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Regulating Experimental AIDS Drugs: A Comparison of the United States and France

I. INTRODUCTION

The number of reported cases of Acquired Immunodeficiency Syndrome ("AIDS") in the United States surpassed 100,000 in September 1989.¹ These cases accounted for more than half of the 203,599 reported cases worldwide.² The United States Center for Disease Control has estimated that between 800,000 and 1.3 million people in the United States are infected with the HIV virus that causes AIDS.³ According to the World Health Organization, the number of people infected worldwide may be as high as 10 million.⁴ While the number of HIV-infected persons who will actually develop AIDS remains unknown, some researchers believe that virtually all who are infected will eventually die from the disease.⁵

Although there is no scientifically proven, effective cure for AIDS, a number of possible treatments are widely available in other countries.⁶ Yet, due to the stringent regulations and rigorous review process imposed by the United States Food and Drug Administration ("FDA") on experimental drugs, AIDS victims currently cannot

1. *AIDS Update*, L.A. Daily News, Sept. 4, 1989, § 4, at 10, col. 4.

2. *AIDS Spread Continued in '89*, L.A. Times, Jan. 5, 1990, at A34, col. 2. France is currently third in the number of worldwide AIDS cases, with 7,149 as of September 1989. *Global Cases Near 180,000*, 4 AIDS Pol'y & L. (BNA) No. 17, at 10 (Sept. 6, 1989). The 100,000 cases represent the minimum number of persons with AIDS. *First 100,000 Cases of Acquired Immunodeficiency Syndrome—United States*, 262 J. A.M.A. 1453 (1989). Because of underdiagnosis and underreporting, the reported number of cases underestimates the actual number of people afflicted with the disease. *Id.*

3. Steinbrook, *Slower Spread of AIDS in Gays Seen Nationally*, L.A. Times, Jan. 5, 1990, at A1, col. 3. The HIV virus weakens "the body's ability to resist disease by infecting white blood cells, . . . which are an integral part of the human immune system. As a result, . . . people with AIDS [become] vulnerable to a variety of opportunistic infections and malignant conditions that generally do not [affect healthy individuals]." I. SLOAN, AIDS LAW: IMPLICATIONS FOR THE INDIVIDUAL & SOCIETY 1 (1988).

4. *8 Million Carrying AIDS Virus, Health Group Says*, L.A. Times, Aug. 1, 1990, at A9, col. 2.

5. Van de Kamp, *The Cost of AIDS*, L.A. LAW., Sept. 1988, at 31.

6. Jarvis, *AIDS: A Global View*, 12 NOVA L. REV. 980, 1002 n.119 (1988). Among these treatments are fusidic acid in Denmark; foscavir in Sweden; AL-721 in Israel; and ribavirin and isopronosine in Mexico. *Id.*

legally obtain any of these drugs in the United States.⁷

Four years after it was first approved, zidovudine (marketed as AZT) remains the only FDA-approved drug treatment for the HIV virus.⁸ While AZT has prolonged the lives of some people with AIDS, it does not cure the disease.⁹ As a result, many desperate AIDS sufferers are paying exorbitant black market prices for ribavirin and isopronosine that have been smuggled into the United States from Mexico, where a person can purchase the drugs over the counter, without a prescription.¹⁰ Activist groups have formed underground networks to import nonapproved drugs from Europe and Japan.¹¹ Additionally, patients with sufficient financial resources often travel to Europe seeking effective treatments not available in the United States.¹²

FDA regulations permit use of unapproved drugs only under strict experimental conditions.¹³ Supporters of the FDA regulations believe that this process protects the public's best interests by promot-

7. In a speech given May 21, 1987, California Attorney General John Van de Kamp noted that, because of the long delay in the drug approval process, "over 70 percent of the drugs eventually approved for use in this country are on the market elsewhere long before Americans can buy them." JAMES, AIDS TREATMENT NEWS 187 (1989).

8. The FDA officially approved AZT as a treatment for AIDS and severe AIDS-related conditions in March 1987. Scott & Cimons, *AZT Chronology*, L.A. Times, Jan. 10, 1990, at A15, col. 3. As of March 1989, between 20,000 and 30,000 AIDS patients were receiving AZT. *Burroughs Reports Instances of HIV Resistance to AZT*, 4 AIDS Pol'y & L. (BNA) No. 7, at 5 (Mar. 22, 1989). Patients in 37 foreign countries also receive AZT. Jarvis, *supra* note 6, at 1002 n.119.

9. I. SLOAN, *supra* note 3, at 3, 4. AZT's greatest impact on AIDS occurs during the first twelve to eighteen months of treatment, particularly in patients with less advanced stages of the disease. Between eighteen and thirty months of treatment, the effect tails off and mortality increases. The reason for this phenomenon is unknown. Goldsmith, *AIDS Drug Development Availability Intensify*, 262 J. A.M.A. 452 (1989). "It is clear we desperately need alternative therapy to AZT from the standpoint of . . . clinical failure of the drug on long-term dosage." *Id.* (quoting Dr. Thomas C. Merigan, Director of the National Institute of Allergy and Infectious Diseases ("NIAID") AIDS Clinical Trial Group).

10. Ticer, *'Fast Buck' Artists are Making a Killing on AIDS*, BUS. WK., Dec. 2, 1985, at 47. See also Van de Kamp, *supra* note 5, at 32. In 1985, a twenty-tablet box of isopronosine could be purchased for \$2.50 in Mexico. AIDS patients in San Francisco then paid up to \$1.20 per tablet for the same tablets. R. SHILTS, AND THE BAND PLAYED ON 564 (1988).

11. See *Nonapproved Drugs Brought To US*, AIDS Law & Lit. Rep., at 31 (Apr. 1989).

12. Ticer, *supra* note 10, at 47. Actor Rock Hudson attracted major media attention when he went to France's Pasteur Institute to be treated with the experimental drug HPA-23 shortly before his death from AIDS in 1984. See generally R. SHILTS, *supra* note 10, at 475. Some French scientists resented the United States government for placing a low priority on AIDS treatments, thereby forcing Americans to come to France for treatment with HPA-23. *Id.* at 536.

13. See *infra* text accompanying notes 47-54.

ing overall safety and efficiency. Critics of the drug approval system counter that the regulations increase the cost of drug development, deny Americans access to potentially lifesaving drugs for unnecessarily long periods of time,¹⁴ and "sacrifice today's AIDS patients in order to save tomorrow's patients."¹⁵

Other critics complain that, FDA regulations aside, drug manufacturers have failed to show a sincere interest in developing AIDS treatments because of their concerns about profitability and potential liability for unknown side effects.¹⁶ One commentator has speculated that, even if a cure for AIDS was found, no manufacturer would be willing to produce it.¹⁷ The low potential for profit due to lawsuits resulting from unknown side effects, the expense and delay of exhaustive FDA testing requirements,¹⁸ and recent public pressure over the high cost of drug treatments combine to inhibit the production of AIDS drugs.¹⁹

"[AIDS] has been described as 'one of the most devastating infectious diseases the world has ever known' and, [essentially], the modern equivalent of leprosy."²⁰ The urgent and unique nature of the AIDS crisis presents a serious challenge to the current method of experimental drug development in the United States. This Comment

14. Delaney, *Patient Access to Experimental Drugs*, 261 J. A.M.A. 2444 (1989).

15. *FDA Eying Underground Trials of Trichosanthin Derivative*, 4 AIDS Pol'y & L. (BNA) No. 13, at 5 (July 12, 1989) (quoting Martin Delaney, Co-director of Project Inform in San Francisco). Delaney's group organized an "underground clinical trial" of Compound Q, a drug imported from China, in an attempt to circumvent FDA procedures. *Id.*

16. The concerns of its liability insurer caused the United States-based manufacturer of the experimental drug AL-21 to stop Americans from obtaining the drug at hospital trials in Israel. See Bishop, *Desperate Lives, Unknown Risks*, CAL. LAW., Sept. 1987, at 46.

17. Huber, *AIDS and Lawyers*, NEW REPUBLIC, May 5, 1986, at 14.

18. A potential AIDS vaccine developed by Viral Technologies, Inc. of Washington, D.C., is being tested in Great Britain instead of the United States because company officials felt that the FDA was taking too long to approve human tests in the United States. *Medical Briefs*, 4 AIDS Pol'y & L. (BNA) No. 9, at 8 (May 17, 1989).

19. See Chase, *Company Fights Critics as it Collects AZT Profit*, L.A. Daily News, Sept. 17, 1989, § 3, at 1, col. 3, for a description of the public pressure applied to Burroughs Wellcome Co. to reduce the cost of AZT. At the time, AZT cost approximately \$8,000 for a one year supply. Bowing to public pressure, Burroughs lowered the price of AZT by 20%, thereby reducing the price of a one year supply to \$6,400. *AZT Price Reduced 20 Percent; Advocates Urge Further Cuts*, 4 AIDS Pol'y & L. (BNA) No. 18, at 3 (Sept. 20, 1989). Drug manufacturer Pfizer, Inc. likewise reduced the price of fluconazole, a drug used to treat AIDS-related cryptococcal meningitis, in response to the controversy over the pricing of AIDS drugs. Zonana, *Pfizer Lowers Price of AIDS Drug, Will Provide Some Free*, L.A. Times, Feb. 9, 1990, at D1, col. 5.

20. James, Holmquest & Blinka, *AIDS: A Plague on Institutional Health Policy Development*, 10 J. LEGAL MED. 65 (1989).

will examine, compare, and contrast the existing regulatory processes for experimental drugs in the United States and France.²¹ This Comment will also discuss the political, legal, and bureaucratic realities of this issue. It will conclude with recommendations for dealing with the problems presented, emphasizing the recent California AIDS legislation²² as a possible solution designed both to increase drug availability and to protect the interests of patients and drug manufacturers.²³

II. UNITED STATES FOOD AND DRUG ADMINISTRATION REGULATIONS

The federal government's first attempt to protect the public from dangerous medicinal drugs was the passage in 1848 of An Act to Prevent the Importation of Adulterated and Spurious Drugs and Medicines ("1848 Act").²⁴ Although the 1848 Act required the accu-

21. During 1983 and 1984, research teams in France and the United States independently identified the virus that causes AIDS. W. DORNETTE, AIDS AND THE LAW 6 (1987). In the early days of the AIDS crisis, the Pasteur Institute in Paris was recognized as the "world's most important center for treatment research." R. SHILTS, *supra* note 10, at 496.

