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Limitation of Manufacturer Liability for Administration of an AIDS Vaccine Overseas

As alarming as the threat of AIDS is in the United States,[1] the scope of the epidemic in this country is dwarfed by its magnitude overseas.[2] Worldwide, as of early 1994, more than 22 million people had been infected by the human immunodeficiency virus (HIV), and at least 6.8 million had developed full-blown AIDS.[3] An additional 6,000 people are infected every day, approximately 80 percent of them in the developing world.[4] By the turn of the century the death

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1. In North America, excluding Spanish-speaking countries, there were 1,138,000 accumulated HIV cases as of January 1, 1994, and 327,000 cases of AIDS. David Perlman, *World AIDS Experts Gather in Asia—Current Hot Spot*, S.F. CHRON., Aug. 6, 1994, at A3. The incidence of new infections in the United States has declined slightly. *New AIDS Cases Decline 7% in U.S.*, S.F. CHRON., Apr. 19, 1996, at A2.

2. *Id.*; *see also* Ramon G. McLeod, *AIDS Taking Heavier Toll Around World*, S.F. CHRON., Apr. 29, 1994, at A1, A19.

3. Perlman, *supra* note 1, at A3. Others report over 17 million HIV infections and over 4 million cases of AIDS. *Id.* "Over 90% of all HIV infections worldwide are acquired through heterosexual intercourse." HIV Vaccines—Accelerating the Development of Preventive HIV Vaccines for the World, Summary Report and Recommendations of an International Ad Hoc Scientific Committee 3 (sponsored by The Rockefeller Foundation and the Fondation Mérieux, Paris, France, Oct. 27-28, 1994) [hereinafter Summary Report]. Women now represent 50% of all new HIV infections, *Women Fastest-Growing Group Contracting HIV*, S.F. CHRON., Feb. 9, 1995, at A16, and more than 1.5 million children have the disease. Charles Petit, *AIDS Rife in Asia, Experts Say*, S.F. CHRON., Feb. 21, 1995, at A3.

4. Sven Sandstrom, *Global AIDS Strategy Is Not Doing the Job*, S.F. CHRON., Dec. 1, 1994, at A23. By the end of this decade, 95% of HIV infections will occur in developing countries. *World AIDS Day*, S.F. CHRON., Dec. 1, 1994, at A22. "If not another single African became infected, AIDS deaths in the region over the next decade would still exceed 8.3 million—tripling the current rate. In some African cities, the infection rate is as high as 1 in 3." *Id.* Approximately 25% of Uganda's population of 16 million have the AIDS virus. *Uganda's Harsh AIDS Message*, BOSTON

toll across the globe is estimated to be about 2 million people every year.[5] In terms of death and catastrophic social disruption, the pandemic will match the worst wars of this century,[6] potentially claiming as many as 121 million lives by the year 2020.[7]

These grim facts and predictions demonstrate the obvious need for a cure and for a preventive or therapeutic vaccine.[8] But the virus presents formidable obstacles toward the achievement of these goals. It mutates rapidly and exists in thousands of forms.[9] Distinct viral groups are found in different regions of the world that vary genetically from each other.[10] Thus, a vaccine that targets the viral strain in North America might be ineffective, or less effective, in Southeast Asia or Africa; moreover, it might work today but not tomorrow against new variations of the virus.[11]

Despite these obstacles, efforts to create a vaccine are underway. Two "first generation" vaccines, which employ a specific component of the HIV coating, initially appeared promising, but the AIDS Research Advisory Committee at the National Institutes of Health barred them from large-scale testing in the United

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GLOBE, July 22, 1993, at 10. By the year 2000, however, the majority of infections will occur in Asia. Sandstrom, *supra*, at A23. Perlman, *supra* note 1, at A3. It is estimated that 2 to 4 million of Thailand's 60 million citizens will be HIV positive by the end of this millennium, at an estimated cost of 10% of the nation's current 90 billion gross domestic product. Martha Irvine, *Thai Businesses Join Fight Against AIDS Epidemic*, S.F. CHRON., May 10, 1995, at A16. India now leads the world in people infected with the AIDS virus. Lawrence K. Altman, *India Quickly Leads in HIV Cases, AIDS Meeting Hears*, N.Y. TIMES, July 8, 1996, at A3. Experts predict that 1 million people in India will have AIDS and 5 million will be HIV positive by the year 2000; by 2010, India could have 30 million HIV infected citizens, putting overwhelming pressure on government health facilities and creating millions of orphans. John Ward Anderson, *India Fast Becoming World's Scariest AIDS Flash Point*, S.F. CHRON, Sept. 2, 1995, at C16.

5. Sandstrom, *supra* note 4, at A23.

6. David Perlman, *AIDS Conference Winds Down—Little to Rejoice About*, S.F. CHRON., Aug. 12, 1994, at A17.

7. McLeod, *supra* note 2, at A19. Life expectancies in many countries will be reduced dramatically, e.g., by approximately 28 years in Kenya, 25 years in Tanzania, 33 years in Zambia, and 30 years in Thailand. *Id.*

8. A therapeutic vaccine stops the progression of a disease once an infection is already present, e.g., the vaccination for rabies, whereas a preventive vaccination prevents a disease from occurring at all, e.g., the vaccination for polio. *See* David Perlman, *New Reports of Progress on Post-AIDS Therapies*, S.F. CHRON., July 23, 1992, at A1.

9. *Vaccine Guards Monkeys from Simian AIDS*, S.F. CHRON., Jan. 24, 1992, at A12; *see also* Larry Gostin, *Vaccination for AIDS: Legal and Ethical Challenges From the Test Tube, To the Human Subject, Through to the Marketplace*, 2 AIDS & PUB. POL'Y J. 9, 10 (1987); Sabin Russell, *Rare HIV Strain Eludes Screening Tests*, S.F. CHRON., June 8, 1994, at A2.

10. "Huge variation in the genetic sequence of HIV-1 envelope genes has led to their classification into more than six genetic groups (clades) worldwide. Within each clade, there is considerable viral variation as well." AIDS ACTION FOUNDATION, HIV PREVENTIVE VACCINES: SOCIAL, ETHICAL AND POLITICAL CONSIDERATIONS FOR DOMESTIC EFFICACY TRIALS 5 (1994); *see also* Summary Report, *supra* note 3, at 9.

11. AIDS ACTION FOUNDATION, *supra* note 10; Summary Report, *supra* note 3, at 5.

States.[12] Many "next-generation" vaccines are currently being evaluated in preliminary trials.[13] Nevertheless, a workable vaccine still appears to be far in the future.[14] In addition to the enormous technical difficulties involved, the costs of development are high, and, particularly in the developing world, the return on investment is low.[15] Companies are abandoning the effort.[16]

The development of a vaccine is further inhibited by the fear of tort liability should a recipient, for any reason, claim an adverse reaction.[17] "From a manufacturer's perspective, the single most critical issue will doubtless be the manufacturer's liability for personal injuries associated with the vaccine. . . . [N]o sane manufacturer would be or should be willing to market such a vaccine without some form of tort relief. The liability exposure is too great in view of the scanty profits."[18] This concern is doubtless stimulated by the litigious zeal of the U.S. citizenry,[19] but it could apply also to liability exposure in the rest of the world,

12. AIDS ACTION FOUNDATION, *supra* note 10, at 4; *see also* Sabin Russell, *U.S. Stalls Tests of AIDS Vaccines Made by Bay Firms*, S.F. CHRON., June 18, 1994, at A3; David Perlman, *Controversy Over Testing of Existing AIDS Vaccines*, S.F. CHRON., Aug. 10, 1994, at A4. But Dr. Michael Merson, Director of the World Health Organization's Global Program on AIDS, said that, pending government approval in the countries involved, large-scale tests of the vaccines could take place in Brazil and Uganda. Trials are also planned in Thailand. *Id.*

13. AIDS ACTION FOUNDATION, *supra* note 10, at 6. The next generation vaccines involve live vector envelope subunits, such as a bird or mouse virus, to carry isolated components of HIV or whole killed virus vaccines (which are widely employed to combat other diseases). *Id.* at 4; *see also* David Perlman, *Promising Steps Toward AIDS Vaccine*, S.F. CHRON., Aug. 2, 1994, at 1. A nonvirulent strain of the HIV virus has been discovered with a missing genetic segment that might be the model for an attenuated virus vaccine. *Sign of Hope for Developing AIDS Vaccine*, S.F. CHRON., Nov. 11, 1995, at A1, A21. However, further research on a once promising vaccine has recently been halted, *Highly Touted AIDS Vaccine Found Wanting*, S.F. CHRON., Apr. 19, 1996, at A2, and while strong hope has been expressed, there are mixed reactions to reports about the efficacy of new combination drug therapies. Lawrence K. Altman, *At AIDS Meeting, Experts Find an Uneasy Mix of Hope and Fear*, N.Y. TIMES, July 9, 1996, at C5.

14. Lisa M. Krieger, *Doctors Offer Hope, No Cure, at AIDS Conference in Japan*, S.F. EXAM., Aug. 7, 1994, at 1; David Perlman, *Crown Prince Greets AIDS Scientists*, S.F. CHRON., Aug. 8, 1994, at A3.

15. Donald P. Francis & Donald Kennedy, *A Private-Sector AIDS Vaccine? Don't Hold Your Breath*, WASH. POST, July 19, 1994, at A17. Development costs for a new drug can reach $90-95 million, Nancy E. Pirt, *Regulation of the Export of Pharmaceuticals to Developing Countries*, 25 DUQ. L. REV. 255, 269 (1987). The developing world, which contains three quarters of the world's population, accounts for only 20% of drug sales worldwide because of low per capita income. *Id.* at 271 (citing a study by the Office of Industry Assessment of the International Trade Administration, U.S. Department of Commerce).

16. David Scondras & Dr. Paul Epstein, *Leadership Needed in Development of an AIDS Vaccine*, BOSTON GLOBE, Aug. 5, 1994, at 19.

17. OFFICE OF TECHNOLOGY ASSESSMENT, LIABILITY IS ONE OF MANY DETERRANTS TO AIDS VACCINE DEVELOPMENT (1995). Francis & Kennedy, *supra* note 15, at A17. I have written about the principal liability concerns of drug companies—the litigation explosion, punitive damages, and strict products liability—and the need for a statute similar to the National Childhood Vaccine Injury Act to encourage vaccine development. John P. Wilson, *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495 (1994).

18. Robert P. Charrow, *An AIDS Vaccine: It May Take an Act of Congress*, 6 J. NIH RES. 84 (1994); *see also* Summary Report, *supra* note 3, at 6.

19. Charrow, *supra* note 18, at 54.

the area of greatest need. For once a technique to develop a successful vaccine is mastered in the United States, it should be replicable elsewhere with different viral groupings. As the recent, and possibly ongoing, silicone gel breast implant litigation makes clear[20]—or the less recent representation of hapless shantytown inhabitants following the toxic gas explosion at the Union Carbide chemical facility in Bhopal, India[21]—American lawyers willingly bring suits in American courts on behalf of foreign claimants who are injured overseas.

