

⁴⁴Decision-making under uncertainty is particularly complex. See, e.g., Richard R. Nelson, *The Role of Knowledge in R & D Efficiency*, 47 Q. J. ECON. 453, 459 (1982). It is precisely the uncertainty surrounding AIDS vaccine liability that compels examination of an AIDS vaccine compensation scheme as a possible incentive for vaccine production.

⁴⁵Many would argue that any delay, no matter how small, is unacceptable. While not halting research, a worst case scenario, liability arguably may still pose an unacceptable barrier to bringing a licensed vaccine to market.

⁴⁶These vaccines, consisting of biotechnologically engineered components of the disease-causing organism, appear to be a safer alternative than a vaccine composed of disabled (attenuated) virus. Earley, *supra* note 16, at 363 n.79.

⁴⁷It is not beyond speculation to suppose that manufacturers are indeed banking on such a scenario.

⁴⁸Burk & Boczar, *supra* note 16, at 829-30.

⁴⁹A compensation scheme reflects the belief that those injuries deserving compensation are broader than those for which the manufacturer should be held responsible.

III. IS A FEDERAL COMPENSATION SCHEME NECESSARY FOR THE AIDS VACCINE?

In considering the problem of the threat of potential liability on the development of an AIDS vaccine, many observers have suggested that a federal compensation scheme be modelled on the National Childhood Vaccine Program.⁵⁰ Similar to the assumption about the negative impact of the threat of liability on AIDS vaccine development, this recommendation should also be examined to determine whether a federal AIDS vaccine compensation scheme is indeed necessary in the AIDS context. Perhaps this proposal is a predictable, but inappropriate, response. Since the National Childhood Vaccine Program is the most oft-cited template for AIDS vaccine legislation, a brief background of this scheme will preface the larger question of whether a federal compensation scheme is appropriate in the AIDS vaccine context.

A. *The National Childhood Vaccine Compensation Program*

The National Childhood Vaccine Program is a narrowly-focused no-fault scheme for vaccine-caused injury. Seven mandatory childhood vaccines are covered by the scheme,⁵¹ which provides compensation for victims (usually children) who have suffered injuries delineated in the Vaccine Injury Table.⁵² The Vaccine Injury Table is a device to streamline otherwise long and expensive causation inquiries: the claimant must establish an injury listed in the table which in turn creates a presumption of causation.⁵³

In order to receive compensation, a victim must initially file a claim in federal claims court, where a special master examines the evidence and determines the award.⁵⁴ The scheme pays for unreimbursed medical expenses, lost earnings, and limits damages for pain and suffering to \$250,000.⁵⁵ For claims filed for injuries sustained after October 1988, a claimant must first file a claim under the Program;⁵⁶ however, a claimant is entitled to reject the special master's award and seek tort relief instead. Once resorting to the tort system, however, the claimant foregoes the right to collect the original award determined by the special master.⁵⁷

⁵⁰See, e.g., KEYSTONE, *supra* note 17; 138 CONG. REC. H8130-04, *supra* note 21.

⁵¹The scheme covers vaccines for measles, mumps, rubella, polio, diphtheria, pertussis (whooping cough), and tetanus. The Act does not necessarily cover children, although children are virtually the only recipients. See Mariner, *supra* note 11, at 416.

⁵²42 U.S.C. 300aa-14(a). See Mariner, *supra* note 11, at 430.

⁵³Mariner, *supra* note 11, at 439-42. If the injury is not listed on the table, the claimant bears the burden of proving causation. *Id.* at 431.

⁵⁴*Id.* at 429-431.

⁵⁵*Id.* at 434. There is also a fixed death benefit of \$250,000. Mariner, *supra* note 11, at 434.

⁵⁶*Id.* at 426-27.

⁵⁷*Id.* at 436.

The purportedly efficient adjudication resulting from streamlined causation determinations from the Injury Table, and use of a special master, was designed to provide incentives for victims to use the Program rather than resort to costly and prolonged tort litigation. The Program has met with some success, as evidenced by fewer lawsuits against vaccine manufacturers,⁵⁸ although there are those who complain that the Injury Table is arbitrarily and unfairly narrow in scope.⁵⁹

*B. The Current Vaccine Landscape: Does the AIDS
Vaccine Warrant Special Federal Treatment?*

Commentators, who point to special vaccine liability protection provided by the National Childhood Act as a basis for extending this protection to the AIDS vaccine, often fail to consider the entire vaccine landscape in assessing whether a federal scheme of liability protection is warranted for the AIDS vaccine in particular. A salient observation, however, is that other adult vaccines are not presently afforded special liability protection.⁶⁰ Vaccines for hepatitis b, *Haemophilus influenzae* type b, pneumococcal pneumonia, and influenza are recommended and routinely given to adults,⁶¹ yet none of these vaccines qualify for the special federal liability treatment.

Conversely, several vaccines recommended for children are not presently covered by the National Childhood Vaccine Injury Act. Adverse reactions to *Haemophilus influenzae* type b and hepatitis b are not reimbursed by any federal plan, although these vaccines have been recommended for all children by the Centers for Disease Control.⁶² Recommendations for these vaccines

⁵⁸ See Laura Mazzuca, *Shot Through with Problems: A Partial Success, Vaccine Injury Fund Faces Case Logjam, Funding Shortfalls*, BUS. INS. (Aug. 24, 1992). Vaccine-related lawsuits against Lederle Laboratories, a leading maker of the DPT vaccine, have fallen from over 300 in 1988 to a total of only 20 since then. *Id.* at 1.

⁵⁹ *Id.* A recommendation to further narrow the injury table has caused much consternation by proponents of the compensation scheme who argue that this will unfairly exclude many deserving recipients. See *infra* note 116.

⁶⁰ Except when, in rare instances, an adult is injured from a childhood vaccine covered by the National Childhood Vaccine Injury Act.

⁶¹ See generally American College of Physicians, GUIDE FOR ADULT IMMUNIZATION (1990) [hereinafter ADULT IMMUNIZATION]. There are also other vaccines, such as those for yellow fever or cholera, given to adults for special circumstances, such as international travel or military service. *Id.* at 63, 118.

⁶² See Centers for Disease Control, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination, Recommendations of the Immunization Practices Advisory Committee*, 40 MORBIDITY AND MORTALITY WKLY. REP. RR-13 (1991); Centers for Disease Control, *Haemophilus B Conjugate Vaccines for Prevention of Haemophilus influenza Type b Disease Among Infants and Children Two Months of Age and Older*, 40 MORBIDITY AND MORTALITY WKLY. REP. RR-1 (1991). Recently, the American College Health Association issued a report calling for

occurred after passage of the National Childhood Vaccine Injury Act; yet they were not added to the list of covered childhood vaccines.

There is presently no federal compensation for injuries caused by non-mandatory vaccines.⁶³ Indeed, the axis dividing federally compensated versus non-compensated vaccine-caused injury may best be characterized as whether or not the vaccine is mandatory. It may be difficult to justify awarding federal compensation for injury in which the risk of vaccine-related injury is voluntarily undertaken by consenting adults. Allowing compensation for AIDS vaccine injury in this context may also invite calls for compensation for injury due to involuntary exposure to other toxic substances.⁶⁴

As a final observation, the lack of a federal compensation scheme conferring liability protection for vaccine manufacturers has not stopped introduction of other, successful vaccines,⁶⁵ nor prevented current active research into development of still others.⁶⁶ The promise of biotechnology has increased the perception that more safe vaccines will be introduced against other infectious diseases.⁶⁷ This "explosion of vaccine research," fueled in large part by biotechnology, could be taken as further evidence that the liability shield provided by federal compensation for vaccine-caused injury is no longer

colleges and universities to recommend hepatitis b vaccination for all students. See *Collegians Urged to Get Hepatitis B Vaccinations*, THE HONOLULU ADVERTISER, May 31, 1992 at A-2.

⁶³ See Mariner, *supra* note 11, at 416; Mark A. Hofman, *No-Fault System to Compensate Vaccine Injuries*, BUS. INS., Feb. 1, 1988.

⁶⁴ See generally Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, MD. L. REV. 951 (1993).

⁶⁵ An example is the recombinant hepatitis b vaccine. See E. M. Scolnick et al., *Clinical Evaluation in Healthy Adults of a Hepatitis B Vaccine Made by Recombinant DNA*, 251 JAMA 2812 (1984). Recommended for children and health care workers, this vaccine generated approximately \$200 million in sales in 1992, with growth projections up to \$2 billion. An estimated 800,000 received the vaccine in 1992; as many as 30-35 million people per year are projected to be inoculated world-wide. See *AAP Advice Could Boost Hep-b Vaccine Sales at Merck and Smith-Kline Beecham*, 14 INSTITUTIONAL INVESTOR 9 (1992).

⁶⁶ Wyeth-Ayerherst plans to develop a live attenuated respiratory syncytial virus vaccine. See FDC "Pink Sheet", 12/7/92. Smith-Kline Beecham will invest up to \$12 million to develop a hepatitis e vaccine, and plans to market its hepatitis a vaccine in the U.S. See FDC "Pink Sheet," 9/7/92. Merck is currently developing a vaccine for chicken pox and hepatitis a. See FDC "Pink Sheet", 11/9/92.

⁶⁷ See generally Maurice R. Hilleman, *Newer Directions in Vaccine Development and Utilization*, 151 J. OF INFECTIOUS DISEASES 407 (1985). Recently, direct injections of a gene from influenza A virus were shown to immunize mice; this simple, inexpensive approach may prove to be effective in combatting other pathogens, such as HIV. See Jon Cohen, *Naked DNA Points Way to Vaccines*, 259 SCI. 1691 (1993). It is perhaps ironic that biotechnology, in producing potentially safer vaccines, may prove to be its own best insurance policy against liability costs in the vaccine arena. But cf. Earley, *supra* note 16 (arguing that potentially lower efficacy of recombinant subunit vaccines may pose a different liability threat).

needed or justified.⁶⁸ Manufacturers are developing and bringing these products to market without asking for immunity. Should the AIDS vaccine be treated any differently?

