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The Right to Choose an Unproven Method of Treatment

V. Anthony Unan

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THE RIGHT TO CHOOSE AN UNPROVEN METHOD OF TREATMENT

I. INTRODUCTION

In the past decade there has been a growing controversy over the right of medical patients to choose treatments of unproven efficacy. A prominent focal point of the controversy was the use of laetrile\(^1\) for the treatment of cancer. Laetrile has not been approved as a new drug by the Food and Drug Administration (FDA) and therefore cannot be sold or distributed in interstate commerce.\(^2\) In addition, various state regulations have prohibited its use. For example, the California Health and Safety Code prohibits the use, sale, prescription, or distribution of laetrile within the state.\(^3\) Thus deprived of the use of laetrile, cancer patients have sought judicial pronouncement that these statutes violate

1. Laetrile, also referred to as amygdalin, aprikem, Bee 17, Vitamin B17, and nitrilo-side, is a food extract obtained from the pits of edible fruits such as peaches and apricots. Advocates of laetrile believe that cancer is the result of a deficiency that can be cured by Vitamin B17 found in food extracts. "The theory was that cancer cells were rich in the enzyme betaglucuronidase which was supposed to cleave Laetrile eventually to cyanide, thereupon killing the cancer cells, but normal cells survived since they were low in that enzyme." The normal cells contain another enzyme known as rhodanase that inactivates the cyanide, making it harmless. Thus the cyanide seeks out cancer cells, low in rhodanase, and destroys them. Price & Price, *Laetrile—An Overview*, 48 J. SCH. HEALTH 409, 409-10 (1978) [hereinafter cited as *Overview*]; Stang, *Laetrile—Freedom of Choice in Cancer Therapy*, 2:4 CANCER CONT. J. 9, 10-11 (1974) [hereinafter cited as *Freedom of Choice*].

2. An application pursuant to 21 U.S.C. § 355 (1976) must be filed and approved before a drug can be transported in interstate commerce. Since the FDA has not granted this approval to the manufacturers of laetrile, laetrile is barred from interstate commerce. The FDA, however, has now approved human testing with laetrile. *FDA Indicates It Will OK Laetrile Tests on Humans*, L.A. Times, Jan. 3, 1980, Part 1, at 1, col. 1.


3. CAL. HEALTH & SAFETY CODE § 1707.1 (West Supp. 1979) provides:
   The sale, offering for sale, . . . prescribing or administering of any drug . . . to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application . . . has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act, or (2) there has been approved an application filed with the board . . .

Since no application has been approved, the sale or distribution of laetrile is prohibited in California. Section 505 of the Federal Food, Drug, and Cosmetic Act has been repealed and the California section should be read to refer to § 355 of the Act instead.
their constitutional rights. To date, these efforts have been unsuccessful.

In People v. Privitera, the California Supreme Court decided that cancer patients have no right under either the Federal or California Constitution to use laetrile. This comment proposes that terminally ill patients should have a protected right under both the Federal and California Constitutions to use drugs of unproven efficacy, including laetrile. There are, however, factors that may justify governmental restrictions upon the use of unproven remedies by patients who are not terminally ill.

This comment first examines the constitutional right of privacy and its application to medical patients and then examines state interests in limiting the use of treatments or drugs of unproven efficacy, particularly laetrile. Finally, a proposed regulation is suggested that attempts to meet state interests without impinging unduly upon the interests of terminally ill patients.

II. RIGHT OF PRIVACY

The Supreme Court has granted special protection to those individual rights that are classified as “fundamental.” If a state law interferes with a fundamental right, a strict scrutiny test is invoked that requires a showing by the state that the law is necessary to protect a

4. 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431 (1979). A licensed physician who prescribed laetrile for the treatment of cancer was charged, as were two other defendants, with illegally importing and supplying laetrile.

5. The court held that the “right to obtain drugs of unproven efficacy is not encompassed by the right of privacy embodied in either the federal or state Constitutions.” Id. at 702, 591 P.2d at 921, 153 Cal. Rptr. at 433.

6. The U.S. Supreme Court has specifically held that there is no exemption from the FDA’s regulations over the interstate transportation of laetrile for its use by terminally ill persons. United States v. Rutherford, 442 U.S. 544, 555 (1979).

7. “Fundamental rights” are also referred to as rights that are “implicit in the concept of ordered liberty.” Palko v. Connecticut, 302 U.S. 319, 325 (1937). Rights deemed fundamental include the right of privacy, the right to interstate travel, the right to equal voting opportunity, the right to equal litigation opportunity, and the right against invidious racial discrimination. L. Tribe, American Constitutional Law 1003-11 (1978).

8. There are two major standards of review of state regulations: the strict scrutiny test and the rational basis test. When fundamental rights are effected by the particular regulation, then the strict scrutiny test is invoked, which provides that the “regulation limiting these rights may be justified only by a ‘compelling state interest,’ . . . [and] the legislative enactments must be narrowly drawn to express only the legitimate state interests at stake.” Roe v. Wade, 410 U.S. 113, 155 (1973). When the individual right involved is not fundamental, the regulation usually is reviewed by the lower rational basis standard under which the particular regulation will be upheld if there is any rational relationship between the regulation and a legitimate state interest.
compelling state interest. Unless the state sustains its burden of proof in establishing a compelling interest, the statute should be held unconstitutional.

