THE LEGAL ASPECTS OF LAETRILE AND OTHER PROPOSED CANCER REMEDIES OF QUESTIONABLE SAFETY OR EFFICACY

The Impact of the Laetrile Phenomenon on the Legal Profession

Paper 1980, ABA Annual Meeting: Grace Powers Monaco, partner, Fairman, Frisk & Monaco, Washington, D.C., J.D., '63, Georgetown. Thanks to Barry R. Lenk, associate, LHM, J.D., '78, George Washington; Becky Burke, law student, Georgetown; Scott Berman, law student, NYU for their assistance in the researching and writing of this paper.
INTRODUCTION

I. LEGISLATIVE HISTORY

II. CASE OVERVIEW
   A. Seizure Cases
   B. Rutherford Cases
   C. Privitera Case
   D. Issues Centering On The Application Of The Scientific Process
      1. Safety/efficacy--the controlled clinical trial
      2. Is it unfair to expect a drug like laetrile to meet the federal drug law standards?

III. THE POLITICS OF LAETRILE
   A. National Cancer Institute Tests
   B. Federal and State Legislation
   C. Preemption

IV. THE LAETRILE CASES CONCERNED WITH PARENT/CHILD RIGHTS

V. OTHER TYPES OF LITIGATION THAT CONFORM TO LAETRILE ISSUES
   A. Patient Cases Relating To The Right To Obtain Laetrile [See § II,B, supra.]
   B. Physician Rights Derivative From Patient [See § II,C, supra.]
   C. Seizure Cases [See § II,A, supra.]
   D. Smuggling
   E. Reimbursement
   F. Actions Against The Physician
      1. Malpractice
         a. Responsibility of the physician to select the best drug
         (1) laetrile toxicity
         (2) delay or avoidance of treatment
b. The physician's duty to keep informed about drug claims and effects

(1) misleading/contradictory claims for laetrile

(2) the laetrile publications present mixed messages to the physician about what amygdalin products to use in treatment

(3) no agreement among laetrile advocates on effectiveness of laetrile treatment upon the patient who has exhausted effective therapy

(4) there is division in the laetrile camp as to whether laetrile therapy can be effectively used with chemotherapy

c. The physician's responsibility to determine the best drug dosage

d. The physician's duty to prevent dangers from drug storage and preparation

e. Duty of the physician to warn patients of possible adverse drug reactions

f. The physician's duty to continually evaluate the patient's drug needs

g. Liability of physician for punitive damages

2. Reimbursement for Medical Fees Paid

3. Suits based on absence of effective informed consent to treatment

G. Product Liability

H. Libel/Slander
INTRODUCTION

The emotional, scientific, legal and philosophic issues related to unproven methods of cancer management are tellingly stated by Senator Edward Kennedy in his introductory remarks to the Laetrile Hearings of 1977 (1, p. 1):

The role of the Food and Drug Administration . . . is to guarantee that the available drug therapies are the best and most effective that science can devise. Their role is to protect both the patient and his family from remedies that are neither safe nor effective. The elimination of useless treatments is a valid Federal role. It is a humanitarian role. It reduces the burden on cancer patients and their families and allows them to exercise their freedom of choice on the basis of informed judgments among viable alternatives. 1/

Unproven methods of cancer management have or can be expected to produce cases and controversies involving state and federal administrative, legislative and judicial processes. Some areas in which activity occurs are injunctive actions, malpractice, drug regulation, personal injury and product liability. It is my intention to present a general description of the actual and anticipated background which gives rise to such suits; familiarize the attorney with the questions involved and provide some guideposts on where to search for answers.

I. LEGISLATIVE HISTORY

The legislative history surrounding the first federal drug law in 1906 showed a particular concern with the protection of victims of serious and life threatening illness from frauds. 2/

1/ Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, "Evaluation of Information on which the FDA Based Its Decision to Ban the Drug Laetrile From Interstate Commerce," 97th Congress, 1st Session 1977, (hereinafter "Laetrile Hearings").

2/ See e.g., 40 Cong. Rec. 1416, 9073; 48 Cong. Rec. part 12, Appendix at 625-630.
Against this background, Congress expressed disbelief when the Supreme Court held that the 1906 Act did not apply to misrepresentations of fact relating to a drug as a treatment or cure of disease but only to whether the ingredients were properly stated on the label. \(^3\) President Taft called for remedial legislation to protect the seriously ill against statements of curative effect that seduce the ill away from proven treatments "while their diseases progress unchecked". \(^4\) Congress acted promptly to remedy this defect and provide that misstatements of curative effect fall within the Act. \(^5\) Congressional concern with those with life threatening illness was mirrored in the administrative interpretation of the federal drug laws. Even before the "efficacy" provisions were added to the federal drug laws in 1962, the administrative interpretation of those laws construed the term "safety" as applied to drugs dealing with life threatening illness to include "efficacy". \(^6\) The Courts accepted as correct this administrative interpretation of "safety" to include "efficacy" when drugs relating to life threatening illness were involved. \(^7\) However, in 1962 the "Drug Amendments" added the effectiveness criteria for all drugs and also recognized that it was by administrative interpretation already present in the Act vis a vis life threatening illness. \(^8\)

II. CASE OVERVIEW

There are many types of unproven cancer treatment methods. This paper concentrates on the best known of these methods at this time - laetrile. The overview which follows provides a general

\(^3\)/ United States v. Johnson, 221 U.S. 488(1911).

\(^4\)/ See 48 Cong. Rec. 11322(1911) and Belmont Laboratories v. FTC, 103 F.2d 538 (3d. Cir. 1939).


\(^7\)/ See Durovic v. Richardson, 479 F.2d 242(7th Cir. 1973), cert. denied, 414 U.S. 944.

description of the ways in which unproven methods touch the legal system. The overview focuses on the Rutherford cases which embraced a spectrum of patient rights and federal drug law problems and Privitera which embraced the physicians rights issues and provided the first definitive resolution of the right of medical privacy issue on the federal appeals court level. The parent/child/state rights in treatment issues are not treated in this overview but are specifically treated at pp.41-50, infra.

A. Seizure Cases

In 1960 the FDA began the first in a continuing series of enforcement actions with the seizure of laetrile in Dallas. These actions have generally been decided promptly in favor of the FDA based on the finding that laetrile is not generally recognized as safe and effective and has not been approved for marketing. Recent enforcement actions have also included the seizure of interstate shipments of apricot kernels destined for use in the manufacture of laetrile. Because laetrile is not approved by the FDA, the knowing importation of laetrile into the United States constitutes a felony, (See 18 U.S.C. § 545 (1976)), unless it is imported through the Rutherford affidavit procedure. (For a full discussion of seizure cases, see Lerner & Weeks, The Laetrile Power Play in Drug Marketing, 3 HAMLINE L.R. 1, (1980).) Therefore, the receipt, concealment, purchase, or sale of laetrile after importation, with knowledge of its illegality, are criminal acts. Id. at 34. See 18 U.S.C. § 545 (1976). Additionally, any conspiracy to use or transfer laetrile in violation of the FDA regulations is a felony. See 18 U.S.C. § 371 (1976).

The FDA has prosecuted a number of manufacturers and distributors of laetrile for violations of the Food and Drug Act. These actions usually involve violations of the provisions dealing


10/ United States v. Articles of Food and Drug, 444 F. Supp. 266 (E.D. Wis. 1978) The defendants were permanently enjoined from manufacturing and distributing any article of food and drug containing amygdalin or its components. United States v. Articles of Food and Drug, No. 77-C-285 (E.D. Wis., March 3, 1980).

Millet Pit and Seed Co. v. United States, 436 F. Supp. 84 (E.D. Tenn. 1977), appeal pending sub nom. United States v. An Article of Food and Drug (6th Cir. No. 78-1202).
with adulteration (21 U.S.C. § 351 (1976), misbranding (id. at § 352), and "new drug" (id. at §355). In U.S. v. General Research Laboratories, 397 F. Supp. 197 (C.D. Cal. 1975) B-17 and apricotin, marketed as a food supplement, were found to be adulterated and misbranded food and drugs because of their ingredients (amygdalin and hydrogen cyanide), and their commercial misrepresentation as cancer remedies.

In U.S. v. Articles of Food and Drug (see footnote the Wisconsin manufacturers and distributors of laetrile were permanently enjoined from manufacturing and distributing any laetrile product. The laetrile in this case was in drug form - injectables, tablets, powders. Some issues involved were: failing to register as drug producers, (id. at 272); failing to meet the federal standards for manufacturing practices, (id.); knowingly representing their products as cancer therapy (id. at 270); selling their products below purported potency without warnings, directions, or prescriptions (id. at 271-72); and failing to meet either the new drug requirements for safety and efficacy or qualifying under the grandfather exemptions (id.). The court found that the promotion or sale of laetrile for food or drug use constituted a consumer fraud (id. at 273) and that laetrile was an unapproved new drug, both misbranded and adulterated, and also an adulterated food. (id. at 273-74).

B. RUTHERFORD CASES

In contrast, Rutherford v. United States 11/ was instituted by cancer patients in the United States District Court for the Western District of Oklahoma on March 12, 1975. 12/ The suit sought to prevent the government from interfering with the sale

11/ Rutherford v. United States, 399 F. Supp. 1208 (W.D. Okla. 1975), aff'd, remanded on other grounds, 542 F.2d 1137 (10th Cir. 1976), modified on remand, 424 F. Supp. 105 (W.D. Okla.), modified, 429 F. Supp. 506 (W.D. Okla. modified, agency decision vacated, 438 F. Supp. 1287 (W.D. Okla. 1977), aff'd as modified, 582 F.2d 1234 (10th Cir. 1978), rev'd and remanded, 99 S.Ct. 2470 (1979). The Tenth Circuit issued its decision that laetrile was not grandfathered and that there was no medical right of privacy re the substance on February 19, 1980, 616 F.2d 455; (10th Cir. 1980)

12/ The action was originally instituted by Juanita Stowe, a cancer patient, and her husband, Jimmie Stowe. After Mrs. Stowe's death, an amended complaint was filed by two other patients, Glen L. Rutherford and Phyllis S. Schneider, and Mrs. Schneider's husband, on behalf of a class composed of cancer victims and their spouses who are responsible for the costs of treatment. Mrs. Schneider (continued on next page)
and distribution of laetrile by obtaining a decree which would preclude the government from conducting seizure, injunctive or criminal actions against Laetrile and its proponents. The district court entered an order which permitted Mr. Rutherford to obtain a limited quantity of laetrile. The government sought review of this order before the United States Court of Appeals for the Tenth Circuit in Denver. The Tenth Circuit directed that the case be remanded to the FDA for the development of an administrative record on whether laetrile is a "new drug", and if so, whether it is exempt from the pre-marketing approval requirements of the Act. 13/

In rendering this opinion, the Tenth Circuit made two significant findings -- one in accord and one not in accord with the Act.

Before determining whether laetrile was a "new drug" it was necessary for the Appeals Court to decide whether it was a drug under the Act. The laetrile proponents had argued that laetrile was a vitamin, a dietary supplement, or a naturally occurring food, but that it was not a drug. The court found, however, that laetrile was "unquestionably" intended as a treatment for cancer, and that even if it is a food, it is also a drug subject to the Act because it is intended for use in the cure, mitigation, treatment or prevention of cancer. 14/ This decision is in accord with both the legislative history of the Act and a well-established body of case law indicating that it is the intended use of a substance which determines whether a

12/ Continuation

subsequently died. By order entered April 8, 1977, the district court certified this case as a class action on behalf of a class composed of terminally ill cancer patients. Rutherford v. United States, 429 F. Supp. 506, 509 (W.D. Okla. 1977).


14/ 542 F.2d 1137 at p.
product is considered a food, a drug, or both under the regulatory plan. 15/

The holding not in accord with the Act dealt with standards and burden of proof. The court of appeals and the district court below, from the outset, have eschewed the statutory standard and have created a hybrid standard which literally requires the FDA to initiate an administrative proceeding on drug status and bear the burden of proof in that proceeding at anytime the FDA has stated that a product is a "new drug" but does not have an administrative record, opinion or application to point to in substantiation of its statement:

We are unable, however, to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is . . . To support its determination the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as "safe and effective," and that Laetrile is not grandfathered by either of the exemptions discussed above. 16/

The FDA is not required by any provision in the federal drug laws or any principle of administrative law to initiate a rulemaking proceeding to determine the "new drug" or "grandfather" status of a product before the agency can declare that product to be a "new drug". Further, Judge Kiley, in Tutoki v. Celebrezze, 17/ denying declaratory relief against the FDA to cancer patients seeking Krebiozen for failure to exhaust their administrative remedies expressly found that the statute did not preclude cancer patients from sponsoring an NDA for Krebiozen. Finally, Judge Hastings speaking for a unanimous court in Rutherford v. American Medical Association et al. 18/ as one basis for his decision denying an injunction against the FDA


16/ 542 F.2d at p.

17/ Tutoki v. Celebrezze, 375 F.2d 105 (7th Cir. 1967).

requiring it to cease interfering with patient/physician procurement of Krebiozen, held that the Krebiozen proponents had not shown that they had made a good faith attempt to comply with the procedures established by Congress for the introduction of new drugs.

Thus in a number of cases parallel to Rutherford, courts have held that they would permit no dilution of the standards and procedures for determination of the status of a drug if proponent position was shifted from manufacturer/developer to patient. Deviation from the prescribed statutory standard of proof is also inconsistent with the positions of the parties in Rutherford. The "evidence" which the FDA is suppose to provide lies within the control of those physicians and manufacturers who are said to be using and making laetrile. This process can "require" the production of evidence.

The administrative proceedings required by Judge Bohanon produced over 400 written submissions, comprising some 5,500 pages of material, and included two days of public hearings. The submissions represented a broad spectrum of views from cancer patients, consumers, experts in drug testing and cancer therapy, physicians, state governments, universities, hospitals, and organizations such as the American Cancer Society and the Committee for Freedom of Choice in Cancer Therapy. It is upon this body of information that the Commissioner of the Food and Drug Administration based his decision. The Commissioner found laetrile did not qualify for exemption under either of the grandfather clauses. He concluded that laetrile was not exempt from the safety and effectiveness requirements under the 1938 grandfather clause because there was "no proof submitted to show that what was termed 'Laetrile' or 'amygdalin' as used before 1938 was the same drug which is now being marketed . . . " and that there is no "indication whatever that the labeling . . . before 1938 contained representations concerning conditions of use which are identical to the representations associated with the presently marketed drug". 19/

19/ D. Kennedy, "Laetrile: Commissioner's Decision on Status," Federal Register 42(151), 39768, 39788 (1977). The issue was raised in the tenth circuit that since the rulemaking proceeding was in a non-adjudicatory format, the due process rights of laetrile proponents to cross examine were denied. The Tenth Circuit in both its opinions treated the record as appropriate for review but indicated that a more formal proceeding in the future would be necessary. See 582 F.2d 123 (10th Cir. 1978) and 616 F.2d 455 (1980)(10th Cir.)
Laetrile did not qualify for exemption under the 1962 grandfather because, first, the composition of the drug presently referred to as laetrile was not shown to be the same as the drug used during the grandfather period. Second, laetrile was not commercially used or sold in the United States on the grandfather date. This conclusion is supported by the new drug application filed by proponents of laetrile on October 3, 1962. The drug had previously been shipped for investigational and not commercial purposes, as Dr. Krebs, Sr. indicated, and a June 1962 court order, entered following the conviction of Mr. Krebs, Jr., for violating the new drug provisions of the Act, substantiates this. The new drug application itself indicates that the drug was not commercially available for use. 20/

The third basis for denying the 1962 grandfather exemption was the lack of information concerning the labeled conditions of use on the grandfather date. No labeling was described or submitted for a product in use on the grandfather date, and labeling proposed for use and in use before and after the grandfather date were not similar. Finally, the Commissioner found that on the grandfather date, experts did not recognize laetrile as safe for use under any conditions since they were largely unfamiliar with the drug, lacked information as to its composition and labeled conditions of use, and, in the absence of any published literature reporting results of tests which showed the drug to be safe or effective, had no basis in scientific data upon which to recognize the drug as safe. 21/

The district court then reviewed the Commissioner's decision. In reviewing administrative decisions the court's duty is only to decide whether the agency has acted arbitrarily, or in abuse of its discretion. The district court characterized the administrative record as revealing "a substantial and well-developed controversy among medical professionals and other scientists as to the efficacy of laetrile", and accepted the Commissioner's conclusion that laetrile is not generally recognized as safe and effective. Similarly, the court sustained the Commissioner's denial of an exemption for Laetrile based on the 1938 grandfather clause. 22/

20/ Laetrile Rulemaking Proceedings 42 Fed. Register at p. 39779.