The current vaccine landscape provides strong arguments against granting special immunity to manufacturers of an AIDS vaccine. Yet it is the inherent uncertainty of the AIDS context, coupled with the seriousness and spread of the disease,⁶⁹ that compels a serious in-depth look at the creation of a federal AIDS vaccine compensation scheme. As already pointed out, a federal AIDS vaccine compensation scheme may provide a crucial, equitable element of market certainty as an incentive for bringing the vaccine to market. The AIDS vaccine may prove to be very safe; however, given the etiology and genetic variation of HIV,⁷⁰ the risks associated with an AIDS vaccine could well be less predictable and potentially more serious than risks associated with other vaccines. Further, given the huge cost savings the federal government may realize upon a successful vaccine immunization strategy,⁷¹ it seems reasonable for the government to share some of the liability burden, particularly since federal regulations will have licensed the vaccine as safe. A federal plan, with unified standards and a centralized forum, is a far more preferable scheme than the patchwork of the state laws that may erupt in response to a licensed AIDS vaccine. Perhaps most importantly, a federal plan may give additional impetus to a national AIDS vaccine strategy, the success of which is critical to disease prevention and ultimate eradication. Clearly, such a scheme may well be justified, in spite of credible arguments against it.

IV. THE AIDS CONTEXT: IMPLICATIONS FOR COMPENSATION SCHEME DESIGN

The AIDS context represents a singular convergence of elements that necessarily must influence the design of a federal compensation scheme. To the extent that this context differs from that of the National Childhood Vaccine Injury Act, strict replication of the Act will prove to be an inadequate approach to the problem of AIDS vaccine liability. The following section will examine the unique elements of the AIDS context and their impact on the design of a federal compensation scheme.

⁶⁸"[T]here is a renaissance of vaccine research in smaller biotechnology companies—which large pharmaceuticals often invest in or buy outright—for AIDS, herpes, malaria, rheumatoid arthritis, cancer and lupus" See Cohen, *supra* note 14.

⁶⁹As well as AIDS' staggering economic costs. See *infra* note 182 and accompanying text.

⁷⁰See generally AIDS VACCINE RESEARCH, *supra* note 3.

⁷¹See *infra* notes 181-84 and accompanying text.

A. The Political Climate Surrounding AIDS

The AIDS context has, from the beginning, been highly politically charged.⁷² Almost constant media attention reminds the public about the AIDS epidemic and the need for prevention and cure.⁷³ Political pressures have already influenced the course of the development of therapies for AIDS: initiation of the compassionate use exemption, a form of expedited testing, was largely the result of intense political pressure.⁷⁴ Political lobbying by MicroGeneSys, a major player in the therapeutic vaccine arena, resulted in an unprecedented twenty million dollar award for a clinical trial, at the exclusion of other vaccines.⁷⁵ The same biotechnology company was also largely responsible for the passage of the Connecticut AIDS law providing liability protection.⁷⁶

The highly charged political backdrop of the AIDS context implies that political forces will probably loom large should Congress decide to craft a compensation scheme for AIDS vaccine victims. This means pressure from interest groups, notably the AIDS pro-patient lobby and the biopharmaceutical industry. To the extent that these highly vocal groups perceive that a compensation scheme will promote the promulgation of an AIDS vaccine, both of these interests will probably press hard for a passage of a broad compensation program. The most obvious implication of this kind of political influence is its potential impact on the cost of the program: pressure for a broad compensation program means higher potential aggregate liability, which in turn increases the cost of the program.⁷⁷

Political pressure may also translate into an altered standard for approval of a vaccine. A changing—some would say lowering—threshold of product approval, characterized by a loosening of stringent peer review and approval of data through acceleration of the approval process, has a potentially crucial

⁷²See generally *AIDS: Cases and Materials*, 177-262 (M.L. Closten et al. eds., 1989).

⁷³The media will also undoubtedly play a larger role should an AIDS vaccine be licensed, or if any serious side effects are discovered.

⁷⁴See *The Social Impact of AIDS in the U.S.* (National Research Council, 1993), 92. This development has already raised concern that this marks the beginning of a troubling erosion of review standards in the drug approval process. *Id.* at 93.

⁷⁵See Jon Cohen, *Did Political Clout Win Vaccine Trial for MicroGeneSys?*, 258 SCI. 211 (1992); *MicroGeneSys Defends Its AIDS Vaccine Trial*, 12(12) GENETIC TECH. NEWS 3 (1992). Responding to the ensuing criticism that the government was favoring one pharmaceutical company over others, the Defense Department and the Department of Health and Human Services recently agreed to broaden the trial to include other vaccines. See Gregory N. Racz, *Federal Agencies Agree to Broaden AIDS Vaccine Test*, WALL ST. J., Apr. 16, 1993, at B-2. This provides yet another example of how political forces are shaping the progression of development of AIDS vaccines.

⁷⁶See Frank Spencer-Molloy & Lyn Bixby, *A Clever Move Leads to the Conflict in the Research World; One Company's Race for an AIDS Vaccine*, THE HARTFORD COURANT, Feb. 2, 1993, at A1.

⁷⁷See *infra* notes 159-75 and accompanying text.

impact on the compensation program: the extent of injury, and thus liability, turns on the underlying safety of the vaccine itself. A lowered threshold of licensure resulting from intense political pressure could have devastating effects on the liability cost question, particularly when the vaccine enters into the mass immunization context.⁷⁸

The political climate of AIDS, therefore, sends a note of caution to Congress: lawmakers must craft a program to carefully circumscribe potential liability, guarding against an over-inclusive program hastily enacted in response to what may be intense pressure. In considering liability, Congress and the FDA must also be wary of the ramifications of altering previously successful product approval protocols; not only must careful research and design of the vaccine attest to its safety, so must the federal government, in adhering to prudent licensing standards.

B. The Disease

AIDS, like hepatitis b, has been characterized as a "lifestyle" disease.⁷⁹ The high-risk groups are defined by behavior that many find distasteful.⁸⁰ This behavior is also voluntary; indeed, virtually all of the present prevention effort is aimed at trying to make people aware of this high-risk behavior and change it.⁸¹ Many may thus view victims of AIDS vaccine-related injury less sympathetically, since vaccine administration will most likely be targeted to these high-risk groups. The fact that the primary victims of AIDS are responsible adults may erode overall popular support for an AIDS vaccine compensation program, particularly in view of the fact that many other types of injury arising from involuntary exposure to environmental or workplace toxic substances are not currently compensated by a federal scheme.⁸²

The predominant age of AIDS victims⁸³ could have a substantial impact on the aggregate liability of a compensation scheme. Because many injured adults

⁷⁸See *infra* notes 157-58 *infra* and accompanying text.

⁷⁹This picture is changing as the incidence rate among homosexuals is receding while the incident rate among heterosexuals is increasing. See Timothy A. Green et al., *Changes in AIDS Incidence Trends in the United States*, 5 J. OF AIDS 547 (1992). However, in terms of prevalence—that is, number of current cases—the majority of AIDS victims (74%) are homosexuals and intravenous drug users. See Centers for Disease Control, *HIV/AIDS Surveillance*, Oct. 1992.

⁸⁰Examples of high-risk categories are homosexual men and intravenous drug users. See *HIV/AIDS Surveillance*, *supra* note 79.

⁸¹See, e.g., World Health Organization, *Prevention of Sexual Transmission of Human Immunodeficiency Virus*, WHO AIDS Series 6 (1990); J.L. SORESEN ET AL., PREVENTING AIDS IN DRUG USERS AND THEIR SEXUAL PARTNERS (1991).

⁸²See Rabin, *supra* note 64.

⁸³Seventy-nine percent of all HIV/AIDS-related hospitalizations during 1983-1988 were for patients aged 25-44. See Lisa S. Rosenblum et al., *Increasing Impact of HIV Infection on Hospitalizations in the United States*, 5 J. OF AIDS 497 (1992). Seventy to ninety

will qualify for lost wages, the extent of benefits may be much larger than the present liability under the Childhood Act, where virtually all the victims are young children.⁸⁴

C. The Vaccine

The AIDS vaccine will most likely be recommended, not mandatory. There are presently no required adult vaccines, whereas all fifty states have immunization requirements for most children's vaccines.⁸⁵ Involuntary exposure to state-mandated vaccines provided one of the strongest arguments for providing compensation to victims of vaccine-related injury.⁸⁶ A child who is injured as the result of involuntary exposure to a required vaccine is a much more compelling recipient of benefits than an adult who takes the vaccine voluntarily.⁸⁷ The probable voluntary aspect of AIDS immunization may thus greatly erode support for providing compensation to AIDS vaccine victims.

The AIDS vaccine will most likely be a genetically engineered product, similar to the recombinant vaccine for hepatitis b.⁸⁸ Such a vaccine is perceived to be much safer than attenuated, whole virus vaccines, which pose the frightening possibility of causing disease.⁸⁹ But recent data has indicated that the "old fashioned" attenuated whole virus vaccine may also hold promise.⁹⁰ The type of AIDS vaccine used might have serious implications for a compensation scheme. Depending on which vaccine is licensed, the extent of liability could vary over a drastic range. If a sub unit vaccine is developed,

percent of all HIV-related deaths are males aged 25-44. See James W. Beuhler et al., *The Completeness of AIDS Surveillance*, 5 J. OF AIDS 257 (1992).

⁸⁴But note that, in the case of permanent disability, a child would be entitled to receive lost wages (payable at age 18). In this case, the child's injury would be more expensive than that of the adult, based on longer life expectancy. See Appendix B.

⁸⁵See Mariner, *supra* note 11, at 416; Alan R. Hinman & William S. Jordan, *Progress Toward Achieving the 1990 Immunization Objectives*, 98 PUB. HEALTH REP. 436, 438 (1983).

⁸⁶See, e.g., Barbara J. Connolly, *The Necessary Complement to Mandatory Immunizations: A National Vaccination Compensation Program*, 8 CARDOZO L. REV. 137 (1986).

⁸⁷Particularly when, as already pointed out, AIDS is a disease that can be largely prevented by behavioral changes, whereas childhood diseases, such as mumps or measles, are contracted by coughing and sneezing. Note, however, that adults will not be the exclusive vaccinees; children and adolescents will also be vaccine recipients.