This article explores the liability exposure of U.S. pharmaceutical corporations that might some day market an AIDS vaccine in the developing world and incur potential liability for injury. Why would suit in the United States be advantageous, and in what ways could a company protect itself? If a U.S. court retains jurisdiction, how would damages be measured? If injury is widespread yet suits are dismissed on forum non conveniens grounds to a nonexistent remedy in a foreign country, what are the implications for both business and U.S. foreign policy relations? Is there a middle position that would permit some compensation, based on verifiable injury, without incurring the potentially staggering costs of the U.S. tort system?

I. Administration of a Vaccine

Drugs, including vaccines, that are developed in the United States may be exported to other countries after approval by the Food and Drug Administration.[22] Unapproved drugs in the domestic approval process may also be exported, but only to certain countries that have well-developed, qualified testing processes and have already approved the drugs for safety and efficacy.[23] The purpose of this control is to limit the dumping of dangerous, untested drugs in countries without sophisticated approval processes and, concomitantly, to encourage the development of safe and useful drugs to combat diseases in such countries.[24]

Ideally, an AIDS vaccine would be administered orally, would be inexpensive,

20. Lindsay v. Dow Corning Corp., Final Order and Judgment and Opinion (Approval of Settlement), Civ. Action No. CV 94-P-11558-S (N.D. Ala. 1994); *see also* Aguinda et al. v. Texaco Inc., 93 CIV 7527 (VLB) (S.D.N.Y. Nov. 3, 1993) (involving a suit against Texaco for the allegedly deliberate contamination of native Indian land during the extraction of oil in Ecuador's rain forest). Laurie Goering, *Texaco Sued over Forest in Ecuador*, BOSTON GLOBE, July 3, 1996, at 2.

21. JAMIE CASSELS, THE UNCERTAIN PROMISE OF LAW: LESSONS FROM BHOPAL 115-17 (1993); *In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. 842, 844 (S.D.N.Y. 1986), *aff'd*, 809 F.2d 195, 197 (2d Cir.), *cert denied*, 484 U.S. 871 (1987).

22. Pirt, *supra* note 15, at 280; James C. Grant, Note, *The Impact of the Drug Export Amendments Act of 1986 on Foreign Tort Victims*, 21 VAND. J. TRANSNAT'L L. 809, 814 (1988).

23. The Drug Export Amendments Act of 1986, 21 U.S.C. § 382 (Supp. IV 1986), amending the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-332 (1982 & Supp. IV 1986). The listed countries are set forth at 21 U.S.C. § 382(b)(4)(A) (Supp. IV 1986). *See also* Pirt, *supra* note 15, at 282; Grant, *supra* note 22, at 812, 813. An immediate prohibition will result if an importer in an approved country reexports to an unapproved country or if a drug is exported directly to an unapproved country. *Id.* at 818. There is, however, no enforcement mechanism. *Id.* at 819.

24. *Id.* at 810, 811. This provision has been labeled "a case of responsible paternalism." Pirt, *supra* note 15, at 281.

safe, and heat stable, would require a single dose for a lifetime, and would be effective against all viral strains and all routes of exposure.[25] The vaccine could be distributed and administered through a variety of channels using different legal forms.[26] Examples include direct sales by American pharmaceutical companies to private or public clinics; sales through partially or wholly owned subsidiaries located in the host or another foreign country, which could act either as conduits or under licenses to manufacture and distribute American-engineered pharmaceutical products; sales from foreign corporations that have licensing agreements with U.S. corporations; or sales of vaccines under contracts between parent or subsidiary corporations and foreign governments, the latter then organizing distribution through state clinics or possibly, in rural areas, by village health workers in traveling vans.

Before widespread administration, of course, clinical trials must first make sure that a vaccine is both safe and efficacious. Such research will require thousands of participants.[27] Informed consent is critical in both the research and administration phases.[28] Effective informed consent requires detailed warnings that describe known contra-indications to administering entities and, if appropriate, direct recipients. However, the consent process must conform to the cultural norms of the participants.[29] It is important to recognize that prevailing Western, and particularly American, expectations, attitudes, and legal requirements will not necessarily be the custom in other countries.

Many vaccine recipients in underdeveloped countries may be illiterate, rendering written communication for the purpose of consent meaningless. A large number of these recipients will be children.

> In some cultures there is little perception of conflict between self and society, except perhaps if the society is someone else's. For example, in the Indian subcontinent and West Africa great deference may be given to clinicians/healers/elders. Decisions are characteristically made in consultation with leaders in the setting of village meetings. If permission has already been given by a community or family representative, the idea of an informed refusal by the individual may not even arise.[30]

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25. AIDS ACTION FOUNDATION, *supra* note 10, at 2.

26. *See* William Schurtman, Book Review, 23 Int'l Law. 774, 777 (1989) (reviewing WARREN FREEDMAN, PRODUCT LIABILITY ACTIONS BY FOREIGN PLAINTIFFS IN THE UNITED STATES (1988)). For an example of the intricate corporate arrangements that are possible to limit taxation or liability, see *infra* notes 93-94 and accompanying text.

27. AIDS ACTION FOUNDATION, *supra* note 10, at i (Introduction).

28. *Id.* at 25; *see* International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), Dec. 16, 1966, 21 U.N. GAOR Supp. No. 16, at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, *entered into force* on Jan. 3, 1976, pt. III, art. 7, which states that "no one shall be subjected without his free consent to medical or scientific experimentation."

29. *Id.* at 26; *see also* Joan E. Sieber, *Ethical Considerations in Planning and Conducting Research on Human Subjects*, 68 ACAD. MED. S9-S13 (Sept. Supp. 1993).

30. Larry Gostin, *Ethical Principles for the Conduct of Human Subject Research: Population-Based Research and Ethics*, 19 LAW, MED. & HEALTH CARE, RES. ON HUMAN POPULATIONS: NATIONAL AND INTERNATIONAL ETHICAL GUIDELINES, Fall-Winter 1991, at 193 (citations omitted). The author describes the process as "permission" and states that "researchers [still] have an ethical obligation to seek consent from the individual." *Id.* at 194.

In addition to the potential problems associated with obtaining informed consent, other difficulties such as lack of telephones, money, and sophisticated laboratories, poor transportation, political upheaval, and in some impoverished parts of the world, the disruptions caused by famine and war, will impede effective immunization programs.[31] Possibilities for accident and injury are clearly present. Despite careful preliminary trials, there may be unanticipated reactions in the form of increased vulnerability to HIV or harmful side effects.[32] Production problems are a possibility. For example, in 1976 two million swine flu doses were made from the wrong virus.[33] Additionally, contamination could occur in the process of distribution, improper administration, or a failure to communicate known hazards adequately. In this regard, the possibility always exists that protection could vary, causing some recipients to believe erroneously that infection is no longer possible and that they can engage in risk-enhancing behavior.[34]

II. Advantages of Bringing Suit Against a U.S. Manufacturer in the United States and Defenses Against Such Suits

A. Advantages of Bringing Suit in the United States

A foreign plaintiff who has been injured by a vaccine might sue the local medical personnel who dispensed the vaccine or attempted treatment thereafter, the clinic where the vaccine was administered (unless it is state-operated and sovereign immunity applies), or a local subsidiary corporation (of a U.S. manufacturer) that may have produced and marketed the vaccine. But in all likelihood, particularly if vaccine-related injuries occurred on a wide, broadly reported scale, the injured foreign plaintiff would attempt to bring suit in this country in state or federal court against the U.S. pharmaceutical corporation that developed the vaccine. An attempt might be made to hold a parent American company responsible for the acts of its foreign subsidiary.[35] In the alternative, if research, develop-

31. Tina Susman, *Zaire Doesn't Fit the Movie*, S.F. Chron., May 16, 1995, at A8. Even though a vaccine for polio has been in existence for about four decades, only half of Africa's children have been immunized. *Id.*

32. AIDS Action Foundation, *supra* note 10, at 27; *see also* Robert L. Turner, *Hurdles for an AIDS Vaccine*, Boston Globe, July 20, 1993, at 15.

33. *Id.*

34. AIDS Action Foundation, *supra* note 10, at 8.

35. In the Bhopal litigation, the attempt within the United States was unsuccessful, but by returning the case to India, the concept of responsibility was implicitly affirmed. *In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 842; *see also Obligations of a Company Belonging to an International Group and Their Effect on Other Companies of That Group*, Institut de Droit International; Session de Lisbonne, Fifteenth Commission, Draft Resolution Rev. 2, Aug. 29, 1995, II 2(b) ("Liability for claims arising out of torts may be imputed to the controlling entity . . . in circumstances, such as mass disasters, in which the resources of the member or members of the multinational enterprise directly involved are insufficient to respond to the claim in full"), II 2(c) ("Liability . . . may also be imputed to another member of the multinational enterprise . . . when that other member has participated in the activity on which the claim is based or has derived direct economic benefit from that activity"), and II 3(a)(a)(i) and (ii) ("a parent company or a controlling entity of

ment, and/or production took place in this country, a claim could be pressed that the American company, itself, fell below an appropriate standard of care in its research and testing, its manufacturing processes, or its warnings accompanying product distribution.[36] The legal theories, as in all actions arising from injury caused by a product, would be breach of express or implied warranty, negligence, or strict product liability in the form of production flaw, design defect or failure to warn.[37]

Despite the apparent, enormous inconvenience, why would an injured foreign plaintiff attempt to file a claim in the United States against the parent corporation? The answer is twofold: the problematic nature of legal proceedings in many countries, particularly those in the less developed world, and the attractive nature of legal processes and doctrine in the United States. In a foreign country, the plaintiff could encounter substantial delay, limited opportunities for discovery, a lack of juries (and their potential pro-plaintiff biases) and contingent fee arrangements, doctrine rooted in negligence rather than strict products liability, a potentially nonindependent judiciary, and vastly limited damages relative to comparable awards in the United States.[38] Moreover, if a claim is filed in a foreign forum against a U.S. corporation and a judgment is obtained, the plaintiff would, in all likelihood, be compelled to enforce that judgment in the United States, because the assets of the corporation would be located in the United States and not in the foreign jurisdiction.[39] Thus, a second, costly legal proceeding would be required.[40]

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a multinational enterprise is subject to . . . jurisdiction . . . on the basis . . . of the permanent presence in the State of a branch or . . . a subsidiary"); CASSELS, *supra* note 21, at 146-47 (in the *Union Carbide* case, the argument of the Indian government was that a "parent company must, in its dealings abroad, maintain responsibility for its subordinates").

36. *See, e.g.*, Friends of All Children, Inc. v. Lockheed Aircraft Corp., 717 F.2d 602, 604 (D.C. Cir. 1983); Carlenstolpe v. Merck & Co., 638 F. Supp. 901, 903 (S.D.N.Y. 1986); Harrison v. Wyeth Labs, 510 F. Supp. 1, 2-3 (E.D. Pa. 1980).

