

A DOSE OF REALITY: REVISITING PHARMACEUTICAL MANUFACTURER LIABILITY FOR AN HIV VACCINE

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“My fellow Americans, if the 21st Century is to be the century of biology, let us make an AIDS vaccine its first great triumph.”
- President Bill Clinton¹

I. INTRODUCTION

The importance of vaccines in improving public health cannot be overstated. According to the Centers for Disease Control and Prevention (CDC), vaccines are among the greatest public health achievements of the twentieth century, if not one of the greatest achievements ever.² Widespread use of vaccines has smashed morbidity and mortality rates associated with preventable infectious diseases such as polio, smallpox, and influenza.³ Vaccines also account for substantial economic gains by reducing lost work time, enhancing productivity, and protecting the most valuable economic benefit of all—future workers.⁴

Nevertheless, instead of rushing to produce and distribute vaccines for the good of mankind, pharmaceutical manufacturing companies fled the market to such a degree that today there are only five pharmaceutical manufacturers for the five basic vaccines recommended in the United States.⁵ Furthermore, pharmaceutical companies have been slow to invest in research for vaccines that will not be rewarded with paying customers, thus largely excluding vaccines for diseases that primarily affect developing countries.⁶

1. President William Jefferson Clinton, Commencement Address at Morgan State University (May 18, 1997), <http://www.clintonfoundation.org/legacy/051897-speech-by-president-address-at-morgan-state-commencement.htm>.

2. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Ten Great Public Health Achievements—United States, 1900–1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241 (1999).

3. INST. OF MED., FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 22–23 (2004).

4. *See id.* at 28 (discussing the societal benefits of vaccines).

5. *Id.* at 1.

6. Amir Attaran et al., Ctr. For Int'l Dev., Harvard Univ., A Tax Credit for Sales of HIV, Tuberculosis, and Malaria Vaccines 2 (2000) (unpublished paper), http://www.economics.harvard.edu/faculty/kremer/files/Tax_Credit.pdf. The terms “developing countries” and “developed countries” are used throughout this Comment to

Unfortunately, the lackluster vaccine market has coincided with “one of the most formidable challenges to human life and dignity:” HIV/AIDS.⁷ With an estimated 33.2 million individuals around the world living with HIV,⁸ great hope is placed on the fact that an HIV vaccine⁹ will be developed. It will.¹⁰ But this is not the end of the struggle.¹¹ Once an HIV vaccine is developed, it must be produced, distributed, and properly administered. Since even the most fastidious scientific research will be unable to develop a perfect vaccine without any side effects, it is likely that the HIV vaccine will give rise to a certain unavoidable number of injuries and deaths.¹² These unfortunate consequences will inevitably give rise to a barrage of tort suits from injured vaccinees and the families of deceased vaccinees

differentiate between the Organization for Economic Co-operation and Development (OECD) countries, such as the United States and Japan, and the rest of the world.

7. Joint United Nations Programme on HIV/AIDS (UNAIDS), Goals, Declarations and Resolutions on AIDS, <http://www.unaids.org/en/AboutUNAIDS/Goals/default.asp> (last visited Mar. 29, 2008) [hereinafter UNAIDS Goals, Declarations and Resolutions].

8. Press Release, UNAIDS, Global HIV Prevalence Has Levelled Off; AIDS is Among the Leading Causes of Death Globally and Remains the Primary Cause of Death in Africa (Nov. 20, 2007), available at http://data.unaids.org/pub/PressRelease/2007/071119_epi_pressrelease_en.pdf (estimating the range of infected individuals globally at 30.6-36.1 million). *But see*, UNAIDS, 2006 REPORT ON THE GLOBAL AIDS EPIDEMIC 143 (2006) [hereinafter UNAIDS 2006 REPORT] (estimating a range of 34.1–47.1 million).

9. For consistency, the term “HIV vaccine” is used throughout, though the literature also refers to an “AIDS vaccine.” Furthermore, the term is used in the singular, even though it is likely that multiple vaccines will be developed. *See* NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., NIH PUBL’N NO. 04-5279, HIV VACCINES EXPLAINED: MAKING HIV VACCINES A REALITY (2005), available at <http://www.niaid.nih.gov/Publications/pdf/HIVvaccinebrochure.pdf> (explaining that multiple HIV vaccines may be necessary in order to prevent infection and treat those already infected).

10. *African HIV Vaccine Trial Launch*, BBC NEWS, Feb. 8, 2007, <http://news.bbc.co.uk/2/hi/health/6342575.stm> (reporting on the progress of the “first large-scale trial of an HIV vaccine”).

11. *See* John D. Blum, *Law as Development: Reshaping the Global Legal Structures of Public Health*, 12 MICH. ST. J. INT’L L. 207, 207 (2004) (“[I]t is often . . . an interaction of numerous factors outside of health and medicine, such as culture, politics, and economics, which block our abilities to implement solutions.”).

12. *See* OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, ADVERSE REACTIONS TO HIV VACCINES: MEDICAL, ETHICAL, AND LEGAL ISSUES 1–2 (1995) [hereinafter ADVERSE REACTIONS TO HIV VACCINES] (discussing the various risks associated with developing vaccines).

seeking compensation.¹³ Neither “the elaborate testing and review procedures mandated by the FDA, [nor] the lure of profit, [nor] the dictates of urgent medical necessity” can overcome the concern about liability exposure.¹⁴ Liability threatens manufacturers, and it threatens our public health.¹⁵

While the world is not facing a liability crisis like it did in the 1980s,¹⁶ this Comment argues that novel factors have emerged since then that make vaccine production and distribution so problematic that unless swift action is taken, an HIV vaccine, fully developed and effective, will sit unused in a science lab. The Author concludes that an International Compensation Fund is the crucial solution to ensure that manufacturers will produce an HIV vaccine in a time of uncertainty, while providing compensation for injured claimants.

Part II of this Comment provides an overview of the HIV/AIDS epidemic and the vaccine market. Part III introduces the liability context that confronts vaccine manufacturers. Part IV presents and critiques the current proposals for incentivizing manufacturers. Part V analyzes the factors that contribute to a nebulous liability context. Part VI explores solutions to the liability crisis and advocates the creation of an International Compensation Fund. Part VII concludes and advocates that immediate action be taken.

II. BACKGROUND: HIV AND THE MANUFACTURING CONTEXT

It has been over twenty years since the HIV virus was first identified and nearly as long since a vaccine has been

13. See *id.* at 3–4 (discussing the potential liability for HIV vaccines).

14. John P. Wilson, *The Resolution of Legal Impediments to the Manufacturer and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495, 504 (1994) [hereinafter Wilson I] (stating that the concerns are “partly perceptual . . . , partly rooted in bitter experience, and partly an outgrowth of understandings and misunderstandings about legal doctrine”).

15. See Philip M. Boffey, *Vaccine Liability Threatens Supplies*, N.Y. TIMES, June 26, 1984, at C1 (noting that major drug companies have dropped vaccine production due to liability costs).

16. See Wilson I, *supra* note 14, at 517 (pointing out that the crisis “crested in the middle of the [1980s]”).

promised.¹⁷ An astounding 4.3 million people became infected with HIV in 2006, while some 2.9 million died of AIDS in 2006.¹⁸ An overwhelming majority (95%) of those newly infected live in developing countries, most especially in sub-Saharan Africa, South Asia, and the former Soviet republics.¹⁹ In sub-Saharan Africa, women aged 15-24 are disproportionately affected by HIV/AIDS,²⁰ and children suffer both from the infection itself and the loss of one or both parents.²¹

Despite the gravity of the epidemic, only 24% of people in developing countries, or 1.6 million individuals, were being treated for HIV/AIDS as of June 2006.²² While the percentage of those being treated in sub-Saharan Africa rose from 2% in 2003 to 23% in 2006, the region still hosts 70% of unmet treatment in the developing world.²³ There are numerous difficulties burdening the treatment process, including high cost, the requirement of taking a multi-drug cocktail every day, lack of infrastructure, and the stigma of having HIV/AIDS.²⁴ The need for an HIV vaccine is clear: it offers the best hope for those at risk of infection and the community as a whole.²⁵ Developing a

17. See JON COHEN, SHOTS IN THE DARK 10–11 (2001) (explaining that the discovery of the AIDS virus—HIV was not yet known—was announced in 1984 and vaccine testing was promised to occur two to three years later).

18. UNAIDS 2006 REPORT, *supra* note 8, at 8. Estimates for new infections range from 3.4–6.2 million and estimates for deaths range from 2.4–3.3 million. *Id.*

19. INT'L AIDS VACCINE INITIATIVE, AIDS VACCINE BLUEPRINT 2006 1 (2006) [hereinafter IAVI BLUEPRINT]; Seth Berkley, *International Perspectives on HIV Vaccine Development*, in AIDS VACCINE RESEARCH 311, 311 (Flossie Wong-Staal & Robert C. Gallo eds., 2002).

20. See UNAIDS 2006 REPORT, *supra* note 8, at 5 (reporting that three women aged 15–24 are infected for every one man).

21. Two million children are living with HIV, and, as of 2005, 12 million children have been orphaned by AIDS. *Id.* at 15.

22. WORLD HEALTH ORG., PROGRESS IN SCALING UP ACCESS TO HIV TREATMENT IN LOW AND MIDDLE-INCOME COUNTRIES, JUNE 2006 1 (2006).

23. *Id.*

24. See *generally* UNAIDS, Policies, <http://unaids.org/en/PolicyAndPractice/default.asp> (discussing various policymaking concerns, including the driving causes of the epidemic as well as care, support, and prevention issues).

25. Vaccines directly benefit those receiving the immunization, as well as protect the unvaccinated community at large, through a process known as herd immunity, in which “[e]ven individuals not vaccinated . . . are offered some protection because the

vaccine, however, is no easy task.

First and foremost, the scientific obstacles are daunting and have largely thwarted research efforts until now.²⁶ Second, the HIV clade²⁷ most prevalent in the developed countries is not the same clade that is most prevalent in sub-Saharan Africa and much of the developing world.²⁸ Consequently, most of the vaccine research has focused on the clades most prevalent in developed countries, despite the greater need elsewhere.²⁹ This is problematic because any successful HIV vaccine for developing countries must “be appropriate for use in those environments” and thus must involve scientists and policymakers in the developing countries.³⁰

Third, the global market for vaccines is simply too small to draw significant interest from large pharmaceutical manufacturers: the \$6 billion annual revenues from vaccines represent a mere 1.5% of the \$535 billion global pharmaceutical market.³¹ Ironically, vaccine sales are destined to remain only a

disease has little opportunity to spread within the community.” Ctrs. for Disease Control & Prevention, Dep’t of Health & Human Servs., Vaccines & Immunizations: Glossary, <http://www.cdc.gov/vaccines/about/terms/glossary.htm> (last visited Mar. 29, 2008).