⁸⁸Emphasis has been on development of a "clean" AIDS vaccine composed of viral sub units. See Koff and Hoth, *supra* note 3, at 427-428; Earley, *supra* note 16 at 362-65.

⁸⁹See AIDS VACCINE RESEARCH, *supra* note 3, at 3-4, 169. In extremely rare instances, the polio vaccine, comprised of attenuated virus, can cause vaccine-associated paralytic disease. See Centers for Disease Control, *Polio Myelitis Prevention, Recommendation of the Immunization Practices Advisory Committee*, 31 MORBIDITY AND MORTALITY WKLY. REP. 22, 301 (1982).

⁹⁰See Jon Cohen, *Aids Vaccines: Is Older Better?* 258 SCI. 1880 (1992); *Vaccine Protects Monkeys Against AIDS-Like Disease*, 13(1) GENETIC TECH. NEWS 6 (1993).

liability may be a much smaller concern.⁹¹ If akin to the polio vaccine, however, an attenuated whole virus AIDS vaccine could cause very rare but vaccine-caused AIDS, or possibly other serious complications, such as cancer.⁹² Moreover, varying efficacy rates of different vaccines may necessitate the use of a more dangerous (i.e., one that elicits a higher rate of serious adverse reactions) vaccine for certain risk groups. For example, a sub unit vaccine may provide sufficient protection to occupational-exposure groups, such as health care workers; but an attenuated whole virus vaccine may be required for "behavioral" high-risk groups, such as intravenous drug users. In response, an AIDS vaccine compensation program may have to be bifurcated, with two sub-classifications depending on what type of vaccine is used. Alternatively, there may only be a need for a compensation scheme for the more risky vaccine.

When the AIDS vaccine goes into the mass immunization phase, potential rare serious adverse effects will not be known.⁹³ This necessarily creates an extremely problematic delineation of compensable injuries. In contrast, when the National Childhood Vaccine Act was passed in 1986, the childhood vaccines had been in widespread use for some years, and serious side effects were well-documented.⁹⁴ This allowed creation of an injury table at the outset of the compensation scheme, a useful device for streamlining the causation determination of a claim.⁹⁵ The inherently prospective nature of an AIDS compensation scheme poses the greatest difficulty in its design. This problem dictates that a compensation scheme implemented at the beginning of a mass immunization phase must have in place a mechanism for determining a compensable event. This will be considered in more detail below.⁹⁶

Unlike the climate surrounding passage of the Childhood Vaccine Injury Act, where near-eradication of disease by the vaccines had shifted public focus to the risk of serious adverse reactions caused by the vaccines, the risk of contracting AIDS looms much larger in the public mind than fear of side effects from a successful vaccine that prevents contracting the disease. The public will therefore probably be very receptive to a licensed vaccine.⁹⁷ Whether this

⁹¹Unless the sub unit vaccine has lower efficacy and liability coverage extends to contracting AIDS. See *infra* notes 106-10 and accompanying text. See also Earley, *supra* note 16, at 365-67.

⁹²See Cohen, *supra* note 23.

⁹³Phase III trials, involving at most in the few thousands, will be the only basis of known adverse side effects at the time of licensure. Rarer side effects will not be discovered until the vaccine is given to many thousands of recipients; that is, a mass immunization context.

⁹⁴Although causation has been, and still is, contested for some of these injuries. See Mazzuca, *supra* note 58.

⁹⁵See *supra* notes 52-53 and accompanying text.

⁹⁶See *infra* notes 112-21 and accompanying text.

⁹⁷The fear of AIDS may extend to its vaccine, however, especially if the vaccine were composed of attenuated virus. See *supra* note 92 and accompanying text. Further, a

receptiveness will add pressure to enact an AIDS compensation scheme or diminish it, as high-risk groups may eagerly accept the inherent risk of vaccine-caused injury in return for the invaluable protection against the disease, is not clear. At the very least, public acceptance of an AIDS vaccine will help ensure participation in a post-market surveillance system that will be crucial in obtaining valuable data on vaccine-caused injuries for a compensation scheme.⁹⁸

In sum, examination of the salient unique features of the AIDS context divides them into several categories, each with a powerful impact on the creation and implementation of an AIDS vaccine compensation plan. The first is the political climate surrounding AIDS. Congress must guard against distortions of entitlements enacted in response to what may be intense political pressure. The second is the typical victim of an AIDS vaccine-related injury, a young adult who voluntarily took the vaccine. Lastly, the unknown extent and frequency of serious side effects poses difficult problems of delineating a compensable event and determining causation.

The AIDS mass immunization context forms a complicated landscape of strong competing forces that will preclude simple replication of existing legislative templates. In the next section, I will present one possible model for a federal AIDS vaccine compensation scheme.

V. A FEDERAL AIDS VACCINE COMPENSATION SCHEME

An AIDS vaccine compensation scheme must be designed in response to the AIDS context; it must evolve with the emerging picture of vaccine-caused injury; and it must carefully circumscribe liability. To be successful, an AIDS vaccine compensation program must provide fair compensation to AIDS vaccine victims efficiently and help ensure a reliable vaccine supply by providing a significant level of liability protection to vaccine manufacturers. To those ends, a hypothetical AIDS compensation scheme would incorporate features discussed below.

A. *Should the AIDS Vaccine Compensation Program Be a Separate, Independent Compensation Scheme?*

A preliminary consideration is whether the AIDS compensation scheme should be separate, specialized legislation or an expansion of the existing National Childhood Vaccine Injury Act. Given the singular problems created by the AIDS vaccine mass immunization context,⁹⁹ and the wide age swath of potential vaccine recipients, the AIDS compensation scheme lends itself to being a separate plan.

perceived inherent lifestyle disclosure in taking an AIDS vaccine may impede public acceptance. See *supra* notes 79-80 and accompanying text.

⁹⁸ See *infra* notes 143-53 and accompanying text.

⁹⁹ See *supra* notes 72-98 and accompanying text.

Since the National Childhood Vaccine Injury Act covers vaccines given to young children and the AIDS vaccine will be given primarily to adults, it seems inappropriate to suddenly include among the list of vaccines for childhood diseases a vaccine for AIDS. Incorporation of the AIDS vaccine into the existing childhood program is possible, but only with major changes in the structure and perceived intent of the Childhood Vaccine Injury Act. Unless entitlement to compensation will be dictated by age, with young children the sole intended recipients of benefits, compensation for AIDS vaccine-caused injuries is best an independent compensation scheme, based solely on exposure to the AIDS vaccine.

Secondly, since the creation of this compensation scheme would be in large part experimental and prospective, a specially designed hybrid program would be the more appropriate as a legislative experimental vehicle.

B. Eligibility Criteria

A critical feature of an AIDS vaccine compensation scheme is its eligibility criteria. Eligibility determines who is entitled to receive benefits and thus determines extent of coverage and potential liability exposure. Issues of fairness arising from degree of inclusiveness are thus triggered by delineation of eligibility.

1. Jurisdictional Eligibility

Jurisdictional eligibility delineates the population entitled to seek benefits. For the AIDS compensation scheme, jurisdictional eligibility would be identical to that of the Childhood Vaccine Injury Program: anyone receiving a vaccine¹⁰⁰ in the United States would be eligible for access to the program. Certain limitations to this general requirement, such as limiting jurisdiction to only high-risk recipients, would pose unacceptable fairness and potentially sensitive privacy issues.¹⁰¹

A possible jurisdictional limitation based on the recipient's age would serve to limit eligibility to those who presumably had less choice in receiving the vaccine. Moreover, a program accessible only to children under a certain age may evoke less opposition than a program that offered wider coverage that extended to consenting adults voluntarily receiving the vaccine.¹⁰² However, since AIDS is increasingly perceived as a problem that cuts across all age groups, notably including adolescents, drawing a jurisdictional age line may prove to be problematic and unacceptable.

Another jurisdictional requirement could turn on whether the AIDS vaccine is mandatory for certain populations, such as infants born to sero-positive

¹⁰⁰By an authorized administrator.

¹⁰¹Consider, for example, whether a vaccine recipient who suffered injury would want to declare that she was an intravenous drug user and a prostitute.

¹⁰²See *supra* notes 85-87 and accompanying text.

mothers.¹⁰³ The creation of involuntary vaccine recipient groups may compel a somewhat different jurisdictional axis that allows program access only for mandatory vaccine recipients. Adoption of this delineation of qualifying populations may be complicated by the inevitable piecemeal state adoption of mandatory AIDS vaccination.¹⁰⁴

As for date of eligibility, an AIDS compensation scheme implemented concurrently with the initiation of a mass immunization vaccine program would logically have an effective date as of the date of passage. That is, a recipient would be entitled to access to the program as of the vaccination date.

2. Entitlement Eligibility

Entitlement eligibility determines who out of the pre-selected jurisdictional pool will actually receive compensation by defining the characteristics a qualified recipient must have in order to receive compensation. Accordingly, AIDS vaccine compensation scheme eligibility depends on defining the precise nature of the injury that qualifies for compensation. This comprises the most critical and problematic element of the program, both from the administrative and liability perspective.

a. What kind of injury should be compensated?

The type of injury historically covered by vaccine compensation plans is a serious, acute, systemic injury, such as anaphylactic shock or neurological disorders.¹⁰⁵ In the AIDS context, however, the question has arisen whether an AIDS vaccine compensation scheme should cover onset of the disease itself due to lack of protection by the vaccine.¹⁰⁶ Such a question can be answered by history and practicality. No existing vaccine is 100% effective at preventing

¹⁰³Another possible jurisdictional restriction is limiting program access to those who take the vaccine because of occupational exposure to the virus. Health care workers, for example, arguably have less choice concerning their exposure to HIV than other risk groups.

