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## 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 (1987)

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## COMMENTS

### THE RIGHT OF PRIVACY IN CHOOSING MEDICAL TREATMENT: SHOULD TERMINALLY ILL<sup>1</sup> PERSONS HAVE ACCESS TO DRUGS, NOT YET APPROVED BY THE FOOD AND DRUG ADMINISTRATION?

David was a young man lying in a hospital bed, slowly succumbing to a disease that was attacking his once strong and healthy body. David had acquired immunodeficiency syndrome ("AIDS"). Doctors told David that they could do nothing more for him other than make his inevitable death as painless as possible. David was expected to die within two years. He had heard that an experimental drug was being tested that appeared to be effective in fighting AIDS, but was told that the drug was unavailable because the Food and Drug Administration ("FDA") had not determined it to be safe and effective. David died before the FDA made any decision concerning the availability of the new drug.<sup>2</sup> David's predicament was not unlike the one a group of cancer patients faced in *United States v. Rutherford*.<sup>3</sup> In *Rutherford*, the cancer patients asserted that they

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1. A terminal illness as used throughout this comment is a disease known to be fatal in every case. Consequently, a terminal illness has no treatment effective in fighting the disease.

2. David is a fictitious person representing all terminally ill persons who face a similar situation.

3. 442 U.S. 544 (1979). The *Rutherford* litigation began when Juanita Stowe, a cancer patient, filed a complaint seeking a preliminary injunction granting her access to laetrile. Her request was denied and Mrs. Stowe subsequently died. An amended complaint was filed by Glen Rutherford and Phyllis Schneider. Mrs. Schneider died shortly thereafter. The district court granted injunctive relief and stated that the FDA failed to prove a real interest in denying access to laetrile. The court also noted that the inevitable harm to the plaintiff outweighed the possible harm to the government. *Rutherford*, 399 F. Supp. 1208, 1212-15 (W.D. Okla. 1975). On appeal, the Court of Appeals for the Tenth Circuit allowed the injunction to stand but required the district court to remand to the FDA to determine whether laetrile was a "new drug" under the FDCA. *Rutherford*, 542 F.2d 1137 (10th Cir. 1976), *rev'd*, 442 U.S. 544 (1979). The Commissioner of the FDA determined that laetrile was not a new drug under the FDCA. 42 Fed. Reg. 39,768 (1977). The district court sustained the FDA's findings, but exempted laetrile from the rigorous pre-market testing requirements. *Rutherford*, 438 F. Supp. 1287 (W.D. Okla. 1977). The Court of Appeals affirmed the district court's ruling and held that the terms "safe" and "effective" were

had, as incident to their fundamental right of privacy, a right to access laetrile,<sup>4</sup> a drug not FDA approved. The Supreme Court, however, decided that the cancer patient's privacy rights to choose unapproved drugs for the treatment of their fatal disease did not merit discussion.<sup>5</sup> The Court relied upon the fact that Congress could have created an exception to allow terminally ill patients to access unapproved drugs,<sup>6</sup> but such a provision was absent from the Food, Drug and Cosmetic Act<sup>7</sup> ("FDCA"). In an apparent attempt to rationalize its rather harsh decision which denied cancer patients access to laetrile, the Court noted that it is impossible to characterize a person as terminally ill except in retrospect.<sup>8</sup> The Court appears to suggest that, even if terminally ill persons have a right to choose unapproved drugs, cancer patients cannot be considered terminally ill.<sup>9</sup> Doctors, however, are now capable of correctly diagnosing a person with AIDS ("PWA") as terminally ill.<sup>10</sup>

The nature and extent of the AIDS epidemic will compel the government to recognize the urgent need of terminally ill persons to access drugs approved for experimental testing in humans,<sup>11</sup> but not yet approved for marketing by the FDA.<sup>12</sup> The present state of the

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meaningless when applied to terminally ill persons. *Rutherford*, 582 F.2d 1234 (10th Cir. 1978). The Supreme Court unanimously overruled the tenth circuit decision and found no exception in the requirements of the FDCA for terminally ill persons. *Rutherford*, 442 U.S. 544 (1979). The Court stated that Congress made it clear from the plain language of the FDCA that all persons are protected from unsafe or ineffective drugs. *Id.* at 555.

4. Laetrile is a drug composed primarily of amygdalin, and is precisely defined as a "class of cyanogenic glucosides." Dorr & Paxinos, *The Current Status of Laetrile*, 89 ANNUALS OF INTERNAL MED. 389 (1978). Laetrile is also known as amygdalin, aprikern, Bee 17, vitamin B17, and nitriloside. It is a substance found in the pits of edible fruits such as peaches, plums and apricots. Advocates of laetrile believe that the difference in the chemical make up of a normal cell and cancer cell allow laetrile to react with and destroy cancer cells while leaving normal cells unscathed. Price & Price, *Laetrile-An Overview*, 48 J. SCH. HEALTH 409, 409-10 (1978). Laetrile was patented by Ernst T. Krebs Sr. and Jr. and purportedly was used only as an investigational drug for the treatment of cancer. 42 Fed. Reg. 39,768, 39,789 (1977).

5. The issue of whether the right of privacy protects the terminally ill person's decision to choose unapproved drugs was discussed extensively at the trial and appellate court levels, and in briefs before the Supreme Court, but the Court chose to ignore the issue. The Court instead concluded that the FDCA made no exceptions for terminally ill persons and that all drugs must be proven safe and effective before they can be marketed. *Rutherford*, 442 U.S. at 544.

6. *Id.* at 551-54.

7. Federal Food, Drug and Cosmetic Act, ch. 675, §1-902, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§301-392 (1982)).

8. See *infra* note 81 and accompanying text for a discussion of the definition of a terminal illness.

9. See *Rutherford*, 442 U.S. at 556.

10. See *infra* note 82 and accompanying text for a discussion of AIDS.

11. A new drug must undergo clinical testing on humans before it can be approved for marketing by the FDA. 21 U.S.C. §355(d) (1985).

12. During the writing of this comment, the FDA proposed and approved a change in the regulations surrounding new drug applications. 52 Fed. Reg. 19,466,

FDCA conflicts with an individual's constitutionally protected right of privacy. With society confronting the most menacing health problem ever, the government must prepare to accommodate people whose only hope of continued life lies in a drug they are proscribed from obtaining. If the government waits until a drug is produced that effectively fights AIDS before it recognizes that certain individuals are entitled to use such a drug, it will be too late, because "justice delayed is justice denied"<sup>13</sup> for a terminally ill person.

This comment will begin with a discussion of the relevant history of the FDCA as it impacts upon terminally ill persons' right to choose unapproved drugs. The comment will furthermore establish that a terminally ill person's right to choose unapproved drugs is a fundamental right derived from the right of privacy. The comment will then establish that a living person can accurately be diagnosed to be terminally ill. Next, it will explore the possible state interests in denying terminally ill persons access to unapproved drugs. Finally, this comment suggests general amendments to the FDCA that, once adopted, would achieve the state's goal of safeguarding the public health from potentially dangerous unapproved drugs, while preserving the terminally ill person's privacy right to choose experimental drugs

The FDA is the administrative agency responsible for keeping unsafe or ineffective drugs out of the marketplace.<sup>14</sup> The FDA enforces the Congressional guidelines set forth in the FDCA. In short, the FDCA states that a new drug must be proven safe and effective before it will be approved for marketing.<sup>15</sup> To better understand why Congress decided it was necessary for new drugs, including experimental drugs for the treatment of AIDS to undergo pre-market

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19,476-77 (to be codified at 21 C.F.R. §§312.7, 312.34, 312.35, and 312.42) These regulations in essence shift the burden of proof onto the FDA. *Id.* They require the FDA to prove that a drug for an immediately life-threatening disease is not effective before they can make the drug unavailable to people with that disease. *Id.*

13. *Suenram v. Society of Valley Hosp.*, 155 N.J. Super. 593, 383 A.2d 143 (1977) (quoting *Rutherford v. United States*, 542 F.2d 1137 (10th Cir. 1976)). In *Suenram*, an elderly woman, terminally ill from cancer and non-responsive to conventional treatment, enjoined the hospital where she was a patient from interfering with her decision to obtain laetrile.