21/ 42 Fed. Register at p. 39792-95.

22/ Rutherford v. United States, 438 F. Supp. at 1287, 1298. The court held that the record failed to establish the details of laetrile's use from 1906 to 1938 sufficiently to successfully challenge the FDA's denial of this exemption.
The district court concluded, however, that laetrile was exempt under the 1962 grandfather clause. In reaching this conclusion the district court rejected each of the Commissioner's factual findings. The district court found that laetrile is identical to amygdalin and has had a continuous identical composition, that the availability of amygdalin from chemical supply houses establishes the commercial availability of laetrile as a pharmaceutical product, that the labeling for laetrile was established by a new drug application filed in October 1962 and that laetrile was generally recognized as safe prior to the grandfather date.

In reaching its decision the district court virtually ignored the evidence relied upon by the Commissioner to support his findings and simply cited other evidence. Such a re-weighing of evidence was improper. The district court also held that by denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right to privacy. 23/

The decision of the district court was reviewed by the United States Court of Appeals of the Tenth Circuit. Rather surprisingly, the court of appeals did not explicitly address the statutory or constitutional issues on which the district court decided the case. Rather, in a short opinion unsupported by citation of authority or the record, the court of appeals held that the "safety" and "effectiveness" requirements of the Act have no application to terminally ill cancer patients who desire to take laetrile intravenously. The FDA, in the court's opinion, had not advanced a standard against which to measure the safety and effectiveness of laetrile as applied to such plaintiffs. 24/

The court emphasized that its opinion is strictly limited to terminally ill cancer patients and the intravenous use of laetrile. A certificate by a licensed medical practitioner that a particular person is terminally ill with cancer was considered sufficient although "terminal" was left undefined. The court did not mention the use of laetrile in tablet form or explain why it restricted usage to intravenous administration. The FDA was left to "promulgate regulations within the above limitations as if the drug was found by the Commission (sic)

---

23/ Id.
24/ Rutherford v. United States, 582 F.2d 1234 (10th Cir. 1978).
to be 'safe' and 'effective' for the limited group of persons here considered". 25/ Rutherford's later request to allow the oral use of laetrile was denied by the court without comment.

The decision of the court of appeals broke new ground when it flatly declared that the safety and efficacy provisions of the Act were inapplicable to laetrile administered intravenously by a physician to terminally ill cancer patients. There is no basis in the language of the statute or the legislative history which supports an exception for terminally ill cancer patients. The essential purpose of the Act is to ensure that all available drugs are both safe and effective for their intended uses. 26/

While the court of appeals held the statutory criteria of safety and efficacy inapplicable, it employed two separate safety criteria and misconstrued the meaning of efficacy in formulating its opinion. First, it required that the drug be administered by a physician; that is a criteria of safety embodied in the Act. 27/ Second, the court of appeals limited its holding to intravenous administration; it did not deem orally administered laetrile to be within the exception it created. This distinction is unexplained. 28/ While neither oral or intravenous administration have been systematically studied, the court recognized by implication that oral administration may result in cyanide poisoning. The effects of intravenous administration are more uncertain.

The government asked the Supreme Court to review the decision in the Rutherford case. Review was granted on January 22, 1979. The issues which were presented for review and briefed to the Court are the application of the federal drug laws to the terminal and also the alternative grounds for decision presented in the district court opinion -- the grandfather exemption and the right of privacy.

On June 18, 1979, the Supreme Court issued its decision on laetrile. 29/ The Court did not address the constitutional and

25/ Id. at p. 6.
26/ This holding is particularly confusing in light of the Court's holding that safety and efficacy have no meaning in the context of the terminally ill.
28/ The Act distinguishes between drugs which are safe for self-administration and those which are safe only when administered by a physician. See, e.g., § 503(b) of the Act, 21 U.S.C. 353(b).
grandfather clause issues. It confined its opinion to the terminal exception created by the Tenth Circuit. The bottom line of the Supreme Court's decision is that the rationale for the 10th Circuit's opinion is unsupportable, that there is nothing in the congressional history or administrative interpretation of the federal drug laws that supports an exemption for the terminally ill. Further, as the Court explains at length, the inclusion of the terminal within the coverage of the Act, is reasonably related to the Act's purposes as the Court perceives them. The Court thus reversed the 10th Circuit and remanded the case for further proceedings consistent with its opinion. These further proceedings mean that the 10th Circuit should now look at the grounds for decision articulated by the district court (grandfather clause/constitution) which it did not deal with in its opinion and issue an opinion dealing with the bases upon which the district court reached its decision.

The key points of the Court's decision are:

The federal drug laws make no express exemption for drugs used by the terminally ill.

(1) No implicit exemption is necessary to attain congressional objectives. 30/

(a) Legislative history indicates that Congress was concerned with the protection of those with fatal illnesses. 31/

(b) The administrative authority implementing the federal drug laws (FDA) in its application and interpretation of the Act has not made an exemption for drugs used for terminal or those with life-threatening illness.

(c) Congress was aware of the FDA's interpretation of the Act and approved of it (1962 Amendments & Reports).

(d) The history of purportedly simple and painless cancer cures suggests why Congress could "reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise". 32/

---

30/ Id. at
31/ Id. at
32/ Id. at
(2) An implicit exemption is not necessary to avert an unreasonable reading of the terms "safe" and "effective".

Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs.

(a) Effectiveness does not necessarily mean capacity to cure, it also extends to a sponsor's claims of prolonged life, improved physical condition or reduced pain.

(b) Safety does have meaning for the terminal. A drug is unsafe for the terminal, as for anyone else, if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. The 10th Circuit implicitly acknowledged safety as a factor by restricting laetrile to IV use.

(c) Safety/efficacy have a special meaning in the context of incurable illness: "if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible". 33/ This special meaning is supported by FDA administrative interpretation and by expert testimony in the record.

(d) Experimental drugs are available for the terminal for whom conventional treatment is unavailing through special FDA procedures.

The Supreme Court's decision removed only part of the cloud in federal regulation of interstate laetrile posed by the Rutherford decision. Since the legal access to laetrile by cancer patients lies through the affidavit process in the Rutherford court and that access could be sustained by a finding that there is a constitutional right to use laetrile or that it is grandfathered.

The 10th Circuit acted to remove that cloud by an opinion issued February 19, 1980. 34/ The Court of Appeals held that a

33/ Id. at
34/ Rutherford v. U.S., 616 F.2d 455 (10th Cir. 1980).
review of the Supreme Court opinions treating the privacy issue make it clear that:

"the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health" 35/

The Court also held that the proponents had not met the conditions that would entitle them to a grandfather clause exemption from the pre-marketing clearance provisions of the Act. 36/

The final door to legitimate laetrile marketing without meeting the federal drug law proof of safety/efficacy requirements will not close until the Supreme Court decides the issue. However, there is no indication in the Supreme Court's opinion of receptiveness to the issues raised by Rutherford on grandfathering/privacy.

C. Privitera Case

The issues raised with respect to a right of medical privacy in the Rutherford case and the Privitera case parallel each other:

1) Freedom to care for one's health and person comes within the purview of the right of privacy guaranteed by the Constitution.

2) Implicit in the right of privacy is the right "to be let alone".

3) The right of privacy includes the privilege of an individual to plan his own affairs, for "outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, to do what he pleases, go where he pleases".

4) A patient has the right to refuse cancer treatment altogether, therefore, he has a further right, should he decide to forego conventional treatment, to enlist such non-toxic

35/ Id. at
36/ Id. at
treatment, however unconventional, as he finds to be of comfort—particularly where recommended by his physician. 37/

Privitera concerned § 1707.1 of the California Health and Safety Code which requires the pre-marketing clearance of a drug used in connection with cancer— to wit, a drug must be approved either by the state board as safe and effective, or by the FDA pursuant to Section 505 of the Food, Drug and Cosmetic Act which requires proof of safety and effectiveness. The state and federal statutes contain nearly identical language requiring "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . . "

The Privitera appeals court 38/ found in general that the purpose of the California statute which is stated as frustrating cancer quacks and promoting early and effective care of cancer is not served by prohibiting a licensed doctor from giving an unapproved drug. With specific reference to physicians' rights, the court agreed with the arguments of Dr. Privitera who was convicted of a felony, conspiracy to sell or prescribe an unproven drug intended for the alleviation or cure of cancer— that a patient's constitutionally grounded right of privacy to use laetrile therapy extends to physicians willing to administer the drug and to suppliers of that drug and further, that physicians possess an independent right to practice medicine generally and to prescribe medicine and to use procedures without unreasonable government intervention.

The derivative right argument is completely addressed by the Supreme Court in Whalen v. Roe 39/ " . . . the doctor's claim is derivative from, and therefore no stronger than, the patient's. Our rejection of their claim there disposes of the doctor's as well". If there is a compelling state interest in precluding the choice of treatments involving unsafe or ineffective drugs for cancer— there is then no right to choose in the patient and no derivative right in the physician. Therein, contrasted against the Supreme Court's holdings, lies one error of the Privitera court.

The error was addressed and corrected by the highest court of the state of California in an opinion issued on March 15, 1979. 40/


38/ 141 Cal. Rptr. 764.


40/ 153 Cal. Rptr. 431
The principles underpinning that court's refusal to recognize a patient's right of privacy and a derivative physician right are as follows:

The United States Supreme Court has not recognized a right of privacy in the case of medical treatment. The court indicated that several Supreme Court cases present lessons that are applicable to the California Supreme Court's deliberation.

Roe v. Wade 41/ upheld the regulation of abortion procedure locations and appropriate personnel by the state, applying the rational basis test. The specific application of this case to the Supreme Court of California's deliberations are stated as follows by Justice Clark: "A requirement that a drug be certified effective for its intended use is a reasonable means to 'insure maximum safety for the patient'".

The Supreme Court of California discussed the decision of Planned Parenthood v. Danforth 42/ and the assistance it was to their decision as follows. The decision to be treated (have an abortion) "may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by the government, providing a rational basis for such regulation exists".

Whalen v. Roe 43/ dealt with controlled substances. The Court characterized the importance of this case to its decision as follows: "If the state has the power to ban a drug with a recognized medical use because of its potential for abuse, then - given a rationale basis for doing so - the state clearly has the power to ban a drug not recognized as effective for its intended use".

The Supreme Court of California found the statute satisfies the rational relationship test.

Judge Clark speaking for the Court found that California's legitimate state interest was set forth in Section 1700 of its state statute which expressed the state's concern with the effective and early diagnosis, and treatment or the cure of persons suffering from cancer.

In further support of the finding that the rational relationship test was fulfilled, the Court cited the Commissioner's rulemaking decision in the laetrile proceeding, and specifically the Commissioner's finding that laetrile is not generally recognized as a safe and effective cancer drug and does not qualify for an exemption from the Food, Drug and Cosmetic Act under the grandfather clause.

The Supreme Court of California discussed and held inapplicable the exemption of the terminally ill from coverage of the Federal Drug Laws as was done in the Rutherford opinion.

The Supreme Court of California discussed the Rutherford v. United States Court of Appeals decision which was entered by the Tenth Circuit on July 10, 1978. The Court held this decision inapplicable in the California forum because (1) there is "no indication in the record that the defendant's (physician) sought to restrict their activities to that class of patients". In addition, Judge Clark noted that "Dr. Privitera sometimes took neither a medical history from or personally examined the patients for whom he prescribed laetrile. The lay defendants, of course, were not qualified to diagnose cancer, much less to determine whether a cancerous condition was 'terminal'". (2) the Commissioner's refusal to approve laetrile for terminal patients in the laetrile rulemaking proceedings was reasonable and supported by substantial evidence; and (3) the record in the California proceeding does not inspire confidence that laetrile advocates would cooperate with a regulation restricting its use to the "terminal". Judge Clark states: "In studied defiance of current law, Dr. Privitera prescribed and administered the drug as a cancer cure, advised his patients to discontinue conventional treatment, and warned them not to let their regular physicians know they were taking laetrile".

Doctor Privitera applied for a writ of certiorari to the United States Supreme Court on June 12, 1979, and the writ was denied. Subsequently, the 10th Circuit also struck down the medical privacy claim but that opinion was not as well articulated as the Privitera court's decision. As noted previously, the door will not be closed on this issue vis a vis unproven methods until the U.S. Supreme Court has acted.

---

44/ See note 124 on p. 35, infra.
D. Issues Centering On The Application Of The Scientific Process

1. Safety/efficacy— the controlled clinical trial

As is evident from the preceding review of cases involving unproven methods, the beginning point of controversy in unproven methods lies in the safety/efficacy, controlled clinical trials criteria to validate a drug for marketing which is contained in federal and state drug laws and applied and interpreted in administrative and court proceedings. I will use the federal drug laws as illustration.

Under the federal law, a drug is considered "new and hence may not be marketed to the consuming public until its safety and efficacy is established. 45/ 

Section 201(p) of the Food, Drug and Cosmetic Act of 1938, as amended in 1962, defines a "new drug" as:

(1) Any drug . . . the composition of which 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 . . . or

(2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Under the statutory definition set forth in Section 201(p)(1) a drug escapes "new drug" status only if it has (1) attained general recognition among qualified experts (2) as being safe and effective for its intended use. Additionally, Section 201(p)(2) requires that once general recognition of safety and effectiveness has been attained among experts, the drug still must be used to a "material extent" and for a "material time" before losing its "new drug" status.

However, the Supreme Court held, in *Hynson* 46/, that Section 201(p) of the Act did not define what constitutes "general recognition among experts." Consequently, the Court looked to the overall statutory scheme of the Act and the overriding purpose of the 1962 Amendments before concluding that:

a drug can be "generally recognized" by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon "substantial evidence" as defined in § 505 (d). 47/

Section 505 (d) defines "substantial evidence" as evidence consisting of adequate and well-controlled 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. 48/

The elements set forth above for general recognition of safety are described more fully by FDA Commissioner Kennedy in the Laetrile Rulemaking opinion: 49/

...for a drug to be generally recognized as safe it must have accumulated at least the amount of evidence of safety that would be required for the approval of a new drug application and that evidence must be generally available to the community of experts through publication in the scientific literature. In order for a new drug application for a drug to be approved, there must exist as to that drug "adequate tests by all methods reasonably applicable" that show the drug's safety.

47/ *Hynson*, 412 U.S. at 632.
48/ § 505 (d); 21 U.S.C.A. § 355 (d).
In the case of drugs for cancer, the courts have generally considered as experts, physicians recognized in the area of cancer research and treatment who are in a position in their field to be aware of drugs being used effectively. No court except the District Court in Rutherford has sought to define expert as only physicians who have used laetrile (metabolic physicians).

The controlled clinical trial requirement is another area depicted as non-essential by the proponents of laetrile. The bones of contention are well stated in the affidavit of William T. Beaver, M.D., submitted in the FDA laetrile rulemaking proceeding.

Critics of the controlled clinical trial often point out the undisputed fact that great strides have been made in therapy in the past without the benefit of this experimental device, but simply on the basis of the uncontrolled observations of astute clinicians. It is true that modern controlled clinical trials were not needed to establish that such spectacular agents as digatalis, ether, penicillin, quinine, the sulfonamides and the like had therapeutic effectiveness. But controlled trials were needed to define their exact therapeutic roles. Further, these critics often fail to mention the thousands of drugs which, on the basis of "clinical experiences", were once accorded an "indispensable place" in therapy, and which are now known to be useless. Many of these subsequently discarded agents and therapies (gold therapy in tuberculosis, violent purging, bleeding, total colectomies for "sutotoxifications") lingered on for great periods of time in the practice of medicine, and were not only inefficacious, but seriously injurious or occasionally lethal for some patients.