¹⁰⁴Historically, rules regarding mandatory vaccination have been state laws. A recent exception has been OSHA's mandated hepatitis b vaccine requirements. 54 Fed. Reg. 64004 (1991). OSHA's rule, however, does not make the vaccine itself mandatory; rather, the employer must make the vaccine available to employees, and the choice of whether or not to take the vaccine is voluntary. Considering the predominantly adult population of AIDS victims, and the fact that contracting the disease is preventable by behavior modification, it seems unlikely that the federal government would choose to make the AIDS vaccine mandatory.

¹⁰⁵See Wendy K. Mariner, *Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U. L.J. 599 (1987).

¹⁰⁶Indeed, commentators have pointed to this very danger in citing reasons why manufacturers may be unwilling to bring an AIDS vaccine to market. Such observations reflect the assumption that development of AIDS in spite of vaccination is within the purview of manufacturer liability. See, e.g., Helen H. Blake, *The AIDS Vaccine: Legislation to Limit Manufacturer Liability*, 27 TULSA L.J. 757, 771 (1992); Earley, *supra* note 16, at 363-65.

disease; studies report 90-95% efficacy for the most protective vaccines, such as measles and polio.¹⁰⁷ For any population receiving the AIDS vaccine, therefore, there will be a quantifiable (but very small) number of recipients who may contract the disease.¹⁰⁸ Presently, no compensation program in place in any country offers protection for development of the disease the vaccine was administered to prevent, unless that disease is shown to be caused by the vaccine itself, as in polio.¹⁰⁹ The purpose of a vaccine compensation scheme is to reimburse victims who, in taking the risk of the vaccine, suffered from severe unavoidable side effects. The risk of contracting the disease itself is drastically reduced by receiving the vaccine in the first place. This presumably is the reward for the vaccines, albeit not a guaranteed reward for every single recipient.

There may nonetheless be pressure to extend compensation coverage to development of AIDS after vaccination, as some may view such coverage as an inducement to take the vaccine. Implementation of this potentially broad coverage could drastically increase the cost of the program due to the extensive and prolonged medical care required by AIDS.¹¹⁰ Further, if vaccine efficacy were eroded by recipients engaging in high-risk behavior, a problem would arise as to whether efficacy voluntarily lowered would qualify the recipient for compensation. Such a plan would also necessarily entail administrative complications, such as requiring testing for sero-presence of HIV antibodies before administering the vaccine.¹¹¹ Moreover, given the possibility of a therapeutic benefit of an AIDS vaccine, this plan, by excluding vaccination of sero-positive recipients, would ignore the potentially positive aspects of inadvertently inoculating a sero-positive recipient. Besides possibly increasing cost and entailing administrative complications, such a plan would change the focus of the insurance scope of the compensation scheme.

Allowance for coverage of contracted disease in the AIDS context is arguably an option, but one that is not supported by the precedent or purpose of other vaccine compensation schemes.

¹⁰⁷See Sharon Snider, *Childhood Vaccines*, 24 FDA CONSUMER 19 (September 1990).

¹⁰⁸Until complete herd immunity is achieved. Herd immunity is defined as the percentage of the population that needs to be immune to interrupt transmission. See J.W.G. Smith, *Proceedings of the International Conference of the Application of Vaccines Against Viral, Rickettsial, and Bacterial Diseases of Man*, Pan American Health Org. 316-18 (1971).

¹⁰⁹See generally Mariner, *supra* note 105; see also *supra* note 89.

¹¹⁰See *infra* note 175 and accompanying text.

¹¹¹This would also be complicated by the lag time between exposure to the virus and appearance of the antibodies; thus, a vaccine recipient could have tested sero-negative although he was exposed to the virus and received vaccine, and be eligible for coverage at the onset of the disease.

b. Defining a compensable injury: the "evolving" injury table

In addressing the problem of defining a compensable injury, the injury table has proved to be a valuable means of streamlining the often arduous, expensive, and disparate causation determinations that have plagued jury-based litigation.¹¹² Success of other no-fault compensation schemes for vaccine and medically-based injury is largely determined by the injury tables, which provide a presumption of causation and thus elimination of wasteful duplicative causation determinations.¹¹³ Importantly for cost and funding concerns, the specificity of the table also determines the extent of potential liability exposure: if coverage is too broad due to allowance of attenuated causation, liability exposure may be unnecessarily high; on the other hand, if the table is too stringent, the program will unfairly exclude deserving recipients from its coverage. The more specific an injury table, the more likely the success of the program.¹¹⁴

Since the AIDS compensation scheme probably will be implemented at the initiation of a mass immunization program, data concerning frequency of serious adverse reactions would be little to non-existent.¹¹⁵ Therefore, an injury table itemizing the precise injuries that qualify for compensation will be tentative and open-ended. This is a serious drawback that has an important cost ramification: an injury table based on scarce data runs a serious risk of being overinclusive.¹¹⁶

In designing a solution to this problem, an efficient, reliable administrative mechanism must be implemented to initiate and develop an "evolving injury table." The nascent, or core, injury table at the onset of the program would contain certain "generic" injuries that are known to occur with several other vaccines: anaphylaxis, for example.¹¹⁷ In addition, any significant adverse side effects that appeared in the Phase III trials would likewise be included. A continuous review and recommendation system, discussed below, will be necessary to update and revise the table. This system of adding injuries to the core table employs a scientific basis for defining vaccine-related injuries and

¹¹²See Mariner, *supra* note 11, at 440.

¹¹³See Laura Mazzuca, *Vaccine Fund Could Be Expanded*, BUS. INS. August 24, 1992, at 21.

¹¹⁴*Id.*

¹¹⁵See *supra* note 93 and accompanying text.

¹¹⁶See Mazzuca, *supra* note 113. There are presently recommendations by the Department of Health and Human Services to delete certain injuries from the Vaccine Injury Table. See 57 Fed. Reg. 36878 (1992). See also FDC "Pink Sheet" Aug. 31, 1992, at 7. The proposed narrowing encompasses injuries associated with DPT, measles-mumps-rubella, and inactivated polio vaccine. *Id.* Those recommendations have been challenged on the grounds that they stem from misinterpretation of study results. Jan Erickson, Director, National Vaccine Information Center, personal communication and unpublished comment.

¹¹⁷The potential exists for hypersensitive reaction to any vaccine component.

offers the cost advantage of expanding liability only when such expansion is supported by scientific evidence.¹¹⁸

Development of the table will be dictated by causation determinations made by a scientific panel. Once the scientific panel makes a causation finding, it would submit a recommendation of whether or not to incorporate an injury into the existing injury table. During the initial mass immunization period, when injuries are not yet established, panel determinations and recommendations would be more frequent; as the injury table stabilized due to conclusive causation determinations, the need for a scientific panel would lessen and perhaps ultimately disappear.

Treatment of data concerning vaccine-caused injury would parallel that of clinical studies. Likelihood of causation, based on existing knowledge, would be reflected in tentative causation categories.¹¹⁹ Temporal correlation would obviously be the most compelling initial support for causation; however, since there is a possibility that, in the AIDS context, other, more complicated, longer-latency injuries may arise, temporal considerations must not be dispositive.¹²⁰

There is currently much debate over whether a jury or an expert scientific panel is the appropriate forum for deciding certain causation issues.¹²¹ In the AIDS vaccine context, a scientific panel seems much more appropriate to determine causation questions than lay juries selected over many state jurisdictions. First, a scientific panel has the benefit of expertise in interpreting often difficult data. Second, as a centralized repository of such data, such a panel would lend consistency to decisionmaking. Third, employing a scientific panel to determine causation is a logical extension of the federally regulated approval system that already exists for vaccines. Most importantly, an impartial scientific basis for causation is paramount in the AIDS vaccine context, where reliability and certainty are presently scarce.

¹¹⁸The reverse process, as exemplified by the Childhood Injury Table, results in overpayment of benefits. See Mariner, *supra* note 11, at 431, 439-42. See also *The National Vaccine Injury Compensation Program: A Program Review* (Office of Inspector General, Dept. of Health and Human Services, 1992) [hereinafter *Program Review*] (finding that the present vaccine injury table does not reflect the latest scientific evidence and conforming the table to concur with scientific evidence would result in significantly lower compensation rates).

¹¹⁹Causation categories: definite, probable, possible, none.

¹²⁰However, as with other long-latency diseases, the causation determination becomes extremely problematic, particularly if multiple causes contribute to the resulting complication. Note that, if the injury is AIDS, caused by the use of an attenuated whole virus vaccine, the latency period may be as long as ten years. See *THE EPIDEMIOLOGY OF AIDS: EXPRESSION, OCCURRENCE, AND CONTROL OF HUMAN IMMUNODEFICIENCY VIRUS TYPE I INFECTION* (Richard A. Kaslow & Donald P. Francis, eds., 1989).

¹²¹See generally, Dan L. Burk, *When Scientists Act Like Lawyers: The Problem of Adversary Science*, 33 *JURIMETRICS J.* 363 (1993).

Development of an evolving AIDS vaccine injury table depends on obtaining reliable data concerning possible vaccine-caused injuries as well as expert interpretation of that data to determine whether the injury was indeed caused by the vaccine. This suggests the need for a uniform, coordinated data gathering mechanism akin to an extended clinical study. To this end, a formal post-marketing data surveillance program should be implemented concurrent to an AIDS vaccine compensation program.¹²²

3. Benefits

The benefits covered by the AIDS vaccine compensation scheme would be modeled after the National Childhood Vaccine Act, which provides for unreimbursed medical expenses, lost wages, a death benefit, and a capped non-economic award.¹²³ A limit on the non-economic award is critical to containing costs of the program.

Should the notion of comparative fault as reducing the amount of the award be considered if certain injuries are correlated with certain behaviors or population groups?¹²⁴ Probably not. Besides the difficulty in getting claimants to admit or divulge perhaps personal sensitive information, a perceived impediment to receiving compensation on these grounds could have the undesired effect of souring public acceptance of the vaccine, due to stigmatizing effects.

4. Administrative Structure and Procedure

Procedure for claim submission and eligibility and award determination would closely parallel the Childhood Vaccine Injury Program,¹²⁵ with a slight procedural modification based on the evolving injury table concept. Claims would be submitted initially to the United States Claims Court. For injuries that are on the existing injury table, the claim would be submitted to a special master for causation affirmation and award determination. If an injury is not on the existing injury table, a finding of probable causation from the scientific panel would be required before the claim would go to the special master for award

¹²²See *infra* notes 143-53 and accompanying text.