14. The authority to enforce the FDCA was delegated to the Secretary of Health, Education and Welfare. The Secretary transferred his authority to the Commissioner of the FDA. 21 C.F.R. §5.10 (1986). The FDA is organized within the Department of Health and Human Services. The Bureau of Drugs is the department within the FDA responsible for overseeing experimental human drugs. H. GRABOWSKI & J. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* 24 (1983) [hereinafter GRABOWSKI & VERNON]. The organization of the FDA is set forth in 21 C.F.R. §5.100 (1986). Currently three modes of enforcing the new drug requirements are available to the Commissioner of the FDA: condemnation and seizure of unapproved drugs, 21 U.S.C. §334 (1982); injunctive proceedings, 21 U.S.C. §332 (1982); and criminal proceedings, 21 U.S.C. §335 (1982).

15. 21 U.S.C. §355 (1985).

approval, it is helpful to examine the history surrounding the FDCA.

### HISTORY OF THE FOOD, DRUG AND COSMETIC ACT

Drugs are chemical substances that nearly every person at some point in life depends upon to help overcome illness or injury. In all instances where consumers introduce drugs into their body, they place a certain amount of faith in the drug producer's claims of purity, safety and efficacy of their product. Congress first recognized the need for the government to protect consumers from dangerous drugs in 1848 when it passed "An Act to prevent the Importation of adulterated and spurious Drugs and Medicines."<sup>16</sup>

It was commonly believed that spurious drugs were prepared in other countries for sale in the United States.<sup>17</sup> The 1848 Act was designed to halt the importation of dangerous or substandard drugs. The Act required imported drugs to be accurately identified and to pass inspection as to their overall quality and fitness for medical purpose.<sup>18</sup> Although the 1848 Act was a step in the right direction, it failed to set objective standards necessary to determine whether the imported drugs were impure or detrimental to society. Furthermore, the Act neglected to even attempt to regulate possibly dangerous drugs manufactured in the United States.<sup>19</sup>

Despite the 1848 Act's shortcomings, the next significant legislation addressing drug regulation came almost sixty years later when Congress passed the "Pure Food and Drug Act" of 1906.<sup>20</sup> The 1906 Act is considered the precursor of the present day FDCA. The 1906 Act was, in part, designed to prevent both domestic and foreign drug manufacturers from making unsubstantiated therapeutic claims about their drugs sold in the United States.<sup>21</sup> It required drug producers to list the amount and nature of potent ingredients included in their products, and to refrain from labeling them in a false or

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16. Ch.70, 9 Stat. 237 (1848).

17. *The Congressional Globe* 858 (June 20, 1848).

18. Ch. 70, §3, 9 Stat. 237, 238 (1848).

19. *Id.*

20. Food and Drug Act, ch. 3915, §§1-13, 34 Stat. 768 (1906). Pure food and drug bills were often submitted to Congress in the early 1900's without any success. It was not until 1906 when the muckraking articles by Samuel Hopkins Adams appeared in *Collier's* and Upton Sinclair's *THE JUNGLE* was published graphically displaying the image of lard made from remains of workmen who fell into the cooking vats, that public pressure forced passage of the Pure Food and Drug Act. P. TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 27-37 (1980). See also Yakowitz, *The Evolution of the Drug Laws of the United States, 1906-1964*, 19 *FOOD DRUG COSM. L.J.*, 296, 297 (1964).

21. See Comment, *Picking Your Poison: The Drug Efficacy Requirement and the Right of Privacy*, 25 *U.C.L.A. L. REV.* 577, 580 (1978)[hereinafter *Picking Your Poison*].

misleading fashion.<sup>22</sup> The 1906 Act attempted to interject objectivity into the process of determining whether a drug was adulterated or misbranded. A drug was considered adulterated if it differed in strength, quality or purity from the standard set forth in United States Pharmacopoeia or National Formulary.<sup>23</sup> Likewise, a drug was considered misbranded if it were falsely named or failed to reveal the presence of one or more of a list of ingredients the statute considered dangerous. The deficiencies of the 1906 Act were rooted in the absence of any pre-market review of drugs, making it impossible to insure consumer protection from unsafe products.

The 1906 Act was replaced in 1938 by the original version of the present day FDCA.<sup>24</sup> The 1938 Act expanded upon the 1906 Act's definition of adulterated or misbranded drugs. The 1938 Act stated that a drug is adulterated if the contents or packaging conditions are insanitary or if the composition of the drug's container might render the contents dangerous.<sup>25</sup> The Act further stated that a drug is misbranded if the labeling is false or misleading or does not include adequate written warnings or directions for proper use.<sup>26</sup> The significant difference between the 1906 and 1938 Acts however, was the latter's pre-market safety requirement of all new drugs.<sup>27</sup>

The 1938 Act prohibited the introduction into interstate commerce, of any new drug not proven safe.<sup>28</sup> Congress however, granted to the FDA the authority to exempt drugs used solely for investigative purposes from the interstate commerce prohibition of drugs not yet proven safe.<sup>29</sup> The Act required a new drug proponent to submit an application to the FDA which shows, through the results of all

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22. GRABOWSKI & VERNON, *supra* note 14, at 1-6. The 1906 Act did not deter drug producers from mislabeling or making false claims about their products. Understaffing of scientists to examine drugs and a series of court decisions requiring the government to meet the burden of proving actual fraud on the part of drug proponents, made enforcement of the Act difficult. *Id.* at 2.

23. *Id.*

24. The FDCA bill was introduced in Congress in 1933, but remained in a state of limbo until passage in 1938. The bill passed in response to the elixir of sulfanilamide disaster of 1937. TEMIN, *supra* note 20, at 38-41. One hundred and seven people died from the ingestion of the substance elixir. The drug company manufacturing elixir checked it for appearance, flavor and fragrance. No tests were performed on animals. No research of the available literature regarding the lethal nature of the drug was performed. The only basis for FDA intervention was that the product was mislabeled. The substance was not an "elixir" because it contained no alcohol, and the lethal substance, diethylene glycol, was not a listed ingredient. See Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions*, 6 L. & CONTEMP. PROBS. 2, 20 (1939).

25. Ch. 675, §501, 52 Stat. 1040, 1049 (1938).

26. *Id.* §502.

27. Food, Drug and Cosmetic Act, ch. 675, §505, 52 Stat. 1040, 1052 (1938) (current version at 21 U.S.C. §355 (1982)).

28. *Id.*

29. *Id.* §505(i).

reasonable tests, that the drug is safe before it can be approved for marketing. The 1938 Act was the first legislative attempt to regulate drugs before their widespread distribution. Although the 1938 Act placed more stringent controls on new drugs, even these were rather limited. Generally, a largely ineffective but safe drug could be approved under the 1938 Act's guidelines.<sup>30</sup> Once approved, only false labeling or advertising claims provided the FDA with an after-the-fact basis for removal of an ineffective drug from the market.<sup>31</sup> The 1938 Act was criticized for its failure to protect consumers from ineffective drugs, the use of which proved economically costly and physically dangerous to people electing to substitute the ineffective drug for an effective one.

The 1938 Act remained relatively unchanged until Congress passed the Kefauver-Harris Drug Amendments of 1962.<sup>32</sup> Growing public concern over pharmaceutical practices provided the impetus to amend the 1938 Act.<sup>33</sup> The single most important change result-

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30. See *Picking Your Poison*, *supra* note 21, at 580-81.

