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Laetrile: The Battle Moves into the Courtroom

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No issue except medical malpractice has given rise to as much argument between (and among) physicians and lawyers as the use of an easily refined extract of the apricot pit—laetrile. No drug that is neither addicting nor hallucinogenic has been the subject of such an intense eradication effort by the government, and never before has the response from the defenders of a drug been so intense and constant.

Laetrile, with an allegedly active substance that was used by ancient Greek physicians, has been available in the United States, legally or illegally, for a quarter of a century. The government's increased efforts to eliminate laetrile "pushing" by what are seen to be profiteering physicians has created a strengthened laetrile lobby that has successfully fought the medical establishment and succeeded in making the drug legal in more than a dozen states.

The pro-laetrile lobby—an assortment of cancer patients and their families, medical professionals, and conservative politicians—threatens to eliminate much of the Food, Drug, and Cosmetic Act and drastically weaken the Food and Drug Administration.

That the mention of laetrile should evoke vigorous self-righteousness from both its defenders and detractors is not surprising. Although laetrile may be, as the government claims, only one in a long series of cancer cure hoaxes, it has attained its popularity at a time when many people are willing to question the wisdom of conventional medicine and the infallibility of methods of treatment, especially cancer treatment, sanctioned by the medical establishment. It is not difficult to understand the desperation of cancer patients who are told they have incurable cancer, are terminally ill, and cannot be helped by any medical treatment available. It is easier yet to understand their frustration when they are told they cannot seek or use a harmless substance that some people say can arrest, and perhaps even cure, what the medical profession calls incurable.

On the other hand, the American Cancer Society's position, which is shared by the American Medical Association and the F.D.A., also is easy to understand. It is precisely these desperate victims and their helpless families who need governmental protection from the latest million-dollar cancer fraud. As one district attorney has pointed out, more money is spent on quack remedies each year than on legitimate drug research.

In the last five years the battle over laetrile has been moving from the medical laboratories into the state legislatures, Congress, and the courts. This movement will surely be quickened by two stunning legal victories won recently by the proponents of laetrile. These victories have not only opened

Laetrile: The Battle Moves into the Courtroom

Controversy over the supposed cancer-curing drug laetrile continues to rage. Now it's up to the courts.
the door to its legal use but have cast doubt on the legality of the entire system of drug regulation in the United States.

Despite some confusion about the biological mechanism, if any, by which laetrile works, its supporters agree on its content. It is amygdalin, a substance any fairly sophisticated chemistry student should be able to produce from fruits and vegetables found in any garden. Although amygdalin is in heaviest concentration in apricot pits, substantial amounts also are found in a wide variety of foods, including lima beans, almonds, and cherries. Indeed, it would be difficult to have a well-balanced diet without ingesting a fair amount of this substance every day.

The nature of the appropriate legal regulation of laetrile depends on two scientific findings. The first is whether the use of laetrile is safe, and the second is whether it is effective in combating cancer. Before laetrile became a political issue, almost all the formal medical research demonstrated, or assumed, that laetrile was nontoxic. The only evidence the medical profession has offered to show that it is poisonous appears to be in direct support of the medical profession’s political arguments. At worst, laetrile has been compared to the cassava root, a staple of the diet for 200 million Africans, which can be mildly toxic if taken in extremely large amounts. No study has shown that the dosage recommended by physicians who prescribe laetrile in the United States even approaches the toxic level.

The efficacy of laetrile in treating cancer in human beings has not been fully explored, largely because preliminary animal studies have shown it to be absolutely worthless and because available cancer research funds have been invested in research on drugs that appear to be more promising. It is the almost unanimous consensus of cancer researchers, nevertheless, that laetrile has no medical value in the treatment of any form of cancer.

Neither side is satisfied with the research that has been done on the effectiveness and toxicity of laetrile. Given the absence of any evidence that laetrile is either useful or toxic, the question may become whether the state and federal governments legally can and should forbid the use of a substance that can neither help nor hurt its users.

The federal government technically does not forbid the use of laetrile. The Food, Drug, and Cosmetic Act, however, forbids the importation or interstate transportation of any “new drug” not approved by the F.D.A. or excepted from the agency’s jurisdiction. Under this provision the federal government has seized laetrile and enjoined its importation, thus preventing its subsequent use. Laetrile proponents argue that amygdalin cannot be a “new drug” because it is not a drug at all. They claim it is merely a food supplement or vitamin that when consumed regularly retards the growth of several kinds of cancer.

