Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards be Modified in Response to the Needs of Persons with AIDS?

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Hope, it is true, is about all an AIDS patient has to hold on to. Sometimes, it is the hope that the terrible disease will miraculously disappear through some holistic alternative to medicines—a hope, unfortunately, that rarely if ever is realized since miracles, like lottery hits, work on long odds. Many patients, however, are counting on some new drug, or an old one tailored to a new purpose, in hopes that it will rid their bodies of the raging virus.¹

I. INTRODUCTION

The spread of Acquired Immune Deficiency Syndrome (AIDS)² has become a devastating global health threat. In November 1987, approximately 62,000 cases of AIDS were reported to the World Health Organization from 127 countries.³ However, as of February 1990, more than 120,000 cases of AIDS have been reported in the

² Acquired immunodeficiency syndrome is caused by a virus which attacks the T-4 lymphocytes and enters the cells, incorporating itself into the genetic material. When an infection enters the body, these cells are activated and the virus reproduces itself, killing the cell in which it is housed, and releasing itself into the body to kill other cells. The consequence is a diminished immune system which prevents the body from warding off disease and which paves the way for a host of opportunistic infections to attack the body and ultimately lead to the individual's death. See Birchfield, AIDS: The Legal Aspects of a Disease, 6 Med. Law 407, 409 (1987); see also E. Nichols, Mobilizing Against AIDS 190 (1989)(noting that research has centered on drugs that prevent viral replication and the infection of healthy cells).
United States alone, and over half of these individuals have already died as a result of the deadly syndrome.\(^4\) To date, no cure has been discovered, and most individuals who develop full-blown AIDS\(^5\) are destined to die within several years of diagnosis.\(^6\)

Faced with the devastating effects of AIDS and armed with more questions than answers, researchers are actively searching for ways to treat and cure the deadly syndrome,\(^7\) and many experiment-

\(4\). According to statistics compiled by the United States Department of Health and Human Services, Centers For Disease Control in Atlanta, Georgia, approximately 121,645 cases of AIDS were reported in the United States as of February 1, 1990. Of this total, 119,540 (98.3 percent) occurred among adults and 2,055 (1.7 percent) among children less than 13 years of age. Of the adults, 108,538 (90.8 percent) were men and 11,052 (9.2 percent) were women. The mean age at diagnosis was 37.5 years. The overall mortality rate in the United States was 55 percent at the time of reporting and greater than 90 percent 5 years after diagnosis. Between 1 and 2 million more individuals in the United States are believed to be infected with the causative agent, the human immunodeficiency virus (HIV). CENTERS FOR DISEASE CONTROL, U.S. DEP'T. OF HEALTH & HUMAN SERV., HIV/AIDS SURVEILLANCE 1-18 (Feb. 1990), reprinted in M. SANDE & P. VOLBERDING, THE MEDICAL MANAGEMENT OF AIDS 7 (2d ed. 1990).

Global epidemiological studies are equally alarming. World Health Organization (WHO) studies indicate that since 1981, more than 220,000 cases of AIDS have been reported from 153 countries. However, because of underreporting in many developing countries due to the lack of diagnostic equipment and health infrastructure needed to identify AIDS, WHO estimates that in reality more than 500,000 cases of AIDS have occurred worldwide in this period with more than 300,000 deaths resulting from the deadly syndrome. T. Quinn, Global Epidemiology of HIV Infections, in M. SANDE & P. VOLBERDING, supra note 4, at 3.

5. Scientists have separated the acquired immunodeficiency syndrome into three distinct phases. The first phase includes persons who have been infected with the HIV virus and who exhibit laboratory evidence of the infection, but who do not exhibit symptoms of the virus. Scientists have determined that the length of time from when a person is infected with the virus and when symptoms develop can vary from several days to several years. The second phase has been termed AIDS-related complex or “ARC”. Persons with ARC experience a variety of symptoms which are usually not immediately life-threatening including swollen glands, loss of appetite, weight loss, weakness, night sweats, persistent coughing, diarrhea, oral thrush (white deposits in the mouth caused by an overgrowth of yeast in the digestive tract), and shingles (blotching and scaling of the skin). The third and final phase of the syndrome has been classified as “full-blown” AIDS. Full-blown AIDS is characterized by acute immune system dysfunction and the onset of any of a number of life-threatening opportunistic infections including forms of cancer, pneumonia and tuberculosis. See J. LANGONE, supra note 1, at 10-16.


7. See V. Gong, Facts and Fallacies: An AIDS Overview, in AIDS: FACTS AND ISSUES (V. Gong & N. Rudnick eds. 1986) (noting that although an enormous amount of information about AIDS has been collected, knowledge about the syndrome is rapidly evolving and diagnostic criteria must continually be reevaluated as new information on AIDS becomes available); see also J. SLAFF & J. BRUBAKER, THE AIDS EPIDEMIC 167 (1985) (noting that although a tremendous amount of information about AIDS has been learned in a few short years, the medical community's knowledge of the AIDS virus is dwarfed by what is unknown).
tal drugs for the treatment of AIDS have been developed or are currently being developed. However, only one such drug, azidothymidine (AZT), is currently approved for interstate marketing by the Federal Food and Drug Administration (FDA). Unfortunately, many persons with AIDS cannot rely on AZT for the treatment of their illness.

Based on the lack of FDA-approved drugs for the treatment of AIDS, many persons suffering from the syndrome are desperately seeking access to drugs which have been approved for experimental testing on humans, but which have not satisfied the rigid safety and effectiveness testing criteria of the Federal Food, Drug and Cosmetic Act (FDCA). In marked similarity to the lobbying efforts of terminal cancer patients throughout the 1970's, advocates of persons


9. See E. Nichols, supra note 2, at 210; see also U.S. Dep't of Health & Human Servs., HHS News, October 26, 1989 (announcing that the FDA granted permission for the distribution of AZT free of charge for use in treating children under the age of 13 who have AIDS or are suffering from infection with the AIDS virus, and noting that AZT is the only drug that has been shown to be effective in prolonging the lives of people with AIDS).

10. See J. Langone, supra note 1, at 178. The FDA has continually emphasized that although AZT may prolong the lives of some individuals with AIDS, the drug is not a cure for the illness. Id. Studies also have shown that AZT is often effective only in the early stages of the illness. In fact, federal researchers have found that AZT is most effective in people who are infected with the HIV virus and whose immune system cells have been depleted, but who show few or no AIDS symptoms. See Hils, AIDS Drug's Maker Cuts Price By 20%, N.Y. Times, Sept. 19, 1989, at A1, col. 1. Furthermore, studies have shown that AZT is often intolerable by patients with AIDS due to serious side effects associated with the drug including anemia, bone marrow suppression, nausea, headaches, muscle pain, and insomnia. See E. Nichols, supra note 2, at 211.


12. Pursuant to the Federal Food, Drug and Cosmetic Act, no person may introduce or deliver any new drug into interstate commerce unless an approval of a new drug application is filed with the FDA with respect to that new drug, and the new drug application must contain full reports of investigations which have been made to show that the drug is both safe and effective for its intended use. 21 U.S.C. § 355(a)-(b) (1987 & Supp. 1989).

13. See, e.g., United States v. Rutherford, 442 U.S. 544 (1979); People v. Privitera, 23
with AIDS are striving for the recognition of a fundamental right to obtain necessary experimental treatment and are urging the government to modify the experimental drug distribution system so as to permit the distribution of potentially effective new drugs to AIDS patients before they have completed the traditional clinical testing requirements. In response to these lobbying efforts, the United States has recently witnessed important regulatory changes which have the potential to drastically increase accessibility to AIDS experimental drugs before they have met the traditional FDA testing criteria. In addition, further regulatory changes may soon be implemented which would make experimental drugs for the treatment of AIDS available at an earlier stage of the clinical process than ever before.

With the devastating acceleration of the spread of AIDS, and the dim prospects for a cure in the immediate future, the issue of accessibility to unapproved new drugs promises to be a heated legal debate for years to come. Advocates of persons with AIDS and other life-threatening illnesses will undoubtedly continue to rally for the recognition of a fundamental right to choose unproven drugs and for the need for greater and faster access to these unproven alternatives. Opponents will denounce the existence of a constitutional

Cal. 3d 697, 153 Cal. Rptr. 431, 591 P.2d 919 (1979). In both cases patients sought access to an unapproved cancer drug, Laetrile.

14. See Hilts, How The AIDS Crisis Made Drug Regulators Speed Up, N.Y. Times, Sept. 24, 1989, at D5, col. 1 (discussing the strong lobbying efforts of advocates of persons with AIDS to compel the government to loosen the rigid rules on experimental drug distribution for dying patients); see also Complaint at 11-12, National Gay Rights Advocates v. United States Dep't of Health & Human Servs., No. 87-CV-1735 Civ. (D.D.C. April 26, 1988). In this case, the plaintiffs attempted to force the FDA to release its hold on the distribution of promising experimental AIDS treatment. On April 26, 1988, the United States District Court for the District of Columbia granted the defendants' motion for summary judgment and dismissed the complaint on the grounds that the plaintiffs failed to exhaust their administrative remedies pursuant to the Administrative Procedure Act. The FDA has implemented the administrative exhaustion requirements of the Administrative Procedure Act into its regulations which state that "any interested person may petition the Commissioner to issue, amend or revoke a regulation or order to take or refrain from taking any other form of administrative action, under the law administered by him." 21 C.F.R. § 10.25(a) (1987).

15. See infra notes 162-84 and accompanying text.

16. See infra notes 192-203 and accompanying text.

17. See Garrett, AIDS: Hope From Underground, Newsday, Dec. 11, 1989, at 3, col. 2 (Suffolk County ed.) (noting that "[t]he urgency of the [AIDS] epidemic, rage among people with AIDS and the special rules promulgated in Washington to speed drug development ensure that discoveries offering even the slightest bit of hope will be found in unlikely places.").