The Court has found the right of privacy to be fundamental and thereby entitled to this special protection. The scope of activities protected by the privacy right has developed on a case-by-case basis. It is essential, therefore, to examine those activities already held to be protected in order to determine whether the right should be extended to include the right of an individual to choose an unproven medical treatment.

A. Federal Constitution

1. History of the Privacy Right

The right of privacy was first acknowledged as fundamental by the Supreme Court in *Griswold v. Connecticut.* Invoking the strict scrutiny standard, the Court found a Connecticut statute, which prohibited the use of contraceptives, unconstitutional on the basis that it impinged upon the "privacy surrounding the marriage relationship." In *Eisenstadt v. Baird,* the Court shifted the focus of the privacy right from the protection of a relationship to the protection of the rights of individuals. The Court struck down a Massachusetts statute prohibiting the disbursement of contraceptives to unmarried individuals, reasoning that the "right of privacy . . . is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

9. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965). Although the right of privacy is not expressly protected by the Bill of Rights, the Supreme Court found it to be within the penumbral rights of the first eight amendments. *Id.* "Justice Douglas' argument [in the majority opinion] seems to go something like this: since the Constitution, in various 'specifics' of the Bill of Rights and in their penumbra, protects rights which partake of privacy, it protects other aspects of privacy as well, indeed it recognizes a general, complete right of privacy. And since the right emanates from specific fundamental rights, it too is 'fundamental' . . . ." Henkin, *Privacy and Autonomy*, 74 COLUM. L. REV. 1410, 1421 (1974). In concurring opinions in *Griswold*, Justice Goldberg anchored the privacy right to the ninth amendment, 381 U.S. at 487 (Goldberg, J., concurring), while Justice Harlan anchored it to the fourteenth amendment, *id.* at 500 (Harlan, J., concurring).

10. 381 U.S. 479 (1965).

11. *Id.* at 485-86.


13. *Id.* at 453. The Court held that the state statute violated "the rights of single persons under the Equal Protection Clause of the Fourteenth Amendment." *Id.* at 443. "If under *Griswold* the distribution of contraceptives to married persons cannot be prohibited, a ban on distribution to unmarried persons would be equally impermissible." *Id.* at 453.
Still within the context of procreation, the Court in *Roe v. Wade*, further developed the privacy right to include a woman's decision to terminate her pregnancy. The Court justified the expansion of the right on the basis of the significant impact on the lifestyle of the woman if she were denied the choice to have an abortion. However, the Court stated that its expansion of the right did not create an "unlimited right to do with one's body as one pleases." It recognized that there may be state interests that justify regulation of some aspects of activities protected by the right.

The most comprehensive definition of the privacy right appears in dicta in *Whalen v. Roe*. The Court stated that there are two types of interests embraced within the right to "privacy": an "individual interest in avoiding disclosure of personal matters, and . . . the interest in independence in making certain kinds of important decisions." Thus, the Court has expanded the privacy right from protection of a particular relationship or activity to protection of the individual's right to make important decisions.

15. "This right of privacy . . . is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." *Id.* at 153.
16. The Court mentioned specific detrimental effects on the pregnant woman such as the medical harm in early pregnancy, the distressful life of maternity, psychological harm, taxation of the mother's physical health by caring for a child, and the possible distress in raising an unwanted child in a home psychologically unable to care for it. *Id.*
17. *Id.* at 154.
18. *Id.* at 177-78. The Court decided that there are two compelling state interests justifying some regulation of the right to have an abortion: protection of the health of the mother and protection of potential life. Using an analysis that is analogous to that provided herein for resolution of the laetrile dispute, see notes 102-105 *infra*, the Court allowed increasing state regulation as the pregnancy progressed:

(a) For the stage prior to approximately the end of the first trimester, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician.
(b) For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health.
(c) For the stage subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.

*Id.* at 164-65.
20. *Id.* at 599-600. The Court upheld against challenge a New York statute requiring a computerized record of certain prescription drugs, concluding that the impact of the records on the reputation and independence of patients was not sufficient to constitute an invasion of any right or liberty protected by the Constitution. *Id.* at 603.
2. Right To Refuse Medical Treatment

The right to decline medical treatment originally arose in the context of religious objections to blood transfusions and operations. Later, cases extended the right to refuse medical treatment on bases other than first amendment protection of religion, including the basis of the right to privacy. The right to refuse medical treatment is not, however, absolute. Generally, courts have considered two factors when determining whether the right should be recognized in a particular case: whether the patient has minor children who would become wards of the state and whether public health would be endangered if the patient refused treatment. When neither of these dangers exist, the courts have typically recognized the right.

In re President and Directors of Georgetown College, Inc. is a prominent example of a court's refusal to allow a patient with a minor child to decline medical treatment. Because the patient was the mother of a seven-month old child, the court refused to allow her to decline blood transfusions despite her religious objections. In Jacobson v. Massachusetts, the Supreme Court acknowledged "the inherent right of every Freeman to care for his own body and health," but it did not permit Jacobson to refuse vaccination for smallpox because of the dan-

21. The cases in this area primarily have concerned the right of a Jehovah's Witness to refuse blood transfusions. See Cantor, A Patient's Decision To Decline Life-Saving Medical Treatment: Bodily Integrity Versus the Preservation of Life, 26 Rutgers L. Rev. 228, 230-36 (1973).

