

# LAETRILE: INDIVIDUAL CHOICE FOR CANCER PATIENTS

## I INTRODUCTION

Whether it is a cure for cancer or simply another false hope, laetrile has caused great debate in the United States. The Food and Drug Administration (FDA) has banned laetrile from interstate commerce,<sup>1</sup> effectively preventing cancer patients from obtaining the drug.<sup>2</sup> While a majority of states have similar intrastate prohibitions on the use of laetrile, as of September, 1978, seventeen states allow its use subject to substantial regulation.<sup>3</sup> The American Medical Association (AMA) and the American Cancer Society (ACS) endorse prohibitions on laetrile's use as valid public health measures. On the other hand, politically conservative groups<sup>4</sup> and individual cancer patients, their families and doctors, support laetrile and advocate freedom of choice in making medical decisions. This lack of consensus among members of the medical and legal communities leaves the cancer patient in a state of medical and legal limbo. In July, 1977, these issues were presented before the Senate Subcommittee on Health and Scientific Research at a hearing to evaluate the FDA ban.<sup>5</sup>

In an effort to determine whether anti-laetrile legislation is constitutional,

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1. A drug may only travel in interstate commerce if a "Notice of Claimed Investigation Exemption for a New Drug" has been submitted to, and is approved by, the FDA. Because the FDA will not grant this to laetrile sponsors, the drug is effectively banned from interstate commerce. See text accompanying notes 46-50 *infra*.

2. Laetrile is a drug, as defined by the Food, Drug, and Cosmetic Act. 21 U.S.C. § 321(g)(1)(B) (1976). See text accompanying note 53 *infra*.

3. The following state statutes have legalized laetrile: ALASKA STAT. § 08.64.367 (1977); ARIZ. REV. STAT. ANN. § 32-1962 (Supp. 1978); DEL. CODE tit. 16, § 4901-05 (Supp. 1977); FLA. STAT. ANN. § 458.24 (West Supp. 1978); 1978 Advance Leg. Serv. to Idaho Code 18-7301A (West); 1978 Ill. Legis. Serv. 80-1096 (West); IND. CODE ANN. §§ 16-8-8-1 to 16-8-8-7 (Burns Supp. 1977); 1978 Kan. Sess. Laws ch. 239; LA. REV. STAT. ANN. § 40.676 (West 1977); MD. CODE ANN. art. 43, § 133 (Supp. 1978); NEV. REV. STAT. §§ 630.303, 585.495 (1977); N.H. REV. STAT. ANN. § 329.30 (Supp. 1977); N.J. STAT. ANN. § 24:6F-1 (West Supp. 1978); OKLA. STAT. ANN. tit. 63, § 2-313.1 (West Supp. 1977-1978); OR. REV. STAT. § 689.885 (1977); TEX. REV. CIV. STAT. ANN. art. 4476-5a (Vernon Supp. 1978); WASH. REV. CODE ANN. § 70.54.130-150 (Supp. 1977). As of June, 1978, Alabama, California, Georgia, Hawaii, Iowa, Kentucky, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New York, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin have rejected bills to legalize laetrile. Interview with Paul Sage, Litigation and Research Staff, Food and Drug Administration, Rockville, Md. (Sept. 25, 1978).

4. The John Birch Society founded the Committee for Freedom of Choice in Cancer Therapy, which is now a major lobby for laetrile legalization. The group also arranges travel to Mexico for cancer victims who wish to receive laetrile treatment. Washington Star, May 5, 1976, at 1.

5. *Banning of the Drug Laetrile from Interstate Commerce by FDA: Hearings Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 1st Sess. 2 (1977) (statement by Senator Kennedy) [hereinafter cited as 1977 Hearings].

this Note compares the cancer patient's right to choose laetrile with the state's interest in limiting that right. The first section traces the medical and legal history of laetrile in the United States. Next, the Note provides a constitutional framework for analyzing important individual rights and assessing when the government can infringe on these rights. The last section explores the right, if any, to choose laetrile and advocates regulated use by cancer patients who are terminally ill or have no dependents.

## II HISTORY

### A. *Medical Background*

#### 1. *A Chemical Analysis of Laetrile*

Laetrile, the chemical amygdalin,<sup>6</sup> is a food extract used in the treatment of cancer. It is found in more than 1,200 plants,<sup>7</sup> particularly in the kernels of apricots, peaches, plums, and bitter almonds.<sup>8</sup> Laetrile is broken down in the body by Beta-glycosidases enzymes to yield dextrose (sugar) and mandelonitrile, a molecule of hydrogen cyanide combined with a molecule of benzaldehyde.<sup>9</sup> Mandelonitrile, either spontaneously or by the action of a second enzyme, decomposes into benzaldehyde and cyanide.<sup>10</sup>

Laetrile proponents have used various theories to support their claim of its effectiveness. The first major theory, posed by Ernst Krebs, Jr., was that laetrile would be broken down by the enzyme B-glucosidase in cancerous tissues to release cyanide, which would in turn kill the cancer.<sup>11</sup> According to this theory, cancer tissues are selectively killed because they contain more of this enzyme than do normal tissues.<sup>12</sup> This claim was abandoned, however, due to defects in its underlying theory.<sup>13</sup> Proponents then claimed that amygdalin is hydrolyzed to mandelonitrile either in the bloodstream or in the intestinal tract and that it is then converted in the liver to B-glucuronide. This compound is allegedly carried to cancer tissues where it is further broken down to release cyanide.<sup>14</sup> An alternate theory is that rhodanese, an enzyme which detoxifies

6. Jukes, *Laetrile for Cancer*, 236 J.A.M.A. 1284 (1976).

7. Note, *The Cancer Drug Controversy—U.S. v. Laetrile*, 3 U. SAN FERN. V. L. REV. 51 (1974).

8. Arehart-Treichel, *Laetrile: The Science Behind the Controversy*, 112 SCIENCE NEWS (Washington) 92 (1977). The first major use of laetrile as a cancer drug in the United States occurred in 1920, when a California physician, Ernst T. Krebs, Sr., attempted to use apricot kernels as a treatment for cancer. His son, Ernst T. Krebs, Jr., purified laetrile for injection in 1952. *Id.*

9. *Id.*; Jukes, *supra* note 6, at 1284.

10. Jukes, *supra* note 6, at 1284.

11. *Id.*; DiPalma, *Laetrile: When Is a Drug Not a Drug?*, 15 AM. FAM. PHYSICIAN 186 (1977).

12. Arehart-Treichel, *supra* note 8, at 92.

13. This theory failed for two reasons: 1) B-glucosidase is rare in animal tissues and even rarer in cancer tissues, and 2) even if cyanide were released, there is no proof that it would not spread to surrounding tissues because of its high diffusion rate. Jukes, *supra* note 6, at 1284; DiPalma, *supra* note 11, at 186.

14. Jukes, *supra* note 6, at 1284; DiPalma, *supra* note 11, at 186.

cyanide, is less present in tumors than in normal tissues, so that tumors are less able to protect themselves against cyanide.<sup>15</sup>

In response to deficiencies in these theories,<sup>16</sup> proponents have developed a more generalized explanation of how laetrile works. These supporters claim that laetrile is a nutritional substance, vitamin B<sub>17</sub>, which has anti-cancer propensities.<sup>17</sup> Dean Burk, formerly of the National Cancer Institute (NCI), asserts that laetrile is a vitamin.<sup>18</sup> There are objections to this characterization, but there can be no true determination of whether laetrile has vitamin properties until laetrile has been adequately tested.<sup>19</sup>

## 2. *Studies Done on Laetrile*

Scientific studies must be conducted before any conclusive statements about a drug's efficacy and safety can be made.<sup>20</sup> However, the lack of laetrile studies, and the conflicting findings and methodological problems found in the studies which have been undertaken, leave cancer patients and their physicians unable to choose the proper treatment. Present scientific knowledge is so inconclusive that further and more valid research about the safety and efficacy of laetrile must be conducted.