18. See Hilts, supra note 14 (discussing the arguments of advocates for and against streamlined access to unapproved drugs for the treatment of AIDS).
right to obtain unproven treatment and will continue to focus on the
risks associated with early distribution programs. 19

Section II will provide a brief history of the development of the
drug regulatory laws in the United States and the purposes behind
the legislation. 20 Section III will analyze the United States Supreme
Court’s decision in United States v. Rutherford, 21 the first major
challenge regarding the application of the FDCA’s safety and effec-
tiveness testing requirements to drugs for the treatment of terminal
illnesses, in light of the special dilemma faced by persons with
AIDS. 22 Section IV will address the question left open by the Su-
preme Court in United States v. Rutherford: should a person with
AIDS have a fundamental right to obtain unapproved experimental
treatment? 23 Although many commentators on the subject have ar-
gued against the recognition of a fundamental right of access to un-
approved treatment, 24 this Note will espouse a contrary view and ar-
gue that the courts should recognize a fundamental right of terminal
patients to elect and obtain unapproved drugs. 25 The Federal govern-
ment, however, may still have a compelling interest in obstructing
access to these drugs before they are clinically proven to be safe for
their intended use. 26 However, the Federal Food, Drug and Cosmetic
Act may be unconstitutionally overbroad by preventing terminal pa-
tients with no treatment alternatives from gaining access to drugs
which have not met the rigid effectiveness testing requirements of
the FDCA. 27 Finally, Section V will discuss the recent regulatory
measures and new proposals aimed at streamlining necessary experi-
mental drugs to persons with AIDS and how the regulatory changes
will balance the government’s interest in protecting the public’s
health and safety against the terminal patient’s right to obtain neces-
sary life-saving treatment. 28

19. Id.
20. See infra notes 29 to 66 and accompanying text.
22. See infra notes 67-110 and accompanying text.
23. See infra notes 111-61 and accompanying text.
24. For a list of commentaries arguing against the recognition of a fundamental right of
unapproved treatment, see infra note 68.
25. See infra notes 112-49 and accompanying text (discussing the need for the courts to
recognize that the election of unapproved medical treatment is a fundamental right).
26. See infra notes 111-54 and accompanying text.
27. See infra notes 156-61 and accompanying text.
28. See infra notes 162-203 and accompanying text.
II. A CENTURY OF DRUG REGULATION

The advent of drug regulation in the United States is a relatively new phenomenon, evolving slowly in the twentieth century largely in response to a series of tragedies caused by inadequate monitoring of drug manufacturing and distribution in this country. In 1906, Congress passed the first Pure Food and Drug Act ("the 1906 Act"). This legislation was passed in large part in response to the publication in that same year of Upton Sinclair's book, The Jungle, which graphically depicted the horrors of factory work in Chicago in the first years of the twentieth century. The 1906 Act was a rather limited attempt at regulation due to the controlling influence of many different interest groups. The main function of the 1906 Act was to prevent the adulteration and mislabeling of drugs listed in the two national formularies, United States Pharmacopoeia and National Formulary.

Pursuant to the 1906 Act, a drug was considered adulterated if it deviated from the standards supplied by the national formularies without admitting this fact on the label of the product, or if the strength or purity of the drug fell below the standard or quality under which the substance was marketed. A drug was deemed misbranded if it was sold under a false name, if it was sold in the package of a different drug, or if it failed to identify and quantify the existence of specifically enumerated addicting substances such as opium, morphine and cocaine. Under the 1906 Act, if a drug was found to be adulterated or misbranded, the drug could be seized by the government and the manufacturer could be prosecuted.

31. For example, Sinclair's book graphically depicted how a popular brand of lard was found to contain the remains of workmen who had fallen into the cooking vats. See Young, Social History of American Drug Legislation, reprinted in DRUGS IN OUR SOCIETY 223 (P. Talalay ed. 1964) (noting that President Theodore Roosevelt supported the 1906 Act partly as the result of Sinclair's publication); see also P. TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 27-29 (1980) (discussing the impact The Jungle had on the Pure Food and Drug Act).
32. Some of these influential interest groups included manufacturers and dealers of patent medicines and the Proprietary Association which represented dealers in proprietary medicines. See Young, supra note 31, at 218-22.
33. The National Formularies were official listings of drugs manufactured in the United States. P. TEMIN, supra note 31, at 24.
34. Id. at 30.
35. Id.
36. Id. However, under the 1906 Act, dealers in drugs were immunized from prosecution provided they received guarantees from their suppliers that the drugs complied with the
However, the 1906 Act proved inefficient because it aimed only at providing customers with the true identity of the substance purchased; the Act failed to assure purchasers of the drugs’ safety or usefulness. Thus, the legislation forced drug manufacturers to use caution when advertising their products, but had little effect in preventing consumers from purchasing and/or using ineffective, dangerous, or even lethal drugs.

In 1938, the Pure Food and Drug Act was replaced by the Federal Food, Drug and Cosmetic Act (FDCA) (“the 1938 Act”), this time in response to another drug-related crisis—the Elixir Sulfanilimide disaster of 1937. Rather than being limited to drugs listed in the national formularies, the 1938 Act included all “products affecting bodily structure or function in the absence of disease” and, for the first time, medical devices. The 1938 Act also placed greater restrictions on adulteration and misbranding. A drug was deemed to be adulterated if it failed to list all ingredients and their quantities, as well as directions for the drug’s use and any necessary warnings concerning any dangers associated with the drug’s use. Additionally, the concept of misbranding was expanded to include a determination of whether the drug was dangerous to one’s health when used in the dosage recommended on the label.


37. See United States v. Johnson, 221 U.S. 488 (1911). In Johnson, a shipper of an alleged cancer remedy was charged with claiming on the label that it was effective in curing cancer when, in fact, the drug was ineffective for that use. In speaking for the majority of the court, Justice Oliver Wendell Holmes held that the 1906 Act required only that the labelling regarding the identity of the contents of the substance not be misleading; it did not proscribe drug manufacturers from making false or misleading claims regarding the drug’s therapeutic benefits. Id. at 497.

38. Id. at 497-98.


40. The Elixir Sulfanilimide disaster occurred when Massengill Company, a respected pharmaceutical manufacturer, decided to market a liquid form of sulfanilimide which had previously been sold only in tablets and capsules. Although the company tested the substance for appearance, fragrance, and flavor, it failed to test the product for toxicity. As a result, over one hundred people, including many small children, died painful deaths after ingesting the toxic substance. However, under the 1906 Act, the government could not prosecute Massengill Company for causing the deaths; it could only fine the company for misbranding violations. In fact, because of the leniency of the 1906 Act, Massengill Company was only required to pay a fine of $26,100 for mislabeling the product. P. TEMIN, supra note 31, at 42.

41. Id. at 43.

42. Id.

However, the most important change brought about by the 1938 Act was the requirement that no drug could be distributed in interstate commerce unless an effective new drug application (NDA) had been filed with the Secretary of Agriculture. The new drug application had to describe the contents, the manufacturing procedures, and the intended uses of the drug, and had to demonstrate that the new drug was safe for its intended use. The application automatically became effective sixty days after filing unless the Secretary rejected the application for any of a variety of reasons. Additionally, the 1938 Act authorized the Secretary to suspend an existing new drug application for just cause, and to grant exemptions to the new drug application requirements for drugs intended solely for investigational use by qualified experts in order to test the safety of the drug when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

44. The applicant for approval of a new drug was required to submit in full: (1) reports of investigations as to the drug’s safety; (2) a list of its components; (3) a statement of its composition; (4) a description of methods, facilities, and controls used in its production; (5) samples of the drug and its components; and (6) specimens of the drug’s proposed labeling. Federal Food, Drug and Cosmetic Act, ch. 675, § 505(b), 52 Stat. 1052 (1938) (current version at 21 U.S.C. § 355(b) (1987 & Supp. 1989)). The drug regulatory branch of the government went through a series of changes throughout the early part of this century. By the time of the Great Depression in 1929, the regulatory activity of the drug market was well under way, first through the Bureau of Chemistry (which became the Food, Drug and Insecticide Administration in 1927), and then through the Food and Drug Administration in 1931. Each of these regulatory branches were part of the Department of Agriculture. However, it must be noted that prior to the Great Depression, few medicinal drugs were on the market and, consequently, these regulatory branches were mainly involved in monitoring the food supply until 1938. See P. Temin, supra note 31, at 35.

45. The Elixir Sulfanilimide disaster was directly responsible for the addition of these new provisions to the drug control legislation. In proposing the new provisions, Senator Copeland placed special emphasis on the fact that, under the 1906 Act, the only basis for seizure of the toxic substance was the fortuitous fact that the substance was not in fact an “elixir” and, consequently, was deemed misbranded and subject to seizure. In response to the elixir tragedy, Senator Copeland introduced a bill which forbade the introduction into interstate commerce of “any new drug . . . not generally recognized as safe for use under the conditions prescribed in its labelling unless the packer of such drug holds a notice of finding by the Secretary that such drug is not unsafe for use.” Cavers, The Food, Drug, And Cosmetic Act of 1938: Its Legislative History And Its Substantive Provisions, 6 LAW & CONTEMP. PROBS. 2, 20 (1939).

46. See M. Silverman & P. Lee, Pills, Politics, and Profit 87 (1974) (noting that justifiable reasons for refusing a new drug application included a determination that the drug sponsor did not provide adequate evidence of the drug’s safety). Additionally, under the 1938 FDCA, the Secretary could postpone action on a new drug application for 180 days from the filing date if the Secretary determined and provided notice that more time was needed for evaluation of the application. Federal Food, Drug and Cosmetic Act, ch. 675, § 505(c), 52 Stat. 1052 (1938).

Thus, the 1938 Act introduced a fundamental change to the regulation of new drugs by empowering the FDA to determine which drugs could enter the marketplace, as opposed to the free market system which prevailed prior to the enactment of the new legislation. In passing the 1906 Act, the legislature assumed that given the necessary information on a new drug's contents, each consumer could make his own choice as to whether or not to use the drug. However, in implementing the 1938 legislation, Congress realized that the public did not possess the necessary scientific expertise to make an informed decision regarding whether to use a new drug, and for this reason, manufacturers of new drugs would henceforth be required to assure the safety of their products before the new drugs could enter the marketplace.

Although the 1938 Act did provide much needed governmental control over the shipment of potentially dangerous new drugs, the legislation still failed in one critical aspect; it allowed for the distribution of any drug which was shown to be safe, regardless of whether the drug was actually effective for its intended purpose. Consequently, critics of the 1938 Act feared that the new legislation would allow manufacturers to ship safe but ineffective drugs to consumers, a practice which could cause seriously-ill individuals to elect new ineffective drugs over proven effective alternatives.

In 1962, Congress responded to the flaws in the earlier legislation by passing the Kefauver-Harris Amendments to the 1938 Act ("the 1962 Amendments"). Congressional support for this legislative change was fueled by public dismay over yet another drug-related tragedy—this time the thalidomide disaster of the 1950's and

48. Id. at § 505(i).
49. See P. Temin, supra note 31, at 44 (explaining how the FDA would be in charge of determining which new drugs could enter interstate commerce).
50. Id. at 45.
51. Id. However, the House Report on the 1938 FDCA emphasized that the new legislation aimed at improving the safety of self-medication. The Report stated: "The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective." H.R. Rep. No. 2139, 75th Cong., 3d Sess. 8 (1938), reprinted in P. Temin, supra note 31, at 45.
52. See, e.g., M. Silverman & P. Lee, supra note 46, at 87 (noting that "the new law did not require the drug maker to produce convincing evidence of efficacy.").
53. See id. at 87-88. (discussing the 1938 legislation).
The fundamental change brought about by the 1962 Amendments was the addition of an effectiveness testing requirement to the 1938 Act. Under the 1962 Amendments, no new drug could be shipped in interstate commerce unless the drug was proven to be both safe and effective for its intended use. Furthermore, the proof of effectiveness had to be supported by substantial evidence submitted by qualified experts with scientific training.