37. Almost all of these theories of liability were asserted in de Melo v. Lederle Labs, 801 F.2d 1058 (8th Cir. 1986).

38. *In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 847-51; *see also* Sheila L. Birnbaum & Douglas W. Dunham, *Foreign Plaintiffs and Forum Non Conveniens*, 16 BROOK. J. INT'L L. 241, 242 n.4 (citing Itzkowitz, *Don't Denigrate the Indian Legal System*, Nat'l L.J., Feb. 4, 1985, at 12).

39. GARY B. BORN & DAVID WESTIN, INTERNATIONAL CIVIL LITIGATION IN UNITED STATES COURTS 739-40 (2d ed. 1992).

40. The recognition of foreign judgments is governed by the laws of the states. *Id.* at 743, 770-72. Somportex, Ltd. v. Philadelphia Chewing Gum Corp., 318 F. Supp. 161, 164 (E.D. Pa. 1970); R. Doak Bishop & Susan Burnette, *United States Practice Concerning the Recognition of Foreign Judgments*, 16 INT'L LAW 425 (1982). As a general proposition, U.S. courts are "far more willing" to enforce Western European—and particularly English—judgments than judgments from other nations. BORN & WESTIN, *supra* note 39, at 769. Nevertheless, assuming a foreign court has properly asserted personal and subject matter jurisdiction, its judgment will be upheld even though it applies a rule contrary to public policy in the United States. *Id.*; Somportex Ltd. v. Philadelphia Chewing Gum Corp., 318 F. Supp. at 168-69. But enforcement will be denied if the judgment is so unfair and so lacking in impartiality that it is outrageous, amounting to prejudice or fraud, or if it runs "directly contrary to some fundamental policy of the forum." BORN & WESTIN, *supra*

These restrictions substantially inhibit legal redress for injury, and for the poor and ignorant the result can be no redress at all. But many of the difficulties encountered in legal proceedings abroad evaporate if suit is brought directly in the United States, and in consequence the American legal system operates like a magnet attracting foreign claimants.[41] As an example, American lawyers were on the scene within ten days of the gas plant explosion in Bhopal, India, and 145 class action suits were filed in U.S. federal district courts.[42] Although in that case the explosion most probably resulted from negligent plant maintenance,[43] a significant percentage of actions by foreign plaintiffs involves pharmaceuticals.[44] For a foreigner injured by a drug or vaccine developed in the United States, there are multiple reasons why suit here would be attractive, and they constitute virtual reciprocals of the reasons why suit is less attractive in foreign jurisdictions: extensive discovery, contingent fees, jury trials, the availability of strict products liability in most U.S. jurisdictions, greater expertise of American attorneys in products litigation, better access to expert witnesses, the possibility of punitive damages, pain and suffering as an element of damages, no liability for the successful litigants' attorneys fees, and last, but by no means least, the lure of relatively greater damage awards.[45]

The last—greater damage rewards—could constitute a windfall to a foreign plaintiff far greater than a lifetime of earnings. Citizens of foreign countries who are injured by U.S. technology or pharmaceuticals may earn a fraction of the wages commanded by their counterparts in this country. By bringing suit in the United States, they clearly hope to benefit from the largesse of a more lenient legal system, although most U.S. courts would apply foreign law for an injury incurred abroad, even on the damages question.[46] If U.S. law is applied, however, because the tortious conduct (for example, manufacturing or design defect) is

note 39, at 753; *see id.* at 753, 769 (citing Courtland H. Peterson, *Foreign Country Judgments and the Second Restatement of Conflict of Laws*, 72 COLUM. L. REV. 220, 230-32 (1972)); CAL. CIV. PROC. CODE § 1713.4(6)(3) (foreign judgment not recognized if cause of action or defense on which judgment is based "is repugnant to the public policy of this state"); *see also* Ackermann v. Levine, 788 F.2d 830, 841, 844 (2d Cir. 1986). The doctrine of international comity, with its exceptions, was articulated in Hilton v. Guyot, 159 U.S. 113, 202-03 (1885).

41. The United States has been described as "an El Dorado or promised land for foreign plaintiffs." Schurtman, *supra* note 26, at 776; *see also* Mary Sheinwold, *International Products Liability Law*, 1 TOURO J. TRANSNAT'L L. 257, 260 (1988).

42. Birnbaum & Dunham, *supra* note 38, at 241.

43. The reasons and supporting evidence, however, were disputed. CASSELS, *supra* note 21, at 7-11.

44. Schurtman, *supra* note 26, at 776. Airplane crashes also constitute a significant percentage. *Id.*

45. *Id.*; *see also* BORN & WESTIN, *supra* note 39, at 92-93, 222; Birnbaum & Dunham, *supra* note 38, at 242; William L. Reynolds, *The Proper Forum for a Suit: Transnational Forum Non Conveniens and Countersuit Injunctions in the Federal Courts*, 70 TEXAS L. REV. 1663, 1706-07 (1992); Sheinwold, *supra* note 41, at 257-58. Some of these factors are currently the target of reform proposals.

46. RESTATEMENT (SECOND) OF CONFLICT OF LAWS §§ 145, 146, 156 *et seq.*, 171 (1971).

alleged to have taken place in this country, no rules govern the calculation of damages. For example, should a damages verdict or settlement in this country that takes into account the disparate earnings potential of U.S. and foreign plaintiffs be discounted, contrary to the collateral source rule, for a state-run medical system that may provide free medical care for all injuries sustained? Equal protection for a nonresident alien would be based on only a rational basis review, and discrimination against a foreign plaintiff under such a standard would be both justifiable and plainly constitutional.[47] In the original settlement involving domestic and foreign plaintiffs injured by silicone gel implants, the foreign claimants complained of the considerable disparity in the amount allocated to each group and a lack of standards or criteria for establishing these amounts.[48] The court recognized that settlement values would be lower in other countries and took account of the practical effect of factors such as jury trials, punitive and multiple damages, and the extent of governmentally supported health care systems.[49] The result seems to have been very much an educated guess, varying in size from country to country. However, while a foreign claimant might receive a damages award considerably below that which would be awarded a U.S. citizen, in many cases the amount might still be enough to make filing a claim here a lucrative proposition compared to the amount obtainable at home.

B. Defense Strategies to Avoid Suit in the United States

1. *Forum Non Conveniens*

Forum non conveniens is a common law doctrine that allows a court to dismiss a case brought by a foreign plaintiff, even though jurisdiction and venue are

47. Reynolds, *supra* note 45, at 1692.

48. Lindsay v. Dow Corning Corp., No. 94-P-11558-S, at 6, 13 (N.D. Ala. 1994). Mike McKee, *Foreign Women Unhappy with "Global" Implant Settlement*, THE RECORDER, Aug. 22, 1994, at 1. The settlement unraveled after Dow Corning Corp. filed for bankruptcy. *See* Jay Matthews, *Breast Implant Maker Files for Bankruptcy*, S.F. CHRON., May 16, 1995, at A11; *Withdrawal from Implant Settlement Okd*, S.F. CHRON., Oct. 10, 1995, at A2. A new Approval of Revised Settlement Program and Injunctions, Order No. 27, filed December 22, 1995, provides compensation only for domestic plaintiffs and eliminates foreign claimants, who may now file in their own courts or in U.S. courts subject to dismissal for forum non conveniens. In the settlement of the Bhopal litigation in India, individual amounts were "minuscule in comparison with amounts awarded for similar injuries to persons in Western countries . . . Awards to the families of deceased victims might produce, after inflation, annual amounts of about $900 for twenty years . . . Awards to those who were permanently disabled might generate about $350 per year. . . ." CASSELS, *supra* note 21, at 230. These awards did not guarantee future cost of income loss, subsistence, or medical care, nor did it provide for pain and suffering. *Id.*

49. Lindsay v. Dow Corning Corp., No. CV94-P-11558-S, at 13 (N.D. Ala. 1994). Benefits were established as a percentage of the amount for domestic plaintiffs on a country-by-country basis, taking into account compensation typically awarded compensable injuries in those countries. *Id.* at 13-14. Any significant correlation between the breast implants and subsequent ills has been strongly challenged by MARCIA ANGELL, THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996).

proper, if the case should more appropriately be tried in a foreign forum.[50] Only a defendant may invoke the doctrine.[51] Within the federal system, change of venue is effected by transferring the action to another district,[52] whereas, when a foreign plaintiff is involved, the result of a successful forum non conveniens motion is outright dismissal,[53] albeit dismissal frequently subject to limiting conditions.[54]

The growth in international commercial activity and the increasing resort by foreigners to redress in U.S. courts when they are injured abroad by American products has sparked "an explosion of forum non conveniens litigation."[55] The doctrine has won widespread acceptance.[56] Most of the litigation is between foreign plaintiffs and U.S.-based multinational corporations.[57] "The battle over where the litigation occurs is typically the hardest fought and most important issue in a transnational case; if the defendant wins this battle, the case is often effectively over."[58] In consequence, from a defendant's standpoint, removing a case from the United States is far more important than convincing a U.S. court to apply foreign law.[59]

The forum non conveniens inquiry proceeds in four steps. First, the trial court must ascertain whether an adequate alternative forum exists. Assuming a favorable response to the first inquiry, the court must next consider private interest factors that bear on the litigation. If the private interest factors are in equipoise, or near equipoise, the court must then consider public interest factors. Lastly, if the balance tips toward the foreign forum, the court can dismiss for forum

50. Jacqueline Duval-Major, Note, *One-Way Ticket Home: The Federal Doctrine of Forum Non Conveniens and the International Plaintiff*, 77 CORNELL L. REV. 650 (1992).

51. *Id.*

52. 28 U.S.C. § 1404(a) (1990).

53. Duval-Major, *supra* note 50, at 652, 656.

54. Allin C. Seward III, *After Bhopal: Implications for Parent Company Liability*, 21 INT'L LAW. 695, 697, 702-04 (1987). Typical limiting conditions are defendant's consent to suit in the foreign jurisdiction, acceptance of jurisdiction by the foreign court, defendant's waiver of the statute of limitations after filing in the U.S. court, and defendant's amenability to discovery. Ledingham v. Parke-Davis Div. of Warner Lambert Co., 628 F. Supp. 1447, 1452-53 (E.D.N.Y. 1986); *see also In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 867.

55. Reynolds, *supra* note 45, at 1665. Many of the plaintiffs are solicited abroad by American lawyers. *Id.* at 1671.

56. *Id.* at 1664-65.