22. See text accompanying notes 35-38 infra.


24. Jacobson v. Massachusetts, 197 U.S. 11 (1904) (the state's interest in preventing epidemics overrides the individual's right to refuse vaccination).

25. See In re Melideo, 88 Misc. 2d 974, 390 N.Y.S.2d 523 (1976) (a competent patient who is not pregnant and has no children has the right to refuse blood transfusions); Aste v. Brooks, 32 Ill. 2d 361, 373, 205 N.E.2d 435, 440 (1965) (although incompetent at the time of the court order, patient had made known her religious beliefs to her physician for the past two years and had no minor children). Under current analysis, these two factors would be referred to as compelling state interests.


27. Id. at 1008. The court reasoned that the mother of a seven-month old child has a responsibility to take care of the child. "Thus, the people have an interest in preserving the life of this mother." Id. The judge considered four factors: (1) the patient had an infant child, (2) she did not want to die, (3) "a life hung in the balance," and (4) the patient was so physically weak that she could not make a rational decision for herself. Id. at 1008-09. See also United States v. George, 239 F. Supp. 752 (D. Conn. 1965).


29. Id. at 26.
ger to the public from a possible epidemic.\textsuperscript{30} The Court thus acknowledged that the protection of public health can outweigh an individual's right to decline treatment.

A competent adult, however, who does not have a dependent child and does not pose a danger to public health, may refuse medical care even if so doing is substantially certain to result in his death.\textsuperscript{31} In In re \textit{Maida Yetter},\textsuperscript{32} a patient wished to refuse surgery and the court concluded that the "right of privacy includes a right to die with which the State should not interfere where there are no minor or unborn children and no clear and present danger to public health, welfare or morals."\textsuperscript{33}

In the recent controversial case of In re \textit{Quinlan},\textsuperscript{34} the New Jersey Supreme Court presumed that the constitutional right of privacy is "broad enough to encompass a patient's decision to decline medical treatment."\textsuperscript{35} The court concluded that the state's interest, the preservation of human life, and the physician's right to use his best judgment in administering treatment,\textsuperscript{36} are overcome by the individual's rights when there is no chance of his recovering.\textsuperscript{37} The court reasoned that the "State's interest weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims."\textsuperscript{38}

The right recognized in \textit{Quinlan} is protected in California by the Natural Death Act.\textsuperscript{39} According to the Act, "[a]ny adult may execute a directive directing the withholding or withdrawal of life sustaining pro-

\textsuperscript{30} \textit{Id.} at 37.
\textsuperscript{31} The New York Supreme Court held that an adult patient has the right to refuse blood transfusions despite medical opinion that "the patient's decision not to accept blood is just about the taking of his own life." Erickson v. Dilgard, 44 Misc. 2d 27, 28, 252 N.Y.S.2d 705, 706 (1962) (special term).
\textsuperscript{33} \textit{Id.} at 623.
\textsuperscript{35} 70 N.J. at 40, 355 A.2d at 663.
\textsuperscript{36} \textit{Id.}
\textsuperscript{37} \textit{Id.} at 41, 355 A.2d at 664.
\textsuperscript{38} \textit{Id.} Similar to \textit{Roe}, the New Jersey court recognized a change in the state's interests as the health of the patient changes. See note 18 supra.
The legislature recognized that: (1) "adult persons have the fundamental right to control the decisions relating to the rendering of their own medical care"; and (2) "prolongation of life for persons with a terminal condition may cause loss of patient dignity and unnecessary pain and suffering while providing nothing medically necessary." This enactment reflects the conclusion in Quinlan that "[u]ltimately there comes a point at which the individual's rights overcome the State interest." If the courts and legislature recognize a right to refuse treatment when in some instances such treatment would save life, then they likewise should recognize a patient's right to choose an unproven treatment that may preserve his life.

3. The Right To Choose an Unproven Medical Treatment

In order to give any significant protection to the right to choose an unproven treatment, the right must be characterized as fundamental, i.e., within the purview of the privacy right. In People v. Privitera, the California Supreme Court held that an individual's decision regarding medical treatment is not protected by the right of privacy, reasoning that the United States Supreme Court limited the right to "important decisions" involving "matters relating to marriage, procreation, contraception, family relationships, and child rearing and education." The Court in Whalen v. Roe, however, suggested that the decision to acquire and use medication is an important decision that may fall within the protection of the right of privacy. In addition, when determining whether a right is fundamental, the Court considers the impact of the decision on the lifestyle of the individual. The deci-
sion of a patient to use a treatment of unknown efficacy can have a significant impact on his lifestyle, suggesting that such a decision should be included within the privacy right.

Griswold v. Connecticut and Roe v. Wade are leading examples of the Court's emphasis on the degree of intrusion into the individual's lifestyle when determining the fundamental nature of the right involved. In Griswold, the state law forbidding the use of contraceptives had a "maximum destructive impact" upon the marital relationship. The enforcement of the state regulation would have required the "police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives." This severe governmental invasion into the lives of married couples led the Court to conclude that a couple's right to use contraceptives is fundamental. The effect of the state regulation on the individual's lifestyle played an important role when the Court decided in Wade that the right to have an abortion is fundamental. The Court mentioned specific detrimental effects on the pregnant woman, such as medical harm in early pregnancy, taxation of the mother's physical health by caring for a child, and the possible distress in raising an unwanted child.

