Politics, Science, and Cancer: The Laetrile Phenomenon

Edited by
Gerald E. Markle and James C. Petersen

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Politics, Science, and Cancer: The Laetrile Phenomenon

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About the Book

At no time in U.S. history has there been a more effective challenge to medical expertise and authority than that mounted by the contemporary Laetrile movement. The efficacy of Laetrile has been debated for over twenty-five years, but despite vigorous opposition from the medical community, support for the purported cancer treatment continues to grow and the controversy has in recent years intensified and become highly politicized. How does one account for the continuing debate and the spectacular political growth of the movement to promote Laetrile? This and related questions are addressed by an interdisciplinary group of authors in this first scholarly analysis of the Laetrile phenomenon.

About the Series

The *AAAS Selected Symposia Series* was begun in 1977 to provide a means for more permanently recording and more widely disseminating some of the valuable material which is discussed at the AAAS Annual National Meetings. The volumes in this *Series* are based on symposia held at the Meetings which address topics of current and continuing significance, both within and among the sciences, and in the areas in which science and technology impact on public policy. The *Series* format is designed to provide for rapid dissemination of information, so the papers are not typeset but are reproduced directly from the camera-copy submitted by the authors. The papers are organized and edited by the symposium arrangers who then become the editors of the various volumes. Most papers published in this *Series* are original contributions which have not been previously published, although in some cases additional papers from other sources have been added by an editor to provide a more comprehensive view of a particular topic. Symposia may be reports of new research or reviews of established work, particularly work of an interdisciplinary nature, since the AAAS Annual Meetings typically embrace the full range of the sciences and their societal implications.

WILLIAM D. CAREY
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About the Editors and Authors

Gerald E. Markle, *an associate professor in the Department of Sociology at Western Michigan University, was trained in the natural sciences and the social sciences. His specific area of specialization is the sociology of science and technology and he has written about the social aspects of various cancer controversies, the ambiguities involved in the continued use of cigarettes, and the social problems involved in any widespread use of infant sex preselection techniques.*

James C. Petersen *is assistant professor of sociology and associate director of the Center for Sociological Research at Western Michigan University. A specialist in medical and political sociology and in the sociology of organizations and social movements, he has written on the topics of social participation, organizational behavior, and participant behaviors in controversies such as that surrounding Laetrile. He is currently deputy editor of the* Journal of Voluntary Action Research.

Arthur L. Caplan *is associate for the humanities, the Hastings Center, and associate for social medicine, Columbia University. A philosopher of science, he is primarily concerned with medical ethics and has written on a number of controversial issues, including medical fallibility and malpractice and aspects of the sociobiology debate. He is currently at work on* The Concepts of Health and Disease in Medicine *(Addison-Wesley, forthcoming).*

Allan Mazur, *a professor of sociology at Syracuse University, was trained in both the physical and social sciences and has made biosociology and the sociology of science and technology his two specialties. He served on the Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology (1976) and since*

then has served on the Biosocial Science Committee of the Social Science Research Council. He has published numerous articles on sociological aspects of the technological controversies and is currently a member of the editorial board of Sociological Quarterly.

Grace Powers Monaco, *a partner in the law firm of Fairman, Frisk & Monaco in Washington, D.C., specializes in health and energy law. She represented the American Cancer Society as amicus curiae in* United States v. Rutherford, *the Laetrile proceeding heard by the Supreme Court in 1979. She is a former member of the Cancer Control and Rehabilitation Advisory Committee of the National Cancer Institute and is currently president of the Candlelighters Foundation. In 1978 she received the Annual National Award of the American Cancer Society.*

Dorothy Nelkin *is a professor in the Science, Technology and Society Program at Cornell University. She is the author of numerous publications on science and society, among them* Controversy: The Politics of Technical Decisions *(Sage, 1979) and* Science Textbook Controversies and the Politics of Equal Time *(MIT Press, 1978). She is currently president of the Society for the Social Studies of Science.*

Robert F. Rich *is assistant professor of politics and public affairs in the Woodrow Wilson School, Princeton University. A specialist in public policy analysis and knowledge utilization, he has participated in seminars and has written on the current Laetrile controversy. He is editor of the journal* Knowledge: Creation, Diffusion, Utilization *(Sage Publications).*

Richard D. Smith *is editor of* The Sciences, *the journal of the New York Academy of Sciences. A former staff writer and associate editor of the magazine, he has a special interest in and has written numerous articles on the biomedical and behavioral sciences. He is a member of the American Medical Writers Association and the National Association of Science Writers.*

James Harvey Young, *professor of history at Emory University, has specialized in American social and medical history, publishing in the field of food and drug regulation.* The Toadstool Millionaires *and* The Medical Messiahs *(Princeton University Press, 1961, 1967) trace the theme of health quackery through American history. He has also written*

American Self-Dosage Medicines: An Historical Perspective *(Coronado Press, 1974). He received the Edward Kremers Award from the American Institute of the History of Pharmacy (1962) and served the American Association for the History of Medicine as Fielding H. Garrison Lecturer (1979).*

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1. The Laetrile Phenomenon: An Overview

During the 1970s supporters of the purported cancer treatment Laetrile (1) have battled in the courts, state legislatures and mass media. Proponents claim that 3 grams of Laetrile daily, in conjunction with a special "metabolic" diet, will control or eliminate an active cancer in three weeks. Supporters also claim that eating ten raw apricot kernels per day will prevent cancer (2). Most medical experts and authorities have disputed these claims, viewing the use of Laetrile as quackery. For example, Robert Eyerly, Chairman of the Committee on Unproven Methods of Cancer Treatment of the American Cancer Society, has charged that "the use of Laetrile rather than known, effective cancer treatments, is the cruelest of all frauds" (3).

A major social movement had developed around the use of Laetrile (4, 5), and it has even become an element of popular culture. Drinks have been named after Laetrile -- the "B-17 Bomber" (a martini with an apricot kernel), -- Johnny Carson included Laetrile jokes in his monologues, and "Doonesbury" cartoonist Gary Trudeau showed his character 'Duke' planning to make a fortune by purchasing an apricot farm and marketing the pits in Tijuana. The movement to promote Laetrile also made impressive political and legal gains in the seventies despite opposition from the Food and Drug Administration, the American Cancer Society, the American Medical Association, and virtually the entire American medical community. In the fall of 1976 Alaska became the first state to legalize Laetrile. A 1977 Harris Poll revealed that two-thirds of all Americans favored the enactment of pro-Laetrile legislation in their state. By the summer of 1979, a total of twenty-one states had enacted such legislation (6).

Actors in the Controversy

At the core of the Laetrile movement are a few small organizations devoted to the promotion of Laetrile. The oldest of these groups, the International Association of Cancer Victims and Friends, was founded in 1963 by a woman who believed that Laetrile had cured her of cancer. The group has grown to include about 8,000 members and now promotes many alternative treatments for cancer along with Laetrile in its publication the Cancer News Journal. Schisms within this organization have spawned several new organizations that advocate holistic approaches to the treatment of cancer. These include the Cancer Control Society, a major advocate of Laetrile, as well as the Foundation for Alternative Cancer Therapies and the Cancer Federation.

The Cancer Control Society, founded by Betty Lee Morales, promotes Laetrile along with nutritional and "nontoxic" approaches to cancer therapy. It publishes the Cancer Control Journal and sponsors conventions and symposia. Among the frequent speakers at these meetings are Ernst Krebs, Jr., the discoverer of Laetrile; Dean Burk, a scientist who retired from the National Cancer Institute (NCI); and Edward Griffin, author and publicist of Laetrile.

The most influential of the pro-Laetrile organizations is, however, The Committee for Freedom of Choice in Cancer Therapy. Founded in 1972 to aid Dr. John Richardson, a California M.D. being tried for using Laetrile in cancer therapy, the Committee has grown to include over 500 local chapters. It publishes the Choice and has been extremely active in lobbying for state legislation to legalize Laetrile. The Committee has strong ties to the John Birch Society and seems to have drawn on the political experiences of this group in organizing its campaign to promote legalization of Laetrile.

The National Health Federation, an older (founded in 1955) organization concerned with health food, nutrition, and health, has also been active in the promotion of Laetrile. It established a "Fund to Stop Government Ban of Laetrile" and a newspaper, Public Scrutiny, devoted to Laetrile and metabolic therapy. Other organizations, drawn from both the political right and left, have played a peripheral role in the Laetrile movement. For example, in Wisconsin it was charged that an ultra-right group called the Posse Comitatus was linked to the manufacture of Laetrile (7). A leftist group called Second Opinion, claiming to represent the rank-and-file employees of Memorial Sloan-Kettering Cancer Center, published a report, "Laetrile at Sloan-Kettering" (8). The

report claimed that positive results with Laetrile had been ignored and that data had been misinterpreted to make Laetrile look ineffective in laboratory studies.

All of these organizations along with other local and regional groups have contributed to the Laetrile movement. Many of the organizations seem to be loosely linked to one another. Some leaders serve as officers of more than one group and many of the same speakers turn up at conventions and meetings of the various pro-Laetrile organizations.

We are only beginning to gain an understanding of those individuals who advocate or actually take Laetrile. Further, our knowledge at present is almost entirely limited to individuals with ties to the pro-Laetrile organizations. In a study of 252 people who attended a Laetrile symposium sponsored by The Cancer Control Society (9) we found that those attending were predominantly white, female, rural and highly educated. One-third of the participants belonged to pro-Laetrile groups and almost one-half reported that they regularly took some form of Laetrile. Comparing participants with one another, those with higher levels of fear of cancer were less likely to take Laetrile or to attend meetings of Laetrile organizations. Rather than fear of cancer leading to Laetrile use, we suspect that the causal direction is reversed. Those who take Laetrile or are involved in the movement are somewhat more likely to take vitamins regularly, believe that vitamins aid in disease prevention, patronize health food stores, and disapprove of the fluoridation of public water. It was also found that symposium participants were nearly ten times more likely to visit chiropractors than are Americans generally. Furthermore, those participants who were taking Laetrile held more positive views of the effectiveness of chiropractors in both the prevention and the treatment of disease than they did of M.D.s, thus demonstrating a substantial rejection of orthodox medicine (10).

All of these findings point toward a consistent and connected set of ideas behind the use of Laetrile: belief in the overriding importance of nutrition, opposition to orthodox medicine and acceptance of officially condemned health beliefs. Though the leaders of the Laetrile movement often have right-wing connections, the followers seem to be less involved with politics and more involved with health and organic food issues. While the Laetrile controversy has different historical roots than the health food movement, there is clearly an overlap in membership. In fact, Laetrile advocates frequently claim that Laetrile is Vitamin B-17 and often combine the use of Laetrile with special diets

in "nutritional" or "metabolic" therapy.

To elaborate these findings, one of our students conducted a six-month-long observation of a local chapter of the Cancer Control Society including in-depth interviews with 27 participants in the Laetrile movement (11). Twelve of these participants were taking Laetrile to treat cancer, five others were taking Laetrile as a cancer preventive, and -- interestingly -- over a third of the respondents did not take Laetrile personally although they were active in promoting its use and legalization. Respondents were highly educated and well informed about both sides of the Laetrile controversy. While they disagreed with their physicians about Laetrile, preventive medicine, and a holistic approach to treatment, they did not hold completely negative views of M.D.s or report completely negative experiences with their personal physicians. The respondents did, however, want to be able to exercise control over their lives, including medical matters. The study concluded that people become involved in the Laetrile movement more as a result of health and nutritional concerns than because of any particular experience with cancer or because of a unique political ideology.

The opposition to Laetrile has come from a prestigious coalition composed of federal agencies, the American Cancer Society, the American Medical Association, state agencies and medical societies, and medical researchers. The most visible opponent of Laetrile has been the Food and Drug Administration which has attempted to ban interstate commerce of Laetrile. As early as 1960 the FDA began to seize Laetrile and has continued such seizures to the present. The position of the FDA was most clearly stated in the "Commissioner's Decision on Status in 1977," which concluded that Laetrile is neither safe nor effective in the treatment of cancer. Thus its distribution "in interstate commerce is in violation of the Federal Food, Drug and Cosmetic Act and subject to regulatory action" (12, p. 39806).

Other federal agencies, especially the National Cancer Institute, have also been active opponents of the use of Laetrile in cancer therapy. NCI sponsored a series of tests of Laetrile in a variety of animal tumor systems. The results of these tests were uniformly negative; Laetrile showed no significant antitumor effect. In 1976 a spokesman for NCI stated:

> ...We do not at present believe there is any basis for the allegations made by those who speak publicly for Laetrile. The National

> Cancer Institute certainly has not ignored Laetrile. After extensive study, there is in our view, no sound basis for recommending clinical trials of Laetrile (13).

However, by 1978, despite years of opposition to Laetrile, NCI petitioned the FDA for permission to conduct clinical trials of Laetrile. This remarkable reversal of position was partially due to the results of a retrospective study conducted by NCI (14), but it seems clear that social and political pressures were important in producing the change. Guy Newell, Deputy Director of NCI, told us:

> It was thought that we would handle Laetrile like we would any other compound in our decision network flow chart. You see it is not a matter of all or none. We have a battery of compounds to go through animal testing. And it really is a matter of prioritizing. Laetrile is on the list somewhere but we have other compounds that have shown up so much better and we have only limited human clinical resources so we pick higher priority drugs. We never would have gotten down to Laetrile. So Laetrile was really taken out of priority...and I think not for scientific reasons. I think because of other reasons: social, political, human (15).

Several private organizations have been vigorous opponents of the Laetrile movement. Both the American Medical Association and the American Cancer Society have labeled the use of Laetrile in the treatment of cancer as quackery. ACS has been especially active in distributing literature attacking the use of Laetrile. Memorial Sloan-Kettering Cancer Center has also made well-publicized attacks on Laetrile, claiming that a series of animal studies conducted by Sloan-Kettering showed no anti-cancer effects.

Issues in the Controversy

The Laetrile controversy is in fact composed of several interrelated disputes. At issue are both knowledge factors where scientific claims are made and rebutted and value factors where philosophical, political, and constitutional issues are debated.

The central knowledge claim of Laetrile proponents is that cancer is not a tumor disease; instead it is a metabolic disease in which the tumor is merely an obvious

symptom. In this view cancer arises from trophoblasts which are primitive, undifferentiated cells which survive early pregnancy. First formulated by John Beard in 1902 and refined by Ernst Krebs, Jr. in the 1940s and 1950s, the "unitarian" or trophoblastic theory rejects the notion that cancer is caused by unnatural invasion; rather the disease results from uncontrolled trophoblastic growth. As the theory was elaborated by Krebs and others, a biochemical mechanism was proposed by which Laetrile destroyed cancerous growths. Cancer cells, the advocates claimed, have excessive amounts of an enzyme which frees cyanide from the complex Laetrile molecule. The cyanide thus selectively poisons cancer cells while leaving healthy cells alone. More recently, Laetrile proponents have attempted to incorporate the idea that Laetrile is a vitamin (B-17) into these theories. Most cancer researchers reject the trophoblastic thesis. Medical experts also dispute the various claims made for the biochemical mechanisms proposed for Laetrile (12, pp. 39773-39775).

Critics of Laetrile have asserted that the use of Laetrile is not only ineffective but actually dangerous. Several deaths have been attributed to Laetrile poisoning. In one such case in 1977, a 10-month-old girl died, purportedly after swallowing five of her father's 500 mg. Laetrile tablets. The medical examiner attributed her death to "excessive anoxic brain damage due to acute cyanide poisoning due to amygdalin ingestion" (16). Laetrile advocates counter these claims with epidemiological data. Most often cited are the Hunzakuts, a remote Pakistani tribe. Apparently it is not uncommon for these people to live 100 years, and their longevity is attributed to a diet rich in amygdalin. In addition it is claimed that cancer is absent among these people, although a 1955 Japanese expedition did report incidence of the dread disease (17). The current view at the National Cancer Institute is that oral ingestion of Laetrile is more dangerous than Laetrile injections. In fact NCI proposes to use both intravenous injections and oral administration in its proposed clinical trial of Laetrile.

Theory aside, the most important claim made for Laetrile is that it saves lives. Only one pro-Laetrile clinical study has been published in an American medical journal. Reporting on patients treated with Laetrile the author concluded that: "possible regression of the malignant lesion was suggested by therapeutic results in 10 cases of inoperable cancer with metastases" (18). Studies from Germany and the Philippines also claim that Laetrile is efficacious. The most elaborate and dramatic claims for Laetrile have been made by John A. Richardson in his book Laetrile Case

Histories, published by Bantam Books in 1977. The FDA Commissioner has sharply criticized Richardson's work, claiming that he reported only 62 of some 4,000 case studies and that patient follow-ups were irregular (12, p. 39778).

In response to the claims of Laetrile advocates, NCI sponsored laboratory research on mouse tumors at Arthur D. Little, Inc., the Southern Research Institute, Washington University, Battelle Memorial Institute, and Memorial Sloan-Kettering Cancer Center. In each of these studies Laetrile was found to be inactive against a variety of tumor systems, although considerable controversy arose from charges of ambiguous findings and deceit at Sloan-Kettering. Moreover, in 1977 a Loyola biologist claimed that Laetrile, as part of a megavitamin regimen, effectively controlled mammary tumors in mice (19). Despite the fact that the paper was presented in a non-scholarly setting, that the paper was only two pages long, and that the experimental design lacked certain controls, the paper received national media attention.

While empirical issues and knowledge claims have and will continue to shape the Laetrile controversy, an equal role has been played by value disputes. Some political philosophers, particularly conservative ones, have joined with health advocates and Laetrile proponents in asserting that personal and constitutional freedom are the real issues of the controversy. Cancer patients, they declare, have a right to choose their own form of cancer therapy without interference from the medical community or the government. This issue, referred to as "freedom of choice," has been the single most effective argument that Laetrile proponents have used in the courts, state legislatures and media.

Medical authorities, particularly the FDA, contend that freedom of choice is a slogan used to promote a cynical and cruel hoax. They claim that government must prevent deception and the victimization of the weak. They also claim that cancer patients and their families, because of the severe emotional trauma of the disease, are incapable of choosing freely. Rather they should rely on qualified experts to advise them. This debate, though part of Laetrile's history, clearly transcends the fate of any one purported cancer cure.

Laetrile proponents have not only asserted the right to make key medical decisions, they have stressed the desirability of such actions. In a number of important ways they are connected with the holistic health movement. Advocates of Laetrile frequently call for a rejection of medical expertise and a deprofessionalization of medical care. They

emphasize the individual's responsibility for his or her own health and the need for concern with the prevention of cancer.

Current State of the Controversy

The dispute over Laetrile remains in flux. With the Rutherford and other cases still being adjudicated, with the NCI attempting to begin clinical trials, and with state legislatures still considering the deregulation of Laetrile, it is premature to predict the future direction of the controversy (20). Given the momentum of the controversy as well as its complexity, it seems likely that Laetrile will retain its prominence in our culture for some time.

On June 18, 1979, the U.S. Supreme Court unanimously upheld the FDA's authority to ban the distribution of Laetrile to terminally ill cancer patients. The 10th Circuit Court of Appeals, the Supreme Court ruled, had erred in its conclusion that the "safety and effectiveness standards... could have no reasonable application to terminal patients" (21). However, the court did not rule on several broad constitutional issues, but rather remanded the case back to the Appeals Court for further consideration. Further litigation, perhaps lasting years, seems likely.

The safety and effectiveness of Laetrile is also likely to remain in doubt for years. Even if the proposed NCI trials do occur, the outcome is not likely to be definitive. The normal ambiguity of science, compounded by the distrust which has and will continue to characterize the controversy, makes speedy resolution of the controversy unlikely.

References and Notes

1. Laetrile is also known as amygdalin and Vitamin B-17. However it now appears that amygdalin, a substance found naturally in the seeds and kernels of many fruits (most notably apricots) and grains is not identical to Laetrile. Moreover, FDA Commissioner Donald Kennedy charges that confusion over the terms may be a deliberate effort by promoters to obfuscate the efficacy issue (Federal Register 42, 39771, 1977). Authorities also deny that Laetrile is a vitamin. According to the American Institute of Nutrition, there is "no scientific evidence that Laetrile has nutrient properties or is in any way of nutritional value for either animals or humans" (Journal of the American Medical Association, 236, 1284, 1976).
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B-17 Therapy (Science Press International, Sausalito, 1973).

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19. H. W. Manner, "The Remission of Tumors With Laetrile," paper presented before the meetings of the National Health Federation, 1978.
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21. United States v. G. Rutherford, Supreme Court of the United States, No. 78-605 (18 June 1979).

2. Laetrile in Historical Perspective

Laetrile's history has been complex, tortuous, kaleidoscopic. Beginning inauspiciously like hundreds of other small-time anti-cancer schemes, Laetrile soared to a notorious pinnacle as the unorthodox brand-name health promotion generating the largest amount of public furor in the nation's history. Numerous actors played roles in this perfervid drama. Laetrile's history, first, may be placed within three successive periods which may be designated: the creation by the Krebs, the McNaughton ascendancy, the appeal to freedom. Then the Laetrile pattern may be compared with the pattern of earlier cancer unorthodoxies.

The Creation by the Krebs

Two men, each named Ernst T. Krebs, father and son, bring Laetrile to market and dominate its early years. Their backgrounds may prove instructive.

Ernst Krebs, Sr., born in 1876, son of a California pharmacist, himself worked as a pharmacist before attending the San Francisco College of Physicians and Surgeons (1,2). He received his medical degree in 1903. Practicing in Nevada during the influenza pandemic of 1918, Dr. Krebs became persuaded that an old Indian remedy possessed great efficacy in combatting the flu. A rare species of parsley, Leptotoemia dissecta, Krebs wrote in a Nevada State Board of Health bulletin, had permitted the Washoe Indians to survive the epidemic without loss of life, whereas members of other tribes died in great numbers (3,4).

Krebs promptly commercialized his discovery. In San Francisco he set up the Balsamea Company to market a proprietary named Syrup Leptinol, recommended for use in epidemic influenza, bronchial asthma, whooping cough,

pneumonia, and pulmonary tuberculosis (5). A later version called Syrup Bal-Sa-Me-A, with rhubarb added, bore labeling which recounted how Leptotoemia had protected the Washoes and which promised users "miraculous results" (6). "It strikes at the cause," the circular read, "quickly checking germ action." Such claims so disturbed Krebs' fellow physicians that he resigned from medical societies and never rejoined (1). Such claims also disturbed the Bureau of Chemistry of the Department of Agriculture, in charge of enforcing the Pure Food and Drugs Act of 1906. The Bureau had shipments of Krebs' proprietary seized in Missouri, Illinois, and Oregon, terming its labeling false and fraudulent (5, 6). When no claimants appeared, courts condemned the medicines and ordered them destroyed. Dr. Krebs did not give up on his product. At the end of the 1950s a Syrup of Balsamea was still being sold, and Krebs' promotion contained the suggestion that he had discovered the first antibiotic (7, 8). No longer an over-the-counter proprietary, Krebs now distributed Balsamea under the guise of an investigational prescription drug.

In the intervening years Dr. Krebs had continued to seek new therapeutic entities. Before 1951, when Laetrile surfaced surely in the public record, he had been involved with both cancer treatments and apricot kernels. Krebs had promoted an enzyme, chymotrypsin, as a cancer remedy, explaining its action by the same trophoblastic theory, borrowed from John Beard, a turn-of-the-century Edinburgh embryologist, that was to undergird later Laetrile promotion (9). And in 1945 Krebs submitted a New Drug Application (NDA) for a drug called Allergenase, manufactured from the kernels of shelled apricot seeds, and claimed to be "a systemic detoxicant" for treating all allergies, including arthritis, asthma, and "shingles" (10, 11). He had begun work on this drug, he said, in 1924. In due course Allergenase evolved into pangamic acid, otherwise known as Vitamin B-15.

Dr. Krebs told two tales about Laetrile's origin. The earlier account ascribed a recent discovery date. The later account, furnished in a court affidavit signed by Dr. Krebs in 1965, provided a more remote origin. As of 1965, having a long history for Laetrile had become legally important, because of so-called "grandfather" clauses relating to drugs in both the 1938 Food, Drug, and Cosmetic Act and the 1962 Kefauver-Harris Amendments to that law. Drugs in use before critical dates escaped some aspects of regulation.

Some versions of the Laetrile legend traced the drug's origin to Dr. Krebs' researches in the 1920s aimed at making bootleg liquor palatable (12). In his 1965 affidavit Krebs

stated that he had first made an extract from apricot kernels in 1926, calling it Sarcarcinase, containing amygdalin, a chemical known for a century (13). A later critic has denied that Sarcarcinase could have been Laetrile's amygdalin-containing ancestor, because Sarcarcinase was a chloroform extract of apricot kernels, and the amygdalin would have gone down the drain with the discarded aqueous portion (14). In any case, Dr. Krebs stated in his affidavit that Sarcarcinase proved too toxic a drug when injected into rats. Steadily improving his extraction process, Krebs asserted, he achieved an ever higher level of amygdalin purity. In 1949 Krebs' son slightly modified his father's process and named the result Laetrile. This version of Laetrile's origin became the standard canon among its promoters.

The earlier tale that Dr. Krebs had told about Laetrile's beginning dated its birth to 1951. In an interview with Food and Drug Administration officials during December 1952, Dr. Krebs said that ten months before he had begun experimenting with a cyanogenetic glucoside which he had extracted from a mixture containing apricot pits (15). He had tested it successfully on patients, he asserted, but had kept no records. Injected near the site of a cancerous lesion, Laetrile worked by liquefying the malignant growth through the release of cyanide.

Soon Dr. Krebs and his son presented a more elaborate explanation for Laetrile's mode of action. The theory proved to be the same one which they had recently used to justify the presumed anti-cancer activity of an enzyme with which they had been experimenting.

