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GOVERNMENT REGULATION OF HEALTH-CARE
DRUGS OF QUESTIONABLE EFFICACY

INTRODUCTION

Untested drugs of questionable effectiveness have long been promoted in the underground health-care market with claims of curing everything from arthritis to cancer. At present the most widely publicized and most controversial of these illicit health-care drugs is a substance called laetrile, also known as Vitamin B17 and amygdalin. Proponents of laetrile claim the substance is beneficial in arresting and curing cancer. However, nearly the entire

1. M. Culbert, Vitamin B17, at 53 (1974). See United States v. General Research Laboratories, 397 F. Supp. 197, 198 (C.D. Cal. 1975). Laetrile is not the first and certainly will not be the last of these controversial drugs of questionable efficacy. Several years ago a drug known as Krebiozen precipitated a series of suits because its proponents demanded the right to obtain the substance for health-care purposes. E.g., Durovic v. Richardson, 479 F.2d 242 (7th Cir.), cert. denied, 414 U.S. 944, reh'g denied, 414 U.S. 1088 (1973); Rutherford v. American Medical Ass'n, 279 F.2d 641 (7th Cir. 1967), cert. denied, 389 U.S. 1043, reh'g denied, 390 U.S. 975 (1968); Tutoki v. Celebreze, 375 F.2d 105 (7th Cir. 1967). See also 17 CAL. AD. CODE § 10400.7 (1967) (administration of Krebiozen made illegal). Prior to the Krebiozen cases, a substance called Mucorhcin was the center of a legal and medical controversy. E.g., United States v. Nutrition Serv., Inc., 227 F. Supp. 375 (W.D. Pa. 1964), aff'd, 347 F.2d 233 (3d Cir. 1965). See also 17 CAL. AD. CODE § 10400.5 (1967) (administration of Mucorhcin made illegal).

2. J. Schmidt, Attorneys' Dictionary of Medicine 127-28 (1974), defines amygdalin as “a complex substance, generally a glycoside, occurring in bit-
medical establishment, including the American Cancer Society and the American Medical Association, dismisses laetrile as worthless in the treatment of cancer.⁶

Because laetrile has not been approved for shipment in interstate commerce⁴ and because its administration for cancer treatment is illegal in some states,⁵ thousands of American cancer patients have gone to Mexico for laetrile treatments.⁶ The popularity of laetrile has attracted considerable attention from the news media,⁷ and government authorities have started a concerted effort to curtail both the importation and administration of laetrile.⁸ As a result, ter almond, cherry laurel and other plants." The term laetrile is not listed. According to M. Culbert, Vitamin B17, at 22 (1974), laetrile is a brand name for a purified, crystallized, freeze-dried form of amygdalin. For some of the claims made in behalf of laetrile, see id. at 22-25.

3. Time, April 12, 1971, at 80. The Food and Drug Administration (FDA) is attributed as stating that there is no evidence, either preclinical or clinical, that laetrile would be effective for cancer treatment. Id. See also N.Y. Times, Feb. 28, 1971, at 52, col. 3.


8. The principal federal case is United States v. McNaughton, Cr. No. 7600448 (S.D. Cal., filed May 20, 1976). Sixteen individuals and three Mexican companies were charged with taking part in a conspiracy to smuggle laetrile into the United States. The charges, brought under 18 U.S.C. § 371 (1970) (conspiracy to commit offense or to defraud the government) and 18 U.S.C. § 545 (1970) (smuggling goods into the United States), were not directly based on the fact that laetrile is an unapproved health-care drug. Therefore, the health-care issue apparently will not be raised at trial. The defendants are accused of being involved in a multi-million dollar smuggling operation intending to supply thousands of people in the United States with laetrile. For accounts of the indictments, see Los Angeles Times, May 26, 1976, § I, at 3, col. 4 and id., May 27, 1976, § I, at 2, col. 6; N.Y. Times, May 26, 1976, at 1, col. 1; and San Diego Union, May 26, 1976, § A, at 2, col. 7.

The principal state cases dealing with the administration of laetrile are People v. Privitera, 55 Adv. Cal. App. 3d Supp. 39, 128 Cal. Rptr. 151 (1976),
in at least six cases individuals have sought injunctive relief against the federal government in order to obtain laetrile for health-care purposes. Only one case, Rutherford v. United States, thus far has ruled in favor of the individuals requesting relief.

In Rutherford, a federal district court granted temporary injunctive relief to the plaintiff and allowed him to transport laetrile in interstate commerce in order to obtain personal supplies of the drug for a limited time. The court reasoned that the statutory scheme of the Federal Food, Drug, and Cosmetic Act of 1938 denied "freedom of choice" to an individual who as a cancer patient had used laetrile instead of traditional methods of cancer treatment. The district court concluded that this denial violated due process. The constitutional issue was not reached on appeal; rather, the court of appeals upheld the preliminary injunction while remanding the case so that adequate evidence could be produced to support the new drug determination of laetrile.

11. Id. at 1215.
13. 399 F. Supp. at 1213. Apparently plaintiff Rutherford used laetrile for cancer treatment as an alternative to surgery. Rutherford claimed that he was cured of cancer through the use of laetrile after visiting a Tijuana laetrile clinic. However, he claimed that his domestic supply of laetrile had been halted by the arrest of his supplier. The court found that Rutherford could not obtain laetrile without violating the Food, Drug, and Cosmetic Act. The court further found that laetrile was non-toxic when taken in proper amounts and that the Food and Drug Administration had abdicated its duty in failing to decide if laetrile should or should not be placed in interstate commerce. It is especially interesting to consider the court's rationale for granting temporary injunctive relief in light of the fact that Rutherford was using laetrile neither as a last-resort treatment for cancer nor as a supplemental treatment in conjunction with traditional methods. The Court finds that the plaintiff Rutherford and those similarly situated are wholly without means or resources to comply with the provisions of 21 U.S.C. § 355(b) and that for the plaintiff Rutherford and those similarly situated to be denied the freedom of choice for treatment by laetrile to alleviate or cure their cancer, was and is a deprivation of life, liberty or property without due process of law guaranteed by the Fifth Amendment to the Constitution of the United States.

Id. at 1213.
14. 542 F.2d 1137, 1143-44 (10th Cir. 1976). For the definition of new drug, see text accompanying note 50 infra.
Rutherford and similar cases\textsuperscript{16} present several interesting questions. The threshold inquiry in the federal court cases is whether a substance like laetrile falls within the scope of certain sections of the Food, Drug, and Cosmetic Act and is therefore subject to the safety and efficacy requirements of the Act. If the Act is applicable, and the substance is not approved for interstate shipment, it is necessary to determine whether an individual has a fundamental constitutional right\textsuperscript{16} to obtain and use drugs of questionable efficacy for personal health care. If that right were recognized, it would become necessary for the government to show a compelling state interest\textsuperscript{17} and to use narrowly drawn means to justify infringement upon the right.\textsuperscript{18} A final question is whether distributors and physicians have standing to assert the health-care rights possessed by the users of a substance like laetrile.\textsuperscript{19}

\textbf{FOOD, DRUG, AND COSMETIC ACT}

The Federal Food, Drug, and Cosmetic Act of 1938 established a complex set of provisions which required premarketing review

\footnotesize{15. See note 9 supra. See also People v. Privitera, 55 Adv. Cal. App. 3d Supp. 39, 128 Cal. Rptr. 151 (1976), rev'd No. 11825 (Citrus, Cal., Mun. Ct., Feb. 3, 1975). The lower court had held \textit{CAL. HEALTH \& SAFETY CODE} § 1707.1 (West 1970), which prohibits the sale and administration of certain substances for the treatment or cure of cancer, unconstitutional. Defendant challenged the statute as being overbroad because it could stop the distribution of an effective drug. The appeals court cited Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653-54 (1973), for the proposition that such statutes must necessarily be broad in order to protect the public against untested drugs. The court also rejected an argument that the statute, which did not make it unlawful to administer laetrile (the drug in question) for purposes other than treating cancer, violated equal protection in impliedly distinguishing between cancer patients and non-cancer patients. The court rejected a right of privacy argument by saying that Roe v. Wade, 410 U.S. 113 (1973), was simply not applicable.


19. This Comment is not intended to encourage the use of drugs of questionable efficacy nor will it explore the scientific worth of claims made in behalf of these substances. See M. Culbert, \textit{VITAMIN B17}, at 205-07 (1974), for a list of books, articles, and papers concerning studies on laetrile. This Comment will not discuss the many administrative due process problems which arise under the Food, Drug, and Cosmetic Act but instead will focus on the applicability of certain provisions of the Act and substantive constitutional issues.}
of drugs.\textsuperscript{20} That review was directed solely toward ensuring drug safety; efficacy remained a matter largely beyond premarketing review.\textsuperscript{21} The 1962 amendments to the Act\textsuperscript{22} produced significant changes in the scope of the law and introduced the requirement that new drugs must be proven both safe and effective before they may be introduced into interstate commerce.\textsuperscript{23}

The Act sets forth a number of exacting requirements for those distributing and transporting drugs in interstate commerce,\textsuperscript{24} including provisions that deal with adulteration and purity.\textsuperscript{25}
misbranding and labeling, and safety and effectiveness. A person found to have violated any of these provisions is subject to criminal penalties and injunctive remedies, and the goods are subject to seizure. In order to avoid these penalties, people can either claim they fall outside the scope of particular provisions or attempt to comply with the requirements of the Act. Yet, in the area of safety and effectiveness, compliance may be impossible because evidence of the safety and effectiveness of a drug must meet very high standards of proof and because proper clinical analysis in deriving such evidence requires considerable time and expense.