57. Duval-Major, *supra* note 50, at 670.

58. David W. Robertson & Paula K. Speck, *Access to State Courts in Transnational Personal Injury Cases: Forum Non Conveniens and Antisuit Injunctions*, 68 TEXAS L. REV. 937, 938 (1990) (footnotes omitted). "[O]nly an outright dismissal with prejudice could be more 'outcome-determinative' than a [forum non conveniens] dismissal to a distant forum in a foreign land." *Id.* n.4 (citing *In re* Air Crash Disaster, 821 F.2d 1147, 1156 (5th Cir. 1987)) (en banc), *vacated sub nom.* Pan Am. World Airways, Inc. v. Lopez, 490 U.S. 1032, *aff'd in part and vacated in part*, 883 F.2d 17 (5th Cir. 1989).

59. Robertson & Speck, *supra* note 58, at 942.

non conveniens, but only if the plaintiff can reinstate suit without substantial inconvenience or prejudice.[60]

In its original formulation, the plaintiff's choice of forum could rarely be disturbed absent oppressiveness and vexation to a defendant out of all proportion to a plaintiff's convenience or considerations affecting the court's own administrative and legal problems.[61] However, in *Piper Aircraft Co. v. Reyno*,[62] the Supreme Court concluded that the presumption in favor of the plaintiff's choice of forum deserves less deference when the plaintiff is foreign.[63] The *Piper* Court was concerned that U.S. multinationals would become the target of tort litigants from around the world.[64] It also wanted to help U.S. courts "avoid conducting complex exercises in comparative law,"[65] and, indeed, forum non conveniens decisions are often choice of law decisions in disguise,[66] although convenience and choice of law are analytically distinct. However, the shift to less deference—and away from weighing private and public interest factors in favor of the plaintiff—has meant in practice little or no deference when the plaintiff is neither a U.S. citizen nor a resident.[67] From that plaintiff's point of view, the doors of the federal courts are virtually closed when they bring product liability suits against U.S. corporations for injuries suffered abroad.[68] The consequence is an increasing

60. *Friends of All Children*, 717 F.2d at 606; *see also* Frazier v. St. Jude Medical, Inc., 609 F. Supp. 1129, 1130-31 (D. Minn. 1985). The private interest factors include ease of access to sources of proof, availability of compulsory process for attendance of unwilling witnesses, the cost of obtaining attendance of willing witnesses, the possibility of a view of the premises, and the enforceability of the judgment. Gulf Oil Corp. v. Gilbert, 330 U.S. 501, 508 (1947). Factors of public interest include the administrative difficulties that arise when litigation piles up in congested centers, the burden of jury duty, and the local interest in having localized controversies decided at home. *Id.* at 508-09. The convenience of the parties is rarely a factor; rather, the principal issues involve the location of evidence, costs, adequate discovery, local practices, and the ability to implead third parties. Reynolds, *supra* note 45, at 1672-77.

61. Koster v. Lumbermens Mutual Casualty Co., 330 U.S. 518, 524 (1947); Gulf Oil v. Gilbert, 330 U.S. at 508.

62. 454 U.S. 235 (1981).

63. *Id.* at 255. Moreover, the Court concluded that the possibility of a change in substantive law should ordinarily not be given conclusive or even substantial weight in the forum non conveniens inquiry. *Id.* at 247, 254; *see also* Duval-Major, *supra* note 50, at 647. However, under Friendship, Commerce, and Navigation treaties, which give foreign citizens the same access to U.S. courts as nonresident U.S. citizens, the *Piper* standard of less deference does not apply. *Id.* at 658 (citing Allen J. Stevenson, *Forum Non Conveniens and Equal Access Under Friendship, Commerce and Navigation Treaties: A Foreign Plaintiff's Rights*, 13 HASTINGS INT'L & COMP. L. REV. 267, 277-78 (1990)); *see also* Reynolds, *supra* note 45, at 1692.

64. BORN & WESTIN, *supra* note 39, at 303.

65. Piper Aircraft Co. v. Reyno, 454 U.S. at 251; *see also* de Melo v. Lederle Labs, 801 F.2d 1058, 1064 (8th Cir. 1986).

66. Laurel E. Miller, Comment, *Forum Non Conveniens and State Control of Foreign Plaintiff Access to U.S. Courts in International Tort Actions*, 58 U. CHI. L. REV. 1369, 1391 (1991).

67. *Id.* at 1369; Piper Aircraft Co. v. Reyno, 454 U.S. at 242, 255; Duval-Major, *supra* note 50, at 657-58.

68. Miller, *supra* note 66, at 1369; Robertson & Speck, *supra* note 58, at 940.

resort to state courts,[69] but even there the doctrine of forum non conveniens generally follows the federal standard.[70]

If no adequate alternative forum exists;[71] if a foreign forum is manifestly biased, unfair, or unequipped for a particular case;[72] or if virtually no remedy whatsoever is available,[73] a motion for forum non conveniens dismissal will be denied. But the fact is that "courts have found the foreign forum inadequate only in extreme cases."[74] Dismissal effectively ends the case, leaving most foreign plaintiffs with little or no recourse at home.[75] Moreover, once the trial court has ruled on the motion, the decision is given substantial deference on appeal.[76]

Dismissal for forum non conveniens has been granted when the treating doctor and distributing corporation are in the foreign country;[77] where a drug is manufactured, packaged, advertised, promoted, and marketed by a separate and independent foreign subsidiary;[78] and where a product license is issued under the laws of a foreign country.[79] In the case of *Harrison v. Wyeth Laboratories*,[80] even though the fundamental manufacturing and marketing decisions and the withholding of an adequate warning were alleged to have taken place in the United States,

69. *Id.*

70. Duval-Major, *supra* note 50, at 659. A detailed breakdown of the approaches followed in the states may be found in Robertson & Speck, *supra* note 58, at 950 & nn.73-80. An example of a state court decision that follows *Piper Aircraft* and *Gilbert* is Stangvik v. Shiley, 819 P.2d 14 (Cal. 1991), although the California Supreme Court noted that "the cumulative connection of the defendant and its conduct within the state is relevant." *Id.* at 24. It is still "an open question as to whether federal courts sitting in diversity must apply federal or state law" to a forum non conveniens motion. Birnbaum & Dunham, *supra* note 38, at 249 (citing Piper Aircraft Co. v. Reyno, 454 U.S. 235, 248 n.13 (1981); Sibaja v. Dow Chem. Co., 757 F.2d 1215, 1219 (11th Cir.), *cert. denied*, 474 U.S. 948 (1985)); Stein, *Forum Non Conveniens and the Redundancy of Court-Access Doctrine*, 133 U. PA. L. REV. 781, 820 (1985)).

71. BORN & WESTIN, *supra* note 39, at 312.

72. *Id.* at 314.

73. *See* Irish Nat'l Ins. Co. v. Aer Lingus Teoranta, 739 F.2d 90 (2d Cir. 1984); *see also* BORN & WESTIN, *supra* note 39, at 286-87.

74. Reynolds, *supra* note 45, at 1668.

75. *Id.* at 1689 (citing David W. Robertson, *Forum Non Conveniens in America and England: "A Rather Fantastic Fiction,"* 103 LAW Q. REV. 398, 419 (1987) (reporting a survey showing that only 3 of 85 cases dismissed by U.S. courts on forum non conveniens grounds resulted in judgment in a foreign court, and 10 more cases were pending)). These figures, however, are consistent with the percentage of tort cases that are tried in the United States. *Justice Department Study Finds 75 Percent of Tort Cases Settle, Three Percent Go to Trial*, 2 CIV. JUST. DIG., Summer 1995, at 5; Duval-Major, *supra* note 50, at 651, 672; Miller, *supra* note 66, at 1388.

76. Piper Aircraft v. Reyno, 454 U.S. 235, 257 (1981); Hodson v. A.H. Robins Co., 715 F.2d 142, 144 (4th Cir. 1983); de Melo v. Lederle Labs, 801 F.2d 1058, 1061 (8th Cir. 1996); Carlenstolpe v. Merck & Co., 638 F. Supp. 901, 904 (S.D.N.Y 1986); *see also* Reynolds, *supra* note 45, at 1686, who points out that, because appellate courts must engage in meaningful review, they tend to ignore the standard and engage in de novo review.

77. de Melo v. Lederle Labs, 801 F.2d 1058, at 1063.

78. Ledingham v. Parke-Davis Div. of Warner-Lambert Co., 628 F. Supp. 1447, 1449 (E.D.N.Y. 1986).

79. Harrison v. Wyeth Laboratories, 510 F. Supp. 1 (E.D. Pa. 1980), *aff'd*, 676 F.2d 685 (3d Cir. 1982); McCracken v. Eli Lilly & Co., 494 N.E.2d 1289, 1291 (Ind. Ct. App. 1986).

80. Harrison v. Wyeth Laboratories, 510 F. Supp. at 1.

the court was sensitive to the legitimate concerns and unique needs of the foreign country.[81] In granting the forum non conveniens motion, the court noted that the U.S. parent corporation should not be immunized from liability, but the court also believed that it should not impose American notions of safety and risk on a foreign country that might have a "vastly different standard of living, wealth, resources, level of health care and services, values, morals and beliefs than our own."[82] These concerns are only exacerbated when evidence of preexisting medical conditions, the knowledge of treating physicians, and the nature and extent of adverse reactions—in short, evidence of causation, liability, and damages—are located in the foreign country.[83]

Other courts have gone the other way. In terms of injury caused by a drug or vaccine, much appears to depend on how expansively or narrowly courts construe the interest of the United States in regulating and controlling its manufacturers' conduct overseas.[84] As one commentator has noted:

> Recent products liability cases involving prescription drugs suggest that whether the balance tips in favor of the plaintiff's choice or in favor of a foreign forum depends upon (1) the extent of the American manufacturer's active participation in the design, development, testing, labelling and marketing of the allegedly defective product; and (2) the court's view of whether the chosen forum's interest in product safety and in regulating manufacturer conduct within its borders properly extends to transactions and events occurring beyond its borders.[85]

When the litigation involves behavior that occurs in the United States—for example, when a drug is developed, tested, and manufactured in this country; approved by the FDA; and used by American citizens—then American courts have refused to dismiss the action.[86] The courts distinguish cases that involve products developed in the United States but manufactured overseas.[87] Courts have also considered the burden of obtaining translations, different discovery rules, and the lack of contingent fees.[88] Of perhaps greater import, ease of access to sources of proof in the United States, including witnesses, has helped determine the outcome.[89] In addition, although not an articulated factor, it is arguable that the revolution in transpor-

81. *Id.* at 3-4, 8.

82. *Id.* at 4.

83. Birnbaum & Dunham, *supra* note 38, at 255. Dismissal is likely if no plaintiff is an American citizen, no significant events occurred in the United States, and foreign law controls. Reynolds, *supra* note 45, at 1681.

84. Sheila L. Birnbaum & Barbara Wrubel, *Foreign Plaintiffs and the American Manufacturer: Is a Court in the United States a Forum Non Conveniens?* 20 FORUM 59, 67 (1984).

85. *Id.* at 65.