While the extraordinarily large amount of laetrile sold in health food stores makes plausible the claim that it is not a drug, the Food, Drug, and Cosmetic Act defines a drug as an “[a]rticle intended for use in the diagnosis, cure, medication, treatment, or prevention of disease. . . .” 21 U.S.C. § 321(g)(1)(B). As the F.D.A. regularly points out, laetrile is sold as a cure or palliative for cancer or to prevent the development of cancer. Thus the substance may be a food or a vitamin, but it is also a drug and subject to all of the statutory and regulatory limitations imposed on drugs.

But is laetrile a “new drug”? It is if it is not “generally recognized as safe and effective” by experts qualified to evaluate the safety and effectiveness of drugs. Although the safety requirement had been in the Food, Drug, and Cosmetic Act since the 1930s, the effectiveness provision was not added until 1962, in the wake of the thalidomide scandal. This effectiveness provision has created the problem for laetrile. Since most scientific researchers agree that amygdalin is worthless, it hardly can be suggested that it is “generally recognized as effective.”

Thus the importation and interstate transportation of laetrile is illegal, even if it is perfectly safe, unless the drug is excepted from the 1962 amendments to the act. Those amendments specifically
except from the new drug requirements any drug that is "generally recognized as safe," whether or not it is effective, that was commercially available in the United States in 1962. Although the F.D.A. continues to insist that laetrile was not commercially available as early as 1962, a 1953 California Medical Association broadside against the then current use of laetrile as a cancer treatment contributes to the proof of the continuous use of the substance for the last 25 years.

Since laetrile was "generally recognized as safe" by experts in 1962, it would seem that it should be grandfathered out of the 1962 amendments to the act and that its effectiveness should not be subject to F.D.A. inquiry. It is against the backdrop of the apparently arbitrary decision of the F.D.A. to require a new drug application for laetrile despite its long and continuous use that legislatures and courts have considered the issue.

But even if laetrile cannot be imported or moved in interstate commerce, why can't it be used legally if it is grown and processed locally? First, many states lack the facilities for processing the drug or the climate for producing it. Alaska, for example, was the first state to legalize its use, and the drug might be in use more commonly there if a legislature also could cause apricot trees to grow around the Arctic Circle. Second, until 1977 virtually every state had a statute that prohibited the sale, provision, or use of any new drug not approved by the F.D.A. These laws made a crime of any local drug transaction that would be prohibited if it occurred in interstate commerce. Of course, to the extent that the F.D.A.'s limitations on laetrile are legally infirm, so are the correlative state limitations. In addition, some states—California, for example—have made it a crime to prescribe or promote any unapproved cancer remedy.

The first real assaults on the regulation of laetrile occurred in connection with attacks on these state statutes. More than a dozen state legislatures now have either repealed the statutes limiting access to unapproved new drugs or have excepted laetrile from the scope of these statutes. The political revolt against what many people find to be unwarranted government intervention in their private lives has not created a huge legal market for the drug; almost all of it still is imported, and that remains illegal. Yet this public reaction demonstrates a growing frustration with government intrusion into individuals' personal choice of medical procedures.

The battle over the use of laetrile was born of smugglers and fought in Congress and the state legislatures. The new battlefield, however, is the courtroom. For years the judicial arena was the F.D.A. to enforce the ban on the drug. For years courts uncritically accepted the F.D.A.'s argument that it is an unapproved "new drug," and the lower federal courts consistently upheld the F.D.A. seizure of the substance and enjoined its importation and transportation across state lines. The cases brought by cancer patients who wished to use the drug rarely made it into the appellate courts because the patient-plaintiffs did not live to see an appeal.

During recent times, however, the courts have not been reluctant to look behind the F.D.A.'s denomination of the status of amygdalin and have found the classification of the drug to be arbitrary and capricious. These same courts may have curtailed even more substantially the government's authority to regulate health care by deciding that at least some applications of the Food, Drug, and Cosmetic Act may violate a patient's fundamental constitutional right to privacy and the doctor's right to practice medicine as he deems appropriate.

The notion that an infirm person should have a constitutional right to choose any kind of medical treatment available is not a 1970's invention. Two centuries ago Benjamin Rush, surgeon general of the Continental Army of the United States and a signer of the Declaration of Independence, suggested that the "Constitution of this republic should make special provisions for medical freedom as well as religious freedom...To restrict the art of healing to one class of men and deny equal privilege to another will constitute the Bastille of medical science. All such laws are un-American and despotic. They are fragments of monarchy and have no place in a republic."

Although Dr. Rush's suggestion was not heeded by the framers of the Constitution, the Supreme Court's recent expansion and definition of the right of privacy may have the same effect. That right, articulated in Griswold v. Connecticut, 381 U.S. 479 (1965), was first applied to assure a patient the free choice of health care alternatives in the abortion cases of Roe v. Wade, 410 U.S. 113 (1973), and Doe v. Bolton, 410 U.S.
179 (1973). The right has been discussed in a wide variety of state cases, and now the boundaries of the right to choose medical treatment, as a part of one's right of privacy, are being tested by the advocates of laetrile.