22. Arguably, California's response to the AIDS problem sets the standard for reaction at the state level. "California far outpaces every state in AIDS spending. In fiscal 1989, California spent \$76.8 million in state funds on AIDS programs. . . . California was the only state to earmark a large portion of its own money for AIDS research: nearly \$18 million." *AIDS Update*, L.A. Daily News, Sept. 4, 1989, § 4, at 10, col. 1.

23. Although this Comment specifically addresses issues regarding access to experimental treatment in the context of the AIDS crisis, the problems discussed and the arguments made are equally applicable to other terminal diseases for which there is no known cure, such as cancer. The issues are particularly compelling, however, as they relate to AIDS, because of its unique nature as a new infectious disease about which comparatively little is known.

Cancer patients engaged in a similar debate in the 1970s over the right to treatment with laetrile, a non-FDA approved drug that was available in Mexico. Jarvis, *supra* note 6, at 1003 n.119. The controversy reached the United States Supreme Court in *United States v. Rutherford*, 442 U.S. 544 (1979). In *Rutherford*, cancer patients brought suit to enjoin the government from interfering with the interstate shipment and sale of laetrile. *Id.* at 549. The Tenth Circuit Court of Appeals held that the "safety" and "effectiveness" requirements of the Food, Drug and Cosmetic Act, ch. 675, § 505, 52 Stat. 1040, 1052 (1938) (current version at 21 U.S.C. 355 (1988)), had no reasonable application to terminally ill cancer patients. *Rutherford v. United States*, 582 F.2d 1234, 1237 (10th Cir. 1978). The court of appeals reasoned that, because the patients would eventually die anyway, there was no standard by which to measure the safety and effectiveness of the drug. The court thereafter approved the use of laetrile by cancer patients certified as terminally ill by licensed medical practitioners. *Id.* On appeal by the federal government, the Supreme Court reversed the decision, holding that the Act made no special provision for drugs used to treat terminally ill patients. 442 U.S. at 552. The Court refused to imply such an exemption judicially, reasoning that the creation of an exemption for the terminally ill, as a policy decision, was best left to legislative judgment. *Id.* at 559.

24. An Act to Prevent the Importation of Adulterated and Spurious Drugs and Medicines, ch. 70, 9 Stat. 237 (1848).

rate identification and inspection of imported drugs, it did not regulate possibly dangerous drugs manufactured in the United States.²⁵

Attempts to strengthen the 1848 Act were unsuccessful until muckraking journalism published in the early 1900s brought the problem to the public's attention. Works such as Upton Sinclair's *The Jungle*, which exposed the unsanitary conditions in the meat-packing industry, resulted in public outcry that prompted Congress to take action.²⁶ Congress responded to the pressure by passing the Pure Food and Drug Act of 1906 ("1906 Act").²⁷

The 1906 Act prohibited interstate trade in adulterated or misbranded drugs.²⁸ Although it provided greater protection to the consumer than the 1848 Act, the 1906 Act still did not require any pre-market testing of drugs.²⁹ For a second time, public pressure forced Congress to pass stronger legislation. The strong public outcry following the "Elixir Sulfanilamide" tragedy of 1937³⁰ prompted Congress to pass the Federal Food, Drug and Cosmetic Act of 1938 ("1938 Act").³¹ For the first time, the Act required drug manufacturers to prove the safety of a drug before marketing it.

In light of the new, powerful and complex drugs that were developed in the post-World War II years, Senator Estes Kefauver introduced remedial legislation in 1960 designed to strengthen the 1938 Act.³² However, the proposed legislation stalled in committee and its passage appeared unlikely until tragedy once again prompted public outcry and congressional action.³³ The Thalidomide tragedies in Western Europe in 1961 and 1962³⁴ provoked Congress to pass the

25. Comment, *The Right of Privacy in Choosing Medical Treatment*, 20 J. MARSHALL L. REV. 693, 696 (1987).

26. RAY & KSIR, *DRUGS, SOCIETY AND HUMAN BEHAVIOR* 34-35 (1987); Comment, *supra* note 25, at 696 n.20.

27. Pure Food and Drug Act, ch. 3915, §§ 1-13, 34 Stat. 768 (1906).

28. RAY & KSIR, *supra* note 26, at 35.

29. Comment, *supra* note 25, at 697.

30. RAY & KSIR, *supra* note 26, at 37. More than one hundred people died from using an untested, poisonous new drug being marketed as an "elixir." The government was able to seize the product and fine the manufacturer only on the ground that it was misbranded as an elixir. *Id.* A true elixir contained alcohol and this concoction did not. If the product instead had been labeled as a "solution," the government would have lacked the power to take any action under the 1906 Act. *The Evolution of U.S. Drug Law*, FDA CONSUMER, Dec. 1987-Jan. 1988, at 37.

31. Food, Drug and Cosmetic Act of 1938, ch. 675, § 505, 52 Stat. 1040, 1052 (1938) (current version at 21 U.S.C. 355 (1988)).

32. RAY & KSIR, *supra* note 26, at 38.

33. *Id.*

34. Pregnant women took Thalidomide, a sedative and sleeping pill, to reduce morning

Kefauver-Harris Amendments to the 1938 Food, Drug and Cosmetic Act.³⁵ The Kefauver-Harris Amendments ("Amendments"), which were intended to tighten controls over drug availability, added numerous new regulatory provisions.³⁶ According to the Amendments, "[no] person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to . . . this section is effective with respect to such drug."³⁷

For the first time, manufacturers had to make a scientific pre-market showing that their drugs were both effective and safe for their intended uses. "Such person shall submit to the Secretary as a part of the application . . . full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."³⁸ Additionally, the Amendments required companies to obtain approval for clinical testing on humans before any such testing could take place. "The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs."³⁹ The Amendments further provided that:

Such regulations may, within the discretion of the Secretary, . . . provide for conditioning such exemption upon . . . the . . . making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation . . . of data . . . obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug⁴⁰

An application will be denied if there is a lack of "substantial evidence" that the drug will have its purported effect under the use prescribed, recommended, or suggested in its proposed labeling.⁴¹

sickness. Unknown side effects resulted in 3,500-5,000 malformed babies born to mothers who took the Thalidomide. Although the drug was never approved for sale in the United States, public awareness and congressional concern arose over the incidents. *Id.*; see also Note, *Federal Food and Drug Administration Practice and Procedure For New Drug Approval*, 37 TEMP. L.Q. 191, 193 (1964).

35. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 355 (1988)).

36. Note, *supra* note 34, at 193-94.

37. 21 U.S.C. § 355(a) (1988).

38. *Id.* § 355(b)(1).

39. *Id.* § 355(i).

40. *Id.* § 355(i)(3).

41. *Id.* § 355(d). The Act defines "substantial evidence" as:

Under the authority granted in the 1938 Act and its subsequent 1962 amendments, the FDA has developed the world's most comprehensive process for approving new drugs.⁴² This process begins with preclinical testing of the drug's safety and effectiveness on animals.⁴³ Next, the drug's sponsor⁴⁴ files an Investigational New Drug application ("IND") based on the results of the preclinical testing.⁴⁵ Once the FDA approves the IND, clinical testing on humans can begin.⁴⁶

The FDA requires three phases of clinical testing.⁴⁷ Phase 1 trials are conducted on a small number of patients or healthy volunteers and are designed to measure the drug's safety and toxicity in humans.⁴⁸ Phase 2 tests normally involve a group of several hundred patients who suffer from the specific disease. This phase focuses on determining the drug's effectiveness.⁴⁹ Phase 3 testing utilizes expanded numbers of volunteers at clinics and hospitals. This phase is designed to "clarify the drug's benefit-risk relationship, discover less common and even rare side effects and adverse reactions, and generate information that will be incorporated into the drug's professional labeling, the FDA-approved guidance to physicians and others about how to use the drug."⁵⁰

The testing method required in Phase 3 involves a "double-blind" test.⁵¹ In the double-blind test, half of the participants receive the drug, while the other half only receives a placebo.⁵² Neither the

evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof.

Id.

42. INSTITUTE OF MEDICINE—NATIONAL ACADEMY OF SCIENCES, CONFRONTING AIDS: UPDATE 1988, at 137 (1988) [hereinafter INSTITUTE OF MEDICINE].

43. 21 C.F.R. § 312.23(a)(8) (1990). The United States regulations require a twelve-month toxicity study at this stage. In contrast, the European Economic Community, of which France is a member, requires only a six month study. Dunning, *Regulation, New Drug Development, and The Question of Delay*, 41 FOOD DRUG COSM. L.J. 139 (1986).

44. The pharmaceutical manufacturer or a research organization usually sponsors the new drug.

45. 21 C.F.R. § 312.23 (1990).

46. *Id.* § 312.20(b).

47. *Id.* § 312.21.

48. *Id.* § 312.21(a) (usually twenty to eighty patients or volunteers).

49. *Id.* § 312.21(b).