### a. *Laetrile's effectiveness*

In 1953, the California Medical Association commissioned a Cancer Advisory Committee to conduct a study to determine laetrile's effectiveness. The study involved forty-four cancer patients who had received laetrile at some point during their illnesses. The results of this study, which provided the basis for the California ban on laetrile, were unsound. The dosages administered were miniscule, reports of loss of pain were ignored, a pathology report was omitted from the final evaluation, and the authors of the study had no contact with the patients.<sup>21</sup>

In 1957, the National Cancer Institute began studies to test the effectiveness of laetrile on animals with cancer tumors.<sup>22</sup> The Sloan-Kettering Institute

15. Arehart-Treichel, *supra* note 8, at 93.

16. The basic objection to these claims is that scientists have not been able to prove the differences between cancerous and normal tissues. *Id.*

17. *Id.* at 93-94.

18. Jukes, *supra* note 6, at 1285.

19. The crucial property of a vitamin is that its absence from the diet produces a deficiency disease. There is no proof that laetrile exhibits this property. In addition, the Committee on Nomenclature of the American Institution of Nutrition "finds no scientific evidence of the existence of a nutrient identified as B<sub>17</sub> or evidence that laetrile has any nutritional value." *Id.* Dr. DiPalma of Hahnemann Medical College in Philadelphia, Pennsylvania, admits, however, that experts have not yet determined whether laetrile's absence may cause a deficiency disease. Arehart-Treichel, *supra* note 8, at 94.

20. The FDA requires that drugs be both safe and effective. See text accompanying note 49 *infra*.

21. Note, *supra* note 7, at 56-57.

22. Since then, six studies have been conducted by the NCI or by other institutions under NCI contract. Only the results of the last three experiments have been published. See Arehart-Treichel, *supra* note 8, at 94.

and the Catholic Medical Center have undertaken the most extensive studies in the United States on laetrile.<sup>23</sup>

In a preliminary set of experiments, Kanematsu Sugira at Sloan-Kettering found that 90%<sup>24</sup> of the control mice (those receiving saline injection) experienced lung metastases<sup>25</sup> due to the spreading breast tumors. In contrast, the same result occurred in only 21% of the mice that received laetrile.<sup>26</sup> Later experiments, which attempted to confirm these initial tests, resulted in conflicting findings.<sup>27</sup> Therefore, Sugira's studies are not conclusive as to laetrile's effectiveness.

Harold Manner, Ph.D., at Loyola University (Chicago), also claims to have achieved positive test results from a study he conducted on laetrile's effectiveness on mice with breast cancer.<sup>28</sup> Manner claims that his results are different from those of the National Cancer Institute or Sloan-Kettering because he used laetrile in combination with enzymes and vitamin A.<sup>29</sup> Scientists at Sloan-Kettering and the American Cancer Society attack this study for two reasons. First, Manner did not use enzymes alone, as a control.<sup>30</sup> Second, Manner presented his results to lay forums before submitting his findings to the scientific community for scrutiny.<sup>31</sup>

It has been suggested that scientists test laetrile's effectiveness directly on cancer patients.<sup>32</sup> These clinical tests would explore therapeutic effects of laetrile such as pain relief, mood elevation, the effect on immunity processes, and relief from the side effects of traditional therapy, which are not easily tested in animal studies.<sup>33</sup> The National Council on Drugs<sup>34</sup> and Sloan-Kettering advocate such testing.<sup>35</sup> Clinical testing raises ethical and moral issues when scien-

23. *Id.* Eleven series of experiments were conducted to determine whether laetrile has the ability to counter spontaneous breast cancer in mice.

24. Arehart-Treichel, *supra* note 8, at 94.

25. Metastasis is defined as a transfer of a disease-producing agency from an original site of disease to another part of the body, thus causing the development of a similar lesion in the new location. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1421 (P. Gov ed. 1976).

26. Arehart-Treichel, *supra* note 8, at 94.

27. *Id.* In some of the subsequent experiments conducted at Sloan-Kettering and the Catholic Medical Center, these initial results were confirmed. In several of the other studies undertaken at these institutions, however, investigators were not able to achieve such positive results. In a collaborative experiment performed by Kanematsu Sugira and Daniel Martin of the Catholic Medical Center, lung metastases occurred in 42% of treated mice, but only in 21% of the control mice.

The fact that different methods were used to evaluate the experiments probably accounts for the discrepancy in test results. Positive laetrile results occurred in macrovision or microscopic examination, while unfavorable results emerged from bioassay, a process in which the lungs of tested animals are shredded and injected into other mice. If the injection causes cancer tissues to form, then one may conclude that the original lungs contained metastases. *Id.* at 94-95.

28. Am. Med. News, September 19, 1977, at 16, col. 1.

29. *Id.*

30. *Id.* Without knowledge of the effects of enzymes alone, it is impossible to determine what laetrile's contribution is to the positive results.

31. *Id.*

32. 1977 Hearings, *supra* note 5, at 54.

33. *Id.* at 336-37 (statement by John Owen, Jr., M.D.).

34. *Id.*

35. Sloan-Kettering advocates clinical testing under strict NCI supervision aimed at central

tific evidence does not suggest that the drug will be helpful to the patient. It is of major concern whether scientists have the right to provide patients with a drug for which there is no reasonable likelihood of efficacy, thus, in effect, depriving them of other, potentially useful drugs.<sup>36</sup>

The NCI, recognizing the ethical and legal considerations raised by clinical testing, undertook a retrospective analysis of laetrile treatment.<sup>37</sup> The Institute conducted a nationwide search for documented responses to laetrile by soliciting cases from physicians, health professionals, and pro-laetrile groups. A panel of twelve oncologists analyzed sixty-seven cases which were submitted. The panel determined that patients in six cases responded to laetrile. The authors of the study found, however, that because these tests were improperly designed, no conclusions about laetrile's anti-cancer activity could be drawn.<sup>38</sup>

The NCI study illustrates that methodological problems in testing a drug make it difficult to determine the drug's effectiveness. Another problem inherent in clinical tests is the loss of objectivity in analyzing the results. Most cancer scientists do not consider subjective evaluations by cancer patients—"testimonials"—as valid clinical evidence.<sup>39</sup> They believe that laetrile's palliative effects can be achieved by any drug that the patient believes is a cure for cancer.<sup>40</sup> From a scientific point of view, therefore, such evidence cannot be used objectively to determine laetrile's efficacy.<sup>41</sup>

#### b. *Laetrile's toxicity*

A major objection to laetrile is that it contains large amounts of cyanide, which is toxic and potentially fatal to humans. Laetrile's safety, however, has been the subject of even less scientific research than has its efficacy. Studies at Sloan-Kettering and Catholic Medical Center from 1972 to 1976 showed that laetrile caused no harmful effects in mice, except when very large dosages were used.<sup>42</sup> When laetrile was administered in combination with other traditional cancer drugs, it did not alter their toxicity.<sup>43</sup>

Incidences of cyanide poisoning from laetrile have been reported only in

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questions about laetrile, such as whether it prolongs life, relieves pain, or cures cancer. *Id.* at 60 (statement by Lewis Thomas, M.D.).

36. *Id.* at 43 (statement by Donald S. Fredrickson, M.D.).

37. Ellison, Byer & Newell, *Special Report on Laetrile: The NCI Laetrile Review*, 299 *NEW ENG. J. OF MED.* 549 (1978).

38. *Id.* at 552. See also *Am. Med. News*, September 15, 1978, at 1, col. 1.

39. Arehart-Treichel, *supra* note 8, at 95.

40. *Id.* The "placebo effect," a temporary improvement in general well-being, improved appetite, and reduced pain, is the psychologically induced effect of a drug which results when an individual believes strongly enough that a treatment will help. *AMERICAN CANCER SOCIETY, CANCER QUACKERY: LAETRILE* 10 (1977).

41. Arehart-Treichel, *supra* note 8, at 95. Even if laetrile's pain relieving impact were physiologically rather than psychologically induced, this impact would not necessarily be equivalent to anti-tumor activity. *Id.*

42. *Id.* at 92.