55. Thalidomide was a German-manufactured drug used as a sedative for pregnant women in Germany and many other European countries. The sponsor of Thalidomide had submitted new drug applications for distribution of the product in this country on several occasions during the 1960's, but the FDA examiner at the time, Dr. Francis Kelsey, returned the application each time because of insufficient information on the new drug. In the year prior to the passage of the Kefauver-Harris Amendments, news spread detailing how the use of Thalidomide was linked to the incidence in Europe of phocomelia—a condition where infants are born with deformed or missing limbs. Although the drug was never approved for marketing in the United States, the drug had been distributed by the manufacturer's American sponsor to more than 1200 doctors in this country for experimental testing. As a result, a small outbreak of phocomelia occurred in the United States as well. See P. Temin, supra note 31, at 123-24; see also S. Rep. No. 1744, 87th Cong., 2d Sess. 40, reprinted in 1962 U.S. Code Cong. & Admin. News 2884, 2905 (views of Senators Kefauver, Carroll, Dodd, Hart, and Long) (noting that the Thalidomide tragedy dramatically illustrated the need to give FDA physicians adequate time to assess a drug's safety and effectiveness).


57. Id.; see also S. Rep. No. 1744, 87th Cong., 2d Sess. 8, reprinted in 1962 U.S. Code Cong. & Admin. News 2884 (stating that a major purpose of the amendments to the 1938 FDCA was to require "the installation and maintenance of acceptable drug manufacturing and control procedures and a premarketing showing that all new drugs are effective—as well as safe—for their intended uses"). This report also notes that "[t]he Food and Drug Administration now requires, in determining whether a 'new drug' is safe, a showing as to the drug's effectiveness where the drug is offered for use in the treatment of a life-threatening disease, or where it appears that the 'new drug' will occasionally produce serious toxic or even lethal effects so that only its usefulness would justify the risks involved in its use. In such cases, the determination of safety is, in the light of the purposes of the new drug provisions, considered by the Food and Drug Administration to be inseparable from consideration of the drug's effectiveness." Id. at 2891-92.

58. This substantial evidence could not consist of a collection of impressions from physicians in the course of clinical practice. This rigid requirement of scientific proof resulted from the testimony of many notable physicians in hearings on the proposed 1962 Amendments who argued that ordinary physicians in clinical practice were often incapable of adequately evaluating the efficacy of a new drug. See P. Temin, supra note 31, at 122-24; see also S. Rep. No. 1744, 87th Cong., 2d Sess. 14-17, reprinted in 1962 U.S. Code Cong. & Admin. News 2884, 2890-93 (noting that "[i]n such a delicate area of medicine, the committee want[ed] to make sure that safe new drugs become available for use by the medical profession so long as they are supported as to effectiveness by a responsible body of opinion."). The "substantial evidence" test was chosen over a more rigid standard in large measure because of intense pressure from drug company representatives. These representatives argued that a more stringent standard of review for efficacy of new drugs might deter new drug research and development since differences of opinion regarding a new drug's efficacy could prevent an effective new drug from entering the marketplace. Hearings on H.R. 11381 and 11382 Before the House Committee
The 1962 Amendments to the Act introduced other important regulatory changes as well. The Amendments did away with the automatic approval of a new drug application after sixty days, requiring instead that the FDA take affirmative action in approving any new drug application. Furthermore, a new drug sponsor had to apply for approval before it could begin to conduct clinical trials on an investigational new drug. Through the new Amendments, Congress sought to prevent the occurrence of another drug-related crisis caused by inefficient governmental control over the dispensement of experimental drugs.

Today, the 1962 Amendments, requiring that all new drugs be proven safe and effective for their intended use before interstate shipment, remains at the forefront of the modern federal drug legislation. Additionally, the FDA has promulgated detailed regulations

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59. 21 U.S.C. § 355(c) provides:
   (1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either -
   (A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or
   (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question of whether such application is approvable.

Id.; see also S. REP. No. 1744, 87th Cong., 2d Sess. 40-43, reprinted in 1962 U.S. CODE CONG. & ADMIN. NEWS 2905-08 (views of Senators Kefauver, Carroll, Dodd, Hart, and Long) (justifying the elimination of the sixty-day automatic approval on the need to avoid another drug tragedy such as the thalidomide disaster and noting that "the medical officers of the FDA, who are trying to protect the American people from drugs with dangerous side effects, should have an adequate time period in which to assure themselves that the drug is safe, and that applications should not become effective automatically during any time period.").

60. 21 C.F.R. § 312.23(a) provides that "[a] sponsor who intends to conduct a clinical investigation subject to this part shall submit an 'Investigational New Drug Application' (IND)." Before this IND application is approved, the sponsor must provide adequate information about pharmacological and toxicological studies of the drug which have been performed on laboratory animals which tend to show that the drug is safe for testing on human subjects. 21 C.F.R. § 312.23(a)(8) (1989).

61. 108 CONG. REC. 17,398 (1962) (remarks of Senator Carroll) (calling attention to the recent Thalidomide catastrophe and the need to enact regulations that will protect the public against unsafe experimental drugs).

62. The new drug application requirements provide in pertinent part:
   (a) Necessity of effective approval of application
   No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.
   (b) Filing application; contents
   (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit
controlling the clinical testing of unapproved experimental drugs.\textsuperscript{63} Pursuant to the FDA's investigational new drug (IND) regulations, a drug sponsor who wishes to conduct clinical testing of a new drug is required to submit an IND application to the FDA.\textsuperscript{64} The IND application must contain detailed information regarding the identity of the sponsor in charge of the new drug testing, the overall plan for clinical evaluation of the drug, and specific information concerning each phase of the clinical investigation process.\textsuperscript{65} Additionally, the FDA requires a commitment that the investigational drug sponsor will not begin clinical investigations of the drug until the FDA approves the IND application.\textsuperscript{66} Thus, through rigid control over the distribution and clinical testing of new drugs, the modern FDA regulations aim at preventing any reoccurrence of the drug-related catastrophes.

\begin{itemize}
  \item to the Secretary as a part of the application (A) 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; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug . . . .
\end{itemize}


\textsuperscript{64} 21 C.F.R. § 312.23(a)(1989) (providing that "[a] sponsor who intends to conduct a clinical investigation subject to this part shall submit an 'Investigational New Drug Application' (IND) including in the following order: (1) [A] [c]over sheet [for the application] . . . . (2) A table of contents (3) [An] introductory statement and general investigational plan. . . . . . . . . . . . . . . (italics in the original)).

\textsuperscript{65} 21 C.F.R. § 312.23(a)(1) (1989). This section provides, in relevant part, that the cover sheet of the investigational new drug application must include:

(i) The name, address, and telephone number of the sponsor, the date of the application, and the name of the investigational new drug.

(ii) Identification of the phase or phases of the clinical investigation to be conducted.

(iii) A commitment not to begin clinical investigations until an IND covering the investigation is in effect.

(iv) A commitment that an Institutional Review Board (IRB) . . . will be responsible for the initial and continuing review and approval of each of the studies in the proposed clinical investigation and that the investigator will report to the IRB proposed changes in the research activity. . . .

(v) A commitment to conduct the investigation in accordance with all other applicable regulatory requirements.

(vi) The name and title of the person responsible for monitoring the conduct and the progress of the clinical investigations . . . .

Id.

\textsuperscript{66} 21 C.F.R. § 312.23(a)(iii)(1989). This section requires a commitment not to begin clinical investigations until an IND covering the investigation is in effect. Id.
trophes which shattered the public's faith in the drug industry throughout this century.

III. RUTHERFORD REVISITED IN THE ERA OF AIDS

Although few cases involving access to unapproved drugs for the treatment of AIDS have come before the courts to date, this situation is certain to change as more and more individuals are diagnosed with AIDS and find themselves with few, if any, alternative methods of treatment for their AIDS-related illnesses. Scholars have debated whether the rigid FDCA safety and effectiveness testing criteria should apply without modification to drugs for the treatment of terminal illnesses and whether a terminal patient has a constitutional right to obtain unapproved treatment. There has been a lack of legal debate concerning the application of the experimental drug distribution standards, however, in the context of the AIDS pandemic.

The subject of access to unapproved experimental drugs requires a special analysis in the context of AIDS due to special fac-


68. See, e.g., Leitner, Laetrile and the Law: An Analysis of Rutherford v. United States, 5 OKLA. CITY U. L. REV. 11 (1980) (arguing that the right of privacy does not include a terminal cancer patient's right to obtain an unapproved drug); Comment, Laetrile: Supreme Court Upholds FDA "New Drug" Classification; Still No Constitutional Right of Access to Unapproved Drugs, 3 DET. C.L. REV. 871, 883-4 (1980) (authored Catherine J. Brown) (arguing that there is no fundamental right to choose medical treatment with an unapproved drug and that the right of privacy does not guarantee access to medical treatment); Comment, Picking Your Poison: The Drug Efficacy Requirement and the Right of Privacy, 25 UCLA L. REV. 577, 617 (1978) (authored by Don G. Rushing) (arguing that the states' interest in protecting the patient from ineffective drugs is sufficiently important to offset the individual's interest in "picking his own poison"). But see Comment, The Right to Choose An Unproven Method of Treatment, 13 LOY. L.A. L. REV. 227, 245 (1979) (authored by V. Anthony Unan) (arguing that the right to choose an unapproved treatment should be constitutionally protected).

69. Only one commentary has addressed the right to obtain unapproved treatment in the context of the AIDS pandemic. See Comment, The Right of Privacy in Choosing Medical Treatment: Should Terminally Ill Persons Have Access to Drugs Not Yet Approved By The Food and Drug Administration? 20 J. MARSHALL L. REV. 693, 714 (1987) (authored by Scott H. Power) (arguing that the terminally ill, including persons with AIDS, have a constitutional right to obtain unapproved treatment).
tors which differentiate the plight of persons with AIDS from that of individuals with other life-threatening illnesses. Specifically, the complete lack of any cure for AIDS and the critical scarcity of FDA-approved drugs to treat the syndrome requires a rethinking of whether the FDCA's rigid safety and effectiveness requirements should apply without modification in the case of a terminal AIDS patient seeking access to an unapproved drug.\(^7\) In United States v. Rutherford,\(^7\) the United States Supreme Court held that the FDCA's safety and effectiveness testing requirements applied without exception to drugs used to treat the terminally ill. However, in light of the scarcity of treatment alternatives for persons with AIDS, it is important to re-analyze the Rutherford decision and determine whether it should be extended without modification to a person afflicted with AIDS who has no approved medical alternatives.