50. Flieger, *Testing in 'Real People,'* FDA CONSUMER, Nov. 1987, at 11-12.

51. See 21 C.F.R. § 314.126(b)(2)(i).

52. The term placebo literally means "I will please." In a general sense, a placebo is any

doctor nor the patient knows whether the experimental drug or the placebo has been utilized.⁵³ Following Phase 3 testing, the drug's sponsor can file a New Drug application ("NDA") whereupon the drug becomes eligible for FDA approval.⁵⁴

Generally, the journey from preclinical testing to FDA approval can take seven to ten years.⁵⁵ The approval process of the non-AIDS-related drug Lovastatin provides a typical example. Preclinical studies of Lovastatin began in 1979. In 1984, a new drug IND was submitted to the FDA. The Lovastatin NDA was submitted in November 1986. Final approval of the NDA occurred in August 1987—a time lag of over eight years.⁵⁶

Recognizing the problems that the slow approval process created, the FDA introduced a new procedure in 1987. The purpose of this procedure, known as "Treatment IND," was to increase access to experimental drugs at an earlier stage of the approval process.⁵⁷ Under Treatment IND, after completing Phase 2 controlled clinical trials, patients in whom the disease has reached the seriously life-threatening stage may receive an experimental drug.⁵⁸ Treatment IND would apply only to those drugs which show "reasonable evidence of potential benefit" and for which no satisfactory alternative exists.⁵⁹ However, unlike drugs with final FDA marketing approval, which all physicians may prescribe for any patient use, doctors can prescribe Treatment IND drugs only for specific conditions that the FDA designates.⁶⁰

therapeutic procedure without specific activity for the condition being treated. Nielsen, *The Doctor, the Pharmacist, the Patient, and the Placebo, or You're Not My Mother, Doctor*, 44 FOOD DRUG COSM. L.J. 639, 641 (1989).

53. Comment, *supra* note 25, at 700. Under 21 C.F.R. § 312, the person receiving the placebo must receive written notification that he or she may be receiving either the active drug or the placebo and agree to remain in ignorance. Nielsen, *supra* note 52, at 641.

54. 21 U.S.C. § 355(a) (1988).

55. INSTITUTE OF MEDICINE, *supra* note 42, at 137-38.

56. See Flieger, *supra* note 50, at 14.

57. 21 C.F.R. § 312.34 (1990).

58. Young, *Promoting Drug Development Against AIDS and the HIV Infection*, 43 FOOD DRUG COSM. L.J. 215, 218 (1988).

59. *The Evolution of U.S. Drug Law*, FDA CONSUMER, Dec. 1987-Jan. 1988, at 37.

60. *Preliminary FDA Okay Given For Aerosolized Pentamidine*, 4 AIDS Pol'y & L. (BNA) No. 2, at 3 (Feb. 8, 1989). For example, under Treatment IND status, doctors may prescribe aerosolized pentamidine only to patients who have had at least one episode of AIDS-related pneumonia or have a T4 cell count below 200. *Id.* T4 lymphocytes are a type of white blood cell particularly susceptible to the HIV virus. Krim, *The AIDS Virus and its Public Health Implications*, in LEGAL, MEDICAL AND GOVERNMENTAL PERSPECTIVES ON AIDS AS A DISABILITY 3 (1987).

In February 1988, Trimetrexate became the first AIDS treatment available as a Treatment IND drug.⁶¹ In late September 1989, designation of Dideoxyinosine (DDI) as a Treatment IND followed.⁶² However, as Treatment IND drugs, these drugs are available only to those AIDS patients in whom the disease has reached an advanced stage and who have shown an intolerance to AZT. In October 1989, AZT became available for the first time as a Treatment IND drug to children under the age of thirteen who suffer from AIDS or advanced infections from the AIDS virus.⁶³

Despite some progress in expediting the availability of experimental drugs, the prevailing philosophy of the FDA remains the same: the overall, best interest of the public is served by not releasing drugs for use until controlled clinical trials have clearly shown that the drugs are safe.⁶⁴ Former FDA Commissioner Frank Young has stated: "[w]e want the public to know and understand that miracles don't happen overnight, that studies take years not months, and that patients are best served by rigorous testing and careful review."⁶⁵

III. DRUG REGULATION IN FRANCE

Historically, the French government has not regulated consumer protection as comprehensively as the United States. Only in the last fifteen years has this area of French law grown substantially.⁶⁶ Commentators attribute this belated development to "laissez-faire" economic policies and to the general belief that an economic system based on free competition would protect the consumer.⁶⁷ However,

61. INSTITUTE OF MEDICINE, *supra* note 42, at 138.

62. *FDA Okays Wider Availability of DDI in Trials, IND Status*, 4 AIDS Pol'y & L. (BNA) No. 18, at 6 (Oct. 4, 1989).

63. Cimons, *Children to Get AIDS Drug AZT Under New Rule*, L.A. Times, Oct. 26, 1989, at A1, col. 3. Although AZT was approved for adults in 1987, children could not use the drug because of the FDA policy that denies children access to a drug until it has been tested on, and approved for, adults. This generally causes a two to three year time lapse between approval for adults and approval for children. *Id.* According to a spokeswoman for Burroughs, Inc., the manufacturer of AZT, gaining approval for pediatric use of AZT took longer than for adult use because there are fewer child AIDS patients and because the FDA traditionally requires more data for pediatric drugs. *FDA Approves Use of AZT For Children Under 13*, 4 AIDS Pol'y & L. (BNA) No. 20, at 7 (Nov. 1, 1989).

64. Farley, *Benefit vs. Risk: How FDA Approves New Drugs*, FDA CONSUMER, Dec. 1987, at 6.

65. *Id.*

66. Minor, *Consumer Protection In French Law: General Principles and Recent Developments*, 33 INT'L & COMP. L.Q. 108 (1984).

67. See CALAIS-AULOUY, *CONSUMER LEGISLATION IN FRANCE: A STUDY PREPARED FOR THE EC COMMISSION* 1 (1981).

the inequalities between parties which developed as a result of rapid economic growth in the post-World War II period fueled the development of French consumer protection law during the 1950s and 1960s.⁶⁸ The immediate post-war period brought government intervention and regulation into areas not previously regulated.⁶⁹ Public health was foremost among these areas.⁷⁰

The Office of Pharmaceutical Control, which reports to the Minister of Public Health, oversees the quality of medical drugs and pharmaceutical products in France.⁷¹ Generally, manufacturers of products capable of putting the life or health of the consumer at risk must obtain a "visa" or authorization before marketing.⁷² An authorization for a medical drug will be granted if the manufacturer establishes the harmlessness of the drug and proves high manufacturing standards.⁷³ Further, pharmaceutical goods must conform to strict standards concerning manufacture, composition, packaging, labeling, and advertising.⁷⁴

The French marketing authorization is temporary and requires periodic renewal.⁷⁵ In 1982, France established the National Commission on Drug Monitoring to facilitate the gathering of data on adverse reactions to drugs subject to authorization. Its primary functions include "compil[ing] and evaluat[ing] information on the unexpected or toxic effects of medicaments subject to the marketing authorization referred to in Article L 601 of the Public Health Code."⁷⁶ Regional centers acting on behalf of the National Drug Monitoring Commission compile information about the drugs from hospitals, physicians, dentists, midwives, and nurses.⁷⁷ This information is used when evaluating an authorization for renewal. The centers also oversee investigations and studies as requested by the Minister of Public Health.⁷⁸ Adverse reaction reports for drugs avail-

68. *Id.* Inequalities developed between enterprisers and suppliers, on the one hand, and the disadvantaged consumer on the other. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* at 5. The regulations in this area appear in the *Code de la santé publique* (Public Health Code). *Id.*

72. *Id.* at 22.

73. *Id.* (referring to arts. L 601 and L 605 of the *Code de la santé publique*).

74. *Id.* (referring to arts. R 5117 and R 5143 of the *Code de la santé publique*).

75. *Id.* (referring to art. R 5137 of the *Code de la santé publique*).

76. *Journal Officiel de la République Française, Edition des Lois et Décrets Recueil Dalloz*, 4 August 1982, No. 179, at 2498.

77. *Id.*

78. *Id.*

able on the French market are shared with other member nations of the European Economic Community ("EEC").⁷⁹

The French drug approval process utilizes a system of "expertises" which involves more hospital-based clinicians in the decision-making process than the United States system.⁸⁰ Advisory committee restraints which burden the United States administrative procedures do not bind the French system. Rather, the French method focuses on opinions developed from hands-on clinical review.⁸¹

The French authorization system requires clinical investigations conducted in France on French citizens prior to granting approval.⁸² However, the French testing requirements are not as demanding as those in the United States.⁸³ Likewise, the French philosophical approach to these trials is very different than the FDA's.⁸⁴ Unlike the FDA's Phase 3 requirement for controlled studies, French clinical trials do not require the use of a placebo control group.⁸⁵ Rather, doctors at France's premier research facility, the Pasteur Institute, consider the use of double-blind studies cruel and inhumane because the unfortunate patient receiving a placebo has no chance of surviving. These doctors believe that every patient who seeks treatment should receive it.⁸⁶

The United States is one of the last pharmaceutical markets in the world that is free from the restraints of government subsidy.⁸⁷ As such, high development costs do not directly affect the federal government. In contrast, the French government controls and pays drug costs as part of the national social security program.⁸⁸ This direct financial involvement significantly affects the French drug approval

79. O'Reilly, *Three Dimensions of Regulatory Problems: United States, European Economic Community, and National Laws*, 41 FOOD DRUG COSM. L.J. 131, 138 (1986).

80. *Id.* at 134.

81. *Id.*

82. See Tedrow, *Drug Registration Abroad*, 37 TEMP. L.Q. 59, 65 (1963) for an interesting 1963 American observer's comment that the French system resulted in unreasonably long (two year!) delays.

83. See Hoffman, *Advising the Multinational Firm Under the Federal Food, Drug and Cosmetic Act*, 41 FOOD DRUG COSM. L.J. 145, 146 (1986). In order to facilitate subsequent importation, multinational pharmaceutical firms have been advised to structure their drug research programs in foreign countries to meet the additional burden of tougher FDA standards.
Id.