43. *Id.* The results of this study will be published next year in the *JOURNAL OF SURGICAL ONCOLOGY*. *Id.*

non-cancer patients who have taken accidental overdoses<sup>44</sup> or in members of communities that subsist primarily on foods from which laetrile is extracted.<sup>45</sup> Moreover, no drug is absolutely safe. Most drugs, when taken in sufficient quantity, have some potential for toxicity.<sup>46</sup> Any drug that is powerful enough to do good must be powerful enough to do harm.<sup>47</sup>

## B. Legal Background

### 1. Federal Regulation

#### a. The FDA ban

The FDA's jurisdiction over laetrile and other drugs extends only to interstate distribution. Until the federal government decides to regulate the distribution of laetrile, intrastate use is largely left up to the states. The FDA's ban on laetrile from interstate commerce was effected through the Food, Drug, and Cosmetic Act.<sup>48</sup> Since 1962, section 355(b) of the Act has provided that no application to ship a new drug in interstate commerce shall be approved by the FDA unless tests show that the drug is safe under the conditions described in the labeling, and substantial evidence demonstrates that the drug is effective for such use. Though the FDA does not test new drugs itself, it does regulate the use of new drugs for testing purposes. Before the sponsor of a new drug can begin testing to determine the drug's safety and efficacy, the sponsor must submit a Notice of Claimed Investigational Exemption for a New Drug (IND) to the FDA. The FDA reviews the IND to decide whether the data submitted adequately supports the initiation of testing and assures reasonable safety to humans. If a safety problem exists, the sponsor is instructed not to proceed and is notified of the deficiencies. If approved, the IND exempts a new drug manufacturer from the federal prohibition against shipping drugs in interstate commerce, allowing the sponsor to begin testing. Then, based on data from these experiments, the FDA either approves or disapproves the drug for purposes of commercial use.<sup>49</sup>

In 1970 the McNaughton Foundation submitted its claim to test laetrile to the FDA for an exemption from the interstate commerce ban. At that time, aspects of the FDA drug approval process varied from the process described

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44. A ten month-old infant died after accidentally ingesting an unknown quantity of her father's laetrile tablets. A three year-old child who ate fifteen apricot kernels also suffered from cyanide poisoning. *Id.*

45. There have been reports of cyanide poisoning in Jamaican and Malaysian subcultures which subsist on cassava diets and in a California group which ate apricot pits as a health food. *Id.*; See also DiPalma, *supra* note 11, at 186.

46. DEPT. OF HEW, FDA REPORT—REVIEW PANEL ON NEW DRUG REGULATION 61 (May 1977) [hereinafter cited as FDA REPORT]; Dean Burk claims that laetrile is less toxic to animals than common sugar. He also asserts that aspirin is far more toxic than laetrile. Note, *supra* note 7, at 53.

47. M. MINTZ, BY PRESCRIPTION ONLY (1967), reported in FDA REPORT, *supra* note 46, at 61.

48. 21 U.S.C. § 355(a) (1976) provides that no drug may be shipped in interstate commerce unless an application filed pursuant to § 355(b) has been approved.

49. FDA REPORT, *supra* note 46, at 19-25.

above. By filing a claim for the IND, the sponsor was immediately exempted from the interstate ban and could begin testing. Sometime after receiving the sponsor's application, the FDA would review it to determine whether there were any deficiencies in the application. If deficiencies were found, the IND would be revoked and testing would be prohibited. It was at this stage in the drug approval process that the McNaughton Foundation's IND was revoked. The FDA reviewed the Foundation's application and found it deficient for two reasons. First, no evidence was submitted that would justify clinical testing, and second, the application did not include a well designed plan for testing. The FDA so advised the Foundation by letter, and gave it ten days to respond with new information that would cure the deficiency. When the Foundation failed to send any new information, the FDA revoked the IND.<sup>50</sup>

The results of this revocation are twofold. First, the denial of an IND means that laetrile continues to be banned from interstate commerce.<sup>51</sup> Second, because this ban effectively limits the ability to test laetrile to determine its safety and efficacy, drug sponsors have been unable to provide the FDA with data on which it can base approval of the drug. The FDA has merely revoked the right to test laetrile, rather than expressly approving or disapproving of the use of laetrile. This leaves the cancer patient in legal limbo.<sup>52</sup> Laetrile advocates have not pushed for FDA approval. They appear to be satisfied with intrastate use of laetrile which does not subject them to the FDA's requirements for drug approval.

*b. Federal court reaction*

Federal courts have already dealt with some of the issues raised by the laetrile controversy. One dispute entails the question whether laetrile should be classified as a "new drug" within the meaning of the Act, thus subjecting it to FDA approval. Advocates have tried to get laetrile out of the "new drug" classification. Section 321(g)(1)(B) defines "drug" as any article intended for use in the diagnosis, cure, mitigation, or treatment of a disease. The intended use determines whether something is a drug. Even commonly ingested foods are drugs if their intended use falls within this definition.<sup>53</sup>

Section 321(p) defines a new drug as any drug that is not recognized by qualified experts as safe and effective for use under the conditions described in the labeling. Section 321(p)(1) also provides a twofold "grandfather" exception to this definition: (a) if a drug was marketed before the 1962 Amendment for the same uses and was recognized by experts as safe; or (b) if a drug was marketed after the 1906 Act but before the 1938 Act and at such time its labeling contained the same representations concerning use. Therefore, laetrile does

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50. Interview with Paul Sage, *supra* note 3. Since the revocation of the McNaughton Foundation's IND, one other application submitted by a physician was also revoked for similar reasons. *Id.* See also Note, *supra* note 7, at 56.

51. *But see* Rutherford v. United States, 438 F. Supp. 1287 (W.D. Okla. 1977), where the court held that the ban unconstitutionally infringes on a cancer patient's privacy right.

52. Rutherford v. United States, 399 F. Supp. 1208, 1213 (W.D. Okla. 1975).

53. Gadler v. United States, 425 F. Supp. 244, 246 (D. Minn. 1977).

not fall into the new drug category either if experts recognize it as safe and effective, or if it is exempted under the twofold grandfather clause.<sup>54</sup>

Some federal district courts that recognize the FDA's broad discretion to determine the drug's status have deferred to the FDA's pronouncement that laetrile is a new drug.<sup>55</sup> The court in *Rutherford v. United States*,<sup>56</sup> however, held that the FDA must present substantial evidence to support the proposition that it properly classified the drug as "new".<sup>57</sup> In *Rutherford*, cancer victims and their spouses brought a class action suit seeking a court order that would stop the FDA from precluding the administration of laetrile to United States cancer patients. The court held that laetrile cannot be considered a new drug merely because the FDA said it was. An FDA determination must be supported by specific evidence that the drug is not recognized as safe and effective or not excepted under the grandfather clause.<sup>58</sup> The court held that absent an administrative record containing evidence to support its new drug determination, the FDA's determination was arbitrary and without force. The court restrained the FDA from instituting a ban that would have prevented the plaintiff from importing laetrile for personal consumption.<sup>59</sup>

In response to that decision, the FDA submitted a report to the district court which classified laetrile as a new drug.<sup>60</sup> On the basis of scientific studies, testimony from public hearings, and statements from health professionals in the record, the court ruled that the FDA's conclusion that laetrile is not "generally recognized as safe and effective" was not arbitrary and capricious. Its classification, however, of laetrile as a new drug was arbitrary and capricious because laetrile is exempt under the 1962 grandfather clause.<sup>61</sup> The court also held that the Constitution protects a right of personal privacy that the FDA had violated by denying cancer patients the right to use laetrile.<sup>62</sup>

Laetrile advocates have also challenged the constitutionality of the drug approval system. In *Gadler v. United States*,<sup>63</sup> the plaintiff, who wanted to import laetrile, objected to the FDA's drug approval process. The court held that the statutorily mandated procedure for new drug approval is a constitutionally valid exercise of Congress's power to protect the public from unsafe drugs.<sup>64</sup> "The fact that compliance might be expensive or burdensome is not

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54. 21 U.S.C. § 321(p)(1) (1976).

55. See, e.g., 425 F. Supp. at 249 (determination that laetrile is a new drug must be made by someone trained in the field, not by the courts); *Hanson v. United States*, 417 F. Supp. 30 (D. Minn.), *aff'd per curiam*, 540 F.2d 947 (8th Cir. 1976) (Congress intended that the FDA make initial determinations about new drugs).

56. 424 F. Supp. at 105.

57. *Id.* at 107.

58. *Id.*

59. *Id.* This injunction was modified to apply only to terminally ill patients in a later action, *Rutherford v. United States*, Civil No. 75-0218-B (10th Cir. 1978). See text accompanying notes 174-75 *infra*.

60. 42 Fed. Reg. 39767 (1977).

61. *Rutherford v. United States*, 438 F. Supp. 1287, 1295 (W.D. Okla. 1977).

62. *Id.* at 1298-99; see text accompanying notes 131-34 *infra*.

63. 425 F. Supp. at 244.

