

Supreme Court of the United States.
THE UNITED STATES OF AMERICA, et al., Petitioners,
v.
Glen L. RUTHERFORD, et al., Respondents.
No. 78-605.
October Term, 1978.
April 5, 1979.
Brief of *Amicus Curiae*
American Academy of Medical Preventics in Support of Respondents
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By consent of petitioner and respondent American Academy of Medical Preventics files this brief as *Amicus Curiae*. [1]

INTEREST OF *AMICUS CURIAE*

The American Academy of Medical Preventics is a nationwide group of physicians with 133 paid members. The Academy's purpose is the promotion and dissemination of information to physicians and the public regarding alternative methods of essentially nontoxic therapies for the treatment of chronic and degenerative disease.

The Academy is particularly interested in the issues involved in this case

regarding the constitutional right of an [2] informed consenting patient to receive essentially nontoxic therapies from a licensed physician, and whether the flat prohibition of such therapies prior to State approval is reasonably related to the preservation and protection of the public health.

The parties herein are properly concerned with establishing their positions on the facts of the case. The Academy, however, respectfully requests that the Court, in considering the specific issues in the case, also give consideration to the broader aspects of the issues.

SUMMARY OF ARGUMENT

That class of cancer victims who desire to obtain and use Laetrile in a program of nutritional therapy is protected by constitutional guarantees of privacy and personal liberty. Since cancer victims cannot meaningfully exercise this right in isolation (sic), the constitutional protection accorded cancer victims' right to utilize Laetrile extends to physicians willing to administer Laetrile. State interference with informed consenting cancer victims' constitutionally protected right to obtain and use Laetrile administered by a licensed physician is not necessary to further any substantial or compelling State interest. State interests in preventing delay of State sanctioned treatments, preventing fraudulent and deceptive practices, and providing information about State sanctioned treatments are not accomplished by a complete ban on Laetrile. These State interests are certainly not accomplished in the least restrictive way to prevent infringement on cancer victims' constitutional right of privacy and personal [3] liberty.

21 U.S.C. 355, as applied, prohibits all cancer victims from obtaining Laetrile. This includes those cancer victims diagnosed as terminal or too frail for State sanctioned treatments by competent medical advisors, cancer victims who seek to supplement State sanctioned treatments with nutritional treatment that includes Laetrile, and cancer victims who have rejected State sanctioned treatments after receiving competent medical advice. The law, as applied, requires forced State sanctioned treatments or nothing at all. The law is brutal and offensive to human dignity as well as cruel and inhuman. A law that isolates cancer victims from a licensed physician is certainly not reasonably related to the preservation and protection of the public health. [4]

ARGUMENT

I Federal Food, Drug And Cosmetic Act Section 505, 21 U.S.C. 355, And Its Application, Unlawfully Precludes Cancer Victims From Exercising Their Constitutional Rights To Obtain And Use Laetrile In Violation Of United States Constitution Amendments I, IV, V, IX, And XIV.

A. That class of cancer victims who desire to obtain and use Laetrile in a program of nutritional therapy is protected by Constitutional guarantees of privacy

and personal liberty.

Long before our Bill of Rights or our political parties or the State's concern with the nature of treatment received by cancer victims, a zone of privacy, innate in every human being, has existed. The fundamental nature of this right derives from the very nature of man.

In perhaps the best known dissent in American jurisprudence, Justice Brandeis recognized the fundamental nature of the "right to be let alone" in *Olmstead v. United States*, 277 U.S. 438 (1928), where he stated at page 478: The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure, and satisfaction of life are to be found in material things. They sought to protect Americans in their [5] beliefs, their thoughts, their emotions, and their sensations. They conferred, as against the government, the right to be let alone--the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation

Without substantive values beyond those of assuring the fair implementation of the State's own positive decisions, the Constitution could protect little beyond the entitlements government chose to confer. The thesis of substantive values beyond enumerated ones in the Bill of Rights was recognized in *Poe v. Ullman*, 367 U.S. 497 (1961) by Justice Harlan as a "rational continuum" where he stated at page 543: The full scope of the liberty guaranteed by the Due Process Clause cannot be found in or limited by the precise terms of the specific guarantees elsewhere provided in the Constitution. This 'liberty' is not a series of isolated points pricked out in terms of the taking of property; the freedom of speech, press, and religion; the unreasonable searches and seizures; and so on. It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, ... and which also recognizes, ... that certain interests require particularly careful [6] scrutiny of the state needs asserted to justify their abridgement.