26. See NAT’L INSTS. OF HEALTH, FISCAL YEAR 2007 PLAN FOR HIV-RELATED RESEARCH 127 (2007) (providing a comprehensive overview of the scientific issues being researched by the National Institutes of Health).

27. There are at least 10 subtypes, or clades, of the HIV virus in the world. WORLD BANK, ACCELERATING AN AIDS VACCINE FOR DEVELOPING COUNTRIES: HOW CAN INTERNATIONAL DEVELOPMENT HELP? 5 (1999), available at <http://www.worldbank.org/aidsecon/vacc/safrcrca.pdf>. Clade B is the predominant strain found in North America and Europe, while clades A, C, D, and E are predominantly found in sub-Saharan Africa and Asia. *Id.*; Lucy Doral et al., *Distinct Recognition of Non-Clade B Human Immunodeficiency Virus Type 1 Epitopes by Cytotoxic T Lymphocytes Generated from Donors Infected in Africa*, 73 J. VIROLOGY 1708, 1708 (1999).

28. Michael Kremer, *Stimulating R&D on Vaccines for AIDS, Tuberculosis, and Malaria 1* (2000) (unpublished paper), http://www.economics.harvard.edu/faculty/kremer/files/Stimulating_Rnd_Vaccines.pdf [hereinafter Kremer I].

29. *Id.*

30. Berkley, *supra* note 19, at 312. For instance, vaccines that must be refrigerated would not be useful in a country where electricity is scarce. *See id.* at 314. Also, countries differ in their opinions on acceptable risk levels: what is an acceptable or inherent risk to one country is not necessarily the same for another. *See id.*

31. See INST. OF MED., *supra* note 3, at 107–08; INDUS. INFO RES., IIR’S 2007 PHARMACEUTICAL INDUSTRY FORECAST (2007), http://www.industrialinfo.com/outlook_2007_pharm/demo/index.jsp. This is roughly the same size as global sales from one drug such as Lipitor. INST. OF MED., *supra* note 3, at 107–08.

tiny fraction of the market because of the very benefit they seek to confer: prevention, not treatment.³² Many drugs serve a repeat—even lifetime—market, but vaccines are only administered once or a handful of times, thus limiting their potential to reap economic rewards.³³

A. *The Vaccine Production Process*

A larger market, though more attractive financially, would not necessarily make vaccine development any easier because of the inherent difficulties in the research and development process.³⁴ Funding and investment are hard to come by, government regulations are nightmarishly complex, and bulk purchases by governments depress the sales price such that the value of vaccines is underappreciated.³⁵

Still, the greatest barrier to entry is the incredibly high cost involved.³⁶ It costs an estimated \$800 million to bring a single vaccine to market, excluding the marginal production costs of additional doses and the costs of continued compliance and monitoring.³⁷ Three main factors contribute to the high and rising costs of research and development.³⁸ First, the inputs—including scientists, capital equipment, and animal and clinical trials—are highly technical, highly specialized, and thus highly expensive.³⁹ Second, the regulatory process involves stringent requirements that lead to high failure rates: only one in five products reaching the phase of clinical testing in humans is approved by the FDA.⁴⁰ Third, the opportunity cost of capital

32. See INST. OF MED., *supra* note 3, at 108, 116 (citing MERCER MGMT. CONSULTING, LESSONS LEARNED: NEW PROCUREMENT STRATEGIES FOR VACCINES (2002)).

33. PAUL F. BASCH, VACCINES AND WORLD HEALTH 181 (1994).

34. Adel Mahmoud et al., *Product Development Priorities*, in DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 139, 143 (Dean T. Jamison et al. eds., 2006) (discussing difficulties in the vaccine development process).

35. *Id.*

36. *Id.*

37. *Id.* at 141.

38. *Id.*

39. *Id.*

40. *Id.* The typical vaccine cycle is as follows: concept development; pre-clinical testing in animals; clinical testing in humans; production; regulatory assessment; and “access interventions.” INT’L AIDS VACCINE INITIATIVE, A NEW ACCESS PARADIGM:

during the investment period is incorporated into the cost figures.⁴¹ The process is not only incredibly costly but also lengthy: it takes an astounding thirty-five years or more for two-thirds or less of the individuals in developing countries to receive a vaccine.⁴²

Nonetheless, the basic paradigm of vaccine development has begun to shift in favor of increased participation by developing countries.⁴³ While most of the pharmaceutical research, development, and production in the past took place in the United States, the European Union, and Japan—a paradigm that has arguably “served the process of product development well”—many developing countries, notably Brazil, India, and Singapore, are “initiating a new wave of fundamental research institutions.”⁴⁴

B. Research Partnerships

Research investment comes from both the public and private sectors.⁴⁵ Public sector research largely focuses on basic research that advances understanding of underlying diseases.⁴⁶ Some of the largest research efforts to date have been government-funded, including the National Institute of Health’s record \$620 million 2007 budget for HIV vaccine research.⁴⁷ In fact, George W. Bush’s President’s Emergency Plan for AIDS Relief (PEPFAR) represents the “largest commitment ever by

PUBLIC SECTOR ACTIONS TO ASSURE SWIFT, GLOBAL ACCESS TO AIDS VACCINES 6 (2001) [hereinafter IAVI PARADIGM].

41. Mahmoud et al., *supra* note 34, at 141.

42. IAVI PARADIGM, *supra* note 40, at 29.

43. Mahmoud et al., *supra* note 34, at 140.

44. *Id.* Merely conducting trials in developing countries could save pharmaceutical companies ten to twenty percent in costs. *Id.* at 142.

45. *Id.* at 146.

46. Banri Ito & Tatsufui Yamagata, Who Develops Innovations in Medicine for the Poor? Trends in Patent Applications Related to Medicines for HIV/AIDS, Tuberculosis, Malaria, and Neglected Diseases 22 (Apr. 2005), <http://ideas.repec.org/p/jet/dpaper/dpaper24.html> (stating that “it is well known that public research institutes and universities have contributed to both critical and fundamental innovations . . . [and] are likely to engage in upstream and scientific discoveries”).

47. OFFICE OF AIDS RESEARCH, NAT’L INST. OF HEALTH, FY 2007 BUDGET 14 (2006), <http://www.oar.nih.gov/public/pubs/fy2007/fy07oarcj.pdf>.

any nation for an international health initiative dedicated to a single disease.”⁴⁸ Public sector research, however, is less likely to result in a marketable product, such as a vaccine, because of the emphasis on basic, not product-specific, research.⁴⁹

In contrast, private sector research is much more disease-specific and focuses narrowly on developing a product.⁵⁰ Pharmaceutical companies are much more likely, and generally better suited financially, to develop a vaccine; however, unlike the government, they must provide a competitive return to their shareholders and investors.⁵¹ To this end, pharmaceutical companies focus on satisfying the paying market in developed countries.⁵²

Developing countries will generally only benefit from a vaccine when the manufacturer can recoup its investment through sales to developed countries and be satisfied with selling its vaccine at a marginal cost to the rest of the world.⁵³ In order to avoid such inequitable results, a fresh approach is needed.⁵⁴

In order to reap the best of the public and private worlds, the vaccine research community has witnessed the rise of collaborative efforts to tackle HIV vaccine development.⁵⁵ Some organizations, such as public-private partnerships (PPPs), essentially amount to public subsidies of private industry

48. U.S. GLOBAL AIDS COORDINATOR, BUREAU OF PUB. AFFAIRS, U.S. COMMITMENT TO GLOBAL HIV/AIDS (2007), <http://milan.usconsulate.gov/downloads/PEPFAR.pdf>. PEPFAR, a five year, \$15 billion effort to combat HIV/AIDS, was announced by President George W. Bush during his 2003 State of the Union Address. George W. Bush, President of the U.S., Address Before a Joint Session of Congress on the State of the Union (Jan. 28, 2003), in PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES, 2006, at 82–90.

49. Mahmoud et al., *supra* note 34, at 146.

50. *Id.*

51. *Id.*

52. *Id.*

53. *See id.* (noting the relationship between economics and vaccines).

54. *See* FAQ: Global HIV Vaccine Enterprise, http://www.aidsvaccineclearinghouse.org/enterprise_faq.htm (last visited Mar. 29, 2008) (stating the purpose of the Enterprise as “tackling major scientific problems that have proven too difficult for any one group to address alone”).

55. *See* Mahmoud et al., *supra* note 34, at 147–48 (discussing the growth of public-private partnerships).

research.⁵⁶ PPPs coordinate various research efforts under one roof and seek to smooth the road for all entities involved.⁵⁷ Such efforts, most notably the Global HIV Vaccine Enterprise, represent “a new way of doing business”⁵⁸ that tackles the HIV vaccine process from vaccine discovery to regulatory and intellectual property issues.⁵⁹ By recognizing that researchers and manufacturers must be rewarded for their work,⁶⁰ for instance, or that inadequate regulatory schemes in developing countries hinder adequate clinical trials,⁶¹ these cross-disciplined, multinational efforts are reshaping the vaccine development paradigm and arriving at a more equitable and expeditious result.⁶²

III. THE LIABILITY CONTEXT

In the 1980s, tort liability decimated the vaccine industry and left it crippled and forever changed.⁶³ It is estimated that plaintiffs sought \$3.5 billion in damages from vaccine

56. See IAVI BLUEPRINT, *supra* note 19, at 10 (finding that government and private organizations split research and development costs and guarantee a market in developing countries).

57. See Mahmoud et al., *supra* note 34, at 148 (discussing the structure and operation of PPPs).

58. Global HIV Vaccine Enterprise, *supra* note 54.

59. See, e.g., Global HIV Vaccine Enterprise Strategic Plan, <http://www.hivvaccineenterprise.org/plan> (last visited Mar. 29, 2008) (listing the Enterprise’s six priority areas).

60. See, e.g., Global HIV Vaccine Enterprise Intellectual Property Issues, <http://www.hivvaccineenterprise.org/plan/6.aspx> (last visited Mar. 29, 2008) (recommending intellectual property arrangements that “incentivize and protect individual researchers and companies”).