---

51/ See 34 Federal Register 14595 (Sept. 19, 1969) which sets forth the elements of a controlled clinical trial.
52/ AF07, In the Matter of a Rulemaking Proceeding Concerning Laetrile, FDA Docket No. 77N-0048.
53/ Id.
The function of the controlled clinical trial is not the "discovery" of a new drug or therapy. Discoveries are made in the animal laboratory, by chance observation, or at the bedside by an astute clinician. The function of the formal controlled clinical trial is to separate the relative handful of discoveries which proved to be true advances in therapy from a legion of false leads and unverifiable clinical impressions, and to delineate in a scientific way the extent and the limitations which attend the effectiveness of drugs.\[55/\]

The laetrile proponents advance two major theories as to why these controlled clinical trial procedures which provide the underpinning of federal and state drug laws should not apply to their product. These theories are:

1) anecdotal evidence and the general observations of physicians using laetrile are sufficient to permit a basis for marketing. If you are a medical practitioner you should be able to evaluate drugs on your own.\[56/\]

2) the controlled clinical experiment process is too cumbersome and expensive for the little guy to follow.\[57/\]

Addressing their first point, a controlled clinical trial background as the indispensable element for legally marketing a drug has been validated in numerous cases involving unproven methods of cancer treatment.\[58/\] These cases also point out why anecdotal reports of patients or the observations of practitioners cannot satisfy the safety/effectiveness criteria.

\[55/\] Commissioners' 1977 Laetrile Rulemaking Decisions 42 Federal Register at pp. 39785-39786, 39797-397800.

\[56/\] See notes infra.

\[57/\] The Commission in the 1977 Laetrile Rulemaking proceeding found "there are no clinical investigations of Laetrile's effectiveness, published or otherwise, which are even arguably adequate and well-controlled." He found their efforts to be anecdotal and otherwise lacking in scientific detail. 42 Federal Register 39776-39778.

\[58/\] In medical terminology, testimonials are statements made by an individual to the effect that they used a product or treatment personally and, in their opinion, it helped them. Anecdotal reports are descriptions of single cases by an individual other than the person who was treated by which are lacking in scientific methodology, full date, full medical records, or controls. Neither type of evidence is accepted by the scientific or research community as evidence that any substance or treatment is medically effective. Long experience has shown that this type of "evidence" can be, and has been, collected in large amounts to support the alleged "effectiveness" of innumerable worthless and fraudulent cures and remedies.
In Weinberger v. Hynson, Wescott & Dunning, supra, the
Court noted with respect to the FDA regulations regarding the
nature of evidence required to establish efficacy that

[The FDA's] strict and demanding standards, barring
anecdotal evidence indicating that doctors "believe"
in the efficacy of a drug, are amply justified by the
legislative history. The hearing underlying the
1962 Act show a marked concern that impressions
or beliefs of physicians, no matter how fervently
held, are treacherous. 59/ (Emphasis Added.)

Citing the legislative history and the Supreme Court's decision
in Hynson, infra, Judge Smith in the United States v. articles
of Food and Drug held as follows 60/:

Quite properly, it is simply not enough to show that
some people, even experts, have a belief in safety
and effectiveness. A reasonable number of Americans
will sincerely attest to the worth of almost any
product or even idea. To remove the aberrations in
uniformity which can result from a well-staged
"swearing match," the law requires more. Indeed,
it has been heretofore held that the purpose of the
normal inquiry is not to ascertain the drug's general
reputation in the scientific community for such
characteristics. United States v. 41 Cases, More or Less,
420 F.2d 825 (2nd Cir. 1970); AMP, Inc. v. Gardner,
389 F.2d 825 (2nd Cir. 1968), Cert. den. 393 U.S. 825,
89 S. Ct. 86, 21 L.Ed. 2d 95 (1968). It is certain
that a conflicting reputation is insufficient to
establish general recognition. United States v.
an Article of Drug—Forestrol Vaginal Suppositories,
294 F. Supp. 1307 (N. D. Ga. 1968), aff'd 415
F.2d 390 (5th Cir. 1969).

59/ 412 U.S. a 619. The Congressiona hearings referred to by
the Court were: Hearings on S. 1552 before the Subcommittee on
Antitrust and Monopoly of the Senate Committee on the
60/ 372 F, Supp 915, 920-921 (N.D. 1974).
Therefore, what is required is more than belief, even by an expert; it is a general recognition based upon substantial scientific evidence as delineated in the regulatory guidelines. 21 CFR § 130.12. Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 93 S. Ct. 2469, 37 L. Ed. 2d 207 (1973). There is no reason to differentiate the holding in Hynson between human drugs, and animal drugs. United States v. 14 cases--Naremco Medimatic, 374 F. Supp. 922 (W.D. Mo., Number 2806, January 29, 1974). Public Health considerations are similar. Further, logic would dictate no lesser standard after-the-fact than in securing an application. Indeed, the reasoning of the Supreme Court appears to be that "the reach of scientific inquiry" is the same whatever the forum. Weinberger v. Bentex Pharmaceuticals, Inc. 412 U.S. [Emphasis added; footnote omitted.]

* * *

The statement of William T. Beaver, M.D., submitted in the Laetrile Rulemaking Proceeding 61/ contains excerpts from scientific articles which provide specific arguments from scientists and oncologists on the value of and need for the controlled clinical standard:

Let me try to recapitulate briefly. Why are controlled trials important? Because few diseases run a course which is precisely predictable; because patients, doctors, and details of medical care differ greatly from place to place, and from one time to another; and because most patients and most physicians are biased towards expecting therapeutic benefit. A properly designed trial is, therefore, an attempt to safeguard the investigator from unwarranted conclusions. 62/

In order to decide whether patients treated in one way are benefitted more than those treated in another, there is no possibility of avoiding the use of numbers. The mere statement by a clinician that patients do better with this or that treatment is due to having formed an opinion that more patients are helped by the treatment he advocates than by other treatments. The opinion is based on numbers, but having omitted to record exactly how many patients have been treated by different methods and having omitted to ensure that the

only variable factor affecting the patient was the treatment in question, only a "clinical impression", instead of a scientific fact, can be stated. This is a pity, for progress is delayed when convinced opinions are offered in place of convincing facts. The former, though not necessarily wrong, are unreliable, despite the great assurance with which they are often advanced. 63/

Well controlled clinical evaluations reflecting the above ideas are not the invariable rule in practice today. Indeed, some resistance to the very concept often arises. The traditional authoritative attitudes held by most physicians make it difficult for them to believe that they cannot put complete trust in their individual judgements but must defer to the conclusions of some nearly known investigator. However, the individual physician combining the responsibilities of evaluation with those of patient care is easily misled by "mere experience," and an acceptable evaluation can be done only by executing a carefully prepared experimental design. 64/

We have what we call our clinical experience. The difficulty about clinical experience as I have known it in my own case and vicariously in the case of my colleagues is that, in a general way, it is unplanned and haphazard. We are victims of the freaks of chance. We may have a little run of experience which convinces us that a certain treatment is the most useful. We are also the victims of attractive propaganda leaflets that arrived from the drug companies the week before and of the persuasive eloquence of our colleagues. And so, working in this way, we often, in good faith, carry out a treatment for considerable time and at the end of it we do not know whether our treatment has done our patients any good or not....

To my mind, then, the clinical trial is the best way of getting to know what are the probabilities that a given form of treatment will affect one's patient for better or for worse.


64/ AF07 at p. 7, quoting from Pickering, G.W. "Controlled Clinical Trials-- A Symposium" at p. 164.
2. Is it unfair to expect a drug like laetrile to meet the federal drug law standards?

What of the second theory advanced to discredit the application of standards requiring controlled clinical trials to laetrile? Is it unfair to expect a drug like laetrile to maneuver its way through the federal drug approval process? 65/

The courts have required the satisfaction of federal drug clearance criteria in cases in which the manufacturers or distributors of a drug decline to pursue the new drug procedures before the FDA or default on procedures initiated. 66/

There is little question that if their product was meritorious, that the laetrile proponents could collectively afford to finance the types of animal, clinical experiences needed to satisfy the federal drug process:

Laetrile is big business. Investigations by California authorities revealed what huge sums of money some of the Laetrile leaders had been putting in the bank (36, 92). Robert Bradford, according to an agent of the Food and Drug Bureau cited in the New York Times, had been taking in an estimated $150,000 to $200,000 a month in Laetrile sales. In slightly over two years, Dr. John Richardson had deposited some $2,800,000 in a single checking account (203). The quantity of Laetrile that Judge Bohanon determined to be a six-month supply would have cost the user about $2250 (204). Estimating Laetrile user at 75,000, the mathematics mounts to millions 67/

65/ See Brief amicus curiae of the Academy of Preventative Medicine in support of Glenn L. Rutherford, U.S. v. Rutherford, Supreme Court Docket No. 78-606, pp. 6-11.

66/ See e.g., Rutherford v. American Medical Association, 379 F.2d 641 (7th Cir. 1967), cert. denied, 389 U.S. 1043; Tutaki v. Celebreze, 375 F.2d 105 (7th Cir. 1967); Julius H. Morgan, Sr., et al v. Mathews et al,. Civil Action No. 76-1637, Order of November 30, 1976;

Michael O'Carnahan v. United States, bench opinion issued June 6, 1977, by Judge Schwartz, United States District Court, Southern District of California, Trial Transcript page 18. Judge Schwartz dismissed the request for relief against the premarket approval requirements of the federal drug laws as follows: "[T]he proponents of laetrile, although they say they don't have the means to pursue perhaps a new drug application properly, effectively seem to have the means, certain amount of public and legislative support, to pursue legislation in various states..."

67/ Young, "Laetrile in historical Perspective" contained at p. 47-48 of "Politics, Science and Cancer; The Laetrile Phenomenon" (Markle, Petersen, editors, Westview Press 1980)
They have not chosen to pursue this traditional route.

However, there are other procedures available through the FDA and NCI which would permit the impecunious discoverer to have his drug tested.

Laetrile proponents allege that because laetrile is a "folk remedy" or a "natural" cure, it is not commercially lucrative for big pharmaceutical companies to sponsor it. They further assert that the FDA procedures for testing a new drug are so lengthy and expensive as to make it impossible for laetrile proponents to foot the costs themselves.

There are, however, existing mechanisms within the FDA procedures, which facilitate the testing and eventual marketing of drugs like laetrile, provided they have shown some initial therapeutic potential.

The FDA fast tracking procedure allows drugs of "significant" value to receive priority tracking and review. Of the approximately 5400 new drugs approved since 1975, over 60 have received priority review because of their therapeutic significance including some anti-cancer drugs. In addition, FDA's Abbreviated New Drug Applications (ANDA's) permit manufacturers of drugs that were approved prior to the 1962 Food, Drug and Cosmetic Act to file an abbreviated application to comply with the Act's "efficacy" requirement.

---


69/ Brief amicus curiae of National Health Federation, Rutherford v. United States, Supreme Court Docket No. 78-605 at p. 30. Brief amicus curiae of Northwest Academy of Preventative Medicine at p. 33-34 (brief as originally filed); at p. 7-8 (substituted brief).

70/ FDA New Drug "Approvals List."

71/ The Supreme Court observed in its opinion in Rutherford v. United States, June 18, 1979 at p. 13 that its decision did not foreclose resort to experimental drugs by the terminal patient. The court noted the procedure exempted experimental drugs that satisfy preclinical testing criteria from the approval process. The court also noted that some 300 experimental drugs were available to cancer patients and that in 1977 over 90,000 cancer patients participated in federally sponsored investigative programs alone.
Thus, the FDA is not insensitive to the difficulties some drug sponsors may have in fulfilling the FDA requirements for new drugs, and has created mechanisms to make this process less laborious.

Recently the FDA has expressed concern with the problem of "orphan drugs", drugs of significant therapeutic effect but of limited commercial value. 72/ An interagency task force within the DHHS has recently completed a proposal to set up an independent advisory board within the department to address this problem. 73/ The proposal calls for a variety of economic and administrative incentives to encourage the development and marketing of "orphan drugs." The proposal is currently being reviewed by HHS Secretary Harris.

In addition, there is currently a bill before Congress that would create, within the NIH, the office of Drugs of Limited Commercial Value. This legislation would allow the Director to provide financial assistance to entities for the development of such drugs. 74/

In response to laetrile proponent's assertion that the cancer establishment focuses only on chemical or synthetic solutions to cancer, the NCI maintains an active program to screen and develop drugs of plant origin for anti-tumor activity. 75/ Since 1960 when the program began, 25,000 to 35,000 plant extracts have been tested. 76/ Since 1965, 13 plant products or synthetic derivatives have been filed by NCI with the FDA as candidates for clinical trials.

One important cancer drug of plant origin that is commercially available and widely marketed is vincristine, an extract from the plant vinca rosea. After its discovery as an effective anti-tumor agent, Eli Lilly & Company began growing it as a cash crop for the manufacture of vincristine.


73/ Id.

74/ H.R. 7089. A bill to establish an office in the National Institutes of Health to assist in the development of drugs for diseases and conditions of low incidence. 96th Congress, 2nd Session.


76/ Id. at 80.
Another drug of plant origin, maytansine, an extract of the Maytenus serrata plant, is currently in Phase III clinical trials and shows great promise as an anti-cancer agent. 77/

The NCI plant program funds the USDA to investigate the potential for cash crop production of drugs that have been discovered to have good potential as anti-cancer agents. The program also accepts samples from outside sources for anti-tumor screening. In fact a spokesperson from the program noted that "...new plants with anti-cancer activity are regularly discovered this way." 78/

It should be noted that laetrile proponents have made several attempts to get FDA approval to distribute the drug. The most recent was that made by the McNaughton Foundation in 1970 to test laetrile on humans. The FDA found the application inadequate, but in response to the promoter claims that FDA was prejudiced, an independent panel of cancer experts was created to review the application. They reached the same conclusion; the evidence was not adequate to justify testing laetrile on humans. 79/ 80/


78/ Id.


III. THE POLITICS OF LAETRILE

A. The National Cancer Institute Tests

The NCI tests were entered into due to political pressure and public sentiment, not scientific value. The tests waive the proof of effect on animals criteria and after testing out recommended diet and dosage levels in six patients to determine whether a test could be pursued without patient detriment, moved into Phase II clinical trials. Three studies are contemplated; (1) antineoplastic effect; (2) symptomatic and supportive effects (pain control, appetite stimulation, etc.); (3) toxicology, pharmacokinetics and metabolism of laetrile. The test objective is the use of objective methodology by experienced clinical cancer research groups to provide credible answers:

81/ NCI Protocol for "A Clinical Trial of Laetrile (amygdalin) in the treatment of Advanced Cancer." Charles G. Moertel, M.D.


83/ See Ellison, Byar, Newell, "Special Report on Laetrile: The NCI Laetrile Review," New England Journal of Medicine, Vol. 299, No. 10, pp. 549-552 (September 7, 1978). This article reaches the conclusion that applying standard scientific criteria, the results of the blind review of laetrile cases submitted for retrospective review in which 2 complete and 4 partial responses to laetrile out of 67 cases of purported beneficial responses submitted, which had sufficient data to permit analysis allows "no definite conclusions supporting the anti-cancer activity of Laetrile."

84/ The Commissioner in the 1977 Rulemaking Proceeding, evaluated tests which had been conducted on animals and found that they "failed to show that Laetrile (or amygdalin) has anticancer activity in laboratory animals." 42 Fed. Register at 39781.

85/ Oral testimony of Dr. Joseph Zauertnik, Florida Cancer Council, July 26, 1980 hearings before Florida State Board of Medical Examiners on Rule 217-27 to declare amygdalin harmful.
"If Laetrile is indeed worthless and a cruel hoax for the cancer victim, then the thinking, sensible American citizen should be presented with convincing evidence that will serve to protect him against exploitation. If, on the other hand, the wide-spread public acceptance of Laetrile is indicative of some useful palliative effect, it is even more important that this effect be demonstrated in a convincing manner." 86/

The form of amygdalin used corresponds "to the usually distributed forms of the drug. The treatment regimen was designed after discussion with Dr. Ernest T. Krebs, Mr. Andrew R.L. McNaughton and Mr. R.W. Bradford. It would seem to be representative of recent usage of Laetrile in the United States and Mexico. The nutritional and metabolic support measures generally recommended with Laetrile treatment will also be employed in this study." 87/

Will these tests resolve controversy? It is unlikely. The pro-laetrile publications have already outlined the positions that will be taken to discredit the tests if laetrile is proven ineffective.

For example:

(1) The drug used in the tests is inactive and therefore not therapeutic

When the protocol for the NCI laetrile clinical trials was written in 1978 it was decided to use the form of laetrile actually and most commonly being used on cancer patients in this country. Specifically, NCI obtained samples of the Cyta Pharma (Mexican) product for testing. The Cyta Pharma product was found to be sub-potent and exhibited unacceptable disintegration and dissolution characteristics. For that reason, NCI, employing good pharmaceutical practices, produced a product that was uncontaminated and of uniform disintegration and dissolution characteristics. However, the NCI product was formulated to contain the potency then described as needed for therapeutic effect and to conform to the then established product specifications 88/

In "The Choice," as late as Fall, 1979, Robert Bradford appeared to have no quarrel with the form of amygdalin used in the tests. He opined that "some of the earlier preparations of laetrile developed in the 1950's were probably more effective

86/ Moertel, supra.
87/ Id.
than those in use now. However, he concluded that the question of which isomeric configuration or form of amygdalin is more active is essentially irrelevant "because we're not sure which of the isomeric configurations is most effective."  