31. 21 U.S.C. §352(f) (1938). FDA removal of a drug for false advertising or labeling is an ineffective method of protecting the public from unsafe drugs. Removal of a drug for false advertising or labeling required initial approval by the FDA. At this point the public health was jeopardized because the consumer now had access to the ineffective drug. Procedures for the removal of the drug from the market were cumbersome and required accumulation of evidence of the falsity of the claim as well as legal action to have the product removed. *Hearings on H.R. 11581 and 11582 Before the House Comm. on Interstate and Foreign Commerce*, 87th Cong., 2d Sess. 63 (1962)(statement of Abraham Ribicoff, Secretary of HEW)[hereinafter *Hearings on H.R. 11581 and 11582*].

32. Senator Kefauver was initially concerned with the market power and high prices in the drug industry. TEMIN, *supra* note 20, at 120-26. Kefauver exposed the enormous profits being enjoyed by drug companies and called for more competition in and surveillance of the drug industry. *Id.* Kefauver pointed to the fact that the ultimate user of a prescription drug is not the same person deciding which drug will be purchased. *Id.* He believed this feature of the drug market required greater surveillance by the FDA and sponsored legislation to this effect. *Id.*

Congressman Oren Harris sponsored a rewritten version of Kefauver's bill that dropped a licensing requirement of drug companies. *Id.* Without the licensing provision Kefauver refused to support the bill which lacked general support in both the House and Senate. *Id.*

33. Like the elixir disaster that helped pass the 1938 Act, another drug tragedy garnered support for the 1964 amendments to the FDCA. A drug company applied for approval of a tranquilizer drug known as thalidomide in September of 1960. TEMIN, *Id.* at 122-23. It had been widely prescribed by doctors in Europe as a sedative for pregnant women. *Id.* Under the 1938 Act's guidelines, a new drug was automatically approved if no action was taken by the FDA within 60 days of receiving the new drug application. *Id.* Dr. Kelsey, an FDA doctor, repeatedly returned the drug application to its sponsor for insufficient information to determine the drug's safety. *Id.* Even without firm evidence of the drug's harmful nature, Dr. Kelsey refused to approve its application. *Id.*

During the application period of thalidomide, it was determined that this sedative was the cause of a birth defect known as phocomelia. *Id.* Phocomelia, being born without hands or feet, appeared with alarming frequency in mothers using thalidomide in Europe. Without the cautious work of Dr. Kelsey, thalidomide would have been approved for general use in the United States. *Id.* at 123-24.

ing from the 1962 Drug Amendments was the requirement that all new drugs in addition to being proven safe must also be proven effective for their intended use prior to market approval.<sup>34</sup>

The requirement that a new drug be proven safe and effective remains in effect to date. In compliance with authority granted to it in the FDCA, the FDA has promulgated regulations outlining the necessary requirements to prove the safety and efficacy of a new drug. In order to introduce into interstate commerce a new drug not yet proven safe and effective without violating the express intent of the FDCA, its proponent must file a signed "Notice of Claimed Investigational Exemption for a New Drug" ("IND") with the FDA.<sup>35</sup> Before an IND application is approved, the proponent of the drug must produce evidence, including studies on laboratory animals, that show the drug is reasonably safe for introduction into humans for experimental purposes.<sup>36</sup> Furthermore, as part of the IND application, the FDA requires the sponsor of the drug to organize and accept ultimate responsibility for meeting all the requirements of

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It should be noted that the 1938 Act did not give the FDA any control over the clinical testing of drugs. Hence, thalidomide was dispensed in the United States by about 1200 doctors for clinical testing. *Id.*

In light of the fact that the 1962 amendments to the FDCA primarily focused upon the efficacy requirement of new drugs, it is ironic that thalidomide played such a substantial role in passing the 1962 amendments. *Id.* at 124. The original amendments would have done little to prevent the approval of thalidomide. *Id.* The efficacy of thalidomide as a sedative is indisputable, it is the safety of the drug that was disputable. *Id.* After the thalidomide tragedy the proposed amendments were reworded to afford the FDA greater control over new drugs. *Id.*

34. 21 U.S.C. §355(d) states:

(d)Grounds for refusing application; approval of application; "substantial evidence" defined.

If the Secretary finds. . . that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;. . . (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application.

35. 21 C.F.R. §312.23 (1987).

36. *Id.* §312.23(a)(8).



the IND process.<sup>37</sup>

The FDA requires that the new drug investigations follow a three-tiered approach.<sup>38</sup> The first and second phases determine the clinical pharmacology of a new drug, while the third phase is a clinical trial. The first time a new drug is introduced into humans is during phase one. Phase one is therefore designed to test only the toxicity, preferred route of administration and safe dosage range of the drug.<sup>39</sup> Phase two tests the drug's effect on people with a specific disease, but may also expand upon the results obtained in phase one.<sup>40</sup> Phases one and two are normally limited to the least number of participants necessary to obtain scientifically acceptable results.

Phase three is the clinical trial of a new drug, designed to assess a drug's ultimate safety and efficacy.<sup>41</sup> Prior to phase three, a protocol is developed based on the test results of phases one and two.<sup>42</sup> After the protocol is determined, separate test groups are organized, with each group formed from a pool of applicants meeting the designated protocol. The number of people included in phase three, though larger than the groups in phases one and two, is still limited to the reasonable number of people necessary to assure scientifically acceptable results. Meanwhile, the sponsor of the drug must organize a group of at least five experts qualified to review phase three of the IND process.<sup>43</sup> This group is called the Institutional Review Board ("IRB"). The IRB's primary purpose is to protect the rights and welfare of the people involved in clinical trials.<sup>44</sup> After the protocol is determined and the IRB is installed, the actual tests to determine safety and efficacy can begin.

The testing method used in phase three of the IND process is called a "double blind" test.<sup>45</sup> In a "double blind" test neither the doctor nor the patient are told whether they are using the experimental drug or a placebo. The "double blind" test is advocated to ensure scientific results with the least amount of uncontrolled variables. After all the data from phases one, two and three are accumulated and studied, the sponsor of the drug must then file an NDA before the FDA can approve the drug.<sup>46</sup>

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37. *Id.* §312.50.

38. *Id.* §312.21.

39. *Id.* §312.21(a).

40. *Id.* §312.21(b).

41. *Id.* §312.21(c).

42. *Id.* §312.23(a)(6).

43. 21 C.F.R. §56.103 (1986).

44. *Id.* §56.101.

45. 21 C.F.R. §314.126(b)(2)(i) (1986).

46. 21 U.S.C. §355(a) states:

(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

An NDA affords the FDA the opportunity to study the results obtained from the IND process, and to make a determination on the safety and efficacy of the new drug. The FDA will approve a NDA if none of the following criteria exist: (1) the application does not include all reasonably applicable tests to determine the drug's safety; (2) the results of such tests fail to show the drug is safe or do show the drug is unsafe; (3) the manufacturing or packaging of the drug fails to preserve the overall quality of the drug; (4) the application fails to give sufficient information to determine whether the drug is safe; (5) there is lack of substantial evidence to show the drug will have the effect it purports; (6) the necessary patent information is missing; or (7) the proposed labeling is misleading in any aspect.<sup>47</sup> These criteria designed to appraise a drug's safety and efficacy, though helpful in that determination, fail to definitively delineate the necessary safety and efficacy standards.

Currently, proving the safety of a new drug is the most troublesome requirement of the FDCA. Exactly what amount and type of evidence necessary to demonstrate adequate safety escapes meaningful definition. Drugs that may be safe for the general population may be toxic for a small group of people. Conversely, a drug not safe for most people may be relatively safe for a select group of people suffering from life-threatening medical conditions.<sup>48</sup> But one thing is certain: no drug can be termed absolutely safe simply because it is impossible to test or even predict all the variables that could adversely effect the person using a drug.<sup>49</sup> Nevertheless, the FDCA states that a new drug is safe if the results of all reasonable methods of testing give the FDA sufficient information to determine that the drug is safe.<sup>50</sup> This subjective safety test of a new drug affords the FDA wide latitude when determining whether a drug should be approved for marketing.<sup>51</sup>

The efficacy requirement of the 1962 amendments is more precisely defined than the safety requirement.<sup>52</sup> For a new drug to be

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subsection (b) of this section is effective with respect to such drug. *Id.*

47. 21 U.S.C. §355(d). The FDA may determine that a drug is unsafe or ineffective from sources other than those provided with the new drug application, and hence is not limited to only the information provided by the new drug's proponent. 21 U.S.C. §355(d)(4).