61. See, e.g., Global HIV Vaccine Enterprise Regulatory Issues, <http://www.hivvaccineenterprise.org/plan/5.aspx> (last visited Mar. 29, 2008) (recommending “[i]mproving regulatory capacity” to “minimize bottlenecks” in clinical trials).

62. See STAFF TRIP REP. TO THE S. COMM. ON FOREIGN RELATIONS, 109TH CONG., 2005 AIDS VACCINE INT’L CONFERENCE, MONTREAL, CANADA, SEPT. 6–9, 2005 3 (Comm. Print 2005) (statement of Chris Ann Keehner, Counsel, S. Comm. on Foreign Relations) (“[M]ost experts agree that there is a need for a much larger-scaled, better-coordinated, better-funded effort, consisting of researchers from different organizations working together to solve given scientific problems.”).

63. H.R. REP. NO. 99-908, at 6–7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347–48.

manufacturers between 1980 and 1984 alone.⁶⁴ Vaccine manufacturers fled the market as they faced mounting litigation costs and huge jury awards for those suffering adverse side effects and death from mandatory childhood vaccines.⁶⁵ Those manufacturers who remained in the market raised their prices significantly in order to recoup costs.⁶⁶ The net result was a disorganized private vaccine market characterized by fewer manufacturers, higher prices, and a strong aversion to increased research and development.⁶⁷ In short, there was a public health disaster.⁶⁸

While many were quick to point their fingers at enormous jury awards, the real problem, ironically, was the lack of compensation available at all: plaintiffs had little choice but to resort to the judicial process.⁶⁹ In response, the United States Congress enacted the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”)⁷⁰ a national no-fault compensation scheme for victims of certain vaccine-related injuries.⁷¹ The Vaccine Act was seen as a compromise that gave injured plaintiffs a forum for compensation while protecting the manufacturing industry

64. STAFF OF SUBCOMM. ON HEALTH AND THE ENV'T OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., REPORT ON CHILDHOOD IMMUNIZATIONS, 86–99, at 86 (2d Sess. 1986).

65. See U.S. NAT'L VACCINE ADVISORY COMM., DEP'T OF HEALTH & HUMAN SERVS., STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES 16 (2003) (“[L]itigation led to national shortages, withdrawal of manufacturers from the marketplace, and instability of supply of essential childhood vaccines.”).

66. H.R. REP. NO. 99-908, at 4. Costs include not only direct litigation costs, but also insurance coverage. See *id.* at 6 (discussing the impact of insurance availability on vaccine manufacturers).

67. See generally *id.* at 4–7 (discussing the recent history of vaccines in the United States leading to legislation); *Vaccines—Endangered Species?*, 3 NATURE IMMUNOLOGY 695 (2002) (citing the dearth of companies producing vaccines as a reason for the world's vaccine shortages).

68. See H.R. REP. NO. 99-908, at 7 (“The loss of any of the existing manufacturers of . . . vaccines at this time could create a genuine public health hazard in this country.”). In fact, pharmaceutical manufacturers who never even lost a single liability suit were forced to pull drugs off the market, most notably Bendectin, due to the hostile liability climate. Wilson I, *supra* note 14, at 506.

69. H.R. REP. NO. 99-908, at 4.

70. 42 U.S.C. § 300aa (1994) [hereinafter Vaccine Act].

71. H.R. REP. NO. 99-908, at 3.

from crippling liability.⁷² This compromise embodies the ongoing public debate concerning vaccines, namely, striking the proper balance between product safety and product availability.⁷³

A. *Tort Liability in the United States*

In the United States, products liability, in general, and pharmaceutical liability, in particular, are based on strict liability.⁷⁴ Strict liability encourages optimum product safety by granting consumers a cause of action without having to show fault on the part of the manufacturers, but there are significant exceptions built into the doctrine that protect manufacturers.⁷⁵ The European Union and Japan, where most other pharmaceutical companies are located, have also adopted strict liability as the basis for their products liability law.⁷⁶

The doctrine of products liability in the United States has undergone significant doctrinal changes since the crisis of the 1980s and is embodied in the Third Restatement of Torts.⁷⁷ According to Section 6(c), a drug has a defective design if “the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable healthcare providers . . . would not prescribe the drug or medical device for *any* class of patients.”⁷⁸ This is a significant policy statement acknowledging that drugs, such as vaccines, have foreseeable risks of harm, and these risks should

72. *See id.* at 7 (acknowledging that one of the overriding concerns for implementing the Vaccine Act was “the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine”).

73. Daniel A. Cantor, Comment, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1855 (1995).

74. *See generally* Katherine A. Davis, Comment, *An International Drug Administration: Curing Uncertainty in International Pharmaceutical Product Liability*, 18 NW. J. INT’L L. & BUS. 685, 688 (1998) (noting that section 402A of the Second Restatement of Torts adopted the doctrine of strict liability).

75. *Id.* at 688–69.

76. *Id.* at 692, 696.

77. *See* RESTATEMENT (THIRD) OF TORTS § 6 (1998) (specifying tort liability for sellers and distributors of medical drugs and devices).

78. *Id.* § 6(c) (emphasis added).

be tolerated to a degree.⁷⁹ The point at which consumers are no longer required to bear the risk of harm—the point at which the drug is defective—is when there is no net benefit for any class of patients.⁸⁰ By repudiating the much-criticized concept of “[u]navoidably unsafe products” from the Second Restatement⁸¹ and opening the door to liability,⁸² a vaccine manufacturer could be liable for foreseeable risks that it has taken every precaution to avoid.⁸³

Section 6(d) of the Third Restatement defines a drug as defective for not being reasonably safe due to inadequate instructions or warnings in two ways.⁸⁴ The first is where instructions or warnings are not given to “healthcare providers who are in a position to reduce the risks of harm.”⁸⁵ This is an adoption of the “learned intermediary” doctrine, which states that pharmaceutical companies do not need to directly warn ultimate purchasers or consumers of foreseeable risks of harm if those warnings are given to the prescribing physician.⁸⁶ The rationale behind this is that the treating physician, as a learned intermediary, has discharged the manufacturer’s duty to warn by assuming the responsibility to provide the warnings to the patient.⁸⁷ To take advantage of the liability protection, the

79. See Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 647 (2007) (stating a jury must decide if the harm is outweighed by societal benefits). This is essentially a risk-benefit analysis, where a “product is not defective if its social utility and the cost of improving its safety outweigh the accident costs . . .” Peggy Naile, *Tort Liability of DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 678 (1989).

80. See RESTATEMENT (THIRD) OF TORTS § 6(c) (1998).

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

82. RESTATEMENT (THIRD) OF TORTS § 2(b) (stating that a product “is defective in design when the foreseeable risks of harm . . . could have been reduced or avoided” and the resulting product is “not reasonably safe . . .”). This is a much lower threshold for plaintiffs to prove. See AM. LAW OF PRODS. LIAB. 3D § 16:24 (2008) (stating that plaintiffs only need to prove a negligence standard).

83. See *id.* §§ 6(a)–(b) (stating that a manufacturer is subject to liability for manufacturing defects and for drugs that are not reasonably safe due to defective design or inadequate instructions or warnings).

84. *Id.* § 6(d).

85. *Id.* § 6(d)(1).

86. *Reyes v. Wyeth Labs*, 498 F.2d 1264, 1276 (5th Cir. 1974).

87. Jaelyn Carole Hill, *The Learned Intermediary Doctrine and Beyond*, 72 DEF.

manufacturer must provide the warnings and instructions to the healthcare provider who must be able to balance the risks.⁸⁸

The rationale behind the learned intermediary doctrine, however, does not hold up in the context of mass immunizations, where patients do not receive the benefit of having a physician personally detail and balance the risks for them.⁸⁹ The so-called “mass immunizations exception,” which is the second alternative for defining a drug as defective under Section 6(d)(2), states that the drug manufacturer must directly warn the patient “when the manufacturer knows or has reason to know that healthcare providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”⁹⁰ Manufacturers have an obligation, now firmly rooted in the language of the Restatement, to ensure that patients in mass immunization settings—really, any setting where a healthcare provider will not be able to balance risk—are directly provided with warnings.⁹¹ It follows, then, that the more complex and difficult the vaccine distribution is, the more exposed manufacturers are.

IV. EXAMINATION AND CRITIQUE OF CURRENT PROPOSALS TO INCENTIVIZE MANUFACTURERS

Even if an HIV vaccine is developed by scientific researchers, most of whom express optimism that it is scientifically feasible, numerous obstacles impede the production of a vaccine, especially one destined for developing countries.⁹² Researchers have come up with a wide range of proposals to encourage investment in vaccines, ranging from tax credits to

COUNS. J. 362, 367 (2005).

88. RESTATEMENT (THIRD) OF TORTS § 6(d)(1) (1997).

89. *Davis v. Wyeth Labs.*, 399 F.2d 121, 131 (9th Cir. 1968).

90. *See Mazur v. Merck & Co.*, 964 F.2d 1348, 1355 (3d Cir. 1992) (referring to the doctrine as the mass immunizations exception); RESTATEMENT (THIRD) OF TORTS § 6(d)(2) (1997).

91. *See id.* (explaining manufacturers must directly warn the patient when healthcare providers are not in a position to reduce the risks of harm); *Davis*, 399 F.2d at 130–31 (concluding that, in mass immunization settings, manufacturers have a duty to warn the patient).

92. WORLD BANK, ACCELERATING AN AIDS VACCINE FOR DEVELOPING COUNTRIES § 1 ¶ 6 (2000), available at <http://www.worldbank.org/aidsecon/vacc/accelerateb.pdf> [hereinafter WORLD BANK, ACCELERATING AN AIDS VACCINE].

purchase commitments for patent buyouts.⁹³ These proposals can be divided into two major categories: push programs, which seek to reduce the risks and costs associated with investment, and pull programs, which seek to recoup the investment.⁹⁴ However, these proposals, by themselves, will ultimately fail to provide enough incentives for manufacturers to produce and distribute an HIV vaccine. While they address the financial side of vaccine development, they do not address liability.⁹⁵ There is simply too much uncertainty in producing and distributing an HIV vaccine that market incentives do not address.⁹⁶

A. Push Programs

The push programs target the front end of the manufacturing process—basic research—by subsidizing the costs of research and other inputs.⁹⁷ The most common push programs are grants given directly to research entities and pharmaceutical companies or channeled through PPPs such as IAVI.⁹⁸ Those entities involved in the basic research stages are most supportive of direct financial support.⁹⁹ While some of the funding is of a general nature, other push programs take aim at specific aspects of the research cycle, such as reducing the risks

93. Rachel Glennerster & Michael Kremer, *A Better Way to Spur Medical Research and Development*, 23 REGULATION 34, 38 (2000).