84. *See id.*

85. See R. SHILTS, *supra* note 10, at 496.

86. *Id.*

87. Kruezer, *International Drug Registration*, 43 FOOD DRUG COSM. L.J. 559, 560 (1988).

88. BUSINESS INTERNATIONAL, *FRANCE IN TRANSITION* 43 (1979).

process. This type of regulatory system views the advanced efficacy of a drug as a trade-off, to be balanced against higher developmental costs.⁸⁹ "Efficacy and market price decisions in the European drug systems are direct government economic decisions, made at the time of market entry by the national reimbursement authorities. The European nations control entry on value grounds, within the very different context of a national system for governmentally controlled drug marketing"⁹⁰ Because it ultimately subsidizes the cost of drugs to the French consumer, the French government has taken steps to encourage the pharmaceutical industry to establish research operations and manufacturing in France, rather than to continue to import drugs from abroad.⁹¹

IV. PRODUCT LIABILITY AND PROFITABILITY IN THE UNITED STATES

Uncertainty regarding the liability of pharmaceutical companies that manufacture AIDS treatments has slowed the development of these drugs in the United States.⁹² Drug manufacturers are concerned about the potential for liability that arises from supplying a drug which is administered during the experimental treatment stage.⁹³ Potentially, patients who take experimental drugs may suffer immediate adverse reactions or long-term, unanticipated side effects.⁹⁴ Additionally, the market for AIDS drugs does not seem as potentially profitable to some manufacturers as the market for treatments for more common diseases.⁹⁵

Product liability concerns particularly affect the development of an AIDS vaccine. As another commentator noted:

[T]he pragmatic barriers to testing, licensing, and marketing [a vaccine] are staggering. Demonstrating the efficacy of the vaccine would require large groups of willing human subjects at high risk of infection. Confirming the safety of the . . . vaccine would have to take into account issues of liability for perceived complications of immunization—problems that are even more complex than

89. O'Reilly, *supra* note 79, at 133.

90. *Id.*

91. Kruezer, *supra* note 87, at 560.

92. INSTITUTE OF MEDICINE, *supra* note 42, at 139.

93. *Id.*

94. *Id.*

95. R. SHILTS, *supra* note 10, at 475. "A drug for a few thousand AIDS patients would never offer the opportunity for profit that a [treatment for] . . . hypertension would." *Id.*

those that accompany existing vaccines for familiar infectious diseases.⁹⁶

Furthermore, regardless of the precautions taken, adverse reactions to the drug might not appear until some time after the premarketing testing.⁹⁷

Generally, manufacturers are not liable for injuries resulting from properly produced vaccines.⁹⁸ However, some courts in recent years have imposed liability even though the manufacturer exercised the appropriate duty of care.⁹⁹ In describing this development in his hornbook on torts, Dean Prosser noted that "courts have held that strict liability for failure to warn of a risk will be imposed on a manufacturer if, had he known of the danger, he would have been negligent for failing to warn of such risk."¹⁰⁰ For example, in *Reyes v. Wyeth Laboratories*,¹⁰¹ the Fifth Circuit Court of Appeals upheld a strict liability claim against a polio vaccine manufacturer.¹⁰² In *Reyes*, an infant contracted paralytic polio two weeks after immunization with the polio vaccine.¹⁰³ Although the manufacturer had included an insert in the packaging warning doctors and nurses of the potential dangers, this warning was not relayed to the vaccinees or their guardians.¹⁰⁴ In finding that the manufacturer had a duty to warn the individual vac-

96. Osborne, *The AIDS Epidemic: Discovery of a New Disease*, in AIDS AND THE LAW: A GUIDE FOR THE PUBLIC 26 (1987). In August 1989, June Osborne, Dean of the University of Michigan School of Public Health, was selected as the chairperson of the National Commission on AIDS. *New AIDS Commission Convenes, Elects June Osborne as Chair*, 4 AIDS Pol'y & L. (BNA) No. 15, at 2 (Aug. 9, 1989).

97. Mariner & Gallo, *Getting to Market: The Scientific and Legal Climate for Developing an AIDS Vaccine*, 15 L. MED. & HEALTH CARE 17, 20-21 (Summer 1987). Mariner and Gallo assert

[t]he safety of a vaccine is likely to remain in question even after it has been licensed and distributed. Adverse reactions may not be discovered even in the most carefully constructed clinical trials. Since such trials typically involve only a few thousand participants, reactions that occur as rarely as once in 100,000 or 1,000,000 vaccinations are not likely to be seen during premarketing tests. But they may manifest themselves once the vaccine is in regular use nationwide, with unfortunate consequences for all.

Id. at 21.

98. Bishop, *supra* note 16, at 111.

99. PROSSER AND KEETON ON THE LAW OF TORTS 692-94 (W. Keeton 5th ed. 1987).

100. *Id.* at 697.

101. 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). Interestingly, the same Wyeth Laboratories halted manufacture of a whooping cough vaccine in 1984, citing increases in insurance and litigation costs. A number of other companies have left the vaccine market in the last fifteen years for the same reasons. See Huber, *supra* note 17, at 15.

102. *Reyes*, 498 F.2d at 1272.

103. *Id.* at 1270.

104. *Id.*

cinee, the court held that failure to provide an adequate warning "when it is required will present a 'defect' in the product and will, without more, cause a product to be 'unreasonably dangerous as marketed.'" ¹⁰⁵ Thus, the manufacturer was strictly liable because of the failure to warn the plaintiff of the risk inherent in the vaccine. ¹⁰⁶ Furthermore, cases such as *Beshada v. Johns-Manville Products Corp.* ¹⁰⁷ have increased manufacturers' exposure to liability by weakening the defense that a product conformed to the industry's state of the art at the time of its manufacture, such that the manufacturer could not have warned of the defect. ¹⁰⁸

These developments have caused concern among prospective vaccine producers. ¹⁰⁹ These producers fear that the liability exposure resulting from unforeseen adverse reactions might exceed the profit generated from sales of the vaccine. ¹¹⁰ Concerned pharmaceutical manufacturers need only look to the problems encountered during the 1976 Swine Flu epidemic to confirm their apprehension. ¹¹¹ Government-sponsored mass inoculation against a predicted Swine Flu outbreak resulted in serious, unexpected complications. Thousands of people developed Guillain-Barre syndrome, a severe, generalized paralytic disease, as a side effect of the Swine Flu vaccine. ¹¹² Claims filed as a result of the inoculations were further complicated by the fact that

[a]dverse reactions to the vaccines [were] initially logged by recording any untoward events that occur[red] in immunized individuals within several weeks following immunization Mass immunization automatically [brought] to the surface all the ills to which human beings are prone, many of which have unknown causes and [were] therefore ascribed to the vaccine by a litigious

105. *Id.* at 1265.

106. *Id.* at 1277-79. Following *Reyes*, a number of courts held manufacturers strictly liable for failure to warn vaccinees directly of risks associated with the vaccines that they received. *See, e.g., Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977) (Sabin polio vaccine); *Unthank v. United States*, 732 F.2d 1517 (10th Cir. 1984) (Swine Flu vaccine).

107. 90 N.J. 191, 447 A.2d 539 (1982).

108. *See Huber, supra* note 17, at 15.

109. *Mariner & Gallo, supra* note 97, at 21.

110. *Id.*

111. The government feared a potential flu epidemic of the proportion not encountered since 1918-19, when the flu claimed over 500,000 lives. In response, the federal government planned the largest mass inoculation in the nation's history. M. FRANKLIN, *CASES AND MATERIALS ON TORT LAW AND ALTERNATIVES* 742 (4th ed. 1987).

112. *Bishop, supra* note 16, at 111.

public.¹¹³

Ultimately, plaintiffs claiming damages from adverse side effects filed over 5,000 claims. The United States government paid out over \$83 million in victim compensation.¹¹⁴

FDA Commissioner Frank Young summarized the problems with respect to this area of the law by stating that "we are really at sea" in trying to anticipate the effects of liability law on the production of an AIDS vaccine.¹¹⁵

V. PRODUCT LIABILITY IN FRANCE

While French product liability law is considered to be one of the most protective legal structures of the European Community,¹¹⁶ it still is not as well-developed as its counterpart in the United States.¹¹⁷ Although remedies under tort, contract, and penal theories do exist, the recoverable damages are smaller than those in the United States.¹¹⁸ One explanation for this difference is the "principle of French law that compensation should not be of a punitive nature; therefore courts will award only what is deemed equitable in order to 'repair the damage.'"¹¹⁹ Additionally, "[i]n the vast majority of [French] product liability cases, an expert is designated by the court to determine the cause of the injury and frequently to put a monetary amount on [the damages] suffered."¹²⁰

In the French system, the plaintiff must establish the existence of fault before a manufacturer will be subject to liability in tort for damages.¹²¹ To recover, the injured party must show that the supplier intentionally or negligently committed an act or omission relating to

113. Osborne, *supra* note 96, at 26. For example, the deaths of three people over age 70 who died the day after each received the flu shot attracted much media attention. The public was not persuaded by the Center for Disease Control's explanation that about ten to twelve deaths occur on the average each day among people 70 to 74 years of age, and therefore, these deaths were not necessarily attributable to the vaccine. Reitze, *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 179 (1986).

114. M. FRANKLIN, *supra* note 111, at 742.

115. Mariner & Gallo, *supra* note 97, at 23.

116. SARRAILHE, *PRODUCTS LIABILITY, A MANUAL OF PRACTICE-FRANCE* 5 (1981).

117. MOQUET-BORDE, *DOING BUSINESS IN FRANCE* § 8.01, at 8-3 (1989).

118. *Id.*

119. SARRAILHE, *supra* note 116, at 8.

120. Bouckaert & Byrd, *Product Liability Defense in France*, DEF. COUNS. J. 538 (Oct. 1987).

121. CALAIS-AULOY, *supra* note 67, at 28. In contractual disputes, establishing this evidence presents little difficulty because it is sufficient to merely state the fact that the manufacturer or distributor failed to achieve the promised result. *Id.*

the product.¹²² This includes an obligation on the part of the manufacturer to advise and inform the consumer regarding the proper use and risks of the product, particularly those in areas of high technology or those new to the market.¹²³ The injured party must also prove a direct causal relationship between a legally cognizable injury and the fault of the supplier.¹²⁴ Meeting this burden of showing a defect and causation is difficult. As a result, the French courts tend to interpret conservatively the adequacy of warnings and instructions.¹²⁵

In determining the fault of the supplier, the objective standards comprising the custom of the particular trade establishes whether a defect exists in the product. Customs in the pharmaceutical trade are considered particularly demanding. Therefore, drug manufacturers must meet a higher standard than those in other industries.¹²⁶ In addition, manufacturers must act with "prudence and diligence."¹²⁷ Under this standard, a French court has held that "a pharmaceutical laboratory distributing a product which carries certain risks but which is the only treatment available for certain ailments, is not judged to be negligent. The concept of negligence is assessed in the light of other factors."¹²⁸

Generally, in the past, the French legal system has protected the manufacturer. However, one should note that this situation is likely to change in the very near future. France, as a member nation of the EEC, probably will pass new, comprehensive products liability legislation in compliance with the EEC Directive of July 25, 1985 Concerning Defective Products.¹²⁹ This Directive¹³⁰ imposes strict liability on the manufacturer, seller, or importer of defective products.¹³¹ The Directive focuses on providing "fair apportionment of

122. MOQUET-BORDE, *supra* note 117, § 8.02[2][a][i], at 8-5. For example, a supplier could be subject to tort liability under a negligence theory if "he failed . . . to warn the injured party of the inherent dangers of the product that he installed." *Id.*

123. SARRAILHE, *supra* note 116, at 12.

124. MOQUET-BORDE, *supra* note 117, § 8.02[2][c], at 8-7.

125. See Bouckaert & Byrd, *supra* note 120, at 544.

126. CALAIS-AULOY, *supra* note 67, at 29.

127. *Id.* at 28-29.