64. *Id.* at 248. See also *Weinberger v. Hyson, Westcott and Dunning*, 412 U.S. 609 (1973).

unfairness in the procedure, but a consequence of a reasonable Congressional scheme for the introduction of new drugs."<sup>65</sup> This process requires that the FDA, because of its special expertise, be given broad power to make a determination about a new drug's status and to approve its use.<sup>66</sup>

The court in *Gadler* also decided that it did not have jurisdiction to determine the plaintiff's right to use laetrile before the FDA made its findings.<sup>67</sup> The court held that the Food, Drug, and Cosmetic Act does not require the FDA to approve or disapprove of laetrile in the absence of a drug approval application.<sup>68</sup> However, the district court in *Rutherford*,<sup>69</sup> held that if no drug application is submitted because compliance with the scheme is too burdensome for lay people, the FDA on its own initiative should approve or disapprove of laetrile. The court therefore found jurisdiction.<sup>70</sup>

## 2. State Regulation

### a. Preemption

FDA inaction on laetrile has prompted its proponents to seek state approval for its use. This raises the problem of possible federal preemption of state regulation of laetrile. The supremacy clause,<sup>71</sup> which mandates that in certain cases federal law override conflicting state law,<sup>72</sup> applies equally to reg-

65. *Rutherford v. Am. Med. Ass'n*, 379 F.2d 641, 643 (7th Cir. 1967), cert. denied, 389 U.S. 1043 (1968). In this case the court decided a similar question with regard to Krebiozen, another alleged cancer drug.

66. 425 F. Supp. at 249.

67. *Id.* See also 21 U.S.C. § 355(h) (1976).

68. 425 F. Supp. at 248-49.

69. 399 F. Supp. 1208.

70. *Id.* at 1212. On appeal, the court held that the FDA is not compelled to pursue the new drug approval procedure in the absence of an application. However, the court affirmed the district court, reasoning that the FDA's determination that laetrile was a new drug was arbitrary and capricious because unsupported by the record. 542 F.2d 1137 (10th Cir. 1976).

71. U.S. CONST. art. VI, cl. 2. See also *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819).

72. The two tests used to determine whether a state law obstructs congressional objectives are: (1) whether there is congressional intent to occupy the field, i.e., a clear and manifest purpose that there be exclusive federal regulation, or (2) whether the state regulation directly conflicts with federal law. Note, *The Preemption Doctrine: Shifting Perspectives on Federalism and the Burger Court*, 75 *COL. L. REV.* 623, 624-26 (1975). Other objective factors besides an expression of congressional purpose may establish intent. A pervasive scheme of legislation which allows such an inference, or a field in which federal interest is so dominant that it is assumed to preclude state law, may establish intent. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

When there is no express intent to preempt, and it is unclear whether the federal and state laws conflict, special features of the federal regulatory scheme, the value of national uniformity, and the relation of the subject matter to traditional areas of state concern will determine whether a state law is preempted. Note, *Federal Preemption of State Law: The Example of Overbooking in the Airline Industry*, 74 *MICH. L. REV.* 1200, 1212 (1976). See also Hirsch, *Toward a New View of Federal Preemption*, 1972 *U. ILL. L.F.* 515, 555 (1972).

Although a state may not pass a law in an area of exclusive federal regulation, it may do so in an area where Congress has the power to displace it, but has not done so. Under this concurrent power theory, preemption occurs only when the area is such that it cannot be adequately regulated by the state. Thus framed, the question of preemption focuses not only on congressional intent, but

ulations promulgated by federal agencies.<sup>73</sup> Often, however, Congress delegates its power broadly without expressly addressing the preemption issue.<sup>74</sup> Where Congress has not indicated whether it intends to exclusively occupy the area to be regulated, state laws will not be preempted if there is a history of concurrent federal-state regulation, or if the state regulation is not inconsistent with the agency's stated policy.<sup>75</sup>

Federal activity in drug regulation is insufficient to preempt a state law that regulates the use of laetrile by its citizens. The Food, Drug, and Cosmetic Act, which prohibits interstate shipment of a non-approved drug, does not completely occupy the field of drug regulation. The FDA has taken no initiative in seeking to ban or test drugs for their safety or efficacy. Nor has Congress enacted any "anti-laetrile use" laws. Compliance with FDA standards is required only when an individual seeks to ship a drug in interstate commerce.

Regulation of public health has traditionally been left to the states. All states have regulatory agencies. These agencies are confident that courts will support their rights to impose regulations in the interest of local health and safety.<sup>76</sup> Neither Congress nor the FDA has clearly occupied the field of public health. Consequently, state laws that regulate the use of laetrile by its citizens are not likely to be preempted.

#### *b. State legislation*

As of September, 1978, seventeen states had authorized the use or manufacture of laetrile, or both.<sup>77</sup> Unlike the FDA requirement that a drug be safe and effective,<sup>78</sup> states that have approved laetrile's use only require that it be safe for use. Many of these statutes are based on the patient's freedom of choice in treatment and the doctor's right to treat his patient, subject, however, to the state's right to regulate laetrile's use. While some states do regulate the manufacture and sale of laetrile,<sup>79</sup> the major concern is that a physician receive his patient's informed consent before administering the drug. For example, Indiana has enacted a detailed informed consent law requiring that physicians inform their patients that the FDA has banned laetrile, that neither the American Medical Association nor the American Cancer Society recommend its use, and that there are medically recognized alternate treatments.<sup>80</sup>

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also on the proper division between federal and state authority and a balancing of federal and state interests. Note, *Federal Preemption of State Laws: The Effect of Regulatory Agency Attitudes on Judicial Decision Making*, 50 *IND. L.J.* 848 (1975).

73. Hirsch, *supra* note 72, at 554.

74. See Note, *Federal Preemption of State Laws: The Effect of Regulatory Agency Attitudes on Judicial Decision Making*, *supra* note 72, at 855.

75. *Id.*

76. Note, *supra* note 7, at 58.

77. See note 3 *supra*.

78. 21 U.S.C. § 355(b) (1976).

79. For example, Delaware and Nevada require that the State Board of Health adopt regulations prescribing minimum standards for manufacturing, processing, and packaging laetrile and that there be inspections of manufacturers to ascertain that they are complying with these standards. See *DEL. CODE* tit. 16, § 4903 (Supp. 1977); *NEV. REV. STAT.* § 585.495 (1977).

80. *IND. CODE ANN.* §§ 16-8-8-1 to 16-8-8-7 (Burns Supp. 1977).

California, a major participant in state laetrile litigation, has statutorily forbidden the use of any drug in the treatment of cancer that has not received prior FDA or state approval.<sup>81</sup> In August, 1977, the California State Assembly's Health Committee rejected a bill to legalize laetrile.<sup>82</sup> As a result, three California doctors recently were arrested for prescribing laetrile to cancer victims.<sup>83</sup> These physicians challenged California's law, which prevented them from prescribing laetrile for their patients, in *California v. Privitera*.<sup>84</sup> The court held that California's law banning laetrile violated the patient's right to privacy and that no compelling state interest existed to justify the state's ban on laetrile.<sup>85</sup>

### III CONSTITUTIONAL FRAMEWORK

#### A. *Fundamental Right of Privacy*

The due process clause of the fourteenth amendment guarantees that the government cannot infringe on certain fundamental rights, not specifically provided for in the Constitution, without a high level of justification.<sup>86</sup> Although the right of privacy is not specifically mentioned in the Bill of Rights, it emanates from the total constitutional scheme under which we live.<sup>87</sup> In two landmark decisions,<sup>88</sup> the Supreme Court struck down state laws which infringed on that aspect of privacy which guarantees the freedom to care for one's own health and person.<sup>89</sup>

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81. CAL. HEALTH & SAFETY CODE § 1707.1 (West 1970).

82. Am. Med. News, Aug. 22, 1977, at 3, col. 1.

83. Note, *Restrictions of Unorthodox Health Treatment in California: A Legal and Economic Analysis*, 24 U.C.L.A. L. REV. 647, 683 (1977).

84. 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (1977).

85. *Id.* See text accompanying notes 135-37 *infra*.