48. *Picking Your Poison*, *supra* note 21, at 585-86.

49. P. COOPER, AN INDEX OF ADVERSE REACTIONS TO DRUGS (1971). See generally L. GOODMAN & A. GILLAM, THE PHARMACOLOGICAL BASIS OF THERAPEUTICS (1975).

50. 21 U.S.C. §355(d)(1).

51. 21 U.S.C. §355(d)(1)(2)(3)(4). Whether a new drug is approved is predicated upon whether the FDA considers that drug safe. *Id.* Although the FDA relies heavily upon data gathered through scientific analysis of the drug, in the end, the decision of whether the drug is safe is a statutorily mandated subjective decision. *Id.*

52. 21 U.S.C. §355(d)(5) states that a drug is considered effective when substantial evidence responsibly leads experts to conclude the drug will have the effect it purports. Compare *Picking Your Poison*, *supra* note 21, at 586 (stating that the effi-

considered effective, there must be substantial evidence that the drug has the effect its proponents claim.<sup>53</sup> Evidence is considered substantial when experts fairly and responsibly conclude that the drug has the effect it purports.<sup>54</sup> A new drug, however, need only be effective for its intended purpose and not more effective than drugs already FDA-approved.<sup>55</sup> While the FDA's efficacy determination is subjective, it relies heavily upon the subjective opinions of experts. Therefore, although the ultimate efficacy determination is subjective, the subjectivity is in part placed in the hands of people outside the FDA.

The well established objective of the FDCA's safety and efficacy requirements is to protect the population from harmful drugs.<sup>56</sup> Throughout the history of drug legislation, the best interests of consumers were foremost in the minds of the legislatures. In most instances, strict regulation equates with better protection of society. In some situations, however, too much protection is detrimental to the consumer. When a person is harmed as a direct result of the lengthy drug approval process, strict regulation ceases to be beneficial, and actually promotes harm and suffering. Whenever the state objective to promote the health and welfare of its population pro-

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cy requirement is relatively well defined by the FDCA) with *TEMIN*, *supra* note 20, at 126-28 (stating that the FDCA poorly defines the efficacy requirements of new drugs).

53. 21 U.S.C. §355(d) states:

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

54. "Substantial evidence" was one standard considered by the committee revising the 1962 amendments. *TEMIN*, *supra* note 20, at 124. The other standard considered was a "preponderance of the evidence." *Id.* Of the two standards, the substantial evidence test required the least amount of evidence in order for a drug to be considered effective for the purposes of the FDCA. *Id.* The substantial evidence test did not require agreement on the part of experts as to the efficacy of the drug. *Id.* The committee determined this agreement was unnecessary as long as substantial evidence existed that tended to prove the effectiveness of a drug. *Id.*

55. S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 1, at 16 (1962). Representatives from the drug industry argued strongly for an efficacy standard that allows new drugs to be approved even if existing drugs are more effective agents against a medical condition. *See id.* The representatives stated that a comparative standard would severely limit the treating physician's discretion when prescribing drugs for his patients. *Hearings on H.R. 11581 and 11582*, *supra* note 31, at 236 (T. Klump, president of Winthrop Laboratories representing the drug industry).

56. *TEMIN*, *supra* note 20, at 1-2; *Picking Your Poison*, *supra* note 21, at 579. *See generally Rutherford*, 442 U.S. 544, 555-56 (refusing to allow the administration of an unapproved drug to terminally ill patients because of the unproven safety of the drug); *People v. Privitera*, 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, *cert. denied*, 444 U.S. 949 (1979) (affirming a conviction for distribution of an unapproved drug because of the possible threat to public safety).

hibits any person, regardless of medical condition, from accessing unapproved drugs, the health and welfare of society fails to be promoted. Before the state's objectives are more fully analyzed, a fundamental right to choose unapproved drugs must be established. This fundamental right should be found in the constitutionally protected right of privacy.

#### THE RIGHT OF PRIVACY IN PERSONAL DECISIONS

The right of privacy is a fundamental right that emanates from several constitutional provisions.<sup>57</sup> The right protects the individual

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57. Judge Cardozo recognized a common law right to be let alone as early as 1914. In an action for damages against a doctor for an unconsented surgery, Cardozo wrote: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 127, 105 N.E. 92, 93 (1914).

The right of privacy derives from the common law right known as the right "to be let alone." T. COOLEY, *TORTS* 29 (2d ed. 1888). Justice Brandeis commented upon the constitutional basis of this right in his dissent in *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) *rev'd*, in *Katz v. United States*, 389 U.S. 347 (1967), which stated:

The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men.

*Id.*

Commenting on Brandeis' dissent in *Application of President & Directors of Georgetown College*, 331 F.2d 1010, 1017 (1964), *cert. denied*, 377 U.S. 978 (1965) former Chief Justice Burger, then Circuit Judge Burger, stated:

Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights as to *sensible* beliefs, *valid* thoughts, *reasonable* emotions, or *well-founded* sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk.

*Id.* (emphasis in original).

The first case to recognize the separate and distinct right of privacy was *Griswold v. Connecticut*, 381 U.S. 479 (1965). In *Griswold*, the executive and medical directors of the Planned Parenthood League of Connecticut were convicted for assisting a married couple in their practice of contraception. *Id.* at 480. *Griswold* held that the decision to practice contraception was protected by the right of privacy. *Id.* at 485. Although separate concurring opinions differed as to the rationale for striking down the Connecticut law, Justice Douglas writing for the majority was highly concerned with the only possible way of enforcing the law: "Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationship." *Id.*

In *Griswold*, the Court stated that other rights not explicitly mentioned in the Bill of Rights were nonetheless derived from its guarantees. *Id.* at 483. The first amendment protects the right to educate children in private, public or parochial schools. *Pierce v. Society of Sisters*, 268 U.S. 510 (1925). It also protects the right to learn a foreign language. *Meyer v. Nebraska*, 262 U.S. 390 (1923). It was these unarticulated guarantees in the Bill of Rights that spawned the creation of the right to

from unwarranted governmental interference into certain personal decisions.<sup>58</sup> The right of privacy protects personal decisions that have some relation to child rearing and education,<sup>59</sup> contraception,<sup>60</sup> marriage,<sup>61</sup> family relationships<sup>62</sup> and procreation.<sup>63</sup> The right of privacy also protects personal decisions in other areas the Supreme Court has not yet defined.<sup>64</sup> When a statute infringes upon a funda-

privacy in *Griswold*. 381 U.S. at 484.

*Griswold* was the first in a long line of cases invoking the right of privacy to invalidate state legislation. In *Eisenstadt v. Baird*, 405 U.S. 438, 452-55 (1972), the Supreme Court elaborated upon the holding in *Griswold*. In *Baird*, the Court struck down a law relied upon to convict the defendant for distributing contraceptives to unmarried persons. *Id.* The Court stated that the right of privacy was invoked not to protect the marital relationship, but instead to protect the individual, married or single. *Id.* at 453. *Baird* was a very important step in the development of the right of privacy, because it stressed the right as an individual right. It enabled the Court to expand the very narrow ruling in *Griswold* into the very broad holding in *Roe v. Wade*, 410 U.S. 113 (1973). G. GUNTHER, CONSTITUTIONAL LAW 514-15 (11th ed. 1985).