United States v. Rutherford commenced when a group of terminally-ill cancer patients brought a class action to enjoin the government from interfering with the interstate shipment of Laetrile, a cancer drug which had not been approved for distribution under the FDCA.\(^7\) The class challenged an earlier administrative decision by the FDA which ruled that Laetrile was a new drug within the meaning of the FDCA and, as a result, could not be placed in interstate shipment until a new drug application was filed on its behalf.\(^7\) The class based its argument on several grounds, including, inter alia, that the drug was not a new drug within the meaning of the FDCA, that the drug fell within a grandfather clause in the FDCA, and that terminal cancer patients have a fundamental right, incident to the right of privacy, to choose an unapproved drug for the treatment of their illness.\(^7\) The District Court ruled that Laetrile was exempted from premarketing approval under the 1962 FDCA's grandfather clause.\(^7\) Additionally, the Court noted that the Commissioner of the FDA may have infringed on a constitutionally protected right, incident to the right of privacy, by denying the cancer patients the abil-

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70. See M. SANDE & P. VOLBERDING, supra note 4, at xiii (noting that the outlook in the near future for curative treatment or an effective vaccine to combat AIDS is grim).

71. See J. LANGONE, supra note 1 (discussing the absence of a cure for AIDS and the scarcity of therapeutic alternatives approved by the FDA).


74. Rutherford, 438 F. Supp. at 1289.

75. Id. at 1289-92.

76. Id. at 1294-98.
ity to obtain the unapproved drug.\textsuperscript{77}

On appeal, the court of appeals did not address the constitutional or statutory bases of the lower court's decision. Instead, the court held that the safety and effectiveness requirements of the FDCA have no reasonable application to terminally-ill cancer patients.\textsuperscript{78} In support of its decision, the court reasoned that the safety and effectiveness standard bore little weight if the patient was going to die "regardless of what may be done."\textsuperscript{79} Additionally, the court emphasized that there was no reasonable standard against which to measure the safety and effectiveness of a drug for the treatment of a terminal illness and, consequently, that the standard could not be applied in the case of a terminal patient.\textsuperscript{80}

However, in 1979, the Supreme Court reviewed the lower court's decision and addressed for the first time the issue of accessibility to unapproved drugs.\textsuperscript{81} In unanimously overruling the lower court's decision, the Court held that the FDCA makes no express exemptions for drugs used by the terminally ill.\textsuperscript{82} Moreover, the Court determined that an implied exemption was unnecessary in the case of drugs to treat terminal cancer to fulfill Congress' objectives in implementing the drug regulatory laws or to avert an unreasonable reading of the terms "safe" and "effective" in the legislation.\textsuperscript{83} However, a careful study of the legislative history behind the FDCA and a re-analysis of the Supreme Court's decision in light of the AIDS pandemic requires that the \textit{Rutherford} ruling be limited to the question of access to experimental treatment for terminal patients where alternative approved methods are available. A modification of the FDCA testing criteria should be required when dealing with questions of access to drugs for terminal illnesses, such as AIDS, where there are often no treatment alternatives available.

In rendering its decision in \textit{Rutherford}, the Supreme Court focused on the legislative history behind the 1938 Act which first established the safety testing requirement for new drug approval, and the 1962 Amendments, which added the effectiveness testing re-

\textsuperscript{77} \textit{Id.} at 1298-1301.


\textsuperscript{79} \textit{Id.}

\textsuperscript{80} \textit{Id.}

\textsuperscript{81} \textit{United States v. Rutherford}, 442 U.S. 544 (1979).

\textsuperscript{82} \textit{Id.} at 551.

\textsuperscript{83} \textit{Id.} at 552.
quirement. The Court noted that in deliberations before the passage of the 1938 Act, Congress was concerned with the need to protect all persons, including individuals with terminal illnesses, from sham remedies. Additionally, the Court noted that in deliberations before the passage of the 1962 Amendments, Congress referred to the need to apply the safety and effectiveness criteria to all drugs, including drugs for the treatment of terminal illnesses.

In justifying the application of the safety testing requirement to drugs for the treatment of terminal illnesses, the Court determined that the safety testing requirement applied to all drugs, including drugs for the treatment of terminal illnesses, because any drug is unsafe “if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefits.”

However, in justifying the need to apply the effectiveness testing requirement to drugs for the treatment of terminal illnesses, the Court noted that the effectiveness testing requirement was added to the 1962 Amendments to assure that sick individuals would not elect to forego conventional proven drugs over ineffective unproven alternatives. The Court noted that “[a]n otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.”

An analysis of the legislative history behind the FDCA suggests that the Supreme Court's decision in Rutherford, regarding the application of the safety testing requirement, is consistent when confronted with the issue of experimental drug access for persons with

84. Id.
85. Id. (citing 79 CONG. REC. 5023 (1935) (remarks of Senator Copeland) and 83 CONG. REC. 7786-87 (1938) (remarks of Representatives Phillips and Lea)).
86. Id. at 553 (citing 108 CONG. REC. 17399-401 (1962) (remarks of Senator Kefauver)) (discussing the application of the safety and effectiveness requirement for terminal patients and the problems with rigid informed consent requirements in such circumstances) and (remarks of Senator Eastland) (discussing the need to apply the requirements to patients with life-threatening conditions and the problems associated with informed consent).
87. Id. at 556.
88. Id.
89. Id. The United States Supreme Court emphasized that with diseases such as cancer it is often only possible to diagnose a patient as critically ill in retrospect, and that many critically ill cancer patients have had unexpected remissions and have responded to conventional treatment. Consequently, the Court held that exempting drugs with no proved effectiveness from the FDCA's safety and effectiveness requirements could lead to “needless death and suffering” among patients who might respond to legitimate approved therapy. Id. at 557.
AIDS. In *Rutherford*, the Supreme Court aptly noted that one of the main purposes behind the safety testing requirement of the FDCA was the concern that individuals be protected against potentially dangerous or even lethal substances. In fact, in urging the passage of the 1938 FDCA with the new safety testing requirement, the FDA introduced what they coined the “Chamber of Horrors,” a series of pictures, labels and advertisements of harmful and even potentially lethal substances which, under the existing law, could not be proscribed. Additionally, the legislative history indicates that the Elixir Sulfanilimide disaster led to the addition of the new safety testing requirement for new drugs. Under the pre-existing 1906 Act, the only basis for removing the lethal drug Sulfanilimide from the market was the fact that it was mislabeled as an “elixir” which applied only to alcoholic solutions. Absent this fortuitous circumstance, the FDA would not have had authority to remove the substance from the marketplace. Thus, the safety testing requirement assured that no new drug could enter the marketplace until clinical testing was conducted which proved that the drug was not dangerous or lethal when used for its intended purpose.

In the context of AIDS, the need to deter reliance on potentially dangerous or lethal substances remains equally strong since the near absence of approved drugs for the treatment of the syndrome has led many AIDS sufferers to resort to a host of unconventional and potentially hazardous remedies. For example, in response to the desperation of persons with AIDS, many underground networks have developed throughout the nation to distribute AIDS drugs from foreign countries. Other advocates of persons with the illness have

90. See Cavers, *supra* note 45, at 16 (noting that the safety requirement was added due to the lack of protections afforded by the mislabeling and adulteration provisions of the 1906 Act).
91. Id. at 8. For example, “Banbar,” an extract of the horsetail weed, had been marketed even though it was found to be deadly if used by a diabetic in place of insulin. Id. at 16.
92. Id. at 20 (discussing the influence that the elixir disaster had on the addition of the safety testing requirement to the Food and Drug Act).
93. Id.
94. Id.
95. For example, a recent controversy has arisen over the clandestine private study of an unapproved experimental AIDS drug called “Compound Q,” a drug derived from Chinese cucumber roots, which was purported to have a remarkable ability in the test tube to kill cells infected with the AIDS virus, but to leave healthy cells alone. The study, which was neither government sponsored nor government endorsed, was intended to remain secret, but was widely publicized when several patients died after taking the experimental drug. See Kolata, *Critics Fault Secret Effort to Test Aids Drug*, N.Y. Times, Sept. 19, 1989, at C1, col. 5.
96. See Waters, *Obtaining Experimental Drugs For Severely Ill Clients: The Dilemma*
formed self-treatment centers, also known as “guerrilla clinics,” where instead of waiting for new drugs to become available through the traditional clinical testing process, they have created a variety of homemade treatments. The absence of approved drugs has led other persons with AIDS to spend enormous amounts of money to travel to foreign countries in order to obtain access to experimental drugs which are either not available in the United States or are only available in clinical trials to which the patients cannot gain admittance.

Thus, the safety testing requirement should be maintained when dealing with the issue of accessibility of unapproved drugs for the treatment of AIDS. The safety requirement will serve to prevent individuals with AIDS, faced with the pain and urgency brought about by the lack of approved alternatives, from falling prey to persons selling untested cures which could be dangerous, if not lethal. Applying the rationale for the safety requirement supplied by the Supreme Court in *Rutherford*, even an unapproved drug for the treatment of AIDS, a life threatening illness for which there are few available alternatives, may be dangerous if “the possibility for inflicting death or physical injury is not offset by the possibility of therapeutic benefits.” Accordingly, the safety requirement must be applied in the

Caused By AIDS, Fla. B. J., May 1989, at 7 (describing the emergence of such underground networks and noting also that AIDS sufferers have even resorted to begging the relatives of victims of AIDS to give them left over experimental drugs).

97. See Bishop, *Desperate Lives, Unknown Risks*, Cal. L. W., Sept. 1987, at 45, 46 (recounting how a host of “guerrilla clinics” have developed self-made treatments out of egg yolks, hand lotions, and other household products, and how one particular clinic in San Francisco was treating AIDS patients with a mixture of hand lotion and a chemical used in photoprocessing that irritates the skin, but has been found to have some beneficial reaction with the immune system).

98. See Waters, *supra* note 96, at 10 n.5. The author discusses the high incidence of travel by AIDS sufferers to Mexico and other foreign countries in order to gain access to non-FDA approved experimental drugs, as well as the emergence of a flourishing black market for experimental drugs smuggled into this country from abroad. Additionally, the author notes that the most famous case of such travel was the recent pilgrimage of the late actor, Rock Hudson, to the Institut Pasteur in Paris to obtain the experimental drug, HPA-23. *Id.* Access to AIDS drugs is extremely limited in that the experimental drugs are distributed in clinical trials where researchers are focusing on studying the effects of the drug on one type of group whom they think the drug might help. These clinical trials are often geographically restricting since they are most often found in large urban research hospitals or medical centers. See U.S. DEP’T OF HEALTH & HUMAN SERVS., AIDS CLINICAL TRIALS: TALKING IT OVER 6-7 (1989).