86. G. GUNTHER, CASES AND MATERIALS ON CONSTITUTIONAL LAW 548 (9th ed. 1975). The due process clause of the fourteenth amendment guarantees that no state shall deprive any person of life, liberty, or property without due process of law. The fourteenth amendment strikes a balance between respect for individual liberty and the demands of an organized society. *Poe v. Ullman*, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting). Although the state does have broad powers to protect public welfare, the due process clause guarantees that the state may not do so at the expense of certain individual rights. *Meyer v. Nebraska*, 262 U.S. 390 (1923). "[E]ven though the governmental purpose be legitimate . . . , that purpose cannot be pursued by means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved." *Wooley v. Maynard*, 430 U.S. 705, 716-17 (1977) (quoting *Shelton v. Tucker*, 364 U.S. 479, 488 (1960)).

87. The rights protected by substantive due process include those specifically mentioned in the Bill of Rights as well as such underlying rights as are necessary to ensure a free society. *Poe v. Ullman*, 367 U.S. 497, 540-41 (1961) (Harlan, J., dissenting). Appropriate limitations on substantive due process emerge from the teachings of history and from recognition of the basic values that uphold our society. *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977).

88. *Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

89. See text accompanying note 108 *infra*.

### 1. *Privacy and Griswold v. Connecticut*

In *Griswold v. Connecticut*,<sup>90</sup> the Court invalidated a state law that prohibited the use of contraceptives by married couples, on the ground that the law interfered with the couple's right of privacy.<sup>91</sup> Recognizing that the privacy right is not expressly provided for in the Constitution, the Court offered three alternative analyses to support its holding that the right to privacy was incorporated in the due process clause.

According to Justice Douglas, writing for the majority, there are rights in addition to the specific guarantees of the Bill of Rights that help give life and substance to the express guarantees.<sup>92</sup> The Court found that several of the enumerated rights create a zone of privacy sufficient to protect the marital relationship from unjustified state interference.<sup>93</sup>

The second mode of analysis, expressed in Justice Goldberg's concurrence, was that the ninth amendment<sup>94</sup> protects rights that are not specifically mentioned in the Constitution, but are "so rooted in the traditions and conscience of our people as to be ranked as fundamental."<sup>95</sup> The ninth amendment recognizes that, in addition to the first eight amendments, there are other fundamental rights retained by the people.<sup>96</sup> If a right cannot be denied without violating the principles of liberty and justice, then that right is fundamental.<sup>97</sup> This theory does not give unrestricted freedoms to the Court to decide cases according to its personal ideas about liberty. Specific guarantees of the Constitution provide a basis for determining which rights are fundamental. Of non-enumerated rights, only those which are analogous to the general pattern of defined rights will be protected.<sup>98</sup>

The third line of reasoning, expressed in Justice Harlan's concurrence is that the fourteenth amendment itself suffices to protect the fundamental rights which are implicit in the concept of liberty.<sup>99</sup> Liberty can only be understood as it emerges from history and tradition. By reference to his dissent in *Poe v. Ullman*,<sup>100</sup> Justice Harlan broadly defines liberty not as "a series of isolated points . . . [but rather as] a rational continuum which . . . includes . . . freedom from all substantial[ly] arbitrary impositions. . . ."<sup>101</sup> Any law which abridges a fundamental right protected by liberty under the fourteenth amendment re-

90. 381 U.S. 479.

91. *Id.*

92. *Id.* at 484.

93. *Id.* at 484-86.

94. "The enumerations in the Constitution of certain rights, shall not be construed to deny or disparage others retained by the people." U.S. CONST. amend. IX.

95. 381 U.S. at 487 (Goldberg, J., concurring) (quoting *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934)).

96. *Id.* at 488. See also Redlich, *Are There "Certain Rights . . . Retained by the People"?*, 37 N.Y.U. L. REV. 787 (1962).

97. 381 U.S. at 493 (Goldberg, J., concurring).

98. *Id.* at 493-94 (Goldberg, J., concurring); Redlich, *supra* note 96, at 812. See also Note, *On Privacy: Constitutional Protection for Personal Liberty*, 48 N.Y.U. L. REV. 670, 677-78 (1973).

99. 381 U.S. at 500 (Harlan, J., concurring).

100. 367 U.S. 497.

101. *Id.* at 543 (Harlan, J., dissenting).

quires close scrutiny and is not justified by a mere rational relation to a legitimate state purpose.<sup>102</sup>

## 2. *The Private Right to Abortion*

The second decision upholding the right of privacy as it relates to personal health decisions is *Roe v. Wade*.<sup>103</sup> In *Roe* the Court extended the right of privacy to a woman's decision whether or not to terminate her pregnancy, reasoning that the choice has great impact on her life.<sup>104</sup> In an effort to find some textual support for this right the majority relied on the liberty protected by the fourteenth amendment rather than on the other theories expressed in *Griswold*.<sup>105</sup>

The fourteenth amendment, which gains meaning from the traditions of our country,<sup>106</sup> historically has protected private decision making. The Court in *Roe* concluded that a woman's right to make the abortion decision is a privacy right protected by the fourteenth amendment.<sup>107</sup> Justice Douglas, in a concur-

102. *Id.* at 554. The Court in *Griswold* found that privacy protected the marital relationship. 381 U.S. at 485-86. In *Eisenstadt v. Baird*, 405 U.S. 438 (1972), the Court extended the right of privacy when it struck down a statute which banned the distribution of contraceptives to unmarried people. *Id.* at 454-55. The Court held that the right of privacy is not limited to the marital relationship but necessarily protects individuals as well. *Id.*; see also *Carey v. Population Services Int'l*, 431 U.S. 678 (1977), where the Court struck down a statute regulating access to contraceptives not on grounds that there is a fundamental right to access, but on grounds that access is essential to the exercise of the fundamental right to decide whether to bear a child. The government may not unjustifiably intrude on a decision that has a fundamental effect on a person's life. *Id.* at 687-88.

103. 410 U.S. 113.

104. *Id.* at 153-56.

105. Although the ninth amendment has occasionally been used to support the right of privacy, see, e.g., *Mindel v. U.S. Civil Service Comm'n*, 312 F. Supp. 485 (N.D. Calif. 1970) (termination of postal clerk because of living out of wedlock with a woman violated right to privacy guaranteed by the ninth amendment), other attempts to invoke its protection have not proven successful. See, e.g., *United States v. Warin*, 530 F.2d 103 (6th Cir.), cert. denied, 426 U.S. 948 (1976) (ninth amendment does not protect the right to possess firearms); *Cervantes v. Immigration and Naturalization Service*, 510 F.2d 89 (10th Cir. 1975) (ninth amendment cannot prevent the deportation of the alien parents of a child who is a United States citizen); *Gaspar v. Louisiana Stadium and Exposition District*, 418 F. Supp. 716 (E.D. La. 1976).

106. 410 U.S. at 169 (Stewart, J., concurring).

107. Other cases have followed *Roe* in holding that the right of privacy protects a woman's decision to have an abortion. See *Hodgson v. Lawson*, 542 F.2d 1350 (8th Cir. 1976); *Wolfe v. Schroering*, 541 F.2d 523 (6th Cir. 1976); *Doe v. Charleston Area Medical Center*, 529 F.2d 638 (4th Cir. 1975). In *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52 (1976), the Court struck down a Missouri statute regulating abortion. The Court held unconstitutional provisions concerning spousal or parental consent to abortion during the first twelve weeks of pregnancy and prohibiting the saline method of abortion after the first twelve weeks. The Court invalidated the first two requirements on the basis of *Roe v. Wade*. If, as held in *Roe*, the state cannot regulate the abortion during the first trimester, then the state cannot delegate regulatory power to anyone else. 428 U.S. at 69. When a wife and husband disagree about an abortion, the woman's decision is dispositive because the impact of the decision on her is greater than on her husband. 428 U.S. at 71. With regard to the issue of parental consent to the abortion of a pregnant child, the Court held that the child's right of privacy overrides the parent's right to withhold consent for the abortion. 428 U.S. at 74-75.

Although the Court in *Roe* held that the state may regulate abortions after the first trimester, this

ring opinion, categorized the rights which are protected by the fourteenth amendment as those which involve either (1) the freedom of choice in basic decisions of one's life respecting marriage, divorce, procreation, contraception, education, and upbringing children, or (2) freedom to care for one's own health and person, and freedom from bodily restraint or compulsion.<sup>108</sup>

### B. State Regulation of Fundamental Rights

Even in the area of fundamental rights there is some room for state regulation. In *Roe*, the Court recognized the right to privacy but added the caveat that "this right is not unqualified and must be considered against important state interests in regulation."<sup>109</sup> The individual decision is no longer protected from state intervention when the state's interest becomes compelling.<sup>110</sup>

Whether a particular law is a valid interference with individual rights depends on the nature of the right involved. When the law interferes with a freedom which is not fundamental, the law need only have a reasonable relation to a legitimate government purpose.<sup>111</sup> When fundamental rights are interfered with, however, the law will be upheld only if it is justified by a compelling state interest and is narrowly drawn to serve the legitimate interests at stake.<sup>112</sup> State interference with the right of privacy has been justified on two theories: *parens patriae* and the state police power.