That the constitutional right of privacy includes the right to treat one's own body as one pleases can hardly be doubted after the Supreme Court's decisions in the abortion cases. There are, of course, several limitations on that right. Although the crude practice of arresting people for attempted suicide has now largely disappeared, the statutes defining suicide as a crime remain on the books. States do constitutionally proscribe the use of some socially harmful drugs. There are other circumstances, too, in which the government may limit the risks to which an individual can subject his body; for example, several courts have upheld regulations that require motorcyclists to wear helmets.

Although most courts that have addressed the issue agree it is improper for the state to act solely for the protection of the individual from his own folly, courts have always recognized a state interest in protecting other members of the community and especially dependents of the one asserting a right to harm himself. Courts have also recognized a state interest in protecting state resources and limiting the demand placed on state medical facilities.

The Alaska Supreme Court has concluded that the right of privacy in its own constitution “shields the ingestion of food, beverages, and other substances.” Gray v. State, 525 P. 2d 524, 528 (1974). Although no federal court has gone that far, the constitutional cornerstone for this approach was laid by Justice Blackmun in Roe v. Wade, in which he specifically upheld the “right of the physician to administer medical treatment according to his professional judgment up to the point where an important state interest provides compelling justification for intervention.” That point, he explained, is reached when the medical treatment sought to be prohibited is more dangerous than the state-sanctioned alternatives. At least until that point is reached, the constitutional right of privacy protects the one seeking treatment and, apparently, the physician who offers that treatment.

Thus, any right the courts develop to protect the use of laetrile will have to be weighed against the state's interest in regulating the drug. The state's interest is the protection of cancer patients and their families from fraud. There are few who are as vulnerable to snake oil salesmen as people who are told they have cancer. There are few people who so desperately look for a positive, guaranteed, and painless cure as those who are told they will not recover from a disease that can be treated only by often painful and disfiguring surgery, radiation therapy, and chemotherapy.

There is hope of treating some forms of cancer only if the victim gets proper medical treatment early in the course of the disease. If a patient is coaxed into trying laetrile before seeking traditional help, it may be too late to help him when he does seek more orthodox care. The number of people who have been lured away from proved treatments to their death by the enticing arguments in favor of a painless, “natural” cancer cure is simply unknown. It is certain that tremendous amounts of money have been spent by desperate families on worthless cancer cures. It is to aid these medical consumers and their families that the government has effectively banned the legal use of worthless, but harmless, drugs like laetrile.

On the other hand, there is no evidence the prohibition on laetrile has caused any cancer patient to choose a state-sanctionned alternative to amygda-lin. In fact, many patients concurrently undergo both traditional and laetrile therapies. There is no doubt many people who wish both laetrile and traditional therapy have been forced to forgo traditional treatment because the laetrile they desire is unavailable in this country. The resources many of the patients would have expended on the orthodox care recommended by their physicians are instead spent on travel to and from Mexico to receive the drug.

How, then, has the judiciary balanced these competing interests? The courts are no longer satisfied to accept the F.D.A.'s administrative determination. Two dramatic opinions that have come down recently demonstrate the courts' new position. The first is California v. Privitera, 141 Cal.Rptr. 764 (1977), in which James Privitera, a physician, and several others were charged with conspiring to sell an unapproved drug (laetrile) as a cancer cure. Dr. Privitera originally had been charged with the substantive crime, a misdemeanor. After that charge was dismissed by the municipal court judge, Dr. Privitera was charged with conspiracy to commit the misdemeanor, a felony in California. All of the defendants were convicted of either the substantive crime or the conspiracy to commit it.

In reviewing the convictions, the California Court of Appeal, in a two-
to one decision, concluded that the statute "as here sought to be applied invades the patient's and doctor's zone of privacy without a showing of external compelling state interest in violation of the Fourteenth Amendment to the federal Constitution."

The court recognized the agonizing desperation of the patients treated by Dr. Privitera. "The 19, or witnesses testifying for Dr. Privitera, conveyed a felt imminence of death. One senses a mortal fear of both the disease and the orthodox alternatives. This is a desperate utterly human seeking to avoid the pain and to prolong life. . . ."

"To these 19 cancer victims . . . the denial . . . of medical treatment, albeit unorthodox, albeit unapproved by a state agency, must surely take on a Kafkaesque, a nightmare quality. No demonstrated public danger, no compelling interest of the state, warrants an Orwellian intrusion into the most private zone of privacy. . . ."