99. See United States v. Rutherford, 442 U.S. 544, 556 (1979) (arguing that “[a]n otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effects . . . . But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties the consequences can be irreversible.”) (emphasis added).
context of AIDS in order to assure that drugs which have not met minimal safety tests are not made available where these drugs could inflict added pain or lead to a speedier death.

However, the Supreme Court’s rationale in Rutherford for application of the rigid effectiveness testing standard to drugs for the treatment of terminal illnesses falls short in many ways when confronted with the new problems faced by individuals with AIDS seeking access to unapproved treatment. In Rutherford, the Court emphasized that the purpose behind the addition of the effectiveness standard in the 1962 Amendments was to assure that individuals did not elect unapproved drugs over proven effective alternatives. However, in the context of the treatment of AIDS, the Court’s rationale only applies if the person with AIDS can utilize the only approved AIDS drug, AZT, or if the individual can gain access to any of the investigational drug clinical trials. If the individual cannot tolerate AZT due to its serious side effects, and cannot gain access to a clinical trial, the Supreme Court’s rationale for the rigid effectiveness requirement quickly loses force.

In fact, in expressing doubt over the application of the rigid effectiveness requirement for drugs for the treatment of terminal illnesses, the court of appeals in Rutherford discredited the FDA’s assertion that a drug offered for use in treating a life-threatening disease that is deemed to be not effective is therefore not safe. The court of appeals noted that the FDA’s assertion “may lose its force in the case of a terminally-ill patient or in the case of a patient suffering from a disease for which there are in fact no ‘effective’ remedies.” Thus, the court of appeals’ decision implies that the effectiveness standard could be separated from the safety standard when deciding whether to allow access to an unapproved drug for the treatment of a terminal disease or a disease for which there is a lack

100. Id. at 556 (noting that “[a]n otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect.” (citing 107 Cong. Rec. 5640 (1961) (remarks of Senator Kefauver))).

101. See supra note 10 (discussing the fact that AZT, the only currently approved AIDS drug, is not a cure and often causes serious side effects which makes the drug intolerable by many AIDS sufferers).

102. See supra note 98 (noting that traditional clinical trials are limited to specific study groups and are limited geographically as well and, as a result, are not accessible to all individuals with the illness).

103. See Rutherford v. United States, 582 F.2d 1234, 1236 (10th Cir. 1978), rev’d, 442 U.S. 544 (1979).

104. Id.
of treatment alternatives. Accordingly, the strict effectiveness testing requirement should be modified in releasing unapproved drugs to AIDS patients who cannot tolerate the only approved drug, AZT, and who cannot gain access to traditional clinical trials.

However, the Supreme Court appears to have taken the special dilemma faced by terminal patients and patients with diseases for which there are few if any treatment alternatives into account in rendering its decision in Rutherford. Although the Court upheld the application of the FDCA testing requirement to drugs for the treatment of terminal illnesses, the Court noted that this did not foreclose all resort to drugs which had not completed the safety and effectiveness testing process. The Court specifically noted that the FDCA empowers the FDA to enact specific provisions for carefully regulated use of certain investigational drugs which have not yet been demonstrated as safe and effective. The existence of this regulatory alternative reinforced the Court's decision that no exception should be judicially implied for drugs to treat terminal illnesses. Thus, the Court appears to have implied that the rigid safety and effectiveness standards could be modified in the case of certain terminal illnesses, but that this was an activity which had to be decided and implemented by the FDA rather than the judiciary.

Recently, in large measure sparked by the desperation of patients with AIDS, the FDA has, in fact, enacted a new regulatory program which allows some patients with life-threatening and serious illnesses to obtain experimental drugs before they have satisfied the traditional testing criteria. Indeed, the detailed analysis of the recent experimental drug regulatory changes in Section V of this Note will suggest that the FDA has recognized the need for modification of the drug testing standards in light of the urgency and desperation caused by the AIDS pandemic.

105. Id.
107. Id. at 558-59 (noting that § 505(e) of the 1962 FDCA [currently at 21 U.S.C. § 355(i)] provides the Secretary of the FDA with the authority to promulgate regulations for exempting from the safety and effectiveness requirements certain drugs to be used solely for investigations by experts qualified by scientific training and experience to investigate the safety and effectiveness of the drugs).
108. Id. at 558-59.
109. See infra notes 177-84 and accompanying text.
110. See infra notes 192-203 and accompanying text.
IV. A CONSTITUTIONAL RIGHT TO EXPERIMENTAL TREATMENT?

Scholars have long debated whether terminal patients have a constitutional right, incident to the right of privacy, to obtain necessary medical treatment.\(^1\) Contrary to the views of most of these commentators, the right to obtain necessary medical treatment should be deemed fundamental. Additionally, for those individuals with AIDS who cannot tolerate AZT and who do not have access to other approved treatment alternatives, the government should not have a compelling interest in restricting access to drugs which have not fully completed the traditional clinical testing requirements of the FDCA.

The Constitution of the United States does not explicitly recognize any right of privacy.\(^1\) However, throughout this century, the Supreme Court has recognized a right or "zone" of privacy which is deemed "fundamental" and, therefore, protected under the Constitution.\(^1\) The Court has construed "fundamental" rights to include personal liberties "so rooted in the traditions and conscience of our people as to be ranked as fundamental."\(^1\) The Supreme Court has determined that where a state law appears to interfere with a funda-

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111. See supra notes 68-69 and accompanying text.
112. See Roe v. Wade, 410 U.S. 113, 152 (1973) (noting that a line of decisions going back as far as the 19th century have developed the right of privacy).
113. Id.; see also Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) (noting that "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."); Griswold v. Connecticut, 381 U.S. 479, 484 (1969) (noting that "specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance" and that "various guarantees create zones of privacy"); Mapp v. Ohio, 367 U.S. 643, 656 (1961) (referring to the Fourth Amendment as creating a "right to privacy, no less important than any other right carefully and particularly reserved to the people."); Skinner v. Oklahoma, 316 U.S. 535, 541 (1942) (invalidating Oklahoma's Habitual Criminal Sterilization Act and finding that "[m]arriage and procreation are fundamental to the very existence and survival of the race."); Pierce v. Society of Sisters, 268 U.S. 510, 534-35 (1925) (holding that an Oregon law requiring children to attend public schools interfered "with the liberty of parents and guardians to direct the upbringing and education of children under their control."); Meyer v. Nebraska, 262 U.S. 390, 399 (1923) (noting that liberty "denotes not merely freedom from bodily restraint but also the right of an individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, to establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.").
114. See Griswold, 381 U.S. at 487 (1965); see also Palko v. Connecticut, 302 U.S. 319, 325 (1937) (defining fundamental rights as rights that are "implicit in the concept of ordered liberty.").
mental right, a strict scrutiny test must be applied by the court and the state must show that the conflicting law promotes a compelling state interest.\textsuperscript{115} Furthermore, under the strict scrutiny test, the Supreme Court has required that legislative enactments be narrowly drawn to express only the legitimate state interest at issue.\textsuperscript{116}

The Supreme Court has expanded the scope of the fundamental right of privacy on a case by case basis. The ever-expanding case law on the subject reveals that the areas included in the zone of protected privacy include certain activities related to marriage,\textsuperscript{117} procréation,\textsuperscript{118} contraception,\textsuperscript{119} family relationships,\textsuperscript{120} and the decision to bear children.\textsuperscript{121} This "zone of privacy" has also been extended to include personal decisions related to a variety of health issues.\textsuperscript{122} An analysis of the case law developing the zone of privacy as it relates to health-related issues provides a logical basis for arguing that the fundamental right of privacy should encompass, under certain limited circumstances, a terminal patient's election to obtain a drug which has not met the rigid safety and effectiveness testing requirements of the FDCA.

A series of cases has focused on the right of privacy as it relates

\begin{thebibliography}{122}
\bibitem{115} See \textit{Roe}, 410 U.S. at 155; see also \textit{Griswold}, 381 U.S. at 496-97 (Goldberg, J., concurring) (finding the right of marital privacy to be fundamental and finding a statute forbidding the use of contraceptives as violating that right because it was not necessary for the fulfillment of a compelling state objective); Bates v. Little Rock, 361 U.S. 516 (1960) (noting that "where there is a significant encroachment upon personal liberty, the State may prevail only upon showing a subordinating interest which is compelling."); \textit{Skinner v. Oklahoma}, 316 U.S. at 541 (arguing that strict scrutiny of the classification made by a state in a sterilization law is essential).

\bibitem{116} See \textit{Roe} v. \textit{Wade}, 410 U.S. 113, 155 (1973); see also \textit{Planned Parenthood Ass'n v. Ashcroft}, 462 U.S. 476, 498 (1983) (noting specifically that "legislative enactments must be narrowly drawn to express only the legitimate state interest at stake.").

\bibitem{117} See \textit{Loving v. Virginia}, 388 U.S. 1, 12 (1967) (finding a Virginia statutory scheme preventing marriages between persons solely on the basis of race to be in violation of the right of privacy).

\bibitem{118} See \textit{Skinner v. Oklahoma}, 316 U.S. 535 (1942) (finding an Oklahoma statute providing for the forced sterilization of habitual criminals to be in violation of the right of privacy).


\bibitem{120} See \textit{Prince v. Massachusetts}, 321 U.S. 158, 166 (1944) (upholding as constitutional a law prohibiting minors from selling newspapers, magazines, etc., in the streets or public places despite recognizing a right of individuals to rear children in their own interest pursuant to a constitutionally protected right of privacy).

\bibitem{121} See \textit{Roe} v. \textit{Wade}, 410 U.S. 113, 154 (1973) (holding that the right of personal privacy includes a woman's right to elect to have an abortion under limited circumstances).