The Court has found a constitutional right to privacy or personal liberty in several constitutional provisions. A privacy right has been held implicit in the "Penumbra" of the specific guarantees of the 1st, 4th, and 5th Amendments of the Constitution, *Griswold v. Connecticut*, 381 U.S. 479 (1965); the 9th Amendment's reservation of certain rights to the people, *Griswold v. Connecticut*, *supra*, (Goldberg, J., concurring); and the 14th Amendment's guarantee of liberty, *Roe v. Wade*, 410 U.S. 113 (1973).

Although these rights are not specifically enumerated, there are certain areas of individual freedom that are constitutionally protected from government intrusion, and these rights include many different individual activities. The outer limits of the

right of privacy and personal liberty have not yet been determined, but this Court has made it clear that unjustified government interference with personal decisions relating to marriage, *Loving v. Virginia*, 388 U.S. 1, 12 (1967); procreation, *Skinner v. Oklahoma*, 316 U.S. 535, 541-42 (1942); contraception, *Griswold v. Connecticut*, 381 U.S. 479 (1965); and child rearing and education, *Meyer v. Nebraska*, 262 U.S. 390 (1923), *Pierce v. Society of Sisters*, 268 U.S. 510 (1925); violate this concept.

Perhaps the Court's most comprehensive attempt thus far to define the constitutional right of privacy came in *Whalen v. Roe*, 429 U.S. 589, 599- 600 (1977) where, writing for a unanimous Court, [7] Justice Stevens suggested that the right encompassed something beyond the least common denominator of the Court's prior decisions with respect to marital choice, procreation, contraception, child rearing and education, and in fact embraced both a general "individual interest in avoiding disclosure of personal matters" and a similarly general, but nonetheless distinct, "interest in independence in making certain kinds of important decisions." The very core of personal freedom includes the right to control and make decisions about essentially personal affairs. Such decisions have a profound effect on the individual and a negligible effect on society at large. As the State seeks to apply Section 505, 21 U.S.C. 355, cancer victims are prohibited from obtaining Laetrile from a licensed physician and are permitted to choose only State sanctioned treatments of surgery, radiation therapy, or various forms of chemotherapy. Cancer victims are prevented from making their own personal and intimate decisions with respect to life and death and their own bodies before their lives are consumed by the cancer.

Many cancer victims who are competent and responsible adults seek the right to use a simple and harmless food substance known as "Laetrile," or "amygdalin," or "vitamin B-17," for its subjective effects in relieving them of Cachexia, the horrible physical wasting away of the body which accompanies the cancer, and for other effects that it may possibly have in relieving them of their cancer. They seek to use Laetrile not only for its possible benefits but [8] for its known benefits. While cancer victims cannot be certain that Laetrile will cure or control cancer, they do know, based upon personal experience, that it provides relief from the terrible pain, depression, and weight loss which mark the progression of their disease. Although such "anecdotal" evidence is condemned by the scientific establishment as "unscientific," courts have historically placed primary reliance on sworn testimony in resolving serious and important disputes. Because of personal experience, contacts with other cancer patients treated with Laetrile, and a wide variety of literature and other types of information which they have encountered in their attempts to learn more about the disease which threatens their lives, many cancer victims have acquired a conscientious personal conviction that there is substantial validity to a concept of disease and health care which has arisen within the medical and scientific professions in recent years and which is generally known as "metabolic" or "nutritional" therapy.

This conviction is that the metabolic processes of the human body, when

functioning properly, include highly sophisticated and effective immunity defenses against cancer; that cancer can only occur and spread when the normal human metabolic processes are not functioning properly; and that the correction of a metabolic imbalance or deficiency in the body may result in the elimination or control of cancer by the body's natural immunity defenses.

Although it is an authorized form of practice under state physicians and surgeons [9] certificates, and although it is practiced by a substantial number of physicians within the United States, metabolic therapy is not accepted or recognized by the American Medical Association. However, recent developments indicate that conventional practitioners are now beginning to recognize the value of nutrition in cancer treatment as well as the acute lack of government funds allocated for research in this area. (See U.S. Congress. Senate. Committee on Agriculture, Subcommittee on Nutrition, Nutrition and Cancer Research, Hearings 95th Cong., 2d Sess., June 12 and 13, 1978).