128. *Id.* at 38, n.213 (referring to Civ. 19 May 1973, Bull. Civ. I, No. 181, at 161).

129. MOQUET-BORDE, *supra* note 117, § 8.01, at 8-3.

130. *European Economic Community Council of Ministers Directive of July 25, 1985 Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member-States Concerning Liability for Defective Products*, 28 O.J. EUR. COMM. (No. L210) 29 (1985) [hereinafter *Directive*].

131. Thieffry, *EEC Directive 85/374 on Liability for Defective Products: Implementation and Practice*, in PRACTISING LAW INSTITUTE, LITIGATION AND ADMINISTRATIVE PRACTISE

the risks inherent in modern technological production."¹³²

Of all industries, the pharmaceutical industry has the greatest potential for increased liability claims as a result of the Directive.¹³³ However, one commentator has noted that "while product liability has had a significant impact on American industry in terms of cost and disincentives for innovation, the general feeling is that the liability potential will most likely not be as severe in Europe"¹³⁴ There are two reasons for this conclusion. First, awards for pain and suffering are not allowed under the Directive.¹³⁵ Second, European countries do not provide for jury trials in civil cases, which are generally believed to lead to higher awards.¹³⁶ The EEC Directive also contains a proposed provision "that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million Ecu."¹³⁷

VI. INFORMED CONSENT AND THE RISKS OF EXPERIMENTAL DRUGS

Over the past forty years, the trend in United States drug law has been toward tighter control. This control is intended to protect the public by identifying harmful substances before they arrive on the market.¹³⁸ When the FDA promulgated the current regulations, the medical profession generally did not believe that it was necessary to inform unknowing patients of the experimental or investigational nature of the drug being tested on them. Likewise, doctors often did not inform their patients that the prescribed treatment drug did not have FDA approval.¹³⁹

SERIES, No. 371, EEC STRICT LIABILITY IN 1992: THE NEW PRODUCT LIABILITY RULES 13 (1989).

132. Whitehead, *Product Liability and European Integration in Light of the EEC Strict Liability Directive*, in PRACTISING LAW INSTITUTE, LITIGATION AND ADMINISTRATIVE PRACTISE SERIES, No. 371, EEC STRICT LIABILITY IN 1992: THE NEW PRODUCT LIABILITY RULES 66 (1989).

133. *Id.* at 67.

134. *Id.*

135. *Id.*

136. *Id.*

137. *Directive*, *supra* note 130, art. 16-1.

138. See Janssen, *The U.S. Food and Drug Law: How It Came; How It Works*, 35 FOOD DRUG COSM. L.J. 132 (1980).

139. See Sobel, *Policy Considerations of the IND Rewrite*, 43 FOOD DRUG COSM. L.J. 185, 186-87 (1988) for a discussion of the attitude toward and abuses of informed consent in the

The 1962 Amendments to the Food Drug and Cosmetic Act remedied this problem by requiring that

experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings. . . .¹⁴⁰

Despite the change in the medical profession's attitude toward the importance of obtaining the patient's informed consent, and the presence of added legislative safeguards, the FDA still maintains that

[c]areful FDA review is necessary and mandated by law to minimize the risk of allowing potentially unsafe and ineffective products from coming onto the market. Unsafe products cause unnecessary suffering. Ineffective ones raise false hopes, cause the patient to defer the use of other more effective measures, and are burdensome and economically costly besides.¹⁴¹

In comparison, under French case law, a physician has a duty to warn a patient of the possible risks associated with a recommended therapy, in order to obtain his informed consent.¹⁴² If injury does occur, the patient bears the burden of establishing that he did not consent to the treatment or procedure.¹⁴³ The application of this approach to drug testing allowed French researchers at the Pasteur Institute to "eagerly test all . . . sorts of drugs on AIDS patients, all of whom were more than willing subjects since they knew the alternative to treatment was death."¹⁴⁴

The problem that the AIDS crisis presents is quite different than those resulting from other diseases. As of this writing, no clearly effective treatment exists. Additionally, the disease appears to be inevitably fatal.¹⁴⁵ Desperate AIDS sufferers are crying out for access to treatment drugs which they know are still experimental and un-

early 1960s that prompted tighter regulatory control of the experimental drug investigation process.

140. 21 U.S.C. § 355(i) (1962).

141. Norris, *FDA's AIDS Program*, 12 NOVA L. REV. 1103 (1988) (John Norris is the chief operating officer of the FDA).

142. Carbonneau, *The Principles of Medical and Psychiatric Liability in French Law*, 29 INT'L & COMP. L.Q. 742, 749 n.46 (Oct. 1980).

143. *Id.* at 749.

144. R. SHILTS, *supra* note 10, at 496.

145. See *supra* text accompanying note 5 regarding the belief that virtually all who currently suffer from AIDS will eventually die as a result of the disease.

proven. Arguably, under these special circumstances, such individuals should be allowed to make that choice.

Under the informed consent doctrine, the patient essentially performs a risk-benefit analysis, balancing the potential risks of treatment against the potential benefits.¹⁴⁶ "To be informed, a person must be appraised of the risks and benefits of the proposed procedure, the alternative procedures if any, and of not having the procedure carried out at all."¹⁴⁷ A person with AIDS would weigh the detriment of not having access to any experimental treatment (almost certain death), the unknown potential benefits of experimental treatment (a possible cure), and the risk of unknown side effects from the drug. Until a proven alternative exists, doctors should provide AIDS patients themselves with sufficient information on which to base their informed consent. Faced with the consequences that the lack of an effective treatment present, the patient should be allowed to risk exposure to unforeseen side effects or ineffective treatment if he or she so chooses.

The regulation of experimental drugs is intended as a protective measure. However, when the protective intent delays access to potentially beneficial treatments, and no viable treatment alternatives exist, the regulations no longer benefit those whom they are designed to protect. In such a situation, a patient should have the option of giving his or her informed consent to an unproven treatment, once the drug has been shown to be nontoxic.

One AIDS activist group proposes that a number of proven nontoxic drugs should be released to the public immediately, even if testing for potential side effects is incomplete.¹⁴⁸ Given the disease's fatal nature and the lack of any proven effective treatments, the patients themselves should weigh the potential for unknown harmful side ef-

146. Informed consent is the name for a general principle of law that a physician has a duty to disclose what a reasonably prudent physician in the medical community in the exercise of reasonable care would disclose to his patient as to whatever grave risks of injury might be incurred from a proposed course of treatment, so that a patient, exercising ordinary care for his own welfare, and faced with a choice of undergoing the proposed treatment, or alternative treatment, or none at all, may intelligently exercise his judgment by reasonably balancing the probable risks against the probable benefits.

BLACK'S LAW DICTIONARY 701 (5th ed. 1979).

147. DORNETTE, AIDS AND THE LAW 7 (Supp. 1989).

148. Dawsey, *80 Arrested As AIDS Protest Broken Up*, L.A. Times, Oct. 7, 1989, at B4, col. 1. In June of 1989, ACT UP/N.Y., an AIDS activist group, announced the names of five drugs (DDI, EPO, fluconazole, foscarnet and GM-CSF) which they felt should be made available immediately because enough was already known about them from underground and clinical testing. Sadownick, *ACT UP and the Politics of AIDS*, L.A. Weekly, Oct. 6, 1989, at 23.

fects against the risk of foregoing treatment. Arguably, patients whose lives are threatened should be allowed to make an informed choice as to how much risk they wish to bear. That choice should not be made by a regulatory bureaucracy.¹⁴⁹

VII. THE DEBATE OVER CLINICAL TESTING

The argument generated by the required Phase 3 placebo trials is essentially an ethical one: "Is it ethical to give a placebo to patients in drug studies whose condition is serious or life threatening for the purpose of drug studies?"¹⁵⁰ For a test participant who receives only the placebo, the government's ultimate determination that the drug is indeed effective in fighting AIDS may come too late and at the expense of the test participant's life. Opponents of the testing process contend that "in such cases *all* patients should be given the experimental drug, since it offers at least *some* hope, where the placebo offers none."¹⁵¹ However, adherents to the FDA philosophy counter that to abandon the use of the placebo "would defeat the purpose of the clinical trial, making it impossible to learn whether the experimental drug does, in fact, have any more effect than no treatment at all."¹⁵²

To further its goal of protecting the public as a whole, the FDA maintains that "the importance of controlled clinical trials cannot be overemphasized, particularly in the case of a poorly understood disease such as AIDS."¹⁵³ Consistent with this philosophy, the FDA has denied approval of new drug applications for AIDS treatments because the supporting data was derived from compassionate-use protocols rather than from placebo-controlled trials,¹⁵⁴ and because the test conditions did not measure up to strict FDA standards.¹⁵⁵ The FDA attitude can be summed up by FDA Medical Officer Alexander Fleming's statement that:

[I]t's a disservice . . . to let even a dying patient use an unproven drug unless qualified physicians believe it has some chance of helping. . . . A "try anything" approach prevents physicians from

149. See Delaney, *supra* note 14, at 2444.

150. Flieger, *supra* note 50, at 12.

151. *Id.*

152. *Id.*

153. Hecht, *AIDS Progress Report*, FDA CONSUMER, Feb. 1986, at 35.

154. See Delaney, *supra* note 14, for a discussion of the FDA's denial of a license to obtain ganciclovir.

155. See Bishop, *supra* note 16, at 48, for a discussion of the FDA's denial of expanded ribavirin use.

quickly learning whether a drug works, and that's a disservice to others similarly ill who could be helped by an effective drug.¹⁵⁶

Some commentators suggest that once an effective drug is found, the efficacy of future experimental drugs should be measured against it rather than against a placebo.¹⁵⁷ However, because so much is still unknown about the HIV virus and AIDS, some researchers maintain that it will be a long time before they can abandon placebo-controlled trials altogether.¹⁵⁸

Even if the medical community discontinued placebo use in clinical trials, allowing access to treatment drugs only through participation in trials raises other problems. Access to space in clinical trial programs is often limited for other reasons. For example, intravenous drug users and prostitutes, two groups with a high incidence of AIDS, are traditionally excluded from clinical trials.¹⁵⁹ Likewise, research centers which conduct trials are generally concentrated in academic centers of major cities, thus making access to trials difficult for patients in suburban and rural areas.¹⁶⁰

Regulators maintain that restricting access to experimental drugs to clinical trial participants is necessary because "patients would not enter studies, especially placebo-controlled studies, if they could get the desired experimental drug some other way. Thus, they feel they must nobly restrict access to force participation in clinical studies, for the benefit of all."¹⁶¹ However, one can argue that forcing participants to enter controlled studies as the only means of access to a desired drug damages the study's accuracy. The problems cited include widespread use of concurrent treatments, pooling of drugs to minimize the risk of receiving a placebo, and rapid drop-out rates once

156. See Farley, *supra* note 64, at 6.

157. Macklin & Friedland, *AIDS Research: The Ethics of Clinical Trials*, 14 L. MED. & HEALTH CARE 273 (Dec. 1986). For example, one protocol for the testing of DDI called for a randomized, double-blind comparison of DDI and AZT, rather than a placebo. *Bristol-Myers DDI (VIDEX) Treatment IND Approved for People with AIDS, Severe ARC Who Are Intolerant to AZT*, The Blue Sheet, Oct. 4, 1989, at 2 [hereinafter *Bristol-Myers DDI Treatment IND Approved*].

158. Macklin & Friedland, *supra* note 157, at 274.

159. Levine, *Has AIDS Changed the Ethics of Human Subjects Research*, 16 L. MED. & HEALTH CARE 167, 171 (Winter 1988).

160. *Id.* The UCLA Medical School was criticized in late 1989 for charging AIDS patients a \$260 "consultation fee" to determine their eligibility to participate in clinical trials conducted at the school. Garcia, *UCLA Criticized for Charging Fees to AIDS Patients in Drug Studies*, L.A. Times, Nov. 15, 1989, at B1, col. 1. Critics felt that the practice excluded minorities and the poor from experimental treatment.

161. Delaney, *supra* note 14, at 2444.

patients learn that they are receiving a placebo.¹⁶² Arguably, voluntary rather than forced participation would produce more accurate results.

Given the importance that the FDA places on the use of clinical trials, the issue becomes whether it is ethical for the FDA to place greater emphasis on its long term regulatory needs than on the immediate needs of individual patients.¹⁶³ In an international context, United States proceduralism is excessive.¹⁶⁴

Different cultures often make different value judgments about important life-sustaining drugs and acceptable levels of risk.¹⁶⁵ For example, the French do not require placebo testing and view the practice as morally objectionable.¹⁶⁶ A number of United States critics, such as Dr. Mathilde Krim, founder of the American Foundation for AIDS Research, have adopted a position very close to that of the doctors at the Pasteur Institute and maintain that "it is inhumane to deny those who otherwise inevitably will die the opportunity to use any drug they can—even if they are not enrolled in a clinical trial."¹⁶⁷

The needs of the patients seeking treatment must be balanced with the needs of researchers. Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases ("NIAID"), has suggested a "parallel track" program wherein Phase 2 drugs would be made available to patients who do not otherwise qualify for clinical trials.¹⁶⁸ When implementing this idea during the testing of DDI, the FDA required patients who desired the drug to seek enrollment in a clinical trial first before considering them for Treatment IND or compassionate-use distribution of the drug.¹⁶⁹ Although the FDA expressed support of the "parallel track" concept when it was proposed in June 1989,¹⁷⁰ this system had not been officially implemented as of

162. *Id.*; see Grady, *Look, Doctor, I'm Dying: Give Me the Drug*, DISCOVER, Aug. 1986, at 78-86, for an extensive general discussion regarding the problems and issues raised by the first clinical trials of AZT in 1986.

163. Delaney, *supra* note 14, at 2444.

164. O'Reilly, *supra* note 79, at 135. "[United States] proceduralism has been carried to extremes, and . . . it may need to change to make it more compatible with the world market's needs." *Id.*

165. *Id.*

166. See *supra* text accompanying notes 84-86.

167. N. KRIEGER & R. APPLEMAN, *THE POLITICS OF AIDS* 226 (1986).

168. *Fauci Urges 'Parallel Track' Program; Critics Say ddi Trial Plan Isn't Working*, 4 AIDS Pol'y & L. (BNA) No. 22, at 1 (Nov. 29, 1989).

169. *Bristol-Myers DDI Treatment IND Approved*, *supra* note 157.

170. Goldsmith, *supra* note 9, at 452.

March 1990.¹⁷¹

Dr. Marvin Zelen, a Harvard public health scientist, has proposed a major overhaul of the current approach to clinical trials of potential AIDS treatments.¹⁷² This proposal, called the "Open Protocol System,"¹⁷³ is similar in several respects to the French system. This approach would eliminate the use of placebos in the clinical trials of AIDS drugs, with emphasis placed instead on varying drug dosages and testing combinations with other drugs.¹⁷⁴ The second part of Zelen's proposal focuses on "learn[ing] something from every AIDS patient,"¹⁷⁵ by involving physicians throughout the country, not just those at university research hospitals, in the collection of AIDS treatment data.¹⁷⁶ This portion of the proposal resembles the French Drug Monitoring system, which collects data from all levels of the medical health professions in France.¹⁷⁷ Such a monitoring system, if implemented in the United States, would balance the needs of researchers and patients. An extensive, centralized monitoring system would allow access to experimental treatments even to those not involved in trials, while still providing necessary data to researchers.

VIII. ADDRESSING THE VACCINE LIABILITY ISSUE

The current doctrine of strict liability for pharmaceutical manufacturers in the United States has evolved primarily over the last twenty years. Developments in this field are sometimes described as dramatic, illogical, inconsistent, and confusing.¹⁷⁸ However, the European Community is moving to adopt a strict liability standard as well.¹⁷⁹ Special action must address the problem as it relates to the development of an AIDS vaccine, for the current state of the law hinders drug manufacturers' interest in development of a vaccine. If fear of liability stops producers from pursuing research or seeking to market a vaccine, the battle against AIDS will have lost a valuable

171. Cimon & Steinbrook, *6 AIDS Patient Deaths May Renew Drug Debate*, L.A. Times, Mar. 10, 1989, at A27, col. 1.

172. *Scientist Proposes New Way of Conducting Clinical Trials*, 4 AIDS Pol'y & L. (BNA) No. 1, at 2 (Jan. 25, 1989).

173. *Id.* at 3.

174. *Id.*

175. *Id.*

176. *Id.*

177. *See supra* text accompanying notes 76-79.

178. Maedgen & McCall, *A Survey of Law Regarding the Liability of Manufacturers and Sellers of Drug Products and Medical Devices*, 18 ST. MARY'S L.J. 395, 397 (1986).

179. *See supra* text accompanying notes 129-37.

weapon.¹⁸⁰

The federal government previously addressed the problem of liability for unknown side effects caused by vaccines on two occasions. The government first approached the vaccine liability issue in 1976, at the time of the predicted Swine Flu epidemic.¹⁸¹ On the advice of the Center for Disease Control, Congress appropriated funds for a mass inoculation program against the Swine Flu.¹⁸² In the wake of the potential for manufacturers' liability foreshadowed by *Reyes v. Wyeth Laboratories*,¹⁸³ neither drug manufacturers nor their insurers were willing to undertake the risk of providing the vaccine.¹⁸⁴ To ensure that the public could obtain the inoculations, Congress passed the Swine Flu Act,¹⁸⁵ which imposed liability upon the United States for any damages that arose from the vaccine.¹⁸⁶

Under the Swine Flu Act, the United States replaced the named defendants in any suit, resulting from the Swine Flu vaccine,¹⁸⁷ which the plaintiff originally filed against a manufacturer or distributor of the vaccine, or any private or public health care facility which had provided the vaccine at no cost.¹⁸⁸ The United States reserved the right to bring an action against any vaccine manufacturer whose negligence resulted in an award.¹⁸⁹ The government eventually paid out over \$83 million in damages under the Act for side effects which developed from the vaccine.¹⁹⁰

The federal government next addressed the vaccine liability problem ten years later in 1986. Throughout the early 1980s, the number of drug manufacturers willing to produce vaccines had dropped dramatically.¹⁹¹ In response to pressure from parents' groups, vaccine manufacturers, and medical groups, Congress enacted the National

180. Mariner & Gallo, *supra* note 97, at 23.

181. See *supra* text accompanying notes 111-14.

182. See Bishop, *supra* note 16, at 111.

183. 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

184. M. FRANKLIN, *supra* note 111, at 742.

185. 42 U.S.C. § 247b (1988).

186. For an extensive discussion of the Swine Flu Act, see Reitze, *supra* note 113.

187. 42 U.S.C. § 247b(k)(2)(A).

188. *Id.* § 247b(k)(1).

189. *Id.* § 247b(k)(7).