\bibitem{122} See \textit{infra} notes 123-48 and accompanying text.
\end{thebibliography}
to medical decisions. In *Jacobson v. Massachusetts*, the United States Supreme Court addressed the issue of whether a person could refuse to comply with a regulation mandating that adults be vaccinated for smallpox. In upholding the constitutionality of the regulation, the Court held that although an individual has an inherent right to care for his own body and health, the state interest in eradicating the smallpox epidemic outweighed the individual’s right to refuse treatment.124

Other cases have focused on the fundamental right of an individual to refuse medical treatment on religious grounds. For instance, in *In re President and Directors of Georgetown College, Inc.*, a Jehovah’s Witness refused a life-saving blood transfusion on religious grounds. In that case, the court refused to allow the woman to forego the necessary treatment, focusing on the fact that she was responsible for a young child.126

However, in similar challenges based on religious grounds, other courts have recognized the fundamental right to refuse treatment and have upheld the patient’s decision to refuse necessary medical treatment where the patient was deemed competent and did not have dependent minor children.127 In each of these cases, the controlling factor has been whether the patient refusing treatment was a competent adult making an informed decision, and whether the patient had minor children who might become wards of the state.128 Read in conjunction, these cases indicate that the decision to forego necessary medical treatment is a fundamental right which may only be outweighed by a compelling state interest, such as a States’ interest

123. 197 U.S. 11 (1905).
124. Id. at 26.
126. Id.
127. See, e.g., *In re Melideo*, 88 Misc. 2d 974, 390 N.Y.S.2d 523 (Sup. Ct. 1976) (allowing a patient who was competent and childless to reject necessary blood transfusions); *Aste v. Brooks*, 32 Ill. 2d 361, 205 N.E.2d 435 (1965) (allowing a patient to refuse a necessary blood transfusion on religious grounds); *Erickson v. Dilgard*, 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962) (upholding patient’s right to refuse a blood transfusion).
128. The case law indicates that the courts are reluctant to allow a parent to refuse necessary medical care for his/her child on religious grounds. See, e.g., *People v. Labrenz*, 411 Ill. 618, 104 N.E.2d 769 (1952) (finding that a child whose parents refused to permit a blood transfusion on religious grounds was a neglected child where the child would almost certainly die or be mentally impaired for life without the necessary transfusion); *Jehovah’s Witnesses v. King County Hosp. Unit No. 1*, 278 F. Supp. 488, 506 (W.D. Wash. 1967) (holding that Washington statute empowering superior court judges to declare children dependent for purposes of authorizing blood transfusions of children against the express objections of parents was not invalid under the U.S. Constitution).
In safeguarding the best interests of minors.

In a more recent decision, the Supreme Court of the State of New Jersey extended the right of privacy to encompass the right of an individual to refuse necessary life support. In In re Quinlan, the father of a 22 year-old woman in a comatose, vegetative state, with no chance of recovery, sought a court order to appoint him as his daughter's guardian with the power to request the disconnection of all life-support systems artificially sustaining his daughter's life. The New Jersey Supreme Court ruled that the right of privacy encompasses an individual's decision to refuse treatment, and held that the right to refuse treatment in a situation where there is no chance to recover to a cognitive state clearly outweighs the state's interest in sustaining the life of the patient. The court emphasized that "the State's interest weakens and the individual's right of privacy grows as the degree of bodily invasion increases and the prognosis dims."

To date, the Supreme Court has not determined whether the right of privacy should be extended to include the right to gain access to necessary unapproved treatment. In United States v. Rutherford, neither the court of appeals nor the Supreme Court addressed the District Court's ruling which determined that by denying the class of terminal cancer patients access to an unapproved drug, the FDA had violated a constitutional right of privacy.

However, several state courts have addressed this issue, with differing results. In People v. Privitera, the Supreme Court of California refused to recognize the decision to obtain an unapproved drug as a fundamental right. In upholding the constitutionality of a state statute forbidding the introduction into interstate commerce of any unapproved new drug, the court ruled that the decision to obtain an unapproved drug is not fundamental and, therefore, should be reviewed under a rational basis test rather than a compelling state interest test. In Privitera, as in most constitutional challenges to the rigid new drug approval standards, the defendant relied on the

130. Id. at 41, 355 A.2d at 664.
131. Id.
134. Id. at 700, 591 P.2d at 922, 153 Cal. Rptr. at 434.
United State Supreme Court’s ruling in *Roe v. Wade*, which extended the right of privacy to the right of a woman to elect to have an abortion. However, the court in *Privitera* argued that the ruling in *Roe* related to the area of procreation and, for this reason, should not be extended to include the right to obtain unapproved treatment. The California Supreme Court noted that the right of privacy is not absolute and that “a State may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life.” Consequently, the court held that the statute proscribing the sale or delivery of a drug which had not been approved by the designated federal agency bore a rational relationship to the achievement of a legitimate state interests in the health and safety of its citizens.

However, in *Suenram v. Society of the Valley Hospital*, the Superior Court of New Jersey followed a different analysis, and held that the right of an elderly terminally-ill cancer patient to choose or reject a cancer treatment on the advice of a licensed physician was a fundamental right, whether or not the drug was approved by the state or the hospital in which it was sought to be administered. The court relied on *Canterbury v. Spence*, which, in developing the need for informed consent, emphasized that “[t]he root premise is the concept, fundamental in American jurisprudence, that every human being of adult years and sound mind has a right to determine what shall be done to his own body.” In recognizing the fundamental right of a patient to choose unapproved treatment, the court in *Suenram* noted that it was not dealing with “a naïve patient [who] has been led away from the more effective ‘orthodox’ treatments.” On the contrary, the court noted that the patient seeking access to the unapproved cancer drug had already turned to chemotherapy and all other conventional treatments available, and was turning to the unapproved drug, laetrile, as a last resort. In recognizing the

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135. See, e.g., Comment, supra note 69, at 706 (arguing that the *Roe v. Wade* decision suggests that a person has a fundamental right to undergo unapproved treatment when the state’s denial of such treatment severely affects the lifestyle of that individual).
136. See *Privitera*, 23 Cal. 3d at 700, 591 P.2d at 922, 153 Cal. Rptr. at 434.
138. See *Privitera*, 23 Cal. 3d at 700, 591 P.2d at 922, 153 Cal. Rptr. at 434.
140. Id. at 602, 383 A.2d at 148.
143. Id.
patient's fundamental right to elect the unapproved drug, the court noted that "[w]here a person is terminally ill . . . and unresponsive to other treatments, the public harm is considerably reduced." The court also noted that "[t]he Constitutions of the Nation and this State are irrevocably committed to the principle that individuals must be given the maximum latitude in determining their own destiny."

In fact, in Privitera, the California Supreme Court explicitly noted that the case had to be distinguished from the United States District Court's decision in United States v. Rutherford, which held that the right to choose unapproved treatment was a fundamental right, since the individuals seeking access to unapproved drugs in the California case were not terminally ill. Furthermore, in a strong dissent in Privitera, Judge Byrd argued that the right of a patient to choose or reject treatment, whether orthodox or unorthodox, is a fundamental right, incident to the right of privacy, which may only be overcome by a compelling state interest. Noting that cancer is a disease whose causes and treatments continue to baffle the medical community, Judge Byrd argued that "[s]o long as there is no clear evidence that laetrile is unsafe to the user, . . . each individual patient has the right to obtain the substance from a licensed physician who feels it appropriate to prescribe it to him."

Based on the cases developing the right of privacy as it relates

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144. Id. (citing Carnohan v. United States, No. 77-0010-GT Civ. (S.D. Cal. 1977)). In Carnohan, the plaintiff was a terminal cancer patient who sought to enjoin the FDA from interfering with his importation or interstate shipment of laetrile for his personal use. Id. In balancing its power to issue injunctive relief against the possible harm to the public by allowing the weakening of laws aimed at preventing the victimization of desperate cancer patients, the court held that "where a person is terminally ill with cancer and unresponsive to other treatments, the public harm is considerably reduced." Id.

145. Id. at 598, 383 A.2d at 146.

146. See Privitera, 23 Cal. 3d at 703, 591 P.2d at 925, 153 Cal. Rptr. at 437 (stating that "the [d]efendants can take no comfort in the court of appeals decision [in Rutherford], for, unlike Rutherford, this case is not an action on behalf of the class of terminally-ill cancer patients. Whatever can be said in favor of permitting 'terminal' cancer patients access to laetrile, there is no indication in the record that defendants sought to restrict their activities to that class when prescribing, distributing and administering laetrile.").

147. Id. at 705, 591 P.2d at 927, 153 Cal. Rptr. at 439 (Bird, C.J., dissenting). Judge Bird argued that "[c]ancer is a disease with potentially fatal consequences; this makes the choice of treatment one of the more important decisions a person may ever make, touching intimately on his or her being. For this reason, I believe the right of privacy, under both the state and federal Constitutions, prevents the state from interfering with a person's choice of treatment on the sole grounds that the person has chosen a treatment that the state considers 'ineffective.' " Id.

148. Id.
to decisions concerning health, the fundamental right of privacy should be logically extended to the right of a terminal patient with no approved treatment alternatives to elect to use an unapproved experimental drug. It is illogical to recognize the fundamental right of a patient to refuse necessary medical treatment and the fundamental right of a patient to refuse necessary life-sustaining mechanisms, while refusing to recognize the fundamental right of a terminal patient with no approved treatment alternatives to elect to use an unapproved experimental drug. As Justice Douglas stated in his concurring opinion in *Doe v. Bolton*, the right of privacy encompasses "the freedom to care for one's own health or person, freedom from bodily restraint or compulsion . . . ."149 Accordingly, the fundamental right of privacy should encompass the right of a terminally-ill individual to choose unapproved experimental treatment.

However, even if the decision to elect unapproved treatment is deemed a fundamental right, its exercise may nevertheless be infringed by a compelling state interest.150 Furthermore, any legislative enactment must be narrowly drawn to express only the legitimate interest at stake.151 Where the state fails to show either that it has a compelling state interest or that the statute is narrowly tailored to serve that compelling interest, the statute will be struck down as unconstitutional.152 Thus, once the courts recognize that the decision to obtain necessary medical treatment is a fundamental right, only a compelling state interest would justify the infringement of that right. Moreover, to withstand a constitutional challenge, the statute proscribing access to unapproved drugs—i.e. the FDCA, must be narrowly drawn to serve only that compelling interest.

It is well settled that the state has an interest in promoting the health, safety and welfare of its citizens.153 It is equally well estab-

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149. See *Doe v. Bolton*, 410 U.S. 179, 213 (1973) (Douglas J., concurring) (finding that three procedural conditions in a Georgia abortion statute were unconstitutional and noting that the freedom to care for one's own health comes within the meaning of the term "liberty" as used in the Fourteenth Amendment).

150. See *supra* note 115 and accompanying text (outlining the requirements under the strict scrutiny test).

151. See *supra* note 116 and accompanying text.


153. *Roe*, 410 U.S. at 154 (noting that "[a] state may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life"); *see also Akron v. Akron Center For Reproductive Health*, 462 U.S. 416 (1983) (noting that some regulations, "those justified by important state health objectives, are permissible even in the first trimester [of pregnancy]"); *Lochner v. New York*, 198 U.S. 45 (1905) (recogn-
lished that the main objective of the FDCA is to protect the public from the dangers of unsafe and ineffective drugs. However, if courts recognize that the decision to elect an unapproved treatment is a fundamental right, the FDCA cannot withstand a constitutional challenge unless it can show that: (1) the government has a compelling interest in protecting terminal AIDS patients from the dangers associated with experimental drugs; and (2) the FDCA is narrowly drawn to protect only that compelling interest.