Ernst Krebs, Jr., who coined the name Laetrile, had come home to California after peripatetic schooling. He did not have a Ph.D. from the University of Illnois, as he sometimes asserted, nor had he yet received his only claim to the doctorate, an honorary Doctor of Science degree from the American Christian College in Tulsa, Oklahoma (16). According to California state investigators, Krebs had attended colleges in Mississippi, Tennessee, and California before receiving a bachelor of arts degree in 1942 from the University of Illinois. Also before going to Illinois, Krebs had spent three years as a medical student at Hahnemann Medical College in Philadelphia, the second of which was a repetition of the first year's work. Krebs devoted two years, from 1943 to 1945, to graduate study of anatomy at the University of California, but was dismissed because of his pursuit of what was deemed unorthodoxy (17).

Krebs, Jr., continued his researches in collaboration

with Dr. Charles Gurchot, a pharmacologist who also had left the university (18). The two had published a letter in Science, "Growth of Trophoblast in the Anterior Chamber of the Eye of the Rabbit" (19), and now set up a foundation bearing Beard's name to seek a cancer cure fitting his principles (18).

In 1950 Krebs-père and -fils published their own version of Beard's trophoblastic or unitarian thesis (9). All cancer, they asserted, is one, brought on when the normal trophoblast cell goes wrong. This cell, which in both sexes emerges from a very primitive cell, is best known for its role in securing the embryo to the uterine wall. This function, the Krebs stated, demands erosion, infiltration, and metastasizing. In becoming cancerous, trophoblasts do the same things, dangerously. Beard had said that some pancreatic enzymes attack trophoblasts. The Krebs and Gurchot had found an enzyme they believed to be specifically antithetical to malignant cells.

The 1950 article, seeing great promise in the enzyme chymotrypsin, did not mention Laetrile. At about the very same time, however, -- at least, according to Dr. Krebs' 1952 account -- Laetrile was born. And soon the Krebs presented a Beardian explanation for Laetrile's mode of action. The Laetrile molecule, the theory held, when it reached the site of the cancer, was hydrolyzed by an enzyme, beta-glucosidase, releasing cancer-killing hydrogen cyanide (20, 21). This enzyme accumulated in cancerous areas in much greater quantity than it did in healthy cells, so the cyanide was released where it was needed. Moreover, normal cells were protected by another enzyme, rhodanese, which detoxified any cyanide that might be liberated in or stray to them. Cancerous cells lacked rhodanese. Thus Laetrile, according to its promoters' theory, fulfilled a prime objective of the nascent field of cancer chemotherapy, specificity of action: it targeted damage to cancerous cells without injuring normal cells unduly.

Right from the start Laetrile became related to a number of separate but intertwining organizations, legally distinct but linked, at least so FDA officials came to believe, through Ernst Krebs, Jr., their "guiding light" (8, 22). The John Beard Memorial Foundation, the research unit, became Krebs, Sr.'s province. Krebs, Jr., personally supervised production in the Krebs' Research Laboratories. The finished product then went to the Spicer-Gerhart Company in Pasadena which distributed Laetrile as an investigational drug. Some California general practitioners began to use it in treating patients with cancer, and requests for it came in from other states and from overseas. A New Jersey group

of doctors, for example, used Laetrile. Their business manager, Glenn Kittler, upon hearing a tape recording of Krebs' explanation of the trophoblastic theory, responded by opining that Krebs was "well on his way toward the Nobel Prize" (22).

California cancer specialists were not so quickly persuaded. The Cancer Commission of the California Medical Association sought to secure some Laetrile from Krebs to permit a clinical trial under the direction of the Research Committee and the Tumor Board of the Los Angeles Hospital. While "anxious" to have clinical work commenced, Krebs, Jr., replied, he foresaw difficulties (23). Especially he objected to tests made by physicians ignorant of trophoblastic theory. "Conducting work under these conditions," he wrote, "is almost tantamount to attempting to conduct an orderly practical industrial implementation of nuclear fission with the cooperation of physicists who failed to accept the $E=mc^2$ formula and were gravely in doubt about the atomic constitution of matter." Unless a doctor of his own choosing could direct the experiment, Krebs would send no Laetrile. Such a stance recurred not infrequently in Laetrile's future: an expressed desire, sometimes a demand, for trials, but heel-dragging about complying with the established parameters of scientific research, a denial that mainstream scientists could test Laetrile fairly. In Krebs' metaphor from physics, be it noted, he baldly transposed orthodoxy and unorthodoxy.

With a supply of Laetrile secured from the Food and Drug Administration (24), the Cancer Commission of the California Medical Association sponsored at three cancer research centers controlled trials of Laetrile as a treatment for various cancers in mice (25). None of the tests revealed that Laetrile had any effect on the course of the disease. The Commission also assembled as much information as it could about patients who had been treated with Laetrile -- forty-four cases in all -- and found no objective evidence that Laetrile alone exercised any control over cancer. The conclusion was based on examination of seventeen cancer sufferers still alive and on autopsies of nine of the nineteen patients who had died. Furthermore, the Commission disputed the explanation by the Krebs as to how Laetrile purportedly functioned. The molecule-cleaving enzyme which supposedly released hydrogen cyanide at the site of the cancer, held by the Krebs to be more abundant in cancerous than in normal cells, in fact, said the Commission, was not; normal cells contained more of the enzyme than did neoplastic tissue. In time scientists were to presume that, because of the extremely small concentrations of beta-glucosidase in human tissues, Laetrile administered

parenterally would undergo scarcely any metabolic breakdown and would leave the body in the urine virtually intact (26).

Krebs, Jr., and the small coterie of Laetrile physicians dismissed the California Cancer Commission's report. A newer improved version of Laetrile and new dosage levels, they said, invalidated the Commission's distorted findings (22, 27). In any case, asserted one Laetrile doctor, no curative claims had ever been held out, only the promise of stopping the cancer's growth and prolonging the patient's life with diminished pain and greater comfort. Despite the denial, Dr. Krebs, Sr., had in fact been quoted in the press as saying that Laetrile wrought cures in forty percent of cancer patients and brought improvement to the remaining sixty percent (28).

Laetrile's proponents no doubt welcomed controversy as a way of making their product better known. They had courted publicity. The Cancer Commission first heard about Laetrile through a barrage of inquiries from national magazines, news services, and the California press (25). A Laetrile physician had given a list of his patients to a newspaper, inviting reporters to interview and photograph them. Krebs, Jr., worked hard at expanding the market for his investigational drug. Some insight into his zeal may be derived from what he wrote, some years later, to an entrepreneur hoping to market Laetrile under his own trade name in foreign areas: ". . . [T]he field of cancer chemotherapy is a law to itself. This jungle offers the greatest opportunity anywhere in commerce at this moment, but there are snakes in every bush. I believe . . . it's best to push hard, sell, don't be backward about disaffecting a few, and establish . . . [Laetrile] right from the start as something precious that not even hospitals get for nothing" (29). In the same letter Krebs noted: ". . . [O]ne can usually buy even the top medical investigators as one does sirloin steak -- and at about the same price."

In fact, reports suggesting Laetrile's utility in cancer came not from the top but from a few clinicians overseas and several American general practitioners (26). American cancer experts dismissed the pro-Laetrile studies as purely anecdotal or so poorly designed as to lack validity. If the market grew for Laetrile during the 1950s, it was at a modest rate. Krebs, Jr., secured a British patent for the product, but it did not mention cancer (30). He joined with Fred J. Hart, a promoter of therapeutic devices, in testifying against a California bill aimed at curbing cancer quackery, but the law passed anyway (31). Another signal ominous for the Krebs appeared at the start of the new

decade. In 1960 the Food and Drug Administration made its first seizure of an interstate shipment of Laetrile. That same year a decade of litigation had finally driven Harry Hoxsey from the field of cancer quackery (32). His successor at the Dallas clinic, barred from using Hoxsey's mix of botanicals, had ordered the lot of Laetrile which the FDA had seized (33).

The Food and Drug Administration had watched the Laetrile venture from its early days. The California Cancer Commission critique of 1953 raised the question of taking regulatory steps. After weighing the matter at the highest level, FDA opted for continuing close scrutiny of operations, not immediate action. Other projects held higher priority, and manpower was short. Laetrile was both small in size and difficult to combat. ". . . [T]his type of promotion, namely an article distributed as a new drug for investigational purposes but indirectly promoted for use in cancer, is hard to handle" (34). So concluded a headquarters memorandum. If Laetrile were directly offered as a cancer treatment in printed labeling, chances for controlling it through regulation would be "brighter." Thus the Krebs' cautious approach, depending mainly on word of mouth promotion instead of bold labeling claims, postponed trouble, probably at the expense of growth. The 1960 seizure signaled a change.

The first period of Laetrile's history, during which the Krebs' brand of amygdalin, shrewdly but cautiously promoted, made modest gains without encountering serious regulatory troubles, ended about 1963. By then both state and federal governments, the latter with powerful new weapons given it by the Kefauver-Harris law, had attacked in force. Public worry about drugs, cued by Senator Estes Kefauver's hearings and the frightening thalidomide episode, which lay behind the Tennessee Senator's law, had soared to new heights. Besieged by regulatory actions, the Krebs yielded real control over their enterprise to a Canadian citizen possessing capital, audacity, and a broader vision of Laetrile's destiny.

The McNaughton Ascendancy

Andrew Robert Leslie McNaughton first met Ernst Krebs, Jr., so McNaughton testified, in a Miami drugstore in 1956 or 1957 (35). Shortly before this, McNaughton had informally set up a foundation in Montreal, incorporated in 1958, to support researchers possessing unorthodox but possibly useful ideas who found it difficult to secure funds elsewhere. In 1960, after spending several weeks in the Krebs' San Francisco laboratory, McNaughton took some Laetrile back

with him to Canada, persuaded several tobacco companies to contribute research funds, and, through his McNaughton Foundation, distributed Laetrile to a number of Quebec physicians as an investigational drug. In 1961 McNaughton founded Biozymes International Ltd., a manufacturing concern, which the next year began to produce Laetrile (36).

McNaughton came from a notable family and had enjoyed a glamorous if at times checkered career (36, 37, 38). His father had headed Canada's armed forces during World War II. The son had served as chief test pilot for the Royal Canadian Air Force. He had sold arms to Israel and had let Fidel Castro capture weapons which McNaughton had been commissioned to sell to Batista, the Cuban president, for use in suppressing Castro's insurgency. In time McNaughton and his foundation became targets of a suit brought by the U.S. Securities and Exchange Commission, charging promotion and sale of unregulated securities, stock in Biozymes International. In 1973 a district court in California, not having received an answer to the complaint, rendered a default judgment of permanent injunction (39).

Besides launching his Laetrile enterprises in Canada, McNaughton undertook an initiative in the United States. Taking Krebs, Jr., and a pro-Laetrile physician along, McNaughton went to Washington. Through the good offices of a New Jersey Congressman, he secured conferences with Health, Education and Welfare and Food and Drug Administration officials (40, 41). What would it take, the Laetrile party asked, to have a New Drug Application favorably considered? Krebs explained the rationale behind Laetrile's purported action, indicating that dosage levels now were higher than those first used. No claims for cure of cancer would be made, only for palliation. While safety data seemed complete, evidence of effectiveness admittedly rested on clinical research outside the nation's borders, although three United States clinical investigations were under way. In the granting of an NDA was only safety considered? Not, FDA officials replied, with drugs prescribed for life-threatening diseases. In such cases safety and efficacy could not be separated. An innocuous product which failed to help the patient would constitute a hazard when used in lieu of treatment that offered some promise of success. Without sound clinical evidence from recognized experts, the government men told Krebs and McNaughton, a New Drug Application could not be deemed complete.

In November 1961 the FDA charged Krebs and the John Beard Memorial Foundation with violating the law (42). The case involved not Laetrile, but Krebs' other major product,

pangamic acid or Vitamin B-15. Krebs had shipped capsules of this new drug into Oregon and Florida without having an effective NDA, in the same way in which he was distributing Laetrile. Both the Foundation and its sole officer pleaded guilty to the charge, Krebs being fined $3750 and sentenced to prison. Imprisonment was suspended when Krebs agreed to the terms of a three-year probation. One of those terms barred Krebs and his Foundation from manufacturing and distributing Laetrile until there should be an approved NDA. The court shortly agreed to a modification of the probation order permitting Krebs to exhaust the supply of Laetrile on hand by shipping it without payment to the McNaughton Foundation in Montreal and to a few physicians in the United States so that experiments might continue (43, 44). Laetrile patients and their families had written pleading letters to the judge.

When the small reserve supply of Laetrile came to an end, interstate distribution supposedly would cease. NDAs submitted by both Krebs, Jr., and Krebs, Sr., fell short of meeting FDA's standards for acceptance (45). Krebs, Jr., and the John Beard Memorial Foundation obeyed the court's ruling and stopped making Laetrile. But production and distribution did not stop. Krebs, Sr., and Krebs Laboratories, according to FDA records, picked up the task. And McNaughton's Canadian venture quickened. He got some of his raw material for making Laetrile from England, Krebs, Jr., thought, and for one stage in the production process sent the drug into New Jersey (46).

Indeed, McNaughton increasingly made his powerful presence felt on the entire Laetrile scene. He strove, without success, to get the Damon Runyon Cancer Fund to evaluate Laetrile, reaping some headlines from the effort (47). However, a vastly more successful publicity coup soon followed. The American Weekly, a Hearst publication, during March 1963 ran two articles presenting Laetrile in a most favorable light (48). They were followed shortly by a paperback book from which they had been taken, Laetrile, Control for Cancer (2). "The most important medical news of our time," the cover promised, "First major breakthrough in the cancer mystery. The day is near when no one need die from cancer. LAETRILE, the revolutionary new anti-cancer drug . . . WILL BE TO CANCER WHAT INSULIN IS TO DIABETES." Written by Glenn D. Kittler, who earlier had acclaimed Krebs, Jr., as Nobel Prize material, the book presented a highly dramatic version of Laetrile's discovery and a most optimistic rendering of Krebs-sponsored clinical experience with the drug. To use the term "cures" for cancer Kittler considered "inaccurate," but he added: "The idea of a cancer control, on the other

hand, is perfectly plausible. In the minds of an increasing number of leading scientists, the best control now available is Laetrile." The book concluded by quoting Andrew McNaughton to the same effect. McNaughton contributed also the book's foreword, to which he appended his Foundation's Montreal address. Letters of inquiry sent to the Foundation received replies saying Laetrile might soon be available from Canada and asking cancer sufferers to have their doctors write the Foundation (49). Some United States citizens crossed the border to Montreal to get Laetrile injections (50).

While thus deeply involved in a publicity venture tremendously expanding Laetrile's national visibility, McNaughton also worked away on other fronts. He sent Laetrile made in Canada to a foreign trade zone in San Francisco for transshipment to markets in the Far and Middle East (51). And he continued to deal with the Krebs. Relations were sometimes tense, but McNaughton -- at least in the judgment of observing food and drug officials -- came to assume the upper hand (52). In speaking of Laetrile, he often used the proprietary "we," and he acted as if he were making the important decisions. When the probation stock of Laetrile ran out, it was McNaughton who went to Washington, this time alone, to see if he could pressure the FDA into letting him have more, arguing that he should not be penalized for the misdeeds of Ernst Krebs, Jr. (53). FDA officials pointed out that Laetrile still did not have a completed NDA and that the new Kefauver law had stiffened standards for admitting new drugs to the market.

Legal difficulties, indeed, soon cast shadows across the publicity coup resulting from Kittler's book. California, after holding hearings under its new law aimed at specious cancer treatments, banned Laetrile as a quack remedy (54, 55). The Canadian Food and Drug Directorate barred further distribution of Laetrile by the McNaughton Foundation on the grounds that its safety and efficacy had not been proved (56). McNaughton, calling unconstitutional the law under which the Directorate had moved, sought in 1964 to enjoin the Directorate from enforcing it. But McNaughton lost in court. The next year the Food and Drug Administration strove to curb Dr. Krebs, Sr.'s small-scale but persistent shipment of Laetrile in interstate commerce. After protracted court action, he was enjoined, later cited for criminal contempt, and finally fined for violating his probation (57). Dr. Krebs probably prescribed Laetrile for his patients through the remainder of his life, although he gave up manufacturing and distributing it, while maintaining the production of pangamic acid (58). He died in 1970 from a fall on the stairs at the age of 94 (59, 60).

In the meantime, Andrew McNaughton had moved to California. Both the Krebs, father and son, had been enjoined from dealing in Laetrile, and in Canada so had McNaughton himself. Using several corporate names, McNaughton continued the manufacture of Laetrile in San Francisco, then in Sausalito (38, 61), and from his transplanted McNaughton Foundation he tried once more in 1970 to get FDA approval for experimental use of Laetrile on human subjects (62, 63, 64). McNaughton's submission of an IND, an Investigational New Drug application, a document required by the Kefauver-Harris Act before human trials could proceed, became a cause célèbre. Upon receipt of the IND, the FDA routinely approved it, in accordance with then prevailing practice. A quick appraisal did not reveal in the application the kind of promising evidence from animal experimentation that would provide a reasonable basis for expecting anti-tumor activity in man. Eight days later the FDA wrote McNaughton that the IND could not be continued without more satisfactory data, and when no new information arrived before the deadline set in regulations, the FDA cancelled the application. Further information later submitted by McNaughton did not persuade Food and Drug officials to change their minds. Manufacturing controls and preclinical and clinical data all remained unsatisfactory.

Laetrile supporters reinterpreted these events into a tale of FDA's perfidy. According to this version, FDA's initial automatic acceptance of an IND until the evidence could be examined became instead a bona fide acceptance which the agency then reversed under pressure from the political moguls of the cancer research establishment (65, 66). A pro-Laetrile reporter predicted "a showdown" between the hidden forces of repressive orthodoxy and champions of alternate modalities (65).

A showdown did indeed occur. A varied constellation of circumstances had moved the Laetrile cause upward on the path of political power. Not only had Hoxsey's star set through governmental action and exposure, so too had Krebiozen's virtual demise arrived by 1966, thus creating a vacuum at the apex of cancer unorthodoxy ready for filling by a new contender. The publicity generated by Kittler's book gave Laetrile a good boost toward the top. Moreover, McNaughton gained a recruit to his cause from the inner citadel of the cancer research establishment who was destined to play for Laetrile something like the role Andrew Ivy had played for Krebiozen. Dean Burk, who had received his Ph.D. in biochemistry from the University of California, had devoted a more than forty-year career to cancer investigation, with many honors along the way, and now was chief of the Cytochemistry Section of the National Cancer Institute (65, 67). In 1968 McNaughton

had persuaded Burk to undertake research on Laetrile, and by the time two years later of FDA's rejection of the McNaughton Foundation's IND, Burk had become a fervent Laetrile champion, calling many of his contrary-minded governmental associates "scientifically immoral" (65). Stepped-up Laetrile publicity focused the spotlight on Burk.

The scope of Laetrile publicity had also broadened because a new organization had sprung up to wave its banner and because an established league of unorthodox health promoters had taken up Laetrile's cause. The new group, the International Association of Cancer Victims and Friends, was founded in 1963 by a San Diego schoolteacher, Cecile Pollack Hoffman (50, 68). She herself had turned to Laetrile with despair and hope. In 1959 she had sustained a radical mastectomy because of breast cancer, and three years later the spread of cancer led to further surgery. She learned of Laetrile when her husband saw a copy of Kittler's book in an airport lobby. Cued by McNaughton's foreword, Mrs. Hoffman journeyed to Montreal for Laetrile injections. She continued receiving them closer to home, by crossing the border to Tijuana, becoming the first Laetrile patient of a Mexican physician, Ernesto Contreras Rodriguez. Persuaded that Laetrile had saved her life, angry that this treatment was not legally available in the United States, Mrs. Hoffman established her International Association. Through print, meetings, and personal evangelism, the association castigated "out-of-date, out-moded, so-called 'orthodox' treatment," and vigorously espoused what Mrs. Hoffman termed "non-toxic, beneficial therapies," especially Laetrile. Krebs, Jr., Contreras, and in time Dean Burk addressed IACVF assemblies (69, 70, 71). The organization provided cancer sufferers with information on how to get to Tijuana. When Canada joined the United States in making Laetrile illegal, Dr. Contreras' business boomed. Mrs. Hoffman died in 1969 of metastatic cancer, but her organization continued on (72).

Mrs. Hoffman's emphasis upon "Freedom of Choice" in cancer treatment echoed the constantly reiterated dominant theme of another organization which had been established eight years before she founded the IACVF. The National Health Federation was founded in 1955 (73, 74). Moving spirit in its creation was Fred J. Hart, a California promoter of health devices who had just been enjoined by Food and Drug Administration initiative from distributing them in interstate commerce. Other NHF founding fathers also had encountered legal restraints, some spending time in jail, for false claims about devices, dietary wares, and so-called cancer treatments. One of Harry Hoxsey's lawyers became the

Federation's first legal representative in Washington. The Federation developed into a powerful league linking the various segments of health unorthodoxy. They held up each other's spirits and sought new converts at frequent meetings, developed skillful propaganda playing on public anxieties and frustrations, grew adept at pressure politics, mobilizing the faithful for letter-writing campaigns and confrontation lobbying. Hart and Krebs both testified against the California cancer law, and the Federation welcomed Laetrile supporters to its ranks and gave their cause strong support. Condemning overweening and bumbling bureaucracy for administering health laws to favor the medical establishment, the NHF pleaded for patient freedom of choice so that each ailing person might treat himself from amongst unorthodoxy's abundant catalog of wares. The Federation journal pictured Washington and Lincoln on its cover over the caption, "They Too Fought for Liberty Against Great Odds." These criticisms of governmental actions in the health field mounted amidst the growing broader disillusion with governmental policy resulting from the war in Vietnam.

The distorted Laetrile version of the FDA's rejection of McNaughton's IND received widespread coverage in the publications of unorthodoxy and in the sensationalist press (75). A barrage of angry mail bombarded Washington. FDA's police state tactics, charged one protester, "reduce[d] Hitler and Stalin to the status of small time hoodlums" (76).

Mail deluged the Congress as well as the FDA (77). The National Health Federation Bulletin had explicitly urged this action (78). Representative Lawrence H. Fountain, after committee hearings, brought pressure on Elliot Richardson, Secretary of Health, Education, and Welfare, to sponsor further evaluation of Laetrile's efficacy (79). The FDA checked its own internal judgment by soliciting external expert opinion. A panel of independent cancer specialists was assembled, which reviewed the data submitted in McNaughton's application, heard face-to-face what McNaughton and Burk had to say, sought whatever new information Laetrile physicians like Contreras might have to offer, then concluded that the sum total of evidence did not warrant testing Laetrile on humans. Further rodent tests in recognized independent laboratories, the committee held, might be desirable. The Secretary considered the conclusions of FDA's ad hoc committee valid (63, 80). National Cancer Institute tests on mice had offered no promise of Laetrile's effectiveness, and no new NCI tests seemed worth undertaking. That Institute, however, the Secretary said, would recognize grant applications for further testing from qualified independent investigators.

Secretary Richardson reported his judgments to Congressman Fountain who did not continue to press the issue. A bill introduced into the House by another member, to authorize research on and testing of non-toxic substances for the diagnosis, treatment, and prevention of cancer, made no headway (81).

Regulatory pressure on Laetrile promoters did not subside. In 1971 the state of California began a criminal case against Ernst Krebs, Jr., charging him with practicing medicine without a license and, aided by his brother Byron, an osteopathic physician, with distributing a prohibited drug (82, 83, 84). Two years later the brothers pleaded nolo contendere to violating the state cancer act's taboo on Laetrile. The judge fined them and placed them on probation. The terms required them to obey all city, state, and federal laws, especially the cancer treatment provisions of the California code, and forbade Krebs, Jr., to practice medicine without a license. California took further legal steps as well. A case against Mary Whelchel sought to impede the turning wheels of an accelerating "underground railroad" which assembled cancer victims from all over the nation in a boarding house on the United States side of the border, then ran them across to Tijuana for Laetrile treatment in Dr. Contreras' flourishing operation (84, 85). In 1971, Mrs. Whelchel was convicted of delivering an illegal compound for treating cancer, fined, and, as a term of her probation, was forbidden to transport anyone to Mexico. (It should be noted, however, that this conviction was set aside two years later.)

The Appeal to Freedom

Such relentless regulation coupled with scant success from the epistolary campaign in Washington sped changes already launched that remade Laetrile's self-image, the explanation for its therapeutic action, indications for its use, the strategy and tactics of its promotion, even its very name. Andrew McNaughton remained commanding general, but became an officer in exile. In 1974 his reputation in his Canadian homeland suffered a blow when a judge convicted him of conspiring fraudulently to affect the market price of a mining stock (86). The United States, with Laetrile under attack on both state and federal levels, must have seemed increasingly hostile. McNaughton took up residence in Tijuana. The press credited his foundation with sponsoring both manufacturing and clinical facilities for Laetrile in the Mexican city (36), stations at the underground railroad's terminus. The railroad began to run the other way, carrying smuggled Mexican Laetrile into the U.S.A. (87).

McNaughton thus continued, as a reporter put it, "more than any other man . . . the driving force behind the Laetrile movement" (88). In this third period, however, McNaughton in exile gained powerful allies of great leadership potential in the United States. This chain of events began in 1972 when a California general practitioner, Dr. John A. Richardson, was arrested at his Albany clinic, charged with prescribing Laetrile in violation of the state's anti-quackery law (89). The dramatic arrest, filmed on television cameras, involved policemen with drawn guns and a thorough search of the premises. The physician spent a brief time in jail. A trial before a judge, finding Richardson guilty, was quashed on appeal. Two jury trials followed, both ending with jurors split (36, 90). Eventually the California Board of Medical Quality Assurance revoked Dr. Richardson's license to practice medicine on grounds of "Gross negligence and incompetence" (91, 92).