86. Carlenstolpe v. Merck & Co., 638 F. Supp. 901, 906-09 (S.D.N.Y. 1986); Hodson v. A.H. Robins Co., 715 F.2d 142, 143 (4th Cir. 1983); Birnbaum & Dunham, *supra* note 38, at 252.

87. Carlenstolpe v. Merck & Co., 638 F. Supp. at 908. Arguably, if the crux of the plaintiff's complaint is defect in design, the foreign place of manufacture should not make a difference.

88. Joaquim Macedo v. Boeing Co., 693 F.2d 683, 688 (7th Cir. 1982).

89. Irish Nat'l Ins. Co. v. Aer Lingus Teoranta, 739 F.2d 90, 92 (2d Cir. 1984); Friends of All Children, Inc. v. Lockheed Aircraft Corp., 717 F.2d 602, 608-09 (D.C. Cir. 1983).

tation and communication and the deliberate dispersion of corporate authority through the creation of multinational subsidiaries call for a reexamination of the lesser deference given to a foreign plaintiff's choice of forum.[90]

2. *Corporate Form*

A corporation may avoid potential liability through the creation of an organizational structure that locates responsibility for tortious behavior in legally separate corporate entities.[91] Company law tends to focus on each individual entity, granting to each limited liability and not piercing the corporate veil.[92] The general rule, therefore, is that an American corporation that establishes an independent foreign subsidiary to manufacture and/or sell a product later found to be defective is not individually liable as a parent corporation.[93]

The labyrinthine, multilayered corporate structures that result are a testament to human—and particularly lawyerly—ingenuity. As an example, albeit in a different context, take the case of *De Mateos v. Texaco, Inc.*,[94] which involved a suit, dismissed on forum non conveniens grounds, brought by a mother for the death of her son, a seaman aboard a ship of Liberian registry owned by Texpan, a Panamanian corporation. Texaco Overseas Tankship Limited (TOT), a United Kingdom corporation with its principal place of business in London, managed the ship. TOT was a wholly owned subsidiary of Texaco Limited, another United Kingdom corporation with its principal place of business in London. Texaco Limited was wholly owned by Texas Operations (Europe) Ltd. (TOEL), a Delaware corporation. Texaco Inc. (the defendant), also a Delaware corporation, owned all the stock of TOEL and of Texpan.[95]

Many forum non conveniens cases involve attempts to penetrate these complex corporate mazes, leapfrogging a local subsidiary in order to bring suit directly against the American corporate parent.[96] When the subsidiary is wholly owned, rather than the creature of a joint venture, and is part of a complex multinational

90. *See* Fitzgerald v. Texaco, Inc., 521 F.2d 448, 456 (2d Cir. 1975) (Oakes, J., dissenting), *cert. denied*, 423 U.S. 1052 (1976).

91. Enterprises linked by ownership that share knowledge, resources, and responsibilities include incorporated branches, subsidiaries, and joint ventures. Watter Kolvenbach, *European Reflections on Bhopal and the Consequences for Transnational Corporations*, INT. BUS. LAW., Nov. 1986, at 358.

92. *Id.* at 359.

93. Affiliated v. Trane Co., 831 F.2d 153, 155 (7th Cir. 1987). Bewers v. American Home Prods. Corp., 474 N.E.2d 247 (N.Y. 1984). *But see Obligations of a Company Belonging to an International Group*, *supra* note 35.

94. 562 F.2d 895 (3d Cir. 1977).

95. *Id.* at 897-98. For other examples, see Fitzgerald v. Texaco, Inc., 521 F.2d 448, 455 (2d Cir. 1975); McCracken v. Eli Lilly & Co., 494 N.E.2d 1289, 1291 (Ind. Ct. App. 1986); *see also* Robertson & Speck, *supra* note 58, at 939 nn.13, 14.

96. Dowling v. Richardson-Merrell, Inc., 727 F.2d 608, 610-11 (6th Cir. 1984); Harrison v. Wyeth Laboratories, 510 F. Supp. 1, 3 (E.D. Pa. 1980); *see also* de Melo v. Lederle Labs, 801 F.2d 1058, 1059 (8th Cir. 1986).

enterprise that is ultimately directed and controlled in the United States, the temptation to bring suit in the United States is particularly strong despite dispersed decision making, separate boards of directors, and overseas manufacturing and research facilities.[97] The fact that U.S. courts grant forum non conveniens motions against parent companies subject to conditions indicates a willingness to look behind the corporate form and find a kind of multinational enterprise liability.[98] Implicit is an acknowledgment of a central decision-making structure, without regard for legal personality, and a recognition that modern management forms have rendered older forms at least partially obsolete.[99]

As a practical matter, this point of view may make sense. In the sale of pharmaceuticals, the general trend is toward collaboration between American and foreign companies, and an ever-increasing percentage of American drug production is performed by foreign-based subsidiaries of U.S. parent firms.[100] Nevertheless, permitting suit against an American firm for injuries resulting from a vaccine manufactured overseas by its foreign subsidiary could dampen distribution efforts and represents "a variety of social jingoism, which presumes that the 'liberal purposes' of American law must be exported to wherever our multinational corporations are permitted to do business."[101]

3. *Contractual Provisions*

If a vaccine is administered privately, as it could and would be in many countries, the company responsible for its manufacture and distribution might attempt to obtain a release from liability as part of the consent to treatment. However, in addition to the fact that many recipients would fail to understand the full nature of such a provision,[102] an attempt to avoid a general tort obligation through contract would presumably fail on public policy grounds. Conditioning an essential service—and surely an AIDS vaccine would fit into that category—on the waiver of any legal redress could not constitute a legally enforceable, express assumption of risk.[103]

Most vaccinees, however, would probably receive the vaccine through part of a massive government effort, and distribution would take place in public clinics or at the hands of local public health officials. Thus, a drug company would sell the vaccine to the foreign government, or to an agency or instrumentality of the government, and not to individual recipients. The government would then clearly

97. Kolvenbach, *supra* note 91, at 359.

98. Seward, *supra* note 54, at 704; Kolvenbach, *supra* note 91, at 359; *In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 867; Ledingham v. Parke-Davis Div. of Warner Lambert Co., 1628 F. Supp. 1447, 1452-53 (1986).

99. Kolvenbach, *supra* note 91, at 357, 360.

100. Pirt, *supra* note 15, at 266-67.

101. De Mateos v. Texaco, Inc., 562 F.2d 895, 902 (3d Cir. 1977).

102. *See supra* notes 29-30 and accompanying text.

103. *See, e.g.*, Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963).

be part of the chain of distribution. Nevertheless, if the vaccine were defective or administered negligently, the government might escape liability in its own courts through either sovereign immunity, the absence in its law of a doctrine of strict products liability, or the absence of a rule, as in the United States, that imposes liability on a conduit in the chain of distribution.[104] If, instead, the foreign government were made a party to a suit in the United States, it would probably escape liability by invoking the Foreign Sovereign Immunity Act or the "act of state" doctrine.[105] And, no doubt, it would move for dismissal on the basis of forum non conveniens.

In the most likely scenario, however, the foreign government would not be a defendant. Rather, it would function as plaintiff acting as representative of its injured citizens.[106] This last is what happened with regard to the Indian citizens injured by the gas plant explosion at Bhopal, even though government regulatory failures were strongly indicated as partly responsible for the disaster.[107]

In its contract for the sale of the vaccine to the foreign government, an American pharmaceutical corporation could bargain for choice of law and choice of forum clauses.[108] In the event of a dispute between the parties, these clauses could compel

104. W. PAGE KEATON ET AL., PROSSER AND KEATON ON THE LAW OF TORTS § 100(4) (5th ed. 1984).

105. The Foreign Sovereign Immunity Act, 28 U.S.C.A. §§ 1300, 1602-1611, grants a foreign state immunity from jurisdiction in U.S. courts unless one of several statutorily defined exceptions applies. Republic of Argentina v. Weltover, Inc., 504 U.S. 607, 610-11 (1992). One exception is for commercial activity giving rise to a tort outside the United States that causes a direct effect in the United States. 28 U.S.C.A. § 1605(a)(2). But, arguably, distribution of an AIDS vaccine would not be such an activity if, after purchase, the vaccine were administered without charge or at least without profit. Moreover, there would appear to be no direct effect in the United States. Sudano v. Federal Airports Corp., 699 F. Supp. 824, 826 (D. Haw. 1988) (direct effect must be substantial (citing Zernicek v. Brown & Root, Inc., 826 F.2d 415, 417 (5th Cir. 1985), *cert. denied*, 484 U.S. 1043 (1988)); Tucker v. Whitaker Travel Ltd., 620 F. Supp. 578 (D. Pa. 1985), *aff'd*, 800 F.2d 1140, *cert. denied*, 479 U.S. 986 (1986). There is also no sovereign immunity when a foreign state waives its immunity either explicitly or by implication. 28 U.S.C.A. § 1605(a)(1). The "act of state" doctrine precludes American courts from inquiring into the validity (or legality) of the public acts committed by a recognized foreign state within its own territory. Arango v. Guzman Travel Advisors Corp., 621 F.2d 1371, 1380 (5th Cir. 1980); Eckert Int'l v. Government of Fiji, 834 F. Supp. 167, 171 (D. Va. 1993). Presumably, distribution of an AIDS vaccine by a foreign government to its own citizens would be a public, not a commercial, act.

106. *See, e.g., In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 844; CASSELS, *supra* note 21, at 118-19.

107. CASSELS, *supra* note 21, at 16, 22-25, 120.

108. BORN & WESTIN, *supra* note 39, at 223. Forum selection clauses, if the result of a freely negotiated, private international commercial agreement, are enforceable unless they are unreasonable (due to serious inconvenience), unjust, or invalid because of fraud or overreaching. The Bremen v. Zapata Off-Shore Co., 407 U.S. 1, 9, 16 (1972); Carnival Cruise Lines, Inc. v. Shute, 499 U.S. 585, 595 (1991). "Only rarely (and usually not explicitly)" have U.S. courts "relied on the alleged bias of a foreign forum to deny enforcement to a forum selection clause." BORN & WESTIN, *supra* note 39, at 263 (citing cases). Forum selection clauses will usually be enforced by U.S. courts even when the choice is the foreign party's home country. *Id.* at 273-74. Similarly, most U.S. courts enforce choice of law provisions unless they violate an important public policy of the forum state, or the choice of law lacks a reasonable relation to the parties' transaction, because it appears to

litigation in a country with more favorable substantive law and procedural rules than could be found in the United States.[109] The advantages of forum non conveniens could, in effect, be written into the contract.[110] However, it is not clear that injured individuals, even individuals represented by their government, would be bound by their government's contract clauses. If redress in their home courts would be very difficult or impossible to obtain, a forum in the United States might still be available, as discussed more fully in the next section of this article.