94. Amie Batson & Martha Ainsworth, *Private Investment in AIDS Vaccine Development: Obstacles and Solutions*, 79 BULL. OF THE WORLD HEALTH ORG. 721, 724 (2001).

95. The difference between a company implementing financial incentives and actually realizing the potential savings is a “matter of judgment depending on perceived liability risks.” Mahmoud et al., *supra* note 34, at 142.

96. See Davis, *supra* note 74, at 702 (“Uncertainty breeds fear, and in the pharmaceutical market, the uncertainty surrounding product liability cases has bred a fear of devastating liability.”).

97. See INT’L AIDS VACCINE INITIATIVE, MORE ON PUSH MECHANISMS, <http://www.iavi.org/viewfile.cfm?fid=1087> (2007) [hereinafter IAVI PUSH] (discussing how push mechanisms reduce the cost of research and development).

98. See Alan Dove, *World Bank Task Force Push/Pulls AIDS Vaccines*, 17 NATURE BIOTECHNOLOGY 846, 846 (1999) (stating that many biotechnology companies prefer push mechanisms that are often funded by non-profit organizations). The World Bank, for instance, contributes \$1 million annually to IAVI. *Id.* at 846 tbl.1.

99. *Id.* at 846.

associated with clinical trials.¹⁰⁰ For instance, funding could be used to improve the public health infrastructure in the developing countries where the vaccine trials will take place.¹⁰¹

A different push program uses tax credits as incentives, such that a certain percentage of research and development expenditures can be written off tax-free, generating significant savings for firms heavily investing in research.¹⁰² For those companies without taxable income, such as small biotechnology companies, alternative incentives, including simple refunds or carry-forward tax credit provisions that can be used once the company begins to make taxable income, might be more appropriate.¹⁰³

A separate set of tax credits targets the sales of vaccines, such that every dollar off the sale of a vaccine sold to an accredited buyer such as the United Nations would garner one dollar in tax credit.¹⁰⁴ This would benefit buyers (accredited organizations) in addition to sellers (manufacturers), because the buyers, by guaranteeing the pharmaceutical companies' tax savings, are put in a better bargaining position.¹⁰⁵ Perhaps the greatest benefit of the tax credits is that nothing would be lost until and unless a vaccine is developed: there are no premature expenditures, thus tax credits are a politically attractive solution.¹⁰⁶ Both the United States and the United Kingdom have introduced legislation codifying the tax credits.¹⁰⁷

Push programs could also target the lengthy and

100. *Id.* at 846 tbl.1.

101. *Id.* at 846.

102. IAVI PUSH, *supra* note 97.

103. *Id.* Small biotech companies could benefit indirectly from tax credits because a pharmaceutical company will more likely invest in and produce a vaccine developed by a small biotech if they are able to reap tax credits. Kremer I, *supra* note 28, ¶ 3.

104. Attaran et al., *supra* note 6, at 2–3.

105. Kremer I, *supra* note 28, ¶ 2. It is further hoped that more buyers would come forward and purchase vaccines, bestowing additional tax credits on the producers and thus creating a program of matching contributions. Attaran et al., *supra* note 6, at 3.

106. Attaran et al., *supra* note 6, at 3; Kremer I, *supra* note 28, ¶ 6.

107. Chris Collins, *AIDS Vaccine Tax Legislation Proposed in the US and UK*, IAVI REP. (Int'l AIDS Vaccine Initiative, New York, N.Y.), Apr.-June 2001, at 7, 7–8, available at <http://www.aegis.com/pubs/iavi/2001/IAVI2001-0405.html>.

complicated regulatory approval process.¹⁰⁸ While the approval process necessarily requires exceptionally high standards and thorough review in order to protect consumers, it need not be lengthy and costly.¹⁰⁹ The Food and Drug Administration (FDA), for instance, has “fast track” and “priority review” procedures that can cut approval time in half.¹¹⁰ The European Medicines Agency (EMA) also offers expedited review that is applicable for “drugs that are likely to have their largest impact in[]developing countries.”¹¹¹ The hope is that such fast track procedures will prioritize approval of an HIV vaccine and drastically cut down the time and costs involved, while maintaining the same high standards.¹¹²

B. . . . Are Not Enough

It is unclear, however, whether or not tax credits effectively stimulate research. Some studies suggest that, at most, tax credits have a “modest impact in stimulating private R&D investment.”¹¹³ Many companies see the probability of developing an effective vaccine as too low to merit research.¹¹⁴ It is the risk in development that should be reduced, not the future market reward that should be increased.¹¹⁵ Tax credit incentives have been utilized in the past to foster commercially viable products in developed countries, but they have been far less successful at stimulating research for products needed most in developing countries.¹¹⁶ In addition, carry-forward tax provisions are mostly applicable to smaller research companies

108. Mahmoud et al., *supra* note 34, at 152.

109. IAVI PUSH, *supra* note 97.

110. *Id.*

111. *Id.*

112. See IAVI PARADIGM, *supra* note 40, at 22 (“[R]egulatory systems are not appropriately geared to ensure the most rapid access possible (without compromising safety) to AIDS vaccines.”).

113. Collins, *supra* note 107, at 8, 16.

114. Batson & Ainsworth, *supra* note 94, at 724.

115. See *id.* (“[C]orporate decisions were heavily biased towards reducing the risk in development rather than . . . increasing the potential reward.”).

116. Collins, *supra* note 107; see also IAVI PARADIGM, *supra* note 40, at 20 (suggesting a “limited impact on research for AIDS vaccines and other diseases afflicting developing countries”).

and not the large pharmaceutical companies that will likely develop an HIV vaccine.¹¹⁷ Furthermore, the tax credits targeting sales assume the development of a vaccine.¹¹⁸ Companies need incentives to develop a vaccine *before* a vaccine is developed.

While it is true that there might not be much to lose by implementing tax credits, there might not be much to gain either. Tax credits are largely geared toward spurring investment in research and development, while much of the apathy towards producing a vaccine for a disease that predominately affects the developing world is the lack of a commercial market.¹¹⁹ Tax credits have the potential to affect the commercial market by lowering costs, but this is only an indirect benefit at best and is far from a guarantee.¹²⁰ The reason for this is simple: a tax credit is an incentive for firms to invest, not a mechanism for lowering the sales price of a vaccine.¹²¹ A lower sales price will only result from the firms themselves lowering the price after internalizing the savings from the tax credit or negotiating lower prices from organizational purchasers.¹²² The onus to benefit the commercial market is still placed on the pharmaceutical company selling the vaccine, which is exactly where it always was.

Consider: if manufacturers require tax credits to encourage HIV vaccine development in the first place, it logically follows that they will not cancel out any resulting profits by lowering vaccine prices. Likely, this would require additional tax incentives.¹²³ The optimism with a tax credit must be tempered

117. Kremer I, *supra* note 28, ¶ 3.

118. Attaran et al., *supra* note 6, at 1 (“Either a vaccine will be developed, or the tax credit will cost nothing.”).

119. Attaran et al., *supra* note 6, at 1–2. In fact, market assurances alone are not enough: the assurances must be *credible*. Batson & Ainsworth, *supra* note 94, at 724.

120. See Kremer I, *supra* note 28.

121. Attaran et al., *supra* note 6, at 1.

122. *Id.* at 3.

123. See Benedict Irvine, *Private Sector Needs Incentives for AIDS Vaccine*, 329 BRIT. MED. J. 979, 979 (2004), available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=524154&blobtype=pdf> (listing additional incentives as “guaranteed volume sales, tiered pricing alongside anti-

by the realization that it took a tax credit just to get the manufacturer to the starting line; more is required to get them to actually run the race. By itself, a tax credit does not fundamentally alter the incentive structure.

Furthermore, market strategies to encourage production of an HIV vaccine for a market that does not yet exist *must* fail. It is imperative, therefore, that an HIV vaccine not be treated like a commodity that only responds to market pressures. The HIV vaccine is not like a toy that will be produced as long as a demand exists and then taken off the shelves as demand shrinks; it is a vital weapon to combat the most serious obstacle hindering progress in the developing world.¹²⁴ It is too important to be treated like a commodity.

C. Pull Programs

Pull programs seek to encourage vaccine development by focusing on the market for vaccines,¹²⁵ “combin[ing] market-based financing tools with public intervention.”¹²⁶ A market for an HIV vaccine will exist, but it will be a largely non-paying market.¹²⁷ Consequently, the purpose of pull programs, for the most part, is to transform a non-paying market into one that does pay and reward manufacturers for developing a vaccine.¹²⁸

reimportation measures, public and intergovernment subsidies and philanthropic donations”).

124. See IAVI BLUEPRINT, *supra* note 19 at 1 (“AIDS has dramatically reduced life expectancy, created an unprecedented orphan crisis, and fostered social and political instability—AIDS has become a true development issue.”).

125. Dove, *supra* note 98, at 846, 846 tbl.1.

126. Press Release, GAVI Alliance, Five Nations and the Bill & Melinda Gates Foundation Launch Advance Market Commitment for Vaccines to Combat Deadly Disease in Poor Nations (Feb. 9, 2007), http://www.gavialliance.org/media_centre/press_releases/2007_02_09_en_pr_amc.php (quoting Tommaso Padoa-Schioppa, Italian Finance Minister).

127. See WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 5 (emphasizing that the *needs* of the 2.5 billion uninfected persons in developing countries do not necessarily equate to actual *demand*, as there are far fewer willing and able buyers than infected individuals).