Richardson's initial arrest upset some of his fellow members of the John Birch Society. Such dedicated disciples of freedom-from-government doctrine saw in Richardson's plight a prime example of bureaucratic oppression. Led by Robert W. Bradford of Los Altos, a small group of ultraconservatives founded yet another organization to help Laetrile's besieged prescribers (93). Bradford was a nuclear technician on the Stanford University staff, working on the building of a linear accelerator for research in subatomic physics. Poised, articulate, skilled at organization, Bradford, aided by equally dedicated associates, quickly made a success of the new Committee for Freedom of Choice in Cancer Therapy (36, 94, 95). In 1975 he gave up his Stanford job to devote full time to the Committee and to Laetrile. Ties with the nation's already existing conservative network surely helped immensely in the speed with which the Committee established local branches. By 1977 Bradford claimed five hundred chapters with some 35,000 members.

The Committee and its allies focused upon freedom, making any governmental interference with a cancer sufferer's right to take any remedy available seem a violation of the Constitution and the fundamental rights of man. Thus an atmosphere of high principle infused the zealous campaigning in Laetrile's behalf. Laetrile's opponents, in the Committee's propaganda, constituted a selfish conspiracy of those involved in orthodox cancer research and therapy, futilely cutting, burning, and poisoning their victims, and rejecting hopeful treatments like Laetrile for fear of doing themselves out of their jobs. The Committee showed great ingenuity at making their message widely known. They employed meetings,

films, pamphlets, paperback books, quickly triggered letter-writing campaigns, and the assembling of the faithful for legislative hearings. Full-time crusaders sought out cancer victims and urged Laetrile upon them and upon members of their families (96). Counsel could be given as to how to get to Contreras' clinic in Mexico or how to acquire Laetrile in the United States. Indeed, some Committee leaders, including President Bradford himself, allegedly at great personal profit, engaged in a conspiracy to smuggle Laetrile in from Mexico and, with much surreptitious ingenuity, distribute it within the United States. After a three-month trial in 1977, Bradford, Dr. Richardson, and others were convicted of this conspiracy; the Court of Appeals for the Ninth Circuit confirmed the convictions (97). McNaughton, also indicted, pleaded guilty (87).

Laetrile in the 1970s assumed a different character from the chemotherapeutic Laetrile with which the Krebs began. In 1963, in a letter to the Food and Drug Administration, Dr. Krebs had asserted: "The cyanogenetic glucosides belong to the nutritional vitamins and should not be classified as drugs" (98). Here appears the earliest reference encountered in the file to Laetrile's future destiny. Already, Krebs, Jr., had committed himself, as part of his probation, not to distribute Laetrile as a drug. Perhaps both father and son had begun to wonder if legal restrictions might not be less stringent under the food sections of the law. Such a shift in Laetrile's status would require a modification of the prevailing chemotherapeutic explanations of Laetrile's mode of action. Shortly Krebs, Jr., published a pamphlet, not really retreating, but adding the suggestion that Laetrile could be characterized as a pro-vitamin for B-12. The pamphlet bore the title, "Cancer Is a Deficiency Disease" (21).

As regulatory actions mounted, Krebs, Jr., in 1970 brought his pamphlet title to full flower. In an article in the Journal of Applied Nutrition he asserted that Laetrile and other "nitrolosides" made up a true vitamin which he denominated B-17 (99). Vitamin B-17, he wrote, amounted to a cancer-protective factor. Moreover, Krebs asserted, in this "new vitamin . . . all of us are severely deficient." Cancer could be cured by massive injections of the vitamin. Cancer could also be prevented by smaller quantities, made from defatted apricot kernels, regularly taken by mouth. Four years before the appearance of this article Dr. Krebs had begun to distribute an oral dosage form of Laetrile (100). Now that form became popular, widely publicized by McNaughton, as co-therapy with injections of Laetrile in cancer treatment and, among perfectly healthy people, as a presumed preventive. Chewing unprocessed apricot kernels bought at health food stores also came into vogue.

If one were interested in Laetrile as a commercial venture, one might anticipate several advantages from this combination of new directions. Vitamin status for a product, one could argue and hope, might bring some immunity from actions under the drug provisions of both state and federal law. Moreover, the concept of cancer prevention would certainly elicit broad public interest, for of all threats, including war, Americans feared cancer most. Potential sales of a preventive could be enormous. And, if to the popular mind the word "cancer" bore ominous overtones, the word "vitamin" evoked glamorous reverberations of buoyant health (101). Americans had mounted to a new plateau of concern about their health, accompanied by a wide variety of approaches toward do-it-yourself safeguarding, by no means all of them sound. Health food marketers, including National Health Federation members, both agitated the public's concern about health and oversold the need for vitamin supplementation (102).

Nutritional scientists repeatedly denied that Laetrile fulfilled any of the criteria for a true vitamin (103, 104, 105). "In short," summed up a veteran vitamin researcher, Dr. Thomas H. Jukes, "nothing could be less like a vitamin than laetrile" (106). Despite such criticism, Laetrile's vendors continued to assert this claim. In testifying in 1977 before Senator Edward Kennedy's Subcommittee on Health, Ernst Krebs, Jr., termed Laetrile "a scientific revolution as profound as the germ theory of disease . . . and the Copernican theory" (107). What Vitamin C is to scurvy, niacin to pellagra, and Vitamin D to rickets, he suggested, Vitamin B-17 is to cancer. If every American took Laetrile regularly, Dr. Richardson told the subcommittee, "in 20 years cancer would be relegated to the dusty pages of history."

To make amygdalin accessible for regular self-dosage by the American public, Laetrile's sponsors displayed much marketing skill. In 1972 there appeared in California a consumer product bearing the trade name Seventeen. Just in front of the name on the carton came a picture of a bee. A McNaughton Foundation representative offered a reporter from a San Jose newspaper a chance to interview the noted cancer specialist, Dean Burk, who happened to be visiting the Bay area (108, 109). By this route Burk's praise for the new food supplement found its way into the press. Bee-Seventeen, Burk said, contained three percent Laetrile, thirty percent protein, fifty percent unsaturated fats, with the remainder minerals. The powder was to be taken daily with juices or milk. Laetrile, Burk told the reporter, could both prevent and cure cancer, but no medical claims were being made in

behalf of Bee-Seventeen. It was offered for sale solely as a food.

Such a ruse did not protect the product from action by the Food and Drug Administration. The manufacturers of Bee-Seventeen were enjoined from distributing what the court termed both an unapproved food additive and a misbranded drug (110). Other amygdalin-containing products, like Aprikern, though devoid of therapeutic claims in their labeling, were also barred from the marketplace (111).

Laetrile's champions not only propagated their vitamin gospel with aggressive vigor; they also took the offensive against their critics in other ways. Oppressed by federal food and drug law and by the California anti-quackery statute, the Laetrile coalition turned its attention to legislative chambers. Several efforts to repeal the efficacy provision in the California law failed (112). In the national Congress, Laetrile supporters favored a bill introduced by Representative Steven D. Symms of Idaho which would have repealed the provision of the Kefauver-Harris Act requiring that new drugs be proved effective before being permitted on the market (113, 114). This bill gained some 140 co-sponsors in the House but made no progress toward enactment.

Laetrile's major legislative push aimed at persuading state legislatures to pass laws legalizing the extract made from apricot kernels. Bills differed in substance from state to state, although most would at least permit physicians to prescribe Laetrile for patients certified as terminally ill of cancer (115). Cancer specialists pointed to the great difficulty in achieving any satisfactory definition of the word "terminal" (116). Alaska enacted the first such law in September 1976, and within two years sixteen other states had followed suit. Other legislatures pondered Laetrile bills and defeated them. The deliberative bodies in Indiana, Illinois, and Rhode Island enacted their measures over vetoes by the governors (117, 118). In New York, two years in succession the governor's veto held.

The scenarios in the several states had much in common (119). A cooperative assemblyman introduced a bill at the request of a constituent. In due course the health committee held hearings. The hearings, replete with drama, became newsworthy happenings, recorded by television cameras, widely reported in the press. In some states, orthodoxy and unorthodoxy got equal time in number of testifying witnesses. In other states, pro-Laetrile sentiment was dominant. In news coverage, unorthodoxy--the underdog, the challenger--

received the greater play. Members of The Committee for Freedom of Choice in Cancer Therapy turned out in force. Wearing campaign buttons, they packed the galleries, intense, completely absorbed. Depending on the strictness of the rules imposed, Laetrile's friends either shouted or murmured praise for pro-Laetrile testimony, and heaped imprecations, either loudly or sotto voce, upon spokesmen from the state medical society, nearby universities, the American Cancer Society, the Food and Drug Administration, who explicated Laetrile's unproven status. The Laetrile lobby produced living testimonials claiming to demonstrate the contrary. After my operation--so the pattern went--my doctors gave me only a year to live, but I took Laetrile and here I am three years later, speaking before you legislators. The main thrust, however, of Laetrile spokesmen, often the national leaders of the movement, fell upon freedom of choice. State legislators had their own problems with the powerful federal presence, and might listen with sympathy to constituents blasting segments of the Washington bureaucracy. In any case, pleaded Laetrile witnesses in many states, only a little freedom was being sought, freedom for the dying, under a doctor's direction, to try Laetrile as a last resort.

After the hearings came continued pressure upon legislators, through conversations and a massive deluge of mail. Occasionally, if the terms of initial bills seemed too broad for acceptance, successive versions would follow with ever weaker provisions, until skeptical assemblymen would consider the measure too innocuous to matter and could thus satisfy both their consciences and the demands of those who had sent in the preponderance of mail.

No matter how weak the laws enacted, each one, announced to the nation through growing media coverage, contributed to bandwagon psychology, giving the imprimatur of another state's approval to Laetrile. To the ordinary citizen, sanction might equate with efficacy. Thus each new law enhancing Laetrile's prestige made it seem like legitimate therapy to victims of cancer and their families, including those victims whose cancer had just been diagnosed. And each law, making a specific exemption of Laetrile, dealt a new blow to the theory behind the federal law, which many states had imitated, that promoters of new drugs must prove them efficacious and safe before they could be marketed. The Kefauver law, moreover, demanded a high standard for proving efficacy, the results of adequate and well-controlled studies, not random cases proclaiming benefit, whether presented in paperback book or in testimony at committee hearing.

The state laws, however, did not negate the national law, and Laetrile remained illegal in interstate commerce. It was reported that McNaughton, allied with Bradford in a new John Beard Research Institute in Palo Alto, hoped to set up plants to manufacture Laetrile and clinics to dispense it within states enacting favorable laws (120), although these projects did not move rapidly forward. And in Illinois at least, where legal use of Laetrile was hedged in with many restrictions, the pattern set by the law has not been much employed (121). Rather, black market Laetrile has continued to be vended in the most dangerously careless way. A Chicago reporter told of buying Laetrile surreptitiously from a foot doctor downstate who asked no medical questions (122).

A second legal route for Laetrile prescribing, this one breaching the ban on interstate commerce, developed from action in the federal courts. As the Laetrile forces undertook a counter-offensive against regulation on the legislative front, so also did they on the judicial front. The key case in the campaign centered on Glen L. Rutherford, a manufacturer's representative who lived in Conway Springs, Kansas (123). Upon receiving a medical diagnosis that he suffered from a cancerous polyp, Rutherford refused radical surgery of the larger bowel. Instead he went to Dr. Contreras' clinic in Tijuana. The physician in charge of Rutherford's case later wrote a federal judge that Rutherford was treated with Laetrile and proteolytic enzymes, and then the remaining polyp was "cauterized" (123). Cancer specialists indicate that the excision of a polyp of this type solves the problem in a high proportion of cancer cases (124).

Upon returning home, Rutherford sought to ensure himself of a continuing supply of Laetrile. He joined a law suit already begun, became the sole surviving plaintiff, and in 1975 won from the United States District Court in Oklahoma an injunction against federal regulators which permitted him and other terminally ill cancer patients to import from Mexico a limited amount of the drug for their personal use (123). Judge Luther Bohanon insisted that each patient present a physician's affidavit certifying to the stage of illness and specifying the quantity of Laetrile needed to be imported.

Upon appeal of the Rutherford case, the United States Court of Appeals for the Tenth Circuit upheld the injunction (125). The court also instructed Judge Bohanon to require the Food and Drug Administration to develop an administrative record on two points contested in the case: whether or not Laetrile was a "new drug" as defined by law, and whether or not it was exempt from premarketing approval requirements by

reason of being "grandfathered." FDA complied. In its proceeding, the agency received four hundred written statements from friends and foes of Laetrile and held in May 1977 two days of public hearings in Kansas City (126). Jammed with Laetrile supporters, these hearings had the emotional flavor of hearings in the states (105). Cheers greeted pro-Laetrile speakers, boos and hisses their opponents. To one distinguished scientist present, "the affair appeared to be a confrontation between two cultures. One side was characterized by the voice of science--skeptical, analytical, orderly, but sometimes bluntly critical and uncompromising. The other side faced the situation with fervor, passion, conviction, revolt against logic, all emotionally expressed. They seemed to willfully reject distasteful facts" (105).

Food and Drug Commissioner Donald Kennedy and his staff turned their court-appointed responsibility into a comprehensive review of Laetrile, as thorough, broad-gauged, and insightful an analysis of a highly promoted but unorthodox drug as could be found in the American literature (21). Besides answering the court-posed issues--Laetrile had not been "grandfathered" under either the 1938 or 1962 law; experts did not consider it either safe or effective for its prescribed uses--the report discussed other significant matters relating to Laetrile. Laetrile's composition and identity would be difficult to define, the report stated, because so many different chemical entities had appeared under that name in both the literature printed about and the products distributed as Laetrile. The Commissioner countered the various claims made for Laetrile's effectiveness in cancer, disputing the shifting theories, remarking the inadequate anecdotal character of pro-Laetrile case reporting, and citing the lack of promise in numerous well controlled animal studies that had been made by the National Cancer Institute and private cancer research centers. The few animal tests interpreted as favorable to Laetrile by Dean Burk and others, the report criticized directly, concluding that Laetrile had failed "to show any effect in the animal system." The document found the nature of Laetrile's appeal in the psychology of patients and their loved ones caught in the crushing cancer crisis. The "disparagement of conventional therapy," the Commissioner stated, "a bulwark of the campaigns of Laetrile proponents, is perhaps the most morally reprehensible aspect of the pattern of the drug's promotion." This disparagement led sufferers away from proven remedies, that might offer some chance, to almost certain disaster. Even short delays could mean the difference between life and death.

Commissioner Kennedy met the "freedom of choice" argument head on. Congress had decided, he noted, "that the

absolute freedom to choose an ineffective drug was properly surrendered in exchange for the freedom from the danger to each person's health and well-being from the sale and use of worthless drugs." In any case, the choice to use Laetrile, made in an atmosphere of double stress, compounded from fear of disease and from the zeal of Laetrile advocates, with seldom any "rational laying out of competing arguments," can seldom be properly described as free.

The Commissioner's conclusions and all their buttressing evidence did not persuade the Oklahoma judge. He ruled that Laetrile was exempt from the need for pre-market approval and forbade the Food and Drug Administration from interfering with its importation and transport in interstate commerce or with its use by licensed medical practitioners in treating cancer patients (127). Again the FDA appealed.

When the Tenth Circuit considered FDA's appeal of this new Rutherford decision, the judges cut back markedly on the District Court's liberality toward Laetrile, but still authorized its use for a restricted segment of the population (128). Ruling in July 1978, the appellate judges concluded that the law's taboo against unsafe and ineffective drugs did not apply to people who were dying. Therefore, patients whose physicians would certify that they were terminally ill with cancer could legally import Laetrile--but only for intravenous injections, not in its oral form.

This last proviso revealed that the Court of Appeals was taking into account, as the District Court had not, evidence of amygdalin's toxicity when taken by mouth. Evidence submitted to the Commissioner's review, testimony given before Senator Kennedy's subcommittee, and stories in the press cited severe poisonings and even deaths from the ingestion of Laetrile tablets and apricot kernels (21, 129, 130, 131, 132). Enzymes in the gastrointestinal tract split the amygdalin molecule and released its cyanide.

The Tenth Circuit did not heed other evidence submitted to it with the FDA's appeal, that the long-vaunted claims made in behalf of injectable Laetrile's non-toxicity might not be completely true. Little research had been undertaken on Laetrile's action when injected into the body. Some physicians began to report unfortunate consequences, surmising that many such adverse effects had earlier occurred but had been blamed not upon the treatment but upon the disease (133).

That the dying should be barred from the law's protective mantle, Commissioner Kennedy deemed a "remarkable find-

ing" indeed, and he urged an appeal of the Tenth Circuit's opinion to the Supreme Court (134). In August 1978 the Commissioner thought his hand strengthened when the Court of Appeals for the Seventh Circuit rendered an anti-Laetrile decision. In 1977 FDA had seized apricot kernels, partially processed kernels, and empty capsules intended for filling with Laetrile at perhaps the largest processing plant in the United States, a former dairy in Manitowoc, Wisconsin. Later the company, which had sold two million dollars worth of its illegal product, was enjoined from continuing its business (135). On appeal, the Seventh Circuit ruled that Laetrile could properly be excluded from interstate commerce until it should be proven safe and effective (136). In due course the Supreme Court could be expected to decide between the contrary opinions of the Tenth and Seventh Circuits (137).

Other con and pro decisions marked Laetrile's increasingly litigious history. In California, the state's effort to restrain Laetrile practitioners ran into a snag. A state appeals court called the California cancer law unconstitutional, ruling that the state had no power to deny doctors the right to use non-toxic unorthodox cancer treatments (138). The state Supreme Court in 1978 granted a petition for review of this decision (139). In Georgia, a jury exonerated one of the most notable personages in the ranks of Laetrile proponents. Larry P. McDonald, physician and member of the John Birch Society and of the United States Congress, had prescribed only Laetrile for a patient's cancer (140). When the man died, his family sued for malpractice. The jury decided not so, yet feeling sympathy for the widow decided that she should be reimbursed for the expense of her dead husband's treatment.

The Food and Drug Administration continued seizing imports of Laetrile from Mexico and from Germany not protected by court-ordered physician affidavits swearing that the drug was intended for a particular patient who was terminally ill. Moreover, some samples offered for import turned out to be not amygdalin at all, but a dangerous fever reducer; other samples were contaminated with fungus (141, 142). Indeed, even the affidavit system itself, the FDA soon charged, had become a cloak for fraud (143). Reporters visiting Tijuana observed stacks of presigned affidavits available for the asking to Laetrile purchasers (122). Hitherto Laetrile smuggling, as revealed in the trial at which Dr. Richardson and Bradford had been convicted, had been an underground operation. Now, the government alleged in a seizure action, the druggist at a Baltimore pharmacy had manipulated the affidavit system for his own profit (144, 145). He had obtained

affidavits from a physician and had filled them in for the maximum importable amount of Laetrile, using the names of cancer patients who had in fact ordered smaller quantities or none at all. The druggist had then sold the surplus to other patients, sometimes getting the authorized release and sometimes not. A judge upheld the validity of the seizure, but, pending a Supreme Court decision, would not order the seized Laetrile destroyed.

The extensive litigation and the legislative battles in the states made Laetrile an issue of national interest and debate. News magazines carried cover stories (37). Television--including the program "60 Minutes" (146)--looked at Laetrile. The press kept tabulated track of contests in the states. Conservative columnists, most notably James J. Kilpatrick, attracted to the freedom of choice theme, repeatedly gave Laetrile users a prestigious boost (147). The promoters intensified their own publicity. Paperback successors followed Kittler's original success: G. Edward Griffin's World Without Cancer in 1974 (148); Mike Culbert's Freedom from Cancer in 1976 (149); John Richardson's Laetrile Case Histories (90) and Robert Bradford's Now That You Have Cancer in 1977 (150). A majority of American citizens, according to a Louis Harris poll, thought decriminalization of Laetrile would be a good idea (151). Some Laetrile leaders sounded smug at their success.

"Rest assured, gentlemen," Bradford told Senator Kennedy's subcommittee, "that the people demand Laetrile. . . And they are going to get it whether Big Brother wants it or not. . . . [W]e cannot expect that thousands of American cancer sufferers are going to wait for more long years, while the Federal Government fiddle-faddles through animal tests and more redtape. . . Do we really want another American civil war?" (152).

So disturbed became the state of the mass mind that a segment of sober opinion, unbelievers in Laetrile's efficacy, concluded that the speediest way to quiet public clamor would be to let Laetrile's worthlessness be proved either by widespread use or in a series of well controlled clinical trials in humans conducted by investigators of unimpeachable integrity and skill. Some scientists, indeed, believe that any drug should be tested for which suggestive evidence exists, even hearsay, that the drug might be of benefit. To test Laetrile in humans would breach the prevailing system, which puts the burden of proof upon a new drug's sponsor. Such a step, further, would fly in the face of the weight of animal evidence. The major pro-Laetrile

animal experiments, announced in 1977 at a National Health Federation meeting by Harold W. Manner, a zoologist at Loyola University in Chicago (153, 154), have received severe criticism on the grounds of inadequate methodology (155). Human trials with Laetrile, therefore, posed grave ethical questions respecting patient rights and the value of expending limited resources available for testing in such a way (156). But so dangerous seemed the consequences of the spirit behind the new Laetrile state laws that some commentators, both laymen and physicians, resorted to the forbidden fruit argument. The way to dampen "Laetrilomania," suggested F. J. Ingelfinger, distinguished editor of the New England Journal of Medicine, might be to reduce the glamor derived from its illicit status by making it freely available, and then keeping accurate records of patient experience (157). The editors of the New York Times took a similar tolerant approach toward Laetrile distribution (158). Charles G. Moertel of the Mayo Clinic favored a less extreme course: if Laetrile's sponsors would not assume their legal obligations, then reputable scientists must undertake the task. "The only established means of proving a drug effective or ineffective, safe or unsafe[,] is by a properly designed, tightly controlled clinical trial" (159).

Officials at the National Cancer Institute reluctantly reached the same conclusion. If such action had to come, FDA Commissioner Kennedy argued at Senator Kennedy's hearing, at least all parties must agree on the specific chemical formula, among the many that had been posited and marketed, of the "Laetrile" to be tested (160). Senator Kennedy labored diligently throughout the hearing and believed he had achieved a consensus on this point which included Laetrile's promoters. Tests would weigh the merit of amygdalin (161).

After careful review of the situation, National Cancer Institute officials decided not to launch human trials immediately, but to undertake a retrospective study of patients who, according to their physicians, might have benefited objectively from the use of Laetrile (162). From the purportedly 70,000 patients in the United States who had been treated with Laetrile, the NCI hoped to get full enough records to permit analysis of two or three hundred cases. In quest of such records a much publicized appeal went forth to the more than 400,000 physicians and other health professionals in the nation. The director of the project sought to persuade the Laetrile inner ring of leadership to urge physicians active in Laetrile prescribing to submit case records (163).

In the end, however, only ninety-three cancer cases were

submitted for evaluation, only twenty-two of them concerning patients who had been treated with Laetrile alone for whom the records were adequate for appraisal (164). A panel of twelve cancer experts stated that under Laetrile treatment apparently seven of the patients had worsened, nine had remained the same, and six had responded favorably, two with complete and four with partial remissions. These conclusions, the reviewers granted, had to be taken with a grain of salt because of the possible "submission of incorrect clinical interpretations, falsified data and intentional or unintentional omission of data." Nor had the review been designed to discover patients who had not responded to Laetrile. Nonetheless, more than two hundred physicians had volunteered evidence about more than a thousand patients who had shown no beneficial response.

After further review, the National Cancer Institute revived its earlier decision to undertake a clinical trial of amygdalin in some 150 to three hundred terminal cancer patients. Dr. Arthur Upton, NCI director, announced the plan in September 1978, expressing hope that the outcome would resolve the debate over Laetrile "once and for all" (165).

Such optimism seemed scarcely warranted. Laetrile proponents, while publicly appealing for testing, had been customarily reluctant or unable to provide complete data on patients for evaluation. The FDA's request for clinical records to Dr. Contreras and to a German experimenter, Dr. Hans Nieper, had not brought in usable material. Nieper submitted no data at all, and Contreras' case records, when evaluated by NCI scientists, showed no patient benefits ascribable to Laetrile (166). Contreras, in fact, insisted to a reporter that employing his clinic for purposes of research would be unethical (167). Nor had a whole succession of animal experiments, which to established cancer researchers offered no hint of Laetrile's efficacy, satisfied Laetrile's proponents, who sought to reinterpret a few such trials in a way favorable to their product (168).

From the beginning, indeed, as a basic premise, Laetrile's supporters questioned the validity of experiments conducted by experimenters who did not share faith in the theories supporting Laetrile's value. Pro-Laetrile physicians must direct the clinical trials, Krebs, Jr., had told the California Cancer Commission in 1952, or he would not provide Laetrile for experimentation (23). In 1977 Krebs made essentially the same point: those inside and outside the Laetrile movement "do not necessarily speak the same language" (107). Each dwells "in a different universe" (60). Unless, a pro-Laetrile physician told the Kennedy

subcommittee, the NCI study should be conducted "in the way that the proponents of Laetrile . . . are urging that it be done," then "it will be an absolute sham" (107). Robert Bradford echoed these sentiments: "the protocols that exist for orthodox therapy are not applicable[,] for the most part, to metabolic therapy and Laetrile" (95). Traditional oncologists, for example, held that the removal or reduction in the size of a neoplasm measured the success of therapy, whereas espousers of Vitamin B-17, believing cancer to be a deficiency disease, considered the size of the lump irrelevant. "You do not and cannot expect to get results from laetrile treatment," Bradford said at the Kansas City hearing, "unless you are a trained metabolic physician" (169).