In the spring of 1980, Mr. Bradford filed suit in federal district court in California to stop the laetrile tests. The reason given was that the NCI was using a decomposed and toxic substance in its tests that was not pure amygdalin. The crux of the suit is that NCI is using the DL form of the injectable product rather than the D form of Bradford's product, Amygatrile. However, the NCI tests on Amygatrile in April of 1980 indicated that it was an unstable drug which readily decomposed to DL on the shelf and could not be forced back into the D configuration before injection. Further, the crystallization of the amygatrile tested by the Institute at body temperature (37°C) not only gives it an uncertain shelf life but also meant that the substance could crystallize in the blood stream after injection and cause an embolism.

---

89/ The Choice, Fall, 1979 at 2; to same effect, see The Choice, Summer, 1980.

90/ Id. at 2.

91/ The Choice, Spring issue.

92/ Id.

93/ Public Scrutiny, July 1980 at p. 10.


95/ Conversation with J. Paul Davignon, Chief, Pharmaceutical Resources Branch, NCI.

The Choice, Spring and Summer issues claim as one indication that the NCI test of laetrile is biologically inert, an infra-red scan (spectrogram) which it is alleged shows weaker CN group peaks in the NCI product vis a vis amygatrile. According to Paul D'Avignon at the Cancer Institute, the tests compared apples with oranges since different concentrations of the drug were used opposite each other. Used in the same concentrations, both showed equal CN peaks. Thus, the NCI product is not biologically inert.
If the tests do not show therapeutic effect for laetrile, the proponents can claim that this is due to use of an inappropriate product even though that is the product which most of the patients using laetrile were receiving.

(2) If test results are poor, they can be attributed to the tests being conducted by physicians who have not used laetrile before and who don't believe in it.

The laetrile proponents find no comfort in the fact that the tests are being conducted by objective scientific criteria by physicians skilled in treating cancer patients. Clinton Miller, Executive Director of the National Health Federation likened NCI's testing to "having people who didn't believe in flying, test the Wright Brothers Airplane." 97/

(3) The drug was used only on patients who have exhausted available conventional therapy and so the failure of the tests can prove nothing.

The publications put out by the laetrile proponents treat the restriction of the test of laetrile to those who are terminal as a guarantee of failure.

"Proponents of amygdalin therapy have generally been cheered by the government agreement to include a full metabolic therapy program for cancer patients, but also dismayed by the fact that only terminal patients will be involved in the tests." 98/

"Whatever the proposed test will prove is unknown. The only cancer patients who will be allowed to participate are those who are in the late stages of their cancers and who have been unsuccessful with standard, orthodox, toxic therapies." 99/

96/ Public Scrutiny, July 1980 at p. 10.

97/ Public Scrutiny, February, 1980 at p. 2.

98/ The Choice (publication of the "Committee for Freedom of Choice in Cancer Therapy, 146 Main Street, Suite 408, Los Altos, CA 94022) Spring, 1980 at p. 11.

99/ Public Scrutiny, February, 1980 at p. 2.
"Only cancer victims with totally destroyed immune systems will be accepted in the test. The results are predictable. Too little, too late." 100

"The NCI protocol only allows patients in whom all known conventional therapy has failed. In other words, the metabolic therapy will be used on cancer victims whose immune systems have been destroyed by FDA approved "safe and effective" chemotherapy and radiation therapy. At least the brains at NCI will probably prove that very little can be done for cancer patients who have accepted government approved remedies." 101

Dr. James Privetera is quoted as saying: "I worry that they're going to be using people who have already had chemotherapy and radiation, which means the body's immune system is burned out, suppressed." 102

These protests are inconsistent with the claims of success when treating the terminal: "[C]ancer is nearly 100% curable if the patient has at least 5 1/2 months to live. Even in the terminal stage, nutritional or non-toxic treatments have effected recovery rates of nearly 50%." 103

B. Legislation

Bills introduced in the federal arena to permit medical freedom of choice 104 or to legalize laetrile 105 have either died or are dormant.

100/ Public Scrutiny, May, 1980 at p. 2.
101/ Public Scrutiny, March, 1980 at p. 3.
103/ Brochure, The Arlin J. Brown Information Center, Inc., P.O. Box 251, For Fort Belvoir, VA 22060.

104/ A Bill to expand the medical freedom of choice of consumers by amending the Federal Food, Drug and Cosmetic Act to provide that drugs will be regulated under the Act solely to assure their safety, H.R. 54, 95th Congress, 1st Session (1977); S. 1683, 95th Congress, 1st Session 123 Cong. Rec. 9510 (1977).

105/ On May 10, 1979, Congressman Lawrence McDonald introduced H.R.4045 to permit the introduction or delivery for introduction of laetrile into interstate commerce without the approval of a new drug application under the federal drug laws. As of the end of June, 1980, no hearings on this bill were scheduled. This means the bill will die and have to be reintroduced next Congress.
In contrast, states have been very active in protecting their citizenry against unproven methods of cancer treatment or in some fashion permitting the use of unproven methods within the state. Most of the protectionist statutes provide that cancer can be treated only by licensed physicians and dentists that therapies with alleged curative powers can only be sold by prescription; some provide that detailed information and samples be provided to state health agencies and set administrative and criminal penalties for non-compliance; and others establish advisory boards to make recommendations or finds with respect to cancer treatments.

106/ See the discussion of cancer quackery statutes in Lerner & Weeks "The Laetrile Power Play in Drug Marketing" 3 HAMLINE L. REV. 1, 40-44 (1980) (hereinafter cited as "Lerner").


108/ Lerner at pp. 40-44.

109/ Id.

110/ Id.

111/ Id.
Some of the statutes provide that laetrile may be restricted if found harmful by the state medical authority. The Florida Board of Medical Examiners and Board of Osteopathic Medical Examiners on July 26, 1980 held hearings on a proposed rule (Number 21M-27) which would declare laetrile harmful. The Economic Impact Statement in support of the rule covered harm related to the inefficacy of the drug, concern over the effect of delay in seeking effective treatment on the life expectancy of cancer patients. The Osteopathic Board in its vote restricted to meaning of harmful to toxic and voted that although they did not approve of laetrile as a treatment, they did not have sufficient scientific evidence in the record to declare the drug toxic. In contrast, the Board of Medical Examiners found the drug harmful.

All of the statutes provide for some type of patient request or consent to treatment. These provisions vis a vis malpractice claims is discussed infra. The patient informed request/consents take the following forms:

- Patient request
- Patient informed request
- Patient written informed consent
- Informed consent
- Written informed consent

Informed request/consent must be filed with state agency.

---

112/ Alaska, Delaware, Florida, Maryland, North Dakota, South Dakota, Texas. See also the Washington State statute. That state does not directly provide for a state proceeding to determine whether laetrile is harmful. However, in the preamble to the statute it expresses the sense of giving the patient an informed choice with the caveat that "the substance is not proven to be directly detrimental to health." This appears to leave the door open to request the State Board of Pharmacy to determine harmfulness.


114/ Alaska, N.Dak., S. Dak.

115/ Idaho. The Idaho statute does not provide for informed consent but following the Rutherford opinion, the Board of Pharmacy developed a two part affidavit. Ind., N.H., N. Dak. Okla.

116/ Colo., Washington.


118/ Ind., N.J.
The California statute is the best known and most unique. It restricts the use of cancer remedies in the state unless they have met state or federal freemarketing clearance (safety/efficacy) standards. It also contains provisions protecting the public from misrepresentation, fraud, etc. It has been the subject of considerable litigation specifically with regard to the criminal and injunctive provisions. Physician convictions under this statute have lead to state medical board revocation of a license to practice medicine. The key case, discussed earlier is Privitera. This case involved the right of a physician to assert a patient's right to privacy as a defense to statutory or medical board prohibitions against a physician administering a treatment not regarded as safe and effective by qualified experts. The court held that there was no right of privacy involved and hence none which Dr. Privitera could assert. The court further held that the premarket approval provision §1701.1 of the California Health and Safety Code bears a reasonable relationship to the legitimate state interest in the health and safety of its citizens.

The state statutes dealing with laetrile do not insulate physicians, manufacturers, hospitals, health care facilities, pharmacists or distributors from actions in the nature of malpractice, product liability, fraud or misrepresentation. The state statutes rather:

---

120 Id. § 1701.1
121 Lerner at pp. 40-44.
122 See Lerner at p. 43, note 253 which details suits brought in California to enforce the statute which involves laetrile.
123 Lerner at page 43 note 253.
125 See also, By advise letter of September 16, 1976, the Alaska Attorney General's office opines that "failure of a physician to advise the patient on the nature of laetrile, may, of course, be an independent violation of professional standards and, as such, subject him/her to disciplinary proceedings by the State Board on that basis."
- permit physician use without the interference of a hospital or health care facility.\textsuperscript{126}

- protect physicians/pharmacists/hospitals and health care facilities from civil and criminal liability stemming solely from the prescription or administration of laetrile.\textsuperscript{127}

- protects physicians from disciplinary action for use of laetrile.\textsuperscript{128}

- protects manufacturers from civil and criminal penalties for manufacture or distributors from penalties for introduction for delivery \textbf{if} the state law is followed.\textsuperscript{129}

Statutes do not:

- require physicians or pharmacists to sell, administer or prescribe.\textsuperscript{130}

- encourage use.\textsuperscript{131}

- do not constitute an approval or endorsement.\textsuperscript{132}

\begin{itemize}
\item \textsuperscript{126} Alaska, Delaware, Florida, Illinois, Indiana, Kansas, Maryland, Montana, Nevada, New Hampshire, New Jersey, North Dakota, Oklahoma, South Dakota, Texas, Washington.
\item \textsuperscript{127} Colorado, Delaware, Florida, Montana, Nevada, New Jersey, Oklahoma, South Dakota.
\item \textsuperscript{128} Alaska, Delaware, Illinois, Indiana, Montana, New Hampshire, Washington.
\item \textsuperscript{129} New Jersey
\item \textsuperscript{130} Indiana, Montana, Oklahoma, South Dakota
\item \textsuperscript{131} Colorado
\item \textsuperscript{132} Colorado, Indiana, Kansas, Montana, Oklahoma, Washington
\end{itemize}
Finally, although many statutes provide for the manufacture of laetrile, these statutes have had little actual effect due to the lack of raw materials, such as apricot kernels in the state. Interstate shipment of apricot kernels or other raw materials intended for use in manufacture of Laetrile is prohibited by the federal Act for it reaches interstate shipment of the major components or active ingredients of a drug. Similarly, a drug manufactured and distributed solely within one state is still subject to the federal Act as its main component was shipped in interstate commerce.

Attorneys can then expect the opportunity for involvement to arise:

* in the legislative drafting, lobbying, interpretation, implementation of statutes.

* prosecution or defense of criminal actions arising under the "protectionist" statutes.

* advising clients relating to regulations implementing the laetrile statutes particularly in the areas of manufacturing, distribution, promotion of the product, quality control.

---

C. PREEMPTION

Although the issue has not been litigated, the validity of state laetrile legalization in the face of federal prohibition may be questioned. Under the supremacy clause of the federal constitution where "Congress has taken the particular subject matter in hand," the states are precluded from regulating that same "subject matter." Where preemption occurs, all state regulation is invalid. In the context of the laetrile controversy, it can be argued that the federal act, which requires safety and effectiveness, by its very nature demands national uniformity of a virtually absolute character. A federal act which regulates drugs in all states except those which prefer otherwise may be deemed incompatible with the notion of providing effective protection against unsafe and ineffective drugs.

The legalization of laetrile for intrastate use in 19 states and the operation of the affidavit system can be viewed as obstacles to the accomplishment and execution of the full purpose and objectives of Congress in the establishment of uniform standards for drug access. Cf. Ray v. Atlantic Richfield Co., 55 L.Ed.2d. 179 (1978). A substantial amount of legislative history exists as early as the original 1906 Act of which the passage quoted below is representative, indicating an intent on the part of Congress that the federal drug laws establish uniform standards. Senator McCumber, a co-sponsor of the Senate bill stated:

Another object is to prevent the evil of diverse rulings of the several commissioners of the States having pure-food laws...

We well know, Mr. President, that the moment we do pass a general law upon this subject, by virtue of that law covering ninety-odd percent of all of the commerce in impure products, that law must become the dominant law; and, if there is any difference, the State laws will soon accommodate and modify themselves in conformity with the national legislation.

10 Congressional Record 1216 (1906). See e.g., 21 U.S.C. §355


135/ The Florida State Boards of Medical and Osteopathic Medical Examiners, in the "Economic Impact Statement" accompanying proposed Rule 21M-27, which declares laetrile/amygdalin "Harmful", opines that individual state legislation declaring laetrile lawful within their state "weakens" the Food and Drug Administration. This observation bears on pre-emption.
(new drug provisions) and compare with Section 202 of Public Law 87-781 which provides that the 1962 Amendments to the Federal Food, Drug and Cosmetic Act invalidate any provision of state law that is in "direct and positive conflict" with the Act.

It is well settled that a state is permitted to legislate or regulate with a view to the protection of its citizenry against fraud or imposition by impure or ineffective drugs. However, it is equally well settled that a:

...state may not, under the guise of exercising its police power or otherwise, ...enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does to the extent that the state law interferes with or frustrates the operation of the acts of Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution.

McDermott v. Wisconsin, 228 U.S. 115, 131-132(1912) (citations omitted)

The pre-emption rationale applies not only to states but also, as recognized by Judge Chapman in Julian H. Morgan, Sr. v. David Matthews(Civil Action No. 76-1636, USDC,So. Car.,Spartanburg Div. ,Order of Nov. 30, 1976). The Judge denied injunctive relief restraining federal officers from interfering with their procurement of laetrile:

Finally, it has not been shown that the granting of injunctive relief in this case would not injure other parties or the public. To the contrary, to permit the distribution of Laetrile in this case would be to circumvent the laws enacted to assure that drugs distributed in interstate commerce be both safe and effective for their recommended use, and would undermine the ability of those charged with upholding these laws to do so most effectively in the future. Such a holding would also provide any future proponent of unproven remedies a basis for arguing to another court that it should allow the distribution of substances in a manner contrary to the law.

Slip Opinion at page 6.

The legislative history and court interpretations alluded to indicate a congressional intent that the Act establish uniform drug standards. The question then becomes whether the state statutes exempting Laetrile do so in a manner violative of the federal requirements of uniformity. Under the circumstances it is not unreasonable to contend that it may. For example, a number of the laetrile statutes specifically provide that the state board of health or pharmacy may set standards to assure that the substance is not adulterated, misbranded or otherwise
contaminated If these provisions are not being enforced, enforcement could be mandated through administrative action. But, what of those states that do not specifically provide for adulteration/misbranding control? Are the guidelines or the state drug laws requiring procedures to assure that drugs sold within the state are neither adulterated nor misbranded automatically written into the laetrile statutes? This question can only be answered by direct inquiry to the various Attorneys General. If the answer is negative, there is a serious question of danger to the public health. This danger may support a federal pre-emption argument


137/ See e.g., the Illinois statute dealing with laetrile. Ill. Ann. Stat. ch. 56 1/2, §§1801-04 (Smith Hurd Suppl. 1979). The Illinois Department of Public Health assumes no responsibility for the safety, efficacy, quality, purity, labeling or any other requirement of approved "New Drugs" in regard to the compound Amygdalin-Laetrile. The reason given for this is that the drug is imprecise in both name and composition. Laetrile is several different non-uniform preparations; laetrile and amygdalin are not the same chemical compound; proponents of Laetrile do not agree as to the identity of the chemical compound bearing that name; no adequate and well-controlled chemical investigations have been carried out and overwhelming evidence is that it is not recognized as safe and effective. The Department reasons that since Laetrile has no set composition, varies depending upon manufacturer and has no pharmaceutical standard, "the mechanism for assuring the safety, purity and quality of the drug is missing. See Department Policy Statement of June 26, 1979.
IV. THE CHILD WITH LIFE-THREATENING ILLNESS: PARENT/CHILD RIGHTS IN TREATMENT DECISIONS; ROLE OF THE STATE

Issue: When the parents/guardian of a pediatric cancer patient involve their child in a treatment program based on unproven methods, when does the state's interest overrule the parents right to decide what is the best treatment for the child?