¹²³See Mariner, *supra* note 11, at 434. The non-economic award is limited to \$250,000; the death benefit is \$250,000.

¹²⁴This kind of injury would indicate multi-factorial causation; assignment of liability would become even more problematic if one of the correlative variables was a voluntary behavior, such as needle drug use.

¹²⁵See Mariner, *supra* note 11, 429-31. See also *Program Review*, *supra* note 118, at 10-14 (finding processing of cases is efficient under present compensation program). The only exception to that general opinion is the large influx of pre-1988 cases. *Id.* at 8-9 (finding that the program was struggling with the unanticipated influx of retrospective cases, where retrospective cases are for injuries sustained before the effective date of the Act). This cumulative caseload would presumably not appear in the AIDS vaccine context, however, since the compensation program would presumably be enacted almost concurrently with the promulgation of the AIDS vaccine.

determination. Injuries classified by the panel as definite or probable would thus qualify for award determination. Injuries with null causation classification would be denied award. Injuries classified as possible causation would have a pending status; outcome of those cases would have to wait for additional data, with a maximum period of a year for disqualification. If not disqualified, the claimant would be awarded compensation.

The additional procedural layer of causation classification for injuries not delineated on the injury table would create some delay for claimants, but probably no more than traditional litigation. Moreover, for the sake of ultimate accuracy, acquiring more information is the proper way to approach causation determination, rather than forcing a jury to come to a decision at the arbitrary point of an individual trial.

5. Funding Mechanism

Funding for an AIDS compensation scheme would be provided by a combination of an excise tax on the vaccine and general appropriations, as in the National Childhood Vaccine Injury Act.¹²⁶ Since the entire population will benefit from preventing the disease through vaccination, funding from general appropriations seems a fair way to spread the cost of the program. Further, the federal government will realize substantial cost savings in prevented AIDS cases;¹²⁷ some of those cost savings could be earmarked for compensation to those who participated in vaccination.

If the cost burden were placed solely on an excise tax, there is a danger that the cost—which is invariably passed onto the consumer—would be disproportionately high. The exact cost of an excise tax is uncertain;¹²⁸ the present excise tax cost for DPT, the most costly vaccine in terms of liability, is \$4.56 per dose.¹²⁹ California has placed a limit of \$10 per dose as a state-wide excise tax for AIDS vaccines sold in California.¹³⁰ If recently licensed vaccines

¹²⁶An excise tax funds all post-1988 cases, however. As of August 1992, the tax was generating an estimated \$10 million per month. See Mazzuca, *supra* note 58.

¹²⁷See Jesse Green & Peter S. Arno, *The Medicaidization of AIDS, Trends in the Financing of HIV-Related Medical Care*, 264 JAMA 1261 (1990). There has been a marked shift toward public support of medical costs in treating AIDS.

¹²⁸The amount of the excise tax depends primarily on two variables: the extent to which the excise tax is the sole source of funding for compensation; and the overall cost of the program, which in turn depends on the extent of liability exposure. See *infra* notes 156-75 and accompanying text.

¹²⁹See FDC "Pink Sheet," 8/16/93. The vaccine is given in a five dose series. See Centers for Disease Control, *Pertussis Vaccination: Acellular Pertussis Vaccine for the Fourth and Fifth Doses of the DTP Series*, 41 MORBIDITY AND MORTALITY WKLY. REP. RR-15 (1992).

¹³⁰CAL. HEALTH & SAFETY CODE § 199.50 (Supp. 1995).

are a reliable indication, the cost of the AIDS vaccine will probably be high.¹³¹ Adding an excise tax may make an expensive vaccine even more expensive.

Another problem with sole reliance on an excise tax is that the amount of revenue generated could easily turn out to be deficient. The funding requirements of an AIDS vaccine injury program depend in large part on the extent of liability exposure.¹³² The amount accrued by an excise tax on vaccines is a function of the number of doses sold as well as the amount per dose; therefore, the more targeted and narrow the vaccine strategy, the less revenue generated by this funding mechanism. The parameters determining funding liability will be considered in more detail below, when the cost of an AIDS compensation scheme is assessed.¹³³

6. Exclusive or Alternative Protection?

Implementation of an AIDS vaccine compensation scheme rests on the assumption that potential liability is a disincentive for vaccine manufacturers to enter or stay in the market. Thus, a key to the success of an AIDS compensation scheme is its ability to provide a quantum (i.e., significant) degree of market predictability for manufacturers through reduced liability exposure and therefore stability of the vaccine supply. The degree of residual liability for manufacturers depends on the degree to which the compensation scheme is an exclusive remedy; or, more precisely, the degree to which the compensation program is de facto exclusive. De facto exclusiveness by an alternative remedy is determined by its success in attracting claimants away from the tort system.¹³⁴

A compensation scheme that is an exclusive remedy for the injured victim would provide virtual immunity for AIDS vaccine manufacturers. The difficulty with this program structure is not feasibility but rather perceived unfairness. To deny a victim the option of pursuing a tort remedy appears arbitrary and coercive. Further, many would argue that removal of the tort system would also remove proper incentives for the manufacturer to adhere to acceptable safety standards.¹³⁵ While an exclusive remedy would assuredly

¹³¹The wholesale price of a recently licensed vaccine for Japanese encephalitis is \$37.14. See FDC "Pink Sheet" 12/21/92.

¹³²Which will in turn depend on the adopted vaccine strategy, as well as public participation in the vaccine effort. See *infra* notes 154-185 and accompanying text.

¹³³*Id.*

¹³⁴This is important for manufacturers, for as the more successful the program is in diverting claimants away from the tort system, the lower and more predictable is their liability exposure.

¹³⁵That the assurance of safety is necessitated by the tort system seems inappropriate in the AIDS—indeed, any—vaccine context, where stringent federal licensing standards dictate whether such a product ever comes to market.

grant a greater degree of manufacturer immunity, a program offering alternative compensation is preferable.¹³⁶

A simple alternative mechanism for compensation would have the self-defeating attribute of leaving manufacturers open to an unknown degree of liability. Given the inherent uncertainty of the AIDS vaccine context,¹³⁷ leaving residual liability as an open-ended question for manufacturers may render the program a near-nullity in terms of its liability protection.

A hybrid solution that allows alternative compensation but incorporates adequate disincentives for using the tort system provides a more desirable liability framework in the AIDS context. The Childhood Vaccine Injury Program serves as an excellent model.¹³⁸ This system, with its aim for providing a claimant with a faster, more efficient settlement, is designed to build in rather equitable disincentives for victims who use the tort system. In order to pursue a tort-based remedy, a claimant must first file under the administrative system. If a claimant is dissatisfied with the award, she may pursue a tort-based claim, but will be automatically barred from receiving the administrative award.

In sum, an alternative liability system with built-in incentives for using the federal mechanism of compensation provides the best equitable balance between the manufacturers' liability uncertainty and the claimant's award.

7. Sharing Liability: Supported by Federal Approval?

For the same reasons the manufacturers want to avoid seemingly unfair liability exposure, the federal government should be cautious about blindly accepting all liability arising from the AIDS vaccine.¹³⁹ However, the federal approval process for drugs and vaccines, with the resultant symbiotic relationship between vaccine manufacturers and the federal government, virtually dictates a more shared liability structure between the private and public sector.

Given federal approval of an AIDS vaccine in terms of its safety through the stringent testing process of expensive clinical trials, it may not be unreasonable to suggest that the federal government shoulder at least some of the initial liability burden for any unavoidable adverse side effects, even if hindsight proves that a superior design of a vaccine would have been safer.¹⁴⁰ From the

¹³⁶There is another reason why a strictly exclusive program may be undesirable. If this factor is considered while an AIDS vaccine compensation program is being drafted, cost constraints may compel the program designers to considerably narrow the eligibility requirements of an exclusive program.

¹³⁷See *supra* notes 88-96 and accompanying text.

¹³⁸See *supra* notes 51-59 and accompanying text.

¹³⁹See *supra* notes 29-31 and accompanying text.

¹⁴⁰Except when the manufacturer shows "unacceptable behavior" subject to tort action. Unacceptable behavior has been defined as intentional violation of the law,

manufacturer's point of view, such endorsement through liability protection would reinforce the government approval process and strongly encourage the risk-taking step of market participation.

Further, the AIDS epidemic, as pointed out, is extremely costly to the federal government in terms of medical care expenditures.¹⁴¹ When the AIDS vaccine is first introduced to the general public, it is in the government's best interest to do all it can to encourage the use of the vaccine by the voluntary recipients; to the extent that the vaccine is accepted, the number of AIDS cases and the concomitant costs will decline. Government sponsorship by assumption of initial liability provides further endorsement of vaccine use by the general population. Thus, providing at least a temporary window of immunity for manufacturers may help accomplish several important goals of a proposed successful vaccine program.¹⁴²

V. AN AIDS VACCINE POST-MARKET SURVEILLANCE PROGRAM

As discussed, development of an AIDS vaccine injury table, a critical component of the compensation scheme, depends on availability of reliable data as well as expert interpretation of that data. To the extent that an adverse side-effect is rare, or causation is attenuated or probabilistic, large numbers of vaccine recipients must be analyzed in order to adequately support causation. The uncertainty of the AIDS vaccine context, combined with the urgent need for a successful vaccine strategy, suggests the necessity of designing a program that will serve as an important extension to the foundation laid by the clinical trials. Therefore, an extensive, centralized post-licensing study should be initiated at the time of the creation of the vaccine compensation scheme and promulgation of the vaccine into the general marketplace.¹⁴³ A carefully

conscious disregard for safety of others, or intentional conduct that was designed to deceive or conceal. See KEYSTONE, *supra* note 17, at 11.

¹⁴¹See *infra* note 181.