#### 1. *Parens Patriae*

The doctrine of *parens patriae* recognizes the state as the ultimate guardian of citizens who are incapable of caring for their own interests.<sup>113</sup> When an individual poses a serious threat of harm to him or herself the state may confine an individual for his or her own protection<sup>114</sup> and may require compulsory treatment.<sup>115</sup> Since this doctrine permits the state to deny an individual the right to decide whether to accept or reject treatment it presumes that the indi-

does not permit the state to proscribe saline abortions during this period. In *Planned Parenthood* the Court examined the state's prohibition of saline abortions in light of medical evidence that this is the most commonly used method of abortion and results in a lower incidence of maternal mortality. From this evidence, the Court concluded that the proscription of saline abortions is an arbitrary and unreasonable regulation, designed to inhibit abortions after the first trimester. 428 U.S. at 52.

108. *Roe v. Wade*, 410 U.S. 113; *Doe v. Bolton*, 410 U.S. 179 (1973) (Douglas, J., concurring in both opinions).

109. The state has two interests in the abortion procedure: protection of the mother's health and protection of a potential life. The Court has allowed increasing state regulation at each stage of pregnancy, because as the pregnancy comes to term, the interests which the state may justifiably protect increase. 410 U.S. at 154.

110. *Id.* at 154, 165-66.

111. *Williamson v. Lee Optical Co.*, 348 U.S. 483, 488 (1955).

112. *Carey v. Population Services Int'l*, 431 U.S. 678 (1977); *Wooley v. Maynard*, 430 U.S. 705 (1977); *Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

113. *Lynch v. Baxley*, 386 F. Supp. 378, 390 (M.D. Ala. 1974). See also 72 AM. JUR. 2D, *States, Territories and Dependencies* § 1 (1974).

114. *Hawks v. Lazaro*, 202 S.E.2d 109, 123-24 (Sup. Ct. App. W. Va. 1974).

115. 386 F. Supp. at 390. This doctrine is often used to justify the involuntary commitment of mentally incompetent citizens.

vidual is incapable of managing his or her own affairs or weighing the benefits of treatment against the risks of freedom and lack of treatment.<sup>116</sup> Application of the doctrine of *parens patriae* is justified only when the state can prove that the individual is incompetent and that the state can offer treatment which has a reasonable likelihood of success.<sup>117</sup>

## 2. Police Power

The second and more common justification for state intervention where fundamental rights are involved is the police power. Acting under its police power the state may restrain an individual from engaging in an activity which affects his body, provided such behavior threatens the health, safety, or general welfare of its citizens. The major Supreme Court decision enunciating this doctrine is *Jacobson v. Massachusetts*.<sup>118</sup> In that case the Court upheld a mandatory state vaccination plan because the state interest in preventing an epidemic was sufficient to justify the restraint on individual rights.<sup>119</sup>

Since *Jacobson*, courts have found that other decisions which an individual makes concerning his body may be regulated by the state if necessary to prevent public harm. For example, it is a valid exercise of its police power for a state to require that motorcyclists wear protective headgear,<sup>120</sup> to establish hair length and other personal appearance standards for members of its police force,<sup>121</sup> to prohibit sodomy between consenting adults,<sup>122</sup> or to regulate the sale and use of habit-forming drugs.<sup>123</sup> Consequently, liberty, which includes the "freedom to care for one's health and person, freedom from bodily re-

116. *Id.* at 391.

117. 202 S.E.2d at 123-24.

118. 197 U.S. 11 (1905).

119. *Id.* See also *Zucht v. King*, 260 U.S. 174 (1922), where the Court held that a city ordinance making vaccinations a condition of school attendance was within the state's police power.

120. *Simon v. Sargent*, 346 F. Supp. 277 (D. Mass.), *aff'd*, 409 U.S. 1020 (1972) (consequences of injury caused by a motorcycle accident are not limited to the individual); *Bogue v. Faircloth*, 316 F. Supp. 486 (S.D. Fla. 1970), *appeal dismissed*, 441 F.2d 623 (5th Cir. 1971) (it is in the public's interest to have a healthy citizenry and to make the highways as safe as possible); *State v. Laitinen*, 77 Wash. 2d 130, 459 P.2d 789 (1969), *cert. denied*, 397 U.S. 1055 (1970) (regulation is a valid exercise of police power since it reduces injuries and the consequent burden on public medical, hospital, ambulance, and police services); *State v. Albertson*, 93 Idaho 640, 470 P.2d 300 (1970) (individual right of privacy is subservient to the state's interest in protecting the safety of other highway users). *But see* *State v. Betts*, 21 Ohio Misc. 175, 252 N.E.2d 866 (1969), and *People v. Fries*, 42 Ill. 2d 446, 250 N.E.2d 149 (1969) (state laws requiring motorcyclists to wear protective helmets were not a valid exercise of state police power because at issue was personal, not public, safety).

121. *Kelley v. Johnson*, 425 U.S. 238 (1976) (regulation of policemen's hair length promotes safety of persons and property which is at the core of the state's police power).

122. *Doe v. Commonwealth's Attorney for the City of Richmond*, 403 F. Supp. 1199 (E.D. Va. 1975), *aff'd*, 425 U.S. 901 (1976) (state can make sodomy a crime to promote morality and decency).

123. *Whipple v. Martinson*, 256 U.S. 41 (1921) (state may validly exercise police power to regulate the administration, sale, prescription, and use of dangerous and habit-forming drugs). *But see* *Ravin v. State*, 537 P.2d 494, 511 (Alas. 1975) (use of marijuana in the home does not cause sufficient public harm to justify infringement on the individual's right of privacy).

straint or compulsion. . . ,"<sup>124</sup> is not absolute; it is subjected to qualifications imposed for the public good.<sup>125</sup> Where fundamental rights are involved, however, the corrective legislation must be narrowly confined to the specific area of compelling state interest. Such a restriction prevents the police power from becoming "the great leveler of all constitutional rights and liberties."<sup>126</sup>

#### IV LAETRILE

##### *A. The Right to Choose Medical Treatment is a Fundamental Right*

The right of privacy guarantees that individuals should be free to make certain medical decisions.<sup>127</sup> In *Roe v. Wade* and *Griswold v. Connecticut*<sup>128</sup> the Court held that the right of privacy included certain personal rights, even though these rights were not specifically mentioned in the Constitution. This expansive view of privacy indicates that the Court would extend the right to the protection of other medical decisions as well. Not all medical decisions are included in a person's right to privacy however. The *Roe-Griswold* standard requires that autonomous, personal decisions, which have great influence on the individual's life, are protected under the right of privacy. While the personal decisions in those cases involved marriage and procreation,<sup>129</sup> the decisions were basic to the individuals' lives. The essence of privacy is that certain basic decisions about how one's life will be conducted are reserved to the individual most affected by that decision.<sup>130</sup>

For some patients, the decision to choose laetrile as an alternate form of cancer treatment is crucial to the victim's life. This choice is particularly important to the terminally ill patient who has tried other treatments without success. For those individuals, it is imperative that the right of privacy extend to protect their power to make such a fundamental decision.

##### *B. Recent Case Law*

The rights of laetrile users are now gaining the support of the courts which hear their claims. In *Rutherford v. United States*,<sup>131</sup> the court held that the

124. 410 U.S. 113; 410 U.S. at 213 (Douglas, J., concurring in both opinions).

125. *Id.*; *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905).

126. 410 U.S. 113; 410 U.S. at 216 (Douglas, J., concurring in both opinions). In deciding whether state regulation which infringes on a fundamental right is a valid exercise of its police power, courts often intervene in the legislative process to examine whether the law can be justified on the basis of available medical evidence. Courts require the state to support its regulation with evidence and will refuse to uphold the statute if evidence to the contrary is more persuasive. *See Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 78 (1976); *Roe v. Wade*, 410 U.S. at 164; *Eisenstadt v. Baird*, 405 U.S. 438, 463-64 (1972).