The severity of the impact resulting from a state's prohibition on the use of unproven remedies varies with the severity of the illness. A prohibition on using unproven remedies usually will not have a particularly severe impact on non-terminal patients who retain a chance of recovery from orthodox treatments. To deny a terminal patient his last chance of recovery, however, results in a "maximum destructive impact" and the right to choose a treatment of unproven efficacy

48. 381 U.S. 479 (1965).
50. 381 U.S. at 485.
51. Id.
52. Id.
53. 410 U.S. 113 (1973). See also Planned Parenthood v. Danforth, 428 U.S. 52, 79 (1976) (state law prohibiting a particular technique of abortion held invalid because of its inhibiting effect upon the exercise of the individual's abortion right). But see Fitzgerald v. Porter Mem. Hosp., 523 F.2d 716 (7th Cir. 1975), cert. denied, 425 U.S. 916 (1976) (the decision regarding the method of childbirth held to be of less importance to married couples than the question of whether the child shall be born).
54. 410 U.S. at 153.
55. Since there exist remedies proven to be effective, the deprivation of the unproven remedy does not result in a severe enough impact. See text accompanying notes 87-96 infra.
should therefore be given protection. Chief Justice Bird, in her dissent in Privitera, stated that "[f]rom the terminal patient's viewpoint a new depth of inhumanity is reached by a broad sweep of . . . [this California] law." \(^{57}\)

There is no basis in logic for refusing to recognize the right to choose an unproven remedy while at the same time protecting a patient's right to refuse proven remedies. In Erickson v. Dilgard,\(^ {58}\) the court recognized the right to refuse treatment on the basis that it is the patient who is the subject of the decision and, therefore, he should have the final say.\(^ {59}\) It is ironic that the courts protect the right to refuse medical treatment when in some instances such treatment would save life but refuse to protect the right of a terminally ill patient to accept treatment of unknown efficacy as a last resort to preserve life. The decision to live should be considered more important than the decision to die; for courts to protect the latter but not the former is more than inconsistent, it is absurd.

Thus, recognizing a right of terminally ill patients to choose an unproven remedy would be a logical progression from recognizing the right to refuse treatment, as well as an appropriate expansion of the privacy doctrine. Once the right is recognized as fundamental, the state must prove a compelling interest to justify any infringement upon it.

B. State Constitution

While states are required to protect rights guaranteed by the Federal Constitution, they may also grant greater protection. If the right to choose an unproven treatment is within the purview of the federal right of privacy,\(^ {60}\) then state laws must not impinge upon the right in the absence of a compelling state interest. Even if this right is not protected under the Federal Constitution, the state may create an independent right of privacy and give to it a broader scope of protection than that already provided by the federal privacy right.

In California, the state constitution was amended by the voters to expressly protect the right of privacy.\(^ {61}\) It now reads: "All people are by nature free and independent and have inalienable rights. Among

\(^{57}\) 23 Cal. 3d at 740, 591 P.2d at 946, 153 Cal. Rptr. at 458 (Bird, C.J., dissenting).
\(^{58}\) 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962).
\(^{59}\) Id. at 28, 252 N.Y.S.2d at 706. Consistent with Erickson, Professor Gerety stated that "if we don't control our bodies, what do we control? — and who are we? The body is the necessary condition of both identity and autonomy." Gerety, Redefining Privacy, 12 HARV. C.R.-C.L. REV. 233, 266 n.119 (1977).
\(^{60}\) See text accompanying notes 47-54 supra.
\(^{61}\) CAL. CONST. art. I, § 1.
these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy.” Dispute, however, has arisen over the scope of the protection created by this language. In Privitera, the California Supreme Court stated that the purpose of the provision is to protect against surveillance and data collecting, basing its conclusion on a prior case involving these activities, White v. Davis, and the amendment’s election brochure. An examination, however, of both the White opinion and the election brochure demonstrates that the right of privacy created by the California Constitution has a much broader scope.

While the California Supreme Court in White found that “the moving force behind the new constitutional provision was a more focused privacy concern,” it stated that “the full contours of the new constitutional provision have as yet not even tentatively been sketched,” and it intimated “no opinion as to the resolution of the ultimate constitutional question.” Therefore, the White court merely addressed one facet of the new privacy right, data gathering and surveillance, but did not intend its conclusion to be dispositive of the full scope of the provision.

A recognized method of construing a constitutional amendment approved by a vote of the people is to look to the statements of the election brochure. The election brochure for this constitutional amendment provides:

“The right of privacy is the right to be left alone. It is a fundamental and compelling interest. It protects our homes, our families, our thoughts, our emotions, our expressions, our personalities, our freedom of communion, and our freedom to associate with the people we choose.

. . . .