III. Should Suit in the United States against a U.S. Pharmaceutical Corporation Be Permitted?

A. Arguments in Favor of Suit in the United States

The parochial advantages to a foreign claimant of bringing suit in the United States were set forth in the preceding section.[111] The concerns of such a plaintiff are rooted largely in questions of legal procedure, doctrine, and assessment of damages, and defenses such as forum non conveniens seem similarly rooted in the practical details of access to proof, docket congestion, and choice of law.[112] Transcending these matters is an issue of more general concern: Does it make sense from a policy perspective for a United States corporation, in particular a large, multinational corporation, to shield itself from liability in a world that is increasingly interconnected due to advances in transportation and communication technology? Specifically, to address the theme of this article, does it make sense for a U.S. pharmaceutical company that has developed an AIDS vaccine for desperate recipients throughout the world to avoid all responsibility if the vaccine causes injuries?

There are cogent reasons for permitting liability. Since 1947, when the Supreme Court first adopted the doctrine of forum non conveniens, major changes have oc-

circumvent local laws when a local transaction is involved. *Id.* at 229-30. The corporation might also attempt to secure a full indemnity provision, but, depending on the urgency of the need, it is unlikely that most, if any, governments would agree to it.

109. "Because judicial systems, procedural rules, substantive law, choice-of-law principles and political climates vary significantly from country to country, the selection of the forum can often have an important influence on the outcome of the litigation." Born & Westin, *supra* note 39, at 22. Factors bearing on forum selection, e.g., discovery, awarding costs, size of damage awards, and exchange controls, are set forth in detail. *Id.*

110. However, if factors are present such as unequal bargaining power or inconvenience, a U.S. court could ignore a forum selection clause and, under a reasonableness analysis, entertain the action. Restatement (Second) of Conflict of Laws § 80 cmt. c (1986). Colonial Leasing Co. v. Pugh Brothers Garage, 735 F.2d 380, 382 (9th Cir. 1984). Although agreement in advance on a forum acceptable to both parties is an indispensable element in international trade, The Bremen v. Zapata Off-Shore Co., 407 U.S. at 13-14, the choice of forum should be unenforceable if it contravenes a strong public policy of the forum where suit is brought or where enforcement would be unreasonable and unjust due to fraud and overreaching. *Id.* at 15. Moreover, "the tort law of a foreign country will not be applied if that country is shown to be 'uncivilized.' " Zschernig v. Miller, 389 U.S. 429, 461-62 (1968) (Harlan, J., concurring), a term of imprecise and possibly outdated meaning.

111. *See supra* notes 38-45 and accompanying text.

112. *See supra* notes 60-76 and accompanying test.

curred in the worldwide organizational scope of business operations and in the linkage of different parts of the globe through advances in the speed and efficiency of transportation and communication.[113] Large multinational corporations command the resources to take advantage of these advances,[114] which have substantially ameliorated the difficulties associated with obtaining witnesses and transporting documents.[115] It makes sense to permit suit in the United States under U.S. law when, in addition to research and development, a U.S. corporation engages directly in the manufacture of a product and its subsequent distribution from these shores. Under such circumstances, a state would have a significant interest in regulating the quality of production within its borders, as crucial evidence would be located at the site of manufacture as well as at the site of injury.[116]

Even if manufacturing takes place overseas by a foreign subsidiary, the degree of control exercised by the American parent over the foreign operation should be a crucial consideration. Limited responsibility cannot be defended when a local entity does not have power to make its own decisions.[117] If the parent's role is restricted to overall strategy and establishing general policies, and if the subsidiary has substantial autonomy in operational matters, the argument is much stronger that the parent should be immune from liability.[118] But even when autonomy is granted, a parent should be responsible for insuring quality control.[119] It seems indefensible to argue that a parent U.S. corporation, responsible for research and development, could thereafter delegate responsibility for both a decision whether or not to warn of possible, known adverse consequences and the contents of the warning.[120]

The most troubling issue involves the important, but ephemeral, question of national policy and image. Opponents of the notion that foreign nations adequately

113. Duval-Major, *supra* note 50, at 651. "[T]he assessment of whether the balance of public and private interests strongly overcomes the plaintiff's choice of forum must be made in light of the realities of modern transportation and communications. . . . Jet travel and satellite communications have significantly altered the meaning of 'non conveniens.' " Calavo Growers v. Generali Belgium, 632 F.2d 963, 969 (2d Cir. 1980) (Newman, J., concurring); *see also* Overseas Nat'l Airways v. Cargolux Airlines Int'l, 712 F.2d 11, 14 (2d Cir. 1983) (Oakes, J., concurring).

114. Duval-Major, *supra* note 50, at 677.

115. Birnbaum & Dunham, *supra* note 38, at 256 (citing Manu Int'l, S.A. v. Avon Prods. Inc., 641 F.2d 62, 65 (2d Cir. 1981) (quoting Fitzgerald v. Texaco, Inc., 521 F.2d 448, 456 (2d Cir. 1975) (Oakes, J., dissenting)); Note, *Foreign Plaintiffs and Forum Non Conveniens: Going Beyond* Reyno, 64 TEX. L. REV. 193, 216 (1985)).

116. Carlenstolpe v. Merck & Co., 638 F. Supp. 901, 909-10 (citing *In re* Air Crash Disaster, 769 F.2d 115 (3d Cir. 1985)); *see also* Birnbaum & Dunham, *supra* note 38, at 258. For a discussion of interest analysis in resolving a conflicts of law question, see RUSSELL J. WEINTRAUB, COMMENTARY ON THE CONFLICT OF LAWS 315-23 (3d ed. 1986); Hertado v. Superior Court, 11 Cal. 3d 574 (1974).

117. Kolvenbach, *supra* note 91, at 359. It would matter, too, whether the foreign subsidiary was wholly owned.

118. Seward, *supra* note 54, at 706-07.

119. *Id.* at 707; Kolvenbach, *supra* note 91, at 361.

120. *See* de Melo v. Lederle Labs, 801 F.2d 1058, 1065 (8th Cir. 1986) (Swygert, J., dissenting). A multinational corporation that has chosen to do business abroad should not, by that fact, evade U.S. law, particularly as the decision to warn was made in the United States by an American employee. *Id.*; *see also Obligations of a Company Belonging to an International Group, supra* note 35.

protect their citizens from corporate predators argue that multinational corporations search for countries that offer the lowest cost and highest return, and part of the low cost may be attributed to low regulatory standards and less sophisticated tort systems than in the United States.[121] "The largest United States–based [multinational corporations] earn an average of forty percent of their net profits outside the United States."[122] Should this country, through the rules governing forum non conveniens dismissals, appear to condone the reaping of these profits in countries where injured plaintiffs have little chance of vindication?[123] Should the deterrent effect of tort liability be based upon whether harm takes place at home or overseas? Variable rules make it appear that the United States itself is engaged in harmful conduct or, at the least, is indifferent to its consequences if gross national product is increased at the expense of foreign nationals.[124] To avoid this perception, imposing regulatory standards on U.S. multinational corporations should be within the legitimate scope of U.S. foreign policy and would avoid the appearance of a double standard that damages the U.S. image abroad.[125]

B. Arguments Opposed to Suit in the United States

Despite the aforementioned arguments, American corporations with foreign subsidiaries need not fear the imminent demise of the forum non conveniens doctrine.[126] Most U.S. courts have concluded that they do not have a significant interest in regulating the sale of products outside the United States.[127] When a drug is manufactured and marketed in a foreign country under a license granted by that country, and where the injury takes place in that country, U.S. courts are loathe to entertain jurisdiction even though development and testing took place in the United States.[128]

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121. Duval-Major, *supra* note 50, at 674-75.

122. *Id.* at 675. But 80% of profits overseas from the sale of pharmaceuticals are derived from the developed, not the developing, world. Pirt, *supra* note 15, at 271.

123. Duval-Major, *supra* note 50, at 673; *see also* de Melo v. Lederle Labs, 801 F.2d at 1065 (Swygert, J., dissenting), where plaintiff's witness testified that the case could take twenty years to be heard and that plaintiff might not recover even $10,000, despite permanent blindness caused by defendant's drug.

124. Duval-Major, *supra* note 50, at 675.

125. Miller, *supra* note 66, at 1386 (citing Note, *Exporting Hazardous Industries: Should American Standards Apply?* 20 N.Y.U. J. Int'l & Pol. 777, 782-83 (1988); Note, *An Economic Approach to Forum Non Conveniens Dismissals Requested by U.S. Multinational Corporations*, 22 Geo. Wash. J. Int'l & Econ. 215 (1988)).

126. Seward, *supra* note 54, at 705.

127. Birnbaum & Dunham, *supra* note 38, at 259; Reynolds, *supra* note 45, at 1695 (citing David W. Robertson, *Forum Non Conveniens in America and England: "A Rather Fantastic Fiction,"* 103 Law Q. Rev. 398, 405 (1987)).

128. Dowling v. Richardson-Merrell, Inc., 727 F.2d 608, 615-16 (6th Cir. 1984); Reynolds, *supra* note 45, at 1681 (arguing that "[t]he country where the injury occurred has a greater interest in the ensuing products liability litigation than the country where the product was manufactured") (citing Kryvicky v. Scandinavian Airlines Sys., 807 F.2d 514, 517 (6th Cir. 1986)); *see also* Overseas Nat'l Airways v. Cargolux Airlines Int'l, 712 F.2d 11, 12 (2d Cir. 1983).

Indeed, imposing U.S. law with respect to safety, warnings, and duty of care in the resolution of a problem that arises in a foreign country might be viewed as a form of unwarranted paternalism. This would be particularly so if the foreign government conducted the activity or had enacted a comprehensive regulatory scheme to control the activity in question.[129] Even when production and marketing decisions are made in the United States, one court has stated that:

> Faced with different needs, problems and resources [a foreign country] may, in balancing the pros and cons of a drug's use, give different weight to various factors than would our society, and more easily conclude that any risks associated with the use of a particular [drug] are far outweighed by its overall benefits to [the country] and its people. Should we impose our standards upon them in spite of such differences? We think not.[130]
>
> . . . [I]t is manifestly unfair to the defendant, as well as an inappropriate usurpation of a foreign court's proper authority to decide a matter of local interest, for a court in this country to set a higher standard of care than is required by the government of the country in which the product is sold and used.[131]

The incremental deterrence gained by bringing suit in the United States would have, according to Justice Marshall, only an "insignificant" impact.[132] And suing a corporate parent in the United States would breach notions of separate corporate personality and limited liability that are widely relied upon to encourage economic development and foreign investment.[133]

Moreover, as mentioned previously,[134] permitting foreign claimants to sue in this country under U.S. law could result in vastly inflated recoveries relative to what they might receive at home. This risk, in the final analysis, may be the most significant reason to limit suits by foreigners against U.S. corporations. The threat of substantial liability raises costs for American firms competing

129. Seward, *supra* note 54, at 706; Miller, *supra* note 66, at 1384. One author has suggested a "low road" approach in which a recipient country is warned of danger; the persons at risk may never be informed, but the foreign government would decide how to confront the danger, and a paternalistic approach would be avoided. Thomas O. McGarity, *Bhopal and the Export of Hazardous Technologies*, 20 TEX. INT'L L.J. 333, 335 (1985). Moreover, under the act of state doctrine in its traditional formulation, the courts of this country may not inquire into the validity of the public acts of a foreign sovereign power within its own territory. Banco Nacional de Cuba v. Sabbatino, 376 U.S. 398, 401, 439 (1964). The most recent clarification of the act of state doctrine is W.S. Kirkpatrick & Co. v. Environmental Textonics Corp., Int'l, 493 U.S. 400 (1990).