127. *See* text accompanying notes 90-108 *supra*.

128. 410 U.S. 113; 381 U.S. 479.

129. *See* text accompanying notes 108 *supra*.

130. Note, *supra* note 98, at 705.

131. 438 F. Supp. 1287 (W.D. Okla. 1977).

U.S. Constitution protects a right of personal privacy that includes the freedom to care for one's health and person.<sup>132</sup> By denying the cancer patient the right to choose laetrile in connection with personal health, the FDA has offended the constitutional right of privacy.<sup>133</sup> The denial of this right also has brought needless hardship and expense to cancer victims. If they travel elsewhere for treatment, they are denied close contact with their families and doctors. Or, if they are unsuccessful in their attempts to obtain laetrile, they suffer the additional mental anguish of being denied a last hope for recovery. The *Rutherford* court concluded that because this country is "committed to the principle that the individual must be given maximum latitude in determining his own personal destiny," the choice to use laetrile, "regardless of its correctness, is the sole prerogative of the person whose body is being ravaged."<sup>134</sup>

When a California physician challenged a state law that prevented physicians from prescribing laetrile for cancer patients, the court held in *California v. Privitera*<sup>135</sup> that the right of privacy included the right of cancer patients to choose or reject treatment, whether orthodox or unorthodox, accepted or unaccepted. This right is fundamental; therefore its free exercise can be impinged upon only to further a compelling state interest.<sup>136</sup> The court held that California's law infringed on the patient's right of privacy and that there is no compelling state interest sufficient to warrant this invasion.<sup>137</sup> In both cases mentioned above, the courts focused not on whether laetrile was actually an effective cancer cure, but on whether, from the victim's viewpoint, this was a decision basic to life and, therefore, protected by the right of privacy.

### C. *Compelling State Interests in Regulation*

The infringement on the fundamental right to choose laetrile is justified only by a compelling state interest. Whether the state's interest in protecting the health of its citizens is compelling enough to justify infringement on the right to choose laetrile depends on the possible harm laetrile may cause, and the validity of these harms for terminally ill cancer patients.

#### 1. *Refusing Treatment*

Some laetrile opponents believe that laetrile users are actually refusing any medical treatment for their cancers. The courts, however, have recognized that individual medical decisions are constitutionally protected,<sup>138</sup> and that legally competent adults may decide to refuse treatment.<sup>139</sup> Where courts have held

132. *Id.* at 1299.

133. *Id.* at 1301.

134. *Id.* at 1300.

135. 74 Cal. App. 3d 936 \_\_\_\_, 141 Cal. Rptr. 764, 769 (1977).

136. *Id.* at \_\_\_\_, 141 Cal. Rptr. at 777.

137. *Id.* at \_\_\_\_, 141 Cal. Rptr. at 782-83.

138. *Rutherford v. United States*, 438 F. Supp. 1287 (W.D. Okla. 1977); *Friendship Medical Center Ltd. v. Chicago Bd. of Health*, 505 F.2d 1141 (7th Cir. 1974), *cert. denied*, 420 U.S. 997 (1975); *Roe v. Wade*, 410 U.S. 113 (1973).

139. 438 F. Supp. at 1299; *Erickson v. Dilgard*, 44 Misc. 2d 27, 252 N.Y.S.2d 705, 706 (1962).

that the individual decision to refuse treatment was not protected there has been an overriding state interest to justify the infringement.<sup>140</sup> For example, the state has an overriding interest in preventing epidemics and in protecting its children from tooth decay.<sup>141</sup> Even though the state's action may force its citizens to take medication, the individual's right is not protected because the impact on the individual's life is negligible when compared to the broader state interest.<sup>142</sup>

The claim of a would-be laetrile user should be distinguished from the claims of those refusing treatment. First, laetrile users are not simply refusing treatment; instead they have found an alternate treatment that they wish to use. Second, the state laws which have, for example, forced the vaccination of children or fluoridation of water involved an organized plan of treatment. The state had a goal it wished to achieve for the common good of all its citizens. Individual rights were suppressed only when necessary to achieve this interest. When the state forces a cancer patient to submit to recognized treatment in lieu of laetrile, however, it is only legislating for the individual. The law is not part of an organized health plan enacted to serve the interests of all citizens.

## 2. Ineffective Treatment

The primary reason for banning laetrile is to protect citizens from the harms of ineffective treatment. Ineffective treatment, though harmless in itself, may become harmful if it delays effective treatment.<sup>143</sup> Laws banning laetrile protect the public from individuals who misrepresent laetrile's effectiveness and encourage cancer victims to forego approved treatments.<sup>144</sup> Knowing that a seriously ill patient is desperate for a cure, the state may protect its citizens from a less painful but also fallacious cure.<sup>145</sup> However, the strength of the argument that the state, pursuant to its police powers, may protect its citizens by denying them the right to choose laetrile, depends on the actual success of those approved treatments that are available. Only a small percentage of cancer patients respond positively to traditional treatment.<sup>146</sup> Even patients who do have success experience the great risks and debilitating side effects of such treatment.<sup>147</sup> Further, patients only turn to unconventional cures as a last re-

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140. *Jacobson v. Massachusetts*, 197 U.S. 11 (state's interest in preventing an epidemic justifies compulsory vaccinations).

141. *Minn. State Bd. of Health v. City of Brainerd*, 308 Minn. 24, 241 N.W.2d 624, *appeal dismissed*, 429 U.S. 803 (1976) (state's interest in the health of its children justifies fluoridation of public drinking water); *Paduano v. City of New York*, 45 Misc. 2d 718, 257 N.Y.S.2d 531, *aff'd*, 24 A.D.2d 437, 260 N.Y.S.2d 831 (1965), *aff'd*, 17 N.Y.2d 875, 218 N.E.2d 339, 271 N.Y.S.2d 305, *remititur amend.*, 18 N.Y.2d 721, 220 N.E.2d 803, 274 N.Y.S.2d 158, *remititur amend.*, 18 N.Y.2d 785, 221 N.E.2d 810, 275 N.Y.S.2d 270 (1966), *cert. denied*, 385 U.S. 1026 (1967) (state may fluoridate its drinking water to prevent tooth decay).

142. *Minn. State Bd. of Health v. City of Brainerd*, 308 Minn. at 38, 241 N.W.2d at 632.

143. Note, *supra* note 83, at 665.

144. *People v. Privitera*, 55 Cal. App. 3d Supp. 39, 48, 128 Cal. Rptr. 151, 157 (1976).

145. *Id.* at 52, 128 Cal. Rptr. at 159.

146. Only 15% of cancers respond well to treatment. Note, *supra* note 83, at 666.

147. *Id.*

sort, after all of the conventional treatments have proven ineffective.<sup>148</sup> For these cancer victims, resort to laetrile does not delay effective treatment, either because accepted treatment will not be effective for them, or because treatment has already been tried without success.

### 3. Toxicity

The state also has an interest in protecting its citizens from drugs that are unsafe. Laetrile opponents claim the drug is toxic and therefore harmful to the cancer patient. While there has not been much scientific research done on the effects of laetrile, the research that has been done has found laetrile safe for use.<sup>149</sup>

Although the doctrine of *parens patriae* allows the state to prevent individuals from harming themselves,<sup>150</sup> use of the doctrine to justify state intervention in the cancer patient's laetrile decision is greatly limited. First, there is no evidence that laetrile users are inflicting sufficient harm on themselves to justify intervention.<sup>151</sup> Second, cancer victims are, in many cases, capable of caring for their own interests and able to rationally weigh the risks and benefits of the various treatments.<sup>152</sup> Finally, the available accepted treatments may not have a reasonable likelihood of success in many cases.<sup>153</sup> In situations where individuals need protection because they have been unsuccessful with all accepted treatments and are willing to try anything, the treatments which the state offers will probably not have a likelihood of success. These factors greatly limit the state's ability to deprive cancer patients of the right to choose laetrile, based solely on the notion that they are harming themselves.