The right of privacy is an important American heritage and essential to the fundamental rights guaranteed by the First, Third, Fourth, Fifth and Ninth Amendments to the U.S. Constitution. This right should be abridged only when

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62. Id. (emphasis added).
63. 13 Cal. 3d 757, 533 P.2d 222, 120 Cal. Rptr. 94 (1975).
64. 23 Cal. 3d at 709-10, 591 P.2d at 926, 153 Cal. Rptr. at 438. See text accompanying note 69 infra for quotation from brochure.
65. 13 Cal. 3d at 774, 533 P.2d at 233, 120 Cal. Rptr. at 106.
66. Id. at 773, 533 P.2d at 233, 120 Cal. Rptr. at 105.
67. Id. at 776, 533 P.2d at 235, 120 Cal. Rptr. at 107.
68. Id. at 775 n.11, 533 P.2d at 234 n.11, 120 Cal. Rptr. at 106 n.11.
Based upon the express language of the brochure, the new constitutional provision was intended to shield against more than surveillance and data collecting; it was meant to protect "our thoughts, our emotions, our expressions, [and] our personalities." As stated in *White*, this encompasses an "enormously broad and diverse field of personal action and belief." Therefore, contrary to the holding in *Privitera*, the California right of privacy at its inception seems to have been intended to provide similar but broader protection than does the federal privacy right and could be reasonably interpreted as including the right to choose treatments of unproven efficacy.

### III. State Interests

A statute that impinges upon a fundamental right is constitutional only if it is narrowly drawn to serve a compelling state interest. The principal state interest served by regulating unproven drugs is the protection of the health and welfare of the state's inhabitants. Using a rational basis standard, the court in *Privitera* concluded that the state's interest in public health bears a reasonable relationship to the statute that prohibits the use of laetrile. An examination of this interest, however, demonstrates that it is not sufficiently compelling to warrant an absolute prohibition of the drug.

#### A. Protection of Health and Welfare

*Roe v. Wade* is a leading example of the analysis the Court uses to determine the sufficiency of a state's interest in the protection of a person's health when a statute is challenged as impinging upon a fundamental right to choose a medical procedure. In *Wade*, the Court held that no compelling state interest exists until after the end of the first trimester of pregnancy, at which point the risk of mortality from the abortion procedure is higher than at normal childbirth.
Court basically used a risk/benefit analysis. The conclusion seems to be that there is no compelling state interest in the protection of an individual's health until it can be shown that the patient's health is benefitted more by the state's alternative than by the treatment chosen by the patient. Applying this approach to cancer patients, whether or not there exists a compelling state interest can be determined by analyzing the risk/benefit ratio of the orthodox treatments and treatments of unproven efficacy.

Orthodox treatments are currently successful fifty percent of the time in curing fifteen of the one hundred ascertained types of cancer for five years. This amounts to an overall success rate of 7.5%. Because there is no indication of more successful cures in the near future, the plight of the cancer patient appears dim.

Currently, chemotherapy, radiation, and surgery, the three primary methods of treatment, have a low rate of success and present a high risk of harm to the patient. One commentator admits that "toxic chemotherapy is much more a guess than a therapeutic certainty in the majority of cancer cases." Chemotherapy is known to eradicate only two types of cancer. Furthermore, chemotherapy results in various side effects and, in some instances, death. Some of the milder effects include nausea, vomiting, diarrhea, infections, hemorrhage, cramps, diminished appetite, and loss of hair. More seriously, one study indicates that there is a death rate of ten percent from chemotherapy.

For a detailed analysis of the risks and benefits inherent in drug regulation, see W. Ross, The Life/Death Ratio—Benefits and Risks in Modern Medicines (1977) [hereinafter cited as Life/Death]. Freedom of Choice, supra note 1, at 10. Each year cancer is the cause of 350,000 deaths. It is estimated that 50 million people will contract the disease in the future. Id. Id.

80. James Watson, Nobel Prize winning biologist, stated, "While . . . [many people are] being told about cancer cures, the cure rate has improved only about one per cent." Cancer Program a Sham, Nobel Laureate Asserts, 4:5 Cancer Cont. J. 37, 37 (1976).


83. Burkitt's tumor and placental choriocarcinoma are the only types of cancer that chemotherapy is able to eradicate. Id. at 238. See also The Myth of Proven Remedies—"A Very Grim Picture," 1:1 Cancer Cont. J. 6, 7 (1973) [hereinafter cited as Grim Picture].

84. Serious side effects occur with chemotherapy because of the drug's imperfect selective destruction, which causes damage to normal tissues. "An evaluation of the worth of any chemotherapeutic regimen must be analyzed as cost versus benefit, in which benefit is tumor regression and the cost is host toxicity." Friedman, Serious Toxicities Associated with Chemotherapy, 5 Seminars in Oncology 193, 193 (1978). Freedom of Choice, supra note 1, at 10; Chemotherapy, supra note 81, at 1117.

85. Freedom of Choice, supra note 1, at 10.
Treatment by use of radiation therapy does not paint a brighter picture. Although it has been in extensive use for decades, "it is still not possible to prove an unequivocal clinical benefit."\textsuperscript{87} Radiation therapy proves effective in curing or controlling a localized tumor but has failed, with only rare exception, to control or cure a metastatic type of cancer.\textsuperscript{88} The evaluation of clinical evidence by one commentator is that "no increase in survival has been achieved by the addition of irradiation."\textsuperscript{89}

Similarly, surgery has not proven very effective in halting cancer. As with radiation therapy, surgery is effective in the cure and control of a localized tumor, but has proved useless, with rare exceptions, in the treatment of a metastatic cancer.\textsuperscript{90} Yet the mortality risk of surgery has been estimated by some at 20,000 to 30,000 deaths in nearly 2,000,000 procedures per year.\textsuperscript{91} Thus, not only do the three orthodox methods of treatment have low rates of success, but each involves serious risks to the patient's health.