Commissioner Donald Kennedy wondered if some maneuvers by Laetrile's promoters might not be intended for the purpose of disparaging test results adverse to the drug (160). "[I]n sifting the strange mixture of nomenclature, alleged chemical identity, and proposed mechanism of action that comprises Laetrile's record of the past twenty-five years," Dr. Kennedy said, "one becomes gradually convinced that these uncertainties are not accidental. They provide an effective cover for the promoters, since failure to achieve a result can always be attributed to having used the wrong material and arguments against one hypothesis of action can always be met by embracing another."

During the Vitamin B-17 period, the increasing stress upon "total metabolic therapy" marked another change in approach to the promotion of Laetrile. In treating cancer, according to the new doctrine, Laetrile alone could not be relied upon. While Vitamin B-17 held the indispensable place, it needed to be administered as part of a complex program involving a multitude of variables (150). The other parts consisted of diet, exercise, rest, detoxification, minerals, enzymes, vitamins A, C, and E, and that other major Krebs' promotion, Vitamin B-15 or pangamic acid. A patient might require "several dozen tablets every day."

In Bradford's book, Now That You Have Cancer, he likened the metabolic program to a crown containing nine jewels, with Laetrile "the crown jewel within that diadem" (150). Such a "total approach," combining an attack on the cancer, a bolstering of the body, and a positive mental attitude, metabolic physicians held, provided "the best chance to control cancer." If the metabolic doctrine bolstered Laetrile with a host of attendant therapies, the system also expanded Laetrile's prowess beyond cancer. In a book entitled How You Can Beat the Killer Diseases, Harold W. Harper accorded Laetrile a role in preventing and treating

a broad range of other ailments, including diabetes, emphysema, arthritis, and cardiovascular disease (170).

The diversified regimen of metabolic therapy certainly complicated the problem of evaluating in human trials Laetrile's role as a possible therapeutic agent for cancer, and made second-guessing of results inevitable. Nonetheless, the National Cancer Institute's Dr. Upton stated that, in devising the Institute's experiments, he would "not rule out the possibility of looking at combinations" of Laetrile and high-potency vitamins (165). Laetrile's advocates greeted the NCI's retrospective review as "Laetrile's biggest breakthrough," because "from now on the myth as to the 'officially' observed lack of validity in Laetrile has been destroyed" (171). Yet Bradford had told the Kansas City hearing that no "effective agreed upon protocol" for a study of cancer under metabolic therapy could be set up (169). Whatever a NCI trial might show, disputations between advocates of orthodoxy and champions of unorthodoxy seemed certain to continue.

The Pattern of Cancer Unorthodoxies

Health quackery has flourished since that ancient day when, as Voltaire put it, the first knave met the first fool. Through most of American history, nourished by the Enlightenment concepts of the Revolutionary generation, the presence of quackery has been acknowledged but its status has been considered transitory. When medical science had expanded its horizons a little further, when the populace had received a little more schooling, when the Congress had enacted another protective law, then would quackery vanish, consigned to the museum of outmoded delusions. Certainly through the Progressive period at the beginning of our own century, such optimism sustained itself (172). When the Pure Food and Drugs Act became law in 1906, the New York Times editorialized: "the purity and honesty of the . . . medicines of the people are guaranteed" (173).

As the twentieth century has proceeded, despite enhanced medical science, more universal schooling, and a great increase in social legislation, observers have grown less confident about predicting quackery's imminent demise. The course of events and the pathways of philosophy both have chilled such naive optimism. The doctrine of inevitable progress fell under the impact of a series of terrible wars. Faith in the inherent goodness of human nature, battered by new philosophical perspectives, crumbled under the revelations from the Nazi concentration camps. Belief in education as a panacea withered. Science-technology

inventiveness did continue to produce wondrous products for mankind's benefit but also devised nuclear weapons and polluted the environment. Modern industrial civilization struck many people as part of the cause for burgeoning unhappiness, Ernst Krebs, Jr., among them. At the Kansas City hearing, Krebs expressed abhorrence for "the horrible onslaught of technology blindly impinging upon the fragile flesh that contains our flame of life" (60). Some disturbed souls sought to return to nature. Pressing upon this long developing crisis of confidence came Vietnam, an unpopular and unsuccessful war that put generations at each other's throats, and Watergate, seeming proof of what some voices had long been crying, that blame for the discontents of civilization could be laid upon leadership.

Such an atmosphere induces irrational approaches to fundamental problems. The disillusioned, questing for new faith, are terribly vulnerable to false prophets. Distrust of established authorities encompasses all those who have traditionally sought to protect the public from charlatanry. The medical profession suffers suspicion, including the specialists within it concerned with cancer. In a behavioral survey sponsored by the Food and Drug Administration and other federal agencies, it was revealed that forty-two percent of American adults would not be persuaded by almost unanimous expert opinion that an unorthodox "cancer cure" held out false hope (101).

Cancer quackery in America goes back to the earliest days. In colonial times one purported cure consisted of alleged "Chinese Stones" vended by a self-styled Frenchman who hawked his wares from town to town (174). At the beginning of this century, the first major case lost by the government under the 1906 law had aimed at suppressing Dr. Johnson's Mild Combination Treatment for Cancer (175). By mid-century unorthodox cancer promotions loomed largest among the illegal operations which regulatory agencies sought to control.

Basic to this circumstance were both the impact and the image of cancer in our society. With the decline of infectious diseases as a cause of death, due to sanitation, vaccines, and chemotherapy, cancer had risen to second place in the mortality lists. The 1900 death rate for malignant neoplasms was 64 per 100,000 deaths, the 1977 estimated rate 177 (176). On the disease and death front, cancer had moved to the center of public attention. A sense of urgency led to an all-out attack, with billions of dollars appropriated by the Congress in imitation of the nation's venture into

outer space, in an effort to conquer cancer once and for all. But the enemy proved to be too complex for such a battle plan. Despite many advances, failure to fulfill the central promise brought new disillusionment (177).

Yet the image of cancer may be an even more important force for quackery than its factual circumstances. Heart deaths exceed cancer deaths, but no wave of cardiovascular cures has surfaced similar to those in the cancer field. That centuries ago cancer began to acquire a hostile and terrifying image may be deduced from the word "cancer" itself, derived from the Greek work for crab. The crawling spread of cancer, gradual but mainly relentless, whether external and observable or internal and secretive, through the centuries appeared to be, and indeed generally did amount to, a sentence of death. This image hangs on, a powerful force in men's minds, a force not adequately revised by the victories orthodoxy increasingly has won. In our mythology, Susan Sontag has written, cancer has become a "cosmic disease: the emblem of all the destructive, alien powers to which the organism is host . . . [C]ancer is thought of as a disease of the contamination of the whole world" (178). "As long as a particular disease is treated as an evil, invincible predator, not just a disease," she states, "most people with cancer will indeed be demoralized by learning what disease they have." And Sontag cites Karl Menninger to the effect that "the very word 'cancer' is said to kill some patients." This deeply imbedded fear is constantly revivified in the lurid tracts and the camp meeting oratory of orthodoxy's opponents.

Four major unorthodoxies have emerged in the United States during the last half century. First, a Detroit physician, William F. Koch, proclaimed his newly discovered Glyoxilide an anti-toxin for cancer. Each ampul, costing $25, Koch said, contained one part Glyoxilide to one trillion parts of water. Three thousand American health practitioners bought and administered the purported chemical, charging up to $300 per injection (179).

Second, a former coal miner, Harry Hoxsey, after treating external cancers with caustics here and there in Illinois, made his way to Dallas, Texas, where he set up a clinic for treating internal cancer. At its peak, the clinic had ten thousand patients on its books, charging each one a fixed four hundred dollar fee, prescribing a "pink medicine" and a "black medicine." The former contained lactated pepsin and potassium iodide, the latter a botanical laxative in an extract of prickly ash bark, buckthorn bark, barberry

root, licorice root, pokeweed, alfalfa, and red clover blossoms (32, 179).

Third, two Yugoslavian brothers named Durovic brought from Argentina to the United States a whitish powder called Krebiozen, said to have come from the blood of horses which had been injected with a micro-organism responsible for "lumpy jaw" in cattle (179, 180). Their assertion that Krebiozen could cure cancer won the dogged allegiance of one of the nation's leading cancer experts, Dr. Andrew Ivy of the University of Illinois. Thousands of physicians secured vials of this so-called investigational drug for eager patients, making a nine dollar "donation" for each ampul. In 1963 a team of FDA chemists, analyzing the only sample of Krebiozen ever secured from its sponsor, discovered it to be the common amino acid, creatin monohydrate. Simultaneous analyses of the Krebiozen distributed to physicians revealed it to be nothing but mineral oil.

The fourth major promotion has been that of Laetrile.

Laetrile possesses a more complex chronicle and a more varied cast of characters than those of Glyoxilide, Hoxsey's botanicals, and Krebiozen, and has created greater public impact and gained more political power than did its three predecessors. Nonetheless, Laetrile impresses the historian as conforming to a ten-point profile of health quackery derived from a study of past quackish ventures (181).

Exploitation of Fear

Quacks have traditionally scared their victims with disturbing language, frightening pictures, and grim statistics, stressing pain and threat of death. A turn-of-the-century pamphlet described gruesomely how cancer ate away the sufferer's nose, face, palate, and throat (182).

The modern promotional mode employs greater subtlety in playing on the morbid fear of cancer in our society. Laetrile agents try to reach patients when cancer has just been diagnosed and panic is high, and, like others before them, interpret orthodox therapies as essentially useless and more painful than the disease itself. One physician testifying in Kansas City told of a patient who, within a day of having lung cancer diagnosed, received Laetrile advertising in the mail (183). "Cutting, burning, and poisoning" to characterize surgery, radiation, and chemotherapy have become a litany in Laetrile literature (184). "Voodoo witchcraft" would do more good.

Promise of Painless Treatment and Good Results

"No knife or pain," advertised a Chicago cancer quack in 1912, promising to cure breast cancer (185). The history of cancer quackery reveals constant assurances of easy treatment and good results. In earlier days, sure cures were promised. More recently, prudence has dictated greater caution. By treating cancer with nothing more painful than injections of a non-toxic drug, according to a Laetrile tract, fifteen percent of patients with advanced metastasized cancer and eighty percent of those with early diagnosed cancer "will be saved" (186). And Dr. Richardson evoked the vision of a cancerless nation in a mere two-score years, achieved by nothing more arduous than regular oral doses of Laetrile (107).

Claims of a Miraculous Scientific Breakthrough

Marvelous new discoveries are a dime a dozen in the literature of quack promotions. In earlier times the secret might be an herb brought back by a missionary from some primitive overseas tribe or pried loose by an explorer from an Indian medicine man (187). Hoxsey attributed his botanical formula to the perception of his great-grandfather who noted the healing of the cancer on the leg of his horse which grazed in a pasture where the plants grew (32). Recent "discoveries" have generally been said to derive from inspired research. The Durovics' horse experiments in the Argentine furnish an example.

Laetrile's heroic tale centers on the humble physician, Ernst Krebs, Sr., busy with his practice yet always seeking out drugs and vitamins to benefit mankind, and on his son, Krebs, Jr., inveterate researcher, who modified the cyanide-containing chemical his father had found in apricot kernels so that it could kill cancer cells but leave healthy cells unharmed (2). To the audiences at the legion of Laetrile meetings before which Krebs, Jr., appears, he has become a figure of awe and veneration, acclaimed as a Pasteur and linked with the signers of the Declaration of Independence (188), a myth in his own time.

One Cause/One Therapeutic System

Quacks often win allegiance to their doctrines by promising to end confusion and doubt and to make complexity simple and comprehensible to the untutored mind. Disease, the quack says, has but one cause. Therefore, one treatment is all that is needed to fight it. In the nineteenth century Benjamin Brandreth blamed all illness on vitiation of

the blood caused by constipation (189). For a perfect panacea, therefore, try Brandreth's cathartic pills. Later Samuel Hartman's high-alcoholic Peruna promised only to cure catarrh, but Hartman defined catarrh to cover almost every symptom in the book (190).

A similar sweeping boldness has operated in the cancer realm. Reputable authorities now assert that there are as many different cancers as there are different common colds, over a hundred, with a broad range of causes. But for Koch all cancer came from a single toxin. For Hoxsey all cancer resulted from a disturbance in body chemistry. At the start, Laetrile's sponsors rooted their explanation in the unitarian or trophoblastic theory, and more lately have denominated all cancer dietary deficiency disease. Initially Laetrile alone played the role of virtual specific. "Laetrile does not palliate," Dr. Krebs wrote in an early pamphlet, "it acts chemically to kill the cancer cell selectively without injury to the normal tissues of the body" (191). Recently Laetrile in its new guise of Vitamin B-17 has assumed central place in a therapeutic system, complex, but according to its proponents, integrated. Robert Bradford envisioned metabolic health centers as "the wave of the medical future," replacing orthodoxy's rugged and allegedly futile methods, and heralding the day "when the killer degenerative [disease] . . . of the civilized world would come to an end" (150). In the same year Dr. John Richardson could posit use of Laetrile alone as a universal cancer preventive (107).

The implication of these futuristic claims is bold enough, in contrast with the restraint about Laetrile's current effectiveness in public utterances. At the hearings held by the FDA in Kansas City and by Senator Kennedy's subcommittee in Washington, Laetrile's sponsors made the most modest of claims. The public record, however, and private conversations sometimes take on a different tone. Ernst Krebs, Jr., could say in Kansas City, "We disclaim saving anyone's life" (60). But during a trial at which the state of California had charged Krebs with violating his probation, evidence indicated that his promises were not so circumscribed (192). A widow testified that her husband, learning that he had lung cancer, had rejected the operation which his doctor had told him had a ninety percent chance of success. Instead, having heard Krebs on television, the man looked his name up in the telephone directory and asked his advice. Krebs told the inquirer that, if he relied on Laetrile, his chance of recovery would be one hundred percent. Krebs sent the man to Dr. Richardson. Nine months later the man was dead.

The Galileo Ploy

In response to criticism from the community of scientists, quackery has often brought into play the Galileo ploy. The unorthodox say the orthodox are wrong, just as earlier critics condemned pioneering explorers, inventors, and scientists. We are, the unorthodox assert, like Columbus, Jenner, and Pasteur -- the list is long. We are today misunderstood by blind men but are destined to be heroes to future generations.

In 1951 at the trial of a woman who sold a so-called Radio Therapeutic Instrument, claiming it could cure cancer of the breast with rays beamed over great distances, her attorney trotted out Columbus, Harvey, and Semmelweiss in her defense (193). Laetrile promoters have offered the same gambit. The text of a film strip, World Without Cancer, likened Krebs, Jr., to these three worthies, as well as to Galileo and the Wright brothers (184). In praising Krebs before Senator Kennedy's subcommittee, Robert Bradford admitted that Krebs had "only an honorary doctorate," then added: "Are you aware, gentlemen, that Christopher Columbus never went to nautical school? Can we recall the shoddy credentials of Thomas Edison? Was Albert Einstein all that bright a student in school?" (95).

The Conspiracy Theory

Another time-tested response to criticism is the shouting of conspiracy. The scientific establishment doesn't dare recognize the validity of my great discovery, the quack claims, for it will undermine their power and prestige and eliminate their jobs. So the establishment scientists conspire to suppress the wonderful new remedy.

Koch, Hoxsey, and the Krebiozen forces all resorted to the conspiracy theory, and so do the Laetrile supporters. Dr. Richardson sees the Rockefeller family at the center of the web, controlling pharmaceutical manufacturers and preventing them from developing drugs not made from oil (194). The Rockefellers also control the American Cancer Society, a staunch foe of Laetrile. In this nightmare, the National Cancer Institute, the Food and Drug Administration, and organized medicine are likewise deemed members of the selfish conspiracy to suppress Laetrile.

Shifts to Adjust to Circumstances

Quackery has never felt obliged to retain a given posture if some change might offer greater prosperity or safety.

In the nineteenth century a cold cure that wasn't selling became a stomach remedy and reaped huge profits.

Laetrile's history has been marked by many changes. When the Krebs' version of amygdalin emerged, chemotherapy as a mode of treating cancer was new, public excitement about it high. The first pro-Laetrile paperback, Kittler's Control for Cancer, grafted the apricot pit drug onto that interest, stressed Laetrile's chemical nature, did not mention the word "vitamin" (2). By the 1970s nature's way toward health enjoyed great public favor, chemicals in cancer therapy had slipped some in popular prestige, and chemicals in the environment had come under grave suspicion. John Richardson's Laetrile Case Histories blasted chemotherapy in cancer, denied explicitly that Laetrile was a "drug," and concluded that control of cancer had been found "in nature" (195). From drug to vitamin, from cure to palliative and preventive, from low dosage to high dosage level, the pattern of Laetrile's postures has been kaleidoscopic. "The mere fact that there is a constantly changing set of theories as to why laetrile should be used or how it does work," asserted the American Medical Association to the Kennedy subcommittee, "is sufficient to lead objective persons to question the validity of any of the theories put forth" (196).

Reliance on Testimonials

Through history the testimonial has been a major weapon in the arsenal of quackery. When someone just like you and me says, with urgent sincerity, "I was cured," the persuasive power ranks high. "Our experience of more than thirty years in the enforcement of the Food and Drug Act," a former Commissioner once wrote, "has demonstrated that testimonials may be obtained for practically any article labeled as a treatment for practically any disease" (197). But testimonials given in the first flush of hope prove sadly premature. Old newspapers contain instances of testimonials appearing in the same issues with the obituaries of the testators (198). Modern science holds that drug efficacy can not be determined by individual instances, nor even by a series of such cases. Much more sophisticated scientific methods are required. As a matter of law, the Supreme Court has so ruled (199).

All major cancer unorthodoxies have relied heavily on testimonials. The despairing cancer victim hears or reads such success stories as part of an enthusiastic promotional presentation, one that resounds with a sense of conviction and with every evidence of sincere concern for the victim's welfare. He is offered hope, told things he himself may do

to take his own treatment into his own hands. His new painless therapy, his new diet, his sense of support from new acquaintances, his more cheerful expectations, do indeed enhance the way he feels. The placebo effect is powerful, if temporary, medicine. An injection of confidence may indeed give the patient a better appetite, let him gain weight, enhance the way he looks, improve the way he feels. If he has been suffering from the side effects of effective treatment, perhaps nausea and the loss of hair, a switch to unorthodoxy may end these unpleasant consequences. Under these circumstances both the patient and the doctor who is administering the unorthodox treatment may pen testimonials. If, as a result of previous or concomitant orthodox therapy, the patient's health may indeed be improved, the testimonial may nonetheless give all the credit to unorthodoxy.

In preparing for legal action against Hoxsey's enterprise, the Food and Drug Administration investigated the writers of all the testimonials which Hoxsey had printed in behalf of his internal cancer treatment (32). Hoxsey's claimed cures, the FDA was able to demonstrate in court, fell into three classes. Either the patients had never had cancer -- and some cancers are extremely difficult to diagnose -- although treated for it at Hoxsey's Dallas clinic. Or they had been cured of cancer by proper orthodox treatment before or while consulting Hoxsey. Or they had had cancer and either still were afflicted despite Hoxsey's treatment or else had died. This evidence substantiated the scientific inadequacy of anecdotal evidence, no matter how sincere the testimony. The same findings resulted from the National Cancer Institute's evaluation of Dr. Contreras' cases (166).

Further, one of the odd paradoxes relating to quackery is that failure seldom diminishes patient loyalty. The duped seem unable to realize deception has occurred. The quack has done such a good job of exuding sincerity and concern that the victim believes the false explanation that the specious remedy or routine would have healed had treatment only begun a little sooner. And the misery of the decline toward death had seemed, under the unorthodox regimen, less arduous than would otherwise have been the case (200).

Laetrile promotion has relied heavily on testimonial evidence, given by patients before legislative committees, compiled by Laetrile advocates between the covers of books. The scientific weakness of such an approach, as exemplified by Dr. John Richardson's Laetrile Case Histories, receives stark underlining in the analysis of this volume presented in Commissioner Kennedy's report to the Oklahoma court (21).

Distortion of the Idea of "Freedom"

Before food and drug laws were enacted, quacks waved the banner of "freedom" to smear criticism aimed at them by physicians and pharmacists. When drug laws came, quacks formed protest groups with high-sounding names, like the National League for Medical Freedom and the American Medical Liberty League (201). "Freedom" is certainly one of the most treasured words in the American lexicon. As has been seen above, the manipulation of this word by unorthodox health promoters has constituted their major symbolic campaign during the last quarter century. Thus Laetrile's loud appeal for "freedom of choice" in cancer therapy is nothing new. Pushed with vigor, however, by those with untraconservative convictions about the governmental role in society, in a climate of opinion worried about over-regulation, Laetrile's "freedom" pitch has persuaded more numerous converts to its cause than any previous unorthodoxy has succeeded in winning. The prevailing mythology of cancer, Susan Sontag has written, conjoins with "a simplistic view of the world that can turn paranoid." "Perhaps," she adds, "right-wing groups are the main organized support for quack cures like Laetrile because they also share a paranoid view of the world" (178).

Such a direction for "freedom" leads toward the license of those ancient days, when "the toadstool millionaires," operating without restraint, fleeced and often killed their victims. That is a fate from which seven decades of constructive legislation, beginning with the Pure Food and Drugs Act of 1906, has somewhat rescued the nation. Complex, modern, industrial, urbanized society, with standards of medical judgment far more precise than in the nineteenth century, can not afford to let the nation's health concerns be governed by a distorted definition of that great symbol "freedom" which would return piratical anarchy to the realm of health.

Large Sums of Money Are Involved

It was Oliver Wendell Holmes who termed nineteenth century nostrum vendors "toadstool millionaires" (202). They might not make a million, but money was their goal.

Laetrile is big business. Investigations by California authorities revealed what huge sums 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 users at 75,000, the mathematics mounts to millions.

Laetrile Within the Perspective of the Past

Fear of cancer, suspicion of government, a primitivistic retreat from complex civilization to "natural" ways, skillful organization, adept lobbying, and a shrewdness at borrowing time-tested techniques from quackery's well-stocked past, such factors undergird the Laetrile movement. In the face of scientific evidence and informed advice, frightened people place vain hope in it.

What guide might the past provide as to Laetrile's future? The other major cancer unorthodoxies of the twentieth century, Glyoxilide, Hoxsey's botanicals, Krebiozen, have virtually disappeared within the United States, although they linger outside the nation's borders, available to the desperate traveler. What brought Koch, Hoxsey, the Durovics and Ivy down from their peaks of prominence was a combination of vigorous regulatory action, sustained critique, and faddist fascination with still newer unorthodoxies.

Dr. William Koch underwent two very long trials in 1943 and 1946, charged with promoting misbranded and ineffective drugs (179). The first ended with a hung jury, the second when a juror became ill. Koch gave up business and retired to Brazil. Against Harry Hoxsey, the Food and Drug Administration initiated numerous actions. Injunction proceedings begun in 1950 before a judge disposed in Hoxsey's favor were finally won only after the case had twice reached the Supreme Court (32). In 1957 an injunction closed Hoxsey's satellite operation in Pennsylvania. Krebiozen came to a halt in interstate commerce when its sponsors withdrew a plan for the investigational use of the drug which they had submitted to the FDA (179, 180). This ban held, even though the government failed to convict the Durovics and Dr. Ivy in a nine-month criminal case decided in 1966 by a Chicago jury. Later, an investigation of jury tampering led to the conviction and jailing of one of the jurors. Thus regulatory action almost completely removed the unorthodox cancer treatments from interstate commerce, permitting their sponsors almost no elbow room for continuing promotion.

Not that unorthodoxy did not fight back. Hoxsey, for example, strove strenuously for political support, gaining favorable recognition from several United States Senators (32). And he sought to establish and ally with organized support for his cancer clinic. In 1959 Hoxsey spoke at a naturopathic convention in Chicago, which also hearkened to the National Health Federation's president, Fred J. Hart. At NHF membership rallies, Hart solicited funds to help Hoxsey carry on his contest with the FDA, and Hoxsey in turn gave royalties from his autobiography to help finance the NHF. Despite his efforts, Hoxsey did not develop an institutional base broad and strong enough to permit his unorthodox clinics to survive. Nor did the promoters of Glyoxilide or Krebiozen succeed with similar attempts.

Prior to Laetrile's series of victories in the legislatures of seventeen states, the major political triumph achieved by the forces of unorthodoxy came in the national Congress with the enactment of the Vitamin Amendments of 1976 (102). Led by the National Health Federation, promoters of nutritional products skillfully mobilized their followers into a powerful lobbying force. By securing the new law, the health food industry not only succeeded in thwarting the Food and Drug Administration's attempt to tighten the stringency of regulation in this field, they won from Congress a curtailment of FDA's authority below that which had been given the agency by Congress in the 1938 law.

This episode reveals that health unorthodoxy has the capability of mounting sufficient political power to win important victories. The obviously growing strength of nutritional unorthodoxy may well have played a role in Laetrile's transmogrification into a "vitamin." The National Health Federation has accepted and promoted Laetrile's vitamin status. In 1977 the NHF made legalizing Laetrile its "No. 1 priority" (205). It remains to be seen whether the millions of Americans who flirt with nutritional unorthodoxy will welcome an anti-cancer Vitamin B-17. Not all citizens who believe in extra vitamins as a sure road to extra pep may so readily accept vitamins in the treatment of cancer.