¹⁴²One possible solution to the allocation of liability is a "phased" liability model, where a subdivision of liability occurs along a temporal axis. Just as testing the vaccine occurs in stages, so could the liability assignment. During the first liability phase, when the vaccine is at its most experimental posture for the general population, the federal government could shoulder virtually all liability for vaccine-related injury, except when the manufacturer shows unacceptable behavior. See *supra* note 140. A possible correlative posture would be to have the federal government assume liability for all non-null causation classifications for the first three years of the post-marketing surveillance study. See notes 143-53 *infra* and accompanying text.

¹⁴³There are presently several post-market surveillance systems for vaccines in the United States, utilizing the Vaccine Adverse Event Reporting System (VAER) coordinated by the Centers for Disease Control. Most systems are entirely voluntary and thus have limited reliability. Adverse reactions from childhood vaccines are required to be reported; however, this data is likewise somewhat questionable because of the unknown extent of participation. See generally Centers for Disease Control, 37 MORBIDITY AND MORTALITY WKLY. REP. 197 (1988). An AIDS vaccine post marketing

coordinated surveillance system would serve two crucial purposes: first, it would provide a centralized repository for important data about the vaccine, its side effects, and efficacy; and second, it would form an integral part of the overall vaccine strategy by calling attention to the vaccination effort through its very involvement and follow-up on recipients of the vaccine.

A. Study Design

The population to be followed for purposes of the post-market surveillance program would be recipients during the first three years of mass immunization.¹⁴⁴ To be eligible for the study, participants would have to be willing to cooperate with post-market surveillance for five years after receipt of the vaccine.¹⁴⁵ These voluntary recipients would be advised of the possibility of attendant risk of the vaccine, and that, in return for receiving the vaccine for free, must be willing to participate in the program for five years. Participants will also be advised to avoid high-risk behavior, and any other recommendations concerning avoiding the contraction of AIDS. Other general safety protocols standard for clinical trials would be followed.

Upon receipt of the vaccine, the participant and administrator would be responsible for recording any adverse events that occur. Reports of adverse events would be turned into the appropriate state or local health agency, which in turn would submit the data to the Centers for Disease Control (hereinafter CDC). Reports of adverse events made to the manufacturer would also be turned over to the CDC. The recipient would be closely monitored (i.e., once a week) for the first month; monthly for the rest of the first year; then every six months for the remainder of the study.

The data received at the federal vaccine study center would be classified and analyzed.¹⁴⁶ Cases of similar presentation of side effects would be grouped and the data further examined for causation determination by the scientific panel. At the end of the study, a comprehensive picture would emerge about the safety of the vaccine, made possible by the extensive centralized data pool.

What kind of data would be collected? Besides medical reports of injury, ancillary data would help to elucidate other correlative variables. Such data

surveillance program would differ from those in place in its clinical-study like format, with more detailed information and follow-up on participants.

¹⁴⁴This would give a sufficiently large group for study. One would expect an initial "bulge" of vaccine recipients when the AIDS vaccine is first available. Further, information on adverse drug reactions during the life cycles of drugs indicates that the "reporting rate during the second year is about five times greater than that after the fifth year of marketing." Harold E. Paulus, *FDA Arthritis Advisory Committee Meeting: Post-marketing Surveillance of Nonsteroidal Anti Inflammatory Drugs*, 28 *ARTHRITIS AND RHEUMATISM* 1168-69 (1985).

¹⁴⁵Length of monitoring period would depend on the extent of the study, with the idea that long-term effects may be important in the AIDS context.

¹⁴⁶A comprehensive, computerized database would consolidate the information from disparate sources.

would include disclosure of lifestyle choices, sexual activity, and other potentially sensitive information. Hence, the extent and quality of data beyond the mere reporting of an adverse event will depend greatly upon the ability to attract an adequate number of willing participants to the study.¹⁴⁷ Receiving the vaccine—even for free—and contributing to a body of knowledge that may have no primary impact on the participant may not provide a sufficient incentive for surveillance participation. Structuring a federal vaccine compensation program to include coverage for AIDS contracted by surveillance participants may be deemed necessary in order to attract fully cooperative, reliable participants.¹⁴⁸

B. Advantages of the AIDS Post-Market Surveillance Program

The AIDS context provides a particularly compelling forum for embarking on an ambitious coordinated post-market surveillance program. The seriousness of the disease, the stubbornness of the epidemic, and the unusual nature of the etiological agent, all argue for an extended quasi-clinical studies forum for detecting and gathering data when the vaccine enters the mass immunization context. Because the basic structure for a reporting system now exists through the CDC HIV / AIDS surveillance system,¹⁴⁹ the incremental cost of putting the AIDS post-market monitoring system in place may not be prohibitive.¹⁵⁰

An objection to this post-market surveillance program is that the data obtained will not be controlled; that is, there will not be a corresponding number of study participants who do not take the vaccine. Ethical considerations, as well as the scale of this surveillance program, preclude such a study design. Public health interests dictate that all willing recipients must be able to obtain a licensed vaccine. The value of information gleaned from a control population is miniscule in comparison to the benefit of prevented cases of AIDS. Further, the value of the study itself, as designed, must be weighed against the alternative: a completely voluntary reporting system confined to adverse events. The coordinated, centralized data collection and processing of

¹⁴⁷In any study, the more complete the data, the more reliable. Completeness is a function of quality (i.e., the type of information obtained) as well as quantity (i.e., the amount of information obtained).

¹⁴⁸Another strategy is to target the post-market surveillance program to states with a history of cooperative populations for clinical studies.

¹⁴⁹See generally *HIV/AIDS Surveillance*, *supra* note 79 at 17.

¹⁵⁰One possible cost saving device would be to mimic the test centers' approach of regular clinical studies. Vaccination for the post-market surveillance program could be conducted at several immunization centers located in large urban areas where the prevalence of AIDS is high (such as New York, Los Angeles, and San Francisco). Since the data generated by such a study would benefit vaccine manufacturers, they too could shoulder some of the cost burden.

vaccine-related information is also consonant with the overall trend toward centralization of the national AIDS research and prevention effort.¹⁵¹

An AIDS post-market surveillance program would accomplish several objectives outside the immediate scope of establishing AIDS vaccine-related injury. A large problem in adult vaccination programs is their lack of participation.¹⁵² An AIDS post-market surveillance program would undoubtedly raise public awareness of the AIDS vaccination effort, and hence encourage participation. By closely monitoring and expanding the realm of data collection, important information concerning the AIDS vaccine and AIDS would also be gathered. A systematic surveillance for adverse reactions will also help call attention to evolving issues in the immunization program, which will most likely have generic value for other immunization programs. Finally, a formal post-market surveillance program would re-emphasize the semi-contractual nature of the immunization process by extension of the concept of informed consent.¹⁵³

VI. COST OF AN AIDS VACCINE COMPENSATION SCHEME

In assessing whether to create a new administrative compensation scheme for the AIDS vaccine, cost of the program is an obvious pertinent consideration. An estimate of program cost determines the funding obligation. Given the present emphasis on deficit reduction, Congress may be especially sensitive about the extent of cost exposure of such a program,¹⁵⁴ in spite of political pressure to fund it.¹⁵⁵ While a detailed, accurate cost-benefit analysis is beyond the scope of this paper, I will address some general points.

A. Aggregate Liability Costs

The approximate cost of an AIDS compensation scheme is the sum of the cost of aggregate liability (arising from the claims) and administrative costs. Administrative costs, while not inconsequential, will probably not be the

¹⁵¹See *HIV/AIDS Surveillance*, *supra* note 79.

¹⁵²See generally *National Coalition for Adult Immunization: Activities to Increase Influenza Vaccination Levels, 1989-1991*, Centers for Disease Control, 41 MORBIDITY AND MORTALITY WKLY. REP. 772, 774 (1992).

¹⁵³Re-emphasis on individual responsibility and choice, based on contract principles, is an alternative means of tort reform. See generally *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* (Peter W. Huber, Robert E. Litan eds. 1991).

¹⁵⁴Particularly in view of the funding problems currently plaguing the existing childhood vaccine injury compensation program. See Mazzuca, *supra* note 58. As of 11/30/92, the program had made 600 awards totalling over \$263 million. Expected caseload is 180-200 claims per year. See Dept. Health and Human Services, *Weekly Status Report*, 8/31/92. The major funding problem is due to the large number of so-called retrospective cases, or claims arising from injuries sustained prior to 1988. See *supra* note 125.

¹⁵⁵See *supra* notes 72-77 and accompanying text. •

primary cost concern, even if a post-market surveillance system is taken into account. As discussed above, the mechanism for implementing a post-marketing surveillance program is already in place.¹⁵⁶ Further, it is difficult to imagine that, compared to administrative costs of litigation, the administrative costs of the AIDS vaccine compensation scheme would be any greater, particularly given the costly causation determinations.

The amount of aggregate liability arising from the claims depends on two variables: the number of awarded claims and the extent of the award per claim. The number of claims in turn depends upon the number of people receiving the vaccine as well as the frequency of injury occurrence.¹⁵⁷ The frequency of injury occurrence depends on the safety of the vaccine itself, which is determined in large part by licensing standards enforced by the FDA.¹⁵⁸

1. Aggregate Liability and Vaccine Strategy

Since the number of claims submitted is determined in part by the total number of vaccine recipients, vaccine strategy has a potentially crucial impact on liability exposure.¹⁵⁹ Vaccine strategy, a plan which delineates the targeted recipients for immunization, is determined by a host of interrelated factors.¹⁶⁰ In the AIDS context, vaccine strategy will probably focus on epidemiological and immunological factors, such as high-risk groups and duration of immunity. Vaccination strategies can range from the very broad to the very narrow. For example, an extremely narrow AIDS vaccine strategy would be to vaccinate only partners of sero-positive patients.¹⁶¹ A broad vaccination strategy would be vaccination of the entire population.¹⁶²

A comparison of the number of potential claims made under each type of strategy illustrates the potential wide range of liability exposure of an AIDS

¹⁵⁶See *supra* note 149 and accompanying text.

¹⁵⁷The number of claims submitted is also a function of both public awareness and use of the compensation scheme itself. See *infra* notes 176-178 and accompanying text.