The key provision for regulating safety and effectiveness is section 505 of the Act, which provides that new drugs cannot be introduced or delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA). Section 505(b) of the Act requires that an NDA applicant submit, inter alia, full reports of adequate and well-controlled clinical investigations which have been made to show whether the drug is safe and effective for its intended use. Commercial success in the marketplace and acceptance by physicians are not appropriate standards for judging a drug’s safety and

28. Id. § 201(e), 21 U.S.C. § 321(e) (1970), defines persons as including any individual, partnership, corporation, or association.
33. The millions of dollars and years of effort spent on cancer research alone are an indication of the resources required in the more complex areas of health-care research.
35. New drug is a term of art. See text accompanying note 50 infra for the statutory definition of new drug.
36. 21 U.S.C. § 355(b) (1970). This provision requires that applicants file with the Secretary of Health, Education and Welfare: (1) full reports of investigations which have been made to show whether the drug is safe for use and whether it is effective in use; (2) a full list of the articles used as components of the drug; (3) a full statement of the composition of the drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug; (5)
effectiveness. In this respect, proponents of laetrile or similar drugs could not obtain NDA approval on the basis of testimony by physicians who believe in the merits of the drug. If there is lack of "substantial evidence"—that is, lack of adequate and well-controlled clinical investigations on proof of safety or efficacy—the NDA will be rejected by the government. Proponents of a drug like laetrile undoubtedly could not meet the stringent standards of proof of effectiveness required by the Act because they lack the necessary data from well-controlled clinical investigations.

Typically, the substantial evidence requirement is only a theoretical hurdle for drugs like laetrile because a formal new drug application ordinarily will not be submitted for such drugs. Rather, because the requirements of section 505 apply only to new drugs, proponents of an unapproved drug will often contend that the substance in question is not a drug, or even if it is a drug, that it is not a new drug. The Act defines the word drug as a substance intended for use in the diagnosis, cure, mitigation, treat-

samples of the drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for the drug.

   Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labeled in mysterious scientific dress. The standard of "well-controlled investigations" particularized by the Regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness.

Id. at 622. Because of these strict standards, physicians who firmly believe in the attributes of a drug like laetrile could not provide acceptable evidence of the drug's safety and effectiveness without support of well-controlled scientific studies.

39. Food, Drug, and Cosmetic Act § 505(d), 21 U.S.C. § 355(d) (1970). The term substantial evidence means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

40. Id. § 505(e), 21 U.S.C. § 355(e). It probably is safe to assume that if laetrile proponents could meet the FDA standards, they would submit an NDA and proceed to market the drug as a proven cancer cure in order to obtain maximum financial gain.

41. In April 1970, the Food and Drug Administration assigned an Investigative New Drug application to the McNaughton Foundation to test laetrile, but permission for testing was revoked 10 days later. M. Culbert, Vitamin B17, at 81 (1974).
ment, or prevention of disease. The intended use of a substance determines whether it is a drug, regardless of its inherent properties or dictionary definition. A substance which is a food may also be a drug depending on its intended use. Product labels, promotional materials, advertisements, and even oral representations are relevant sources for determining whether the product is intended to be used as drug. Although labeling may state that a substance is intended for use as a flavoring or food substitute, widespread publicity can still be determinative that a product is intended to be used as a curative drug. Courts have concluded that the concentrated effort to publicize laetrile for use in cancer treatment demonstrates that laetrile is intended for such use, despite the limited uses that may be suggested on the labeling. Courts are inclined to give an extremely broad definition of the term drug and repeatedly have rejected contentions that a sub-


46. United States v. Nutrition Serv., Inc., 227 F. Supp. 375, 380-81 (W.D. Pa. 1964), aff'd, 347 F.2d 233 (3d Cir. 1965). In this case, defendants under the names of two medical clinics began promoting Mucorhcin as safe and effective in the treatment and cure of many ailments and diseases, including cancer, by mailing literature about the results of their studies. Subsequently, the defendants stopped making these claims, formed defendant corporation, and began marketing Mucorhcin as a dietary food product. The court found that the intended use of Mucorhcin was for treating disease because of the prior publicity and found defendants guilty of violating several provisions of the Act. Id. at 380-87.


stance like laetrile, widely publicized as an alleged cancer cure, is a food or vitamin.49

If the substance in question is determined to be a drug, it becomes necessary to determine whether it is a new drug within the meaning of the Act. The term new drug is defined under the Act as

any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .50

Proponents of a drug who desire to prove it is not a new drug must show that it is generally recognized by scientific experts as safe and effective in order to avoid securing an NDA. Thus, supporting affidavits from users of the substance, or even from physicians, will not be sufficient to remove the substance from the new drug classification if it is not generally recognized by qualified experts as safe and effective.51 Utilizing this rationale, several courts have found that laetrile is a new drug and within the scope of requirements of section 505 of the Act.52

49. See cases cited note 47 supra.
50. Food, Drug, and Cosmetic Act § 201(p) (1), 21 U.S.C. § 321(p) (1) (1970). This subsection, and in particular the term generally recognized, have been the target of considerable litigation. One indication that a drug is not generally recognized among qualified experts as safe and effective for its intended use is the absence of any published medical or scientific literature concerning the safety or effectiveness of the drug. This lack of documented sources of information curtails the widespread knowledge of the drug's safety and effectiveness. It should be noted that under this provision the actual safety and effectiveness of the drug are not in issue; rather, the issue is one of the general recognition of the drug. United States v. Article of Drug . . . “Mykocert,” 345 F. Supp. 571, 574 (N.D. Ill. 1972). Some courts have taken the position that the mere existence of conflict among qualified experts in supporting affidavits establishes a lack of general recognition as a matter of law. Merritt Corp. v. Folsom, 165 F. Supp. 418, 421 (D.D.C. 1958). Other courts have said that when a genuine difference of opinion exists on the question of whether the safety and effectiveness of a drug is generally recognized, a drug will not be deemed to be generally recognized as safe and effective and thus will fall within the new drug definition. United States v. Article of Drug . . . Labeled . . . (Box) “Furestrol Vaginal Suppositories,” 415 F.2d 390, 392 (5th Cir. 1969). Accord, United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 853 (D.N.J. 1959). But see United States v. 1,048,000 Capsules, More or Less, 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff’d, 494 F.2d 1158 (5th Cir. 1974), in which the court said extensive recognition rather than universal recognition will suffice. See also Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1973).
52. Hanson v. United States, 417 F. Supp. 30, 36 (D. Minn.), aff’d, 540
A grandfather clause in the Act exempts older drugs from the safety and effectiveness requirements if the drugs were in use at the time the Act was enacted in 1938 and if the labeling of such drugs contained the same representations as are now being made concerning the conditions of use.53 Although the grandfather clause has been the subject of extensive litigation in recent years,64 proponents of laetrile-type drugs have little hope of escaping the safety and effectiveness requirements by virtue of this provision. It is apparent that proponents of most unapproved drugs cannot claim that their drug is intended for use under the same conditions as prescribed or recommended in the original labeling because there generally was no prior labeling of those drugs. Furthermore, many of the "miracle drugs" of unproven safety and efficacy simply were not in use prior to 1938. Thus, they do not fall within the grandfather exception.

In essence, a health-care drug of unproven safety or efficacy ordinarily cannot be transported in interstate commerce without violating the Act, even if the substance is transported for personal use.55 As a result, people are deprived of an opportunity to obtain

53. Food, Drug, and Cosmetic Act § 102(a)(1), 21 U.S.C. § 321(p)(1) (1970). Because the 1962 amendments added the requirement of effectiveness, if on October 9, 1962, a drug like laetrile was marketed for exactly the same uses for which it is presently being sold and was generally recognized by qualified experts as safe for those uses, it is exempt from the general recognition requirements of safety and effectiveness. Rutherford v. United States, 542 F.2d 1137, 1141 (10th Cir. 1976).
55. A person transporting drugs in interstate commerce is concerned about much more than simply the safety and efficacy requirements. Of major importance also are the adulteration and misbranding standards. The misbranding provisions of section 502 of the Act, 21 U.S.C. § 352 (1970), are somewhat interrelated with the efficacy and safety standards. A drug may be misbranded if its labeling contains too much information (unfounded claims) or too little information (inadequate directions for use and inadequate warnings of potential dangers). Furthermore, the Federal Trade Commission Act, § 12, 15 U.S.C. § 52 (Supp. V 1975), makes it unlawful for any person to disseminate any false advertisements in the mails or in commerce for the purpose of inducing, directly or indirectly, the purchase of drugs. It should also be noted that section 505(i) of the Food,
and use these unapproved substances, except through illicit chan-
nels.\(^5\) If all of the technical arguments to avoid the safety and
efficacy requirements fail, a person wishing to transport unap-
proved drugs in interstate commerce has two legal options: First,
he can attempt to meet the difficult, expensive, and time-consuming
standards of proof for safety and efficacy which Congress has found
necessary for protection of public health; or, second, he can try
attacking the Act on constitutional grounds. Increasing numbers
of laetrile proponents are resorting to constitutional arguments.