In *Roe*, a pregnant woman challenged Texas' laws that proscribed abortions except in those situations where the woman's life was endangered. 410 U.S. at 117-18. The Court stated that the right of privacy protects a woman's decision to abort a fetus. *Id.* at 153. The Court recognized that the right was not absolute and could be countered by a compelling state interest. *Id.* at 154-55. In short, the Court stated that as the fetus matures, the state's interest in protecting the mother's health increases and eventually outweighs the mother's privacy right to have an abortion. *Id.* at 156, 162-63. After *Roe*, it was clear that the right of privacy was a fundamental right, but the compelling state interest needed to counter that right seemed easier to find than when other fundamental rights were reviewed. See Jackson, *The Coerced Use of Ritalin for Behavior Control in Public Schools: Legal Challenges*, 10 CLEARINGHOUSE REV. 181, 189-90 (1976); see also *The Uncertain Application of the Right of Privacy in Personal Medical Decisions: The Laetrile Cases*, 42 OHIO ST. L.J. 523, 525-26 (1981).

The right of privacy protected the fundamental right to have an abortion, but did not leave the state powerless to regulate the procedure. *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976). When the state regulated, but did not prohibit abortions, the Court upheld the statute. *Id.* at 65-67, 79-81. When the state placed the decision to have an abortion in someone other than the mother's hand, or proscribed the safest and most widely practiced method of abortion, the Court struck down the statute. *Id.* at 67-79. See also *Akron v. Akron Center for Reproductive Health*, 462 U.S. 416 (1983) (struck down a law requiring all second trimester abortions to be performed in a hospital because it imposed a heavy and unnecessary burden on the right to have an abortion).

58. See generally *Roe*, 410 U.S. 113 (decision to have an abortion affects only the pregnant woman); *Baird*, 405 U.S. 438; *Griswold*, 381 U.S. 479 (stating that decision to practice contraception affects only the individual).

59. *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (decision to educate children in public, private or parochial school protected); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (decision to study a foreign language protected).

60. *Baird*, 405 U.S. 438; *Griswold*, 381 U.S. 479 (protecting the individual's decision to distribute and use contraceptives).

61. *Loving v. Virginia*, 388 U.S. 1 (1967) (freedom to marry is a personal decision afforded protection from unreasonable state regulation).

62. *Prince v. Massachusetts*, 321 U.S. 158 (1944) (recognizing the realm of family life is protected from state action).

63. *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (protecting the individual from involuntary sterilization).

64. The right of privacy is a doctrine without a clearly articulated scope. See G. GUNTHER, CONSTITUTIONAL LAW 514-16, 525-26 (11th ed. 1986). Inherent in the defini-

mental right, it is subject to strict judicial scrutiny.<sup>65</sup> In order for a regulation to withstand strict judicial review, the state must demonstrate a compelling interest to justify the statutory interference with the individual's fundamental right.<sup>66</sup> Furthermore, "legislative enactments must be narrowly drawn to express only the legitimate state interest at stake."<sup>67</sup> If the state fails to demonstrate either a compelling interest or that the statute is narrowly drawn to regulate that interest, then the statute violates the constitutional right of privacy and is held invalid.<sup>68</sup>

The Supreme Court has defined the scope of privacy as protecting personal rights deemed 'fundamental'<sup>69</sup> or "implicit in the concept of ordered liberty."<sup>70</sup> These terms of art are of little help in determining whether the right of privacy protects a decision to choose unapproved drugs. Highly personal and intimate individual decisions appear to be the type that the right of privacy consistently protects.<sup>71</sup>

The right of privacy should be extended to protect a terminally ill person's decision to choose unapproved drugs for three reasons: (1) The freedom to care for one's health is of a highly personal nature that should ultimately rest with the individual; (2) a regulation denying access to unapproved drugs severely interferes with the lifestyle of the terminally ill individual; and (3) only the terminally ill person is affected by the decision to choose unapproved drugs. Further analysis of these criteria establishes that a terminally ill

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tion of a right that has *some relation* to certain zones of protected conduct is the absence of an all inclusive definition of that right. The right of privacy is defined on a case by case basis. See generally *Roe*, 410 U.S. 113; *Baird*, 405 U.S. 438; *Griswold*, 381 U.S. 479.

65. See *Roe*, 410 U.S. at 155-56.

66. *Id.* *Kramer v. Union Free School Dist.*, 395 U.S. 621, 627 (1969); *Shapiro v. Thompson*, 394 U.S. 618, 634 (1969); *Griswold*, 381 U.S. 479.

67. *Roe*, 410 U.S. at 155.

68. See generally *id.* The regulation in *Roe* was not representative of a compelling interest nor narrowly tailored to represent the actual state interest. The Court held that the state's interests in protecting the health of the pregnant woman and life of the fetus were not compelling during the first trimester of pregnancy. *Id.* at 163-64. Therefore, a law restricting abortions during the first trimester of pregnancy is not representative of any compelling state interest. The Court further stated that the state's interest in protecting the health of the mother was compelling during the second trimester. *Id.* at 163-65. Nevertheless, the Court stated that prohibition of all therapeutic abortions was an overly broad rule unrepresentative of the state's interest. *Id.* But, reasonable regulation of abortions procedures that did not discourage the choice of abortions was allowable during the second trimester of pregnancy. *Id.* After viability of the fetus, the state has a compelling interest in the life of the fetus. *Id.* at 163-65. At this point a state regulation proscribing all but emergency abortions is both compelling and narrowly drawn and will survive strict scrutiny.

69. *Roe*, 410 U.S. at 152.

70. *Palko v. Connecticut*, 302 U.S. 319, 324-25 (1937).

71. See *supra* note 57; but see *Bowers v. Hardwick*, 106 S. Ct. 2841 (1986)(holding the right of privacy does not protect consenting homosexual activity).

person's decision to choose unapproved drugs is a fundamental privacy right entitled to the protection of strict judicial scrutiny.

Justice Douglas, concurring in *Roe*, stated that much of the right of privacy comes from the meaning of the term liberty as used in the fourteenth amendment. Included in his definition of liberty was "the freedom to care for one's health" subject only to a contrary compelling state interest.<sup>72</sup> Justice Douglas' opinion suggests that absent any compelling state interest, the right of privacy protects a terminally ill person's decision to care for his health with unapproved drugs.

In the medical care context, the Supreme Court often looks to the degree of state intrusion into the patient's lifestyle when determining whether a fundamental right of privacy exists.<sup>73</sup> In *Roe*, the Supreme Court invalidated a law impeding a woman's right to prematurely end a pregnancy. In this decision, the Court stated that the harsh effect of forcing an unwanted child upon a woman's lifestyle was a factor considered when determining whether the right of privacy protects the decision to have an abortion.<sup>74</sup> The *Roe* decision suggests that a fundamental right to undergo unapproved treatment exists when the state's denial of that treatment severely affects the lifestyle of the individual.<sup>75</sup> The degree of intrusion upon a terminally ill person's lifestyle, when denied access to a drug that offers a possibility for continued life, as opposed to certain death, is unreasonably severe. The government intrusion not only adversely effects the terminally ill person's lifestyle, it threatens his actual existence.<sup>76</sup> The degree of intrusion into the terminally ill person's life-

72. Justice Douglas stated that the right of privacy includes "the freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll, or loaf." *Roe*, 410 U.S. at 213 (Douglas, J., concurring).

73. In *Roe*, the Court stated that state regulations proscribing abortions could cause physical and emotional harm to the pregnant woman:

The detriment that the State would impose upon the pregnant woman by denying this choice altogether is apparent. Specific and direct harm medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it. In other cases, as in this one, the additional difficulties and continuing stigma of unwed motherhood may be involved. All these are factors the woman and her responsible physician necessarily will consider in consultation.

413 U.S. at 153. See also *Fitzgerald v. Porter Mem. Hosp.*, 523 F.2d 716, 721 (7th Cir. 1975) (stating that hospitals denial of the La Maze childbirth method had only a minimal effect on the parents' lifestyle and is not protected by the right of privacy), *cert. denied* 425 U.S. 916 (1976).