¹⁵⁸Viewed in this light, bowing to political pressure to expedite approval of an AIDS vaccine could have serious cost repercussions. See *supra* note 78 and accompanying text.

¹⁵⁹Unless the vaccine turns out to be perfectly safe; that is, no serious side effects. This is not an impossible scenario. Several existing vaccines have no serious side effects reported. See ADULT IMMUNIZATION, *supra* note 61, at 7.

¹⁶⁰See generally *Influenza: Virus, Vaccines, and Strategy* (Philip Selby ed., 1976), 271-94.

¹⁶¹Such a strategy is probably administratively unworkable, however. First, the strategy could only be used on partners of identified sero-positive people; since AIDS testing is still voluntary, only a fraction of all potential targets would be known. Also, immunization of partners necessarily involves disclosing the danger of HIV infection to that partner(s). This entails an obviously sensitive disclosure that many people would rather not make.

¹⁶²This was the strategy taken with the swine flu vaccine, with disastrous results, in terms of liability. The immunization program was halted after over 40 million people were vaccinated. See SWINE FLU, *supra* note 30 and accompanying text.

vaccine compensation scheme.¹⁶³ A strategy aimed at immunizing high-risk groups could indicate as many as 9 million initial vaccine recipients.¹⁶⁴ A strategy that included vaccination of all children would add at least 4 million to that figure.¹⁶⁵ A broad vaccination strategy akin to that adopted by swine flu could translate into over 150 million recipients.¹⁶⁶ Thus, for a given frequency of side effects, the incidence of vaccine-related injury would concomitantly vary over a wide range. For an injury that occurred once in every 200,000 recipients,¹⁶⁷ the maximum number of claims for this particular injury could range from less than 50 to over 700, or over a ten-fold range, depending on the adopted strategy.¹⁶⁸

The size of the award for each claim depends primarily on two variables: the extent of the injury and the age of the victim. The extent of the injury determines the amount of reimbursable medical costs; the age of the victim, in conjunction with the extent of the injury, will dictate the amount of lost wages. As a possible scenario, consider the occurrence of a hypothetical injury that

¹⁶³These figures are necessarily speculative; their primary purpose is to provide a preliminary comparison of possible scenarios.

¹⁶⁴This general figure was deduced by summing average estimates of each of the high-risk populations. See Appendix A. Population estimates were obtained from various sources. High-risk groups for this analysis were: homosexual males, intravenous drug users, children of HIV-infected mothers, and occupational exposure employees. To simplify the model, all population groups were assumed to have a 100% immunization rate, which is abnormally high. Although AIDS has a low transmission rate, as much as the entire susceptible population may be targeted for immunization. The long latency of AIDS, coupled with the approximation of an asymptomatic carrier state of people who are unaware that they are sero-positive, is further argument for immunizing the maximum number within each high-risk group. For more precise estimates, each component of the high-risk population would be in turn reduced by a fractional multiplier designed to incorporate HIV sero-prevalence (since presumably these people would not seek vaccination).

¹⁶⁵See Appendix A.

¹⁶⁶Based on 150 million total population. See Appendix A. This large number was reduced by a factor designed to reflect less than full participation. Such a plan has many inherent difficulties, such as assuring adequate vaccine supply for such a vast undertaking. See SWINE FLU, *supra* note 30.

¹⁶⁷This is the recorded occurrence for Guillain-Barre syndrome (GBS), an acute neuritis, for the swine flu vaccine and serum-derived hepatitis b vaccine. See also Centers for Disease Control, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination*, 40 MORBIDITY AND MORTALITY WEEKLY REP. RR-13, at 10-11 (Nov. 21, 1991). See also Alexander D. Langmuir et al., *An Epidemiological and Clinical Evaluation of Guillain-Barre Syndrome Reported in Association with the Administration of Swine Influenza Vaccines*, 119 AM. J. EPIDEMIOLOGY 841 (1984). The causative association between these vaccines and GBS has come into question; this injury was selected for purposes of this analysis because of its seriousness and relatively high frequency. See Appendix B.

¹⁶⁸The maximum number of claims assumes full public participation in the compensation program.

causes 30 days of disability. Cost per case, subdivided by productive age, could be \$22,000 for victims under the age of twenty-five, and \$25,000 for victims over the age of twenty-five.¹⁶⁹ If the injury occurs at the frequency quoted above, a strategy that targeted high-risk groups could generate aggregate liability of \$1.15 million.¹⁷⁰ Compare that figure with \$18.7 million, the estimated aggregate liability of a broad immunization strategy.¹⁷¹ Given the broad range of potential liability for one hypothetical injury,¹⁷² it is clear that the adopted vaccination strategy has serious liability implications for a federal AIDS vaccine compensation scheme.

The above example is merely a speculative foundation of cost estimates; depending on the extent of injury, claim cost could rise dramatically. Injuries causing permanent disability would be the most costly.¹⁷³ For example, if 25% of victims of the above injury were permanently disabled, a narrower strategy, based on exposure risk, could cost \$12 million, while the broad-based strategy cost could approach \$200 million.¹⁷⁴ A program that covered the contracting of AIDS itself would have a per-claim cost approaching \$1 million.¹⁷⁵

¹⁶⁹This is a somewhat arbitrary axis; the underlying assumption is that, for injuries sustained over the age of 25, lost wages must be included. Cost was calculated to be based on ten days of hospital care at \$2000 per day. See Appendix B. Lost wages were estimated to be the average between \$20,000 and \$50,000 per year. *Id.* Note that lost wages vary greatly depending upon the occupation of the claimant.

¹⁷⁰See Appendix B. Figure is based on the incidence of 46 total cases at a cost of \$25,000 per case.

¹⁷¹See Appendix B. Figure is based on the incidence of 750 total cases at a cost of \$25,000 per case. These calculations do not include an award for non-economic injuries. Note also that these figures are not annualized; that is, I have worked with totals without estimating what percentage of these totals per year may be immunized.

¹⁷²Note that the calculation was further simplified by considering only one injury. The liability picture could be further complicated, and made more expensive, by manifestations of more than one serious side effect.

¹⁷³See Appendix B. In the Childhood Vaccine Injury Compensation Program, awards for permanent (neurologic) disability are typically over \$1 million. See Mazzuca, *supra* note 58, at 21. The ironic result is that, given the present cost figures, it would be more expensive to care for a person permanently disabled by a vaccine-related injury than had that person contracted AIDS.

¹⁷⁴See Appendix B. Injury cost is based on a 35 year old male, with life expectancy of 35 years. The cost of each strategy would dramatically increase if the victims were primarily young children, due to the much longer life expectancy. *Id.*

¹⁷⁵This figure is based on lifetime medical care cost of \$100,000. Added to this base figure is the maximum pain and suffering benefit (here, \$250,000); lost wages (\$150,000); and a death benefit (\$250,000). For cost estimates on AIDS medical care, see Fred J. Hellinger, *Updated Forecasts of the Costs of Medical Care for Persons with AIDS, 1989-93*, 105 PUBLIC HEALTH REPORT 1 (1990). The projected cost of AIDS care is speculative, since the treatment type and cost for illness can change as new drugs are developed.

2. Other Determinants of Extent of Immunization

Vaccine strategy is only the initial variable that determines the extent of immunization. If the AIDS vaccine is recommended rather than mandatory, then the degree of public acceptance of the vaccine and participation in the immunization effort play an equally important role in the extent of immunization. These variables are even more difficult to quantify or estimate than those above; yet they will be crucial determinants of liability exposure.¹⁷⁶

Public participation in the immunization strategy will depend on availability and cost of the vaccine, as well as perceived benefits and risks of the vaccine versus risks of the disease. The established high-profile AIDS constituency and the prevailing emphasis on prevention support the idea that public receptiveness of the AIDS vaccine will be high. However, issues such as sero-conversion must also be addressed in order to maximize participation by an otherwise willing public.¹⁷⁷ The problem of historically low levels of participation in voluntary immunization efforts may also pose a problem in the AIDS context, in spite of ostensible public support.¹⁷⁸

3. Cost-Mitigating Factors

An AIDS vaccine compensation scheme would pay for unreimbursed medical expenses; that is, expenses not already paid for by a third party insurer.¹⁷⁹ Many victims of vaccine-related injuries may be insured; to the extent that their policies cover this kind of injury, the cost of the federal program will drop accordingly.¹⁸⁰ However, given the high percentage of AIDS medical costs that is paid for by Medicaid,¹⁸¹ insurance reimbursement may be a relatively inconsequential cost-mitigating factor.

An obvious cost-mitigating factor for an AIDS vaccine compensation program are the substantial cost savings of prevented disease. By present

¹⁷⁶As well as the possible success in eventually eradicating the disease.

¹⁷⁷A vaccine recipient, in generating antibodies, will test positive for HIV, based on current diagnostic methods. Even if vaccination is an available explanation for sero-positivity, admitting to taking the vaccine may, for many people, be an unwanted lifestyle proclamation.

¹⁷⁸See *supra* note 97 and accompanying text.

¹⁷⁹For post-1988 injuries, the Childhood Vaccine Injury Compensation Program provides coverage for actual past and estimated future medical expenses that are not reimbursable by private insurance. See Mariner, *supra* note 11, at 434.

¹⁸⁰In 1989, 38.9% of all hospital discharges were paid for by private insurance. See BUREAU OF THE CENSUS, U.S. DEPARTMENT OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES at 118 (1992) [hereinafter BUREAU OF THE CENSUS].

¹⁸¹In 1988, 29% of HIV hospitalizations were covered by Medicaid. Observers agree that the burden of AIDS health care is increasingly borne by the federal government. See Lisa S. Rosenblum et al., *Increasing Impact of HIV Infection on Hospitalizations in the United States, 1983-1988*, 5 J. OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 497; see also Green & Arno, *supra* note 127.

estimates, each AIDS case has a projected cost of over \$100,000.¹⁸² Currently, approximately 50,000 new cases of AIDS are reported in the United States every year.¹⁸³ If just half of those cases were currently prevented, a minimum direct cost saving of \$2.5 billion of direct medical costs would be saved.¹⁸⁴ A significant portion of these medical costs are borne by the federal government.¹⁸⁵ For an AIDS vaccine compensation program to fail to be cost-effective, one could argue that the aggregate liability must at least exceed the aggregate costs saved by preventing the disease.