**THE RIGHT TO OBTAIN HEALTH-CARE DRUGS**

A constitutional right to obtain and use health-care drugs of ques-
tionable efficacy might be derived from either a substantive due
process concept of liberty\(^5\) or from a right of privacy.\(^6\) Because of
the uncertain scope of liberty and privacy, use of the term *privacy*
is primarily for convenience and is not intended to exclude the con-
cept of liberty.\(^5\) Privacy in this context does not deal with the
right of selective disclosure; rather, it focuses on broader aspects
of autonomy and is concerned with a more generalized ability of
individuals to determine for themselves whether to perform certain
acts or to undergo certain experiences.\(^6\)

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to be a further hindrance to a person's ability to obtain and use unapproved
drugs for health-care purposes. That provision requires that every person
who owns or operates any establishment engaged in the manufacture, prep-
paration, propagation, compounding, or processing of drugs must register
with the Secretary of the Department of Health, Education and Welfare.
The only exceptions to this requirement are practitioners compounding
drugs solely for use in course of professional practice, people manufacturing
drugs solely for research purposes, and people engaged in other limited ac-
tivities.

57. Whenever a federal act is under attack, the fifth amendment due
process clause is asserted. *E.g.*, Louisville Joint Stock Land Bank v. Rad-
ford, 295 U.S. 555, 589 (1935). The same arguments apply to state statutes
under the fourteenth amendment due process clause. *E.g.*, Rochin v. Cali-
factor depending on how the Food and Drug Administration handled a par-
ticular new drug application, but the success of such a challenge would
depend upon the particular circumstances of each case. For instance, an
applicant might be able to show unjust discrimination against an NDA for
laetrile because of its controversial background.


59. *See Roe v. Wade, 410 U.S. 113, 153 (1973) (privacy concept is founded
in fourteenth amendment).* *See also Doe v. Bolton, 410 U.S. 179, 211-20
(1973) (Douglas, J., concurring).*

60. *See cases cited note 59 supra.* The "right of selective disclosure" has
been defined as the ability of "individuals, groups, or institutions to deter-
If some type of fundamental privacy right is recognized within the context of health-care treatment, the government could limit such right only by a compelling state interest and by a statute narrowly drawn to express only the legitimate interests at stake.61 Failure to establish that a fundamental right is at issue would mean that the statute could be upheld on a mere rational relation basis—that is, by showing that the statutory scheme is rationally related to a permissible state objective.62

At first impression, the Food, Drug, and Cosmetic Act seems to restrict only commercial rights. However, it has been noted that the Act does not distinguish between commercial and personal traffic of health-care drugs.63 Because an individual violates the Act by transporting unapproved health-care drugs in interstate commerce for his own personal use, the Act intrudes on more than mere commercial or property rights of drug distributors. If only commercial rights were at stake, the Act would undoubtedly be upheld by a showing that its statutory scheme is rationally related to the protection of public health and well-being.64 However, with personal rights at stake, a stricter standard of scrutiny may be appropriate.65

The rights of which a person may not be deprived without due process of law include the "right to life."66 Although there has been no acceptable scientific proof that a drug like laetrile can arrest cancer, many users of laetrile attest to the curative worth of mine for themselves when, how, and to what extent information about them is communicated to others.” A. Westin, PRIVACY AND FREEDOM 7 (1967). See also Note, Roe and Paris: Does Privacy Have a Principle? 26 STAN. L. REV. 1161, 1163 (1974).
65. At least one decision has indicated that a stricter standard of scrutiny is appropriate even when personal rights tend to merge with quasi-commercial interests. Eisenstadt v. Baird, 405 U.S. 438, 445-46 (1972).
66. U.S. CONST. amends. V & XIV.
the drug.⁶⁷ Users of the substance claim that the denial of an opportunity to obtain and use laetrile results in denial of an opportunity to protect their lives. Such claims require some proof of efficacy and raise questions concerning a court's jurisdiction to determine the effectiveness of a drug.⁶⁸

It is important, however, to note that a right of privacy in a health-care context could have a direct bearing on a person's ability to live. Because freedom of action is at stake, it is more feasible to view this freedom of choice as falling within the scope of privacy rather than treating it as an independent right to life. Otherwise, any type of situation which could affect a person's ability to live—be it air pollution standards or auto safety requirements—could be said to encompass a right to life. Nonetheless, the significance of the privacy right is enhanced because it could have life-determining consequences. The basis for extending a right of privacy into personal health care is best demonstrated by analyzing related areas of law in which the privacy issue has been raised.

**ANALOGOUS AREAS OF PRIVACY**

Support can be found for a right of privacy in a health-care context by analyzing privacy issues as related to (1) marijuana possession, (2) fluoridation of public water supplies, (3) compulsory vaccinations, and (4) contraception and abortion.

**Marijuana**

Marijuana in its ordinary usage is not considered a health-care substance.⁶⁹ However, like laetrile it is proscribed despite substantial public demand and despite its questionable physical effects.⁷⁰ Although a number of different constitutional challenges, ranging from equal protection to cruel and unusual punishment, have been made to laws proscribing possession of marijuana, only those cases involving a theme of privacy or individual liberty are relevant to this Comment.⁷¹

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⁶⁸. See notes 129-31 infra and accompanying text.

⁶⁹. But see Newsweek, Nov. 8, 1976, at 53; San Diego Union, Oct. 6, 1976, § C, at 1, col. 1 (Marijuana is being tested for effectiveness in the treatment of glaucoma).

⁷⁰. The differences between statutes affecting marijuana and those affecting laetrile must be pointed out. Whereas marijuana is directly proscribed, laetrile is affected only because it is considered a health-care drug. A substance like laetrile may be legalized by fulfilling the requirements of an NDA.

A large majority of courts has flatly rejected constitutional attacks on marijuana statutes. Two federal courts, however, were willing to entertain, though not embrace, the concept of a right of privacy protecting private possession of marijuana, indicating that they might recognize a right to possess marijuana for personal use were that the issue. These courts flatly rejected any extension of such a right to include distribution. One court, noting that the defendants were prosecuted for possession of marijuana with intent to distribute, said it need not decide the necessity of invoking strict scrutiny that adheres to a “fundamental right of the individual to control of his own body and to indulge in private what may be condemned in public or deemed immoral or unacceptable to society at large.”

In a similar case, People v. Sinclair, the Michigan Supreme Court reversed on several grounds a defendant's conviction for illegal possession of marijuana. One justice thought that a statute proscribing mere possession represented “an impermissible intru-


74. Id.


76. 387 Mich. 91, 194 N.W.2d 878 (1972). Two judges based the reversal on their opinion that the statutory categorization of marijuana along with “hard drug” narcotics for purposes of imposition of penalties denied equal protection. One judge based reversal on the opinion that the statute denied the right to liberty. Two judges believed that the marijuana cigarettes should have been excluded as evidence obtained as a result of illegal entrapment, and two judges supported reversal on the basis that a minimum sentence of 9½ years constituted cruel and inhuman punishment.
sion of the fundamental right to liberty," although he indicated that a proper public interest may exist in controlling the traffic in marijuana. Comparable arguments were made in separate opinions in another marijuana case. Decisions following the rationale voiced in *Sinclair* indicate that the government interest in prohibiting possession of marijuana for personal use must yield to the individual's privacy interest. However, when courts conclude that marijuana may be considered harmful, the privacy interest must yield to the government interest in protecting health. When weighing the potential for harm against the privacy interest, consideration of the type of privacy at stake may be appropriate. Privacy in the context of health care would seem to deserve more weight than privacy in the context of marijuana use.