A. Background: Unique Situation of Children With Cancer

Any approach to this question requires a background in the unique position of the child vis a vis cancer. Children constitute only one percent of the cancer cases in this country but cancer represents the most serious threat to childlife next to accidents. Ten years ago, no more than 10-20% of children treated with cancer were alive five years after diagnosis. Today the story is different. Childhood cancers are the category in which the greatest strides in long term survival and "cure" have been made.

Dr. Vincent De Vita of the National Cancer Institute, in a report to the National Cancer Advisory Board in 1979, reported that in acute lymphocytic leukemia more than 90 percent of children with null cell variety of the disease are curable; in Wilm's Tumor—in 1971 40 percent were curable with surgery and irradiation. Presently, 90 percent of children can be cured using drugs, irradiation and surgery together; in Rhabdomysarcoma and Ewings Sarcoma a cure of 60-70 percent is now possible compared with 10-20 percent in the pre-1972 era. These are the rates for specific cancers. There are other cancers in children in which the results are not so rosy. However, the overall nationwide survival rate in pediatric cancers for children is, according to the End Results Section of the Branch of the Division of Cancer Cause and Prevention at NCI, thirty three percent and 60-65 percent five year life expectancies for childhood and adolescent cancer cases pertain to those treated in centers adequately staffed and equipped.

Ten years ago, the choices in treatment mode by a parent would have little effect on whether a child would be an ultimate survivor. The opposite is true today. Parents are presented with such excellent recognized treatment possibilities that in most cases they can be assured that their child will be a long term survivor or a cured cancer patient. Wrong choices can deprive the child of the chance of survival, and deprive the parents of their child.

One of the most poignant example of delay in treatment and resultant death occurred in Florida and involved a child with acute lymphocytic leukemia under the care of Dr. Paulette Mehta.

Morra and Potts, Choices (Avon, 1980) at p. 555.
To the same effect see Morra and Potts, supra. at 558-566.
The child had null cell acute lymphocytic leukemia and her diagnostic features permitted an expectation of "cure" in the 90 percentile. The mother initially refused all treatment but transfusions. The child was started on laetrile, a "natural therapy"; two weeks later she was hospitalized. This time the parent agreed to therapy to reach remission and followed maintenance therapy for 3 months. The mother then took the child for laetrile treatment for 3 months. The child relapsed and was reinduced. The parent again started laetrile therapy, relapsed, the mother then left the country to obtain laetrile abroad and the child died in 3 months.

Discussion and Application of Legal Principles

General

In the Privitera section, supra, the cases involving a competent adults' request to choose laetrile or other metabolic therapies are discussed. The laetrile cases as decided by courts of last resort to date have held that there is no right of medical privacy that permits a choice of drugs that have not been shown safe/effective. These cases have rested their decisions on the states interest in preserving and protecting the health and safety of its citizens.

The issue of treatment choice is greatly complicated when the patient is a child and the parents choose that the child be treated with laetrile.

Parents possess the derivative constitutional right of a minor to self-determination, privacy, informed consent and bodily function. 141/ It is well-established that there is a "private realm of family life which the state cannot enter," 142/ and parents possess certain rights of control over the upbringing of their children. 143/ This parental prerogative, however, is not absolute, particularly in the area of medical treatment. A number of courts have authorized medical care over parental objection, when the life of the child weighed in the balance. 144/ The courts have justified this intervention into family

141/ Custody of a Minor (Chad Green), 379 N.E.2d 1053 (1978), re-determination on review aff'd, 393 N.E.2d 836 (1979).

142/ Prince v. Massachusetts, 321 U.S. 158, 166 (1944).


life under a "parents patrie" or "best interests of the child" theory when adjudging the child "neglected" when the parents have refused to permit medical treatment. The courts have reached their decision by substituting their judgment for what the child would do if it was competent to decide.

The usurpation of parental control over the child in order to protect the best interests of the child was well stated in a case dealing with child labor:

"Parents may be free to become martyrs themselves but it does not follow that they are free in identical circumstances to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."

This statement is particularly significant in regard to the subjecting of children to unproven modes of cancer treatment.

Specific Application to Cases Involving Cancer in Children

Unquestionably the welfare of the child is the governing principle in any decision concerning proposed medical treatment. In life threatening situations, the child's right to life must take precedence over familial rights.

It is the natural desire of parents to protect their children from needless suffering. The statement of the pro-laetrile groups advise avoidance of side-effects, cutting, burning or mutilation of

---


147/ Prince v. Massachusetts, 321 U.S. 158, 170 (1944).

148/ Custody of a Minor, supra. The Green case raises some interesting questions in the informed consent area. The transcript in that case contains statements by the doctors testifying for the Greens that laetrile is not recognized effective against the leukemias. See Tr. at pp This is in accord with statements made in pre-1962 laetrile labeling. See Record on Appeal, United States v. Rutherford, Docket No. 78-605, H.R.R. 201 at H 232 (a 1962 pamphlet that states that laetrile is not recommended for the leukemias). However, in its publications, the laetrile proponents report anecdotal cures involving leukemia treatment with laetrile. See Cancer Control Journal, Vol. 5, Nos. 3/4-5/6 at pp. 51-52 (recounting three stories of children with leukemia being treated by laetrile).
orthodox cancer treatment and choice of their non-toxic therapies. 149

Their newsletters are replete with glowing anecdotal reports of cures. 150 These representations may seduce parents completely away from seeking proven treatments for their child or delay seeking treatment, increasing the likelihood that a child will not be cured or will not be a long term survivor. 151

149/ Brief amicus curiae of the "Save the U.S. Movement, et., U.S. v. Rutherford, Supreme Court Docket No. 78-605,

"Informed Laetrilists, who generally accept the...thesis of Dr. Krebs, approach the cancer problem, not with the objective of trying to find some miracle treatment that can destroy, by excising, burning, or poisoning the visible manifestations of cancer (polyps, tumors, lesions, etc.), but to find and remove the underlying causes, or conditions, or cancer, which, according to them, are associated with metabolic deficiency."

and

"after cancer cells have extensively proliferated into vital areas of the body, and after the patient has subjected himself to injurious surgery, radiation, and/or chemotherapy, the probabilities are that serious damage will have been caused to vital organs, and to the body's natural defense mechanism. Even the most effective cancer remedy cannot render whole an organ which has been irreparably damaged either by cancer, or by destructive cancer treatments."

150/ See e.g., Cancer Control Journal, Vol. 5, Nos. 3/4-5/6 at pp.51-56 which reports therapy success stories involving children.

Some courts have, however, been reluctant to abridge the parents' right to determine what is best for the child in a non-life threatening situation. At least one commentator has stated that the interest should be just as strong in non-life threatening situations because there is little sense in allowing a child to become a physical or psychological cripple. In fact, the state's interest may be stronger in cases where life is not in danger because society might have to furnish the child with long-term financial support.

In the first Chad Green case (Custody of a Minor, April, 1978), Judge Volterra discussed the aforementioned constitutional considerations, invoked the doctrine of substitute judgment and found that a rational competent person would undergo chemotherapy. He reached this decision by balancing the factors for and against the treatment. The decisions of Judge Volterra and the affirming court in the first Chad Green case focused on the medical consequences to the child if left untreated:

"According to the experience of the medical experts in this case, the effect of this type of treatment on the long-term survival of leukemic children has been gratifying. After one year of treatment, 90% of the children are found to be disease free. In the second year of treatment, 70% are in a state of remission. At the end of the third year, 65% are still in remission. In the fourth year the survival rate curve flattens to show a steady survival pattern of approximately 50%.

The Massachusetts court affirmed the lower court and held that the record supported the four tenets of the lower court's decision:

"(1) that acute lymphocytic leukemia in children is fatal if untreated; (2) that chemotherapy is the only available medical treatment offering a hope for cure; (3) that the risks of the treatment are minimal when compared to the consequences of allowing the disease to go untreated; and (4) that the parents are unwilling to continue the child's chemotherapy, regardless of the consequences. We conclude that these findings were supported by the evidence and were sufficient to meet the requirements of the care and protection statute (52, pp. 25-26)."

152/ In re Green, 448 Pa. 338 (1972); In re Seiferth, 309 NY 80 (1955).
154/ Id.
155/ Custody of A Minor (Chad Green) supra, at 25 (slip opinion).
156/ Id.
157/ Id.
Judge Volterra found that the Greens were sincere but their medical policy untenable because they failed to show an alternate treatment and their fear of chemotherapy was unsubstantiated. Judge Volterra stated that the parents' conduct indicated an unwillingness to properly provide necessary and proper care for the child and ordered that the child undergo chemotherapy treatment under the custody of the Massachusetts Department of Public Welfare. Physical custody of the child remained with the parents. This decision was affirmed by the Massachusetts Supreme Court.

In 1979 the Greens sought to reopen the case; to regain full custody of their child and to supplement his chemotherapy with laetrile. Judge Volterra found metabolic therapy to be ineffective, posing a serious risk of injury to the child and therefore inconsistent with good medical practice and the best interests of the child. Judge Volterra reiterated from his previous decision that the child's welfare is paramount and further stated that the interest of the child in combination with the state's interest in protecting the child and preserving life, outweighed the constitutional rights asserted by the parents. The parental rights are likened to a trust, subject to a correlative duty to care for and protect the child and terminated by the parents' failure to discharge their obligations, i.e., parental decision-making that jeopardizes the health or safety of the child. Additionally, Volterra found Rutherford to be inapplicable because the child was not terminally ill.

In a case decided before the second "Chad Green" case, the New York Appellate Court affirmed a lower court ruling that parents could decide to have their child undergo metabolic therapy. (In the Matter of Hofbauer, 411 N.Y.S.2d 416 (1978)). In this case the court did not rule on the merits of conventional therapy versus laetrile but on whether the parents supplied the child with adequate medical treatment. The Hofbauer court found that the parent has the primary right to select medical care and held that the state failed to prove that laetrile therapy instead of conventional therapy constituted parental neglect. The second Chad Green decision distinguished Hofbauer by stating that: (1) the findings of that court concerning laetrile were at variance with the Massachusetts Court; (2) the child's condition was stable and the parents intended to resort to chemotherapy should it deteriorate; (3) a course of parental conduct that was demonstrably threatening the child's well-being was not established in Hofbauer. In essence, Hofbauer was decided differently from Custody of a Minor because the legal issues were different. In Green, the appropriateness of laetrile therapy was the substantive question.

159/ Custody of a Minor, supra, Slip opinion p. 27.
159/ Id.
160/ Id.
Hofbauer, the issue was parental neglect and the inquiry was not the merits of individual treatments or the selection of the "right" or best therapy, but rather whether the parents had made a reasonable choice among medical alternatives. Since the laetrile therapy and conventional therapy were recommended by doctors licensed to practice in the state, in the court's view, they had made a selection among reasonable alternatives and could not be charged with neglect.

In conclusion, current authority seems to be in favor of the welfare of the child being paramount and the interest of the state in protecting the child from subjection to unproven methods of cancer treatment. The state has a legitimate interest in protecting the health and safety of its citizens and particularly children who are not competent to make this determination. This interest was well expressed in In re Clark, 185 N.E.2d 128, 132 (Ohio, 1962):

"The child is a citizen of the state. While he "belongs" to his parents, he belongs also to the state. Their rights in him entail many duties. Likewise the fact that the child belongs to the State imposes upon the State many duties. Chief among them is to protect his right to live and to grow up with a sound mind in a sound body, and to brook no interference with that right by any person or organization."
Potential Actions By Parents Against Laetrile Administering Physicians and Against Manufactures/Distributors.

The legal framework for actions against physicians, manufacturers, distributors are discussed in Part V of this paper. Applying those criteria to children with leukemia treated with laetrile demonstrates the potential for successful judicial recourse. The crux of acceptance or avoidance of harm in medical choices lies in whether the patient is properly informed as to the risks/benefits of a particular treatment. The mixed messages presented to parents of children with leukemia on whether the drug is effective for that disease and whether it can be used along with other metabolic therapies or should be used only as an adjunct to chemotherapy, makes binding informed consent probably impossible and lays the groundwork for judicial relief against physicians, manufacturers and distributors.

*Laetrile publications contain glowing reports of the success in treating leukemia and Hodkgins with laetrile and metabolic therapy. Volume 5 No. 3/4-5/6 of the Cancer Control Journal features Joey Hofbauer on the cover. The issues contain accounts of how well the following children are doing on metabolic therapy:
  -Chad Green—he died in October of 1979.
  -Nikki Dekker—he is the Florida child reported on in the article by Dr. Mehta, supra. She died in 1979.
  -Kimberly Cox—she relapsed in Mexico and returned to the United States. She is now receiving generally recognized medical treatment. Her case is reported on in Dr. Herbert's article—Cult of Cyanide, supra.
  -Natina Price—she relapsed in Mexico and is not receiving generally recognized treatment.

In most cases, children who do not continue to do well on laetrile are not heard from again in the laetrile publications.

*Court records and laetrile labeling do not support laetrile as a treatment for leukemia. In the Chad Green case Dr. Contreras testified that laetrile alone was not a treatment for leukemias but rather was an adjunct to chemotherapy.

Some of the labeling which is part of the Supreme Court record in the Rutherford case, expressly provides that laetrile is not to be employed to the exclusion of other cancer treatments and specifically, that it is not recommended for the leukemias. Other labe-
ling contradicts this and states that the laetrile program should be used exclusively.\textsuperscript{165}

Against this background, parents cannot execute a binding informed consent with respect to laetrile. This leaves physician, manufacturer, and distributor open to liability.

\textsuperscript{165}Ad. R. 201 at H. 233.
V. OTHER TYPES OF LITIGATION THAT CONFORM TO LAETRILE ISSUES

A. Patient Cases Relating To The Right
   Right To Obtain Laetrile
   [see § II, B, supra.]

B. Physician Rights Derivative From Patient
   [see § II, C, supra.]

C. Seizure Cases
   [see § II, A, supra.]

D. Smuggling

Before the Rutherford cases fathered the affidavit system which allows access to laetrile by patients who were declared to be terminally ill, cases of laetrile smuggling were frequent. The affidavit system is so loosely monitored that almost anyone who wants laetrile can acquire it thus making the smuggling operations of the pre-affadavit period unnecessary. 166 With the possibly imminent demise of the affidavit system 167, it is foreseeable that the incidence of laetrile smuggling will increase. If the Supreme

166/ See United States v. Articles of Drug ... Amygdalina Cyto Pharna De Mexico, S.A., Docket No. K77-1283 filed on Aug. 4, 1977;
In Custody of a Minor, Dr. Ernesto Contreras testified that the minor does not have terminal cancer. He also testified that despite the fact that the minor does not have terminal cancer, he would be willing to sign a "Bohanon affidavit" attesting that Chad does have terminal cancer. On the following day, Dr. Bruce Halstead made the same statement.

167 The affidavit system was instituted by the Federal District Court in Oklahoma to permit terminal cancer patients legal access to laetrile pending resolution of the right of the Food and Drug Administration to prohibit its interstate transport until the safety and efficacy requirements of the federal drug laws were met. By opinion of February 19, 1980, the Federal Appeals Court for the 10th Circuit found that laetrile was not grandfathered and that no constitution based right of medical privacy existed to permit circumvention of the federal drug law requirements. The court so finding, "recalled its mandate" and reversed the District Court judgment in Rutherford v. United States, 616 F. 2d 455 (1980); reversing 438 F. Supp 1287 (W.D. Okla., 1977). The Court denied a stay pending application to the Supreme Court for certiorari. Technically the affidavit system is dead unless the Supreme Court provides for its continuance in the event that certiorari is applied for and granted. But see further proceedings in the Federal District Court in which the attorneys for Mr. Rutherford are seeking further hearings before that court and also seeking continuation of the affidavit system. Rutherford v. United States Docket No. CIV -75-0218-B. (Western District Oklahoma)
Court upholds the most recent decision of the 10th Circuit in Rutherford v. United States, 616 F.2d 455 (1980) there will, in effect, be no legal way of obtaining laetrile through interstate channels in the United States. Therefore, an examination of the various statutes the government has used to prosecute smugglers of laetrile in the years preceding the Rutherford decision and the affidavit system is pertinent to this presentation.