130. Harrison v. Wyeth Laboratories, 510 F. Supp. 1, 4-5 (E.D. Pa. 1980), *aff'd*, 676 F.2d 685 (3d Cir. 1982); *see also* McCracken v. Eli Lilly & Co., 494 N.E.2d 1289, 1293 (Ind. Ct. App. 1986); *In re* Union Carbide Corp. Gas Plant Disaster, 809 F.2d at 201; *see also* Weintraub, *supra* note 116, at 353.

131. Harrison v. Wyeth Laboratories, 510 F. Supp. at 5.

132. Piper Aircraft Co. v. Reyno, 454 U.S. 235, 260-61 (1981); *see also* Reynolds, *supra* note 45, at 1681-82, 1707. *But see supra* text accompanying note 18 (suggesting that deterrence to achieve a safer product is not at issue but rather deterrence that could impede marketing a vaccine at all).

133. CASSELS, *supra* note 21, at 178. The author urges, however, that "the corporate form can too easily be used to avoid taking financial responsibility for risks not consented to" and that this problem "is acute in the case of multinational corporations." *Id.* He argues further that "[T]he principle of limited liability is an instrument of public policy and is ultimately justifiable only when grounded in the public good." *Id.* at 210.

134. *See supra* notes 45-48 and accompanying text.

against foreign firms that do not face the same danger.[135] It also may impede foreign investment, because a relatively low risk of significant damages may play a role in attracting foreign business and stimulating a developing economy.[136] Not least, if huge verdicts were permitted, a U.S. company could potentially be forced into bankruptcy, and the United States might lose a valuable domestic manufacturer.[137]

C. Possible Solutions Involving Different Approaches to Compensation

Clearly, the reasons to limit the scope of liability—and their accompanying legal doctrines, such as forum non conveniens and the sanctity of corporate form—carry substantial weight. Yet there is something deeply troubling about the prospect of indigent people (and their families) throughout the world receiving little or no compensation for injuries incurred as a result of receiving a defective AIDS vaccine. It is not inconceivable that, out of millions of potential recipients, thousands or possibly tens of thousands of innocent people could be harmed. The United States itself, not just the drug companies for which it is the home country, might suffer a damaging blow to its relations with other states if it ignored a problem created by a vaccine developed in the United States.

One possibility for compensation, if an American drug company were so bold as to invent, develop, test, produce, and distribute a vaccine from this country, would be suit by injured foreigners in U.S. courts against that company—subject, at a minimum, to any limitations on damages that might apply to U.S. citizens.[138] Presumably, it would be more difficult to apply the doctrine of forum non conveniens if all decisions and most actions in the production and distribution of the vaccine took place in the United States, even if administration of the vaccine and injury occurred overseas.[139]

In a much more likely scenario, the U.S. company would be the parent of a foreign subsidiary (possibly incorporated and having its principal place of business

135. Birnbaum & Dunham, *supra* note 38, at 264 n.107 (citing Besharov, *Whose Law Should Apply for Foreign Torts*, Nat'l L.J., July 20, 1987, at 30)).

136. Reynolds, *supra* note 45, at 1708. The author also mentions that, if an American court were to award damages many times higher than would be awarded by a foreign court, the policies of the foreign courts' country would be disrupted. *Id.*

137. The legal actions against Dow Corning Corp., including claims by foreign plaintiffs, compelled the company to file for bankruptcy. *See supra* note 48.

138. Wilson, *supra* note 17. Compensation to U.S. citizens for injury caused by an AIDS vaccine should be determined through provisions similar to those found in the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3755 (1986) (codified at 42 U.S.C. §§ 300aa-1 to -34 (1988)) and damages capped at $250,000. *Id.* at 562-66.

139. *See In Re* Air Crash Disaster, 531 F. Supp. 1175 (1982); *see also supra* note 86. Abuses can occur, however, that would not necessarily be the fault of the pharmaceutical company, e.g., drugs approved by a foreign government for marketing that are dispensed without adequate warnings. Pirt, *supra* note 15, at 273-74.

in the host country) that would be responsible for production and distribution of the vaccine. In this situation, an injured vaccine recipient might feel constrained to bring suit in the host country under host country law against the subsidiary, which might have been thinly capitalized and thus have little in the way of resources to compensate victims.[140] In order to avoid this possibility, lawyers for injured vaccinees might attempt to bring suit directly against the parent corporation on a theory of multinational-enterprise liability, as India did against Union Carbide Corporation in the case of the Bhopal disaster.[141] Although that case in the United States was dismissed on forum non conveniens grounds, thus returning it to India and the Indian legal system, the U.S. court implicitly accepted the enterprise liability theory of the Indian government by requiring Union Carbide to submit to the jurisdiction of the courts of India,[142] and it did so despite the fact that the parent American corporation owned only 50.9 percent of its Indian subsidiary.[143] It should be said, however, that Union Carbide exercised significant control over the finances and management of its Indian operation, despite the dilution of its ownership, and there was an overlapping board of directors.[144]

For injured citizens of a foreign country, suits in the host country against a subsidiary or its parent may bring relief, particularly if there are many plaintiffs to force a settlement, but such suits have significant drawbacks. The process is thereby legalized, with the attendant potential for delay, uneven judicial experience with suits of this nature, and the exclusion of many potentially deserving plaintiffs who simply cannot afford the costs and fees that a lawsuit entails.[145] A potential solution to this dilemma might be an administrative claims process established on a country-by-country basis. In this approach, a pharmaceutical company marketing an AIDS vaccine would contract directly with a foreign government wishing to distribute the vaccine to its citizens. The government

140. "[I]n industries involving hazardous processes and materials, there is strong evidence that operations have been fragmented and segregated into smaller, thinly capitalized corporations in an effort to avoid liability." CASSELS, *supra* note 21, at 178 (citing A. Ringleb & S. Wiggins, "*Liability and Large-Scale, Long-Term Hazards*, 98 J. POL. ECON. 574 (1990)). "When a disaster does occur, the assets and insurance of the local company are insufficient to compensate the victims, while the assets of the parent are shielded from any claim." *Id.* at 178.

141. *Id.* at 179-80. The "duty would not depend upon vicarious liability or 'piercing the corporate veil,' " although these concepts were argued, "but would be based on the concept that [the parent] committed a wrong, independent of any . . . tort committed by [the subsidiary] or its employees." *Id.*

142. *In re* Union Carbide Corp. Gas Plant Disaster, 634 F. Supp. at 867; *see also supra* notes 97-99 and accompanying text; *Obligations of a Company Belonging to an International Group, supra* note 35.

143. CASSELS, *supra* note 21, at 13, 181.

144. *Id.* at 182, 210. In the context of U.S. law, there was a sufficient connection between the defendant and the forum state to find the minimum contact necessary for jurisdiction. Asahi Metal Indus. Co. v. Superior Ct., 480 U.S. 102, 112 (1987).

145. As stated previously, companies fight hard for forum non conveniens dismissals because, in most cases, such dismissals effectively end the legal proceedings. *See supra* note 75 and accompanying text.

might—or might not—mandate universal administration of the vaccine to its citizens and the optimum ways to achieve whatever number of vaccinations it might choose. Its decision would be based upon its own assessment of need, the delivery vehicles available, and the characteristics of its population. It would be responsible for informed consent, thereby eliminating the difficulty of securing individual consent.[146] If the government lacked resources and trained personnel to test adequately for safety and efficacy, U.S. export controls would presumably ensure equivalent safety in home and host countries.[147]

An important section of the contract would require the contracting government to waive the legal liability of the pharmaceutical company in favor of the administrative claims procedure. This procedure, perhaps similar to workers' compensation, could be established to provide exclusive redress to its citizens for injuries.[148] In effect, the contract would provide that the host state would be the "choice of forum" and its substantive law and procedure would be the "choice of law." Litigation would be avoided, because liability would be without fault.[149] As with workers' compensation, the issues to be resolved would be inclusion within the covered class (for example, was the claimant a vaccine recipient?), causation (for example, did injury result from administration of a vaccine?), and the level of each injured person's compensation.[150] The latter could be regulated through resort to schedules providing payment based upon the extent and duration of illness or injury.[151] Administrators of the claims process would be host country personnel, possibly trained by the drug company, who would acquire considerable experience in assessing causation and who, in establishing payment schedules, would undoubtedly be familiar with appropriate amounts of compensation in light of prevailing wages, the general standard of living, and the social services available in the country.[152] Because a remedy would be afforded, it seems highly

146. While individual informed consent is generally required, mandatory, government-ordered vaccinations can override individual refusal. Jacobson v. Massachusetts, 197 U.S. 11 (1905).

147. *See supra* notes 22-24 and accompanying text. Admittedly, a perception of imperialism could arise in this context, but it would be unlikely to prevail in the face of urgent need. *See* CASSELS, *supra* note 21, at 281.

148. *Id.* at 253-55 & 278; *see* Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development, in* THE LIABILITY MAZE 334, 348-53 (Peter W. Huber & Robert E. Litan eds., 1991).

149. ARTHUR LARSON, WORKERS' COMPENSATION LAW 1, 3 (1992); JACK B. HOOD ET AL., WORKERS' COMPENSATION AND EMPLOYEE PROTECTION LAWS 58 (1990).

150. HOOD, *supra* note 149, at 59-60 (did injury arise out of or in the scope of employment?), 68-69, 84-85 (determining causation when a preexisting condition or outside influence may be present), 100-04 (kinds of disabilities covered and compensation for each). LARSON, *supra* note 149, at 29-34, 101-02, 402-04, 557; *see also* CASSELS, *supra* note 21, at 261-62.

151. HOOD, *supra* note 149, at 99-109; LARSON, *supra* note 149, at 402-04; *see also* National Childhood Vaccine Injury Act of 1986, *supra* note 138, 42 U.S.C. §§ 300aa-10(a), -11(a)(2)(A), -14(a).

152. An administrative rather than judicial process would be preferable. HOOD, *supra* note 149, at 111-12, 115-17. The windfall that a foreign plaintiff might receive in U.S. courts would be avoided; *see supra* notes 47-49 and accompanying text; *see also* BORN & WESTIN, *supra* note 39, at 289.

unlikely that in most cases U.S. courts would not defer to this process on forum non conveniens grounds.