These cases indicate that a handful of authorities are willing to accept the idea that an individual has a right to possess for personal use a substance capable of producing questionable physical effects. One judge also stated that the right to use something has little meaning unless one also has the right to acquire it. Although the right to possess something logically would seem to entail the right to obtain it, the Supreme Court has said that the right to view obscene materials in one's own home does not include the right to

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77. Id. at 133, 194 N.W.2d at 896 (Kavanagh, J., concurring).
78. State v. Kantner, 53 Hawaii 327, 493 P.2d 306, cert. denied, 409 U.S. 948 (1972). One justice emphasized the individual's "fundamental right of liberty." Id. at 336-37, 493 P.2d at 312 (Abe, J., concurring). Another justice said "[t]he very concept of limited government evinces a desire to free persons from the unbounded control of the State, in order that they most productively pursue their own life goals." Id. at 339, 493 P.2d at 313 (Levinson, J., dissenting).
80. Although authorities upholding a right of privacy to allow possession and use of marijuana conclude that the harmful effects of marijuana are negligible and do not justify infringement upon a person's privacy, courts usually reach an opposite conclusion. E.g., People v. Aguiar, 257 Cal. App. 2d 597, 605, 65 Cal. Rptr. 171, 176, cert. denied, 393 U.S. 970 (1968) (It is rational to conclude that marijuana use is dangerous and that there is no protected right for its use.); Commonwealth v. Leis, 355 Mass. 189, 194-95, 243 N.E.2d 898, 902-04 (1969) (Marijuana use could lead to hard drug use, and its use does not fall within protection of any penumbra of constitutional amendments.). Because of the uncertain safety, the above cases apparently reason that the government has a strong interest in restricting use of marijuana.
obtain those materials. However, in the context of “drugs” within the scope of the Food, Drug, and Cosmetic Act, Eisenstadt v. Baird indicates that a right of privacy protecting use also protects the right to obtain. Like the statute under attack in Eisenstadt, the Food, Drug, and Cosmetic Act similarly restricts an individual’s right to obtain unapproved drugs. In this respect, the federal act proscribing interstate transportation and the state acts proscribing administration intrude upon the individual’s privacy to use such substances, even though use or mere possession is not directly prohibited.

Fluoridation

Unlike the marijuana cases, fluoridation of public water supplies directly concerns the issue of health care. Fluoridated water is not forced upon anyone, but obviously people dependent upon the public water supply must ingest the fluoride. Although fluoridation might be considered a form of compulsory medical treatment, courts have repeatedly upheld the government’s right to fluoridate public water supplies.

83. See United States v. Orito, 413 U.S. 139 (1973) (no right to transport obscenity in interstate commerce for personal use); United States v. 12,200-ft. Reels of 8mm. Film, 413 U.S. 123 (1973) (no right to import obscenity for personal use); United States v. Reidel, 402 U.S. 351 (1971) (no right to distribute obscenity to consenting adult purchaser). Rather than setting precedent for restricting other personal rights, these cases, as the dissenting opinions suggest, probably stand for a de facto overruling of Stanley v. Georgia, 394 U.S. 557 (1969), which recognized a person’s right to possess obscene material for private use. See, e.g., United States v. Orito, 413 U.S. 139, 145-48 (Douglas & Brennan, JJ., dissenting).

84. 405 U.S. 438, 446 (1972). The Supreme Court strongly emphasized a right of privacy for single people seeking the use of contraceptives and concluded that enforcement of the statute restricting distribution to married couples materially impaired the ability of single people to obtain contraceptives. The substance in Eisenstadt was vaginal foam, which, like laetrile, apparently falls within the definition of drug as used in the Food, Drug, and Cosmetic Act. Despite the same classification, there are obvious differences between the two substances. For further discussion, see notes 107, 108, & 111 infra and accompanying text.

85. See Food, Drug, and Cosmetic Act § 505, 21 U.S.C. § 355 (Supp. V 1975). Plaintiffs like Rutherford claim that the statutory provisions prohibiting interstate transportation of unapproved drugs cut off their ability to obtain, and consequently, to use such substances. Cf. Cal. Health & Safety Code § 1707.1 (West 1970), which prohibits the sale, offering for sale, holding for sale, delivering, giving away, prescribing, or administering of any drug or substance to be used in the treatment or cure of cancer.

86. See list of authorities cited in Minnesota State Bd. of Health v. City of Brainerd, 241 N.W.2d 624, 630 (Minn. Sup. Ct.), appeal dismissed for lack of a federal question, 97 S. Ct. 35 (1976).
dation decision, the Minnesota Supreme Court held that while forced fluoridation does intrude upon an individual's decision to ingest fluoride, the impact of this intrusion on an individual's life is negligible. The court added that the impact of putting microscopic amounts of fluoride into a person's body is especially slight when compared to the right of privacy deemed protected by the contraception and abortion decisions of the United States Supreme Court.

The rationale used in upholding fluoridation of public water supplies has not been universally accepted. The dissent in one case maintained that the mandatory fluoridation established by a city deprived a person of liberty without due process of law. The dissent in effect concluded that the city ordinance deprived an individual of the freedom to choose his own mode of health-care treatment.

It is apparent that the fluoridation cases uphold the government's right to fluoridate public water mainly because of the nature of the infringement. Many of the courts have emphasized that fluoridation is a harmless, trivial intrusion. As a consequence, courts reason that the protection of public health afforded by fluoridation far outweighs any infringement of individual liberty. Further, because a city cannot feasibly fluoridate part of its water supply, the cities are applying the least restrictive alternative. Although prohibiting interstate movement of an unapproved drug like laetrile is also justified on grounds of public health, a serious question exists of whether the current blanket prohibition is the most narrowly defined means of serving the state interest.

Vaccination

Both the fluoridation and compulsory vaccination cases involve the government's right to take affirmative action to intrude upon privacy for purposes of health care. Obviously vaccinations represent the more significant intrusion upon personal autonomy.

88. Id.
90. Id.
92. Id.
93. This question is discussed in notes 155-59 infra and accompanying text.
The leading case on the vaccination issue, Jacobson v. Massachusetts, upheld compulsory vaccination in the face of a threatened smallpox epidemic. In Jacobson the Court stated that forced vaccination under the circumstances was not an unconstitutional infringement of any rights guaranteed by the fourteenth amendment. The Court, rather than downplaying the personal interest at stake, emphasized the imminence of the deadly disease. In explaining the principle underlying its decision, the Court paralleled the state's intrusion upon personal liberty with military conscription to protect national security and emphasized the compelling state interest to justify the invasion of personal rights. Although the Court stated it did not perceive that the statute invaded any right secured by the Constitution, its entire analysis in showing the necessity of such a compulsory vaccination indicates an implied recognition of some personal right. Jacobson arguably embodies the principle that the personal right to care for one's health is a fundamental right of privacy which may be abridged only when justified by a compelling state interest. In Jacobson the compelling state interest was to protect the individual against the threat of disease and the public at large against the spread of disease. However, the Court implied that even this strong state

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94. 197 U.S. 11 (1905).
95. Id. at 37-38.
96. Id. at 26. Defendant termed the personal right at stake "the inherent right of every freeman to care for his own body and health in such way as he deems best." Id.
97. Id. at 29-30. The Court stated:
   There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members, the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand. It is not, therefore, true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the state, for the purpose of protecting the public effectively against such danger.
98. Id. at 38.
99. A similar analysis and conclusion based on Jacobson is found in Brief for Appellants at 94-95, Roe v. Wade, 410 U.S. 113 (1973). The Supreme Court left appellant's contentions unanswered and merely cited Jacobson for authority that there is not an unlimited right to do with one's body as one pleases. 410 U.S. at 154.
terest is insufficient to overcome the personal right if an individual's life were threatened by compulsory vaccination. 100

In the fluoridation and vaccination cases, the courts seem to be upholding the interests of the state in keeping its citizens healthy—a type of affirmative action health care whereby the state may force medicinal substances upon a person under certain conditions. In the laetrile and contraception-abortion areas, the state has engaged in a type of negative action health care by hindering access to certain health-care aids. Arguably the government has a greater burden in justifying denial of health-care remedies because a person might be denied an actual cure. 101

Contraception and Abortion

In essence, the cases of Griswold v. Connecticut, 102 Eisenstadt v. Baird, 103 and Roe v. Wade 104 address the issue of a person's constitutional right to take health-care action. In all three cases, the individual right was deemed superior to the state interest.

The Supreme Court in Griswold held that the state could not ban the use of contraceptives without abridging a couple's right to privacy which underlies the marriage relationship. 105

100. 197 U.S. at 39. The Court stated:

[W]e are not inclined to hold that the statute established the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination or that vaccination, by reason of his then condition, would seriously impair his health or probably cause his death.

The court's analysis indicates that an individual's interest in personal autonomy must be weighed against the government's interest in public health. When the individual's interest has life-determining consequences, his right of privacy will be superior to the general government interest in protecting health. A less restrictive means is readily available in vaccination situations—the government need only refrain from giving vaccinations to individuals whose lives are endangered by such action.

101. Even if an individual is forced to take a health-care substance such as a vaccine or fluoride, he probably will not be harmed. However, denial of a potentially effective drug could have severe repercussions.