The Food and Drug Act definition of a drug is, inter alia, "... any article intended for the diagnosis, cure, mitigation,treatment or prevention of a disease in man or other animals". 168/ Although some of the state statutes dealing with laetrile have treated it as a food supplement, the courts have uniformly declared it a drug. (See e.g. Hanson v. United States, 417 F. Supp 30, 34-35 (D. Minn.) ,aff'd, 540 F.2d 947 (8th Cir. 1976). In that case, the plaintiffs argued that laetrile was a food or a vitamin. However, the court rejected this argument, reasoning that since the vials and tablets in question were peddled for the purpose of curing or mitigating a disease, laetrile was a drug within the meaning of the statute. 169/  

In light of the FDA import ban on any unapproved drug, the knowing introduction of laetrile into the United States, as well as its concealment, purchase or sale, are all criminal acts. 170/ Similarly, any shipping of an unapproved drug such as laetrile or products used in its manufacture in interstate commerce is also a felony. 171/  


E. Suits Dealing With Reimbursement: Who Pays For Unproven Treatments

One of the most telling inducements to the use of a product, drug or medical procedure is whether it can be reimbursed by third party payers or with regard to the veteran, military and dependents and medicare/medicaid recipients, by the federal government. For this reason it is likely that suits for reimbursements for unproven methods will be brought by consumers under their medical coverage policies and that federal actions precluding reimbursement would be challenged. The federal government has acted in this area. The Health Care Financing Administration on June 5, 1980 issued a notice of proposed rulemaking that would prohibit the use of federal funds under medicare and medicaid to pay for "less than effective drugs". 45 Federal Register 37858 (June 5, 1980). One category for which reimbursement is proposed to be prohibited "includes drugs, such as Laetrile, that are subject to premarket approval, but have been introduced onto the market without seeking FDA's approval". (45 Federal Register at 37859). The agency specifically comments on the current legality of laetrile in some states and the reimbursement dilemma that was posed under medicare/medicaid:

"While these drugs have not been approved by FDA for sale across state lines (interstate commerce), some are currently authorized by certain states to be prescribed legally and are being marketed within state's boundaries. As a result, Federal funds under Medicaid have been available for their purchase in these states. Medicare funds have not been available for these drugs because our long-standing program policy under the authority of Section 1862(a)(1) of the Act has been not to pay for drugs of this type...". 45 Federal Register 37860 (1980)

Comments on the proposed rule are to be filed by August 4th, 1980.

The challenges to insurance companies who refuse to pay for unproven methods might involve administrative protests before state insurance departments or court actions for reimbursement.

Although insurers will agree to provide whatever reimbursement package the insured or his employer request, if the premiums can meet the anticipated cost of reimbursement, the usual and customary provisions in insurance contracts probably protect insurers

172/ The rule makes express provision for drugs that are distributed by the National Cancer Institute to physicians registered under its "Cancer Therapy Evaluation Program". These drugs have demonstrated their efficacy within a tumor type and shown that benefit to the patient exceeds the risk.
from a successful challenge for laetrile reimbursement.

For example, in 1979, Blue Cross/Blue Shield put into effect for subscribers with individual contracts and those who are members of community rated group a provision which states:

"We will not cover any procedure if it is no longer generally recognized as effective or if it is experimental in the sense that its effectiveness is not generally recognized. A procedure will be covered if an appropriate governmental agency, Federal or New York State, recognizes it as sufficiently effective to justify any risks that may be involved for a hospital stay for such an experimental or obsolete procedure."

Since under court decisions discussed supra at pp. 4-13, supra. laetrile is not generally recognized as effective, this language should shield the insurer from liability. If general recognition provides the standard against which what is reasonably medically necessary for the care of a patient's illness is measured, insurers with such a clause should also be insulated from ultimate liability. If the standard is constricted, as was attempted by The District Court in Rutherford, to recognition by practitioners who are using the drug or even further to whatever a physician prescribes, the exposure of insurers is greater. However, although under the latter construction, the case may be lost on the lower level, the strong support for the traditional interpretation of the general recognition standard in the higher courts should prevail on appeal.

Besides the patient/insured, another type of insured has entered into the legal forum vis a vis laetrile, - the pharmacist. The case arose in Maryland and involved a pharmacy that had converted its general pharmacy business to a laetrile/metabolic therapy establishment. The insurer notified the pharmacy, inter alia, that it did not desire to renew his liability policy since it had no way at that time of assessing the potential liability

176/ Hynson, supra
its changed business would subject the insurer to. The State Insurance Division, on petition from the druggists, initially refused to relieve the insurer of its coverage obligation. The insurance division based this on an absence of an objective evidentiary showing by the insurer showing the renewal to have a direct and substantial effect upon losses and expenses:

"[T]here was evidence presented that Laetrile has been sold commercially in the country for more than twenty-five years. Nevertheless, Aetna did not produce any evidence that any claim has even been filed against any pharmacist in this State or in the rest of the country because of Laetrile. Nor was there evidence or any deaths or injuries caused by the use of Laetrile. In this context, adverse experience with Laetrile sales based on statistical data could properly be required by the Commissioner as a necessary part of the insurer's "burden of persuasion". The absence of such objective evidence in this particular case under this particular set of facts could permit the Commissioner to conclude that the reasons for non-renewal were not "reasonably related to [the insurer's] economic and business purposes."177/

The insurer appealed. The court's decision was hinged on the final outcome of the Rutherford cases:

"If the Federal Government's position is sustained in whole or in part, than the Insured's right to continue the sale of Laetrile in Maryland will be curtailed or eliminated, ..."178/

The opinion hinged on the result of the pending Supreme Court decision in Rutherford. However, since that decision did not finally resolve the question of interstate traffic, it is anticipated that Aetna will continue to cover the pharmacist until the interstate issue is finally resolved in the Rutherford cases.

177/ See Order on Hearing, June 7, 1978, Slip Opinion at p. 5, Robert W. Henderson v. Aetna Casualty and Surety Co., Case No. 2098, Insurance Division, Maryland Department of Licensing and Regulation

178/ See Aetna Casualty and Surety Co. v. Edward J. Birrane, Jr., Insurance Commissioner, Order entered by Judge Greenfield, Baltimore City Court, Docket 24P/63/8 - 101641.
F. Actions Against The Physician

Let us pose a hypothetical. The attorney represents a laetrile user in a medical reimbursement case. He is bound by the Code of Professional Responsibility to zealously represent his client and does so. However, a reasonable assessment of the evidence convinces him: (1) that the laetrile treatment was not medically necessary; (2) it delayed the application of proven methods of curative treatment; (3) the client was subjected to fraudulent claims and duress calculated to result in his purchase of laetrile and consent to laetrile treatment; (4) the client's purported informed consent to laetrile treatment did not meet legal requirements as a result of intentional misrepresentations by laetrile proponents; (5) the lack of proof concerning the effectiveness of laetrile and the confusions, contradictions and divisions within the laetrile community concerning the administration of laetrile in any event makes informed consent legally impossible; and (6) the client was overborn and subjected to extreme duress to begin laetrile treatment.

The solution to the attorney's dilemma recognizes that the lawyer wears two hats. The attorney is not only an advocate, he is also an advisor to the client. In the latter role, it is his responsibility to inform and counsel the client on those avenues of recovery which are in line with the facts. These alternative methods of recovery include the following options:

1. A Malpractice Action Against the Physician

Although some state statutes have decriminalized the prescription of laetrile and prohibited the state licensing boards or medical societies from taking disciplinary action, none of the laws passed exempt the physician from malpractice liability. Ample case-law has been developed regarding the physician's liability in the prescription and administration of drugs. Many of these theories are especially applicable to laetrile treatment.

a) Responsibility of the Physician to Select the Best Drug

As a general rule, a physician will not be held liable for the exercise of his judgment in selecting one of several alternative drugs for treatment of a given condition. A very important exception to this rule, however, is where the drug is ineffective and there is any degree of risk in its use. In such a case, the physician is responsible for any loss or injury which accrues from use of the drug. This principle was affirmed in Rotan v. Greenbaum in which penicillin is was administered by a physician.

in the treatment of mumps, although mumps is caused by a virus while penicillin is only effective against bacteria. Immediately after the injection, the patient suffered an anaphylactic reaction and died. Because the drug was ineffective against the disease, even though the drug had an ordinary and accepted risk, the court found that the minimal utility of the drug was not sufficient to counter-balance the harm which resulted. This principle can be readily applied to laetrile treatment. Because laetrile has not been proven effective, any harm arising from its administration is clearly actionable. Laetrile may cause injury in at least two ways:

(1) Ample evidence exists of laetrile’s toxicity

(2) Recourse to an reliance on laetrile may result in avoidance or delay in seeking and receiving effective methods of treatment.

1) Laetrile Toxicity

Although there are a number of facets of laetrile or metabolic therapy that have potentially harmful effects, the frequent cases of cyanide poisoning associated with laetrile ingestion are probably the most unequivocal manifestations of "harmfulness" to the patient.

Many of the reported cases of cyanide poisoning resulting from the use of laetrile have occurred while the patient receiving laetrile and metabolic therapy was doing so under the direction of a physician. Thus, not all the reported cases of cyanide poisoning are due to accidental overdose from inept attempts at self-medication.180

For example, several patients at the Contreras Clinic in Tijuana reported serious reactions to laetrile injections, including diarrhea, vomiting and high fevers.181

There is also evidence in the testimony in Scott v. McDonald that John Scott, who received laetrile injections from Dr. Lawrence McDonald, suffered from hypotension, a common symptom of cyanide poisoning, after receiving a slow drip of an iv injection of


181/ V. Herbert, supra at 1129.
Because cyanide has been known for centuries to be a toxic agent in humans, its immediate symptoms and side-effects are well known by the medical profession. Some symptoms associated with chronic low-grade cyanide poisoning are loss of appetite, weight loss, cachexia, mental deterioration, weakness, vomiting and dizziness.\textsuperscript{183} Many of these symptoms were observed by a team of physicians at the Georgetown University School of Medicine in two patients who had sought laetrile therapy.\textsuperscript{184} When the patients reported to the hospital suffering from these symptoms and were taken off laetrile, the symptoms went away.

Nevertheless, in some cases patients recovering from cyanide poisoning have complained of weakness, fatigue, insomnia, and cardiac distress which occasionally continue for months.\textsuperscript{185} In cases of acute poisoning the patient may experience symptoms similar to Parkinsonism, polio, periodic excitement and violence.\textsuperscript{186}

Though laetrile proponents aver that the possible toxic effects of laetrile are greatly reduced when taken intravenously, as opposed to orally, there are a number of cases on record showing cyanide poisoning from intravenous infusion.\textsuperscript{187} Because there are no controls on the production of laetrile, "free cyanide" has been found in some deteriorated dosages, which, possibly in combination with the water/glucose iv solution, has caused cyanide poisoning in the form of hypotension in humans.\textsuperscript{188}

While laetrile proponents claim that the cyanide in laetrile is immediately detoxified into thiocyanate and thereby rendered harmless, evidence shows that thiocyanate itself can be toxic and can produce weakness, nausea, and vomiting.\textsuperscript{189} In patients with renal insufficiency, there is a tendency for the thiocyanate to accumulate in the blood.\textsuperscript{190}

\textsuperscript{182} Id. at 1130
\textsuperscript{183} Id.
\textsuperscript{184} Smith, Butler, Cohan and Schein, supra.
\textsuperscript{185} V. Herbert, supra at 1130
\textsuperscript{186} Id.
\textsuperscript{187} Id.; Smith, Butler, Cohan and Schein, supra.
\textsuperscript{188} J. Morrone, supra.
\textsuperscript{189} V. Herbert, supra at 1131.
\textsuperscript{190} Id. at 1130.
The metabolic or vegetarian diet advocated by many laetrile proponents as being a necessary complement to laetrile therapy, not only deprives the patient of sources of certain essential proteins and iron 191/, but also results in greater amounts of cyanide being released into the body because plants are the main source of the enzyme which releases cyanide from laetrile. 192

In the recent clinical trials conducted by the NCI at the Mayo Clinic, a patient receiving laetrile who ate the prescribed quantities of raw almonds, a staple of the prescribed "metabolic diet", showed clinical evidence of cyanide toxicity. 193

Though there are some reported cases of cyanide toxicity and even death caused by accidental ingestion, or from an overdose arising from self-medication, 194/ it is clear that a great many of the reported cases of cyanide poisoning from laetrile occur while the patient is following his physician's instructions or is in a "supervised clinic".

Thus statutes permitting a patient to receive laetrile from a licensed physician is no insurance that the patient will be protected from the harmful effects associated with the drug. 195/ Additionally, by allowing easy access to laetrile, the possibilities for accidental overdose from self-medication, particularly when the patient has been led to believe from laetrile publications that amygdalin is a vitamin and should be taken as a dietary supplement, are greatly increased. 196

192/ Id. at 98.
195/ See Chad Green case in which the court found that laetrile and metabolic therapy resulted in low-grade chronic toxicity. 393 N.E.2d at 845.
196/ For example in the March, 1980 issue of Public Scrutiny, a vendor disclaimer requires that the purchaser of amygdalin sign a statement that they understand that "the above products have not been represented by the seller to cure, mitigate, alleviate or prevent any disease and will be used only as a dietary supplement." Public Scrutiny, March, 1980 at 14.
One of the more treacherous aspects of cyanide poisoning is the long-term and often delayed effects of cyanide ingestion. Some of these effects we are only just beginning to become aware of. For example, cyanide toxicity has been correlated with an increased incidence of cataracts, which may not appear for months or years after exposure. 197/

There is also evidence that cyanide can cause neurological damage in a fetus. 198/ A child born to a mother who took large doses of laetrile during the last trimester of pregnancy was observed to have abnormal neurological responses and mild jitteriness that was still present at three weeks of age. 199/ Since many of the symptoms associated with cyanide poisoning (e.g., ataxia, peripheral neuropathies, optic atrophy, and nerve deafness) are hard to detect in the newborn, the effect of laetrile on the infant may not be capable of precise documentation for years to come.

Laetrile proponents often depict conventional chemotherapeutic drugs as actually cancer agents themselves and they advertise laetrile as a "non-toxic" or "natural" substance. Yet there is evidence that amygdalin has its own mutagenic effects and may actually cause cancer. 200/ This effect has been observed in animals and humans. 201/

In addition, cyanogenic glycosides, of which laetrile is one, have been shown to cause birth defects in animals. 202/ In a sample of Canadian laetrile, the phenol preservative in the drug showed positive inhibition of DNA. 203/

______________

197/ V. Herbert, supra at 1131
199/ Id. at 181.
200/ Fenselav, Pallante, Batzinger. "Mandelonitrile B-Glucuranide; Synthesis and Characterization". 198 Science 625 (1977); V. Herbert, supra at 1138
201/ V. Herbert, supra at 1138.
2) Delay or Avoidance of Treatment

The use of laetrile may delay recourse to clinically proven methods of treatment and thereby materially reduce the chances that the patient's treatment will be successful.

If the cancer patient is lulled into a sense of complacency by the assurances of the physician that laetrile will help him, or assurances contained in literature the physician makes available to him, the patient may delay seeking the more rigorous and often uncomfortable path of proven treatment methods.

Instances of delay in treatment with resultant loss of life are amply set forth in the Kennedy 1977 Laetrile Hearings\(^ {204/}\) and in the FDA's 1977 Rulemaking Decision on Laetrile.\(^ {205/}\)

However, one of the most poignant examples of delay in treatment and resultant death occurred in Florida and involved a 3 1/2 year old child with acute null cell lymphocytic leukemia, and an excellent prognosis, under the care of Dr. Paulette Mehta,\(^ {206/}\) M.D. of Gainesville, Florida. This case is discussed in the parent child rights section IV, supra.

b) physician's duty to keep informed about drug effects

A corollary to the physician's responsibility to make a calculated choice of drugs for his patients is his responsibility to remain informed about the effects of these drugs. Love v. Wolfe,\(^ {207/}\) addressed whether a physician was negligent for failing to inform himself from sources other than the drug manufacturer concerning the use of a hazardous drug. This theory of liability is particularly strong where the manufacturer or other proponents of the drug were aggressive and misleading in their over-promotion of the drug, thus failing to warn physicians of its appropriate use, if any.

Thus, a physician may be responsible for reviewing whatever laetrile literature exists beyond that body of information provided by laetrile proponents. Because of the aggressively misleading and contradictory claims for the drug by the laetrile community, and

---

\(^ {204/}\) "Evaluation of Information on which the FDA Based its Decision to Ban the Drug Laetrile from Interstate Commerce", Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources. 97th Congress, 1st Session (1977).


the contradictions which are present in these claims, the physician should be held to a high standard of responsibility in reviewing all available clinically sound and valid scientific data involving the use of laetrile. If there is no consistent, accurate body of information on a drug, there is a considerable doubt whether a physician can fulfill his function of providing facts upon which a patient can make an informed choice to accept treatment and risks or avoid harm. If the patient persists in requesting treatment but was not fully informed, is a good faith effort on the physician's part sufficient? What if the physician made only a minimal search of the drug literature?