74. 410 U.S. at 153.

75. *Id.*

76. One court termed the effect on a person denied access to unapproved drugs this way: "Adopting FDA's rationale would mean that an individual suffering from a

style created by withholding experimental drugs warrants recognition of a fundamental right to access unapproved drugs.

Although the decision to choose unapproved drugs is not directly related to child rearing and education, contraception, marriage, family relationships or procreation; these protected zones do not completely define the scope of the right of privacy.<sup>77</sup> The terminally ill person's decision to choose unapproved drugs is of the same type and nature of other personal decisions the right of privacy explicitly protects.<sup>78</sup> Like other protected personal decisions, the decision to choose unapproved drugs exclusively affects the terminally ill person.<sup>79</sup> Therefore since the decision to choose unapproved drugs is highly personal, affects only the terminally ill person, and a severe adverse impact upon the individual would result from denied access to experimental drugs, the terminally ill persons's decision to choose unapproved drugs must be afforded the protection of a fundamental right of privacy.

Critical to the determination of whether a terminally ill person has a fundamental right to choose unapproved drugs is the existence of a medical condition that is 100 percent fatal.<sup>80</sup> Therefore, it is necessary to establish that a terminal disease exists if a fundamental right to choose unapproved drugs is to exist.

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life-threatening disease for which there exists no known effective treatment would not lawfully be entitled to any treatment at all since no drug could be deemed 'generally recognized as effective' in such a situation." *Rutherford*, 429 F. Supp. 506, 511 (W.D. Okla. 1977), *rev'd*, 442 U.S. 544 (1979).

77. See *supra* note 64.

78. See *supra* note 57.

79. The decision to choose an illegal or unapproved method of treatment is analogous to the line of privacy cases protecting decisions to use contraceptives or have an abortion because only the person making the decision was affected by it. One aspect of the decision to choose unapproved drugs for treating a terminal disease is unlike a decision to forego lifesaving medical treatment. The decision to refuse lifesaving medical treatment could force dependents of the individual to become wards of the state. See, e.g., *In re Brooks Estate*, 32 Ill. 2d 361, 205 N.E.2d 435 (1965) (protected a decision to decline a blood transfusion after a finding that spouse and children would not become dependent upon the state for support); *In re Melideo*, 88 Misc. 2d 974, 390 N.Y.S. 2d 523 (1976) (upholding a woman's decision to forego lifesaving medical treatment after finding she had no children and was not pregnant). Even if the decision to choose unapproved drugs turns out to hasten the death of the terminally ill person, any dependents requiring state support would be the same had the individual died from his disease. *Id.*

80. In *Rutherford*, 442 U.S. 544 and *People v. Privitera*, 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, *cert. denied*, 444 U.S. 949 (1979), the United States and California Supreme Courts were reluctant to allow cancer patients to access unapproved drugs because relatively effective treatments were available. In *Rutherford* the Court terms cancer as a potentially fatal disease that could respond to various forms of therapy. 442 U.S. at 556-57. In *Privitera*, the court stated that allowing cancer patients access to unapproved drugs would harm those patients who would clearly benefit from conventional treatment. 23 Cal. 3d at 704, 591 P.2d at 925, 153 Cal. Rptr. at 437.



## IDENTIFYING THE TERMINALLY ILL PERSON

In 1979, the *Rutherford* decision concluded that a person could be identified terminally ill only retrospectively.<sup>81</sup> Eight years after the *Rutherford* decision, AIDS,<sup>82</sup> the biggest threat ever to public health, confronts society. There are several developmental stages of AIDS,<sup>83</sup> the most threatening is known as "full blown" AIDS. A per-

81. The *Rutherford* Court stated that "with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect." 442 U.S. at 556. In a footnote the Court continued: "[N]o one can prospectively define the term 'terminal' with any accuracy. A patient can be said to be terminal only after he dies. Many patients who are critically ill respond to modern day management of cancer." *Id.* at 556-57 n.14 (quoting Dr. Peter Wiernik, Chief of the Clinical Oncology Branch of the National Cancer Institute's Baltimore Research Center). "[T]he distinction of 'terminal' patients from 'non-terminal' patients may not be reliably determined and an assumption that Laetrile may be given to ['terminal'] patients with impunity may deprive such patients of therapeutic measures which could help them." *Id.* at 557 n.14 (quoting Dr. Joseph Ross, Professor of Medicine, Univ. of Cal. School of Medicine at Los Angeles).

82. AIDS is a disease caused by the human immunodeficiency virus ("HIV") also known as human T-cell lymphotropic virus III ("HTLV-III"). There is speculation that AIDS was present in humans as far back as 1960. Williams, Stretton & Leonard, *AIDS in 1959?*, THE LANCET, (Nov. 12 1983). AIDS was first recognized in the United States in the spring of 1981 by doctors in New York and California. D. ALTMAN, AIDS IN THE MIND OF AMERICA 30-33 (1986). Reports of Pneumocystis Carinii Pneumonia ("PCP") and Kaposi's Sarcoma ("KS") in otherwise healthy young men lead doctors to discover the underlying cause of these infections was the HIV virus. *Id.*

The HIV virus is transmitted through the exchange of blood, semen and vaginal fluids and cannot be transmitted by tears, sweat or saliva. Ho, Byington, Schooley, Flynn, Rota & Hirsch, *Infrequency of Isolation of HTLV-III Virus from Saliva in AIDS*, 313 NEW ENG. J. MED. 1606 (1985) (only one saliva sample of 83 PWAs tested for AIDS was positive, and that PWA had active oral lesions). The overwhelming medical evidence leads experts to conclude that the HIV virus cannot be transmitted through casual contact. Fiedland, Saltzman, Rogers, Kahl, Lesser, Mayers, & Klein, *Lack of Transmission of HTLV-III/Lav Infection to Household Contacts of Patients With AIDS or AIDS-Related Complex with Oral Candidiasis*, 314 NEW ENG. J. MED. 344, 346 (1986). The most common method of exposure to the HIV virus is through anal sex. Other methods of infection include contaminated hypodermic needles and blood products, vaginal intercourse, and transmission to unborn fetus from mother. Closen, Conner, Kaufman & Wojcik, *AIDS: Testing Democracy-Irrational Responses to the Public Health Crisis and the Need for Privacy in Serological Testing*, 19 J. MARSHALL L. REV. 835, 864-71 (1986) [hereinafter Closen, *AIDS Crisis*].

Once the HIV virus is present in the blood system, it attacks a specific cell in the immune system known as a T-helper cell for the purpose of stealing the cell's genetic material to reproduce itself. *Id.* at 856-61. The virus' assault destroys the T-helper cell. *Id.* In a normally functioning immune system, the T-helper cell activates the immune systems response to a foreign substance. *Id.* The immune system is later deactivated by T-suppressor cells. *Id.* The HIV virus seeks out the T-helper cells and destroys them. The reduction of T-helper cells leaves an excess of T-suppressor cells causing a shutdown of the body's immune system. *Id.*

After the HIV virus suppresses the immune system, the body is unable to combat infection. *Id.* The body is susceptible to many viruses that it normally would be able to destroy. *Id.* An infection that could normally be prevented by a healthy immune system is called an opportunistic infection. *Id.* It is the opportunistic infection such as PCP and KS that eventually cause the death of an individual, not the HIV virus.

83. AIDS is often inaccurately defined as the presence of the HIV antibodies in

son with "full blown" AIDS is clinically defined as a person with the AIDS virus and the presence of a life-threatening 'opportunistic infection.'<sup>84</sup> Over ninety percent of the PWAs die within two years of contracting 'full blown' AIDS.<sup>85</sup> Unlike most epidemics society has faced, no one has ever recovered from AIDS. Currently, everyone suffering from 'full blown' AIDS is certain to die.<sup>86</sup> Society has never before been faced with a disease that is always fatal, consequently there was little need to seek drugs not yet FDA approved.<sup>87</sup> Never-

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the blood. Although this is a required condition of AIDS, it is not conclusive proof of AIDS. There are three, sometimes overlapping, categories associated with AIDS; exposure to HIV virus, AIDS-Related complex ("ARC"); and AIDS or "full blown" AIDS. *Id.* at 860.