102. 381 U.S. 479 (1965).
103. 405 U.S. 438 (1972).
105. 381 U.S. at 485-86. The Supreme Court's recognition of the right of privacy began with its decision in Union Pacific Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891), which was handed down one year after the appearance of Warren and Brandeis' article, The Right to Privacy, 4 Harv. L. Rev. 193-220 (1890). Subsequently, the right of privacy has been found in the first amendment, Stanley v. Georgia, 394 U.S. 557, 564 (1969); in the fourth and fifth amendments, Terry v. Ohio, 392 U.S. 1, 8-9 (1968), and Katz v. United States, 389 U.S. 347, 350 (1967); in the penumbra of the Bill of Rights, Griswold v. Connecticut, 381 U.S. 479, 484-85 (1965); in the ninth amendment, id. at 486-87 (Goldberg, J., concurring); and in the concept of liberty guaranteed by the fourteenth amendment, Roe v. Wade, 410 U.S. 113, 153 (1973), and Meyer v. Nebraska, 262 U.S. 390, 399 (1923). See generally
wold is significant in that the Supreme Court recognized a right of privacy within the general spirit of health care. However, the substances at issue in Griswold were intended to be used for contraception rather than for prevention of disease. Furthermore, the statute in question prohibited the actual use of contraceptives, not possession or distribution. As previously stated, the Food, Drug, and Cosmetic Act does not prohibit use, or mere possession, of unapproved drugs. It prohibits only interstate transportation while the state statutes prohibit administration of such drugs.\footnote{106}

_Eisenstadt_ upheld the right of a person to distribute contraceptives on grounds that a statute prohibiting distribution to single people violated equal protection by distinguishing between married and single people.\footnote{107} The Court's opinion has a strong right to privacy flavor.\footnote{108} The case is especially significant because the right to privacy argument was recognized beyond mere use of a drug\footnote{109} and was extended to the user's right to obtain such an item.\footnote{110} However, the privacy rights in _Eisenstadt_, like those in Griswold, seem to be directly related to the idea of contraception and sexual relations.\footnote{111} Nevertheless, these two decisions took the first steps in the direction of recognizing a right of privacy encompassing general health-care activities.

_Roe v. Wade_ expanded the right of privacy beyond contraception. The Supreme Court held that the right of privacy encompasses a

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\footnote{106}{See note 85 supra and accompanying text.}
\footnote{107}{405 U.S. at 454-55.}
\footnote{108}{Id. at 453. The Court stated:

If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.}
\footnote{109}{The substance involved in the case was actually vaginal foam, which apparently falls within the definition of a drug under section 201(g)(1) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1) (1970).}
\footnote{110}{405 U.S. at 453-54. Note, however, that the user of the drug was not a party to the case; rather, the distributor was allowed to assert the rights of the user-distributee. See text accompanying notes 172-73 infra.}
\footnote{111}{The health-care aspect of the contraceptive (protecting a woman's health by preventing pregnancy) probably plays only a minor role in supporting the Court's view that contraceptives should be made accessible to the public. The primary considerations seem to be sexual relations and family planning, including the general concern over population growth. See note 84 supra.}

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woman's decision to have an abortion, whether such a right is found in the fourteenth amendment's concept of personal liberty or the ninth amendment's reservation of rights to the people.\textsuperscript{112} The Court stated that only personal rights that can be deemed "fundamental" or "implicit in the concept of ordered liberty" are included in this guarantee of personal privacy.\textsuperscript{113} Because the Court found that the right to an abortion fell within this definition, a right of personal choice for general health-care activities could also be considered in the same category of "fundamental rights." As Justice Douglas said in a companion case, the right of privacy includes "the right to care for one's health and person and to seek out a physician of one's own choice . . . ."\textsuperscript{114}

The existence of a special right of privacy encompassing health-care activities is supported by the fact that numerous decisions have emphasized the importance of health-care treatment. In one decision, the Supreme Court reaffirmed society's expectation that patients receive "such treatment as is necessary to preserve their health."\textsuperscript{115} Similarly, a right of access to health care has been held necessary,\textsuperscript{116} and custodial patients have been accorded a constitutional right to receive a sufficient health-care treatment.\textsuperscript{117} It has also been suggested for purposes of review that there is "a right to medical treatment to the extent that the state may not make unavailable a medically safe and effective drug which is necessary to the maintenance of an individual's health and well-being."\textsuperscript{118} The existence of a physician-patient privilege serves as further evidence of the legal recognition afforded privacy in health-

\textsuperscript{112} 410 U.S. at 153. The Supreme Court believed that a right of privacy was derived from the fourteenth amendment, rather than from the ninth amendment. In essence, the Court held that because a law regulating or prohibiting the performance of abortions limits a woman's fundamental constitutional right to privacy, such a law can be justified only by the showing of a compelling state interest. During the first trimester of pregnancy, a physician's decision, in consultation with his patient, that the pregnancy should be terminated by an abortion, may be effectuated without any interference by the state, for there is no compelling state interest in interfering with such a decision. In the middle trimester the state, in promoting its interest in the health of the mother, may regulate the abortion procedure in ways reasonably related to maternal health. During the final trimester of pregnancy, the state, in promoting its interest in protecting fetal life after viability, may proscribe abortions unless necessary to preserve the mother's life or health.

\textsuperscript{113} Id. at 152. The Court quoted Palko v. Connecticut, 302 U.S. 319, 325 (1937).


Although the Court did not define the dimensions of the privacy right, Roe v. Wade laid the groundwork for eventual recognition of a right to privacy in the area of health care. Furthermore, the marijuana cases are adequate indication of a willingness by some authorities to recognize that the right of privacy includes freedom to possess and obtain certain types of drugs for personal use. The fact that drugs are to be used for personal health-care treatment, rather than for mere hedonistic pursuits, strengthens the argument that individual privacy should be protected in a person's attempt to use these substances. Eisenstadt indicates that the scope of privacy should encompass the right to obtain, as well as to use, health-care drugs.

The fluoridation and vaccination cases do not directly recognize a right of privacy in a health-care context, but the type of analysis undertaken by the courts certainly implies that such a fundamental right exists. These cases suggest that the right of privacy in the area of health care is to be given strong consideration and that it may be infringed only by showing a compelling state interest. In relation to health-care drugs, the analyses of the courts indicate that a person should have a right to obtain and use health-care drugs of questionable efficacy unless the government can show a compelling interest to restrict such a right. In this respect, the critical factor is the determination of the compelling state interests and the necessary means of applying those interests.

STATE INTERESTS IN DRUG REGULATION

The general state interest in enacting the Food, Drug, and Cosmetic Act and similar state laws is protection of public health. The Supreme Court has said the purposes of the federal Act touch phases in the lives and health of people which, in circumstances of modern industrialism, are largely beyond self-protection. Clearly the Act's objective is to prevent the distribution and sale of adulter-

120. 405 U.S. at 453-54. In addition, Justice White said "to sanction a medical restriction upon distribution of a contraceptive not proved hazardous to health would impair the exercise of the constitutional right of privacy." Id. at 464 (White, J., concurring).
ated, unsafe, or ineffective health-care drugs. However, the scope of the Act goes beyond protection of the public from profit-hungry manufacturers and distributors; it also serves to protect a person against himself by prohibiting interstate transportation of unapproved drugs even for personal use.

Although there has been considerable controversy over the government's power to regulate private conduct, it seems well established in American law that a person's self-destructive conduct—be it moral or physical—may be controlled. The Supreme Court in Roe v. Wade specifically stated that there is not an unlimited right to do with one's body as one pleases. Other cases have upheld the government's authority to proscribe possession of dangerous and habit-forming drugs. More recently, a number of cases have upheld statutes requiring motorcyclists to wear safety helmets—an indication that the government has an interest in infringing upon personal choice and personal liberty in order to protect an individual against a mere possibility of self-harm.

Obviously the government has a strong interest in regulating personal use of a physically dangerous drug because of the harmful effects upon the user. Thus, the Supreme Court upheld a state law

122. The federal government's authority to regulate health-care drugs is based on the commerce clause. All agree that Congress in the exercise of its authority over interstate commerce may regulate interstate traffic of food and drugs. E.g., United States v. Walsh, 331 U.S. 432 (1947); Seven Cases v. United States, 239 U.S. 510 (1916). The state government's authority is based on its police power, which gives a state "broad power to establish and enforce standards of conduct . . . relative to the health of everyone." Barsky v. Board of Regents, 347 U.S. 442, 449 (1954).

123. E.g., J. Mill, On Liberty (1856 ed.). Mill states at 13:

The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant . . . Over himself, over his body and mind, the individual is sovereign.


124. See Paris Adult Theater I v. Slaton, 413 U.S. 49, 68 n.15 (1973), in which the Court observed that statute books are replete with constitutionally unchallenged laws against suicide and self-mutilation, implying that the state has a legitimate interest in regulating any activity which may be harmful to the individual.


126. See People v. Poucher, 67 Mich. App. 133, 135-36, 240 N.W.2d 298, 299 (1976), for cases cited upholding the authority of the state to require the wearing of safety helmets and stating that such a requirement is not an unconstitutional invasion of a person's right to be let alone. Courts in 29 states have held helmet legislation valid. Id. The only contrary holding to date is People v. Fries, 42 Ill. 2d 446, 250 N.E.2d 149 (1969).
forbidding the sale, administration, and possession of morphine despite its medical use.\textsuperscript{127} Two California cases held that opium, even though it has beneficial use as a medicinal drug, could be regulated in its sale and disposition, even to the extent of its absolute prohibition.\textsuperscript{128} In both situations, the courts implied that the state’s interest in protecting an individual against the use of dangerous drugs outweighed the medicinal benefit an individual could obtain from the use of such substances.