(1) The misleading and contradictory claims for laetrile ranging from cure, to control, to pain reliever and appetite stimulator, have all been well documented in Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources conducted in 1977, 97th Congress, 1st Session. The hearings were held to evaluate "Information on Which the FDA Based its Decision to Ban the Drug Laetrile From Interstate Commerce." 

For example, compare the remarks of Lewis Thomas, M.D., then Director of the Memorial Sloan-Kettering Cancer Center at pp. 13-14: "It is no longer openly claimed that Laetrile cures cancer, although some of the leaflets and public release hint broadly in this direction," with the remarks of Senator Kennedy at p. 257: "...the thing that's interesting about your careful choice of words about the impact of this [Laetrile] would be you had no reluctance of using the word 'cures' or 'recoveries' in the transcripts here before the California case. It was a tape of the town meeting. And I'll just read: 'Some cases have undergone clinical arrests, or for other practical purposes, we might describe as cures or recoveries.'"

See also, at pp. 13-14, 271-272, 295-297 remarks that attribute to laetrile a prevention role in the avoidance of cancer, pain relief, appetite stimulation, weight gain, feeling of well-being, elimination of bad odor, pallor.

To the same effect, see Record Volume XIV, Transcript on Plaintiff's Motion for Temporary Injunction, July, 1975, United States of America v. Rutherford, No. 78-605, Supreme Court of the United States, Court Transcript at p. 6: "Laetrile...has completely neutralized his...cancer"; page 7 "Cancer victims...have been denied what many, many physicians and high level biochemists feel is a complete cancer remedy. Nothing is complete, but I mean a very effective remedy"; page 30 "I am alive because of it" and "I hope and pray that we will get this protective order to keep him alive."
Further, a brief in a laetrile court case stated that:

Laetrile patients whose cancer has been "controlled" (as opposed to "cured") is significantly higher than that of patients treated with orthodox remedies, under comparable conditions.\(^{209}\)

The brief continued that:

\[E\]ntirely apart from the percentage of cancer patients whose cancer has become "controlled" through the effects of laetrile, there are literally hundreds of thousands who have received other types of very tangible benefits, such as relief from pain and distress and loss of weight. More important, they have been spared the brutal, humiliating, and degrading therapy which is sometimes required by traditional methods, involving the loss of genitals, breasts, rectum, etc. Measured by these immediate benefits, alone, it is argued, Laetrile has justified itself.\(^{210}\)

Finally, on this point, a pro-laetrile publication quotes testimony at a hearing by the California State Assembly's Health Committee from Clinton R. Miller, Executive Director of the National Health Federation: "You know and I know that these people are bieng cured down there". The publication continues to quote testimony from KirkPatrick Dilling, Attorney for the National Health Federation: "Eleven of the common chemotherapy agents approved by the FDA as 'safe and effective', I can tell you, cause cancer and 'a myriad of terrible ghastly bodily damages and side effects....""There are people walking around today that would be marked as grave stones if they hadn't had metabolic therapy, and I've met hundreds of them."\(^{211}\)

---

\(^{209}\) Brief Amicus Curiae of the "Save the U.S. Movement" in United States v. Rutherford, Supreme Court Docket No. 78-605 at page 7.

\(^{210}\) Id.

\(^{211}\) See "Public Scrutiny", issue of February, 1980 at page 15.
(2) The Laetrile Publications Present Mixed Messages To The Physician About What Amygdalin Based Products To Use In Treatment

In the Fall, 1979 issue of The Choice, Robert Bradford, of the Committee for Freedom of Choice in Cancer Therapy opines that "some of the earlier preparations of laetrile developed in the 1950's were probably more effective that those in use now." However, he also states that "[T]he argument over which isomeric configuration or form of amygdalin is more active is essentially irrelevant because we're not even sure which of the isomeric configurations is most effective." However, Mr. McNaughton, and Mr. Bradford, and Krebs assert in the July Public Scrutiny that the D form of amygdalin is the most therapeutically potent. The injectable laetrile available to cancer patients, however, is largely the DL form of the product. Indeed, the D form under NCI tests has been shown to be unstable—that is it hydrolyzes and degrades on long term shelf storage.

(3) There Is No Agreement Among Laetrile Advocates On Effectiveness Of Laetrile Treatment Upon The Terminally Ill

The literature of laetrile proponents reveals uncertainties as to the use of metabolic therapy on the terminal. These uncertainties make informed consent impossible.

"[C]ancer is nearly 100% curable if the patient has at least 5 1/2 months to live. Even in the terminal stage, nutritional or non-toxic treatments have effected recovery rates of nearly 50%" In the Spring, 1980 issue of The Choice, proponents of amygdalin therapy expressed dismay at "...the fact that only terminally patients will be involved in the tests" (referring

---

212/ The Choice, Fall, 1979 at 2.
213/ Id.
214/ Id.
215/ Id.
216/ Id.
218/ Brochure, The Arlin J. Brown Information Center, Inc., P.O. Box 251, Fort Belvoir, Virginia 22060.
to NCI clinical trials of amygdalin). The tests are defined as proving nothing since the subjects immune system is already destroyed. 219/

"Laetrilists agree with anti-Laetrilists that early diagnosis and treatment of cancer is a prerequisite for maximizing the chances of recovery. Delay in receiving treatment may result in destruction of whatever opportunity there is for controlling the cancer (although the cancer patients whose illness had been declared "terminal" by orthodox medicine and whose cancer has subsequently been brought completely under the control through the use of Laetrile, number in the many thousands.)" 220/

(4) There Is A Division In The Laetrile Camp As To Whether Laetrile Therapy Can Be Effectively Used With Chemotherapy

Mr. Ernest T. Krebs, Jr., the discoverer of laetrile, "disputes the idea of mixed therapy" - i.e., the use of non-toxic Vitamin B17 in combination with toxic chemotherapeutic agents - in managing cancer. 221/ Mr. Krebs here defends the use of selective surgery, when absolutely necessary, but argues that seemingly beneficial responses in cancer management from the used of mixed therapies are misleading 222/

Dr. Ernesto Contreras of the Del Mar Medical Center in Mexico expresses alarm that some will not refer patients to him because he uses chemotherapy when appropriate.

Several instances of inconsistencies are contained in the Chad Green case 223/

Dr. Contreras testified that at the Del Mar Clinic they use conventional treatment in connection with metabolic. The only time metabolic (laetrile) is used exclusively is when it is the only alternative left because everything else is exhausted 224/

219/ The Choice, Spring, 1980 at 11

220/ Brief amicus curiae of the "Save the United States Movement..." in favor of respondents, Rutherford v. United States, 995 S.Ct. 2470 (1979) Docket No. 78-605 at 17. (Hereinafter cited as Brief amicus curiae of the "Save the U.S. Movement".

221/ The Cancer Control Journal, Vol. 5, Nos 3/4-5/6 (1979) at 129. (editors Note)

222/ Id.

223/ See Custody of a Minor, 379 N.E.2d 1073 (Mass. Sup. Ct., Docket No. 78-6818.)

224/ Transcript at pp. 34-36.
It is recommended that acute lymphocytic leukemia should be treated conventionally to achieve remission and then metabolic therapy added as an adjunct. \(225/\)

There was also testimony that there is no proof that metabolic therapy does anything to fight cancer, but that it merely helps to detoxify the chemotherapy. Dr. Contreras testified that "...the Oncologists (should) use whatever agents they know could be helpful in a particular moment of the disease; be it herbs, distilled water, Laetrile, Psychotherapy, spiritual therapy or even conventional therapy, as long as the philosophy is preserved and the quality of life is not importantly affected." \(226/\)

In the Mosinee proceeding in Wisconsin, a laetrile proponent, Dr. Thomas Roberts, testified that patient response to laetrile is poorer if the patient is also receiving cobalt or chemotherapy. \(227/\)

Laetrile publications contain references to clinics that aver that they use only metabolic therapy and guarantee that there is absolutely no chemotherapy or radiation treatment for cancer patients. \(228/\)

There is also a question of whether patients who do not want unnatural therapies are unknowingly receiving them with their laetrile and diet programs. \(229/\)

Dr. Rodolgo Alvarez Harta, owner and operator of the Plaza Santa Maria clinic in Mexico in promoting his metabolic clinic states that "[A]t last we have in one place and at one time a total holistic therapy center for patients throughout the world - and we guarantee there is absolutely no chemotherapy or radiation treatment for cancer patients." \(230/\) Compare this with an advertisement for Centro Medico Del Mar Clinic in Mexico: "Centro Medico Del Mar prescribes the following: Spiritual, Nutrition, Immunotherapy, Psychotherapy, Vitamin, Chemotherapy, Radiation"

---

\(225/\) Transcript at p. 37.

\(226/\) Id. at 47.


\(228/\) The Choice, Spring, 1980 at 12

\(229/\) Lansky. "Refusal of Treatment". American Journal of Pediatric Hematology/Oncology. V. 1, No.3. Fall 1979 at pp. 277-279. (Analysis of child's laetrile revealed significant amounts of cortisone).

\(230/\) The Choice, Spring, 1980.
and surgery. Concerning Chemotherapy, one choice is amygdalin (Laetrile), due to its non-toxicity. Radiation and surgery are used conservatively... in cases of emergency or certain types of malignancies, after a thorough clinical evaluation.\textsuperscript{231}

C. The Physician's Responsibility To Determine The Best Drug Dosage

The physician must prescribe drug dosages which are in accord with either FDA approved doses or with the ordinary standards of the profession.\textsuperscript{232} In the cases of laetrile, the absence of FDA approval means that no federally approved dosage guidelines exist. Within the laetrile community the recommendations concerning dosage are varied and contradictory.

Where no consensus exists as to proper dosage they physician should be held to a higher standard of liability for any ill effects due to improper dosage.

Ill effects are probable: there is, in fact, ample evidence that an overdose of laetrile can lead to cyanide poisoning.\textsuperscript{233} The potential for laetrile toxicity where the drug is administered improperly is admitted by proponents of laetrile.\textsuperscript{234}

This probability is compounded in the application of laetrile to children whose dosages must be adjusted not only due to differences in size and weight, but also due to differences in maturity of organs, enzyme systems, and attitudes and tolerance to medication.\textsuperscript{235}

There is also evidence that an overdose of laetrile in pregnant mothers may produce cyanide toxicity in newborn children.\textsuperscript{236}

\textsuperscript{231} Public Scrutiny, December 1979 (National Health Federation Publication, P.O. Box 1307, Monrovia, California 91016) at 9.


\textsuperscript{233} See infra pp.

\textsuperscript{234} Mr. Bradford of American Biologics is quoted in the Spring, 1980 issue of The Choice: "Let's face it... under certain pathological conditions and in the hands of inexperienced physicians, laetrile can be toxic..." (p.17) At p. 18 Bradford said that there can be problems with cyanide toxicity with both oral and injectable laetrile under certain conditions, but that as part of a total program of metabolic or nutritional therapy and in the hands of a competent physician, laetrile therapy is essentially non-toxic.


\textsuperscript{236} Peterson & Runack. "Laetrile and Pregnancy". J. of Clinical Toxicology, V. 15, No. 2. pp. 181-184 (1979)
D. The Physician's Duty To Prevent Dangers From Drug Storage And Preparation.

The physician may also be liable for drug storage and preparation techniques which may affect the safety of the drug. An example of how the preparation and storage or laetrile may violate these standards is provided by the FDA tests on seized Amygatrile in April of 1980. The tests indicated that it was an unstable drug which readily decomposed to the DL form on the shelf and could not be forced back into the D configuration before injection. Further, the crystallization of amygatrile tested by the Institute at body temperature (37°C) not only gives it an uncertain shelf life but also means that the substance could crystallize in the blood stream after injection and cause an embolism.

E. Duty Of The Physician To Warn Patients Of Possible Adverse Drug Reactions

Besides the duty to obtain informed consent (see pp.71-4 infra.) the physician is under a duty to warn patients of the possible side effects or adverse reactions of drugs to prevent injuries, such as automobile accidents, from occurring due to the effects of these drugs. In the case of laetrile, certain side effects related to cyanide toxicity have been reported. These side effects include vomiting, weakness, fatigue, dizziness, mental deterioration, insomnia, cardiac distress, cachexia, loss of appetite and weight loss. In the event that these side effects cause the patient to be injured by, for example, fainting while operating an automobile, and the physician failed to warn of these adverse drug reactions, the physician may be liable for malpractice.

F. The Physician's Duty To Continually Evaluate The Patient's Drug Needs

The physician is under a continuing duty to monitor the patient and to change the prescribed treatment as is indicated by the patient's condition. In Harris v. New York Life Insurance Co., 516


239/ Conversation with J. Paul Davignon, supra.

S.W.2d 303 (Mo. Ct. of App. 1974), the patient had controlled diabetes until undergoing surgery, after which her diabetes went out of control. Although this problem was expected or anticipated, it was ignored by the attending physician until she died from cardiac arrest secondary to diabetic acidosis. The court found that the negligence of the physician was an intervening cause in this death from natural disease.

Similarly, if the physician administering laetrile fails to monitor the patient's condition or ascertains through his monitoring that the treatment is not effective, the physician may be liable for failing to reevaluate the patient's needs and placing him on a proven method of treatment. 241

G. Liability Of The Physician For Punitive Damages

Where a doctor's "conscious conduct indicated a reckless disregard and complete indifference and unconcern for the probable consequences of his alleged wrongful acts and were sufficient to charge him with wanton negligence", the plaintiff can recover punitive damages. 242 Where the physician conceals gravity of the patient's condition or misrepresents the effectiveness of treatment, punitive damages are especially appropriate.

In Los Alamos Medical Center v. Lee 243, the court awarded punitive damages where the physician prescribed a sustained dosage of narcotic painkillers which resulted in the patient's addiction. In response to expressions of concern by the family, the doctor gave assurances that there was no cause for alarm.

The court specifically rejected the defense that the patient's consent to the treatment in any way mitigated the physicians' negligence or constituted contributory negligence:

241 See Hofbauer case discussed in Section IV, supra. The parents and their physician, Dr. Schacter, had agreed that the child would be given chemotherapy if metabolic therapy failed. The child died in an immunotherapy clinic in the Bahamas on July 10, 1980. The natural history of death from Hodgkins disease without treatment permits a survival time of 3-5 years. Joey Hofbauer lived about three years. Anticipated survival time with effective medical treatment is a cure in 90% of cases. If the child's condition was deteriorating and ineffective medical therapy was not recommended by the primary physician, there would be a breach of the physician's duty to continually evaluate and recommend changes in therapy as needed.


"The very relation assumes trust and confidence on the part of the patient in the capacity and skill of the physician; and it would indeed require an unusual state of facts to render a person who is possessed of no medical skill guilty of contributory negligence because he accepts the word of his physician and trusts in the efficacy of the treatment prescribed by him." 244/

The physician who prescribes an unproven method of treatment such as laetrile is particularly susceptible to a malpractice judgment involving punitive damages. Where a patient's condition becomes progressively, visibly worse, and the physician refuses to put the patient on a proven method of treatment, the reckless disregard of the physician to the deterioration in the patient's condition may support a finding of punitive damages in a malpractice action.

Gross negligence by physicians administering laetrile has resulted in widespread horror stories of patient deterioration. In Hearings on Laetrile before the Subcommittee on Health and Scientific Research of the Committee on Human Resources of the U.S. Senate, July 12, 1977 at pp. 206-230 Mr. Castro of the California Attorney General's Office testified that certain physicians administering laetrile were guilty of "gross negligence in the treatment and management of patients". 245/ See, e.g. Dunham & Co., v. Kudra, 44 N.J. Super. 565, 131 A.2d 306 (1957)
The propaganda campaign for laetrile, which capitalizes on the patient and his family's fears of cancer, has taken two approaches. One approach, discussed above, relies on the freedom-of-choice rubric. The other approach is well stated by Orville Kelly, the cancer patient who founded "Make Today Count", an organization for seriously ill patients, their family members and interested health care persons. Mr. Kelly, an advocate of conventional therapy, speaks of the hard sell used by laetrile proponents. He refers to the false rumors that he had taken laetrile, started by the purveyors because of his prominence. Finally, he notes the vulnerability of the cancer patient and his family with particular reference to his own circumstances.