No previous cancer unorthodoxy ever approximated the institutional base which Laetrile achieved, resting on the International Association of Cancer Victims and Friends; the Cancer Control Society, formed by dissident members of the IACVF (206); and particularly the Committee for Freedom of Choice in Cancer Therapy, whose motivation is as much political as therapeutic. The big question is whether this political base is firm enough to establish Laetrile in an

institutionalized sense in our society, whatever else may happen. Indeed, it may be surmised that Laetrile's boom has peaked and now is in decline. Reports about toxicity doubtless dampened public ardor. Laetrile bills before state legislatures did not fare so well during 1978 as in 1977 (115). Future consideration and reconsideration may find state assemblymen looking more probingly past the freedom of choice argument at the scientific facts, following the example of Massachusetts (207). Inquiries about Laetrile to the Food and Drug Administration have fallen off (208). Media coverage has declined, despite such newsworthy events as the announcement of the National Cancer Institute's proposed trials and the Tenth Circuit's decision in the Rutherford case. Even should that decision stand, the legal use of Laetrile would be drastically curtailed from the level defined in Judge Bohanon's decision, with oral dosage forms eliminated. The Supreme Court, in adjudicating between the Tenth and Seventh Circuits, may confirm the FDA's authority to ban Laetrile completely from interstate commerce (209).

Even if Laetrile should follow Krebiozen and the others off center stage, this does not mean unorthodoxy's demise. As long as cancers remain a grave problem and wear a fearful image, quackery threatens. Much disenchantment exists with scientific medicine. Cancer patients have felt rejected by some orthodox physicians who have seemed to lose interest in their cases when nothing more medically could be done. The unorthodox offer considerable psychological support. The quixotic state of public feelings about health conduces to strange enthusiasms and open sesame for charlatans. Despite such a hopeful development as the hospice movement (210), offering skilled and considerate support to the dying and their families, a gloomy prognosis is hard to avoid. The broader and more diffuse approach of metabolic therapy, in which Laetrile is now enveloped, may prove a more difficult regulatory problem to confront than combatting a single unproven entity.

A shrewd and seasoned observer, looking ahead, recently took a somber tone (211): "During the past decade, a change has taken place in public attitudes toward medical science. There has been an increasing acceptance of misinformation, as shown for example by the success of the laetrile and 'health food' movements. This acceptance has been aided by the media, especially television, which publicize sensational and erroneous statements. These are seldom rebutted. There is distrust of the 'establishment,' and a feeling that doctors are exploiting patients. I believe this trend is so well established, and so little

challenged, that its impact will produce a decline of scientific medicine, and its replacement by quackery."

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3. Laetrile at Sloan-Kettering: A Case Study

For promising new anti-cancer agents, the traditional route from laboratory to clinic has been via tests in animals. The Food and Drug Administration usually evaluates the suitability of new drugs for testing in human beings on the basis, in part, of the performance of the drugs in appropriate animal models (1). Success in animal tests is thus a prerequisite for clinical trials. But Laetrile, also known as amygdalin or vitamin B-17, has been used by human cancer patients for years, without having been subjected to controlled clinical trials. What data are available about its effects in human cancer patients are largely anecdotal.

There is, however, now a considerable body of literature on the effects of Laetrile on animal tumors, a significant portion of which is derived from experiments conducted at the Sloan-Kettering Institute for Cancer Research in New York City between 1972 and 1977. Like practically every aspect of the scientific and political history of Laetrile, the testing of the compound at Sloan-Kettering has been surrounded by controversy. And despite the fact that the findings of the prestigious research center were predominantly negative in animal studies, the National Cancer Institute has supported going ahead with clinical trials of Laetrile.

Even prior to the extensive Sloan-Kettering experiments with Laetrile, the National Cancer Institute had sponsored a number of studies of the substance in animals (2). These tests had proved to be negative, at least to the satisfaction of their sponsors and the researchers who conducted them. But even though the results of these tests had been widely publicized, they seemed to have had little dampening effect on the use and promotion of Laetrile, nor on calls for clinical tests. In 1972 Benno Schmidt, a member of the board of directors of Sloan-Kettering, called for that institution to test Laetrile thoroughly in animals so that it might be able

to back its negative responses to frequent inquiries about the purported cancer cure "with some conviction" (3, p. 1231).

From both a scientific and public relations viewpoint Sloan-Kettering should have been the ideal institution to render a final verdict on Laetrile. Not only was it an internationally known center for research on and treatment of cancer, it also boasted a history of having screened tens of thousands of potential anti-cancer agents in animal tests. The techniques of evaluating new drugs were thus highly developed at the institute. "This institution," said Sloan-Kettering president Lewis Thomas in late 1972, "can answer the Laetrile question fairly quickly" (3, p. 1231).

In addition to the expertise and prestige that Sloan-Kettering promised to bring to its Laetrile experiments, the cancer center studies would also have a technical aspect that would make their results more significant than previous animal tests -- the use of so-called spontaneous tumors.

All previous NCI-sponsored tests had been performed on transplantable animal tumors. As the name implies, these are cancers that develop in one animal and are transferred surgically to another, closely related animal. This technique gives experimenters a high degree of control over the timing, size and site of experimental cancers, but it has been criticized for producing an experimental tumor model that may be quite far removed from the tumors that develop naturally in human patients (4). Spontaneous tumors, by contrast, are those that arise naturally in certain strains of laboratory animals and that are treated in the animal in which they develop, a situation many believe to more closely approximate -- especially in terms of immunological response -- the natural history of many human cancers. The Sloan-Kettering tests, being the first extensive systematic studies of the effects of Laetrile in spontaneous animal tumors, thus promised to be particularly relevant to the question of whether or not clinical trials of Laetrile in human patients might be warranted.

The Sloan-Kettering experiments began under the direction of Lloyd Old, the institute's vice-president for basic research and Chester Stock, the vice-president for chemotherapy research. The initial experiments were carried out by Kanematsu Sugiura, a veteran researcher with more than sixty years experience at the institute.

The material that Sugiura tested was amygdalin prepared in Mexico and supplied to Sloan-Kettering by the McNaughton Foundation, an organization that had been granted and then

quickly denied FDA approval to test Laetrile clinically in 1970. Sugiura used this material to treat a strain of laboratory mice called CD_8F_1, a hybrid in which eighty percent of the females spontaneously develop mammary tumors at about the age of ten months.

From the point of view of those who had hoped for a quick, negative judgment on Laetrile, Sugiura came up with resoundingly "wrong" results. In three separate experiments he found that Laetrile, though failing to actually eliminate the primary tumor, did appear to retard its growth. What's more, he found that the Laetrile-treated animals had fewer metastases (secondary tumors) in their lungs than did the control animals, which received an inert saline solution. Since it is often the metastatic spread of cancer that is responsible for the lethal effects of the disease, this finding was of great potential clinical significance. In addition, Sugiura observed that the Laetrile-treated animals appeared to be livelier and healthier-looking than the control animals.

Sugiura's unexpected findings were not published in the scientific literature, nor were they made public by Sloan-Kettering. "If we had published those early positive data," Chester Stock later told a journalist, "it would have raised all kind of havoc" (3). Instead, news of Sugiura's results was leaked from Sloan-Kettering and publicized by an organization called The Committee for Freedom of Choice in Cancer Therapy, a pro-Laetrile group founded in 1972 to aid in the defense of John Richardson, a physician who was being tried for using Laetrile in cancer therapy. The Committee for Freedom of Choice is a right-wing group politically, all but one of its present officers being active members of the ultra-conservative John Birch Society (5). The Committee published Sugiura's findings in a pamphlet, "Anatomy of a Coverup" (6).

Sloan-Kettering's response to Sugiura's results and the attendant publicity was to step up the Laetrile research program. Daniel Martin, a surgeon and cancer researcher who had been supplying the CD_8F_1 mice from his colony at the Catholic Medical Center in Queens, New York, became an active participant in the studies. Martin, an outspoken opponent of Laetrile, conducted independent studies with the substance, as well as collaborative experiments with Sloan-Kettering scientists, including Sugiura.

While these additional experiments were being carried out at Sloan-Kettering and the Catholic Medical Center, the pro-Laetrile movement was gaining political momentum, achiev-

ing a striking series of political victories. By the middle of 1977, despite the fact that federal laws still forbade importation or interstate commerce in Laetrile, the apricot-pit derivative had received some level of legal acceptance in more than a dozen states. Even within the medical establishment, the opinion was being voiced that some kind of clinical evaluation of Laetrile might be desirable, if only to prove once and for all that it had no worth in the treatment of human cancers. Franz Ingelfinger, then editor of the New England Journal of Medicine and a cancer patient himself, wrote an editorial calling for the legalized sale and use of Laetrile. "Prohibition, however," he wrote, "should be replaced by accurate record-keeping so that patients given the agent can be identified and followed. Then, after a period of perhaps two years, an evaluation should be undertaken, not by committees appointed by the FDA or AMA but by a group broadly representative of society" (7, p. 1168).

It was in this atmosphere of increasing pressure for the legalization and clinical evaluation of Laetrile that Sloan-Kettering called a press conference, in June, 1977, to make public the results of their five years of Laetrile experiments. Reporters attending the conference were given copies of two scientific papers that were scheduled to appear the following winter in the Journal of Surgical Oncology. Chester Stock was the principal author of both papers, one of which dealt with experiments in transplantable tumors (8) and the other in spontaneous tumors (9).

The conclusion presented in the two papers, and expressed by Sloan-Kettering spokespersons at the press conference, was overwhelmingly negative. Laetrile, they reported, had been confirmed to have no anti-cancer effects against a wide spectrum of transplantable tumors, and in the spontaneous systems the verdict was that Laetrile "was found to possess neither preventive, nor tumor-regressant, nor anti-metastatic, nor curative anticancer activity" (9).

In none of the collaborative or independent studies conducted after Sugiura's initial positive findings were the veteran researcher's results duplicated. His findings were described as "seriously challenged" by the body of subsequent experiments, including those in which he participated.

Nonetheless it was noted that Sugiura still believed Laetrile to be a "palliative" if not a cure for cancer, and when questioned whether he stood by his positive results in the face of later studies, he responded, "I stick."

As to the question of clinical trials for Laetrile, the

authors of the Sloan-Kettering papers wrote: "We do not have evidence supporting taking amygdalin to clinical trial, although other considerations may require one be conducted" (9).

Among the "other considerations" affecting the future of Laetrile testing was a challenge to the political and scientific integrity of Sloan-Kettering's Laetrile research not from outside or the political right, but from inside and the left. In November of 1977, about five months after the Sloan-Kettering press conference, another press conference was held in New York, this one by a group called Second Opinion, which had just published a 48-page pamphlet on Laetrile at Sloan-Kettering (10). The group charged that the work described in the June Sloan-Kettering papers was "both incomplete and scientifically invalid" (10, p. 1).

The Second Opinion organization described itself as a group of rank-and-file employees of the Memorial Sloan-Kettering Cancer Center, including both scientific and non-scientific personnel. An offshoot of the radical national organization Science For the People, Second Opinion claimed that its basic aim was to organize the workers at Sloan-Kettering. In the "war on cancer," the group advocated "putting prevention first, making research relevant to human diseases," and encouraged "an open-minded policy toward new and unorthodox methods, making the best treatment available to all people, and taking the profit out of cancer"(11, p. 8).

Until the Second Opinion press conference, no employee of Sloan-Kettering had ever publicly identified himself as a member of the organization. The only name openly associated with the group had been that of a City University graduate student. But at this press conference, Ralph Moss, Sloan-Kettering's Assistant Director for Public Affairs, identified himself as a member of Second Opinion. He was fired from that position on the next working day.

According to the Second Opinion report, a fair test of Laetrile had been impossible at Sloan-Kettering from the start. The group's analysis of anti-Laetrile sentiment at the institution included the assertion that Sloan-Kettering had been set up not to produce just any cancer cure, but a patentable one. The pamphlet argued:

> What is wrong is that the promotion of one kind of cancer therapy has brought with it the suppression of other kinds. In this case, a chemical cure for cancer was promoted to the rafters, while most other approaches were ignored or suppressed (10, pp. 46-47).

Though it cited the board of Sloan-Kettering as being made up of some of "the richest and most powerful men in the world," it claimed to "reject all . . . narrow conspiracy theories, which basically exonerate the real culprit: the profit system and especially its twentieth century form, monopoly capitalism" (10, pp. 47-48).

Clearly, the bedfellows made in Laetrile politics proved to be no less strange than those made in the other political arenas. Although Second Opinion's press conference was co-sponsored by the Committee for Freedom of Choice in Cancer Therapy, Second Opinion specifically stated in its report that "freedom of choice is not the issue," partly because it is "not very meaningful to the poor, who cannot afford any decent cancer treatment, much less private cures in a 'metabolic therapy sanitorium'" (10, p. 48).

The anonymous authors of Second Opinion asked readers of their report who did not share their political perspective not to reject their scientific critique of Sloan-Kettering's Laetrile experiments because of ideological differences. That critique proved to be a wide-ranging analysis that included charges that Sloan-Kettering had failed to report pro-Laetrile findings (other than Sugiura's) from experiments conducted at the center and that it had willfully misrepresented the results of those experiments that it did report. Most of the criticism was directed toward the crucial studies of spontaneous tumors. Although Second Opinion claimed to find some flaws in the experiments with transplantable tumors, it conceded that the Sloan-Kettering findings in those systems were consistent with those of other researchers and that in general Laetrile did not seem to be an effective therapeutic agent in such cancers. But in spontaneous tumors the group claimed that there was "still a need for further examination of amygdalin, as well as related compounds, in spontaneous tumor systems in animals and in man" (10, p. 1).

Among the charges of incompleteness made by Second Opinion, the most serious was that an experiment had been carried out between December 1973 and January 1974 in the laboratory of Elisabeth Stockert at Sloan-Kettering. This experiment was conducted with a strain of laboratory mice that, like the CD_8F_1 strain with which Sugiura had worked, develops spontaneous breast cancer. Second Opinion claimed that Stockert had obtained results similar to those reported by Sugiura and included in their pamphlet a copy of a memo written by a technician in Stockert's laboratory and addressed to Sloan-Kettering vice-president Lloyd Old. The technician reported longer life, healthier appearance, retarded tumor growth and fewer lung metastases among the mice treated with

Laetrile than among control animals.

Though not challenging the authenticity of the document, Chester Stock explained that his failure to include a report of the experiment in the scientific papers of which he is principal author hardly indicates a will to maliciously "suppress" pro-Laetrile findings. In the first place, he said, he was not even aware of the work until it was brought to his attention by the Second Opinion report. But even had he known about it he insisted that he would never have published it because the results as presented were "uninterpretable" (3, p. 1234). Elisabeth Stockert, in whose laboratory the work was done, attributed the fact that she did not bring the study to Stock's attention to her view of the experiment as only a preliminary study designed not so much to test Laetrile as to familiarize herself and her staff with the animals and material involved. Furthermore, she pointed out that she had been called away to Europe in the middle of the study and that it was therefore never, in her judgment, properly completed (12).

Sloan-Kettering thus acknowledged the existence, though not the validity, of the Stockert experiment. While the version of the paper on experiments with spontaneous tumors presented at the June press conference claimed to present data from "all anti-tumor experiments with amygdalin tested in these spontaneous tumor systems," the version published in the Journal of Surgical Oncology the following spring included the phrase". . . all properly completed anti-tumor experiments. . . ." (13) [underline mine].

Sloan-Kettering never picked up the Second Opinion gauntlet and answered the group's scientific critique on a point by point basis either in the press conference format in which those results were originally presented nor in the less public medium of the scientific literature. The cancer center maintained its initial conclusions about Laetrile and allowed Sugiura's anomalous results to stand unexplained. However, in response to criticisms from within the scientific establishment as well as from Second Opinion, Sloan-Kettering did make one other change in the paper on spontaneous tumors between the June press conference and the Journal of Surgical Oncology publication. The press conference version of the paper contained the following paragraph:

> It is concluded that Laetrile (amygdalin) lacks anti-cancer activity against the CD_8F_1 spontaneous mammary tumor. It seems particularly relevant as it is a "solid" tumor with demonstrated clinical therapeutic predictive ability. Of those 8 agents

> declared clinically active against human breast cancer by the National Cancer Institute, all 8 agents also are active against this murine breast cancer. This unique therapeutic correlation between this animal tumor and human cancer findings has led to this tumor's selection as one of the four major animal tumor models of the national screening program for anti-cancer agents. Thus, the negative Laetrile findings in this animal tumor model appear particularly significant (9).

To many readers this paragraph gave the impression that Laetrile's failure to show anti-tumor effects in the Sloan-Kettering tests was an excellent indication that Laetrile would also fail to work against human cancers because all the drugs known to work against human breast cancer had been shown to also work against the spontaneous mouse tumor that Laetrile had failed to control. Laetrile, it would seem, had not only proved ineffective, but had proved so where many other drugs had succeeded. Such a notion, however, is a serious distortion of the truth.

A review of the literature published on the CD_8F_1 experimental tumor system at the time of Sloan-Kettering's press conference reveals that the primary spontaneous tumor, treated in the same animal in which it arose, had proved extremely resistant to the effects of many known powerful anti-cancer agents (14). So resistant was the spontaneous tumor that it had been "largely shelved" as a methodology of screening substances for anti-cancer activity, presumably because its great resistance to such effects might mean that agents that had considerable promise in cancer treatment might not reveal that promise against the tumor.

The CD_8F_1 tumor system against which the eight agents referred to in the original Sloan-Kettering paper had shown effects was in fact not the spontaneous tumor treated in the host animal, but a system in which a tumor from a mature female was transplanted to a young male and treated as soon as a day later. These so-called "early" transplantable tumors were described by Daniel Martin, who had pioneered in working with the CD_8F_1 mouse strain, as "the most sensitive in picking up anti-cancer activity" (14). Thus, it appeared that the Sloan-Kettering paper was comparing the negative results of Laetrile in the most resistant CD_8F_1 tumor test with the positive results of other drugs in the least resistant CD_8F_1 test, a comparison in which Laetrile would be certain to suffer, and which would seem to make an especially strong case for keeping Laetrile from being clinically tried.

The publication of the Second Opinion report on Laetrile and the subsequent dismissal of Ralph Moss from Sloan-Kettering's public affairs department was followed, in early December of 1977, by the publication of an article in The Sciences, the magazine of the New York Academy of Sciences, which had been conducting an independent investigation of the handling of Laetrile research at Sloan-Kettering. Although this article did not challenge the overall verdict of Sloan-Kettering on Laetrile, it did call attention to the unusual circumstances and form of the cancer center's publication of their results, and especially to the misleading paragraph about the CD_8F_1 spontaneous tumor system. The article concluded:

> Differences of interpretation are a legitimate and inevitable part of the scientific process. But when they seem to be offered in response to public or political pressure, science suffers and so, ultimately, does the public which depends on it (15, p. 13).

The Sciences' article prompted Lawrence Altman, a physician reporter at the New York Times to interview Chester Stock about the misleading statement. Stock explained that it had originated with Daniel Martin. "We accepted the statement from Dr. Martin as submitted," Stock told The Times, "I did not check the original publications to be certain of the appropriateness of the statement. It should not have been used in the context of this report, and therefore it has been deleted" (16). Stock credited the appearance of the statement to Daniel Martin's "overenthusiasm."

Herbert Kayden, a cardiologist and then president of the New York Academy of Sciences, taking care to remark that "there is nothing that warrants Laetrile as a useful agent in the treatment of cancer," characterized Martin's statement as a "procedural error" and said that the "misinterpretation by Dr. Martin was not excusable." He praised Chester Stock for his commitment to removing the misleading paragraph from the journal version of the Sloan-Kettering paper (16).

Kayden's concern was echoed in the medical press. Derek Cassels, clinical editor of The Medical Post, a fortnightly review of medical news and opinion published in Canada, wrote in a full-page editorial that "like Caesar's wife, the way a scientific argument is put must be above reproach. This is particularly true when it is being used to shoot at another thesis -- one widely thought to be false."

"We sympathize with investigators who are working under

pressure from inside and outside an institution 'to produce,'" the editorial concluded, "But it is in such a situation where there is an enormous amount of public scrutiny that their findings must be absolutely honest" (17).

In the version of the paper published in the Journal of Surgical Oncology, the paragraph was removed, and the following addendum explained:

> The CD_8F_1 murine spontaneous mammary cancer is an animal tumor model with clinical therapeutic predictive ability because the anti-cancer agents considered clinically active against human breast cancer also are effective against this murine breast cancer. Therefore, in this therapeutically relevant animal tumor model, the finding that Laetrile is devoid of anti-cancer activity is particularly pertinent.
>
> In the original pre-publication version of this paper the paragraph making the above point did not state that the test system, which established the unique therapeutic correlations between this animal tumor and human cancer findings, employs first generation tumor transplants. That paragraph placed within the context of a report on spontaneous animal tumors was interpreted by some to indicate that the therapeutic correlations were determined on the murine spontaneous tumor system per se; therefore, that paragraph has been deleted from the paper so as not to be misleading in this regard (13, p. 122).

The Sloan-Kettering experience with Laetrile, characterized by journalist Nicholas Wade of Science as "a painful case of overexposure," (3, p. 1231) appears to have been one in which the political and scientific domains inter-penetrated and affected each other's processes to a far greater extent than usual. This view has perhaps been best expressed by Robert Good, president and director of the Sloan-Kettering Institute: "I sure as hell wish the Sloan-Kettering Institure had not taken on the testing," he said. "It's been such a bag of worms. It has nothing to do with science; it has to do with politics" (3, p. 1231).

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4. The Political Implications of Laetrile: Who Gets What, When and How

We in the Public Health Services are concerned about the increasing use of Laetrile by cancer patients in this country.

Laetrile is a cyanide-containing substance derived from apricot and other fruit kernels. Its proponents say that it is effective in the prevention, cure or control of cancer.

No evidence to support these claims has ever been submitted to the Food and Drug Administration. The National Cancer Institute has conducted five tests on Laetrile and concluded that it is ineffective in animal systems. There have been many other tests of Laetrile in animals, and FDA and NCI have even looked at the records of patients who have used Laetrile to see whether there is any evidence at all that it works.

We have found none. And in fact there is considerable evidence that it does not work.

Julius Richmond, M.D.
Assistant Secretary of Health

...The problem is that one side, the side that opposes Laetrile, is in control of the government, and is using it to suppress the other. In no other area is it more obvious that the government should be kept out. Once again, your editors are not physicians, and do not know whether Laetrile is the answer to cancer or not. But whether or not it is should be decided not by government force -- but by free physicians working with their patients and in

> their laboratories. Why is it that the U.S. Supreme Court says physicians may perform abortions, on the ground that the physician-patient relationship is inviolable -- but that the same physician is not permitted to prescribe Laetrile for his patients...not to destroy life but to save it? Why are we told that a patient has the 'right to die with dignity,' but may not take Laetrile in an attempt to live? Indeed, also because of government intervention and suppression, smugglers are now selling Laetrile which therapists have found defective.
>
> Let's return medicine to the doctors, and patients, before cancer victims and their relatives begin hanging F.D.A. medicrats from trees.
>
> Alan Stang
> American Opinion
> *(Conservative Journal of Public Affairs)*

The quotes cited above help to summarize the highly charged and often emotional debate over the legalization of Laetrile in the U.S. over the last three years. This debate has been most intensive at the State level. Forty-one states have acted on legislative proposals to legalize the sale of Laetrile in their particular states. As of March 1979, 22 states had rejected such proposals for legalization, and by the summer, 21 states had acted positively on them.

How does one explain the "success" of the Laetrile proponents in their efforts to legalize Laetrile at the State level? Is it a case of challenging the power of "big government" represented by the United States Food and Drug Administration (FDA)? Is it part of a nation-wide movement toward deregulation? Is it part of a more global strategy to challenge the mandate of the FDA: to insure that all drugs meet the criteria of being safe and efficacious? This paper will address these questions from the perspective of each of the major actors in the "Laetrile controversy."

It is very clear that the issue of whether to legalize Laetrile and, more importantly, the questions that are being raised in the context of debating this issue, can best be understood when thought of as a classical political controversy (1). There are competing claims for resolution of an issue which is "of great importance" to several different groups, each of which is recognized to have a "legitimate position." None of the positions can be considered to be a priori "right" or "wrong." Political actors (decision-makers) face the dilemma of having the formal/legal responsibility of

reconciling these competing "legitimate positions." Thus, the process of reaching a decision (i.e., a compromise or the decision to adopt one of the competing claims) is as important as the substance of the decision that is ultimately taken.

In the case of Laetrile, there is an important additional political dimension. From the perspective of the federal government and some state governments, the Laetrile movement can be characterized as a political disease: Laetrile is, therefore, only a symptom of a larger political disease, which can be described in terms similar to those used to characterize cancer: it is dreaded, its roots stem from many areas (dissatisfaction with government, the medical profession, and "scientific testing procedures"), and it evokes a great deal of emotion and misunderstanding. Most importantly, this "political disease" is not open to a single cure and certainly not the traditional ones (i.e., more regulation) that have been employed in the past.

This paper is devoted to exploring the politics behind the Laetrile movement: what is at stake, and for whom? Who are the major actors and what assumptions are they making about the nature of Laetrile and the "Laetrile movement"? In what arena is the Laetrile issue being debated, and why was this arena chosen? What can be expected in the future?

Model of Analysis

One can learn a great deal about politics and the political implications of an issue by analyzing the definition of the problem put forward by each of the major actors who have a stake in the ultimate outcome of a particular decision. Problem definitions are based on assumptions about the "causes" of a problem and where they lie. Studies have shown that the way a problem is defined determines the attempts at remediation, suggesting both the foci and the techniques of intervention and by ruling out alternative possibilities (2). More specifically, problem definitions determine the strategy that is adopted to bring about change in a particular issue area (3). It would also seem to follow that whoever can have his/her definition of the problem accepted as the basis of decision-making will have the most to gain when a decision is taken. However, it may also be the case that "integrative modes" of problem solving are employed so as to emphasize collaborative solutions -- how opposing parties can both gain -- as opposed to distributive solutions where only one gains at the expense of another (4).