While the federal and state governments may have a compelling interest in protecting non-terminal patients or terminal patients with approved treatment alternatives from choosing unapproved drugs over proven effective alternatives, this interest quickly loses force when confronted with a person with AIDS who cannot tolerate AZT and who cannot gain access to an experimental drug clinical trial. As the Supreme Court of New Jersey emphasized in In re Quinlan, "the State’s interest [in the life of a patient] weakens and the individual’s right to privacy grows as the degree of bodily invasion increases and the prognosis dims." The state’s interest in the life of a terminal patient with AIDS similarly weakens, especially where the patient cannot tolerate the only approved drug, AZT, and cannot gain access to any traditional clinical trials. While the States may have a compelling interest in protecting even terminal patients against unsafe drugs, the States do not have a compelling interest in protecting a terminal AIDS patient who has no approved treatment alternatives from gaining access to a drug which has not completed the FDCA’s effectiveness testing. Since allowing the individual to elect a drug which may be ineffective will not result in his foregoing a proven effective alternative, the State should not have a compelling interest in protecting the patient from such an unproven alternative.

Moreover, even if the state’s interest in protecting terminal AIDS patients from unproven remedies is deemed to be compelling, the FDCA’s rigid safety and effectiveness testing criteria may still be unconstitutional if they are not narrowly drawn to serve only the State’s compelling interest at stake. For instance, in Roe v. Wade,

154. See supra notes 29-61 and accompanying text (describing the legislative intent in protecting the health and safety of the public through the new drug testing requirements of the FDCA).


156. See Roe, 410 U.S. at 155.
the United States Supreme Court held that there was no compelling state interest in proscribing a patient's fundamental right to elect an abortion until the completion of the first trimester of pregnancy when the health and safety risks to the mother and fetus were compelling enough to warrant state regulation. Accordingly, the Court struck down the Texas abortion statute for overbreadth since it failed to make any distinctions between abortions performed early in pregnancy when there was no compelling state interest in intervention, and those performed later when the state's interest in regulating abortions became compelling.

Applying this same approach to the issue of unapproved experimental treatment for persons with AIDS, the restrictions imposed by the FDCA and similar state provisions could be deemed overly broad and unconstitutional. The federal and state governments can assert a plausible argument that they have a compelling interest in protecting all individuals against gaining access to drugs which have not been proven to be safe. Furthermore, the federal and state governments may have a compelling interest in protecting non-terminal patients and terminal patients with approved treatment alternatives from electing drugs which have not been proven as effective over approved methods. However, the state's interest in protecting individuals against ineffective drugs quickly fades when confronted by the limited class of AIDS patients who cannot tolerate the only approved drug, AZT, and who do not have any access to other experimental alternatives. Under these circumstances, the patient's right to obtain a safe, but potentially ineffective drug, which may be a last chance of hope, clearly outweighs any competing interests. Consequently, the experimental drug regulations should be modified so as to preserve the state's interest in protecting all individuals against unsafe and potentially lethal drugs without interfering with the choice of a patient with no treatment alternatives to gain access to a drug which may or may not be effective in treating his illness.

To date, the Supreme Court has not determined whether a ter-

157. Id. at 163-64.
158. Id. at 164.
159. See supra notes 90-98 and accompanying text (describing states' interest in protecting public, including terminal patients, against unsafe drugs).
160. See supra notes 100-05 and accompanying text (describing states' interest in protecting public against ineffective drugs where effective alternatives are available).
161. See supra notes 100-05 and accompanying text (arguing that states do not have a compelling interest in protecting terminal patients against ineffective drugs where there are no other effective alternatives available).
minal patient has a fundamental right to obtain unapproved treat-
ment. However, the recent FDA regulatory enactments and new pro-
posals for accelerating distribution of experimental drugs may
suggest a recognition on the part of the government, as well as adva-
cates of persons with terminal illnesses, of the need to preserve the
state's interest in protecting public health while at the same time
respecting the right of a patient with no treatment alternatives to
elect experimental treatment whose efficacy has not been fully
shown.

V. RECENT LIBERALIZATION OF THE PROCESS FOR DISTRIBUTING
EXPERIMENTAL DRUGS

While the United States Supreme Court has yet to formally
recognize a fundamental right of access to necessary unapproved
treatment, the FDA appears to have recognized the need to loosen
the rigid drug approval requirements for experimental drugs for cer-
tain life-threatening illnesses, such as AIDS, for which there are few
if any approved treatment alternatives. In response to intense pres-
sure from advocates of persons with AIDS, the FDA is beginning to
make radical changes in the procedures for distributing experimental
drugs. These new changes to the FDCA safety and effectiveness
requirements are encouraging, because they more narrowly tailor the
FDCA to promote the government's compelling interest in protecting
the health and safety of terminal patients, while at the same time
respecting the decision of terminal patients with no therapeutic alter-
atives to obtain necessary experimental treatment.

The traditional method of drug distribution in the United States
is a slow and tedious process. A sponsor of an investigational drug
who intends to conduct clinical investigations is required to submit

162. See infra notes 176-203 and accompanying text.
163. Id.
164. See Waters, supra note 96, at 7-9 (explaining that under the traditional clinical
testing requirements of the FDCA, the average time it took a new drug to go to the market
was 7-10 years). In fact, a major controversy has recently developed concerning the reporting
of new AIDS breakthroughs. Medical experts discovered that treatment with steroid hormones
can halve the death rate from the pneumonia that is the leading killer of people with AIDS.
However, the government agency that had convened a panel of experts to conduct the study
delayed more than five months before notifying AIDS doctors of their findings. The delay was
believed to be due in part to a concern that early notification might jeopardize the publication
of the panel's conclusions in the New England Journal of Medicine. The delay in reporting the
AIDS therapy finding has infuriated many advocates of persons with AIDS. See Kolata, News
of AIDS Therapy Gain Delayed Five Months By Agency, N.Y. Times, Nov. 14, 1990, at A1,
A17.
an investigational new drug (IND) application to the FDA. Once the proper application is submitted, the sponsor is required to clinically investigate the untested drug using a three-phase clinical testing scheme. During the first phase, scientists evaluate the metabolism and pharmacological actions of the drug, determine the side effects associated with increasing dosage of the drug, and attempt to gain some preliminary information on the drug's effectiveness. Thus, phase one concentrates on determining the safety of the investigational new drug.

In phase two, controlled clinical studies are conducted to evaluate the effectiveness of the drug for a particular disease and to determine the short-term side effects of the drug. Thus, phase two provides additional safety assurances, but places greater emphasis on determining the drug's effectiveness.

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165. 21 C.F.R. § 312.20 (1989). This section states that:
(a) A sponsor shall submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to § 312.2(a).
(b) A sponsor shall not begin a clinical investigation subject to § 312.2(a) until the investigation is subject to an IND which is in effect in accordance with § 312.40.

Id.

166. 21 C.F.R. § 312.21 (1989). This section states: "An IND may be submitted for one or more phases of an investigation. The clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap." Id.

167. 21 C.F.R. § 312.21(a)(1)(1989). This section states:
(a) Phase 1. (1) Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacological actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

Id.

168. Id.

169. 21 C.F.R. § 312.21(b)(1989). This section provides:
(b) Phase 2. Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Id.

170. Id.
Phase three consists of expanded controlled and uncontrolled studies which are intended to determine the effectiveness and safety as well as the relative risk/benefit ratio of the drug.\footnote{171} Under the traditional three-tiered system, the average time it takes a drug to move from the test tube to the drug store shelf has been anywhere from seven to ten years.\footnote{172} However, in response to the lack of alternatives for the treatment of AIDS,\footnote{173} the FDA has recently made fundamental changes in the way it allows distribution of drugs for persons with terminal illnesses and has begun to take greater chances than ever before.\footnote{174} First, the FDA allowed the drug AZT to run through the clinical testing process in less than two years, as opposed to the traditional seven to ten year process.\footnote{175} Next, the FDA has recently enacted regulations which allow some patients with serious or life-threatening illnesses to obtain experimental drugs before clinical trials have determined their effectiveness for their intended uses.\footnote{176} In May of 1987, the FDA implemented the Treatment Investigational New Drug (IND) Program, an expanded access program which allows doctors to prescribe experimental drugs to their patients as if the patients were enrolled in traditional clinical trials.\footnote{177}

\footnote{171. 21 C.F.R. § 312.21(c)(1989). This section states:
(c) Phase 3. Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.
}

\footnote{172. See Hils, supra note 14, at A1.
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\footnote{173. See supra notes 7-10 and accompanying text (discussing the scarcity of therapeutic alternatives for persons with AIDS).
}

\footnote{174. See Levine, Has AIDS Changed The Ethics Of Human Subjects Research?, 16 LAW. MED. & HEALTHCARE 167, 171 (1988) (emphasizing that AIDS has become a catalyst for rapid change in the system of testing and approving AIDS drugs).
}

\footnote{175. See Norris, The FDA's AIDS Program, 12 NOVA L. REV. 1103, 1107 (1988) (defending the F.D.A.'s method in rapidly approving the drugs); see also Hils, supra note 14, at A1, col. 2 (noting that other drugs which have been pushed through the FDA drug approval system in record time include a drug to treat the deadly pneumonia which attacks AIDS patients and another for the blindness which sometimes afflicts persons with AIDS).
}

\footnote{176. See E. Nichols, supra note 2, at 210 (discussing how the desire to help desperately ill individuals afflicted with AIDS without access to traditional clinical trials was one of the factors behind the FDA's decision to enact procedures for the early release of certain experimental drugs).
}

\footnote{177. 21 C.F.R. § 312.34(a) (1989). This section states:
(a) General. A drug that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease or condition in patients
}
The purpose behind the new regulatory enactment was to streamline promising experimental drugs to desperately ill individuals as early in the drug approval process as possible and, through this mechanism, to obtain additional clinical data on the drug's safety and effectiveness. The FDA believed that the new regulation would balance the need to adequately investigate experimental treatment with the need to meet the public's demand for promising investigational remedies. Moreover, by promulgating detailed regulations restricting access to experimental drugs under the program, the FDA aimed at balancing the states' interest in protecting the health and safety of its citizens while at the same time respecting the health needs of terminal patients.

The FDA established specific criteria for use of a treatment IND. First, the drug sought through the treatment IND must be intended to treat a serious or immediately life-threatening illness. Second, there must be no comparable drug or therapy available to treat that stage of the illness. Third, the drug must have completed, or be in the process of completing, an investigation under a treatment protocol or treatment IND...

Id.

178. 21 C.F.R. § 312.34(a) (1989) (stating that "[t]he purpose of this section is to facilitate the availability of promising new drugs to desperately ill patients as early in the drug development process as possible, before general marketing begins, and to obtain additional data on the drug's safety and effectiveness."); see also 52 Fed. Reg. 8850 (1987) (to be codified at 21 C.F.R. § 312) (proposed March 19, 1987) (noting that the new procedures were intended to facilitate the availability of promising new drugs to patients with life-threatening or other serious diseases for which no satisfactory alternatives exist, including acquired immune deficiency syndrome (AIDS)).