The benefits and risks of laetrile, as of all unproven drugs, are still in dispute. Many opponents of the drug claim that it is toxic, causing cyanide poisoning.\textsuperscript{92} A few fatalities allegedly caused by excessive consumption of laetrile have been reported;\textsuperscript{93} however, the National Cancer Institute (NCI), at the request of the FDA, conducted toxicity tests on laetrile and concluded that there are no ill effects from its supervised

\textsuperscript{87.} Grim Picture, supra note 83, at 6.  
\textsuperscript{88.} Chemotherapy, supra note 81, at 1117.  
\textsuperscript{89.} Grim Picture, supra note 83, at 7.  
\textsuperscript{90.} Chemotherapy, supra note 81, at 1117.  
\textsuperscript{91.} LIFE/DEATH, supra note 79, at 7. In 1975, it was estimated that 250,000 Americans died during or immediately after surgery. Incompetent Surgery Is Found Not Isolated, N.Y. Times, Jan. 28, 1976, § 1, at 1, col. 6. The degree of risk (the percentage of fatalities) permitted for surgery, which is merely life-improving and not life-saving, is 1 to 1.5%. The risk of fatalities for a life-saving drug, however, must be .0005 to .002% or less before the drug is permitted to enter the market. "Thus, the degree of risk acceptable in a life-saving drug is only a tiny fraction of what is acceptable in life-improving surgery." LIFE/DEATH, supra note 77, at 8-9.  
use.\textsuperscript{94} The NCI results removed "the last remaining obstacle to beginning laetrile trials on humans."\textsuperscript{95} One certified toxicologist stated that he has "yet to see a single, bona fide, clearly scientific case of amygdalin poisoning."\textsuperscript{96} It should be borne in mind, however, that "there is no such thing as a completely safe and effective medicine."\textsuperscript{97} For example, if aspirin were only now to be released, it is doubtful that it could pass the FDA's standards on toxicity.\textsuperscript{98} It therefore seems that the better view is to weigh the side effects and possible risks of a drug against its benefits, rather than totally prohibiting the drug because of its possible risks.\textsuperscript{99} Although laetrile, like the orthodox treatments, has yet to be proven completely effective, studies conducted with animals and humans have demonstrated some success.\textsuperscript{100} In addition, some patients using laetrile experience a relief from pain, improvement in appetite, and a gain in weight.\textsuperscript{101} These benefits alone are a refreshing change for the cancer-ridden patient.

Given the state of the art of cancer therapy, is governmental prohibition of laetrile, which in effect compels the use of orthodox treatment, really promoting public health?\textsuperscript{102} The answer lies in distinguishing the non-terminal patient for whom the orthodox treatments may be ef-

\begin{itemize}
\item \textsuperscript{94} FDA Indicates It Will OK Laetrile Tests on Humans, L.A. Times, Jan. 2, 1980, Part I, at 1, col. 1.
\item \textsuperscript{95} Id.
\item \textsuperscript{96} Toxicologist Blasts FDA on Laetrile Toxicity, 5:3 CANCER CONT. J. 138 (1977).
\item \textsuperscript{97} Life/Death, supra note 77, at 9 (quoting Dunlop, The Problem of the Safety of Drugs in Britain, 23:2 SAETRYKK AV FORMAKOTERAPI at 34 (1967)).
\item \textsuperscript{98} Id. at 56. Aspirin can cause asthma, hypersensitivity, and even death to some persons after the consumption of a single tablet. Id. Also, penicillin, currently a very accepted drug, could not even be tested on humans under present regulations due to its toxicity. Id. at 53.
\item \textsuperscript{99} It is impossible to have effective drugs if they are required to be totally safe. A physician must judge the use of the drug by its benefits and risks. Id. at x.
\item \textsuperscript{100} Morrone, Chemotherapy of Inoperable Cancer—Preliminary Report of 10 Cases Treated with Laetrile, 20 EXP. MED. & SURGERY 299 (1962) (laetrile used on 10 cases of inoperable cancer resulted in relief of pain, improved appetite, and reduction of adenopathy); Navarro, Laetrile Therapy in Cancer, 4 PHILIPPINE J. OF CANCER 204 (1962) (illustrative cases of relief from cancer following large doses of laetrile); Brown & Mortimer, Remission of Canine Squamous Cell Carcinoma After Nitrosamide Therapy, 71 VET. MED. & SMALL ANIMAL CLINICIAN 1561 (1976) (apparently successful use of laetrile in the treatment of squamous cell carcinoma in a dog).
\item \textsuperscript{101} See note 100 supra.
\item \textsuperscript{102} Stated more explicitly:
\begin{itemize}
\item The real sufferer in all this is the public which has little voice or influence in these matters. It is always told that it is being protected—but from what? Should it be guarded . . . from potent drugs . . . that may control or cure its diseases?
\item Or are the real dangers the degenerative, malignant or parasitical diseases which, without new drugs, are likely to cripple or kill them?
\end{itemize}
\end{itemize}

Life/Death, supra note 77, at xiv.
fective from the terminal patient who has exhausted conventional treatments with no success.