Although a substantial number of physicians and scientists as indicated in Note 9 of the District Court's opinion believe that programs of nutritional therapy which utilize Laetrile might be effective in controlling the symptoms of, or curing cancer, such treatments are highly unconventional. Nutritional therapy in general and the use of Laetrile in particular, are officially regarded by the National Cancer Institute to be of no value whatsoever in controlling or curing cancer.

Cancer victims, of course, could very well be wrong in believing that Laetrile or nutritional therapy may save or prolong their lives. However, the "right to be let alone" is not limited in its recognition to any single segment of the political, economic, or social thought spectrum. In commenting upon Justice Brandeis' most valued of rights, that right to be let alone, new Chief Justice Burger, in his dissent in [10] *Application of President and Directors of Georgetown Col.*, 331 F. 2d 1010 (Dist. of Columbia 1964) stated at page 1017:

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

Cancer victims may also be right. There is substantial support for their beliefs in the efficacy of Laetrile contained in the record below.

The question presented, however, is not whether Laetrile can cure or control cancer. In all probability, the question of whether Laetrile is effective will not be decisively settled within the medical and scientific professions for many years to come.

The issue is human liberty. The question is whether an informed cancer victim can be limited in choice of treatment received from a state licensed physician to State sanctioned alternatives.

As the State would apply Section 505, 21 U.S.C. 355, the State makes the ultimate and final decision for the individual cancer victim and denies an otherwise harmless, but controversial treatment, which cancer victims individually, having weighed the possible risks and benefits, believe might save or prolong their lives.

All of these facts are known to many cancer victims who nevertheless believe that there is a substantial possibility [11] that a program of nutritional therapy which includes therapeutic doses of Laetrile will result in their cancer being controlled or cured and their lives substantially prolonged. Their use of Laetrile in the past has resulted in significant subjective improvement in their physical deterioration.

They have decided to pursue a course of treatment which has had a demonstrated effect on the symptoms of their disease and have decided to pursue an unconventional course of treatment which might be effective rather than resign themselves to a slow, painful and certain death.

The decisions were subjective, non-medical ones based on intimate and intensely personal considerations which only individual cancer victims can properly evaluate and weigh. This is the right to make what is for them the most important and intensely personal decisions of their lives.

The decision concerns their personal health, their human dignity, and, for some, their very survival. It is a decision which, in the final analysis, is based not upon scientific or objective criteria which can be applied to society as a whole, but rather upon their deepest and most intimate personal concepts of their own lives, their death, their own self-worth, their families and their personal dignity. For all of them, in varying degrees, and for diverse reasons, a significant element in making this decision is their own personal concepts of health and medicine; whether based upon religious tenets or upon personal beliefs as to the nature of human life, the decision involves the extent to which [12] and under what circumstances one will permit chemicals to enter his body, or a surgeon to remove part of his body. It is difficult to imagine a personal right which is more fundamental and more clearly within the protection of constitutional guarantees of privacy and personal liberty than the right of cancer victims to make this decision.

Long before it was accorded constitutional protection, the basic nature of an individual's right to make decisions concerning his health was recognized by the courts. Justice Cardoza held in *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (1914) that a physician who performs an operation without the consent of the patient commits an assault and stated at page 93:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body

Under the "informed consent" rule, courts have consistently recognized that even where an individual consciously entrusts his care to a licensed physician having superior medical knowledge, the physician may not deprive the patient of the right

to weigh the risks inherent in various courses of treatment and make the final decision. (See *Cobbs v. Grant*, 8 Cal. 3d 229, 243, 104 Cal. Rptr. 505 (1972); Patients Bill of Rights, Medical Ethics and Legal Liability, 337 (1976); Physician Liability for Adverse Drug Reactions, R. Carleton, *Medical Technique Quarterly* 184, 195 (Fall 1977).

The right of individuals to make their own informed decisions with the advice [13] of their own physicians involves a degree of risk-taking. The widespread national opposition to the proposed saccharin ban by the FDA in 1977 by people who preferred running some imperfectly known risk of cancer to a total ban of the substance, resulted in the government almost immediately proposing to make saccharin available as a non-prescription drug. This converted the impact of the chemical's regulation from a serious deprivation to a mild if irritating inconvenience. (See *Plans to Ban Saccharin Use Announced by FDA*, *Food Drug Cos. L. Rep. (CCH)* section 41856 (1977) and *Saccharin Ban Prompts New Look at Anti-Cancer Clause*, *id.*, section 41868 (1977).