128. See Rachel Glennerster et al., *Creating Markets for Vaccines*, INNOVATIONS, Winter 2006, at 67, 71, available at <http://www.mitpressjournals.org/loi/itgg> (arguing that pull programs provide the opportunity to foster research by taking a market-oriented approach to solving the problem). Many vaccine manufacturers admit that

One set of pull programs encourages product research and development by creating a guaranteed market for vaccines.¹²⁹ For instance, a private donor, government, or international organization will make a commitment to purchase a supply of vaccines at a certain price once the vaccine is developed.¹³⁰ One variation, the Advance Market Commitments (AMCs), operates as “a legally-binding promise to vaccine manufacturers to pay a price for a future AIDS vaccine.”¹³¹ Global donors would buy HIV vaccines at a higher price, and the manufacturer would then turn around and sell the vaccines to developing countries at a much lower price.¹³² AMCs would both utilize two-tiered pricing (donor price and actual sale price) and benefit from a guaranteed commercial market.¹³³

Contingent loans or trust funds specifically earmarked to purchase HIV vaccine doses could also help to guarantee a market.¹³⁴ While they effectively amount to third-party subsidization or outright purchase of vaccines, they have the benefit of vesting a certain amount of responsibility in the local governments, a necessary component of improving the health infrastructure.¹³⁵

A corollary to the idea of market assurances for future vaccines is stimulating the market for *existing* vaccines.¹³⁶ By improving existing delivery systems and stimulating demand for vaccines already available on the market, the industry will have

“without firm commitments for future vaccine purchases, the incentive to invest in increased capacity is considerably lessened.” *Vaccines—Endangered Species?*, *supra* note 67, at 695.

129. Glennerster & Kremer, *supra* note 93, at 38–39.

130. *Id.* at 38.

131. INT’L AIDS VACCINE INITIATIVE, ADVANCE MARKET COMMITMENTS: HELPING TO ACCELERATE AIDS VACCINE DEVELOPMENT 1 (2005), <http://www.iavi.org/file.cfm?fid=35155> [hereinafter IAVI COMMITMENTS].

132. *Id.*

133. *Id.* at 1–4.

134. WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 3. The World Bank, for instance, operates such a trust fund. Dove, *supra* note 98, at 846 tbl.1.

135. See IAVI PARADIGM, *supra* note 40, at 26 (stressing the importance of localized involvement if progress is to be made in achieving widespread access to an AIDS vaccine).

136. Dove, *supra* note 98, at 846 tbl.1.

more confidence in the ability of developing countries to purchase and distribute HIV vaccines.¹³⁷

Two final pull programs worth mentioning are differential pricing and the offering of a significant monetary prize to the company that develops the HIV vaccine. Differential, or tiered, pricing allows manufacturers to sell drugs and vaccines at higher prices to developed countries and lower prices to developing countries.¹³⁸ Differential pricing schemes have been tried several times in the past with some success in developing countries, though they have elicited a backlash from developed countries.¹³⁹ As for offering a significant monetary prize to the first company to develop an HIV/AIDS vaccine, it is difficult to see how a prize, while serving a worthy symbolic purpose, can reduce the financial burden placed on manufacturers.¹⁴⁰

There are several benefits to pull programs. First, manufacturers have a strong financial incentive to develop and produce an HIV vaccine¹⁴¹ since they are contractually assured of a purchase.¹⁴² Second, for many donors, including taxpayers, it is easier to justify spending on an actual product that is waiting to be distributed rather than spending on generalized

137. *Id.* Just because a vaccine is currently available does not mean that it is being used and distributed worldwide. Batson & Ainsworth, *supra* note 94, at 722–23. The under-use of the Hepatitis B vaccine is a tragic example of how market forces have prevented a vaccine from being distributed worldwide. *Id.*

138. Mahmoud et al., *supra* note 34, at 146. The net result is that eighty-two percent of vaccine revenues are generated in developed countries, where only twelve percent of vaccine doses are actually administered. INST. OF MED., *supra* note 3, at 109.

139. See Batson & Ainsworth, *supra* note 94, at 724 (alluding to industry concerns regarding the price disparity between vaccines in high and low income nations).

140. *Id.* at 725 (“[T]he existence of a prize would not ensure either production or purchase of the vaccine.”). *But see, e.g.*, Glennerster & Kremer, *supra* note 93, at 36 (noting that prizes provide strong incentives to researchers).

141. See MICHAEL KREMER, U.N. DEV. PROGRAMME, A PURCHASE COMMITMENT FOR VACCINES, <http://www.undp.org/ods/monterrey-papers/kremer.pdf> [hereinafter Kremer II] (explaining that with respect to a purchase commitment, an investor can stimulate vaccine research by committing to purchase and distribute a vaccine once it is developed). Some manufacturers believe that a guaranteed market, albeit one that is willing to purchase vaccines at a high price, is the best incentive for research. Michael Kremer, *Creating Markets for New Vaccines* 41 (Nat’l Bureau of Econ. Research, Working Paper No. 7716, 2000) [hereinafter Kremer III].

142. Glennerster & Kremer, *supra* note 93, at 38.

research that might not yield any results.¹⁴³ This is clearly politically attractive as well. Third, and perhaps most importantly, nothing is spent until and unless a vaccine is developed and produced.¹⁴⁴ Purchase commitments thus represent the ultimate win-win situation for investors, because their money will be well spent on risky research and development while bearing no risk of failure.¹⁴⁵

It is further hoped that such purchase commitments will have a beneficial effect on the distribution process.¹⁴⁶ If the government of an African nation, for instance, commits to purchasing a supply of vaccines, even at a reduced price, it has less motivation to manipulate the market price of vaccines.¹⁴⁷ In addition, participating countries might become more involved in the development process and undertake to monitor whether or not the vaccine is suitable for local use.¹⁴⁸

D. . . . Are Also Not Enough

One of the biggest problems with relying on market incentives to tackle the problem of manufacturer reluctance is that there is a dearth of information available about the market for vaccines in developing countries.¹⁴⁹ Predictions about industry willingness to invest in an HIV vaccine is based almost entirely on very limited information and grand extrapolations that may have very little bearing on reality.¹⁵⁰ The sophisticated market research that is often conducted in developed countries

143. Kremer III, *supra* note 141, at 4.

144. Attaran et al., *supra* note 6, at 3.

145. IAVI COMMITMENTS, *supra* note 131, at 1.

146. *See* Kremer II, *supra* note 141 (describing the temptation to use state power to manipulate vaccine prices).

147. *See id.* (arguing that governments would be more apt to ensure the equitable dissemination of vaccines if their motivations did not conflict with research and development interests).

148. *Id.*

149. WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 3 (“There have been no published empirical studies of the public or private willingness to pay for an AIDS vaccine in developing countries.”).

150. Batson & Ainsworth, *supra* note 94, at 722–23 (contrasting the various scientific uncertainties companies dealt with when researching commercial opportunities for an HIV vaccine).

is largely unavailable for much of the rest of the world, such that current projections are mere guesswork.¹⁵¹ In fact, many analysts argue that more accurate market research alone could assuage—or confirm, of course—manufacturers’ misgivings about the lack of a paying market.¹⁵² Without reliable information, market incentives poorly address manufacturer fears.

Differential pricing brings additional concerns to the table besides the enmity of developed countries. A well-functioning tiered system will require safeguards to ensure that the lower-priced drugs intended for distribution in developing countries are not diverted and sold at cost in developed countries.¹⁵³ Differential pricing, more importantly, is ultimately a balancing act for the manufacturers: what is the lowest price at which they are willing to sell in developing countries and the highest acceptable price at which they can sell in developed countries in order to make up the difference?¹⁵⁴ Should the math not work out favorably, pharmaceutical companies are not likely to support differential pricing.

Arguably, manufacturers might be more willing to invest in an HIV vaccine knowing that there is a guaranteed market of sufficient size. There is no doubt that such assurances will significantly improve the balance sheets, reassure stockholders, and generally paint a rosier picture of how the massive research investments will be recouped. But such incentives do not fundamentally change the manufacturing process. As with many of the push programs, the onus is still on the pharmaceutical

151. See Mahmoud et al., *supra* note 34, at 139 (stating that products development data relating to the treatment of major global diseases in developing countries is not readily available and must be extrapolated).

152. See, e.g., WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 3 (implying that the uncertainty regarding willingness to pay for an AIDS vaccine is emblematic of a glaring lack of market research).

153. Batson & Ainsworth, *supra* note 94, at 724–25; Gregory Crouch, *Europeans Investigate Resale of AIDS Drugs*, N.Y. TIMES, Oct. 29, 2002, at W1 (“Some pharmaceutical companies were leery of discounting precisely because a two-tiered pricing system is such an easy [] target for fraud.”).

154. See IAVI PARADIGM, *supra* note 40, at 16 (describing the difficulty in finding a balance between economics and ethics when pricing HIV vaccines in developing countries).

companies to decide whether or not the guaranteed market is large enough to warrant investment. Financial incentives, whether targeting the front end or the back end, can alter the balance in favor of research and development by changing known variables. What they cannot do, however, is alter what pharmaceutical companies do not know or cannot predict. Tort liability creates a cloud of uncertainty over the entire development process that financial incentives do not address.¹⁵⁵ The problem is that the manufacturing and distribution process itself is filled with numerous opportunities for something to go wrong, and tort liability goes to the heart of the matter.

V. FACTORS CONTRIBUTING TO A NEBULOUS LITIGATION ENVIRONMENT

The current proposals to incentivize pharmaceutical manufacturers to produce an HIV vaccine are collectively weak, because they overlook the looming uncertainty surrounding the development of the HIV vaccine.¹⁵⁶ There are reasons to believe that the crisis of the 1980s is not a thing of the past, and that market incentives, while worthy, are insufficient to assuage the liability fears lurking beneath the surface. This section identifies and analyzes those liability factors awaiting HIV vaccine manufacturers.

A. *Size and Scope*

Vaccine manufacturers are confronted with “the greatest threat ever to humanity from an infectious disease.”¹⁵⁷ Not only is every country in the world affected by the HIV/AIDS epidemic, but each needs to be a part of the solution.¹⁵⁸ A global

155. See, e.g., Wilson I, *supra* note 14, at 506–07 (“[T]he unpredictability of litigation [is a] persuasive force[] making vaccine manufacturers increasingly reluctant to market new products.”).

156. See Wendy Mariner, *Liability and Compensation for Adverse Reactions to HIV Vaccines*, in *ADVERSE REACTIONS TO HIV VACCINES*, *supra* note 12, at 79, 98 (“Where adverse reactions cannot reasonably be predicted, there is always the possibility that serious harm could materialize in the future and, with it, liability claims.”).

157. Malegapuru William Makgoba et al., *Science, Medicine, and the Future: The Search for an HIV Vaccine*, 324 *BMJ* 211, 212 (2002).