The FDA argues that the approval of an unproven drug would cause patients to delay using possibly effective orthodox treatments. This argument could be valid only with reference to non-terminal patients. If a patient is afflicted with one of the fifteen types of cancer that can be controlled, the risks involved in using an unproven treatment may be greater than the benefits from conventional treatments. Therefore, under the *Wade* analysis, there may be a compelling state interest in protecting the health of the non-terminal patient. If, however, a patient’s condition is terminal and therefore orthodox treatments are of no avail, the risks in using unproven treatments are appreciably outweighed by the possible benefit from the treatment. At the point that a patient’s condition becomes terminal, the “interest of the state in protecting the individual from an inherently hazardous procedure . . . has largely disappeared.”

If a terminal patient chooses laetrile with full knowledge that its effectiveness is unproven, the risks he takes are no greater than other self-assumed risks that the state permits. The state allows such “risk-taking” activities as smoking, drinking alcohol, mountain climbing, driving an automobile without a seatbelt, and riding a motorcycle without a helmet.

The state’s interest in the health of its inhabitants is not compelling when the patient’s condition becomes terminal. At early discovery of the illness, the state may require the use of orthodox treatments; however, when the condition becomes terminal, the individual’s right to use treatments of unproven efficacy should not be prohibited by the state.

### B. Economic Interests

Although not referred to as a compelling state interest, the court in *Privitera* stated that there is a legitimate state interest in protecting the economic savings of individuals and families. Economic interests

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103. People v. Privitera, 23 Cal. 3d at 705-06, 591 P.2d at 923-24, 153 Cal. Rptr. at 435-36.
104. Roe v. Wade, 410 U.S. at 149.
105. L. Tribe, *American Constitutional Law* 938 (1978). The risks associated with cigarettes and alcohol are severe. Although the benefits of smoking are small (if any), cigarettes are the cause of 300,000 premature deaths a year, 77 million man-days lost from work, and an economic cost of 20 billion dollars a year. *Life/Death*, *supra* note 77, at 6. The social costs of alcohol include automobile accidents, alcoholism, and industrial accidents. The economic costs are 15 billion dollars a year. *Id.* at 5.
106. 23 Cal. 3d at 705-06, 591 P.2d at 923-24, 153 Cal. Rptr. at 435-36 (citing *Cal. Health & Safety Code* § 1700 (West 1979)).
also have been a major focus of many laetrile opponents.107 The cost of unproven drugs, however, must be compared to the cost of orthodox treatments and counterbalanced against the overall economic loss resulting from the regulation of unproven drugs.

Orthodox treatments for the cure of cancer are expensive. It has been estimated that the median cost for conventional treatment is $19,000 per patient.108 Furthermore, the high incidents of fatalities from orthodox treatments result in an overall morbidity cost to individual families of 3.5 million dollars per year.109 A second consideration should be the social-economic loss incurred in regulating unproven drugs. One study estimated a total loss of 250-350 million dollars per year from the regulation of unproven drugs.110 These figures represent a severe cost to the public, caused by the stringent requirements of the FDA regulations.

Government prohibition has also caused the price of laetrile to increase substantially. There is an average mark up of 600% on the cost of laetrile in the United States over the cost in Mexico.111 In Mexico, the price of tablets ranges from 65 cents to $1.00 and injections range from $6.00 to $9.00 per 3-gram ampule.112 A cancer patient is forced to either pay the expense of traveling to Mexico or purchase laetrile at inflated prices within the United States. Thus, the fact that laetrile is illegal throughout most of the United States is the reason for its high cost to the patient.

The prohibition of laetrile has not protected the economic interests of patients seeking to use it, nor has the state been successful in guarding against extensive economic loss due to the high cost of orthodox treatments. A state's interest in protecting patients from economic loss probably cannot ever be considered a "compelling interest" and certainly is not sufficient in this instance to justify a state's impingement upon a patient's right to use laetrile.

107. See Freedom of Choice, supra note 1, at 16; Overview, supra note 1, at 413.
108. Overview, supra note 1, at 413.
110. A study by Sam Peltzman balanced out the risk/benefit ratio of the 1962 drug amendments in the following economic terms:

Loss of $300,000,000 to $400,000,000 a year in missed benefits from the reduced flow of useful new drugs.
Gain of about $100,000,000 in money not spent on presumably ineffective drugs, barred by the new law.
Loss of about $59,000,000 a year because of higher prices paid for drugs, the result of lessened competition.

Life/Death, supra note 77, at 103.
IV. PROPOSED REGULATION

When a statute regulates a fundamental right, it must be narrowly drafted to protect only the state's legitimate, compelling interests. By tailoring the statute to protect only such state interests, the infringement upon the right of the individual may be avoided or minimized. Although there may exist a compelling state interest in the protection of a non-terminal patient's health, the regulation of drugs of unproven efficacy can be accomplished by less restrictive means than the present absolute prohibition.