180. Id.

181. 21 C.F.R. § 312.34(b) (1989). This section states:
(b) Criteria. (1) FDA shall permit an investigational drug to be used for treatment use under a treatment protocol or treatment IND if:
   (i) The drug is intended to treat a serious or immediately life-threatening disease;
   (ii) There is no comparable or satisfactory alternative drug or therapy available to treat that stage of the disease in the intended patient population;
   (iii) The drug is under investigation in a controlled clinical trial, under an IND in effect for the trial or all clinical trials have been completed; and
   (iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

Id.

182. Id.
controlled clinical trial.\textsuperscript{183} Finally, the sponsor of the clinical trial must be actively and diligently pursuing marketing approval for the investigational drug.\textsuperscript{184}

The treatment IND program is a step in the right direction. The program appears to balance the individual's right to obtain experimental treatment with the states' interest in safeguarding terminal patients against untested alternatives. Moreover, the treatment IND regulations appear to tailor more narrowly the FDCA, recognizing that the state has less of a compelling interest in protecting terminal patients with no treatment alternatives from obtaining drugs which have not completely satisfied the traditional clinical testing requirements for safety and efficacy.

Unfortunately, the new treatment IND program has failed to meet the urgent needs of patients with AIDS in several respects. Under the treatment IND program, the Commissioner of the FDA is authorized to reject a request for treatment use of a drug for different reasons depending on whether the drug is to be used for a severely debilitating\textsuperscript{185} or life-threatening illness.\textsuperscript{186} If an experimental drug is to be used to treat a serious illness, the Commissioner may reject the treatment IND application if it is determined that there is insufficient evidence of safety and effectiveness to support the treatment use of the drug.\textsuperscript{187} If the drug is intended to treat an immediately life-threatening illness, the Commissioner may reject the treatment IND application if the scientific evidence fails to show that the drug may be effective for its intended use or fails to show that the drug would not expose the patient to an unreasonable and significantly additional risk of injury.\textsuperscript{188} Thus, in either situation, the treatment IND regulations still require a rigid clinical showing of both safety and effectiveness before the treatment IND would be granted.\textsuperscript{189} As a result, critics have argued that by continuing to re-

\begin{itemize}
\item \textsuperscript{183} \textit{Id.}
\item \textsuperscript{184} \textit{Id.}
\item \textsuperscript{185} The regulations define a severely debilitating illness as a disease or a condition that causes major irreversible morbidity. 21 C.F.R. § 312.81(b) (1989).
\item \textsuperscript{186} The regulations define "immediately life-threatening" to mean "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." 21 C.F.R. § 312.34(b)(3)(ii) (1989).
\item \textsuperscript{187} 21 C.F.R. § 312.34(b)(2) (1989).
\item \textsuperscript{188} 21 C.F.R. § 312.34(b)(3) (1989).
\item \textsuperscript{189} 21 C.F.R. § 312.34 (1989). This section provides that:
\end{itemize}

In the case of a serious disease, a drug ordinarily may be made available for treatment use under this section during Phase 3 investigations or after all clinical trials
quire that the experimental drugs meet such rigid safety and effectiveness criteria, the treatment IND has failed to live up to its promise of providing experimental drugs to terminal patients with no treatment alternatives at the earliest point in the drug process as possible. Moreover, advocates of persons with AIDS have noted that the treatment IND program has been underutilized by both drug companies and private physicians.

However, the urgency and magnitude of the AIDS pandemic has caused researchers to closely examine the drug evaluation process in hopes of developing new ways to streamline necessary experimental treatment without compromising public safety and health. One proposal currently being discussed by leaders of the public and private health sectors has the potential to allow access to promising drugs for the treatment of AIDS and other terminal illnesses at an earlier point in the traditional clinical testing process than ever before. Under the proposed "parallel track" system, patients who do not qualify for, or have access to, experimental drug clinical trials and who have no approved therapeutic options would be eligible to receive certain experimental drugs as soon as the drugs enter clinical trials. Another option currently being discussed is to conduct huge national drug trials, rather than the limited trials which

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190. See, e.g., Levine, supra note 174, at 171 (noting that the Treatment IND mechanism has failed to live up to its promise).

191. Id. (emphasizing that during the treatment IND mechanism's first year in operation, only one drug for the treatment of AIDS has been approved for early distribution under the program, while other promising AIDS drugs were rejected by the FDA).

192. See Statement By Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, October 5, 1989 (transcript on file at Hofstra Law Review) (noting that "[w]e are in a period of re-examination of some of the traditional concepts of clinical research" and that "[a] consensus is developing around the need for greater flexibility and innovation in our search for new therapies, and the need to expand access to experimental drugs to larger numbers of HIV-infected people, particularly to those who have been underrepresented in clinical trials.").

193. See National Inst. of Allergy and Infectious Diseases, Where Do AIDS Drugs Come From? (on file at Hofstra Law Review) (discussing latest proposals to streamline access to experimental treatment) [hereinafter NIAID, AIDS Drugs].

194. The "parallel track" system was first proposed by Dr. Anthony S. Fauci, Director of the National Inst. of Allergy and Infectious Diseases, at a medical meeting held in San Francisco in June 1989. See National Inst. of Allergy and Infectious Diseases, Update on Parallel Track Proposal, NIAID AIDS AGENDA 5 (July 1989).

195. See NIAID, AIDS Drugs, supra note 193, at 9.
are currently used in studying the safety and effectiveness of new drugs.\textsuperscript{196} Under this new clinical trial approach, trials of experimental drugs could include 10,000 to 20,000 patients, in contrast to traditional trials, which typically include 1,000 patients at most and exclude individuals who do not fall into specific age groups or who have other conditions which might complicate the study.\textsuperscript{197} Advocates of this new drug trial system point out these types of large studies are currently being used with a great deal of success in Europe to test treatments in heart disease patients.\textsuperscript{198} Both proposals appear to recognize the need to shift the balance of risk to the terminally ill patient and his physician when dealing with the decision to choose an unapproved method of treatment.\textsuperscript{199}

Each of the two new proposals carries with it potential problems which will need to be worked out before implementation.\textsuperscript{200} More importantly, however, each symbolizes the recognition of the need to respect the right of a desperately ill individual to elect to obtain necessary experimental medical treatment. Additionally, the two proposals preserve the states' compelling interest in protecting non-terminal patients and terminal patients with approved treatment alternatives from relying upon unapproved therapeutic alternatives. Furthermore, both proposals would more narrowly tailor the FDCA to serve only the states' compelling interest by emphasizing the need to relax the traditional drug distribution requirements when dealing with terminal patients who have no approved medical alternatives.

While the FDA has not yet formally adopted either of the new proposals, a recent unprecedented move by the Administration may indicate that adoption of either plan could soon be underway. In September 1989, the FDA announced that it would release an exper-

\textsuperscript{196} See Kolata, \textit{Radical Change Urged in Testing of AIDS Drugs}, N.Y. Times, Mar. 26, 1990, at A1, col. 1 (noting that the new plan could give quicker results that better reflect what would happen if a given drug was marketed to a diverse population of people with AIDS).

\textsuperscript{197} \textit{Id.} at B8, col. 2.

\textsuperscript{198} \textit{Id.}

\textsuperscript{199} \textit{Id.} (noting that "many Federal health experts and advocates for people with AIDS say [traditional trials] progress too slowly because it takes too long to recruit the perfect patient population. They also say that these studies exclude too many patients and produce results that do not always apply to the diverse group of patients who will take a drug after it is licensed and marketed.").

\textsuperscript{200} For example, some experts have raised concerns that the new proposal for larger national drug trials might tie up so many AIDS patients in these new trials that when a new drug came along there would be too few patients left to try out the new drug in traditional clinical trials. They fear that this could lead to the problem of "a mediocre drug locking out a spectacular drug." See \textit{id.}
EXPERIMENTAL DRUG DISTRIBUTION

The debate over the easing of restrictions on access to unapproved drugs for terminal patients will likely continue for years to come as more and more persons are diagnosed with the deadly syndrome. AIDS activists will undoubtedly continue to pressure the government to loosen the rigid restrictions which obstruct the ability of persons with AIDS and other terminal illnesses from obtaining drugs with the potential to cure or alleviate some of the pain and suffering associated with their illnesses. Persons with AIDS will likely look to the courts to challenge the stringent regulations which stand in the way of experimental drug accessibility. The courts should recognize

VI. CONCLUSION

The debate over the easing of restrictions on access to unapproved drugs for terminal patients will likely continue for years to come as more and more persons are diagnosed with the deadly syndrome. AIDS activists will undoubtedly continue to pressure the government to loosen the rigid restrictions which obstruct the ability of persons with AIDS and other terminal illnesses from obtaining drugs with the potential to cure or alleviate some of the pain and suffering associated with their illnesses. Persons with AIDS will likely look to the courts to challenge the stringent regulations which stand in the way of experimental drug accessibility. The courts should recognize

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201. DDI, a chemical cousin of AZT, is a nucleoside analog, a false building block of DNA, that gets into the HIV virus' genetic material and blocks its duplication. Scientists believe that the drug may be useful to the 40% of AIDS patients who are unable to tolerate AZT due to its serious side effects. See Chase, AIDS Drug DDI to Be Distributed Widely, Wall St. J., Sept. 29, 1989, at B2, col. 1; see also U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS NEWS, Sept. 28, 1989 (announcing the FDA and NIH plan to allow the drug's sponsor, Bristol-Myers, to distribute DDI through the treatment IND program after the drug had only completed Phase 1 clinical testing).


203. Id. (discussing the reactions of advocates of persons with AIDS to the new regulatory change); see also Chase, supra note 201, at B2, col. 3 (discussing the positive reactions of persons with AIDS and their advocates to the easing of restrictions on experimental drug distribution, as well as the more cautious approach taken by some medical professionals regarding the plan). Note that the DDI expanded access plan is very different from the proposal for national trials in that while the expanded access program is intended to collect some information on the response of patients using the new drugs, it is not designed to assess the drug's safety and effectiveness but rather is designed to provide emergency access to patients who have exhausted standard therapies and cannot gain access to traditional clinical trials. The national trial proposal, on the other hand, is designed to gather information on new drugs by simply observing the symptoms of patients and noting whether they are getting better or worse. Thus, the national trials would not be involved in the tremendous amount of data-keeping which often slows down the traditional clinical testing method. See Kolata, supra note 196, at B8, col. 1.
that just as the right to refuse necessary medical treatment has been
deemed a fundamental right under limited circumstances, the right
to obtain necessary medical treatment should also be deemed a fun-
damental right incident to the right of privacy. Once the fundamen-
tal right to obtain necessary treatment is recognized, the courts
should find that while the Federal and State governments do have a
compelling interest in protecting non-terminal individuals and termi-
nal patients with treatment alternatives against unapproved drugs,
the governments do not have a compelling interest in protecting ter-
mina...