The first in a continuum of categories of AIDS conditions is exposure to the HIV virus. *Id.* Exposure to the HIV virus may be evidenced by a positive response to an enzyme-linked immunosorbent assay ("ELISA") test showing the existence of antibodies to the HIV virus. The ELISA test is not 100 percent accurate in identifying the HIV virus, and a more reliable but difficult test is the Western Blot analysis. *Id.* at 872-73. A person testing HIV positive may have no physical manifestations showing he is a carrier of the AIDS, and nonetheless be able to transmit the virus to another person. A person exposed to the HIV virus has a 1 to 10 percent chance of later developing ARC. *Id.* at 860.

The next step in the continuum is ARC. ARC is a mild form of AIDS and is evidenced by fever, night sweats, weight loss, diarrhea, fatigue and swollen lymph nodes. *Id.* A person with ARC may develop "full blown" AIDS, but it is not a foregone conclusion. The incubation period for "full blown" AIDS may be longer than seven years, making it impossible to predict if a person will contract AIDS. *Id.*

AIDS or "full blown" AIDS is the final point on the continuum. AIDS is evidenced by the presence of a life-threatening opportunistic infection such as PCP or KS. *Id.* at 30. Over 90 percent of PWAs die within two years of contracting the disease. A. SILVERSTEIN & V. SILVERSTEIN, AIDS: DEADLY THREAT 48 (1986). Although a few PWAs may survive more than two years, AIDS is presently 100 percent fatal. Closten, *AIDS Crisis*, *supra* note 82, at 857-60.

84. See Centers for Disease Control, *Update on Acquired Immune Deficiency Syndrome (AIDS)-United States*, 31 MORBIDITY & MORTALITY WEEKLY REP. 507, 507-13 (1982); see also Centers for Disease Control, *Revision of the Case Definition for Acquired Immunodeficiency Syndrome for National Reporting-United States*, 34 MORBIDITY & MORTALITY WEEKLY REP. 373, 373-75 (1985).

85. A. SILVERSTEIN & V. SILVERSTEIN, AIDS: DEADLY THREAT 48 (1986).

86. Currently investigation is continuing into the effectiveness of the drugs azidothymidine ("AZT") and ribovarin in the fight against AIDS. AZT is a drug that purports to enter the T-helper cell infected by the HIV virus and block reproduction of the virus. See NEWSWEEK, Sept. 29, 1986 at 57-58; U.S. NEWS & WORLD RPT., Sept. 29, 1986 at 69. In clinical placebo controlled tests, AZT showed remarkable success in battling AIDS, but proponents cautioned that it was not a cure. *Id.* Of the 145 PWAs who received AZT only one died compared to 16 deaths in the similarly sized group receiving placebos. *Id.* The test was scheduled to run from February to December of 1986, but was cut short because of the obvious positive results. *Id.* After the clinical trial was halted, AZT was made available to approximately one-half of all PWAs. An FDA decision is imminent on whether it will allow doctors to prescribe AZT for their patients. AIDS Policy & Law (BNA) vol. 2, no. 1 at 4, Jan. 28 (1987). Ribovarin is another drug purporting decrease the chances of a person exposed to HIV virus or a person with ARC from developing "full blown" AIDS. It has recently been approved for clinical testing by the FDA, but again does not purport to be a cure. *Id.* at 7-8.

87. But see *Rutherford*, 442 U.S. 544 (cancer patients seeking laetrile); *Gadler v. United States*, 425 F. Supp. 244 (1977)(cancer patient seeking unapproved drugs for personal use); *Privitera*, 23 Cal. 3d 697, 591 P. 2d 919, 153 Cal. Rptr. 431

theless, some individuals did seek access to unapproved drugs for the treatment of their disease. In an attempt to obtain unapproved drugs, a few courts recognized the individual's fundamental privacy right to access unapproved drugs. Consequently, these courts examined the state's interest in protecting the health of its citizens to determine if they outweighed the individual's privacy rights. Hence, the state interest in protecting the health of terminally ill persons must be analyzed to determine if it is compelling.

#### STATE INTERESTS IN DENYING ACCESS TO UNAPPROVED DRUGS

It is well settled that the state has a compelling interest in protecting the health of its citizens.<sup>88</sup> The purpose of the FDCA is, in part, to shield the public from unsafe or ineffective drugs.<sup>89</sup> The state's interest in protecting consumer's health by proscribing access to unapproved drugs, raises two questions when addressing the class of terminally ill persons: (1) Does the state have a compelling interest in protecting a terminally ill person's health from the possible harm unproven drugs may cause, even though the drugs could benefit the person and at the very worst might contribute to the impending death of the individual? and; (2) Even if there is a compelling interest in protecting even a terminally ill person's health, is the regulation narrowly tailored so as to represent only the actual state interest claimed?

The state has some interest in protecting the health of even a terminally ill person,<sup>90</sup> but whether the interest is compelling in nature is doubtful. The Supreme Court of New Jersey in *In re Quinlan*<sup>91</sup> stated that the state's interest in the life of a patient in an irreversible vegetative and noncognitive state weakens as the prog-

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(1979)(doctor charged with violating a law proscribing the use or distribution of laetrile); *Suenram*, 155 N.J. Super. 593, 383 A.2d 143 (1977)(elderly cancer patient seeking laetrile).

88. "[A] state may properly assert important interests in safeguarding health, in maintaining medical standards and in protecting potential life." *Roe*, 410 U.S. at 154.

89. See *Lochner v. New York*, 198 U.S. 45, 54 (1905). The tenth amendment reserves to the states the power to promote the health, safety and welfare of its citizens. Nevertheless, the commerce clause grants broad powers to Congress to regulate any activity affecting interstate commerce. The power to regulate new drugs derives from the commerce clause and federal law preempts state law when they are in conflict. See Comment, *The Laetrile Controversy: Background and Issues*, 20 ARIZ. L. REV. 825, 842-60 (1978); see also Kaplan, *The Role of the Law in Drug Control*, 1971 DUKE L.J. 1065, 1089-92.

90. The fundamental privacy right to choose unapproved drugs does not totally prohibit the state from protecting the terminally ill person's health. Clearly, the state would have an interest in denying a terminally ill person unapproved drugs known to be harmful or ineffective.

91. 70 N.J. 10, 355 A.2d 647, cert. denied, 429 U.S. 922 (1976) (father of Karen Quinlan sought court authorization to discontinue all extraordinary treatment enabling his daughter to sustain life).

nosis for recovery dims and the degree of bodily intrusion necessary to sustain life increases.<sup>92</sup> The state's interest in the life of the individual should likewise weaken when an irreversible terminal illness is present.<sup>93</sup> The state is unable to protect the individual from certain death, and consequently should not be allowed to interfere with his only hope of survival. Once a person is identified terminally ill, the state's interest in protecting the health of the individual is diminished and the individual's privacy right to choose his treatment must prevail.

Alternatively, the state's interest in protecting the life of even healthy people may not always be compelling.<sup>94</sup> Many courts dealing with the situation where a competent healthy person refuses a simple lifesaving blood transfusion, will allow that person to refuse the transfusion and die as a direct result.<sup>95</sup> These courts reason that the state's interest in continuing life is subservient to the privacy right to die.<sup>96</sup> Therefore, state's interest in protecting the health of a terminally ill person cannot outweigh the individual's privacy right to choose unapproved drugs, when the interest in the life of a healthy person is held subordinate to the privacy right to die.