190. See *supra* notes 111-14 and accompanying text.

191. M. FRANKLIN, *supra* note 111, at 742-43. Between 1963 and 1986, the number of American companies producing the vaccine to immunize children from diphtheria-pertussis-tetanus (DPT) fell from eight to one. *Id.*

Childhood Vaccine Injury Act.¹⁹² This Act created a federal compensation system for reactions and lasting injuries caused by seven childhood disease vaccines.¹⁹³

The Act set up a special statutory scheme, under which claims are brought in federal court and heard by an appointed special master.¹⁹⁴ Liability depends on a no-fault system, in which proof of whether the injury is vaccine-related is determined by reference to a table of specific vaccine-related injuries.¹⁹⁵ Proof of an enumerated injury or illness raises a presumption of liability. On the other hand, those with a nonenumerated injury must show a connection between the vaccine and the injury.¹⁹⁶ The amount of the eventual award can include actual reimbursable medical expenses,¹⁹⁷ rehabilitation costs,¹⁹⁸ lost wages,¹⁹⁹ and reasonable legal fees.²⁰⁰ However, awards for pain and suffering are capped at \$250,000.²⁰¹ Furthermore, punitive damages may not be awarded.²⁰² The government provides funding for the system by charging a special excise tax on the sale of the vaccine.²⁰³

Under existing French law and the proposed EEC Directive, several factors combine to limit a manufacturer's exposure to liability in France.²⁰⁴ By incorporating some of these same limiting factors, the United States can remove some of the disincentives to the development of an AIDS vaccine. Specifically, such legislation could include a prohibition or limitation on punitive damages, as well as on pain and suffering damages. Furthermore, this legislation could impose a cap on total liability from a vaccine.

The federal government has the ability to address the AIDS vaccine issue with specific legislation, as it has done on previous occasions with the enactment of the Swine Flu and Childhood Vaccine Injury Acts. Nevertheless, the federal government has taken no ac-

192. National Childhood Vaccine Injury Act, Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified as amended in scattered sections of 42 U.S.C.).

193. *Id.*

194. M. FRANKLIN, *supra* note 111, at 743; *see also* Bishop, *supra* note 16, at 112.

195. 42 U.S.C. § 300aa-14(a).

196. *Id.* § 300aa-11(c).

197. *Id.* § 300aa-15(a).

198. *Id.* § 300aa-15(a)(1)(A)(iii)(II).

199. *Id.* § 300aa-15(a)(3)(A).

200. *Id.* § 300aa-15(e).

201. *Id.* § 300aa-15(a)(2), (4).

202. *Id.* § 300aa-15(d).

203. *Id.* § 300aa-15(i)(2).

204. *See supra* text accompanying notes 116-37.

tion to date. However, California has independently addressed the problem at the state level. The California legislature recognized "a decrease in the willingness of pharmaceutical companies to become involved in vaccine research, development, and manufacturing because of uncertain profitability and perceived and actual marketplace risks and disincentives."²⁰⁵ It further determined that "[w]ithout state intervention to assure minimal profitability of an AIDS vaccine, inadequate incentives may exist for the private sector to commit resources and expertise to the accelerated development of an AIDS vaccine."²⁰⁶

To remedy this problem, California lawmakers passed legislation in late 1986 which created an AIDS Vaccine Victims Compensation Fund,²⁰⁷ an AIDS Vaccine Guaranteed Purchase Fund,²⁰⁸ and an AIDS Vaccine Research Development Grant Program.²⁰⁹

The purposes of the AIDS Vaccine Victim Compensation Fund is to provide a source of recovery for injuries proximately caused by an AIDS vaccine.²¹⁰ Under the program, injured parties may recover medical costs,²¹¹ loss of earnings,²¹² and pain and suffering damages which do not exceed \$550,000.²¹³

With the AIDS Vaccine Guaranteed Purchase Fund, the State of California guaranteed the purchase, at a designated price, of at least 500,000 units of an AIDS vaccine within three years of its approval by the FDA.²¹⁴ The legislature hoped that this guarantee would assure the development of such a vaccine.²¹⁵

The AIDS Vaccine Research and Development Grant Program also focused on "encourag[ing] AIDS vaccine research by the private sector" by providing an additional source of funding.²¹⁶ Under this program, if a grant recipient develops an AIDS vaccine, the State of California would be entitled to reimbursement from royalties made from the sale of the vaccine, at the rate of \$1 per dose until full repay-

205. CAL. HEALTH AND SAFETY CODE § 199.45(l) (West 1990).

206. *Id.* § 199.45(o).

207. *Id.* § 199.50.

208. *Id.* § 199.51.

209. *Id.* § 199.56.

210. *Id.* § 199.47(d).

211. *Id.* § 199.47(d)(1).

212. *Id.* § 199.47(d)(2).

213. *Id.* § 199.47(d)(3).

214. *Id.* § 199.51.

215. *Id.*

216. *Id.* § 199.55(h).

ment of the grant.²¹⁷

In passing these acts, California has taken an important and aggressive step in addressing the problems inherent in the development of an AIDS vaccine.²¹⁸ This legislation is currently the only legislation of its kind in the nation. Congress should use its legislative power, as it has done previously in addressing the Swine Flu and childhood disease vaccine problems, to enact similar national legislation to encourage development of an AIDS vaccine.

IX. BUREAUCRATIC ENTANGLEMENTS

One major bureaucratic impediment to drug approval is the "matter of how much data is enough and who should make that value judgment."²¹⁹ An example of this problem is the approval process of ganciclovir, a drug used to fight CMV-retinitis, an AIDS-related infection which causes blindness. Over 3,600 patients have used ganciclovir on a compassionate-use basis since 1984.²²⁰ Treating ophthalmologists reported dramatic evidence that the drug successfully arrested blinding eye infections caused by CMV-retinitis.²²¹ In 1987, despite the opinion of the two ophthalmologists on the committee regarding the drug's effectiveness,²²² the FDA Anti-Infective Drug Advisory Committee did not approve the drug because the data came from compassionate-use treatments rather than controlled trials.²²³ After completion of further clinical trials with the same results, the drug eventually received approval in June 1989.²²⁴

Ganciclovir was widely available in Europe before its approval in

217. *Id.* § 199.60.

218. The California legislation has successfully encouraged research and development of an AIDS vaccine within the state. As of March 1990, three potential vaccines were undergoing research in the state as a result of the legislation. Zonana, *Firm Gets State OK to Test AIDS Vaccine*, L.A. Times, Mar. 6, 1990, at A3, col. 4. The most promising potential vaccine being researched under the California program is a vaccine containing inactivated HIV virus, developed by a team headed by famed polio vaccine developer Jonas Salk. Petit, *Top Scientists Predict Vaccine for AIDS Before End of Century*, L.A. Daily News, June 23, 1990, at 21, col. 3.

219. Lasagna, *Promising Drugs Deserve Faster Approval*, L.A. Times, Oct. 19, 1989, at B15, col. 1. The statute's language requires "substantial evidence" of a drug's effectiveness before approval. See *supra* text accompanying note 41.

220. Delaney, *supra* note 13, at 2444; *Ganciclovir Approved for AIDS-Related CMV-Retinitis*, The Blue Sheet, June 28, 1989.

221. *Despite Promise in AIDS Cases, Drug Faces Testing Hurdle*, AIDS L. & LIT. REP., Jan. 1989, at 6, col. 2.

222. Lasagna, *supra* note 219.

223. The Blue Sheet, *supra* note 220.

224. *Id.*

the United States.²²⁵ While the FDA insists that "its people are the experts,"²²⁶ the French approval system of "expertises" utilizes hospital-based clinicians in the review process.²²⁷ The French focus on hands-on clinical review decreases the importance of administrative proceedings and its resulting bureaucracy, and permits wider availability of a treatment while data is still being collected.

To expedite the drug approval process in the United States, the FDA should implement procedures modeled after the French system of "expertises." Rather than delaying promising drugs while administrative committees make decisions, such a system would allow the opinions of clinicians in the field to provide the "substantial evidence" of the drug's effectiveness necessary for approval.

While not admitting that the FDA creates a bottleneck for new drug approval, the AIDS Activities Oversight Committee noted in its report that:

the FDA could become an impediment to speedy availability. The committee believes that FDA resources for new drug approval should be commensurate with the task. The need to borrow personnel from other parts of the agency should be relieved; the need for space, which appears particularly acute, should also be addressed.²²⁸

Critics have pointed to bureaucratic problems within the FDA itself as being a major obstacle blocking the swift availability of AIDS treatment drugs.

What is wrong with the FDA? Compared to the drug regulatory agencies of other countries, it is huge. Yet it is said to be too small for its innumerable responsibilities. Its headquarters in Maryland is cheerless and inadequate in space, wiring and temperature control. These conditions and low pay scales discourage top-notch applicants for staff positions, and many senior posts are unfilled.²²⁹

Many drug manufacturers have reported difficulty in obtaining new drug approval.²³⁰ Some AIDS activists have accused the FDA of reacting more favorably and more quickly to drugs sponsored by the National Institute of Health ("NIH"), which conducts clinical trials

225. *Despite Promise in AIDS Cases, Drug Faces Testing Hurdle*, AIDS L. & LIT. REP., Jan. 1989, at 6, col. 2.

226. Lasagna, *supra* note 219.

227. *See supra* text accompanying notes 80-81.

228. INSTITUTE OF MEDICINE, *supra* note 42, at 138-39.

229. Lasagna, *supra* note 219.

230. Van de Kamp, *supra* note 5, at 32.

of some drugs, than to other promising drugs submitted by other sources.²³¹ To challenge this practice, a public interest law group sued FDA Commissioner Frank Young and the NIH in June 1987 on behalf of all persons infected with AIDS.²³² Among other things, the lawsuit charged that the NIH and the FDA accelerated their consideration and approval of AZT while ignoring or delaying consideration of other promising drugs.²³³ Although the court dismissed the suit on procedural grounds,²³⁴ the criticisms have merit.²³⁵

The FDA's bureaucratic problems have severely inhibited the development of necessary AIDS treatments. To remedy this problem, the federal government should allocate sufficient resources to fund a separate program within the FDA. This program should concentrate exclusively on coordinating the finding, testing, and distribution of AIDS treatments on a streamlined and expedited basis.