B. How Can Liability Be Equitably Circumscribed?

The potentially wide range of several variables that would determine aggregate liability in the AIDS vaccine context emphasizes the need for careful program design in circumscribing liability scope. At the same time, care must be given not to allow the emphasis on circumscribing liability to overshadow fair compensation of the victims.

A vaccine strategy determined by public health officials and epidemiologists poses the risk of conflicting with the cost containment perspective of a federal AIDS vaccine liability scheme, where the focus may be on vaccinating the fewest number of recipients. The broader the vaccine strategy, the higher the potential cost; conversely, the narrower the vaccine strategy, the lower the potential cost.

The present dearth of information concerning injury variables in the AIDS mass immunization context virtually precludes a reliable cost calculation. However, the exercise illustrates a crucial point: if an AIDS vaccine compensation plan is implemented, the degree of liability exposure will be greatly influenced by the particular vaccine strategy adopted. Careful delineation of liability is of course warranted, especially in the AIDS context. But should the concern for liability exposure extend its influence to

¹⁸²See Hellinger, *supra* note 175. This figure may rise substantially as new, expensive treatments prolong the survival of patients with the disease. Moreover, this figure does not accurately reflect cost of vaccine-prevented AIDS cases, which would not arise for up to ten years after initiation of the vaccine program.

¹⁸³Projections range from 47,000-77,000 newly reported cases in 1992; 47,000-85,000 in 1993. Based on the newly expanded case definition of HIV infection, the number of reported cases could rise by as much as 75% in 1993. See Centers for Disease Control, *Projections of the Number of Persons Diagnosed with AIDS and the Number of Immunosuppressed HIV-Infected Persons—United States, 1992-1994*, 41 MORBIDITY AND MORTALITY WKLY. REP., RR-18, at 8 (Dec. 25, 1992); Centers for Disease Control, *1993 Revised Classifications System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, 41 MORBIDITY AND MORTALITY WKLY. REP. RR-17, at 6 (Dec. 18, 1992).

¹⁸⁴Based on \$100,000 lifetime medical care costs. See Hellinger, *supra* note 175. The cost of treating all patients diagnosed with AIDS has been projected to be \$7.8 billion in 1993. *Id.* The figure in the text does not include other cost savings, such as productivity gains from prevented disease.

¹⁸⁵See *supra* note 181.

determination of the immunization strategy itself? If both plans are crafted simultaneously—a distinct possibility in the AIDS context—there exists the potential for one program to influence the design of the other, a potential for what may be viewed as inappropriate compromise. No doubt these programs must somehow work together; but the extent and cost of compromise must be carefully contemplated.¹⁸⁶

VII. PROMULGATION OF A SUCCESSFUL AIDS VACCINE: TOWARD A COMPREHENSIVE IMMUNIZATION POLICY

As repeatedly noted, the AIDS context is inherently uncertain. Whether a safe, effective vaccine will ever be developed is unknown. If such a vaccine were developed, its unavoidable side effects as well as its ability to eradicate the disease are also unknown. Whether manufacturers would truly refuse to market a federally approved AIDS vaccine without the liability protection provided by an effective federal vaccine compensation scheme is uncertain. Moreover, were such a federal compensation program implemented, its proper design and probable extent of effectiveness are necessarily unclear.

Because a well-designed AIDS vaccine compensation scheme would remove some of this uncertainty, various proposals for such a scheme designed to meet the mass immunization context should be carefully considered. As one possibility, I have advanced a hybrid compensation model which incorporates features of the existing Childhood Vaccine Injury Program along with a post-market surveillance scheme that would serve as an extension of the clinical study milieu that characterizes pre-licensure activities. The information generated by such a model, coupled with the concerted national effort at data collection, promises to yield far more than simply what adverse effects the vaccine causes.

The proposal presented here is a preliminary model, admittedly tentative by virtue of its prematurity. Whether or not this model is the best solution, or what its impact would be on the AIDS vaccine market, is even more speculative. It is presented not only for its own sake, but to spur a more probing multi-disciplinary dialog among the wide-ranging participants of an AIDS mass immunization program with the goal of developing innovative solutions for the impending compensation and liability problem posed by the eventual FDA approval of the AIDS vaccine. The tentative and speculative aspects of the model will perhaps deepen the endeavor to craft a viable, progressive, responsive solution to promote the success of an AIDS immunization program.

¹⁸⁶Since the potential serious adverse side effects will not be known, pressure will bear on the only other controlling variable: the number of vaccine recipients. For example, a strategy dictated by liability concerns of a compensation scheme may target an extremely narrow group of recipients, such as children of sero-positive mothers. See Appendix A. This strategy is clearly not in the public health interest. The alternative is to encourage vaccination for the entire epidemiologically-derived population but offer compensation only to certain members of that group, an approach that is certain to raise serious equity and administrative concerns.

The AIDS vaccine endeavor has one primary goal: to eradicate AIDS through an effective immunization program. A successful AIDS vaccine campaign requires more than an adequate supply of a reasonably safe and effective AIDS vaccine. Widespread acceptance and use by target groups is an equally critical requirement. An AIDS vaccine compensation scheme is but one part of the entire mechanism that must work in order for an AIDS vaccine immunization program to be successful. But to the extent that such a compensation scheme may further the overriding goal of eradication of this deadly disease, it deserves increasing and detailed attention.

APPENDIX A

AGGREGATE LIABILITY AND VACCINE STRATEGY:
POPULATION ESTIMATES

I.	At risk population estimates	
A.	Homosexual males ¹⁸⁷	2.6 million
B.	Intravenous drug users ¹⁸⁸	1.0 million
C.	Occupational exposure ¹⁸⁹	5.6 million
D.	Children born to sero-positive mothers ¹⁹⁰	6,000
II.	General population estimates	
A.	Total population ¹⁹¹	253 million
B.	Children	
	Under 1 year ¹⁹²	4 million
	Under 5 years ¹⁹³	19 million

¹⁸⁷Three percent of males from age 20. Recent data indicates a much lower number of homosexuals than the Kinsey-based figure of 10%. See J. Gordon Muir, *Homosexuals and the 10% Fallacy*, WALL ST. J., Mar. 31, 1993 at A14. Source of general population data: BUREAU OF THE CENSUS, *supra* note 180.

¹⁸⁸Estimates of this population range from 750,000 to 1.2 million.

¹⁸⁹Source: Assistant Labor Secretary Gerard F. Scannell, News Conference on AIDS in the Workplace (Dec. 2, 1991). (transcript available on LEXIS). This category includes those workers who are exposed to HIV while performing job duties (such as health care workers, security guards, police, etc.).

¹⁹⁰Born annually. Cumulative population not calculated due to statistical insignificance of this category. See Jon Cohen, *Pediatric AIDS Vaccine Trials Set*, 258 SCI. 1568 (Dec. 4, 1992).

¹⁹¹Source: BUREAU OF THE CENSUS, *supra* note 180.

¹⁹²*Id.* There were 4.1 million births in 1990. *Id.*

¹⁹³*Id.*

APPENDIX BAGGREGATE LIABILITY: HYPOTHETICAL INJURY
COST ESTIMATES

- I. Type of case (overall frequency 1/200,000)
 - A. 25% mild: 14 days disability; no hospitalization; no sequelae.
 - B. 50% moderate: 30 days disability; 10 days hospitalization; no sequelae.
 - C. 25% severe: permanent disability; no deaths
- II. Health care costs
 - A. Hospitalization, per day¹⁹⁴ \$2,000
 - B. Non-skilled nursing care, per year¹⁹⁵ \$30,000
- III. Cost of injury (for male victim, age 35, salary \$35,000/yr, life expectancy 35 years)
 - A. Mild
 1. Medical costs \$250
 2. Lost wages \$1,500
 - B. Moderate
 1. Medical costs¹⁹⁶ \$22,000
 2. Lost wages¹⁹⁷ \$2,900
 - C. Severe
 1. Medical costs¹⁹⁸ \$480,000
 2. Lost wages¹⁹⁹ \$538,000

¹⁹⁴Director of Immunization Program, San Mateo County General Hospital. Also based on average cost to community hospitals. BUREAU OF THE CENSUS, *supra* note 180.

¹⁹⁵For severe cases.

¹⁹⁶Sum of \$20,000 hospitalization cost and \$2,000 general medical costs.

¹⁹⁷This figure is not applicable to children. Note, however, that lost wages are a small percentage of total cost of this injury category; therefore, cost estimates for this injury are relatively independent of age of victim.

¹⁹⁸Based on present value of annuity, term length 35 years, discount rate 5%. Not corrected for inflation. This figure would increase drastically if victim were a child due to additional years of required medical care. Therefore, cost estimates would be dependent on assumptions about average age of victim for this injury category.

¹⁹⁹Based on present value of annuity, term length 30 years, discount rate 5%. Not corrected for inflation. This figure would increase if victim were a child (although this

IV. Cost of different vaccine strategies²⁰⁰

A. Narrow (at risk) strategy—46 total cases

1. Mild cases (11)	\$19,000
2. Moderate cases (24)	\$600,000
3. Severe cases (11)	\$11,200,000
4. TOTAL ²⁰¹	\$11,819,000 ²⁰²

B. Broad (general) strategy—749 total cases

1. Mild cases (187)	\$327,000
2. Moderate cases (375)	\$9,377,000
3. Severe cases (187)	\$190,366,000
4. TOTAL	\$200,000,000

benefit would not become payable until the child turned 18), due to the additional years of wages lost.

²⁰⁰Based on hypothetical injury victim from part III and population estimates from Appendix A.

²⁰¹Totals in this analysis do not include payment for pain and suffering or attorney's fees.

²⁰²This figure could be lower if a small percentage of deaths occurred. For example, assuming a 5% death rate (30 hospitalization days; \$250,000 death benefit), and a correspondingly lower 20% severe occurrence, the total cost would be approximately \$10.38 million, or 90% of that shown.