Although the state has some interest in protecting the health of terminally ill persons, it is clearly not compelling in nature and must give way to the stronger right of the individual to make decisions regarding his terminal illness. It is only logical to deduce that if the state's interest in protecting health dims in the wake of an irreversible vegetative coma, or is not compelling enough to prevent a person from refusing simple lifesaving medical treatment, then the state's

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92. *Id.* at 27, 355 A.2d at 644.

93. One court suggested that the hopelessness of a cancer patient's prognosis would decrease the state's interest in denying her access to laetrile. "To deny a person her last opportunity to make a choice as to how to combat a disease which has ravaged her body would display a lack of understanding of the meaning of the individual's rights in our free society." *Suenram*, 155 N.J. Super. at 599, 383 A. 2d at 148.

94. See Comment, *The Right to Die: An Extension of the Right to Privacy*, 18 J. MARSHALL L. REV. 895, 897-904 (1985).

95. See *In re Brooks Estate*, 32 Ill. 2d 361, 205 N.E.2d 435 (1965)(healthy person's decision to forego lifesaving blood transfusion is honored); *In re Melideo*, 88 Misc. 2d 974, 390 N.Y.S. 2d 523 (Sup. Ct. 1976)(decision by a healthy competent 23-year-old patient to refuse a simple lifesaving blood transfusion upheld); *Erikson v. Dilgard*, 44 Misc.2d 27, 252 N.Y.S. 2d 705 (Sup. Ct. 1962)(refusal of blood transfusion that would avoid certain death upheld); but see *John F. Kennedy Mem. Hosp., Inc. v. Heston*, 58 N.J. 576, 279 A.2d 670 (1971)(decision to refuse overruled and a court-ordered blood transfusion was administered).

96. The state's interest in the life of the individual asserting a privacy right to die is also inferred from decisions disallowing the right die, not because of the interest in the life of the mother, but because of the interest in the protection of unborn or minor children. See, e.g., *In re President and Directors of Georgetown College, Inc.*, 331 F.2d 1010 (D.C. Cir.)(refused to allow mother of a seven month old child to withhold blood transfusion), *cert. denied*, 377 U.S. 978 (1964); *Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson*, 42 N.J. 421, 201 A.2d 537, (decision to refuse treatment denied pregnant mother), *cert. denied*, 377 U.S. 985 (1964).

interest in protecting the health of a terminally ill person cannot reach a compelling nature.

However, if the state's interest in protecting the health of the terminally ill is deemed compelling, the means employed by the FDA to serve that interest fail to justify the desired end.<sup>97</sup> The FDA's denial of all drugs not yet proven safe and effective is an overbroad method of serving the state's interest in protecting the health of the terminally ill.<sup>98</sup> The FDA will inevitably prevent terminally ill persons from accessing safe and effective experimental drugs because of the considerable amount of evidence the FDA requires before approving a new drug for marketing. Ultimately, the FDA and FDCA impose a death sentence upon the terminally ill, while purporting to protect their health. A statute intending to protect an individual's health that in effect requires the person to accept death is blatantly overbroad. States also possess an interest in gathering as much information as possible about an unapproved drug's safety and efficacy. The state's interest in protecting the health of future generations is achieved by maintaining stringent control over experimental drugs. Releasing experimental drugs to terminally ill persons may hinder the state's ability to promptly and accurately assess the drugs' potential.<sup>99</sup> The state argues that if individuals are allowed unrestricted access to unapproved drugs the state will no longer be able to gather the necessary data to evaluate the drug.<sup>100</sup> Assuming, *arguendo*, that the state's interest in accumulating information concerning a new drug is compelling, this argument fails because it is based on the erroneous assumption that the fundamental right of privacy may not be regulated.<sup>101</sup>

The least restrictive approach of gathering the necessary data on unapproved drugs must be employed when regulating the terminally ill person's fundamental right to choose experimental drugs.<sup>102</sup>

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97. State regulations must be narrowly tailored so as to advance only the interest sought to be protected. *Roe*, 410 U.S. at 155.

98. A statute that prevents terminally ill persons from accessing all new drugs until proven safe and effective will inevitably withhold from the individual an effective drug that would have saved his life. Simply because it would be difficult to draft a law that would more accurately represent only the state's interest in protecting the terminally ill from harmful drugs, does not allow the state to draw up a rule that unnecessarily intrudes upon the fundamental right to choose unapproved drugs.

99. Grady, *Look, Doctor, I'm Dying. Give Me the Drug*, *DISCOVER*, August 1986 at 78-86.

100. *Id.*

101. See *Akron v. Akron Center for Reproductive Health*, 462 U.S. 416 (1983)(recognizing that abortions may be regulated by the state to reflect important state interests); *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976)(regulation of the privacy right to abort a fetus is permissible as long as the state does not prohibit or discourage the exercise of a fundamental right).

102. *Akron*, 462 U.S. 416 (stating that the fundamental right to have an abortion requires that the state not regulate unnecessarily).

For example, the state could require terminally ill persons accessing unapproved drugs to undergo periodical medical examinations thereby providing the necessary information concerning the new drug. Limited regulation, short of proscribing protected conduct, is not an unreasonable hinderance upon the individual's privacy rights.<sup>103</sup> Arguably this information is less reliable than data collected by controlled clinical testing. Nevertheless, it serves a dual purpose. It recognizes the terminally ill person's fundamental right to choose unapproved drugs and the state's interest in gathering the necessary data to evaluate the ultimate safety and efficacy of the drug.

#### SUGGESTED AMENDMENTS TO THE FDCA

Although the FDCA plays a vital role in the protection of the public health, it is overly broad and intrudes upon the terminally ill person's fundamental privacy right to choose unapproved drugs. The FDCA should be amended to allow the terminally ill to access unapproved drugs while concomitantly recognizing the state's less than compelling need to protect the health of the terminally ill and gather data necessary to evaluate a new drug.<sup>104</sup> First, allowing a terminally ill person access to unapproved drugs recognizes the individual's right to choose his own medical treatment. Second, limiting access to only those drugs approved for preliminary testing in humans, acknowledges the state's interest in protecting the terminally ill person from fraudulent claims of miracle cures. Third, the terminally ill persons should be required to undergo periodical medical examinations; such examinations allow the state to determine the safety and efficacy of the drug without intruding upon the individual's decision to use unapproved drugs. In essence, the proposed changes to the FDCA strike a balance between the competing individual and state interests.

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103. See *H.L. v. Matheson*, 450 U.S. 398 (1981)(upholding a law requiring physicians to notify, if possible, the parents of a minor child upon whom they would perform an abortion). The Court stated the law was narrowly drawn to serve only the important state interests at stake. *Id.*

104. The Carter administration sought to reform the FDCA in 1977. The Carter administration's "Drug Regulation Reform Act of 1978" unsuccessfully sought to redefine "safety" to take into account the benefits versus the risks of taking experimental drugs by looking at the specific disease ravaging the body. See *N.Y. Times*, Dec. 9, 1977, at 1, col. 5. The bill called for stringent control over drugs approved under the proposed redefinition of safety. See Note, *Constitutional and Legislative Challenges to the Federal Pre-Market Proof of Drug Effectiveness Requirement*, 13 *NEW ENG. L. REV.* 279, 286 (1977).

## CONCLUSION

People suffering from a fatal disease, such as "full blown" AIDS have a fundamental privacy right to choose unapproved drugs. The state's interest in the health of terminally ill persons is less than compelling, and in any event is not precisely represented by the requirements set forth in the FDCA. Furthermore, the state's interest in accumulating data concerning new drugs may still be advanced by requiring individuals accessing experimental drugs to undergo periodic medical examinations. Individuals suffering from full blown AIDS or any other fatal disease, are entitled to access experimental drugs that offer hope in an otherwise hopeless situation. Immediate recognition of the right to choose unapproved drugs is essential. Delaying recognition of the fundamental right to choose unapproved drugs for treating a terminal illness would unnecessarily jeopardize the lives of individuals who would benefit from experimental drugs.

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