Much of this paper will be devoted to illustrating how

the Laetrile controversy can be viewed in terms of a set of conflicting problem definitions by several key actors (groups).

Before exploring the conflicting assumptions inherent in this movement, it is worth describing the background of this controversy and the areas over which there are no disagreements.

Political Background/History

The terms Laetrile and amygdalin are often used interchangeably (5). Ernst T. Krebs, Sr., a California physician, first attempted to use Laetrile as a cancer treatment in 1920. However, the drug, as extracted from apricot pits, was too toxic for human use. Dr. Krebs' son, Ernst T. Krebs, Jr., developed a purified form of Laetrile which was less toxic and advocated it as an effective treatment for cancer.

In 1961, Mr. Krebs, Jr., doing business with his father as the John Beard Memorial Foundation, and the Foundation, were both convicted of illegally promoting another drug -- "Vitamin B-15" -- for improving the performance of race horses. The U.S. District Court of San Francisco fined Mr. Krebs, Jr., and the Foundation $3,750 and put Mr. Krebs on probation for three years. As a condition of probation he was prohibited from shipping any new drugs, including Laetrile, without first having it approved by the FDA (6).

In April 1970, the McNaughton Foundation of Montreal, Canada, and Sausalito, California, claimed an exemption to sponsor a clinical trial of amygdalin (7). FDA reviewed the claim (IND) and promptly denied it because of inadequate safety testing and other deficiencies.

Yet within six years after the IND was denied, Alaska legalized the use of Laetrile. By March 1979 a total of 19 states had legalized the drug and there had been amendments or bills introduced in at least 41 states.

Competing Sets of Problem Definitions

Given the political history involved with legalizing Laetrile, one is interested in how the Laetrile "issue" has been defined by the major actors involved with it: the FDA, the proponents of legalization, state legislatures, public interest groups, and medical experts. Each of the problem definitions reflects central assumptions about the nature of the problem and the actions that need to be taken to effectively deal with it. Some of the definitions are complemen-

tary (a collaborative solution), and some are clearly distributive (a competitive solution).

Definition I. Laetrile as a Scientific Controversy

One perspective on the Laetrile issue is that this is purely a scientific matter and should be dealt with on scientific grounds. One needs to go through regular drug testing procedures (i.e., NDA, IND) and determine the safety and efficacy of Laetrile.

This view of the issue would lead one to concentrate almost exclusively on the scientific and technical aspects of Laetrile. Is it efficacious? Is it safe? If so, under what conditions? What types of animal and/or human tests should be sanctioned to prove the efficacy and safety of Laetrile? Should a retrospective study of medical records be undertaken to test the safety of this issue?

It is clear that on the formal level, the FDA must appear to be accepting this definition of the problem. The FDA is specifically prohibited by law against lobbying in state legislative actions. It is also prohibited from lobbying in the U.S. Congress. However, on the informal level, the FDA surely could encourage its supporters within HEW and the Congress to take the more general political implications of this issue quite seriously.

However, we have found no evidence of a broader view of the problem -- even at the highest levels of the FDA. A relatively recent internal memorandum from the Commissioner of Food and Drugs to the Secretary of HEW starts off by concentrating on these scientific aspects:

> As you know, Laetrile is a compound known as amygdalin, a glycoside that can readily be extracted from apricot pits and some other natural sources. It can be manufactured on virtually cottage industry basis, and "standards" for its production undoubtedly vary widely; that is one reason why it is difficult to persuade believers that a given test has really proven its lack of efficacy. Five animal studies done at NCI on Laetrile have shown no anti-tumor activity. Now NCI is quietly arranging a well-controlled human study, for which we are in the process of granting an IND. About three INDs for this compound have been received by FDA since 1963, none of them with any convincing efficacy evidence (8).

This memo was summary document of the FDA's views and recommendations to the Secretary of Health, Education, and Welfare. As cited in this essay, similar presentations of the problem were made in a public announcement by the Assistant Secretary of Health.

Action Implications

The action implications which follow from this definition of the problem are fairly straight-forward and clear:

- Sanction and conduct all medical tests/ experiments which seem warranted within the boundaries of the Food, Drug, and Cosmetic Act of 1962. The FDA has done this and even gone beyond it in helping NCI plan for a retrospective case review. FDA officials would contend that this represents their political concession, because of the high emotional content of the issue.

- Conduct a public education campaign on the dangers of Laetrile. The FDA has undertaken a massive educational campaign to warn the public against the dangers of taking Laetrile. As part of this effort, a poster was produced to warn people about Laetrile.

- Testify in front of state legislatures in which they are invited to testify. Since 1976, the FDA has made approximately 50 presentations of facts, figures, and perspectives in various state legislatures. These presentations reflect the FDA definition of the problem. They recognize the political issues, but deal with them by trying to concentrate on the scientific evidence. For example, on the highly volatile issue of freedom of choice, FDA officials would give the following testimony:

  > The issue of 'freedom of choice' is not a valid one as it relates to Laetrile. The concept of freedom is being debased by swindling those who are desperate for their lives. The choice should be among products recognized to be effective. For the believing but uninformed cancer victim, he may be choosing death with Laetrile versus

> the possibility of life with other cancer treatment methods known to be more effective.

Again, the FDA is concentrating on efficacy even when trying to discuss the political implications of the issue (8).

- Conducting research and making educational materials available to the public and any legislator on request.

Definition II. Laetrile as a Quack Cure

A second perspective on the problem, held by a smaller number of FDA officials and some legislators is that Laetrile is just another in a series of quack cures.

In its 70-year history, the FDA has put hundreds of "cures" out of business. It appears that (from the perspective of FDA officials and others who define the problem in this fashion) approximately every ten years, one "cure," usually for cancer, is promoted so effectively that it becomes a national issue. The most recent, prior to Laetrile, was Krebiozen, and prior to that, the "Hoxsey Treatment" and the "Koch Treatment." It is interesting to note that, similar to Laetrile, the Hoxsey treatments continued to be offered by practitioners in Mexico even after the sale of the material was judged illegal in the United States.

Those who define the Laetrile issue in this fashion continue to concentrate on the scientific evidence; by concentrating on "quackery" they feel they are taking the political aspects of the issue into account. The quackery issue is the one "political hazard" cited by the Commissioner in his memo to the Secretary of HEW:

> If one says that Laetrile can escape the efficacy requirement, one opens the door for every quack cure imaginable. In Nevada, Gerovital H even got piggy-backed onto the Laetrile legislation while it was being drafted; I can see no logical place to draw the line short of repealing the Kefauver-Harris amendments (8).

Quackery is also of some concern because some FDA officials believe that the agency could have "nipped [Laetrile] in the bud" many years ago by "taking prompt actions against Laetrile's early promoters." When asked why this wasn't done, one official replied that "it was viewed as an insignificant problem ... we had bigger fish to fry in other areas, such as in drug compliance actions and food safety."

Another FDA official said that quackery was given a relatively low priority at that time. He said, "This was a deliberate decision because of limitations of manpower. In terms of benefit/risk, the emphasis was put on drugs" (9).

Action Implications

Most of the action implications which follow from this definition of the problem are an extension of the ones based on the "scientific perspective":

- Include this element in the public education campaigns and in testimony before the state legislatures. The FDA has done this fairly consistently. It tries to inform the public and their elected representatives of the similarities between Laetrile and other so-called quack cures.

- Convince the Secretary of HEW and the Assistant Secretary of Health of the importance of this problem. The FDA has certainly done this.

- Increase the resources devoted to combating the "Laetrile movement." In the short-turn the FDA has devoted substantial resources to public education, testimony before state legislatures, and legal as well as compliance actions.

- Consider devoting more resources to combating "quackery" in the future. This is a long-term proposal and is being given serious consideration within the FDA.

Definition III. Freedom of Choice

There is a group of proponents for the legalization of Laetrile who concentrate on what they call "the freedom of choice" issue. "Freedom of choice" has several different meanings: (a) the right of a doctor to prescribe whatever treatment that he/she deems to be effective for a particular patient; (b) the freedom of a patient to choose whichever doctor and, by implication, treatment that he chooses--the government should not interfere in this choice; and (c) at a maximum, government intervention should only involve providing the public with information--"on all sides of the question," and the public should then be able to make an informed choice.

Organizations have been formed to represent this point of view. These organizations are growing in size and number. At this writing, the Committee for Freedom of Choice in Cancer Therapy claims to have 450 chapters and 23,000 members and is one of the main actors in the effort to legalize Laetrile. Other groups have also been formed to join in their common goal to legalize Laetrile. Several of the largest are the International Association of Cancer Victims and Friends, the Cancer Control Society, and the National Health Federation.

These groups, which have tens of thousands of members or supporters, publish periodic journals; hold social and business meetings, conventions, etc; and apply pressure on cancer patients and their families, in some instances within 24 hours after diagnosis, to use Laetrile.

Several points should be made about those who define the problem in this fashion:

1. Laetrile is basically a convenient vehicle to help reach a larger, and broader set of ends. The freedom of choice issues are at stake and not Laetrile qua Laetrile.

2. This group does not make any particular claims for the efficacy of Laetrile. Instead, they concentrate on alternative treatments to conventional cancer therapy. They offer a whole package of treatments including diet, and nutritional packages. It is almost as if they are trying to form a culture around the non-traditional treatment of cancer (10).

3. They are challenging long-standing government policies and methods of regulation.

4. This point of view enjoys a good deal of public support. The New York Times and the Detroit Free Press have come out editorially in favor of Laetrile and the Harris Poll reflects substantial support from the public at large. In addition, a survey taken by Cambridge Reports, Inc., asked the following question: "Some people say companies should tell us in plain English what the possible dangers are in a product, as they do on cigarette packages, and then leave it to us as individuals to decide whether or not we want to use that product. Would you agree or disagree?" Eighty-two percent of the respondents

agreed, 9 percent said they didn't know, and 9 percent disagreed.

Action Implications

This group of advocates is extremely careful in the tactics it employs and can also be characterized as being very shrewd political analysts. Their definition of the problem has led them to adopt the following action strategies:

1. Organize letter-writing campaigns to legislators in the states where Laetrile legislation is being considered.

2. Organize testimony before the state legislatures -- both testimonials by those who have used Laetrile and testimony on the issue of freedom of choice.

3. Organize and recruit members at the grassroots level. This involves contacting recently diagnosed cancer patients and encouraging to accept non-traditional forms of therapy and encouraging to join the "appropriate organization."

4. Working at the national level to insure that "freedom of choice" may become a reality. At a United States Senate hearing on July 12, 1977, this group's position was presented by Robert W. Bradford, President of the Committee for Freedom of Choice in Cancer Therapy, Inc.:

> "The FDA MUST get off the backs of physicians, cancer patients, and ourselves. What, in the name of humanity, is this agency doing? Whom does it represent? Surely, not the people. The Harris Poll has already indicated that. How is it possible that at a time when our nation is flooded with heroin, cocaine, uppers and downers and is literally awash in marijuana, the federal government sees fit to expend millions and millions of dollars of taxpayer funds to suppress the extract of apricot kernels? Where is the logic? Where is the morality?" (11).

5. Working at the national level for legislation which might help insure for freedom of choice. The

group is advocating amendments to the New Drug bill currently being considered by Congress. This group would like the efficacy clause of the Food and Drug act to be omitted.

Definition IV. Big Government Interference

The last definition of the Laetrile issue which has been prevalent over the last number of years is the one which stipulates that big government interferes far too much and often in "our lives." Laetrile is simply an example of a more general trend toward government interference in our lives.

The groups representing this point of view are many of the same that were listed above. In addition, this broader definition of the problem allows the advocates of deregulation to become "part of the coalition." While some people in journalistic and academic spheres may not fully accept the definition of the problem in terms of freedom of choice, they are sympathetic to deregulation.

Action Implications

In addition to all of the tactics listed above, this group would work toward broad-scale public support through educational campaigns and generalized legislation. Examples of their success include political erosion of the efficacy and safety provisions of the Food, Drug, and Cosmetic Act: (1) the 1974 vitamin amendments which limits the authority of the FDA to classify a vitamin as a drug solely because it exceeds the level of potency which the Secretary (HEW) determines is nutritionally rational or useful; (2) the saccharin 18-month moratorium passed by Congress. The Delaney Clause of the F, D & C Act prohibits the use of any food additive (i.e., saccharin) which is known to produce cancer (regardless of dose) in man or animals. There have been several animal experiments in which cancer has been produced in animals by high doses of saccharin. Because of a public groundswell against the immediate implementation of a saccharin ban as a food additive and to allow further testing, Congress passed the 18-month moratorium.

It is possible that further challenges such as from Laetrile could lead to the abolishment or modification of the current efficacy requirements for new drugs. In fact, a proposal has been introduced in the House of Representatives with 100 cosigners which would abolish the efficacy provision requirement for new drugs. Such a bill, if enacted, would,

according to FDA officials, negate much of the agency efforts to provide effective drugs to the American public and even lead to a) the resumption of "quack" medical drugs distributed in interstate commerce, or b) exemptions granted for specific items; i.e., Laetrile.

The Debate Over Laetrile

The debate over Laetrile is occuring at several levels utilizing several different definitions of the problem: (1) at the state level the FDA-supplied definitions (I, II) are in direct conflict with the definitions of the proponents of legalizing Laetrile (III, IV); and (2) at the federal level more general legislation is being considered; clearly, the proponents are "having their day in court" for the broader definitions of the problem.

In examining these legislative debates, we analyzed the legislation in each state which has considered a bill to legalize Laetrile (e.g., what provisions were included, which provisions were deleted during debate). Moreover, in three states, face-to-face interviews were conducted with all principal actors: legislators, the governor's office, officials from the State Department of Health, Bureau of Drugs, and pressure/lobby groups. Face-to-face interviews were also conducted at the federal level with representatives from each FDA division involved with this controversy. The FDA monitored the Laetrile debates in each state considering such legislation. Consequently, we were also able to collect FDA data on all of the states debating Laetrile legislation: which actors were involved, what positions were taken, and what implementation procedures were adopted.

The State Level

The Legislation

The debate over the legalization of the sale of Laetrile has followed a rather typical pattern in the states that have considered it. The bill is usually introduced by a Senator or Representative who personally has cancer or who has a relative who has been diagnosed as having cancer.

The proposed legislation typically calls for: (1) protecting physicians; (2) protecting pharmacists; (3) requiring a prescription; (4) permitting its manufacturing within a state; (5) making provisions for quality control; (6) designating an agency responsible for monitoring and implementation; (7) requiring written informed consent or records; (8)

requiring that containers of Laetrile be labelled with the statement: "Amygdalin has not been approved as a treatment or cure of any malignancy, disease, illness, or physical condition by the United States Food and Drug Administration."

Federal statutes prohibit states from importing Laetrile (an exception to this is the recent order by Judge Bohannan which stipulates that Laetrile may be imported for use on terminally ill cancer patients). Therefore, in order not to be in violation of federal law, Laetrile sold "in-state" must be completely manufactured within the state itself.

The Role of the FDA

Once a bill has been introduced, the FDA has proceeded to make its position very clear. Although the FDA cannot actively lobby in a state legislative action, it will, if asked, provide technical assistance or testify at hearings. The FDA can also, upon request, assist state legislative committees by providing factual information.

The FDA has provided such assistance in almost every state considering Laetrile legislation. The interviews conducted at the state level reveal that because the agency believes that Laetrile is a most dangerous type of health fraud, it has expanded technical assistance resources to states in order to prevent or postpone passage of, or to weaken, Laetrile bills.

In fact, the FDA has done everything in its power to indicate how strongly it feels--ranging from technical assistance, to testimony, to telegrams to Governors, and in making it very clear what its legal options were. A telegram from Commissioner Kennedy to Governor Du Pont of Delaware is typical:

> Should Delaware legalize Laetrile, a great number of cancer victims in the state could be irreparably harmed, both by spending large sums of money for this drug and foregoing known effective treatments that are now available for many forms of cancer, especially in early stages. I hope that Delaware would not legitimize this exploitation of a tragic disease. Its [Laetrile] shipment from or into Delaware is now illegal under federal law and passage of state legislation would not alter this situation (8).

With this telegram, the Commissioner of the FDA stated explicitly that his agency was strongly opposed to promoting

Laetrile; more importantly, perhaps, he reminded the states what the limits and powers of the federal law were.

Our interviews reveal that, in informal conversations, some FDA officials would consider regulatory action to control local efforts to manufacture Laetrile if evidence of federal jurisdiction over any of the drug's components could be found. If inert ingredients, containers, or labels used for the production of the product were from interstate sources, they were prepared to consider obtaining injunctions to halt manufacturing operations.

The role of the FDA is complicated. It is not merely acting as would a scientist in a technical discussion. It is acting on the basis of enabling legislation passed by the U.S. Congress. There is not much inclination in Congress to change this legislation. The FDA is acting as a political actor as well as a scientific/technical actor.

In this respect the FDA's role should be differentiated from that of a State Department of Health and/or Bureau of Drugs. The State Bureaus have not been acting under any enabling legislation. Indeed, they have acted in what might be considered "direct contradiction" of a legislative act. In the case of the States, the legislature is the political actor and the State Bureau of Drugs represents the scientific or technical actor.

Other Testimony

In most states, the legislature has been quite thorough in investigating the controversy. Testimony is sought from all concerned parties. Thus, state medical associations, consumer groups, Deans of Medical Schools, and individual citizens treated with Laetrile are heard from. The testimony taken ranges from complex scientific evidence, to expert opinion by Deans, to testimonials by cancer victims.

The Role of Government

Governors of states took on very different roles in this controversy. Some did not want to get involved with the controversy and simply followed the lead of the legislature; these governors usually signed the bills into law without comment. Others vetoed the legislation reemphasizing many of the same messages highlighted by the FDA. Governor James Thompson of Illinois was typical of this group of Governors:

> ....Lastly, if Laetrile is legalized in spite of all scientific evidence to the contrary, then what logic stands in the way of legalizing any

> supposed cancer treatment which can marshall sufficient personal testimony and the necessary advertising dollars. Why not permit the sale of sawdust or Vitamin A as cures for cancer...on the ground that the terminally ill should be permitted freedom of choice (8).

Legalizing the Sale of Laetrile - The Implementation Phase

As already indicated, each bill designated an agency responsible for implementing the law passed by the legislature. Usually this was the State Department of Health.

Some states did not adopt any specific regulations or rules to govern the implementation of the Laetrile legislation. These states relied on existing state regulations or they simply adopted the FDA safety and efficacy standards. The FDA regulations were often adopted on the premise that they were proven and should be adopted at the state level.

However, in three states, the Director of the Bureau of Drugs, acting for the Commissioner of Health, adopted specific regulations to guide the implementation of the Laetrile legislation. The three states vary only slightly in their behavior at this stage of development:

State I

The State Health Department has delegated to their Bureau of Drugs the responsibility for implementing and enforcing the Laetrile Act. The state official who is Director of the Bureau of Drugs is a nationally recognized scientist and administrator. He has published many professional articles concerning drugs, and has recently been elected president of a multi-state Health Association.

The Director, on the basis of the available scientific evidence, emphatically believes that "Laetrile is not only worthless in the treatment of cancer, but that it is a health fraud; and worse still, citizens in the state are foregoing conventional treatment in favor of Laetrile with fatal results."

The Laetrile Act did not change any existing drug laws in the state. The old state drug law does have a safety requirement for "new drugs" produced in intra-state commerce. However, this part of the law has not been enforced in over twenty years because the FDA safety regulations were applied in the state. These FDA regulations require an extensive work-up on the toxicity and toxicology of all new drugs prior to distribution in inter-state commerce. The limits

of exclusive intra-state use of a drug is illustrated by the Director's comment that "he can only remember during the past twenty years, only two requests for state approval of a new drug...and in both cases he convinced the applicant not to apply." However, two applications have been received by the Division of Drugs for approval to manufacture Laetrile in the state. Both companies have followed up their initial requests with phone calls and letters.

Prior to any response to the two manufacturers, the state Director, Bureau of Drugs, has, with the concurrence of the Health Commissioner, promulgated, without public hearings, regulations under the existing "old" state drug laws pertaining to the safety of intra-state new drugs. "In effect," the Director said, "even if a company were able to do this (i.e., meet the safety tests), the approval and legal use of Laetrile in the state could be delayed from three to eleven years." The FDA experience is that it takes an average of seven to eight years for a 'new drug' to be approved.

Our interviews with State and Federal (FDA) officials reveal the following critical facts:

1. This Director of Drugs is a nationally known scientist and, hence, any actions he takes may be followed by other officials (bureaucrats) in states that have Laetrile Acts.
2. There is no question that the Director of the State Bureau of Drugs has consciously contradicted legislative intent. He is neither embarrassed nor secretive about the fact that these new regulations were adopted specifically to stop the widespread usage of Laetrile.
3. In effect, he has taken actions "so that the state will have time to realize that Laetrile is a most dangerous hoax and health fraud and will repeal the law." His actions are based on the commitment to lives which will be saved by conventional cancer treatments rather than lost because of Laetrile.

State II

The situation in another state that we examined was almost exactly the same as the one just described (including a nationally recognized scientist being involved) except for the fact that the Governor had vetoed the bill and the legislature overrode the veto.

State III

In the third state that we looked into, the top state officials adopted a somewhat different tactic in response to the passing of the Laetrile Act. The Director, under the

quality control authority of the Laetrile Act, with the concurrence of the Health Commission and without public hearings, adopted by reference the Good Manufacturing Practices regulations of the FDA. These regulations require that Laetrile manufacturers have adequately equipped facilities, adequately trained technical and professional personnel, the necessary analytical controls and adequate record keeping methods. Laetrile not manufactured under conforming methods or in conforming facilities is considered adulterated and will be seized and destroyed by the state. Our interviews indicate that these regulations were adopted with the explicit intent of delaying the distribution of Laetrile in the state.

In effect. Laetrile is not available in the United States except for patients who have a doctor's affidavit that they are terminally ill. Laetrile is available in Mexico and Europe. Cancer victims not classified as terminally ill by a physician have to rely upon these supplies.

Clearly, this type of scenario just described is not necessarily typical for each state that legalizes the sale of Laetrile.

The Legislative Response

For purposes of implementation there are two possible ways to interpret legislation legalizing Laetrile: (1) "The legislative intent" was to make the drug Laetrile immediately available for public use; (2) The legislative intent was to make the drug available only after it had been tested for safety.

In the three states included in this study, the public officials responsible for implementation all interpreted legislative intent as requiring "vigorous scientific testing" for safety. From their perspective, this should be required despite the delay it would cause in making Laetrile available for use by the general public.

The officials formulated these regulations knowing that the legislators might not understand the full implications of them for "delays" in marketing the drug. One official from a State Bureau of Drugs reported:

> The legislature is aware of the new regulations but, as of yet, is not cognizant of the FDA experience in terms of granting "new drug" approval (average 7-8 years) or the state intention to 'literally' enforce Good Manufacturing practices

on Laetrile manufacturers if and whenever necessary.

It should be understood that these officials promulgated the regulations with the specific intent of blocking the widespread use of Laetrile. These actions were taken on the basis of a commitment and belief that Laetrile represented a "hoax" and a "dangerous health fraud."

Given this background, the state legislators who were the primary sponsors of the legislation to legalize Laetrile were re-interviewed. The interviewer inquired: "Since the passage of legislation to legalize the sale of Laetrile in your state, what has been done to implement this law? What role have you played in the implementation process?"

These interviews with the prime sponsors in three states revealed:

(1) All of the legislators were aware of the activities of the State Department of Health;

(2) They were all aware of the details of the regulations and the fact that the public distribution of Laetrile would be delayed by seven to eight years; and

(3) They were all familiar with the scientific evidence presented by the FDA, the AMA, and local medical professionals. On the basis of this evidence, most of them believed that Laetrile was not efficacious and that the FDA testing was "valid."

However, despite the fact that they were all strong supporters of the initial legislation, they were not going to challenge the regulations promulgated by the officials from the Department of Health through any of the means available to them.

In this context, it is worth noting that legislators were not defenseless against the actions of the state bureaucrats. They could hold public hearings on the regulations, force the bureaucrats to reformulate the proposed regulations, they could "go to the press," or they could encourage supporters to challenge these regulations in court. The legislators interviewed knew of their options and consciously chose not to act on them. One respondent seemed to characterize the general attitude of the strong legislative supporters of legalizing Laetrile: "I have done my job; others now have to address the problem."

The Federal Level

At the federal level, the FDA has been very active; however, there has been no specific legislation concerning

the legalization of Laetrile. Instead, as already discussed Congress is considering a new drug law and there are proposals to repeal the efficacy clause of the Food, Drug, and Cosmetic Act.

The FDA fears that people have lost sight of the history behind the Food, Drug, and Cosmetic Act. The 1962 Drug Amendments were enacted following the Thalidomide disaster. The use of Thalidomide, a sedative, by pregnant women causes severe deformity of the child. Although the drug was never approved for interstate commercial use, it was then legal to distribute the drug to physicians for experimental purposes. It was estimated that the drug was given to over 3800 U.S. women of childbearing age, nine of whom gave birth to malformed children. Thalidomide was approved by many other countries, with birth deformities resulting throughout the world.

The 1962 Drug Amendments extended, expanded and strengthened the regulatory authority of the FDA. Among other provisions, the FDA was authorized to approve a new drug for marketing only after the sponsor had met the statuatory requirements for safety and efficacy. Approval was conditional upon the showing of "substantial evidence" of efficacy, and the burden of proof rested with the manufacturer.