X. POLITICAL REALITIES

"The two principle conditions which have historically led to major food and drug legislation have been the existence of a persuasive leader . . . and the occurrence of a crisis in which the weaknesses of existing protective legislation are exposed to the public through the news media."²³⁶ Despite the fact that over 100,000 Americans have contracted this deadly disease, no strong leader has stepped forward and the government has been slow to take action against AIDS.

Political considerations inevitably affect how the government reacts to controversial situations. AIDS activists and sympathetic politicians have criticized both the Reagan and Bush administrations for an uncaring attitude and inadequate response to the AIDS threat.²³⁷ President Ronald Reagan did not publicly discuss AIDS until

231. *Id.*

232. *National Gay Rights Advocates v. Department of Health and Human Services*, No. 87 Civ. 1735, (D.D.C. Apr. 26, 1988).

233. Bishop, *supra* note 16, at 48.

234. On April 26, 1988, the court granted the defendants' motion to dismiss on the ground that the plaintiffs' had failed to exhaust the appropriate administrative remedies. *National Gay Rights Advocates*, No. 87 Civ. 1735 (D.D.C. Apr. 26, 1988).

235. Perhaps in response to the recent public criticisms of the numerous problems within the FDA, Dr. Frank Young stepped down from his position as Commissioner of the FDA in late 1989. See *FDA Chief Gets New Post but is Seen as Scapegoat*, L.A. Times, Nov. 14, 1989, at A1, col. 1. As of September 1990, no successor had been named.

236. J. O'REILLY, *FOOD AND DRUG ADMINISTRATION* 3-19 (1989).

237. See Pink Sheet, 49(26), June 29, 1987 at 8-9; Simpson, *Using Rage to Fight the Plague*, TIME, Feb. 5, 1990, at 8.

1987.²³⁸ President George Bush has likewise been unresponsive to AIDS concerns.²³⁹

To date, the majority of people who have contracted AIDS are homosexual and bisexual men and intravenous drug users.²⁴⁰ Many people believe that those who suffer from AIDS are somehow responsible for having the disease²⁴¹ and that to research treatments would "merely encourage unhealthy behavior."²⁴² It appears that "[b]ecause a majority of the victims [of AIDS] are homosexual or are otherwise stigmatized by society, the authorities who control medical funds have been unwilling to finance the comprehensive campaigns required to develop preventive and therapeutic regimens."²⁴³

Larry Kramer, a high-profile AIDS activist and founder of ACT UP (AIDS Coalition to Release Power) states this belief in even stronger terms:

Why has there been such complacency about AIDS? . . . [T]here is no question . . . [that it is] . . . because of who it's happening to. I mean, you can say all you want about denial, but this is happening to black people and to Hispanic people and to people who take drugs and to gay people and to babies who are born out of wedlock, and these are all people that a lot of other people would just as soon weren't there.²⁴⁴

238. S. PANEM, *THE AIDS BUREAUCRACY* 29 (1988).

239. President Bush declined an invitation to deliver a speech at the Sixth International Conference on AIDS, held in San Francisco in June 1990. This refusal marked the first time in three years that the host nation's leader did not address the conference. Zonana, *Bush Won't Address S.F. Conference on AIDS*, L.A. Times, Feb. 11, 1990, at A3, col. 5. One critic stated, "[T]he President has good reason for not coming. Neither the city of San Francisco nor the scientific community think much of his AIDS policies." *Id.* at A34, col. 5.

240. INSTITUTE OF MEDICINE, *supra* note 42, at 51. In May 1988, 63% of reported AIDS cases were homosexual or bisexual men, 19% were heterosexual intravenous drug users, and 4% had contracted the disease through heterosexual contact. *Id.*

241. Patrick Buchanan, a conservative columnist and former Reagan speechwriter, once wrote, "The poor homosexuals—they have declared war upon Nature, and now Nature is exacting an awful retribution." Brandt, *AIDS: From Social History to Social Policy*, 14 L. MED. & HEALTH CARE 231, 235 (Dec. 1986). CBS commentator Andy Rooney likewise generated controversy during his 1989 year-end special when he lumped "homosexual unions" with cigarettes, alcohol, and other "self-induced ills" that lead to early death. Rosenberg, *Is CBS News Guilty of Andy Rooney-Bashing?*, L.A. Times, Feb. 10, 1990, at F7, col. 2.

242. Brandt, *supra* note 241, at 235.

243. Editorial, *A Social Disease*, THE NATION, Sept. 14, 1985, at 195-96.

244. Simpson, *supra* note 237, at 8. Blacks and Hispanics make up 12% of the general population but they make up 39% of the AIDS patients in the United States. Rogers, *The Medical Profession and AIDS*, 10 J. LEGAL MED. 1, 5 (1989). Blacks and Hispanics also account for 81% of the heterosexual cases of AIDS. Margolis, *Outreach and Counseling Efforts for High Risk Partners of HIV Infected Individuals*, 10 J. LEGAL MED. 59, 61 (1989).

In contrast to the United States' perception of the disease, French doctors consider the preoccupation with the homosexual aspect of AIDS a strange American idiosyncrasy.²⁴⁵ Early in the AIDS crisis, the French doctors warned of the threat the disease posed to all people.²⁴⁶ As long as the American public continues to perceive AIDS in this narrow manner, expensive government action to speed the availability of treatment drugs remains unlikely. However, statistics now prove that the French perception of the disease is accurate, and that in the future, AIDS will no longer be just a "gay disease."²⁴⁷ The United States Center for Disease Control has noted that "AIDS cases are likely to increase each year in the United States. Most of the increase will occur in cases involving intravenous drug use, heterosexual transmission and perinatal infections of children."²⁴⁸

Additionally, as more of the estimated 800,000 to 1.3 million people in the United States who are currently infected with the HIV virus begin to actually develop AIDS symptoms,²⁴⁹ public opinion may become more sympathetic.²⁵⁰ In the very near future,²⁵¹ the nature and extent of the AIDS epidemic will compel the public and government to recognize the need for terminally ill AIDS victims to have access to experimental drugs as soon as possible. For those currently suffering from AIDS, this recognition will come too late.

XI. CONCLUSION

AIDS constitutes a worldwide epidemic of an entirely new, infectious, and as of today, inevitably fatal disease unlike any faced in modern history. Because of the unique nature of the challenge that AIDS presents, the current "business as usual" approach taken by the federal government and the FDA is inadequate. FDA administrative regulations have overdeveloped to the point where they actually harm

245. R. SHILTS, *supra* note 10, at 511.

246. *Id.* The initial hesitation of French health officials to deal with AIDS stemmed instead from viewing it as an "American problem" that did not fundamentally affect France. *Id.* at 546.

247. Steinbrook, *supra* note 3, at A1, col. 3.

248. *Id.* at A34, col. 1.

249. See *supra* text accompanying note 4.

250. According to the Center for Disease Control, 85% of those estimated to be infected with the AIDS virus are not aware that they are infected. *AIDS Update*, L.A. Daily News, Feb. 19, 1990, § 4, at 8, col. 3.

251. See Katz, *AIDS Isn't Leveling Off*, L.A. Times, Feb. 12, 1990, at B10, col. 3, for one health care provider's opinion that thousands of people will develop AIDS in the next several years because the peak years of HIV infection were 1983-1985, and the interval between infection and diagnosis is seven to ten years.

those that they were designed to protect. Remedial steps must be taken and a new and different approach developed. In conclusion, the following recommendations, which incorporate useful aspects of the French system, are offered:

1. Until an undeniably effective remedy for AIDS is found, all experimental AIDS treatments demonstrating reasonable promise of effectiveness should be made available to the public once the drug has been proven safe and nontoxic in the preliminary testing stage. The government has a less compelling need to protect the terminally ill from unknown side effects of experimental drugs than the public at large. Furthermore, the needs of people with AIDS, who are facing almost certain death, are best met by allowing the patient and his physician to make an individual, informed choice whether to assume the risk of treatment with an unproven drug.

2. The treatment needs of people with AIDS should not be sacrificed to meet the needs of researchers. The use of placebos in clinical trials, viewed abroad as inhumane, and a product of excessive American proceduralism, should be eliminated. All patients involved in a trial should receive the drug. The drug's effectiveness can instead be measured against other drugs, a combination of drugs, or varying dosages.

3. The United States should adopt the French approach and try to learn something from every AIDS patient. A monitoring network which tracks the effects of treatment drugs in widespread use by utilizing all levels of the medical profession should be implemented. This system would continue to provide researchers with needed data while still allowing patients access to the treatments.

4. Treatment with a drug in the clinical trial stage should not be limited to only those patients participating in a trial. Those unable to participate in clinical trials because of reasons beyond the control of the patient, such as geography, lack of space, lack of funds, or other disqualifying factors should be given access to the drug regardless of trial participation.

5. Within the FDA, a single-purpose, streamlined program devoted exclusively to finding, testing, and developing AIDS treatment drugs on an expedited basis should be established to help minimize the time lag in the approval process. The French approval system involves more hospital-based clinicians in the approval process. Implementation of such a system in the United States would help relieve

the bureaucratic bottleneck for the release of new drugs created by the current advisory committee restraints.

6. Congress should address the vaccine liability problem by enacting national AIDS-Vaccine legislation, similar to the 1987 California legislation, to subsidize and encourage AIDS research, and to provide protection for both drug manufacturers and potential victims of unknown side effects. Additionally, this legislation should adopt the limitations on damages recommended by the EEC Directive on Strict Product Liability: no punitive damages, no award for pain and suffering, and an overall cap on liability for incidents from the same product.

7. The general public and the government must recognize that AIDS is not a problem which affects only isolated and unpopular segments of the population, but is instead a major health crisis which must be faced by all. Ignoring the problems presented by AIDS will not make the problem disappear. Only by strong public support and decisive government intervention can this challenge be met.

Anne E. Wells