Courts have held that constitutional guarantees of privacy includes medical decisions that involve protection from risks of death. In *People v. Belous*, 71 Cal. 2d 954, 963, 80 Cal. Rptr 354 (1969), the California Supreme Court in protecting the women's abortion decision based their holding partly on the women's right to life since childbirth involves risks of death. Courts have also held that constitutional guarantees of privacy include the right to select a course of treatment which may result in death. In *Matter of Quinlan*, 355 A. 2d 647 (1976), the New Jersey Supreme Court held that a comatose accident victim, through her family, could terminate extraordinary life-saving measures even though it would probably result in death. Concerning the state's interests in preservation of human health and life, the Court said at page 663:

We have no hesitancy in deciding, [14] in the instant diametrically opposite case, that no external compelling interest of the State could compel Karen to endure the unendurable,

Courts have also held that the state has no power to order life-saving blood transfusions where the patient is opposed to such treatments on the basis of deeply held personal convictions of a religious nature. *Erickson v. Dilgard*, 252 N.Y.S. 2d 705, 706 (1962).

As the District Court discussed below in note 25, the decision to use Laetrile is by no means indicative of suicidal tendencies and State sanctioned cancer treatments are both oppressive and dangerous. (See *New York State Journal of Medicine*, 554 (March 1971) where Drs. T. Nemoto and T. Dao, speaking about 5-Flurouracil, a chemotherapeutic agent, said: "Of 133 patients receiving F-5U, 17, or 13%, demonstrated objective regression (of the tumor) . . . thirteen patients, or 10% died as a result of F-5U toxicity".).

In *Olmstead v. United States*, 277 U.S. 438 (1928), Justice Brandeis

recognized that it is improper for the State to act solely to protect its citizens for their "own good" where he stated at page 479:

Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, wellmeaning [15] but without understanding.

In *People v. Fries*, 42 Ill. 2d 446, 250 N.E. 2d 149 (1969), the Illinois Supreme Court also recognized this premise where they held that state's motorcycle helmet law invalid.

Roe v. Wade, 410 U.S. 113 (1973), dealt specifically with the right to determine one's own medical treatment. This Court made it clear that the right protected was the right of the individual to make important medical decisions relating to her physical and mental health where it stated at page 153:

The detriment that the State would impose upon the pregnant women by denying this choice altogether is apparent. Specific and direct harm medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon the women a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care.

In *Doe v. Bolton*, 410 U.S. 179, 213, 219-20 (1973), Justice Douglas in his concurring opinion recognized that "the freedom to care for one's health and person" comes within the purview of the right of privacy; "the right of privacy has no more conspicuous place than in the physician-patient relationship . . ."; and "the right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic."

It is beyond question, whether one [16] agrees or disagrees with those seeking nutritional therapy that includes Laetrile, that their decisions are to try to survive. For some the decision has been to go forward with orthodox cancer therapy and to supplement that therapy with nutritional therapy. For others, who are not willing to undergo or to continue orthodox therapy, for their own personal reasons, nutritional therapy may be their only hope.

Moreover, aside from a potential benefit cancer victims may receive in curing or controlling their disease, their right to life includes the right to spend the remainder of their lives as productively and fully rewarding as possible. Even if it could be conclusively demonstrated that Laetrile is completely ineffective in curing or controlling cancer, their decision would nevertheless be entitled to the protection of constitutional guarantees of privacy and personal liberty-because of Laetrile's effect on the terrible symptoms of cancer.

This right to select a particular course of treatment from a licensed physician,

otherwise harmless, which may prolong their lives, or at least will allow them to spend the remainder of their lives in dignity, cannot be conditioned on a showing that their ultimate decision is medically or scientifically justified or even that it is reasonable. That determination is uniquely within the province of the individual cancer victim. It is the right to make the decision--the right to weigh the possible benefits, the risks and the expense of a program of nutritional therapy in light of intimate personal feelings and objectives--which is protected by constitutional [17] guarantees of privacy and personal liberty.

B. The constitutional protection accorded cancer victims' right to utilize Laetrile in a program of nutritional therapy extends to physicians willing to administer Laetrile.