158. WORLD BANK, *ACCELERATING AN AIDS VACCINE*, *supra* note 92, § II, ¶ 5 (“The

solution, however essential to develop a vaccine, brings global problems.¹⁵⁹

There will likely be tremendous pressure globally to bring the HIV vaccine to market as quickly as possible by prematurely curtailing the development process and foregoing standard testing.¹⁶⁰ In the haste to roll out the vaccine, it is entirely possible certain tests might not be performed and side effects might not be detected until thousands have already been vaccinated. While the subsequent establishment of unforeseeable side effects is not itself grounds for liability, if the side effects are so egregious that no reasonable health provider would recommend the vaccine for any class of patients, then the vaccine could be judged defective and subject the manufacturer to tort liability.¹⁶¹ Unfortunately, this very scenario happened before with the Swine Flu scare of 1976, and it resulted in more deaths due to the vaccine itself than to the underlying disease.¹⁶² To use a cliché, haste makes waste, and, in the case of vaccine manufacturers, haste means liability exposure.

A related concern is rushing to mass produce and distribute the vaccine immediately.¹⁶³ Governments will not only want the

successful and rapid development of an AIDS vaccine that is effective and affordable cannot be achieved without the cooperation and active involvement of developing countries.”).

159. See Makgoba et al., *supra* note 157, at 213 (advising that “we should determine the rules for access to and distribution of the vaccine before making it widely available”).

160. See, e.g., *id.* at 212 (stating that the scientific community is “under pressure to move with urgency” and “to break down traditional modes of operations”).

161. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(c) (1998).

162. David Freedman & Philip Stark, *The Swine Flu Vaccine and Guillain-Barré Syndrome: A Case Study in Relative Risk and Specific Causation*, 64 LAW & CONTEMP. PROBS., Autumn 2001, at 49, 53. In 1976, following the death of one U.S. soldier and the hospitalization of several others for swine flu, U.S. public health agencies urged the immediate vaccination of some 220 million Americans to prevent a major swine flu epidemic. *Id.* at 51–52. But before even a quarter of the population could be vaccinated, enough cases of Guillain-Barré Syndrome had surfaced to warrant ending the program. *Id.* It is acknowledged today that political pressure to take swift action trumped a prudent response. Mariner, *supra* note 156, at 99.

163. Michael Greer, *HIV/AIDS Vaccine: Demand Likely to Outpace Distribution of Successful Vaccine*, AIDS WEEKLY (2003), available at <http://www.aegis.com/pubs/aidswkly/2003/AW030610.html> (“[T]he demand for a vaccine is likely to far outpace distribution capacity . . .”).

vaccines as early as possible, but also as quickly as possible, a feat that will require enhanced manufacturing capabilities as well as immediate improvements in distribution channels.¹⁶⁴ Production capabilities can be increased by licensing generic production to local manufacturers or entering a subsidiary production agreement with a local manufacturer, but this is riskier for the manufacturers.¹⁶⁵ Local production facilities might have lower technical standards, less supervision from regulatory authorities, and generally less accountability.¹⁶⁶ Where there is less enforcement of standards and protocols, there is more room for error and negligence. Several developing countries, such as South Africa, are already changing their laws to reflect less respect for patents and a greater desire to allow generic production.¹⁶⁷

B. Flu Scare

Another recent development of concern is the flu vaccine shortage of 2003-2004.¹⁶⁸ Not only did this expose a major vulnerability, namely, reliance on two vaccine manufacturers to supply the entire U.S. market, but it also elicited hasty solutions to avoid another shortage.¹⁶⁹ One proposal called for national stockpiles to guard against a shortage.¹⁷⁰ However, most

164. IVAI PARADIGM, *supra* note 40, at 23–25, 30; *cf.* IVAI PUSH, *supra* note 97 (discussing “fast track” and “priority review” procedures by the FDA (United States) and related measures under the EMEA (Europe), whereby products can get into the markets faster).

165. John Wilson, *Limitation of Manufacturer Liability for Administration of an AIDS Vaccine Overseas*, 30 INT’L LAW. 783, 787–89 (1996) [hereinafter Wilson II] (listing different legal forms that could be utilized to distribute the HIV vaccine).

166. *Id.* at 788 (warning of production and contamination problems in developing countries).

167. Glennerster & Kremer, *supra* note 93, at 34.

168. *Law Maker Blames FDA for Vaccine Shortage*, CNN, Dec. 13, 2004, <http://edition.cnn.com/2004/HEALTH/11/17/congress.flu/index.html>. After the pharmaceutical company Chiron Corp.’s Liverpool facility was shut down due to manufacturing concerns, the U.S. flu vaccine supply was instantly cut in half to only one producer. David Brown, *How U.S. Got Down to Two Makers of Flu Vaccine*, WASH. POST, Oct. 17, 2004, at A1.

169. Brown, *supra* note 168, at A12.

170. Kapil Kumar Bhanot, Comment, *What Defines a Public Health Emergency?*, 21 J. CONTEMP. HEALTH L. & POL’Y 137, 138, (2004) (citing NAT’L VACCINE ADVISORY

vaccines only have a shelf-life of a few months and must be discarded if unused.¹⁷¹ Furthermore, the HIV virus is known to mutate quickly and render existing treatments obsolete.¹⁷² If a stockpile were applied to guard against an HIV vaccine shortage, the danger would be twofold: the stockpile would divert resources away from improving distribution channels, and it would open the possibility of distributing expired, unsafe, or ineffective vaccines.¹⁷³ The ramifications of a stockpile of HIV vaccines on a manufacturer are thus far unanswered. For instance, could a manufacturer be held liable for not disposing of expired vaccines or for negligent entrustment to a government health department that lacks the resources to adequately safeguard it?¹⁷⁴

C. *Forum non conveniens*

Today's manufacturers also face a weakening of the doctrine of *forum non conveniens*, a legal doctrine that allows for suits to be dismissed on the jurisdictional ground that another forum is better suited to handle the litigation.¹⁷⁵ Corporate defendants in tort suits brought by foreign plaintiffs¹⁷⁶ in the United States

COMM., STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES: A REPORT 1 (2003) (noting that "[s]tockpiles are the most cost-effective short-term solution to overcome some vaccine shortages").

171. Brown, *supra* note 168, at A12 (reporting that in 2002–2003, thirteen million doses of flu vaccine were discarded).

172. Jim Ritter, *Mutating Virus Tangles Race for AIDS Vaccine*, CHI. SUN-TIMES, Mar. 31, 2002, at E11.

173. NAT'L VACCINE ADVISORY COMM., STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES (2003), <http://www.hhs.gov/nvpo/bulletins/nvac-vsr.htm>.

174. Several other open questions come to mind: Under what conditions are the stockpiles kept? Under whose watch? With what safety and expiration labels? Might some desperate countries be tempted to use expired vaccines, despite knowing full well that they should be discarded?

175. *E.g.*, *Canada Malting Co. v. Paterson Steamships, Ltd.*, 285 U.S. 413, 423 (1932) (stating famously that a court can deny jurisdiction "where for kindred reasons the litigation can more appropriately be conducted in a foreign tribunal"). Perhaps the most notorious application of *forum non conveniens* was in the litigation surrounding the Bhopal tragedy in India, in which hundreds of plaintiffs were denied relief in the United States. *In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India* in Dec. 1984, 809 F.2d 195 (2d Cir. 1987).

176. Plaintiffs are most likely to bring suit against the pharmaceutical

have benefited greatly from *forum non conveniens* because judges have been quite receptive to the argument that the suit is better brought in the country where the harm occurred.¹⁷⁷ While affirmative application of *forum non conveniens* does not mean that a defendant escapes liability,¹⁷⁸ it often means that successful plaintiffs will recover much less.¹⁷⁹ One commentator noted that “as a practical matter, *forum non [conveniens]* dismissals often preclude recovery.”¹⁸⁰

Some academics, however, have pointed out that *forum non conveniens* is losing its bite because of the perceived unfairness in denying foreign litigants the opportunity to sue in the United States.¹⁸¹ Some courts have narrowed the parameters of the doctrine and allowed plaintiffs to proceed on the merits of the case despite a possibly meritorious use of *forum non conveniens*.¹⁸² If indeed a trend has begun, could there be a more appealing fact pattern to further erode the doctrine of *forum non conveniens* than injured HIV vaccinees in sub-Saharan Africa? It is not difficult to imagine a sympathetic court refusing to entertain the charade of a *forum non conveniens* dismissal for fear of precluding recovery for thousands of innocent victims due to a “technicality.”

manufacturer, as opposed to the vaccine administrator or the local subsidiary, for instance. Wilson II, *supra* note 165, at 788.

177. See, e.g., *In re Union Carbide Corp.*, 809 F.2d 195 (applying the *forum non conveniens* doctrine liberally in its decision).

178. See *De Melo v. Lederle Labs.*, 801 F.2d 1058, 1061 (8th Cir. 1986) (stating an alternative forum where the defendant is amenable to process must exist before dismissing the lawsuit). A necessary condition of dismissing the suit in the domestic jurisdiction is that the defendant acquiesce to jurisdiction in the foreign venue. *Id.*

179. See Wilson II, *supra* note 165, at 790–91 (noting greater U.S. damage awards). One of the major reasons for bringing a suit in the United States is to take advantage of generous jury awards and punitive damages. *Id.*

180. James Pfander, *Adding Insult to Overseas Injury: A Failure of the Forum Non Conveniens*, 93 ILL. B.J. 314, 314 (2005). A study noted that, out of a group of eighty-five suits whose claims were dismissed on the grounds of *forum non conveniens*, not one plaintiff reported winning a favorable outcome in the convenient forum, and only a few received modest settlements. *Id.*

181. Wilson II, *supra* note 165, at 800–01.

182. John R. Wilson, *Coming to America to File Suit: Foreign Plaintiffs and the Forum Non Conveniens Barrier in Transnational Litigation*, 65 OHIO ST. L.J. 659, 659 (2004).

D. Scientific Difficulties

The liability threat posed by the complicated science of HIV cannot be overlooked. The fact that multiple clades of the HIV virus exist, each one requiring a unique vaccine, leaves several distinct possibilities for error.¹⁸³ First, a vaccine could be administered to the wrong person.¹⁸⁴ Assuming the vaccine operates by targeting the further spread of HIV in an infected person's body, an individual infected with clade A could be vaccinated for clade B, leading to detrimental side effects or death.¹⁸⁵ Second, there is no guarantee that a vaccinee, who is subsequently exposed to HIV, would be immune to the particular clade to which he or she was exposed.¹⁸⁶ The choice to vaccinate a population for a given clade will most likely be based on epidemiological projections of clade prevalence in a geographic area, a necessarily general and non-specific assessment.¹⁸⁷ This could lead to vaccinees engaging in risk-enhancing behavior under the erroneous belief that they were properly vaccinated.¹⁸⁸ The solution would be to vaccinate persons for all different types of clades, but this might be scientifically proscribed or, at the very least, it would subject the vaccinee to a greater risk of injury.¹⁸⁹

183. WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 1.

184. *See id.* (stating that multiple types of HIV occur in the same area). It would most likely be too costly and impractical to screen every potential recipient beforehand. *Id.*

185. There is not enough research concerning the side effects or even overall effectiveness of an HIV vaccine for one particular clade against others. Batson & Ainsworth, *supra* note 94, at 723.

186. WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra* note 92, § II, ¶ 1 (“There is no guarantee that a vaccine based on subtype B will be effective against [the] other subtypes.”).

187. José Esparza & Donald Burke, *Epidemiological Considerations in Planning HIV Preventive Vaccine Trials*, 15 AIDS S49, S52 (2001) (“[W]e have a reasonably good understanding of the geographic distribution and dynamics of HIV-1 subtypes around world, . . . [but this] may change in the future, with new subtypes being introduced in different regions of the world.”).

188. Wilson II, *supra* note 165, at 788; *see also* Ritter, *supra* note 172 (warning that “a partially effective vaccine [could give] people a false sense of security”).

189. Furthermore, the initial vaccines to come out “are likely to be . . . substantially less than 100% efficacious,” which would certainly impact the vaccinees’ decision to accept increased risk. WORLD BANK, ACCELERATING AN AIDS VACCINE, *supra*

E. Mass Immunization Context

This leads to perhaps the biggest reason why liability remains a concern. The vaccines will almost certainly be distributed in the mass immunization context, either in a clinic or through a vaccination campaign run by a government health ministry or non-profit agency.¹⁹⁰ Vaccine distribution will require a monumental effort of reaching individuals in remote villages or having them travel long distances to a clinic.¹⁹¹ It will involve adults and children, those who are sick and those who are healthy, and those who can read and those who are illiterate.¹⁹² The sheer enormity and complexity of distributing the HIV vaccine will lead to numerous uncertainties.

Most importantly, individualized attention by a physician will almost certainly be lacking, depriving vaccinees of an opportunity to have the risks properly explained and balanced in light of their specific circumstances.¹⁹³ In order for the vaccine manufacturers to benefit from the learned intermediary doctrine and be shielded from liability, the Third Restatement requires that health care providers be present and in a position to reduce the risks of harm, a time consuming process that is ill-adapted to a mass immunization setting.¹⁹⁴

Furthermore, the health care providers must obtain proper informed consent from illiterate and uneducated individuals, and “the consent process must conform to the cultural norms of

note 92, § II, ¶ 3.

190. See Robert M. McKenna, *The Impact of Product Liability Law on The Development of a Vaccine Against the Aids Virus*, 55 U. CHI. L. REV. 943, 952 (1998) (“[T]he government may have to purchase large quantities of the vaccine for free distribution in public health clinics.”).

191. Wilson II, *supra* note 165, at 787–88 (noting that vaccines might be distributed “in rural areas[] by village health workers in traveling vans”).

192. *Id.* at 787.

193. See ADVERSE REACTIONS TO HIV VACCINES, *supra* note 12, at 16, 17 (discussing the application of “less rigorous standards of informed consent” often associated with clinical conditions such as those likely to be met when distributing vaccines). However, the requirements for “HIV screening is an exception,” implying that rigorous informed consent standards might be upheld in the HIV vaccine context. *Id.* at 17.

194. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d)(1) (1998).

the participants.”¹⁹⁵ For example, some societies may require a wife to obtain her husband’s consent for the vaccination, or a tribesman his communal leader’s.¹⁹⁶ Now, arguably, the manufacturer’s duty runs to both the woman and her husband, because both were necessary for fully informed consent. Would the insufficiency of the consent from either suffice for a claim of a defective warning?¹⁹⁷

In the alternative, the vaccine manufacturers must provide the warnings directly to the vaccinees via package inserts, posters, or some other form of advertising; nonetheless, this runs into the difficulty of communicating the message to uneducated and illiterate persons.¹⁹⁸ It is likely that governments will make good use of mass media outlets such as radio, television, or the Internet to promote the HIV vaccine and publicize its risks, but it is unclear whether this discharges the manufacturer’s duty to warn.¹⁹⁹ The HIV vaccine might be treated like a direct-to-consumer (DTC) advertised drug, a nascent and undeveloped field of liability²⁰⁰ where many commentators argue that physicians are necessarily cut out of the equation, rendering nugatory the learned intermediary doctrine.²⁰¹ Even if manufacturers provided warnings along with each dose of the vaccine at the administration sites, it is plausible that an individual might rely on the warning they received over the radio and thus not pay attention to the more detailed description of risks provided to them when they

195. Wilson II, *supra* note 165, at 787.

196. See ADVERSE REACTIONS TO HIV VACCINES, *supra* note 12, at 16 (explaining that some cultures require women to obtain permission from their husbands before participating in trials).

197. Even more troublesome is the scenario where a potential vaccinee must obtain permission from community leaders. *Id.* Now whose consent is valid?

198. Wilson II, *supra* note 165, at 787 (noting that many recipients are illiterate).

199. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. e (1998).

200. Hill, *supra* note 87, at 378–79 (pointing out that it is “too soon to predict the fate of the learned intermediary doctrine in the context of DTC advertising,” but only one court “has created a DTC advertising exception to the doctrine” in its five-year existence).

201. Monica Renee Matter, *Emerging DTC Advertising of Prescription Drugs and the Learned Intermediary Doctrine*, 69 DEF. COUNS. J. 79 (2002) (arguing that the doctrine should be abolished in the DTC context because “advertising removes the physician from the role of a learned intermediary . . .”).

received the HIV vaccine.

F. Regulatory Process

The regulatory process overseeing the development of the HIV vaccine leaves open several questions as well. For instance, the Third Restatement acknowledges that “the regulatory system . . . is a legitimate mechanism for setting the standards for drug design.”²⁰² While compliance with regulatory procedures is not a prima facie indicator of a safe design—though some have argued it should be²⁰³—it nonetheless “has often provided convincing evidence to reject a claim that a product could have been made safer.”²⁰⁴ But which country’s regulations are applied? It is largely acknowledged that FDA regulations are quite stringent and costly, and thus manufacturers are wont to take advantage of looser regulations in foreign countries.²⁰⁵

In fact, several commentators have argued for taking advantage of looser regulations in order to spur development of an HIV vaccine.²⁰⁶ This, however, appears to be a dangerous solution. First of all, avoiding stricter regulatory laws in favor of a lower standard almost, by definition, jeopardizes the health of the vaccinees.²⁰⁷ Secondly, there is no unqualified judicial deference to the regulatory process.²⁰⁸ While vaccine manufacturers might save themselves some costs, they are not buying themselves any greater judicial protection. In determining whether the vaccine is defective or not, judges will

202. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998).

203. See, e.g., Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 762 (2003) (arguing that a regulatory compliance defense is controversial but less cumbersome than other proposals).

204. Mariner, *supra* note 156, at 121.

205. Betsy Bates, *Free Market or Patent Protections? Research Costs, Role of FDA Cited in Drug Debate — Practice Trends*, OB/GYN NEWS, Mar. 1, 2004, available at http://findarticles.com/p/articles/mi_m0CYD/is_5_39/ai_114521566. Even the FDA is able to lower its standards in a process known as “priority review.” IAVI PUSH, *supra* note 97.

206. Bruce Plotkin, *Mission Possible: The Future of the International Health Regulations*, 10 TEMP. INT’L & COMP. L.J. 503, 514-15 (1996).

207. Mariner, *supra* note 156, at 86.

208. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998).

weigh the foreseeable risks of harm against the foreseeable therapeutic benefits,²⁰⁹ and it is hard to see how avoidance of stricter regulatory laws could do anything but increase the foreseeable risks of harm.

Every one of the aforementioned situations leaves the door open to tort suits.²¹⁰ Ultimately, given the complexity of the distribution of the vaccines and the myriad opportunities for something to go wrong, the only limit to the number and type of suits brought against the manufacturers is the creativity of the plaintiffs, or more likely, the creativity of the attorneys.²¹¹ Furthermore, while U.S. tort doctrine suggests that the subsequent discovery of unforeseeable side effects, by itself, is not sufficient grounds on which to recover, there is nothing to stop a foreign jurisdiction from holding otherwise.²¹²

VI. SOLUTIONS AND AN INTERNATIONAL COMPENSATION FUND

The current proposals to develop an HIV vaccine are not enough to handle the “pandemic that will define our current generation.”²¹³ There are simply too many opportunities for something to go wrong. Individuals and governments will demand immediate access, which will pose a logistical nightmare.²¹⁴ Pharmaceuticals will have little control once the vaccine leaves the production facilities. What might result is that, despite everyone’s best efforts, manufacturers will be wary of producing an HIV vaccine and jump ship, leaving it to someone else to assume the burden. But there might not be another willing producer. As long as the manufacturers are the

209. *See id.* § 6(c) (“A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are [greater than] its foreseeable therapeutic benefits”).

210. Wilson II, *supra* note 165, at 788 (“Possibilities for accident and injury are clearly present.”).

211. *Id.* at 785 (noting the “litigious zeal of the U.S. citizenry”).

212. Mahmoud et al., *supra* note 34, at 153 (warning that “many developing nations may not have . . . a tort liability system,” making manufacturers wary of unpredictability).

213. IAVI BLUEPRINT, *supra* note 19, at x.

214. Greer, *supra* note 163. In fact, some suggest that “it would be unconscionable not to make an effective AIDS vaccine widely available as soon as possible after its development.” IAVI BLUEPRINT, *supra* note 19, at 24.

primary target when something goes wrong and the possibility of shelling out millions in settlements and attorney's fees remains, they will not produce.²¹⁵ Manufacturers must be afforded some protection.²¹⁶

The simplest way to protect manufacturers would be to draft legislation that expressly shields HIV vaccine manufacturers from any liability except, perhaps, in cases of fraud or gross negligence.²¹⁷ The legislation would only extend to those manufacturers producing the HIV vaccine, and only for tort suits related to injuries caused by the HIV vaccine.²¹⁸ But the public still suffers with each vaccine injury and would likely reject manufacturer immunity even in the face of a public health crisis.²¹⁹ Furthermore, such immunity gives the manufacturers no incentive to improve their vaccine, which is one of the major benefits of allowing tort suits.²²⁰

A different legislative approach would allow compliance with regulatory laws as a valid defense.²²¹ Essentially, once a manufacturer has successfully complied with regulatory procedures, it is no longer liable in tort for injuries or death caused by the HIV vaccine that it developed. This has some merit to it, because regulatory procedures can be closely monitored and changed as needed to reflect scientific advances, and it would eliminate the burden on manufacturers.