Payments would be made from a fund set up through contributions from both the government and the drug company.[153] Most likely the industry contribution would be small, as it would be based upon a percentage of the price of each dose of vaccine, and for a vaccine to be feasible, the unit cost should be low. The government contribution would be larger, and realistically, in view of the fact that many impoverished nations could ill afford to both buy a vaccine and make contributions to an injury compensation fund, the money would have to be provided through foreign and/or private international relief organizations.[154] As an incentive to proper corporate conduct, the drug company might, after a term of years, be permitted to recoup any unused portion of its contribution (unless its contribution were provided in the form of insurance).

Would a drug company be interested in an administrative claims procedure and thus induced to make an AIDS vaccine available in less developed areas of the world? The answer is probably yes, because it would then be in the company's financial interest to develop a vaccine. Avoidance of the hazards and expense of litigation, even if the outcome of such litigation would usually be favorable to a corporate defendant, would militate in favor of implementing an administrative claims mechanism. At the same time, it must be recognized that this administrative process might not comport with the legal system or societal values of a potential recipient nation. Moreover, even if implemented, there would still be risks that might not alleviate the fears of company counsel. Any procedure in the hands of foreign personnel would have to be scrutinized carefully in view of the graft, inefficiency, mismanagement, and corruption that exist in many countries of the world. A compensation procedure might be mismanaged to a degree that would be unacceptable. Of potentially greater significance, the possibility remains that injured citizens of a foreign country, not bound by the contract to which their government would be a party, would bring suit in tort in the United States where corporate fear of substantial damages is the greatest.[155] A U.S. court would probably dismiss on forum non conveniens grounds, particularly if the plaintiff's country had established a mechanism for compensation. But that result would not be foreordained, and it is at least conceivable that a U.S. court would retain jurisdiction if, for example, manufacturing or design defects, or manifest failure to warn, took place in this country.[156]

153. CASSELS, *supra* note 21, at 258-59; *see also* 26 U.S.C. § 4131(a)-(b) (1988).

154. "The United States government could promote interest by the pharmaceutical industry in the market in developing countries by making certain that a sufficient percentage of the United States' foreign aid money to the Third World is designated for the purpose of essential pharmaceuticals." Pirt, *supra* note 15, at 279. Of course, the United Nations could also play a role in funding local compensation programs.

155. *See supra* notes 17-18 and accompanying text.

156. *See supra* notes 84-87 and accompanying text.

In the final analysis, therefore, the best solution would seem to be a treaty between the United States and recipient nations that would provide a claims process and a compensation fund for individuals injured by a vaccine. The terms of the treaty would automatically displace contrary state law under the supremacy clause and would obviate application of state or federal products liability actions for vaccine-related illnesses or injuries.[157] The treaty could be negotiated bilaterally, but preferably would be a multilateral treaty designed to stimulate widespread distribution of a vaccine by establishing a process to compensate injured vaccine recipients adequately yet concomitantly set limitations on the liability of vaccine manufacturers.

One possible approach under such a treaty might be to internationalize the claims process by establishing a UN-sponsored tribunal administered, perhaps, by the World Health Organization.[158] Such a plan would require the creation of an international bureaucracy to assess the validity of claims and the extent of damages. Payments would be from a fund established through foreign aid and industry contributions. Of course, a drawback would be the understandable fear that a remote officialdom would lack the understanding to distribute funds equitably for lost income, medical costs, and family support to individuals in vastly different regions of the world. Moreover, the establishment of such a centralized enterprise could raise fears of bureaucratic inefficiency on the part of nations donating foreign aid; at the same time, it might also raise suspicions of renewed imperialism in less-developed recipient countries, because the organization would undoubtedly be substantially influenced by the policies of the major donor nations.[159]

In addition to the above-mentioned concerns, it would be difficult to reconcile the use of a central, international claims tribunal with the retention of separate claims procedures in each signatory nation, although suits between parties of the same nationality might be exempted from the treaty provisions. Suits by U.S. citizens for injuries sustained from an AIDS vaccine manufactured by a foreign company would have to be referred to an international agency for resolution by a cadre of international claims adjusters. Politically, therefore, the passage of a treaty denying in-country relief, at least in the major donor nations, seems highly unlikely. A possible solution would be to allow countries to enroll in an international injury compensation process at each one's election, and manufacturers could decline to make their products available in those nations that refuse both to enroll and to prohibit the administration of the vaccine to nonnationals. Here also, however, there would appear to be strong equal protection objections when

157. U.S. CONST. art. VI; United States v. Pink, 315 U.S. 203, 230 (1942); Amaya v. Standard Oil & Gas Co., 158 F.2d 554, 556, *cert. denied*, 331 U.S. 808 (1946).

158. Such an arrangement through the World Health Organization has never yet been implemented in practice.

159. *See* CASSELS, *supra* note 21, at 274, 281.

countries of the less-developed world, even if by apparent choice, are effectively forced into a system that nations of the developed world could most likely avoid.

To avoid these difficulties, perhaps the best solution would be to abandon a centralized international agency approach and simply provide by treaty that each signatory nation (a) forbid relief to citizens of other treaty states for vaccine-related illnesses or injuries that were caused elsewhere, and (b) establish its own procedures for compensating its citizens and others, regardless of the nationality of the manufacturer, whenever an injury from the administration of an AIDS vaccine occurs within its borders. The treaty could also require its adherents not to make an AIDS vaccine available to any person from a nonsignatory state, thereby avoiding the minor, but potentially vexing, problem of a foreigner receiving a vaccine and then initiating a lawsuit for resulting injury either at home or overseas. However, if citizens of signatory nations are inoculated in a signatory state that is not their place of residence, they or their personal representatives could be given the opportunity to seek redress within their home states if compensation would be determined more appropriately in the place of residence.[160] Thus, the claim of each victim would be adjudicated by, and payment made according to, the legal processes and governing law of the place where personal injury occurred or where that person resides. Suit in another jurisdiction, in an attempt to apply foreign law, would be forbidden, and consequently, resort to forum non conveniens, or to the resolution of difficult choice of law questions, would cease.

This approach would leave open the previously described possibility of workers' compensation-type schemes to limit liability.[161] As already mentioned, a

160. In the overwhelming number of cases, of course, the place of injury will also be the place of residence. Much evidence, e.g., testimony by those administering or storing a vaccine, will be available at this location. But damages in the form of lost wages and the cost of medical treatment may be most appropriately determined at the place of new or habitual residence; for example, an American working and vaccinated overseas, but planning to return to the United States, might find an award in a foreign country far below his or her anticipated standard of living. In such cases, moreover, the domicile of a plaintiff has an interest in providing compensation to avoid having him or her become a public charge. WEINTRAUB, *supra* note 116, at 307. Thus, a plaintiff who changes residence should be permitted to bring suit in either the new state of residence or the state of injury. *Id.* at 345-49, 351-52 (citing, by analogy, the Convention on the Law Applicable to Products Liability, III Acts and Documents of the 12th Session of the Hague Conference on Private International Law (1972), *reprinted in* 21 AM. J. COMP. L. 150 (1973), and the proposal of David Cavers, *The Proper Law of Producer's Liability*, 26 INT'L & COMP. L.Q. 703, 728-29 (1977)), and *id.* at 355 (where, among other proposals, the author would permit a plaintiff to choose the law of his or her habitual residence or the law of the place where a product is acquired, if distribution through commercial channels in that location is foreseeable); *see also* Exchange of Letters Constituting an Agreement Concerning the Judicial System in the New Hebrides and Amending the Above-Mentioned Agreement, as Amended, London, 1978, Treaty Series, vol. 1135, United Nations, New York (1990), at 464. Treaty of Friendship, Commerce and Navigation between the United States of America and Japan, arts. III-IV, § 1, 4 U.S.T. 2063, T.I.A.S. No. 2863 (Apr. 2, 1953) (granting nationals of either party national treatment with respect to access to courts and administrative tribunals and application of law within the territories of the other party).

161. *See supra* notes 148-51 and accompanying text. A workers' compensation scheme might, in fact, be built into the treaty, including its foreign aid provisions, as an inducement to join.

procedure of this sort would avoid costly and time-consuming litigation in the host country, and the threat of extraterritorial litigation would be eliminated if a treaty prohibited legal action outside the country of injury or of residence. Creation of this kind of administrative process would be encouraged, because pharmaceutical corporations, while free to sell their products wherever possible throughout the world, could nevertheless refuse to do business in any country whose internal legal processes might lead to onerous liability. Decision making would take place on a country-by-country and company-by-company basis, thereby ensuring maximum flexibility and sensitivity to each country's and company's unique conditions and needs.

Under any scheme that restricts injured vaccinees to redress in, and according to the laws of, their own less-developed countries, inadequate compensation is a very real threat. Impoverished nations may well lack the resources to provide assistance to their own people. In the workers' compensation approach described above,[162] a combination of foreign aid and a premium on the selling price are envisaged as sources of money for compensation funds. Earmarked foreign aid from the wealthy countries of the world will have to underwrite a global inoculation effort. Admittedly, there is no guarantee that such aid will be forthcoming, but certainly money will be needed either to allow recipient nations to compensate their citizens directly or to assist recipient nations in the purchase of vaccines so that those companies selling vaccines can contribute a certain percentage of the purchase price to a fund for injured victims.

IV. Conclusion

The need for a vaccine to stem the disease of AIDS throughout the world is imperative.[163] But all medical procedures entail some degree of risk, and impoverished foreigners, injured by administration of a vaccine developed in the United States, will attempt to take advantage of the lenient legal processes and high damage awards potentially available in this country.[164] American corporations have resorted to the doctrine of forum non conveniens and the creation of foreign subsidiaries to avoid liability to foreign nationals.[165] To the extent these techniques work—and they usually do—they may leave injured foreigners without just compensation; however, without legal protection, most companies are unwilling to do business in the less-developed world.[166] This article proposes passage of a multilateral treaty under the terms of which each contracting state would be limited to adjudicating compensation solely for the vaccine-related injuries of its citizens, or others who receive the vaccine within its borders, according to its

162. *Id.*
163. *See supra* notes 1-11 and accompanying text.
164. *See supra* notes 41-45 and accompanying text.
165. *See supra* notes 50-101 and accompanying text.
166. *See supra* notes 134-37 and accompanying text.

own domestic law and legal processes. This article further proposes that, under such a treaty, as an inducement to foreign vaccine manufacturers, each country that desires an AIDS vaccine waive tort liability in favor of an administrative process similar to workers' compensation. This process would include a compensation fund, established by contributions from both the host government and the pharmaceutical company selling the AIDS vaccine, to handle claims on a no-fault basis from people who claim to have been injured by the vaccine.[167] The funding for the pharmaceutical company's contribution would come from a slight increase in the unit price of each dose of vaccine that is sold, whereas the host government's contribution may be provided largely by the international community.[168] Because AIDS is an international problem, an international response is clearly justified.

167. *See supra* notes 148-51 and accompanying text.
168. *See supra* notes 153-54, 162 and accompanying text.