The fundamental right of cancer victims to pursue a course of nutritional therapy is a right which they cannot meaningfully exercise in isolation. The right is not merely a right to use Laetrile, but a right to use Laetrile as an integral part of a program of nutritional therapy carefully worked out by an expert in the area of human nutrition and tailored to suit their individual needs. The therapy often involves the injection of Laetrile in prescribed doses and at prescribed time intervals in conjunction with the administration of other beneficial nutrients.

With respect to the licensed physician's right to freedom to treat, to minister to the sick, the Court in *Whalen v. Roe*, 429 U.S. 589, 604 (1977) said that "the doctors' claim is derivative from, and therefore no stronger than, the patients." Further, the Court has recognized that the right to make important decisions pertaining to one's health includes the right to obtain the means to implement these decisions. State actions that limit access to the means of effectuating a protected decision are subject to the same strict scrutiny as are state actions that prohibit the decision entirely. *Carey v. Population Services International*, 431 U.S. 678, 688 (1977); *Doe v. Bolton*, 410 U.S. 179 (1973); [18] *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52 (1976).

In *Doe v. Bolton*, 410 U.S. 179 (1973), this Court invalidated statutory restrictions that infringed upon the right of the patient to receive the benefit of the judgment of the physician of her choice where the Court stated at page 197:

The women's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview.

This Court also discussed the right of an individual to choice of treatment with the advice of the individual's physician in *Whalen v. Roe*, 429 U.S. 589 (1977) where it stated at page 603:

Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and use needed medication ... Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient.

In *Roe v. Wade*, 410 U.S. 113 (1973), this Court specifically upheld the right of the physician to administer medical treatment according to the physician's professional judgment, in consultation with his patient, until there is compelling justification for state intervention. *19 At least until the medical treatment sought to be prohibited is more dangerous than the government sanctioned alternatives, the constitutional right of privacy protects the one seeking treatment and the physician who offers that treatment. Concerning termination of pregnancy during the first trimester, Justice Blackmun speaking for the Court stated at page 163:

... the attending physician in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated.

The right of an informed consenting patient to choose unorthodox modalities not yet approved by the State from a licensed physician is within the constitutional protections of privacy and personal liberty. This is certainly compatible with: (1) requiring that certain drugs be available to the public on prescription from a licensed doctor; (2) Compulsory vaccination in which harm to others is readily foreseeable, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); and (3) recognition of a compelling state interest in the health of a prospective mother at approximately the end of the first trimester of pregnancy, *Roe v. Wade*, 410 U.S. 113 (1973).

History, reason and experience supports this premise. Medical progress has been made by physicians with the vision and courage to use alternatives to orthodox modalities and procedures. (See 109 Cong. Rec. 14499 in which Senators Lister Hill and Paul Douglas discuss *20 the persecution of such great medical innovators as Lister, Pasteur, Semmelweis, Jenner, Keen, Koch, and Harvey. Perceptive observations were responsible for their achievements).

The healing arts have certainly not reached perfection and "orthodox" medicine has not cornered the market on truth. It is by the alternatives to orthodoxy that medical progress has been made, and a free, progressive society must recognize and protect this right of the physician. (A relevant example is Soviet geneticist T.D. Lysenko who stultified the science of genetics in the U.S.S.R. for a generation by imposing the State sanctioned view that environmentally acquired characteristics of an organism could be transmitted to offspring by inheritance. The Stalinist concept of ideological conformity politically implanted in genetics paralyzed Soviet science in this field).

The treating doctor, the clinician, is at the cutting edge of medical knowledge and a member of that class of persons best qualified to make medical progress. (See *Drug Regulation and Innovation-Empirical Evidence and Policy Options*, H.G. Grabowsky (1976) which summarizes studies on cost versus benefit analysis of the effects of the 1962 amendment which subjects new drugs to "effective" tests before permitting general prescription and use. Among its findings are: (1) the rate of innovation more than halved by the 1962 amendments with the proportion of

ineffective drugs remaining the same, thus, a large decline took place in effective drugs; (2) U.S. drug innovations declined from one-third of worldwide introductions before the 1967 amendment to less than one-sixth of world- [21] wide introduction afterwards; (3) the 1962 amendment has not enhanced safety because it keeps off the market new drugs that are safer than the drugs they would replace; and (4) one example involving a benzodiazepine hypnotic in use in Great Britain but delayed five years before introduction here could have saved as many as 1200 lives if it had been available in this country. (See also Health Care Reform and Administrative Law: A Structural Approach, Rosenblatt, 88 Yale L.J. 243 (1978) ["The Legal Structure of Health Care Reform: Creating the Appearance of Public Control"].)