The efficacy and safety provisions of the current law are, in the opinion of the FDA, absolutely essential in carrying out its mission of public health and safety.

There is evidence of real public concern that terminal patients should be allowed any drug, regardless of questions concerning its efficacy or other effects. For example, this concept has resulted in a bill, introduced in New York State, which would authorize physicians to administer controlled substances such as marijuana, heroin and others to terminally ill patients. The current practice of careful allocation of "pain killers" for terminally ill patients is, according to Alan G. Hevesi, Chairman of the New York Assembly Health Committee, "silly" because it denies "terminally ill patients certain drugs because of the potential for addiction."

A similar argument has been made for Laetrile in that, even though there is no scientific evidence that the drug is useful in the treatment of cancer, proponents ask, "Why deny the terminal patient or his/her relatives the 'straw' which they so desperately desire?" Moreover, Laetrile very probably produces a real placebo effect, although this effect has <u>not</u> been objectively demonstrated. Oncologists and psychiatrists have argued that Laetrile cannot be considered a <u>safe</u> placebo since it drives patients away from good medical care.

A possible argument against a terminal classification of any patient is that the subjective medical opinion of one physician may be incorrect. The uncertainty of individual medical opinion has also been seen in recent court cases which attempt to ascertain if a patient is dead, so that heroic life-support systems may be legally disconnected.

It is important to underscore the fact that the debate at the federal level is concerned with the broader medical policy issues. There is little concern for Laetrile qua Laetrile. Larger and broader political ends are at stake.

The Current Legal Status of Laetrile

As the discussion of the state case histories illustrate, despite the so-called legalization of Laetrile in 22 states, Laetrile is not available on the market except for the terminally ill.

Legal Issues

Even in those states which have legalized the manufacture of Laetrile, no Laetrile is being manufactured. The fact that a state enacts legislation which permits the use of Laetrile within its boundaries has no effect on the established policies of the FDA. The shipment of Laetrile from or into a state is now illegal under federal law and passage of state legislation does not alter this situation. Passage of such legislation does not protect sponsors, promoters, distributors, dispensors, or sellers of Laetrile from applicable civil or criminal sanctions under the Federal Food, Drug, and Cosmetic Act.

The FDA is continuing to initiate legal action against individuals and firms who are manufacturing and shipping Laetrile illegally in interstate commerce. The largest enforcement action to date occurred on May 16, 1977, when U.S. Marshals in Wisconsin seized approximately 12 tons of apricot kernels, 100,000 unfilled drug capsules and several containers of partially pressed apricot kernels. On August 4, 1977, Judge John W. Reynolds, District Judge for the Eastern District of Wisconsin, issued an injunction against numerous defendants involved in the allegedly illegal operation. The injunction was upheld by the 7th Circuit Court of Appeals in December, 1977. In upholding Judge Reynolds' decision, the 7th Circuit Court considered the decision of Judge Luther Bohannon, but concluded that the public health would be endangered if defendants in the Wisconsin case were permitted to resume the manufacture and sale of Laetrile.

Political Issues

The legal status of Laetrile only represents one dimension of the problem. The other major dimension has been acted out on the state level. Proponents have won a symbolic victory in bringing the issue to the consciousness of the public at large. Since Laetrile is currently not available in any state (except for terminal patients), perhaps, given their definitions of the problem, this symbolic victory is all the proponents were aiming for.

However, the issues of freedom of choice and limiting big government intervention are more generalizable, and these are being considered at the federal level. This interpretation would be consistent with the proponents' definition of the problem and the implementation history at the state level.

It is true that the specific Laetrile controversy at the state level is "dying out." However, other product-specific legislation has been introduced in 29 states over the last year. There has been some early research into the use of tetrahydrocannabinol -- a marijuana based drug -- for the treatment of after-affects of conventional cancer therapy. The FDA is considering whether to allow human testing on this drug. States are now passing laws to legalize the manufacturing and use of the drug before the FDA has finished its review. Four states have passed the legislation and 25 others are considering it this year.

Discussion/Conclusions

The analysis of the Laetrile movement serves to illustrate how competing definitions of a complex problem influence policy making. In addition, it serves to guide us in our understanding of the debate that is likely to ensue on this and related issues in the future.

What Was at Stake?

From the point of view of the FDA, scientific standards of safety and efficacy were at stake. Clearly, these standards were defended -- from a very narrow perspective. No one challenged the scientific evidence concerning Laetrile qua Laetrile.

The proponents simply make the point that there are alternative forms of therapy and there are packages of "cures" that include Laetrile. No individual claims for Laetrile were made.

But, the proponents were really not arguing about Laetrile. They were arguing about freedom of choice and big government interference.

It is clear that they were able to make their definition of the problem stick -- it is one that was accepted by the public at large. This fact accounts for the ground swell (i.e., grass-roots support) supporting the legalization of Laetrile.

The State legislator, however, faced a dilemma: was he or she to vote with the scientific evidence or with the public pressure that was being exerted? The fact that Federal laws apply at the state level (except for intra-state commerce) and that state bureaucrats were in some cases not willing to implement the Laetrile legislation helped some of the legislators out of the dilemma. They could vote for Laetrile knowing that it would still not be available on the market place at large.

This reality does not appear to particularly concern the proponents of Laetrile because they too have succeeded: (1) freedom of choice is on the minds of a great many people; and (2) the Congress is giving serious consideration to legislation which would serve their needs and "cause."

Which Problem Definition Prevailed?

Overall, it seems fairly clear that the proponents of Laetrile had their definition of the problem accepted. In the future, the FDA will have to learn to work with the political definition of the problem if it is to defend its broader interests and needs.

Accountability and Responsibility

The Laetrile case is most interesting for what it suggests more generally about accountability and responsibility in public administration.

Two forms of accountability appear to be operating for these types of issues: (a) short-term responsiveness to the pressures and demands of the public; and (b) paternalistic concern (long-term) for defending the interests that the State Director of Drugs wants to protect: the ultimate health of the public at large. As Friedrich (12) suggests, the experts need to be in a position to decide on issues that require expertise.

Although this standard of accountability is exercised by bureaucrats (and some Governors) and accepted by legislators, the public often believes that bureaucrats are acting autonomously and "abusing their power."

The Laetrile case suggests that our thinking about responsibility and accountability needs to be reexamined. One perspective (13) contends that the public interest is defended through the legislative mandates of their elected representatives. This study suggests that the public interest is defended through the actions of elected representatives in the policy making (legislative mandates) or implementation phases (formulation of regulations) of the problem solving process; as long as the elected representatives consider the actions to be "legitimate," then the public interest is being defended. This reformulation assumes that the legislators are aware of what their options are during the implementation phase, and what implications follow from action or inaction. If elected officials are willing to accept the professional judgment of experts, then in Finer's terms, they are acting responsibly (13).

This case also suggests that traditional assumptions concerning the legitimacy of paternalism need to be reexamined. The Laetrile proponents are most concerned about the interference of big government in the lives of citizens. Yet, the very legislators willing to pass the Laetrile Act were also willing to allow public officials (i.e., government) to take actions that insure for the continued removal of Laetrile from the market.

"Passing the Buck"

This apparent lack of differentiation between political and technical responsibility is not limited to the Laetrile issue. Other public policy issues involving scientific and technical judgments have been handled similarly by elected representatives -- i.e., lip-service to a position of advocacy while fully expecting (or at least willing to accept) that other political actors (e.g., the Governor, President, a high-level bureaucrat or the courts) will take "appropriate actions" reversing their position. Examples of this phenomena include: (a) the environmental and energy issues related to granting U.S. landing rights to the Anglo-French Concorde -- this case ended in the Courts; politicians did not want to be on record as granting permanent landing rights to a plane which produces noise pollution and is energy inefficient; and (b) the siting of nuclear facilities which are also being decided in the courts.

In the future, one should expect other issues to put politicians in the same position -- including other food and drug related issues such as vitamins, nitrites, cyclamates, etc. The politicians are sympathetic to the proponents of reducing the influence of "big government," they are willing to give lip-service to these issues. However, at the point of translating speeches into concrete programs, they recognize that the exercise of technical responsibility is the most legitimate form of public administration.

References and Notes

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Information not otherwise credited in the text or referenced below is from the author's interviews and correspondence.

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Once studies conducted under the IND produce evidence that the drug is safe and effective, the sponsor may submit an NDA. After an NDA is found to contain evidence showing safety and effectiveness for a specific use, FDA will approve it.

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5. The Laetrile Phenomenon: Legal Perspective

Conflicts in the legal philosophy of individual health care choices and the role of federal paternalism have emerged often in the courts. The tugging and pulling at the warp and woof of the legal system exerted by the Laetrile phenomenon's entry into the individual/federal rights thicket is nothing new in the health/cancer arena. The difference in the Laetrile proponents' successes appears to lie not with a real difference in issues but more with the learning process of the advocates and their ability to amass a verbal, supportive constituency. Theirs is a more sophisticated use of the judicial and legislative systems than their predecessors. Further, the appeal of their product -- Laetrile -- is not merely confined to the treatment of cancer. Rather, Laetrile is depicted not only as a drug but as a vitamin or food additive(1).

In this paper five topics are considered: federal drug regulation, informed consent, the right of privacy, physicians' rights and legal implications for cancer patients.

The underlying issue in the Laetrile case is the role of the federal government. The issue is, what kind of government do Americans want: a government that has responsibilities for protecting the consumers from vendors with worthless goods and services, a government that permits the strong to take advantage of the weak, a government that protects the consumer, or a government that sets standards and requires that all live up to those standards? To date, the majority speaking through the Congressional representatives has sought a government that protects the consumer and requires that vendors establish the value of their goods and follow an orderly process in distribution and selling. This process is reflected in the federal statutes regulating drugs. These statutes state that the caveat emptor doctrine is not applicable to the frightening and complex armament of

drugs for life-threatening illnesses. Viewed in this light, federal drug legislation is merely part of a continuing consumer movement.

The emotional, scientific, legal and philosophic issues related to Laetrile and cancer 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 humanatarian 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.

The Federal government, through the federal drug laws, has made it clear that the manufacturers of all drugs must prove their products safe and effective before they can be offered to the consuming public. This congressional mandate, which sets the first line of defense against ineffective remedies, cannot be fulfilled on a discriminatory basis where some remedies are banned as ineffective and others, which have failed to meet identical scientific standards of efficacy but have a dedicated pressure group behind them, are allowed to be marketed. It is questionable whether the congressional mandate can be a viable protection if partial exemptions related to one class of consumer, the terminal patient, are made. Discriminatory enforcement raises questions of the most serious kind relating to equal protection of the laws, and exposes the entire regulatory apparatus to ethical and legal assault.

There is no waffling in the intent of the federal drug laws and regulations. They are to protect consumers, particularly those with life-threatening diseases who are prey to fraudulent treatments. It is also clear from the judicial comment on the Act and its implementing regulations that the tightening of regulations relating to drug safety and efficacy paralleled the complexity of modern medicine and medical practices (2). Federal drug regulation standards require general recognition of safety and efficacy by experts in the treatment and research of the particular disease or condition studied and recognizes the hierarchy of specialization which is a fact of scientific life. The

standards do not equate a general license to practice medicine with expertise in cancer research. The standards perceive that physician and consumer choices arise after the first cut is made -- after safety and efficacy of a product are reasonably established through expert recognition.

Is this congressional directive unwarranted paternalism? This is a political question. From the legal perspective, the Supreme Court, final judicial arbiter of our rights, has not so held.

Federal Drug Regulation

The Regulatory Plan

The Food, Drug, and Cosmetic Act (Act) (3), in conjunction with regulations promulgated by the Food and Drug Administration (FDA) pursuant to its statutory obligation to administer the Act, constitutes a comprehensive body of law governing the marketing of drugs for human or animal use intended to assure that drugs marketed in this country are both safe and effective. The FDA maintains that Laetrile is subject to the Act, while the Laetrile proponents have argued that Laetrile is not a drug, or that even if it is a drug, it is exempt.

Laetrile proponents have filed applications with the FDA. The John Beard Memorial Foundation filed a new drug application on October 3, 1962. However this application failed to provide data sufficient to demonstrate either the safety or efficacy of Laetrile and was declared incomplete by the FDA on February 25, 1963 (4). There is no indication that the John Beard Memorial Foundation came forth at that time with supplemental data adequate to cure the deficiencies in its application.

Again, in 1970 another attempt was made to obtain FDA sanction for the sale of Laetrile. This application was made by the McNaughton Foundation and sought an Investigational New Drug Exemption (IND) pursuant to Section 505(i) of the Act. The purpose of an IND is to allow a drug that has demonstrated its safety and efficacy in pre-clinical tests, for example, animal tests, to proceed to "investigational" testing on human subjects.

The FDA initially awarded the IND (No. 6734), but shortly thereafter, in the course of a routine review of the IND application, found serious problems with the applicant's clinical data. The FDA immediately requested that the applicant respond to two questions on manufacturing controls,

seven questions on pre-clinical tests and four medical questions on data mentioned in the application but not submitted. When the missing data were not provided by McNaughton within the usual ten-day period allowed by the FDA for the elimination of deficiencies, the IND was terminated. It was not until some four months later that the McNaughton Foundation responded to the FDA data request.

The FDA's action in terminating the Laetrile IND generated some Congressional interest. In response to this interest, the FDA appointed a special committee of non-government experts to review the entire Laetrile data file. The committee found that independent laboratory assays provided no in vitro or in vivo evidence in animal models to warrant trial of the substance in humans and thereby affirmed the propriety of the FDA's action.

Critics of the FDA's Laetrile decision, specifically Dean Burk, who at that time was on the National Cancer Institute staff, and Andrew L. McNaughton, who was a party to the application, had the opportunity to participate in the committee's assessment. Rather than attempt to remedy the deficiencies in the application pointed out by the special committee, the Laetrile proponents never perfected their applications.

Two "grandfather" provisions are applicable to the Food, Drug and Cosmetic Act and affect the need for a drug, which otherwise is a "new drug," to comply with the pre-marketing requirements of Section 505. The first of these grandfather provisions is set forth in Section 201(p) itself and provides that notwithstanding the lack of general recognition of safety and effectiveness, a drug shall not be declared to be a "new drug"

> if at any time prior to the enactment of this chapter (June 25, 1938) it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained in the same representations concerning the conditions of its use... (5).

The second grandfather exemption consists of the transitional provisions enacted as part of the 1962 amendments of the Act, which states:

> In the case of any drug which, on the day immediately preceding the enactment date (October 10, 1962), (A) was commercially used or sold in the United States, (B) was not a

> new drug as defined by Section 201(p) of the basic Act as then in force and (C) was not covered by an effective application under Section 505 of the Act, the amendments of Section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug on that day (6).

The effect of the two grandfather clauses is to eliminate the requirement of obtaining an NDA for any drug subject to the 1906 Act marketed in the United States from June 30, 1906, to June 25, 1938, or for any drug commercially used or sold in the United States which in 1962 had attained general recognition among qualified experts as safe for its intended purpose, as the term "safe" was then properly interpreted which for those with life-threatening illnesses included efficacy (7, 26).

The elements required for general recognition of safety are correctly stated by Commissioner Kennedy in the Laetrile Rulemaking decision (8):

> ...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.

Whether or not a drug is exempted from the pre-marketing requirements of Section 505 by virtue of either of the above grandfather clauses is to be determined initially by the FDA (9). Additionally, it is incumbent upon the party seeking to grandfather a drug to establish that the drug is in fact entitled to such status (10). The arguments presented to the Rutherford court by the plaintiff cancer patient class is that Laetrile falls within these grandfather exemptions (11).

Briefly stated, entitlement to the grandfather exemption of the 1962 amendment, i.e., Section 197(c) (4) of the Food and Drug Act, (6) which is the one found applicable by the district court in Rutherford is limited to drugs which: (1) feature today the identical chemical composition, recommended dosages, and claims made in labeling as existed

on October 9, 1962, and; (2) were used or sold commercially in the United States on October 9, 1962, and; (3) were generally recognized by the experts as safe; and (4) were not covered by an effective new drug application (12).

Laetrile and Federal Enforcement Actions

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 (13). Recent enforcement actions have also included the seizure of interstate shipments of apricot kernels destined for use in the manufacture of Laetrile (14).

As in many studies, it is the exceptional case which provides the best medium for analysis. In the Laetrile controversy that exception is Rutherford v. United States (15). Rutherford was instituted by cancer patients in the United States District Court for the Western District of Oklahoma on March 12, 1975 (16). The suit sought to prevent the government from interfering with the sale 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 (18).

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 (15, p. 11, n. 2). This decision was

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 product is considered a food, a drug, or both under the regulatory plan (17).

The holding not in accord with the Act deals 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 doesn't 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 (18).

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 (19), 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. (20), as one basis for his decision denying an injunction against the FDA 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 the 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 supposed to provide lies within in 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 that 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" (8, p. 39788).

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 (8, p. 39779).

The third basis for denying the 1962 grandfather exemp-

tion 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 (8, p. 39792-5).

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 (21).

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 (15).

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 (22).

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) to be 'safe' and 'effective' for the limited group of persons here considered" (22, p. 6). Rutherford's later request to allow the oral use of Laetrile was denied by the court without comment (23).

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 (24). 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. 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 holding of the Court of Appeals that "effective" has no meaning if the person by all prevailing standards is going to die of cancer regardless of what may be done is too

narrow in terms of the class it addresses -- the terminally ill. Where a cure may not be possible, other relief for the terminally ill may be, for example, pain control, appetite stimulation, odor reduction, tranquilization. Under the circumstances, where the current thrust of the Laetrile proponents seems to be that it will dramatically relieve pain, improve appetite, promote weight gain, reduce the odor associated with cancer, improve the cancer patient's general sense of well-being, control or prevent cancer, it would seem logical that the terminally ill are entitled to the assurance that the products they seek to use are effective when measured against the claims of sponsor.

Furthermore, the court of appeals assumes that an objective standard is available or can be formulated and applied to determine who is "terminally ill." This assumption is in conflict with the findings made by the Commissioner in the Laetrile decision. The thrust of those findings is that cancer is a disease that affects individual patients and that physicians dealing with these patients on an individual basis find it difficult to distinguish the in-fact terminal from non-terminal cancer patients with any accuracy. The practical and ethical problems of carving out an exception for the terminally ill from the Act was pointedly addressed by Dr. Samuel Klagsbrun:

> Use of the term "terminally ill" is inappropriate when dealing with an individual cancer patient. Although specific forms of cancer may have a statistically expectable mortality rate, that rate is meaningless when applied to an individual patient. Oncologists are all familiar with experiences where severe cancers, which were statistically considered to be hopeless, have, in some small percentages of cases, undergone a sudden remission. It would be tragic to condemn any individual cancer patient to death because, as a statistical matter, that patient's particular form of cancer may not be curable.
>
> A decision to allow patients who are diagnosed as having a cancer which, as a statistical matter is expected to lead to their death, would move all such patients away from orthodox therapy and condemn even the individual patient whose cancer may unexpectedly move into remission to Laetrile, a worthless and ineffective drug. In addition, such a decision would thereafter remove the patients from the possibility of receiving continuing chemotherapy or radiation therapy which could enhance the effects of any

> remission. Most physicians have undergone the experience of predicting the moment of death and have been unexpectedly and repeatedly proven wrong to a considerable degree. The prolongation of life, therefore, becomes a goal, not simply for the sake of prolongation, but also to render patients available to either a recent advance in chemotherapy or simply to enhance the quality of the time left available to the patients (25).

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 (26). The Court did not address the constitutional and 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 (26, p. 7):
    (a) Legislative history indicates that Congress was concerned with the protection of those

with fatal illnesses (26, pp. 7-8).

(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 the 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" (26, p. 13).

(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 (26, p. 10).

(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" (26, p. 11). 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 removes 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 full reach of federal authority will remain unclear until the 10th Circuit's opinion on remand and possible further action by the Supreme Court. However, language in the Supreme Court's opinion on the federal interest in regulation of drugs for those with life threatening illness signals that the Court would not look favorably on a constitutional right of privacy as applied to ineffective drugs. Further, the confused history of the formula, recommended use and administration of Laetrile prior to 1962 set forth in the Commissioners' decision and briefed to the Supreme Court (27) in Rutherford likewise signals that this rationale for Laetrile access will not stand close judicial scrutiny.

Interplay of Federal and State Statutes

State statutes legitimating the marketing of Laetrile 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. The state statutes that have approved Laetrile do constitute an important statement of either pro-Laetrile or anti-government sentiment.

Although the issue has not been litigated, the validity of state regulation 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" (28). 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 pro-

viding effective protection against unsafe and ineffective drugs. The legislative history of the federal Act also indicates a Congressional intent that the Act establish uniform drug standards (29). 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 does although the answer is not clear. Finally, 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 (30). If these provisions are not being enforced, enforcement could be mandated through administrative action.

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.

The Informed Consent and Physician Liability Issues

The right to bodily control has its expression in the doctrine of informed consent which is a key element in the federal district court cases which have permitted Laetrile treatment to cancer patients and also in a number of statutes legalizing Laetrile.

By way of illustration, a Rutherford informed consent form requires a physician's declaration that the patient is terminally ill; 1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and 2. either (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or (b) that Laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or (c) that the patient has made a knowing and intelligent election to take Laetrile after being fully apprised of the full range of recognized treatments available and of the fact that Laetrile is considered by most cancer experts to be of no value in combatting the disease. In comparison, the Indiana statute legalizing Laetrile contains a consent form which requires a physician's explanation to patient that the manufacture and distribution of Laetrile is banned by FDA; that it is not a recommended

treatment and that there are alternative recognized treatments for that patient's cancer (31).

To assure the level of protection from liability provided by the federal informed consent procedure and required in the case law involving informed consent (32), it would appear that the physician confronted with a patient desiring treatment by Laetrile, should augment the sample statutory or court forms with the traditional elements of informed consent omitted from those forms. Without such protective augmentation, the subjective intent of the patient becomes material. In methods of treatment not yet accepted by the medical professional generally, where the contemplated therapeutic benefits are unknown or speculative, the facts as known or unknown to the attending physician are of material importance to the patient/subject's decision. Does the patient/subject perceive Laetrile as a cure, a pain reliever, a control for cancer, a preventative agent, an appetite stimulant, an aid to the removal of the odor of decaying tumor tissue, a mood elevator? Does the physician represent his utilization of the substance as meeting any of the above conditions?

The Laetrile informed consent issue presents problems not usually confronted in the jurisprudence of informed consent. It is a product which is generally considered by experts in the field of cancer research and treatment as ineffective and unproven after over 20 years in the medical arena. This compares with chemotherapeutic agents which may be of medically recent origin, but which emanate from research centers with reputations which bear out a track record for effective treatment and for which informed consent for human experimentation procedures are a commonplace and crucial part of day-to-day practice.

If the consent procedure has included a clear statement of the elements of treatment and possible outcome, for example, palliate not cure, and the patient consents because he believes the substance will cure, the physician is not responsible if the patient's expectations are not fulfilled. However, what if both the physician and the patient are believers in Laetrile. What if the physician takes the position that the informed consent requirement imposed by the state legislature is merely a nuisance restriction and is meaningless? The physician informs the patient as stated on the sample forms of the non-therapeutic expectations attributable to Laetrile by the general expert medical community but by his own attitudes and remarks reinforces the patient's belief in the cure, prevention or control of the disease by Laetrile. What then?

If the physician-patient contract contains a promise of cure, is the informed consent form which represents that the cure is not a reasonably anticipated benefit of the treatment a nullity? Is the physician then liable for breach of a contract for cure (33)? Further, is a physician who either intentionally or negligently misrepresents the nature or results of treatment he has rendered liable for fraud? There is authority that answers this question in the affirmative (34).

Indeed, can any consent system that operates on the principle that the drug is ineffective have legitimacy when the only reason the placebo effect of a drug works is because the recipient believes the drug to be effective? Placebo effect is described by Dan Martin, M.D. in the Laetrile Rulemaking proceeding as "a form of self-hypnosis based on the power of positive thinking." The underlying assumption by the district court and the court of appeals that the substance is ineffective but it 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.

Finally, what type of recovery will be available to patients, or protection available to physicians if the patterns followed in Nevada and Oklahoma become the rule? In Oklahoma, the law requires patients to agree to waive malpractice suits if Laetrile is prescribed at their request. Nevada Medical Liability Insurance Association which writes 60% of state malpractice suits won't extend malpractice coverage to Laetrile suits. Further, with regard to physician liability, most of the statutes passed by the states that deal with "Laetrile/amygdalin" do not (35) legalize its sale or distribution (36). Most statutes merely affect a physician's use of Laetrile in two very limited ways: (a) prohibiting hospital and health facilities from interfering in the doctor/patient relationship by restricting or forbidding the use of the substance when prescribed or administered by a physician and requested by a patient and (b) prohibiting disciplinary action against a physician who prescribes or administers the substance upon patient request.

Some of these statutes have a criterion which provides a way of effectively nullifying the state statute without further legislative action. I refer to provisions for a hearing by a state medical board to determine if the substance is harmful (37). Once found "harmful," the physician would no longer be covered by the umbrella protection from hospital or health facility interference with his administration of Laetrile or from disciplinary action (30).

According to the Alaska Attorney General, statutes which merely preclude hospital interference or physician discipline may fairly be interpreted as not removing physicians from liability under the states pure drug laws. Under his interpretation, state drug laws which prohibit sale, delivery or "give away" of drugs that are not found safe or effective would still apply to the physician. Thus, in its most liberal interpretation, a physician merely prescribing Laetrile or administering the Laetrile delivered to him by the patient may not be subject to state drug law strictures, but the physician who sells or gives away Laetrile would be (30).