The state's interest diminishes as the individual's health deteriorates, and when the individual's condition becomes terminal, his right to choose an unproven treatment should not be infringed upon by state regulation. There is some difficulty, however, in deciding at which point a patient's condition is "terminal." The Court in United States v. Rutherford recognized that "with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect." The Court faced a similar obstacle in Wade when attempting to define "viability." Unlike Rutherford, the Court in Wade overcame the difficulty in defining this point by recognizing that it is a matter of medical judgment, skill, and technical ability. Similarly, "terminal" can be determined adequately on a case-by-case basis by a licensed physician.

A state's regulation of laetrile and other treatments of unproven efficacy can be tailored to protect the state's interest in the non-terminal patient's health and yet not infringe upon a terminally ill patient's use of the treatment. The Wade Court achieved a similar result by increasing the state's power to regulate and decreasing the individual's right to choose an abortion as the pregnancy continues. Analogously, at the early stages of cancer, the state's interests may be sufficiently compelling to require the use of orthodox treatments, but when the patient's

115. Id. at 556.
116. Viability is that point of fetal development when the unborn child is able to live indefinitely outside the womb by natural or artificial life support systems. 410 U.S. at 160.
117. Id. at 163; Planned Parenthood v. Danforth, 428 U.S. 52, 61 (1976).
118. The court in Quinlan, when deciding that life support systems may be discontinued in some instances, applied the term "terminal" and implied that its decision may be applicable to other medical decisions regarding terminal conditions. 70 N.J. at 54, 355 A.2d at 671. Also the California Natural Death Act requires a determination of when a patient's condition is "terminal." See notes 43-45 supra.
119. The Court divided a woman's pregnancy into trimesters. At each trimester, the individual's rights and the state's interests vary. See note 18 supra.
condition becomes terminal, the right to choose unproven treatments should be restricted by only minimal state interference.

An effective alternative to total prohibition was introduced in the California Senate in 1977. A Senate Bill that would have legalized laetrile for all patients was defeated; its author, Senator Campbell, had proposed an amendment whereby terminally ill patients could use laetrile. Pursuant to the proposed amendment, if two physicians certified in writing "that the patient has terminal cancer and that the patient has requested laetrile and either (a) the patient is currently within a conventional prescribed mode of treatment or (b) conventional treatment would not be of benefit because of advanced progress of the disease" the patient could use laetrile if informed that the drug has not been proved effective in the treatment of cancer thus far. This alternative demonstrates that something less than an absolute prohibition can pro-

120. The Senate Bill provided as follows:

SECTION 1. Section 1708.5 is added to the Health and Safety Code, to read:

1708.5. (a) This chapter shall not apply to laetrile or amygdalin or any vitamins, minerals, enzymes, or foods for special dietary uses deemed adjunctive or necessary to laetrile or amygdalin therapy, when prescribed in accordance with the procedures set forth in subdivision (c) by a physician and surgeon licensed to practice in the State of California.

(b) The manufacture, sale, prescription, and use of laetrile or amygdalin for the purposes and in the manner set forth in subdivision (a) shall be lawful within this state.

(c) A physician and surgeon licensed to practice in the State of California shall meet each of the following requirements as to any patient before prescribing laetrile or amygdalin for such patient:

(1) The patient shall have consented in writing on an informed consent form. Such informed consent form shall include at least the following:

(A) An explanation of the risks and benefits of laetrile or amygdalin as a form of cancer therapy.

(B) An explanation of the risks and benefits of standard treatment modalities; such as chemotherapy, radiation therapy, and surgery, commonly prescribed by most licensed physicians in California, a substantial part of whose practices include treatment for cancer.

(C) A statement explaining to the patient that such patient can withdraw from the laetrile or amygdalin therapy at any time during the course of treatment.

(D) A statement explaining that laetrile or amygdalin need not be used to the exclusion of the standard treatment modalities.

(E) A statement which encourages the patient to consult with a second physician who specializes in the use of standard treatment modalities for cancer prior to using laetrile or amygdalin.

(2) The informed consent form shall be signed and dated by both the physician and patient and shall be retained in the patient's medical record.

(d) In enacting this section, the Legislature finds and declares that the efficacy of the use of laetrile or amygdalin with respect to cancer therapy has not been determined.


121. Assembly Committee on Health—Legislative Hearing on SB 245 (Campbell) Relating to Laetrile 127-28, Aug. 8, 1977. Presently, a similar bill is under consideration in the California Legislature.
tect the state’s interests and yet preserve the fundamental right of the
terminally ill to choose unproven treatments.

V. Conclusion

The constitutional protection afforded to an individual’s right de-
pends upon the nature of the right involved. In accordance with the
Griswold and Wade standard, the right to choose an unproven treat-
ment is a decision that is basic to the life of the individual and therefore
it should be constitutionally protected as a fundamental right. Only a
compelling state interest may justify a statute that infringes upon this
right. The state interest is insufficient to bar a terminally ill patient’s
right to choose alternative treatments. By narrowly drafting the statute
so that its regulations on the use of an unproven treatment vary in ac-
cordance with the stages of illness, the state interest in the public health
of its inhabitants can be protected without impinging upon the funda-
mental right of the terminally ill patient to choose any treatment that
may preserve his life.

V. Anthony Unan