The protection of constitutional guarantees of privacy and personal liberty extends not only to the patient pursuing nutritional therapy that includes Laetrile but also to the physician who prescribes and administers the therapy.

C. State interference with cancer victims' constitutionally protected right to obtain and use Laetrile in a program of nutritional therapy is not necessary to further any substantial or compelling State interest.

Those laws are not challenged which prohibit the advertisement of Laetrile as a cure for cancer or which impose standards for labeling, manufacturing, and packaging or which prohibit the sale of Laetrile to members of the general public for the purpose of treating cancer by persons other than licensed physicians. Those regulations serve to strengthen and reinforce the right of [22] cancer patients to make basic medical decisions which are informed and which can be effectively carried out.

Those laws are challenged which prohibit duly licensed physicians from administering Laetrile to informed consenting cancer patients, and which prohibit the sale of Laetrile to licensed physicians or persons who have obtained prescriptions from licensed physicians. Federal application of Section 505, 21 U.S.C. 355, coupled with the powers of the Commerce Clause has prohibited administration of Laetrile to every cancer victim.

Since these laws directly intrude upon a fundamental constitutional right of cancer victims, they can be given effect to prevent physicians from supplying and administering Laetrile to informed consenting cancer victims only if they are (a) necessary to further a compelling state interest, and (b) they are narrowly drawn to express only the interest of the state at stake. *Roe v. Wade*, 410 U.S. 113, 155 (1973).

The state has a profound interest in maintaining medical standards and in protecting health and life. This justifies testing and licensing doctors and the limits on giving medical advice by qualified practitioners as well as regulation of pharmaceuticals and licensing of pharmacists and dispensers of drugs. It is also well settled that the state has broad police powers in regulating dangerous drugs in the sense that they are narcotic, habit forming, hallucinatory or toxic. (See *Robinson v.*

California, 370 U.S. 660, 664-65 (1962); and Whipple v. Martinson, 256 U.S. 41, 45 (1921). Their use or misuse "concerns others." Laetrile is not in this [23] class. It is generally conceded to be a harmless drug. Its alleged evil lies in its "ineffective" treatment of cancer.

The use of Laetrile in the treatment of cancer is not prohibited because Laetrile is harmful or dangerous to the cancer patient or to others. The policy considerations which motivated the prohibition of unapproved substances in general and Laetrile in particular are: (1) A State interest in providing the public with adequate and accurate information with respect to State sanctioned methods for the diagnosis, treatment and cure of cancer; (2) A State interest in protecting cancer patients and their families from deceptive and fraudulent representations regarding the effectiveness of cancer remedies that are not State sanctioned, and (3) A State interest in preventing reliance on methods of treatment which are not State sanctioned and which could, in some cases, delay the use of State sanctioned treatments until such a time as the cancer could no longer be treated or cured by recognized means.

Although the State clearly has a legitimate and substantial interest in promoting these objections, the absolute ban unnecessarily operates to prohibit the use of Laetrile in instances where no legitimate State interest is served.

1. The State Interest In Preventing The Delay Of State Sanctioned Methods of Treatment

Perhaps the strongest State interest advanced in justification of laws prohibiting the use of Laetrile is an interest [24] in preventing the potential reliance by cancer patients on unapproved treatments to the exclusion of government sanctioned treatments which might be effective in curing or controlling cancer. Thus, the primary evil which these laws envision flowing from the use of Laetrile is the danger that the cancer patient might rely exclusively on Laetrile treatments and that conventional treatments which might cure or control cancer will be delayed until they can no longer be effective.

However, the prohibitions against the use of Laetrile are not narrowly drawn to apply to instances where cancer patients might benefit from conventional treatments. They absolutely prohibit the administration of Laetrile to every cancer victim, including those who are undergoing conventional treatments, those whose conditions are beyond any hope from conventional treatments, those for whom conventional treatments are not indicated, those who have been advised that the dangers of conventional treatments far outweigh any possible benefits, and those who, being fully advised, cannot or will not, subject their bodies to chemicals, radiation or surgery.

The only possible rationale for the absolute ban on the use of Laetrile must necessarily be administrative convenience, for the State interest to be promoted has

no application to cancer victims in such individual situations.