Safety is a compelling government interest in the regulation of health drugs, and efficacy seems to be directly related to the concept of safety. Even though evidence of toxicity is lacking, an ineffective drug promoted as a cure for certain diseases may induce patients who are in a medically aidable condition to delay medical treatment by competent physicians to the extent they become less curable.\textsuperscript{129} As a consequence, interstate shipment of an ineffective drug could cause irreparable injury.\textsuperscript{130} The belief that ineffective drugs are dangerous to public health is based upon two assumptions: First, use of such substances will induce the person to refrain from traditional treatment; and second, traditional treatment might effect a cure of the patient. Proponents of laetrile contest these assumptions, stating that at a minimum a drug of questionable efficacy like laetrile should be available as supplemental treatment.\textsuperscript{131} When used as a supplemental means of treatment along with more traditional methods, a safe drug will cause no additional harm to the user even if ineffective. In sum, if a drug is

\begin{itemize}
\item \textsuperscript{127} Whipple v. Martinson, 256 U.S. 41, 45 (1921).
\item \textsuperscript{128} In re Yun Quong, 159 Cal. 508, 114 P. 835 (1911); In re Hallawell, 8 Cal. App. 563, 97 P. 320 (1908).
\item \textsuperscript{129} United States v. Nutrition Serv., Inc., 227 F. Supp. 375, 388 (W.D. Pa. 1964), aff’d, 347 F.2d 233 (3d Cir. 1965). See also 17 CAL. AD. CODE § 10400.1 (1963), which specifically bans the sale, administration, and prescription, \textit{inter alia}, of laetrile to any patient who has or believes he has cancer. The California Department of Public Health has concluded:
\[ \text{[T]he use of one or more of these agents in early cancer to the exclusion of conventional treatment might well be dangerous since treatment with acceptable, modern, curative methods . . . would thereby be delayed potentially until such time as metastases had occurred and the cancer therefore might no longer be curable.} \]
\item \textsuperscript{131} Proponents of laetrile say 80 to 85% of those who use the substance have already exhausted traditional cancer treatment without obtaining relief or are using it as a mere supplemental means of treatment in conjunction with more traditional treatment. N.Y. Times, Feb. 28, 1971, at 52, col. 3; San Diego Union, March 18, 1976, § A, at 8, col. 5.
\end{itemize}
safe from the standpoint of toxicity\textsuperscript{132} but is of questionable efficacy, arguably the government has no compelling interest in prohibiting its use as a supplemental remedy. In addition, if a fundamental right of privacy is at stake, the government has to show that the statute is narrowly drawn to reflect only the legitimate interests of the state.\textsuperscript{133}

The above analysis points out the critical factor of drug safety—that is, the question of whether the drug is physically safe for human consumption. If a drug is physically unsafe to ingest, the government has a strong interest in regulating the substance. However, because safety is a relative standard, dealing in terms of safety alone is misleading. Aspirin serves as an example. Consumption of aspirin can produce undesired side-effects, but it is generally accepted that the beneficial relief afforded by aspirin outweighs the risk of harm. In short, the concept of safety must be analyzed with reference to efficacy. If a fundamental right of privacy is recognized in health care, courts should weigh the interests of the government against the interests of the individual in determining whether an individual may obtain and use certain health-care drugs. Safety and efficacy are the two primary elements in determining which party has the greater interest.

\textit{People v. Woody}\textsuperscript{134} illustrates the competing interests in an analogous situation. In that case, the state law at issue proscribed possession of peyote, a hallucinogenic substance which defendants used for religious purposes. The court weighed protection of freedom of religion against the state's interest in protection of health. Religious expression was found to be the superior interest because use of peyote presented only a slight danger to the user and the state.\textsuperscript{135}

A test similar to that employed in \textit{Woody} can be utilized when the fundamental right at stake is privacy in the area of health care. It is reasonable to afford greater protection to the individual's right to obtain and use a health-care drug of questionable efficacy as recognition of the drug's effectiveness is shown to increase. However, as recognition of purported effectiveness lessens, the individual's interest in health care lessens, and the state can more easily counter the individual's interest on the basis of questionable safety.\textsuperscript{136}

\textsuperscript{132.} Toxicity means that the substance has adverse physical effects upon the user.
\textsuperscript{134.} 61 Cal. 2d 718, 394 P.2d 813, 40 Cal. Rptr. 69 (1964).
\textsuperscript{135.} \textit{Id.} at 727, 394 P.2d at 821, 40 Cal. Rptr. at 77.
\textsuperscript{136.} See § 201(c), 21 U.S.C. § 811(c) (1970), which outlines a balancing
This type of analysis raises the question of the court's jurisdiction to consider the safety and efficacy of drugs. It is generally assumed that the Food and Drug Administration (FDA) has primary jurisdiction over determining the safety and efficacy of drugs, but at least one court has made findings on its own, and other courts impliedly have questioned the FDA's primary jurisdiction. A person seeking to obtain a substance like laetrile may not have time to go through the normal process of having the FDA make a determination of the drug's safety and effectiveness. An individual should be able to seek immediate relief in court. When such relief is sought, a court need not make any final determination of safety and efficacy in upholding a right to obtain and use healthcare drugs by virtue of this balancing test. Rather, the court could merely determine whether a genuine difference of opinion exists over the drug's safety. The standard employed by the court for testing safety would be similar to the "generally recognized" standard in section 201 of the Food, Drug, and Cosmetic Act. If there test for determining whether a specific drug or substance should be controlled or removed from the schedules provided in that chapter. Factors for the drug include (1) its actual or relative potential for abuse, (2) scientific evidence of its pharmacological effect, if known, (3) the state of current scientific knowledge regarding the drug, (4) what, if any, risk there is to the public health, and (5) its psychic or physiological dependence liability.


138. Rutherford v. United States, 399 F. Supp. 1208, 1212 (W.D. Okla. 1975), remanded, 542 F.2d 1137 (10th Cir. 1976) (specific finding that laetrile is non-toxic when used in moderate amounts). See United States v. An Article or Device . . . "Hubbard Electrometer," 333 F. Supp. 357, 359 (D.D.C. 1971) (Court found that the device had no medical or scientific worth even though FDA had not determined its safety or effectiveness.).

139. See Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652-53 (1973) (In some cases general recognition that a drug is effective might be made without the kind of scientific support necessary to obtain approval of an NDA.); Pfizer, Inc. v. Richardson, 434 F.2d 536, 543 (2d Cir. 1970) (A controversy over the efficacy of a particular drug raises an issue of adjudicative fact.); United States v. Allan Drug Corp., 357 F.2d 713, 719-20 (10th Cir.), cert. denied, 385 U.S. 899 (1968) (Court infers that it could speculate on the effective uses of a drug.).

is a difference of opinion over the drug's safety, the drug may be regulated or absolutely proscribed unless the proponent can show significant recognition of the drug's effectiveness or unless the safety interest is minimal in comparison to the individual privacy interest. If the drug is recognized as dangerous, it may be proscribed unless the proponent can show significant recognition of the drug's effectiveness against life-threatening diseases. The “significant-recognition” test for efficacy could be based on a respected minority opinion of the medical and scientific community.

The competing interests can be analyzed with respect to four classes of health-care drugs distinguished by safety and efficacy recognition factors.

(1) **Drugs of recognized safety, recognized effectiveness.** The government has no legitimate interest in proscribing these drugs because there is neither a question of safety nor a threat of reliance on an ineffective drug. Furthermore, the individual has an overriding interest to use this type of drug for protecting his personal health and well-being.

(2) **Drugs of recognized safety, unrecognized effectiveness.** The government interest is to prevent reliance by users who to their (1970). See note 50 supra. Under this test, the actual safety of the drug is not in issue; the issue is one of general recognition of the drug.

141. A dangerous drug is a substance such as those defined in the schedules of section 202(b) (1) & (2), 21 U.S.C. § 812(b) (1) & (2) (1970). These drugs have a high potential for abuse and their use is not accepted as safe. A mildly unsafe drug is a lesser health hazard. See generally Rutherford v. United States, 542 F.2d 1137, 1142 n.4 (10th Cir. 1976); Oppenheimer v. Sterling Drug., Inc., 7 Ohio App. 2d 103, 107, 219 N.E.2d 54, 57 (1964).

142. The term *significant recognition* is comparable, but not as demanding, as the *generally-recognized* standard used in determining whether a substance is a new drug. See notes 50 & 140 supra. The primary difference is that significant recognition is not intended to require majority recognition of efficacy. Rather, it requires only a respected minority opinion of experts who have based their conclusions on adequate and well-controlled investigations, even if those investigations are not positively conclusive. The significant-recognition standard is necessary to avoid the conflicting, and often harsh, views taken about the interpretation of the term *generally recognized*. See United States v. Article of Drug . . . “Mykocert,” 345 F. Supp. 571, 574-75 (N.D. Ill. 1972). There the court acknowledged that “difficulty has been encountered by the Courts in determining precisely what degree of recognition both in quantity and quality constitutes ‘general recognition’ under the statute . . . .”

143. The classifications of “recognized safety” and “recognized effectiveness” are based on recognition, not actual safety or actual effectiveness. The standards employed, unless otherwise specified, are general recognition for safety and significant evidence for efficacy; see notes 140 & 142 supra.