### 4. Economic Interests

The state also has an interest in preventing economic loss to individuals who choose ineffective treatment.<sup>154</sup> It is estimated that laetrile treatment costs an average of \$350 a week.<sup>155</sup> However, much of this cost would be eliminated if the drug were legalized and marketed. Presently, patients must either travel to Mexico for laetrile treatment or smuggle the drug into the country, paying high markup prices<sup>156</sup> and risking criminal penalties imposed for importation of illegal substances. Counterbalanced against the economic cost of laetrile is the cost to society of suppressing potentially beneficial drugs, as well as the costs of administering traditional therapy, which also involves risks and may not be successful.<sup>157</sup>

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148. *Id.*

149. Arehart-Treichel, *supra* note 8, at 92.

150. See text accompanying notes 113-17 *supra*.

151. See text accompanying notes 143-48 *supra*.

152. See *Lynch v. Baxley*, 386 F. Supp. at 390.

153. See *Hawks v. Lazaro*, 202 S.E.2d at 123.

154. Note, *supra* note 83, at 672.

155. Arehart-Treichel, *supra* note 8, at 93.

156. *Id.*

157. Note, *supra* note 83, at 674.

### 5. *Surviving Dependents*

Finally, the state has an interest in preventing the destitution of the surviving dependents of cancer patients.<sup>158</sup> When patients choose ineffective treatments, they are less productive and may not be able to support their dependents. The state has an interest in protecting the dependents from abandonment by their parents and in avoiding financial responsibility for them.<sup>159</sup> Assuming traditional therapy is effective, these state interests might validly justify restrictions on patients who are not terminally ill, and can still lead productive lives and support minor children. For the terminally ill patient, whose ability to produce is already impaired, or for the patient who has no dependents, however, these state interests do not justify denying cancer patients their choice of treatment.

#### D. *Proposals for Laetrile Regulation*

Any drug approval process must involve weighing the risks a drug poses. Safety and effectiveness are not the only factors relevant to an assessment of a drug's value. Other factors are the patient's adherence to the drugs regimen, the accessibility of proper medical facilities, the availability of other drugs, public health implications, and the patient's personal characteristics. The question is whether in light of all relevant factors the benefits justify the risks.<sup>160</sup>

When fundamental rights are involved, statutes must be narrowly drawn to express only the legitimate state interests involved.<sup>161</sup> The Court in *Griswold* and *Roe*, while recognizing some valid state objectives, held unconstitutional statutes which absolutely banned an activity when these objectives could be achieved through less restrictive means. Statutes must be carefully tailored so that they do not reach beyond the evil sought to be prevented or infringe the privacy right.<sup>162</sup> Therefore, a statute regulating laetrile must represent the least restrictive means to achieve valid state goals.

Even if laetrile is as harmful as its opponents claim, the total proscription of laetrile is unnecessarily broad when the state can serve its interests by more moderate drug regulation. Marketing and labeling controls can serve the state's interests in protecting its citizens from fallacious cures.<sup>163</sup> These controls will

158. Delgado, *Euthanasia Reconsidered—The Choice of Death as an Aspect of the Right of Privacy*, 17 ARIZ. L. REV. 474, 491 (1975).

159. *Compare* *In re Brook's Estate*, 32 Ill. 2d 361, 372-73, 205 N.E.2d 435, 442 (1965) (court did not require a Jehovah's witness to submit to treatment because no minor children would be abandoned upon death) *with* *Application of the President and Director of Georgetown College Inc.*, 331 F.2d 1000, 1008 (D.C. Cir.), *cert. denied*, 371 U.S. 978 (1964) (court held treatment required because a seven month-old child would be abandoned).

160. FDA REPORT, *supra* note 46, at 61-62.

161. *Id.* at 155.

162. *Griswold v. Connecticut*, 381 U.S. at 498 (1965) (Goldberg, J., concurring).

163. The Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977) is an example of how labeling controls can be used to protect and inform the public. Section 4(a) of the Act amends 21 U.S.C. § 343 by adding paragraph (O)(1). Section 343 (O)(1) provides that a food containing saccharin is misbranded unless its label bears the following warning: "USE OF THIS

prevent a cancer patient, who might delay effective treatment by choosing laetrile, from making this choice on the basis of false information.

Physicians who prescribe laetrile for their patients may be permitted to do so only if the patient has given an informed consent. A patient's consent to a medical treatment is an informed exercise of choice only when the patient has had an opportunity to knowledgeably evaluate all the available options and attendant risks.<sup>164</sup> The decision making process initially places responsibility on the physician to make an adequate medical disclosure to the patient.<sup>165</sup> The scope of the physician's duty to disclose is measured by the patient's need for information that is material to his decision.<sup>166</sup> The physician must reveal the inherent and potential risks of the treatment, the alternatives, if any, and the results of foregoing treatment completely.<sup>167</sup> Further, when the treatment is experimental or not recognized by the medical community, the patient must be informed of the treatment's experimental nature.<sup>168</sup> Thus, the cancer patient must know laetrile's risks and benefits, the risks and benefits of alternative treatments which are available, and that neither the American Medical Association nor the American Cancer Society recommends laetrile's use.<sup>169</sup> On the basis of disclosed information, personal values, and non-medical needs, the patient can evaluate the alternatives and make the ultimate informed decision.<sup>170</sup>

The state may also restrict the use of laetrile to a certain population of cancer patients. Such a limited population may be patients who are seriously or terminally ill patients, or patients who have no dependents. For these patients, the state interests are not compelling enough to justify infringement on their right to choose laetrile. A state legislature could conditionally legalize laetrile, subject to withdrawal should subsequent studies prove laetrile chemically dangerous.

The strength of the state interest in regulating laetrile's use varies at different stages of the patient's illness and life expectancy.<sup>171</sup> In *Roe v. Wade*,<sup>172</sup> the Court held that the state's interest in protecting the mother's health and fetus's

PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS.' "

Section 4(b) of the Act added paragraph (p)(1) to 21 U.S.C. § 343. This section requires that all retail establishments selling food which contains saccharin display a notice conveying to consumers the warning statement required by § 343 (O)(1).

164. *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). See also *Karp v. Cooley*, 493 F.2d 408 (5th Cir.), *cert. denied*, 419 U.S. 845 (1974).

165. 464 F.2d at 783; Note, *Informed Consent and the Dying Patient*, 83 YALE L.J. 1632, 1646 (1976).

166. 464 F.2d at 786; *Pegram v. Sisco*, 406 F. Supp. 776 (W.D. Ark.), *aff'd*, 547 F.2d 1172 (1976).

167. 464 F.2d at 787-88.

168. *Ahern v. Veterans Administration*, 537 F.2d 1098, 1102 (10th Cir. 1976).

169. For a state statute containing a similar informed consent requirement, see IND. CODE ANN. § 16-8-8-5 (Burns Supp. 1977) and note 80 *supra*.

170. Note, *supra* note 165, at 1646.

171. Delgado, *supra* note 158, at 492.

172. 410 U.S. 113.

life increased as the pregnancy came to term.<sup>173</sup> As the state's interest increased, so did its ability to regulate abortion procedures. Similarly, as the cancer patient advances to a terminal condition, the state's ability to protect the patient's life or to avoid destitution of dependents decreases. With this decline in the patient's physical condition, there should be a corresponding decrease in the state's power to regulate laetrile's use. The Tenth Circuit recognized this distinction in *Rutherford v. United States*.<sup>174</sup> The court believed that as to terminally-ill patients, the question of laetrile's efficacy is irrelevant. "What can 'effective' mean if the person, by all prevailing standards, and under the position the Commission takes, is going to die of cancer regardless of what may be done?"<sup>175</sup> In enacting laetrile regulations, the legislature must consider the patient's life expectancy, those medical treatments that have already been attempted, and the age and needs of the patient's dependents.<sup>176</sup>

## V

### CONCLUSION

The right to choose laetrile as a form of cancer treatment depends on the degree of constitutional protection given to this right. Under the standard of *Griswold* and *Roe*, the laetrile decision is basic to one's life and is, therefore, protected by the fundamental right of privacy. Once that right has been established as fundamental, state law may infringe on it only insofar as necessary to achieve a compelling state interest. For the cancer patient who is terminally ill, who has tried other treatments, and who has no dependents for whom he would otherwise be providing, the state interests are not sufficiently compelling to justify total proscription of laetrile. These interests can be served best by narrowly drawn regulations of laetrile that address specific areas of concern and that vary with the different needs of cancer victims.

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173. *Id.* at 162-64.

174. Civil No. 75-0218-B (10th Cir. 1978).

175. *Id.* at 5.

176. Delgado, *supra* note 158, at 493.