However, it is clear that where a law may infringe upon fundamental constitutional rights, the State must narrowly confine the force of the law to the specific objective which justifies [25] State interference. That is to say, if a particular State objective constitutionally justifies certain State action, the State cannot adopt a law proscribing a broader range of conduct merely to facilitate enforcement or increase the effectiveness of the valid State objective. As this Court said in *Stanley v. Illinois*, 405 U.S. 645 (1972) at page 656:

The Constitution recognizes higher values than speed and efficiency. Indeed, one might fairly say of the Bill of Rights in general, and the Due Process Clause in particular, that they were designed to protect the fragile values of a vulnerable citizenry from the overbearing concern for efficiency and efficacy that may characterize praiseworthy government officials no less, and perhaps more, than mediocre ones.

It is obvious that the State interest in preventing reliance upon Laetrile to the exclusion of proven treatments could be wholly served by narrowly drawn laws to accomplish that purpose, without an indiscriminate ban that invades the constitutional rights of citizens.

For example, rather than indirectly encouraging treatment by conventional methods, the State could act directly toward that objective by requiring a "monitored" distribution system similar in concept to the monitored system approved by this Court in *Whalen v. Roe*, 429 U.S. 589 (1977). Any cancer patient who seeks to use Laetrile could register, through their physician, [26] and provide on a regulation form such information as name and address, diagnosis, type of cancer, history of conventional treatments, progression of the disease, prognosis, and any reasons why the patient seeks to use Laetrile.

Government health officials could review the registration forms and, in the event it appeared that conventional treatments might still be beneficial, could contact the patient and provide the patient with information on conventional treatments.

For those employing conventional treatments concurrently, or whose conditions are hopeless, the State may wish to do nothing. For those declining conventional treatments for religious or personal reasons, the State may or may not wish to do anything.

However, so long as the State cannot veto the ultimate decision of the patient, such a system would be much more likely to serve the State interest, since there would no longer be reasons to seek underground sources of Laetrile or to seek therapy in foreign countries.

Moreover, by permitting a citizen to obtain Laetrile from any physician, it would substantially increase the probability that a cancer patient would be properly

diagnosed and advised as to conventional treatments. So long as cancer patients cannot legitimately obtain Laetrile from licensed physicians, thousands are driven to clandestine sources, which have neither the medical expertise nor interest of a licensed physician in fully advising of treatments medically indicated. [27]

2. The State Interest In Preventing Fraudulent And Deceptive Practices

It is not disputed that cancer patients particularly those who are beyond benefit from accepted means of treatment, are particularly susceptible to fraudulent representations regarding "miracle" cures. It is also not disputed that the State has a strong interest in preventing the unscrupulous exploitation of desperate victims of this dread disease.

This State interest is reflected in a comprehensive scheme of federal and state laws aimed at prohibiting the defrauding of cancer patients. FDA has ample statutory authority to combat false or fraudulent advertising of ineffectual or unproven drugs (See Food, Drug and Cosmetic Act, misbranded Drugs and Devices, 21 U.S.C. 352 (1976); and Federal Trade Commission Act, Dissemination of False Advertisements, 15 U.S.C. 52 (1975).

Physicians who falsely represent the effect of treatment for cancer face these penalties as well as multiple state statutes for criminal fraud or misrepresentation. The physician who falsely represents the effect of a treatment for cancer is also subject to potentially horrendous civil liability for fraud, assault or negligence. In addition to these penalties, physicians are subject to revocation or suspension of their licenses.

Concerning the licensed physician, this Court in *Doe v. Bolton*, 410 U.S. 179 (1973) stated at page 199-200:

If a physician is licensed by the [28] State, he is recognized by the State as capable of exercising clinical judgment. If he fails in this, professional censure and deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice. The attending physician will know when a consultation is advisable--the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned. It is still true today that '[r]eliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he [the physician] possesses the requisite qualifications.'

This does not mean that a physician who misrepresents the effects of Laetrile is immune from criminal prosecution. It is contended, however, that to prosecute a physician who administers Laetrile to cancer victims, at their request, without representing that it will be effective, violates cancer victims' constitutional right to

make the ultimate decision with respect to their health.

The absolute ban on Laetrile, however, has nothing to do with the prevention of false or misleading information. It operates to prohibit the use of Laetrile irrespective of what representations are [29] made by the physician who dispenses it, even if the physician were to advise the patient against its use.

The State interest in preventing fraud is specifically and directly served by a comprehensive range of professional, civil and criminal sanctions which do just that--prohibit fraud and misrepresentations.