He recounted in his statement the pressures brought to bear on him to abandon conventional therapy and take laetrile:

The pressure upon me as a cancer patient and upon my wife, as a family member, to begin laetrile therapy commenced when publicity about myself and the Make Today Count organization grew nationwide. The pressure has never stopped.

Typical conversations centered around the contention from the proponents of laetrile that the "chemotherapy drugs were poison and were killing me". Then, the caller, or writer, would urge me to try the harmless but effective substance, laetrile or Vitamin B-17, which the AMA, ACS and NCI were suppressing because "cancer drugs are a big business commodity."

One man from Canada called my wife to convince her I should quite receiving medical treatment and try laetrile. When she resisted his arguments for laetrile, he exclaimed, "You're letting them kill your husband! " This, to me, represents nothing but pressure. My wife soon learned to hang up the telephone receiver when she received this type of call.

---

246/ AF-34, testimony of Orville Eugene Kelly, Administrative Record, Laetrile Rulemaking Proceeding, FDA.

247/ Id.

248/ Id.
3. The attorney may advise his client to sue the physician on the theory of lack of informed consent.

The underlying concept behind the right of informed consent to medical treatment was first delineated by Cardozo, "Every human being of adult years and a sound mind has a right to determine what shall be done with his own body." Schloendorff v. Society of N.Y. Hospital, 211 N.Y. 125, 129-130, 105 NE 2d, 92,93 (1914). It was not until Natanson v. Kline, 186 Kan. 393, 350 F.2d 1093 (1960) however, that a clear common law duty to disclose the risks of medical treatment was established. The decision in Natanson was predicated on the view that lack of an informed consent, developing from inadequate disclosure by the physician is a negligent tort based on the breadth of a professional standard of care. Negligence theory is now the prevailing view in informed consent cases, replacing the more traditional intentional tort standard of assault and battery (Prosser, p. 165-166) Under this negligence theory:

The duty of the physician to disclose...is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment...the physician's choice of plausible treatment should not be called into question if it appears, all circumstances considered, that the physician was motivated only by the patient's best therapeutic interest and he proceeded as a competent medical man would have done in similar circumstances.

Natanson v. Kline, supra.

The professional standard in determining the scope of disclosure requirements has also been predicated on the customary disclosure practices of physicians. Bly v. Rhoads, 216 Va. 645,222 S.E.2d 783 (1976). The professional medical standard of informed consent is the view presently taken by slightly more than two thirds of American jurisdictions.

There has, however, been a clear trend within the last eleven years to predicate disclosure requirements and informed consent rights on the informational needs of patients, material to their decision whether to accept or reject that proposed treatment. This "minority" rule has been accepted in some jurisdictions as an outgrowth of the physicians fiduciary relationship with the patient. Berkey v. Anderson, 1 Cal. App.2d 790, 82 Cal.Rptr. 67(1970). More frequently, the minority rule has been accepted because of the belief that every competent adult is entitled to self-determination in regards to medical treatment. Canterbury v. Spence, 464 F.2d 772(1972), Cobbs v. Grant, 8 Cal.3d 229, 104 Cal. Rptr.505,502 P.2d 1(1972).

Most courts in minority jurisdictions have determined causality based on an objective (what a reasonable patient needs to know) rather than a subjective (what a particular patient needs to know) stan-
This standard is used to protect the physician because under the subjective standard he would be forced to second guess the patient whose ideas on materiality could hardly be known to the physician. *Canterbury*, supra.

There are three basic functions of informed consent: (1) promote individual autonomy, (2) encourage rational decisionmaking; (3) avoid fraud and duress. Outlined below are the possible causes of action that might be brought against the physicians administering laetrile in majority and minority jurisdictions when elements of informed consent are not present.

Under both the majority and minority standards of informed consent, the prescribing of an unproven drug such as laetrile clearly includes an obligation not only to explain the risks and alternatives to laetrile, but also to describe the lack of scientific evidence to support laetrile treatment and the probability that laetrile treatment will not be effective. For example, in a state with a statute that legalizes laetrile but makes clear in its informed consent requirements that laetrile is not recognized as an effective treatment, any physician who prescribes laetrile and suggests that it may benefit the patient may be making a material misrepresentation which would invalidate the informed consent. Further, since at this stage of our knowledge, the only postulated human benefit of laetrile which is agreed upon is the placebo effect, a full disclosure would have the effect of invalidating this benefit. This invalidating is a natural consequent of the way in which the placebo effect works. The placebo effect is a form of self-hypnosis based on the power of positive thinking. The underlying assumption by the Rutherford district court that the substance is ineffective but that does not matter if the patients know that and still want it, is false. The patients would not be seeking the drug if they did not believe it effective.


250/ See Section on Legislation, supra. Also, laetrile, as an unproven method of treatment, can be analogized to innovative experimental therapies which require a more stringent disclosure standard than conventional medical treatment because the risk factor is not quantifiable. See "informed Consent to Therapy", Waltz, Scheuneman, 64 Northwestern U.L.Rev. 628 (1970).

251/ See Legislation section, supra.

252/ Compare Florida statute legalizing laetrile §§ 458.333, 459.0153, 500.1515, with the Florida Medical Consent Law § 768.46.
A physician prescribing laetrile is also unable to meet the informed consent criterion under the professional standard because there is a lack of consensus among the laetrile community as to the proper standard for use of the substance. Case law holds that where a chemical "not approved or recognized in the medical profession," is demonstrably physically harmful, consent by the patient in therapy (as contrasted with experimentation) is per se ineffective. Thus, where laetrile is administered in such a manner as to render it toxic, or where the laetrile is contaminated, the consent of the patient is arguably ineffective.

The informational need of the patient is the paramount requirement in minority jurisdictions. Therefore, the lack of consensus within the laetrile community on indications of use and effect is particularly salient because the patient will not be receiving adequate information to rationally reach a decision whether or not to use laetrile. This lack of consensus also requires the use of a subjective standard in determining causability of injury as opposed to an objective standard because there cannot be typicality among cancer patients using laetrile (this is also due to the varying quality of laetrile).

Two exceptions to the general rule of disclosure have been noted by the courts. The first is when the patient is unconscious or otherwise incapable of consenting, and harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment. The second exception is when risk-disclosure poses a medical threat to the patient's well-being. This is known as "therapeutic privilege". In conventional medical treatment this privilege should be carefully circumscribed so that it will not devour the disclosure rule itself. Because of the potential for abuse, therapeutic privilege should not be an exculpatory exception to the disclosure requirement in the prescription of laetrile. The invocation of therapeutic privilege under these circumstances could be actionable for failure to receive an informed consent.

In conclusion, it is highly doubtful if an informed consent can ever be solicited from patients engaged in laetrile therapy.

253/ See section V.F.1.b, supra.
255/ See Herbert article, supra.
256/ See discussion at Section V.F.1.b. and IV, supra.
This is not to say that the patient lacks the mental acuity to make a decision. Rather, it speaks to the absence of consistent, believable information on the risks and benefits of the treatment. In order to protect cancer patients from unproven methods and to indemnify those who are harmed by the use of these methods an action for lack of informed consent can be brought in both minority and majority jurisdictions.

Causality of harm can be linked either to the laetrile itself or the lack of an opportunity to receive alternative, effective treatment. Since laetrile is generally considered ineffective as a drug, the physician who prescribes laetrile is not acting as a reasonable medical practitioner would under the same or similar circumstances. The absence of adequate information on laetrile thus precludes the satisfaction of the minority rule Canterbury criteria because it would be impossible to meet the patient's informational needs.

G. Product Liability

The attorney may advise his client to sue on a product liability cause of action. Attorney's representing individuals (or the individual's family) who have been adversely affected by the use of laetrile as a cancer treatment need not limit the scope of their legal options to a malpractice action against the physician. The manufacturer of laetrile, the distributor, and the pharmacist who dispenses laetrile are all parties that should share liability for injuries cause by laetrile. In order to receive adequate compensation from these parties, a product liability action can be brought against any one of these parties under three different theories: negligence, breach of warranty, and strict liability.

The difficulties of recovery under a warranty theory of product liability for personal injuries is well-established. Although damages may more readily be established under a strict liability action, any product liability plaintiff would be well advised to also bring an action in negligence because awards for negligence tend to be substantially higher than for strict liability.

This section focuses on the respective liability of manufacturers, distributors and pharmacists involved in the dissemination of FDA approved drugs and how this authority can be analogized to those involved in producing and distributing laetrile.

1. Actions Against The Manufacturer

Negligence Theory: To recover under negligence the plaintiff must prove that the manufacturer conduct exposed the patient to unreasonable risk of harm and this conduct was the proximate cause of the plaintiff's injury. Negligence might consist of selecting a dangerous formula, failing properly to maintain or inspect it, or failing to provide adequate warnings of known risks.

There is legal and medical authority that laetrile is harmful in and of itself. There is ample evidence that oral laetrile causes cyanide poisoning. There is no applicable case law in regard to the inherent lack of drug efficacy but an analogy might be drawn to product liability cases dealing with safety devices that did not function. The manufacturer's liability is predicated upon inducing use and creating reliance based on a false sense of usefulness. The failure of a misplaced reliance on the efficacy of laetrile would certainly be the proximate cause of injury. The marketing of an inherently or derivatively dangerous drug does not meet the standard of what a reasonable manufacturer would do. Conceivably an action could also be brought for breach of express warranty based on misrepresentation and false and misleading advertising.

Negligence may also consist of manufacturing a defective (impure) drug, for example substituting ingredients or permitting impurities to enter the drug, and mislabeling the drug.

Since, at present, laetrile is not legally manufactured in the United States, the majority of laetrile used in this country is manufactured in Mexico and Canada. The quality of laetrile in this country is therefore quite poor because there is no FDA testing or standards of quality control. Consequently, American consumed laetrile may be alternately contaminated by bacteria or

259/ See discussion of subpotency and contaminated laetrile in § II & III, supra.
260/ See discussion in § V (F)(1)(a)(1), supra.
262/ See Abbott Laboratories v. Lapp, 78 F.2d, (7th Cir., 1935); Thomas v. Winchester, 6 N.Y. 397 (1890).
fungus, or be of varying and uncertain strengths. These "production" defects can result in anything from a worthless product to a contaminated one capable of causing acute pyrogenesis and even death. Production defects of this kind are clearly foreseeable and preventable and therefore certainly actionable.

Manufacturer's negligence may also be predicated upon the failure to adequately test for safety before marketing. The duty to test is dependent upon the foreseeable risk of harm to potential users in light of current scientific and medical knowledge. O'Hare v. Merck, 318 F.2d 290, 291 (8th Cir. 1967). The quality of laetrile in this country indicates that Mexican and Canadian production of laetrile is inadequately controlled.

Finally, manufacturer negligence can be based on the breach of duty to warn. Generally, all that is required is that a warning be given to the pharmacist. Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974). The manufacturer has the duty to warn of adverse reactions which it knows or has reason to know are inherent in the use of its drug. However, the adequacy of a warning given by laetrile manufacturers may be called into question if it does not warn that laetrile is an unproven method of cancer treatment. In certain states this omission may constitute negligence per se.

Strict Liability Theory: An action brought against a manufacturer for negligence can usually be brought under strict liability theory. Drugs are usually characterized as unavoidably unsafe products. Prosser, Law of Torts, 4th Ed. 1977. Most Courts have agreed with Comment K of the 2nd Restatement of Torts §402A, that strict liability should not be applied to a drug manufacturer where the drug is properly manufactured and accompanied by an adequate warning. Comment K also accepts the negligent concept of the duty to warn for strict liability.

---

263/ Davignon article, supra.
265/ Roginsky v. Richardson Merrill Inc., 374 F.2d 832 (2d Cir. 1967);
266/ McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522 (Ore. 1974);
     Stevens v. Parke Davis Co., 9 Cal 3d 51, 107 Cal Rptr 45,
267/ Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974);
     Drug Inc., 416 F.2d 417 (2d Cir. 1969).
268/ Basko v. Sterling, supra.
There is authority that a manufacturer can be held strictly liable for a production defect such as a physical impurity, even though the manufacturer exercised due care.269/ As for design defects, there is no authority indicating that there is a less stringent recovery standard than under negligence.

A distributor of laetrile should be held to the same standards of liability as the manufacturer consistent with traditional product liability theory.

2. Jurisdictional Problems

The biggest problem in any products liability action against a laetrile manufacturer might be the lack of a forum that has jurisdiction over the Mexican, German, Italian or Canadian corporations that manufacture laetrile. Although an in depth analysis of minimum contacts is beyond the scope of this paper, there appear to be sufficient minimum contacts to subject a laetrile manufacturer to suit in any state where laetrile is legal. This belief is supported by the fact that these corporations advertise in American newspapers and supply enough laetrile to certainly qualify as doing business in the state.270/

To conclude, laetrile is a drug that is in the curious position of not being approved by the FDA but being available to terminally ill patients on an affidavit basis. Consequently, conventional theories of drug product liability are not entirely applicable to manufacturers, distributors and retailers of laetrile. It does appear, however that a successful product liability action could be mounted against the manufacturers of laetrile, as well as the distributor and the pharmacist as a retailer of laetrile. Liability, of course will be allocated among the respective tortfeasors. Finally, as in any product liability action the most efficacious party to be sued is the manufacturer.


H. Libel/Slander Proceedings Involving Laetrile

In a laetrile-related suit for libel, the United States Court of Appeals for the Eighth Circuit affirmed a District Court ruling which ruled that articles in two national news magazines involving laetrile smuggling were not actionable. The court ruled that the articles- which referred to the class of laetrile smugglers generally and not to the plaintiffs specifically and which published the contents of grand jury criminal indictments- were not actionable.

1. The Application Of Libel/Slander Laws To The Laetrile Debate

As the public debate surrounding laetrile intensifies and the number of forums for this controversy multiply, the applicability of libel and slander law to the participants will seriously affect the candor and extent of comment. The case cited above represents one manifestation of this problem.

The forums for the laetrile debate include journal and newspaper articles, speeches and lectures, expert testimony before administrative and judicial bodies, and legislative debate. The following theories of privilege apply to some or all of these opportunities for comment.

2. Privileged Comment or Criticism

Bona fide comments or criticisms on matters of public interest are subject to a qualified privilege, since the structure or criticism is directed at an individual's work rather than the individual himself. Moreover, in most jurisdictions this qualified privilege can only be rebutted if the plaintiff proves actual malice while the defendant only needs to show that he honestly believed the charges that he made.

Closely related to fair comment or criticism is the actual malice standard for establishing defamation against a public figure. To the extent that the laetrile controversy has made certain proponents of laetrile into public figures, any action-

271/ Schuster v. U.S. News & World Report, 602 F.2d 850 (8th Cir. 1979)
272/ See, e.g., O'Regan v. Schermerhorn, 50 A.2d 10,25 (N.J. Misc.)
273/ 53 C.J.S. §87
able defamatory remarks concerning these people must be made with actual knowledge of their falsity or with a reckless disregard of the truth. This high standard of proof virtually assures a free and uninhibited debate in such forums as journal articles, newspapers, symposia, books and lectures.

3. Governmental Proceedings

A different set of privileges come into play if expert testimony on laetrile is sought in a judicial proceeding, a legislative hearing, or before an administrative agency.

In a minority of jurisdictions, the testimony of witnesses in a judicial proceeding is absolutely privileged. In the majority of jurisdictions, the testimony of a witness during the regular course of a judicial proceeding is absolutely privileged, where that testimony is either responsive to questions propounded by counsel or the court or where, in a voluntary statement, the witness acts under an honest belief - whether or not he is correct - that the statement is relevant and pertinent to the subject of inquiry. In the event that these voluntary statements are not relevant or pertinent, a standard of actual malice is applied to them to determine whether they are subject to a qualified privilege. Moreover, the privilege extends to testimony by witnesses who are not parties to the action and the comments made can also concern individuals who are not parties to the action.

Testimony before a legislative committee hearing is treated in the same manner as testimony before a judicial proceeding.

---


275/ See e.g., Sebree v. Thompson, 103 S.W. 374, 126 Ky. 223.


278/ Cooley v. Galyon, 70 S.W. 607, 109 Tenn. 1; Viss v. Calligan, 158 P. 1012, 91 Wash. 673.

If the statement is relevant and pertinent to the subject of inquiry, then it is absolutely privileged; if it is not relevant and pertinent, then it is subject to the standard of actual malice.

Administrative proceedings are generally held to come under similar privilege, either as quasi-judicial adjudicative bodies or as quasi-legislative rulemaking entities. 280

280/ See 53 C.J.S. §102