"No compelling interest of the state requires Dr. Privitera's . . . cancer patients to endure the unendurable, to die, even forbidden hope."

The opinion describes the right of privacy, as it is applied to a patient's right to use worthless drugs, only in terms of terminally ill cancer patients. The implication, then, is that the balance between the state's interest and the individual's right of privacy may be drawn in a different place, perhaps on the side of the government's interest. In the case of a patient with a cancer that may be treated effectively under a traditional cancer management program. Another portion of that opinion, however, may expand the class that can claim protection under the right of privacy. The court held that the right of privacy is not only a right of the patient to treat his body as he may wish but also the right of the physician to practice as he believes is appropriate. This right, the court said, is not only derivative of his patient's right but stands independently as well. The Privitera case was argued to the California Supreme Court on April 5, 1978.

The second case is Rutherford v. United States, 582 F. 2d 1234 (10th Cir. 1978), in which the United States Supreme Court has granted certiorari.

Rutherford is an action initiated several years ago on behalf of "a class composed of terminally ill cancer patients" against the United States to enjoin interference with the class's right to acquire and use laetrile. To qualify as a member of the class of "terminally ill patients," a patient had to show a "rapidly progressing malignancy" leading to almost certain death and to demonstrate either (1) that no orthodox treatment could help, (2) that laetrile would be used only in conjunction with orthodox treatment, or (3) that he or she intelligently and knowingly chose to forgo recognized treatment and to be treated with laetrile instead.

Although the other named plaintiffs who began the suit with Rutherford died years ago, Rutherford, who was told in 1975 that surgery was necessary immediately or death would be imminent, is still alive and using laetrile today. It is his surprising longevity, and his use of the class action device, that has allowed this case to be heard four times by the federal district court, and twice by the Tenth Circuit.

These cases are the first salvos in a new series of battles

The district court initially focused on the administrative infirmities of the F.D.A.'s determination that laetrile was a "new drug." Indeed, the Tenth Circuit finally remanded the case to the F.D.A. so that the agency could develop a formal record on that issue. In Rutherford's first journey to the district court, he sought and received a preliminary injunction against governmental interference with his acquisition and use of laetrile. His last trip to the district court came after the F.D.A. had developed its formal record and after the agency had restated and supported its earlier decision that laetrile was an unapproved "new drug." On this trip the court ruled that the agency's action was arbitrary and capricious, that laetrile was "grandfathered" out of the 1962 amendments to the Food, Drug, and Cosmetic Act, and, finally, that the government's prohibitions on the use of laetrile by terminally ill patients was inconsistent with those patients' right of privacy.

Last July the Tenth Circuit upheld the district court's decision but claimed to limit its decision to the administrative issue. The court, however, was impressed by the obviously human hopes of terminally ill cancer patients who seek anything that might postpone the inevitable. The court concluded that requiring a drug to be "safe and effective" before it can be administered to terminally ill patients is meaningless. How can there be an "effective" drug for a helpless condition? How can we reasonably prevent a patient who, by definition, cannot be helped from using a substance that will neither hurt nor help? As Privitera did earlier, Rutherford limited his holding to terminally ill patients, suggesting that there could be limitations on others' use of the drug.

The Rutherford and Privitera cases may be just the first salvos in a new series of laetrile battles. What distinguishes them from the rest of the war is that they are being fought in the courtroom, and the powerful medical interests are losing. The F.D.A. and its power to regulate safe but ineffective drugs is in jeopardy for the first time since it was challenged by the drug companies in the mid-1960s. The rhetoric of deregulation, so common at other federal agencies, has not been heard from the F.D.A., but the spirit of deregulation may yet be imposed by the courts.

Of course, the war is not over. Both sides have bills pending in the 95th Congress that would amend the Food, Drug, and Cosmetic Act. No court has yet decided that a patient who is not terminally ill has a constitutional right to use laetrile. In addition, no one has suggested the limitation of the heretofore unexercised power of both the F.D.A. and the Federal Trade Commission to proceed against those who falsely or fraudulently claim that laetrile cures cancer.

The analysis being applied by the court is summarized in an early district court opinion in Rutherford: "The point can be couched in simple terms. Many intelligent and mentally competent citizens in this nation have made a deliberate decision that they would like to employ an unproven and largely untested treatment in an effort to comfort, if not save, lives that orthodoxy tells them have already been lost. They do so with an acute awareness of professional medicine's assessment of their choice." 429 F. Supp. 506 (D. Okla. 1977).

During the next few years many courts, including the United States Supreme Court, will be forced to decide under what circumstances, if any, that choice must be respected. The war that began either in a test tube, as the laetrile forces argue, or in the bank accounts of unscrupulous practitioners, as the government suggests, finally will be resolved in the courtroom.

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