144. Even though the government may have no legitimate interest in the proscription of these drugs, it may have an interest in their regulation to assure their proper use.
detriment might refrain from beneficial treatment. However, this interest would not be applicable to those using the drug to combat mild ailments or those who use the drug as supplemental treatment for any type of disease. Because safety is not a factor, people using this type of drug for cure of a mild ailment, such as a common cold, would have an interest in their autonomy of health care superior to any legitimate government interest. Those who use the drug as supplemental treatment for more serious diseases would also have the superior interest if such a class of users could be readily distinguished from other users. In other words, the question is whether the statute can effectively serve the legitimate government interest of protecting against detrimental reliance without including the class of supplemental users.

(3) Drugs of unrecognized safety, recognized effectiveness. The government’s interest in proscribing such substances is the safety factor, while the individual’s interest in obtaining such drugs is the curative factor. To balance the interests of the government and of the individual, safety must be weighed against the type of curative value afforded by the drug. Thus, a truly dangerous drug could be proscribed if it were not intended to treat a life-threatening disease. However, a life-saving drug could not be proscribed even if considered dangerous, although regulation would certainly be appropriate. In general, as recognition of danger increases, an individual will be required to demonstrate a greater

145. See United States v. Article of Drug Labeled “Quick-O-Ver,” 274 F. Supp. 443, 449 (D. Md. 1967); United States v. Article of Drug Labeled “Decholin,” 264 F. Supp. 473, 482–83 (E.D. Mich. 1967). Both cases held that when a drug is designed for use against everyday ailments such as a headache and upset stomach and only the efficacy is in dispute, the government does not have a legitimate claim in saying that the user will be harmed by any delay induced by the taking of the ineffective drug.

146. This issue is discussed in the text accompanying notes 155–58 infra.

147. See In re Yun Quong, 159 Cal. 508, 114 P. 835 (1911); In re Hallwell, 8 Cal. App. 563, 97 P. 320 (1908) (where drugs considered dangerous were subject to complete proscription despite known medicinal benefits not of the life-saving variety).

148. In Roe v. Wade, 410 U.S. 113, 150 (1973), the Supreme Court said that the state retains a definite interest in protecting the woman’s own health and safety when an abortion is proposed at a late stage in pregnancy, but that an abortion may be performed if necessary to save the woman’s life. In Jacobson v. Massachusetts, 197 U.S. 11, 39 (1904), the Court indicated that the state’s interest in protecting health must yield if such action would take the life of the person being vaccinated. Both decisions imply that the government’s interest in protecting health must yield to the life-saving interest of the individual.
personal interest, primarily by showing recognition of effectiveness for the treatment of life-threatening diseases.

(4) *Drugs of unrecognized safety, unrecognized effectiveness.* The safety factor gives the government a strong interest to proscribe, while lack of recognized effectiveness gives a strong government interest against use by those relying on such a drug for treating life-threatening diseases. As in class (2) above, two groups of people could assert countervailing interests to the government's interest in proscribing such substances because of lack of efficacy: (a) those who use the drug as an exclusive remedy to combat mild ailments, and (b) those who use the drug as supplemental treatment for any type of disease. The questionable safety of a drug can offset an individual's personal interest in using such a substance for a mild ailment because of the government's interest in preventing self-harm. Only when the individual's personal interest reaches the magnitude of life-determining consequences, will it be appropriate to find that the individual's interest is comparable to the government's interest. Thus, when a substance is being used to combat a life-threatening disease, an individual may be able to claim an interest superior to the government's safety interest. The appropriate test for people wishing to take drugs of unrecognized safety and efficacy as supplemental treatment for a life-threatening disease would seem to be one of balancing the possibility of harm against the possibility of cure. For instance, a dangerous drug with a nearly absolute lack of recognition for its effectiveness would clearly give the government a superior interest. However, a drug which is recognized as only mildly unsafe, but for which some recognition of effectiveness exists (not reaching the level of significant recognition of effectiveness), would probably be made available to the individual wishing to use it as supplemental treatment for a life-threatening disease.

Application of this analysis to laetrile by weighing the government's interests against the individual's interests is illustrative. There seems to be a genuine difference of opinion over the question of whether laetrile is safe. Some have said laetrile is safe for use in moderate amounts, while others have found harmful

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149. See cases cited in note 72 supra, in which courts said that so long as a rational basis exists for concluding marijuana is harmful to personal health, marijuana possession may be made illegal. The rational belief in danger outweighs personal health interests because of the absence of indication that the drug may prove beneficial.

Furthermore, even though laetrile has some vociferous proponents, the drug does not meet the standard of "significant recognition" for its effective worth. Thus, laetrile falls into class (4), a drug of unrecognized safety, unrecognized effectiveness. Because it is intended for treatment of cancer, a life-threatening disease, only those using it as supplemental treatment could possibly offset the government's interest in preventing detrimental reliance. The test then becomes one of balancing the possibility of harm (mildly toxic) against the possibility of cure (very limited recognition). Although laetrile presents a difficult question, it seems that the stronger interest rests with the individual who desires to use laetrile as a supplemental treatment. The government interest in protecting the individual against harm from toxic effects of laetrile does not appear as great as the individual's right of privacy in obtaining and using this health-care drug. However, the question remains of whether a statute can be drawn to serve a compelling interest in protecting against detrimental reliance on drugs of unproven effectiveness without including the class of supplemental users.

**NECESSARY MEANS OF REGULATION**

In *Roe v. Wade,* the Supreme Court held that when fundamental rights are involved, regulation of those rights may be justified only by statutes that are narrowly drawn to express the

152. The recognition of laetrile as an effective cure of cancer is not significant enough to meet the standard detailed in note 142 supra. Apparently most of the claims of effectiveness stem from personal experiences, not clinical studies.  
153. It must be remembered that the government has a legitimate interest in protecting an individual against self-harm. E.g., note 126 supra, concerning the government's interest in requiring people to wear motorcycle helmets to protect motorcyclists against the mere possibility of self-harm. In the same respect, the government has an interest in protecting people against reliance on drugs of unproven efficacy as their sole remedy against a life-threatening disease. Even if the individual believes he will not get into a motorcycle accident or believes that a laetrile-type drug will cure his disease, the government has a valid interest in protecting against that possibility of self-harm.  
154. This reference is made only to the rights of the individual who uses the drug. It does not necessarily follow that the same rights are held by physicians or distributors.  
compelling state interests at stake. In the instance of health-care drugs of questionable efficacy, a compelling state interest can be shown because an individual might take a drug of unproven effectiveness for a serious disease in lieu of traditional methods of treatment. People seeking a laetrile-type drug as a purely supplemental means of treatment, fully aware of its questionable effectiveness, are not within the ambit of any compelling interest. The question becomes whether statutes could be more narrowly drawn to serve this compelling state interest without including the class of supplemental users.

As an alternative to the federal Act's complete prohibition of laetrile-type drugs in interstate commerce or a state statute's prohibition against administration, such drugs might be made available on a strictly regulated basis. One authority has suggested that laetrile be distributed by a government commission in order to assure that laetrile users are also receiving traditional cancer treatment. Another form of regulation would be to make a laetrile-type drug available only on a tightly controlled prescription basis, leaving it to the physician's judgment to determine whether such a drug is appropriate. If a drug like laetrile is made available through regulated professional channels, rather than only through underground markets, the laetrile user will probably be exposed to truly beneficial medical care. Furthermore, strict misbranding and advertising standards would remain to protect all users from false and misleading claims by distributors, with warnings of the unproven effectiveness. In this sense, the federal and state statutes could be more narrowly drawn to respect an individual's right of privacy in personal health care while protecting on a limited basis a person's right to obtain and use certain drugs of questionable efficacy.

156. See note 129 supra.
157. Dr. Harold A. Harper, professor of biochemistry at the University of California, San Francisco, School of Medicine, suggested that laetrile might be administered by a government agency in order to control distribution more effectively. Dr. Harper stated that he considers laetrile useless in the cure of cancer but suggested that regulated distribution would eliminate the profit-motive and convince cancer patients to obtain traditional cancer treatment. San Diego Union, Sept. 30, 1976, § B, at 1, col. 1.
158. See Food, Drug, and Cosmetic Act § 503(b) (1), 21 U.S.C. § 353(b) (1) (1970), requiring that certain categories of drugs be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs. Under the present system, a laetrile user probably can obtain the drug through illicit channels and without the supervision of a qualified physician. If laetrile were made available through legal channels, laetrile users would be under much closer medical supervision. Furthermore, a physician might be unwilling to administer laetrile because of the malpractice risk and might be able to convince the patient of its unproven effectiveness.
COLLATERAL RIGHTS

It is clear that if an individual is successful in asserting a right to obtain and use an unapproved drug like laetrile, manufacturers will claim a right to distribute the substance, physicians will claim a right to prescribe and administer it, and pharmacists will claim a right to dispense it. Distributors and physicians can attack drug laws in two distinct ways: They can claim an independent right to distribute and administer the substance, and they can claim standing to assert rights held by users of the drug.