Again, at very best it might be argued that an absolute ban serves administrative convenience since if no Laetrile is available, no one will be able to misrepresent its effects. However, such an argument does not even begin to approach the constitutional necessity of limiting the force of a statute to the evil to be remedied without indiscriminately condemning a much broader range of activity not compelled by the specific state interest.

Even if laws directly prohibiting fraudulent and deceptive medical practices were so completely and demonstrably ineffective as to make supplementary regulation necessary, such supplementary regulation could be accomplished by means which are more effective without infringing on the constitutionally protected right of cancer patients to determine a course of treatment.

Thus, rather than an absolute ban on the use of Laetrile or other unapproved substances by physicians the State could, to supplement its fraud laws, institute a mandatory disclosure system enforced by patient registration with the State, under which a physician would be required to provide the patient with materials furnished by the State, or any other information the State feels relevant, and account to the State for having done so [30]

3. The State Interest In Providing Information With Respect To State Sanctioned Methods Of Treatment

The total ban of a particular substance can not inform cancer patients of "approved" methods of therapy. This case illustrates that knowledge of the existence of Laetrile and publicized reports of its benefits to those who have obtained it is widespread. Cancer victims who desire further information must necessarily seek it out of the United States or from an underground source who may or may not be a physician.

A system of mandatory consultation with experts, before Laetrile could be prescribed at the request of a cancer patient, would directly serve rather than tend to defeat the interest of the State.

As this Court held in *Planned Parenthood v. Danforth*, 428 U.S. 52, 74 (1976), a state may legitimately encourage parental counseling and guidance for minors

considering termination of a pregnancy, but it oversteps legitimate state interest where it grants the parent not only the right to consult with the minor but also a veto over her decision. Here the State has vetoed the cancer victim's decision without consultation.

II The Flat Prohibition Of Laetrile Is Not Reasonably Related To The Preservation And Protection Of The Public Health

In *Roe v. Wade*, 410 U.S. 113, 150 (1973), [31] the Court observed that "[T]he State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that insure maximum safety for the patient." In *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 76 (1976), the Court said, "The question ... is whether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health.'"

Section 505, 21 U.S.C. 355, as applied, operates to preclude the administration of Laetrile to an informed consenting cancer patient by a licensed physician.

The flat prohibition includes: (1) Cancer victims who have rejected State sanctioned cancer treatments after receiving competent medical advice; (2) Cancer victims who seek to supplement State sanctioned treatments with nutritional treatment that includes Laetrile; (3) Cancer victims who have received competent medical advice that they are too frail for State sanctioned treatments; and (4) Cancer victims who have been diagnosed as terminal by competent medical advisors and informed that State sanctioned treatments have nothing left to offer.

For cancer victims diagnosed as terminal and informed that State sanctioned alternatives are useless, nutritional treatment that includes Laetrile may provide longer, more active lives during their remaining days, and it may be their only hope. For cancer victims too frail for State sanctioned alternatives, nutritional treatment that includes Laetrile is a safer alternative than the more dangerous State sanctioned alternatives. [32] A law that forces State sanctioned alternatives or nothing at all on these cancer victims is certainly more intrusive than the forcible pumping of a suspect's stomach that the Court found "brutal and ... offensive to human dignity," in *Rochin v. California*, 342 U.S. 165, 174 (1952).

For cancer victims seeking to supplement State sanctioned alternatives with nutritional treatment that includes Laetrile, and for informed cancer victims who have rejected State sanctioned alternatives, the flat prohibition isolates them from a licensed physician. Cancer victims must seek Laetrile in foreign countries or from underground sources who may care nothing about quality, purity or dosage levels. To be legally deprived of any treatment at all from a licensed physician shows governmental indifference to extreme human suffering. Whatever the intentions of such a law, its effect is surely cruel and inhuman.

The effect of this law does not insure maximum safety for the patient. In effect, it turns the whole matter of treatment back to the cancer patient himself if he is unwilling to accept the State sanctioned alternatives. Such a law cannot be reasonably related to the preservation and protection of the public health. [33]

CONCLUSION

For the reasons submitted above, *amicus curiae*, the American Academy of Medical Preventics, respectfully submits that 21 U.S.C. 355, as applied, violates constitutional rights of privacy and personal liberty, and is not reasonably related to the preservation and protection of the public health.

Respectfully submitted,
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