However, once the responsibility for a defective vaccine is taken out of the hands of the manufacturers, on whom does it fall? One possible answer, of course, is that no one assumes any responsibility; any tort claim must fail at this point. Still, this would likely evoke a similar public policy opposition as for

215. See Mariner, *supra* note 156, at 124 (suggesting that "the possibility of one multimillion dollar judgment" deters companies from manufacturing vaccines).

216. Wilson I, *supra* note 14, at 546 (arguing that a "way must be found to speed a vaccine to market by reducing the liability concerns of American manufacturers").

217. *Id.* at 546, 548.

218. *Id.* at 561. Inadequate warnings, inability to get a physician's opinion, substandard vaccine facilities, and a vaccine mix-up could all be scenarios precluded from recovery. *Id.*

219. See Davis, *supra* note 74, at 698 (noting that juries side against powerful manufacturers, who often appear to act above the law).

220. ADVERSE REACTIONS TO HIV VACCINES, *supra* note 12, at 26.

221. Noah, *supra* note 203, at 762.

complete immunity. The more palatable answer is that the government, either that of the manufacturer or that of the situs of the harm, assumes the risk of a defective vaccine once the manufacturer has complied with the regulatory requirements. In fact, participants at a global health forum agreed that “government has a responsibility . . . to ensure more equitable development and distribution of lifesaving vaccines and drugs” while the manufacturers should be left alone to recoup their investments and even turn a profit, as is their right.²²² But is the government really in the best position to assume the risk that the warnings are faulty or inadequate?²²³ The government might not be in the best position to mitigate any potential harm.

A different solution might be to impose a sort of binding settlement agreement on all HIV vaccinees.²²⁴ In short, each individual receiving the HIV vaccine agrees in advance that, in the event of injury or death, they will accept a lump sum of money from the manufacturer and forfeit their right to sue in tort. This moves the harm out of the realm of torts into that of contracts and allows the manufacturer to estimate in advance, based on the predicted injury rate, the amount of money they will lose to claims.²²⁵ While the proposal is fundamentally sound, it still leaves the manufacturers with the huge burden of paying all the claimants.

This brings the Author to what is believed to be a workable solution that balances plaintiffs’ rights to recover for loss with manufacturer incentives to produce an HIV vaccine: an International Compensation Fund (Fund). It is imperative to acknowledge that injured vaccinees and the families of deceased vaccinees must be allowed to recover, regardless of whether or not there is fault on the manufacturer’s behalf. Not only is there a moral obligation to afford victims the right to compensation,

222. News Release, Univ. of Cal., San Francisco, New Incentives Are Needed to Spur Research and Delivery of Vaccines and Drugs to Poor Nations, Say World Health Experts (Feb. 23, 2000), <http://pub.ucsf.edu/newsservices/releases/2004021029/?print>.

223. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. A (1998) (noting that one of the tort system’s fundamental premises is to encourage product safety).

224. See Mariner, *supra* note 156, at 125–26 (describing a voluntary contract approach for vaccine companies to reduce the time and expense of settling claims).

225. *Id.* at 126.

but there is a practical imperative as well. The lack of a structured compensation scheme will force plaintiffs to resort to litigation in order to recover their losses.²²⁶ There are simply too many avenues for a successful tort suit to be brought against an HIV vaccine manufacturer, and there is every reason to believe that a fear of impending lawsuits will dissuade manufacturers from producing an HIV vaccine. The only way to avoid most lawsuits is to compensate the victims, but the cost must be borne by the government and not by individual pharmaceutical companies. An International Compensation Fund will serve this purpose.

An important threshold question, assuming that compensation should be afforded to the victims, is why a fund, and not some other remedy, is the preferred compensation system. Generally, there are four categories of compensation systems: tort liability, voluntary contractual arrangements, insurance, and compensation funds.²²⁷ Reliance on tort liability as a source of compensation, however beneficial and generous a system it might prove for injured plaintiffs, simply leaves too much uncertainty for vaccine manufacturers.²²⁸ As the thesis of this Comment suggests, the cost of such uncertainty is that the public will be irreparably harmed if an HIV vaccine is not produced. The second alternative, voluntary contractual arrangements, was discussed briefly in the preceding paragraph.²²⁹ The basic concept of an agreed-upon lump sum payment should be incorporated into a compensation fund system, while the idea that the manufacturer should be responsible for the payments must be discarded for the reasons set forth above.²³⁰

The third alternative is an insurance system that is willing to compensate vaccine victims for their losses.²³¹ The biggest

226. *See id.* at 119 (explaining how currently, an injured individual's only recourse for compensation is through the tort system).

227. *Id.* at 80.

228. *See id.* at 120–24 (discussing reliance on tort liability and its shortcomings).

229. *See supra* notes 225–26 and accompanying text.

230. *See supra* Part IV.

231. Mariner, *supra* note 156, at 126–28 (discussing different ways in which a government-funded insurance program could operate).

obstacle with such a system is the question of who should pay the premium.²³² The vaccinees cannot be expected to pay a premium. Because the majority of those receiving the vaccine will likely be without means, this would discriminate against those most in need of the vaccine. The vaccine manufacturers could be asked to pay the premium; however, as with the contractual arrangements, the cost will likely be too much to bear for the companies.²³³ That leaves individual governments to pay the insurance premiums. But this result would be no different than having the governments contribute to an International Compensation Fund. In fact, a Fund combines the most appealing aspects of all of these solutions while streamlining the administration.²³⁴

Some suggest simply expanding the National Vaccine Injury Compensation Fund (NVICF) to include victims of the HIV vaccine; however, while this appears logical, it is ultimately incompatible.²³⁵ First of all, the fund was set up to compensate victims of mandatory childhood vaccines. This raises two problems. First, the HIV vaccine most likely would, at least at the outset, not be mandatory.²³⁶ Administration of the HIV vaccine would target at-risk populations.²³⁷ The NVICF, however, is meant to compensate victims who have no choice in determining whether or not to receive the vaccine, and thus the original purpose would be thwarted.²³⁸ Secondly, the HIV

232. *See id.* at 145 (discussing different potential sources of payment for such a program).

233. *See* Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 *FORDHAM L. REV.* 2425, 2431 (2006) (describing how rising insurance premiums helped to cause ten out of thirteen manufacturers of children's vaccines to flee the market in 1983).

234. Once the compensation system is in place, there are plenty of additional restrictions that can be added to limit (or expand) recovery, such as shortening the statute of limitations or increasing the evidentiary threshold to prove causation. Mariner, *supra* note 156, at 122 (discussing how both statutes of limitation and evidentiary screening panels have been used to limit liability). The Author, however, leaves it to the politicians of the world to determine the correct balance between allowing full compensation and limiting the size and/or number of claims.

235. Mariner, *supra* note 156, 135–36.

236. *Id.* at 136.

237. *Id.*

238. *Id.* at 130 (noting that the NVICF provides compensation for children

vaccine would target adults and adolescents in addition to children, and this inconsistency could not be easily reconciled with the NVICF's failure to compensate other adult vaccinees.²³⁹ Thirdly, the NVICF is a statute of the United States and only applies to those injured in the United States.²⁴⁰ Injuries from the HIV vaccine will be worldwide, and all individuals will be deserving of compensation, not just U.S. citizens.²⁴¹

VII. CONCLUSION

The Author proposes that a new, separate, and HIV vaccine-only Injury Compensation Fund ("the Fund") be created. The Fund must require broad support from around the world, both from developing and developed countries. This is not only to meet the financial needs of the Fund but also to invest a certain amount of responsibility in the participating countries, such that they improve their infrastructure, delivery channels, and accountability that is crucial for the success of the HIV vaccine. Furthermore, the donor community must play an active role in helping to set up the Fund, and the involvement of developing countries will boost their confidence.²⁴² As a corollary, victims from all participating countries must be allowed to apply for compensation under the Fund. Those individuals whose governments do not contribute cannot benefit.

The Fund must specify eligibility requirements, types of compensable injuries, causation, benefits levels, and method of

contracting illnesses from vaccines they are required to have in order to attend school).

239. *Id.* at 136 ("Adding HIV vaccines to the program would represent a larger break with the original purpose of the program than adding vaccines recommended for children."); *see also id.* at 140 (stating that "the [NVICF] was originally justified because it covered childhood vaccines required by law If a compensation program covers vaccines that are recommended or voluntary, then it may set a precedent for expanding the program to cover all recommended or voluntary vaccines").

240. *See* 42 U.S.C. § 300aa-11(c)(1)(A) to (B) (2000) (stating that the NVICF applies only to civilians receiving vaccines in the U.S., Armed Forces personnel, U.S. government employees abroad, and individuals receiving a vaccine outside the U.S. and returning within six months of the date of the vaccination).

241. *See* Makgoba, *supra* note 157 (calling for equal treatment of HIV victims regardless of their nation's wealth).

242. IAVI PARADIGM, *supra* note 40, at 8.

payment.²⁴³ The Fund must be centrally administered, either through a new transnational committee or as an extension of the World Health Organization. The process must be streamlined, with special rules, evidentiary standards, and administrative procedures. The Fund must not allow for a tort suit as an alternative compensation mechanism, though certain public policy exceptions could be grafted in, for example, in instances of fraud or gross negligence. Clearly, not every manufacturer mishap will be grounds for compensation, thus the guidelines must be specific. Lastly, of course, the amount of compensation that each injured party receives must be calculated. For administrative ease, the Author proposes that a uniform lump sum payment be authorized, adjusted by the living standards of the country where the recipient lives.

The need for a Fund has never been clearer. Liability threatens to block pharmaceutical manufacturers from producing an HIV vaccine once it is developed. Despite the current scientific uncertainties, an HIV vaccine will be developed. Without any future action, and against the backdrop of a host of new factors, however, the HIV vaccine will never be produced. It may be that inherent difficulties in the manufacturing process are causing the problems, but the solution lies not with the manufacturing process itself. The solution lies in the legal system, and it must begin now. It requires a fundamental paradigm shift in the way manufacturers are treated, and an International Compensation Fund can begin that transformation.

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243. See Mariner, *supra* note 156, at 139–43 (discussing the requisites for an effective no-fault compensation program).

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