Constitutional protection of economic interests has fallen into disfavor in recent years, and courts could not be expected to find a fundamental right of commercial distributors or pharmacists to distribute certain health-care drugs. Thus, the right to distribute may be restricted by any law bearing a rational relationship to a permissible state objective.

Physicians may claim that their right to administer such substances falls within the scope of privacy protecting the physician-patient relationship or within the scope of a physician's discretion in the practice of medicine. The medical profession, however, has long been subject to government regulation. In addition, recent decisions have held that in order to protect public health and safety the state may limit a physician's authority to prescribe drugs for a patient. Protection of the patient requires that a physician be subject to certain medical standards in administering treatment. Privacy in health care should be dependent upon the individual's decisionmaking and should not encompass the entire

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159. See, e.g., Williamson v. Lee Optical Co., 348 U.S. 483 (1955); United States v. Darby, 312 U.S. 100 (1941). One authority has said that no claim of substantive economic rights would be sustained by the Supreme Court. McCloskey, Economic Due Process and the Supreme Court: An Exhumation and Reburial, 1962 Sup. Ct. Rev. 34, 38. See also note 64 supra.

160. See authorities cited note 159 supra.


162. See, e.g., Dent v. West Virginia, 129 U.S. 114 (1889).

163. People v. Nunn, 46 Cal. 2d 460, 469, 296 P.2d 813, 818, cert. denied, 352 U.S. 883 (1956) (Court held that the legislature may deprive a doctor of the right to prescribe for certain patients.); Blinder v. Division of Narcotic Enforcement, 25 Cal. App. 3d 174, 181-82, 101 Cal. Rptr. 635, 640 (1972) (State has the right to regulate administration of drugs, and physicians are granted certain privileges respecting administration of drugs, but this privilege is not absolute as the state has the power to regulate professions in the interest of public health and safety.). See Felber v. Foote, 321 F. Supp. 85, 88 (D. Conn. 1970) (doctor required to report drug dependent patients).
physician-patient relationship. While neither distributor nor physician seemingly has an independent right to administer or distribute a drug like laetrile, a strong case can be made for asserting the rights of a third-party user.

The general rule is that a person whose own constitutional rights are not infringed by a law may not assert the rights of a third party in challenging the constitutionality of that law. However, the Supreme Court has allowed a distributor of contraceptives to assert the interests of unmarried distributees, an employee to assert the rights of his employer, owners of private schools to assert the rights of their patrons, a vendor of property to assert the rights of a Black vendee in defense to a racially restrictive covenant, and an association to assert the rights of its members. Those cases indicate that the Court has adopted a factor analysis to determine whether one party maintains standing to assert rights of other parties. The most important factors appear to be the nature of the right being asserted, the ability of the other party to assert the right himself, and the type of relationship between the parties.

Third-party standing will not be available when the right at stake is a mere contractual or property right. The cases in which the Supreme Court has granted third-party standing reveal that an important personal right of the third party, such as education of children or the equal protection rights of Blacks, was in issue. The privacy right of the health-drug user is a similar type of personal right and thus meets the first criterion.

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164. Cf. Act of Sept. 19, 1976, Pub. Law No. —, 1976, Alaska Sess. Laws ch. 227, which provides that no health facility may interfere with the physician-patient relationship by restricting or forbidding the use of laetrile when prescribed or administered by a physician and requested by a patient unless laetrile is found to be harmful. Significantly, the statute, in allowing laetrile to be administered, requires that the patient request laetrile treatment. In other words, the patient's individual decision is the important element in the physician-patient relationship which is worthy of protection.


171. Sedler, Standing To Assert Constitutional Jus Tertii in the Supreme Court, 71 Yale L.J. 599, 646-47 (1962). This test is of course very subjective, and the importance of the right being asserted depends in part on the equities of the case. The rule denying standing to raise another's rights is only a rule of practice; it may and should be disregarded whenever necessary for effective attainment of justice. Barrows v. Jackson, 346 U.S. 249, 257 (1953).
Because interstate transportation of unapproved health-care drugs for personal use is prohibited by the Food, Drug, and Cosmetic Act, the laetrile user has the ability to assert rights in behalf of himself. Thus, the Court will have little desire to allow a distributor to assert the user’s rights. This situation differs from Eisenstadt v. Baird, in which the statute prohibited only distribution of contraceptives to single people, thereby impairing their privacy rights without subjecting them to prosecution. The distributors were afforded standing to assert the privacy interests because the individuals had no way of asserting their privacy rights. The state statutes proscribing administration of laetrile for cancer treatment do not afford the laetrile user any opportunity to assert his privacy rights because only the one administering the drug is subject to prosecution. A person administering laetrile therefore has a stronger argument for asserting the user’s rights.

The critical factor in the standing issue is the type of relationship enjoyed by the parties. A purely commercial relationship alone should not enable a distributor to assert the rights held by the user-distributee because of its impersonal, non-confidential, and fortuitous nature. In Eisenstadt, where the Supreme Court allowed the distributor to assert the distributee’s rights, considerable emphasis was placed on the special relationship between the distributor and distributee. The Court saw their encounter as encompassing more than a mere commercial transaction. To the extent that a significant rather than a fortuitous relationship can be shown, standing should be granted to the distributor under the Eisenstadt rationale. However, it seems unlikely that the ordinary distributors of laetrile will be able to prove a special relationship with the ultimate distributee. In one case, the distributors of laetrile were alleged to be part of a multi-million dollar operation, a marked contrast to the personal relationship which Baird enjoyed with the distributee in Eisenstadt.

172. 405 U.S. 438, 446 (1972).
173. Id.
174. Sedler, supra note 171, at 647.
175. 405 U.S. at 445. The Court stated: [T]he relationship between Baird and those whose rights he seeks to assert is not simply that between a distributor and potential distributees, but that between an advocate of the rights of persons to obtain contraceptives and those desirous of doing so. The very point of Baird’s giving away the vaginal foam was to challenge the Massachusetts statute that limited access to contraceptives.
While the relationship between distributor and distributee may be viewed in an impersonal, commercial sense, the physician-patient relationship has enjoyed special status in the eyes of the law.\(^\text{177}\) The special intimacy of the relationship appears adequate justification for allowing the physician to assert the rights of the patient.\(^\text{178}\) In *Griswold v. Connecticut*,\(^\text{179}\) the Supreme Court held that in attacking an anti-contraception statute, the executive director of Planned Parenthood and a physician who gave information, instruction, and medical advice to married couples about contraception had standing to raise the constitutional rights of married people with whom they had a professional relationship. One authority asserts that when a party to a professional relationship is adversely affected by action dealing with the subject matter of the relationship, he should have standing to assert that the constitutional rights of the other party to the relationship are infringed upon by such action.\(^\text{180}\) If physicians are allowed to assert the rights of their patients and if the courts recognize a right of privacy in using certain drugs of questionable efficacy, physicians should not be prosecuted under state statutes forbidding the administration of certain substances. This conclusion, of course, assumes that a patient is in the position to assert a personal health-care right and is not being administered a substance like laetrile as the exclusive means of treatment.

**Recent Laetrile Development**

Even as this article goes to press, the controversy surrounding laetrile continues to grow. Another federal district court has followed the lead of the *Rutherford* decision\(^\text{181}\) by granting a preliminary injunction against the FDA in order to allow a terminally ill cancer patient to transport limited amounts of laetrile in interstate commerce for his personal use.\(^\text{182}\) The court concluded that

\(^{177}.\) See, e.g., CAL. EVID. CODE §§ 900-1007 (West Supp. 1976), listing laws dealing with the physician-patient privilege.


\(^{179}.\) 381 U.S. 479, 481 (1965).

\(^{180}.\) Sedler, *supra* note 171, at 649-50. He emphasizes that the relationship must be professional, similar to that enjoyed between physician and patient, as distinct from purely commercial.


"[t]o deny such a person his freedom of choice, when there are no other remedies presently available, would appear grossly paternalistic . . . ." \textsuperscript{183}

**CONCLUSION**

The most practical approach for a person wishing to obtain and use an unapproved health-care drug is to show that a certain substance falls outside particular provisions of the Food, Drug, and Cosmetic Act and is therefore not subject to the Act's pre-marketing requirements. However, such a showing ordinarily cannot be made, and it may be necessary to use a constitutional argument to achieve those objectives. The most feasible constitutional argument is to demonstrate the existence of a fundamental right of privacy in the area of health care.

If a fundamental right is at stake, the appropriate standard of review is strict scrutiny. Under this standard, the government's interest in health and safety cannot offset the individual's privacy interest when a drug of questionable efficacy is used merely as a supplemental treatment. Therefore, statutes regulating drugs of questionable efficacy should be more narrowly drawn so as not to infringe upon the rights of supplemental users of a drug like laetrile. Making such drugs available through professionally staffed agencies would satisfy the health-care rights of these individuals, while removing the uncertainty and mystery surrounding unapproved health cures. Such an approach would improve the current system by assuring that users of laetrile-type drugs receive complete and competent medical treatment.

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