The Right of Privacy

Warner V. Slack, writing in "Points of View" (38) places the physician/patient decision-making issue in perspective helpful to exploration of why the right of privacy concept has emerged as central to the legal aspects of the Laetrile phenomenon. Dr. Slack observes that:

> For centuries, the medical profession has perpetrated paternalism as an essential component of medical care and thereby deprived patients of the self-esteem that comes from self-reliance. "I believe that the loss of decision-making is probably the heaviest blow of all to most patients' morale," wrote J.L.W. Price after a stay in the hospital. It seems to be that patients will be more likely to adhere to treatment regimens when they can make their own decisions and that, given the opportunity, more and more patients will elect to do so.

These perceptions seem to track the psychology of the Laetrile phenomenon. They relate to a concept which touches a strong cord both in the American way of life and in American jurisprudence and encompass the historical concept of control over one's person and destiny: "Outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, do what he pleases, go where he pleases" (39). This quotation from a Justice Douglas' Supreme Court concurring opinion is relied upon by United States District Court Judge Luther Bohanon in his opinion in Rutherford v. United States, to support the right of actual or supposed cancer patients to procure and utilize Laetrile. The keystones of the Judge Bohanon decision are dealt with in detail in the following sections; in brief, they are:

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 treatment, however unconventional, as he finds to be of comfort--particularly where recommended by his physician.

These concepts are also expressed in the appeals court decision in the Privitera case (40) which involved the rights of physicians to assert a patient's right to privacy as a defense to statutory of medical board prohibitions against a physician administering a treatment not regarded as safe and effective by qualified experts: (1) every human being of adult years and sound mind has a right to determine what shall be done with his own body, (2) the right to control one's own body is not restricted to the wise; it includes the "foolish" refusal of medical treatment (41), (3) the right to choose what may be a suicidal medical course has been upheld (42), and (4) Roe dealt specifically with the right to determine one's own medical treatment. Another element of the right of privacy arguments focused on in Privitera is informed consent: "Where informed consent is adequately insured, there is no justification for infringing upon the patient's right to privacy in selecting and consenting to the treatment" (43).

In holding that a right of privacy related to health care does exist and is applicable to the drug Laetrile, Judge Bohanon in Rutherford cites Justice Douglas' concurring opinion in the Roe and Doe cases (39). Justice Douglas contended that many rights not specifically enumerated in the Constitution come within the meaning of the term liberty as used in the Fourteenth Amendment. After listing (1) control over the development and expression of one's intellect, interests, tastes and personality and (2) the freedom of choice in the basic decisions of one's life respecting marriage, divorce, procreation, contraception and the education and upbringing of children, Justice Douglas notes (3) the freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll,

or lope as coming, in his view, within the meaning of the term, "liberty."

Judge Bohanon relied upon Justice Douglas' discussion of his second group of freedoms (44), rather than in the third group of freedoms which ostensibly deal with health. After asserting that this third group of rights are fundamental and subject to regulation only upon a showing of compelling state interest, Justice Douglas does not cite cases to the effect that freedom to care for one's health as opposed to freedom from bodily restraint or compulsion or freedom to work, stroll or lope, are fundamental rights subject to strict judicial scrutiny under the Constitution. The discussion following this third group of rights concerns freedom from bodily restraint, freedom of movement, and protection pursuant to the Fourth Amendment from governmental intrusions. The concept of health care is not delineated or defined. Furthermore, Justice Douglas was not joined by any other Justice in his concurring opinion and the Court's later characterization of these cases markedly differs from that suggested by Justice Douglas.

The Supreme Court has specifically indicated that the rational basis or reasonable means test should be applied where the validity of legislation such as the new drug safety and effectiveness standards established by the Act is at issue. In Whalen v. Roe, the Court upheld a state statute requiring that identification of the prescribing physician and patient be prepared and filed with the state whenever a "Schedule II" drug (45) is prescribed. The court held that the constitutional right of privacy did not attach to the decision to use Schedule II drugs, even though the disclosure requirements would [u]nquestionably ... lead some patients to avoid or postpone needed medical attention" (46, p. 602). The constitutionality of regulation was based on a rational relationship test and not on the compelling state interest standard. The Court also indicated that the state could prohibit entirely the use of a particular Schedule II drug despite its medically recognized use. It would seem, therefore, that if a state may ban a drug which has a recognized medical use, its authority to ban a drug such as Laetrile, which has no recognized medical use, is beyond question.

The conclusion that the United States Supreme Court has not recognized a right of privacy in the case of medical treatment choices involving drugs was the keystone of the California Supreme Court's decision which overturned the state appeals court rationale opening the door to Laetrile access (47). In that opinion the Supreme Court of California speaking through Judge Clark rejected the argument of

Dr. Privitera and his attorney that there is a fundamental right protected by the federal and California constitutions to obtain Laetrile. The court held that since no fundamental right is involved, the appropriate standard of review is the rationale basis test, that is, is there a reasonable relationship of the regulation to legitimate state interests in health and safety of its citizens rather than the compelling state interest test.

The history of cancer therapy in this country illustrates the justification for Government concern that, absent pre-marketing clearance, useless drugs will flourish. As the Commission found in the Laetrile Decision, there has been a long and sorry history of cancer quackery, during which "literally thousands of supposed remedies for cancer" have been promoted (8, pp. 39795-97). As the Commissioner found in the Laetrile Decision, promoters of worthless cancer remedies are often particularly successful because of the fear engendered by the disease, and the modest hope offered by legitimate remedies. The cancer patient wants to believe that there is a painless, effective remedy. The "placebo" effect of Laetrile, if any, is achieved only because the cancer victim is successfully deceived into believing that the drug will be effective.

The district court in Rutherford suggests that the exemption of Laetrile from the Act "in no way portends the return of the traveling snake oil salesman ... FDA is fully empowered under other statutory provisions to combat false or fraudulent advertising of ineffectual or unproven drugs." However, the suggestion that the FDA will be able to adequately police the claims of drug promoters, absent a system of pre-marketing clearance, is wholly unrealistic and bereft of any supportive findings or analysis. The crisis this country faces in environmental and industrial pollutants is one example of what the absence of pre-marketing clearance can produce.

The Food and Drug Administration's authority to control misbranding applies only to false or misleading claims made in a drug's "labeling." "Labeling" refers to matter which accompanies the drugs. FDA would be unable to control claims made for Laetrile, or other drugs, in books, pamphlets, and oral communications which do not "accompany" or which cannot otherwise be linked to the drug. Moreover, by forcing the FDA to prove that a drug is misbranded, the district court in Rutherford has reversed the burden of proof intended by Congress. As the House Committee noted, the FDA, with its limited resources, would be required to amass the scientific material necessary to prove that each fraudulent drug is

ineffective. Promoters of the drug would be able to market it, and reap the profits, pending investigation and litagation. Congress' determination that fraudulent remedies can only be effectively barred from the market by forcing the manufacturer to assume the burden of proving effectiveness is entirely reasonable.

In the case of cancer, a significant number of patients can be cured, or permitted to live normal lives longer, by legitimate therapy, especially if treatment is begun early. The record in the Laetrile Decision proceeding before the FDA indicates that the availability of Laetrile serves to encourage delay in obtaining such legitimate therapy, or avoidance of such therapy altogether. The Supreme Court in its Rutherford opinion recognizes the danger an ineffective drug poses to the patient with a life threatening illness:

> "But 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" (48).

Moreover, even among patients who begin treatment with effective therapy, the readily acknowledged side effects and hazards of that therapy may cause them to abandon such methods at a time when their application might still be beneficial, and to turn instead to Laetrile, a "painless cure." The drug's promoters actively encourage this process, playing on the cancer victims' fears. Particularly in the case of cancer which inspires fear in victims, the only means of preventing patients from being drawn to the simple, fraudulent cures is to ban them from the market.

The Rutherford district court noted that most persons taking Laetrile probably know that the government and most experts consider it worthless. The court did not discuss, however, the FDA Commissioner's findings that the psychological pressures and fears of cancer victims and their families leave them in a position where emotion may overrule intellect. The district court suggests no means by which those who are psychologically incapable of making an objective decision about Laetrile, or any other remedy promoted for a serious disease, may be distinguished from those who are susceptible to being misled by alluring claims of a quick and easy cure.

Physicians' Rights: The Privitera Case

Section 1707.1 of the California Health and Safety Code

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 (49) found in general that the purpose of the California statute which it 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, prescribe an unapproved 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 (46, p. 604) "...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 (47). 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 (39) upheld the regulation of abortion procedure locations and appropriate personnel by the state, applying the rationale 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 (50) 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 (46) 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 that 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 rationale 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 Ruther-

ford 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 (51).

Legal Implication for Cancer Patients

The legalization of Laetrile, as it has occurred to date, is partial legalization. The legalization for the terminally ill removed barriers to Laetrile's use by state statute or by court recognition of a patient's right to freedom of choice as pertains to health procedures.

Cancer victims constitute a minority group in our society; terminal cancer patients, a smaller minority, and minors an even smaller minority.

The so-called terminally ill are entitled under the Act to the assurance that the products they seek to use are effective not only for cure or treatment, but also for these other purposes. Further, approval of Laetrile for the terminally ill would pose a substantial threat to those whose cancer was merely "life-threatening." This very real danger was noted by Dr. Lewis Thomas at the Laetrile Hearings:

> It is often asserted that since Laetrile is not a particularly toxic substance, it should be made available to all patients who

> wish to use it as a matter of free choice. There is, nowever, a very real danger here. If, for example, children with early leukemia or sarcoma, or women with cancer of the breast, or young men with Hodgkin's disease, are persuaded to give Laetrile a trial before doing anything else, the outcome will almost certainly be death in circumstances where appropriate therapy could be life-saving (1).

Also, approval of Laetrile for the terminally ill would give the appearance of an official imprimatur, and would encourage use of the drug by patients who could be helped by legitimate therapy. (See the FDA Commissioner's Decision on Laetrile.) James Harvey Young, a noted medical historian, testified in that proceeding, on the basis of his study of past unproven cures that "[p]ermitting Laetrile's use in terminal cases gives it a credence among the public at large that will expand its use in early cases, for people will prefer taking a 'vitamin' to confronting the surgeon's knife" (8, p. 39805). Dr. Samuel G. Klagsbrun, a psychiatrist who works with cancer patients at St. Luke's Hospital in New York, testified that "[p]ermitting Laetrile to be used by any population of cancer victims would have the correlative effect of creating the misimpression in the minds of other cancer victims that the drug is, in fact, safe and effective for a broader population." Also Laetrile cannot be effectively restricted to a "class" of "terminally ill" cancer patients. The experience in this country in regulating other controlled substances available for limited use, for example cocaine, highlights the impossibility of restricting Laetrile to "terminally ill" cancer patients, and preventing broader promotion.

The danger conveyed by the "gloss of effectiveness" implicit in partial or total legalization is particularly acute in the case of children with cancer. Children constitute only one percentage of the cancer cases in this country but cancer represents the most serious threat to childlife next to accidents. Childhood cancers are also acknowledged to the category in which the greatest success in long term remissions and cures have been made. Yet, the natural desire for parents to avoid the suffering for their child which is a part of conventional treatment makes this class a minority which requires protection from the loophole in the law advanced in the Rutherford appeal court decision.

A child's need for protection is illustrated by a recent Massachusetts case (52) arising from a physician's

request to have a child committed to the Department of Public Welfare for the purpose of providing necessary medical care (chemotherapy) for the treatment of leukemia. The parents opposed the petition on the grounds that it violated their constitutional right to choose the medical treatment appropriate for their child. The record before the Massachusetts court showed that:

> [A]ccording 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 parents had taken the child off chemotherapy and sought alternative treatment methods for the cancer based on diet but the child had relapsed. 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).

The concluding statements of the Massachusetts Supreme Court are particularly significant in demonstrating the impropriety of the role of doctor/legislator assumed by the Rutherford appeals court in its partial legalization of Laetrile and the consequences of the loophole in the law which that court would create.

If, through a judicial right of privacy or state statute, a physician's choice of drugs is removed from federal or state control, and left to the affected individual, a serious question arises in the case of minors. Will parents

be permitted to make therapy choices for their child which do not hold out a reasonable hope of prolonging life or curing disease? What mechanism, if any, will call the offices of the courts and an adversary proceeding into play to protect the minor? At what age or stage of maturity will a child be permitted to make independent decisions?

In past cases, the conflict between parental choice and a child's treatment has come to the court's attention because a physician or child welfare officer at the behest of a physician has brought it there. If parents select a physician committed to therapies which lie outside the mainstream of cancer treatment and the delivery of these treatments at facilities congenial to such treatments and if that physician does not choose to be an arm of the court for the benefit of the child, will children automatically be subjected to their parents treatment decisions without regard for their welfare? These questions assume increasing importance if the gloss of effectiveness created by partial or total legalization of the substance Laetrile becomes a reality. They illustrate the fragile protections available to the minority class of children with cancers that hold a good hope of potential cure or, alternatively, a long remission period in which normal family life is possible.

The recent Massachusetts court order in a case involving a minor treated with Laetrile and a coroner's report of a Laetrile patient death attributed to acute cyanide poisoning both support the emerging profile of Laetrile as a toxic and dangerous substance.

The Coroner of Alameda County, California determined that a female cancer patient who was receiving Laetrile treatment died of cyanide intoxication. The cyanide levels in her blood were 3.8 mcg/ml. The deceased's Laetrile treatment commenced in March of 1978 with a dosage of 9 grms every day for 30 days, then reduced to 3 grms thrice weekly, later reduced to twice weekly and she was on the last course of treatment (once a week injections) when she died. If the deceased was unable to come in for injections, her instructions were to take one 1000 mg tablet of Laetrile (53).

In the case involving the child, Judge Volterra found that starting in April of 1978, the parents of the child, unknown to the physicians treating the child and unknown to the court, administered the following metabolic therapy daily to the child:

1 500 mg. Laetrile tablet
an enzyme enema with a wobe mugos tablet

4500 units of vitamin A
3500 to 4000 mg. of vitamin C
1 mg. of folic acid
650 mg. of calcium lactate
2 tablets of a mineral supplement known as Seroniums

In tests taken October 9, 1978, it was found that "the child was in no danger of acute poisoning (but there was concern) about the possibility of chronic, long-term poisoning." Tests were repeated on November 26, 1978 and in January of 1979 (54).

Further, the court found that: "neither amygdalin alone or the combined metabolic therapy has any curative or ameliorative effect in the treatment of cancer in general or acute lymphocytic leukemia in particular.

[A]ll four of the parents' experts agreed that amygdalin and metabolic therapy have no observable effect in curing acute lymphocytic leukemia. Dr. Contreras said he could make no claim that metabolic therapy has any specific action against leukemic cells. Dr. Manner conceded that the type of localized treatment involved in his experiments is inapposite to the systemic treatment needed to combat nontumorous cancers in humans, and admitted that metabolic therapy has had little success in treating leukemia. According to Dr. Halstead, amygdalin has had relatively poor results in leukemia treatment; according to Dr. Burk, metabolic therapy does not assist at all in the cure of this disease" (54, p.8).

Finally, according to the parents' experts, the court found that much of the supply of Laetrile available in the United States is "contaminated by bacteria and fungi and is of varying and uncertain strength" (54, p. 13). Dr. Halstead, one of the parents' experts, testified that the form of amygdalin manufactured and used by Dr. Contreras - Kemdalin - was unsafe for medical use, due to its unreliable strength and its adverse side effects, including pyrogen reactions (54, p. 25).

Finally, there are strong indications that the affidavit system for procurement of Laetrile and restriction to the terminally ill will not restrict the substance to that class and will make it available to those whose cancers are merely life-threatening and who could be helped by orthodox therapies. One example arose in the case involving a minor treated with chemotherapy under court order discussed above. During a hearing on whether the child was harmed by the addition of Laetrile, massive doses of vitamin A and enzyme enemas, a doctor testifying for the parents stated that he

did not believe that the minor was terminally ill but that he would execute an affidavit such as that required by the district court in the case before this court stating that the minor was terminal in order to permit the child to procure a supply of Laetrile (55).

References and Notes

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. United States v. An Article of Drug. Bacto-Unidisk, 394 U.S. 784, 793-799 (1969); United States v. Dotterweich, 320 U.S. 277, 280-282 (1943); United States v. Sullivan, 332 U.S. 689, 697 (1938).
3. 21 U.S.C. SS301, et seq. Originally enacted in 1938, the Act was substantially amended in 1962. Drug Amendments of 1962, 76 Stat. 780.
4. The Beard Foundation's 1962 application and the circumstances surrounding its rejection are recounted in a letter from the FDA files which is in the record of the Commissioner's "Decision on the Status of Laetrile," August 5, 1977, FDA Docket No. 77N-0048, 42 Federal Register 151, 39768 ("Hereinafter cited "Commissioner's Decision" or "FDA Laetrile Proceeding") as Attachment 12 to AF-15 (Affidavit of W. Sherwood Lawrence, M.D.).
5. Section 201(p) of the Act, 21 U.S.C., Section 321(p).
6. Section 107(c) (4) Pub. L. 87-781.
7. Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), cert. denied, 414 U.S. 944.
8. D. Kennedy, "Laetrile: Commissioner's Decision on Status," Federal Register 42(151), 39768-39806 (1977).
9. Weinberger v. Bentex Pharmaceuticals, 412 U.S. 645 (1973); Rutherford v. AMA, 379 F.2d 641 (7th Cir. 1967); National Ethical Pharmaceutical Ass'n v. Weinberger, 365 F.Supp. 735 (D.S.C. 1973), aff'd, 503 F.2d 1051 (4th Cir. 1974); Hanson v. United States, 417 F.Supp. 30, 37 (D.Minn. 1976).
10. Hanson v. United States, 417 F.Supp. 30 (D.Minn. 1976), aff'd, 540 F.2d 947 (8th Cir. 1976).
11. Rutherford v. United States (notes 15, 16, 21 and 26).
12. United States v. Allan Drug Corp., 357 F.2d 713, 718-19 (10th Cir. 1966), Cert. denied, 385 U.S. 899: United States v. 1,048,000 capsules, 347 F.Supp. 768 (S.D. Texas, 1972).
13. United States v. Spectro Foods Corp., No. 76-101 (D.N.J.

Jan. 1976), aff'd in part and rev'd in part, 544 F.2d 1175 (3rd Cir. 1976); Hanson v. United States, 417 F.Supp. 30 (D.Minn. 1976), aff'd 540 F.2d 947 (8th Cir. 1976); Gadler v. United States, 425 F.Supp. 244 (D.Minn. 1977); United States v. General Research Labs, 397 F.Supp. 197 (C.D. Cal. 1975); In re Morgan v. Matthews, No. 76-1637 (D.S.C., Nov. 30, 1976).

14. 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).
15. Rutherford v. United States, 399 F.Supp. 1208 (W.D. Okla. 1975), remanded for administrative proceedings 542 F.2d 1137 (10th Cir. 1976), 429 F.Supp. 506, 438 F.Supp. 1287 (W.D. Okla. 1977), 10th Cir. No. 77-2049 (decided July 10, 1978), petition for a writ of certiorari filed October 10, 1978, S.Ct. No. 78-605.
16. 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 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).
17. S. Rep. 74-361, 74th Cong. 1st Sess. (1935); Kordell v. United States, 335 U.S. 345 (1948) (mixture of minerals, vitamins and herbs is a drug); United States v. 250 Jars of U.S. Fancy Pure Honey, 218 F.Supp. 208 (E.D. Mich., (1963), aff'd 344 F.2d 288 (6th Cir. 1965) (honey sold for therapeutic purposes is a drug); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F.Supp. 336 (D.N.J. 1953) (cigarettes accompanied by leaflets claiming them effective in preventing respiratory diseases, common colds, influenza, acute sinusitis and other diseases held a drug).
18. Rutherford v. United States, 542 F.2d 1137, 1143 (10 Cir. 1976) and Petitioners Appendix at 32, 13a nn3-4, 14a n5. See Ewing v. Mytinger and Casselberry, Inc. 399 U.S. 594 (1949).
19. Tutoki v. Celebreeze, 375 F.2d 105 (7th Cir. 1967).
20. Rutherford v. American Medical Association, 379 F.2d 641 (7th Cir. 1967).
21. 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.

22. Rutherford v. United States, No. 77-2049, slip op. at 4. (10th Cir. July 10, 1978).
23. 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.
24. 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., Section 503(b) of the Act, 21 U.S.C. 353(b).
25. Laetrile Administrative Rulemaking Hearing: Oral Argument, Docket No. 77N-0048, Food and Drug Administration (2 and 3 May, 1977).
26. United States et al. v. Rutherford et al., Supreme Court Docket No. 78-605, Opinion of June 18, 1979 (slip opinion).
27. See Tables at pp. 65-71 in the brief Amicus Curiae of American Cancer Society, Inc., filed on March 8, 1979. In Rutherford supra. note 24.
28. California v. Zook, 366 U.S. 725, 729 (1949) citing Charleston & Western Carolina Ry. v. Varnville Furniture Co., 237 U.S. 597, 604 (1915).
29. See, e.g., 40 Cong. Rec. 1216 (1906) (statement of Sen. McCumber, co-sponsor of the bill).
30. Opinion of the Attorney General of Alaska Re: "Laetrile Bill," SLA 227 (1976), dated September 16, 1976.
31. House: Enrolled Act No. 1405, amending Indiana Code 516-8 (May, 1977).
32. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) cert. denied 409 U.S. 1064 (1972).
33. E.g., Guilmet v. Campbell, 385 Mich. 57, 68; 188 N.W. 2d 601, 606 (1971).
34. Hundly v. Martinez, 151 W.Va. 877, 158 S.E. 2nd 159 (1967) (physician represented that patient's eye would be fine after cataract operation but in fact the patient became blind).
35. The following states qualify distribution: Alaska, Alabama, Florida, Illinois, Indiana, Kansas, Maryland, Nevada, New Hampshire, New Jersey, North Dakota, South Dakota, Texas, Washington.
36. The following legalize manufacture, sales and distribution: Arizona, Delaware, Idaho, Louisiana, Oregon.
37. Alaska, Florida, Maryland, North Dakota, South Dakota, and Texas.
38. Slack, "Points of View," The Lancet, July 31, 1977, p. 240.
39. Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410

U.S. 179 (1973); Griswold v. Connecticut, 381 U.S. 479 (1965).

40. On January 5, 1978, the California Supreme Court granted a petition for review filed by the State in People v. Privitera, 141 Cal. Rptr., 764 (4th App. Dist.; Nov. 10, 1977). That pending action is denominated People v. Privitera, Supr. Cr. State of California, Docket No. Crim. 20340. Under California Law, the granting of such a petition renders the lower court's decision a nullity and without force, effect or precedential value. See People v. Murphy, 105 Cal. Rptr. 138, 7.13, 503 P. 2d 594 (1972), cert. denied, 414 U.S. 833 (1973). However, since the case focuses on issues which will be emerging in other unproven treatment cases, it is discussed in this article.

41. Privitera, supra, at 770. In commenting upon Justice Brandeis' most valued of rights, that right to be let alone, now Chief Justice Burger in his dissent in Application of President and Directors of Georgetown College, 331 F.2d 1010, stated:

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

However, that opinion is a dissent; the majority permitted the life saving transfusion. The court also held that society has a compelling interest in the preservation of life which justifies state intervention contrary to an individual's wishes. In that case the court observed that there were interests of minor children to protect. See also Raleigh Fitkin-Paul Morgan Memorial Hospital v. Anderson, 42 N.J. 421, 201 A.2d 537 (1964), cert. denied, 377 U.S. 985 (1964).

42. Privitera, supra., at 770. "In Erickson v. Dilgard, 252 N.Y. Supp. 2d 705, a New York court sustained the unwilling Jehovah's Witnesses' objection to a needed blood transfusion despite risk of death. The Court there said at page 706:

> '...it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires.'

To the contra see John F. Kennedy Memorial Hospital v. Heston, 58 N.J. 576, 279 F.2d 670 (1971) in which the court ordered a transfusion to save the life of a 22 year old unmarried accident victim who had refused for religious reasons.

43. Privitera, supra., at 20, quoting from Aden v. Younger, 57 Cal. App. 3d. 662, 684, 129 Cal. Rptr. 535. See also Matter of Quinlan, 70 N.J. 10, 355 A.2d 647. See discussion of informed consent at pp. 18-23 infra. There are real questions pertaining to whether the emotional pressures surrounding the promotion of Laetrile permit informed consent by a cancer patient.
44. The quote relied upon by the Rutherford District Court "That 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, do what he pleases, go where he pleases.'" Kent v. Dulles, 357 U.S. 116, 126. is found in Justice Douglas' discussion of his second group of freedoms. Kent v. Dulles is a passport/freedom of movement case.
45. Under the statutory plan, Schedule II drugs have a medically recognized use but have a potential for abuse while Schedule I drugs have no recognized medical abuse.
46. Whalen v. Roe, 429 U.S. 589, 598-600 and n. 24.
47. People v. Privitera, Crim. 2034, Super. Ct. No. CR-3278, Supreme Court Opinion of March 15, 1979.
48. See Note 26, slip opinion at p. 11 text and note 13.
49. People v. Privitera, 141 C. Rptr. 764 (4th App. Dist; Nov. 10, 1977) appeal pending, Calif. Supreme Ct. Docket No. Crim. 20340 decided March 15, 1979 (47).
50. Planned Parenthood v. Danforth, 428 U.S. 52 (1976).
51. James Robert Privitera, Jr., v. The State of California, Supreme Court Docket No. 78-1850.
52. Custody of a Minor, Supreme Judicial Court No. P-1422, Mass. Supreme Court, July 10, 1978 affirming the decision of Superior Court Plymouth Division of April 18, 1978 in Civil Action No. 78-6916.
53. Alameda County Coroner's Report of 2/1/79, On the Matter of the Death of Jo Anne Etta Pye.
54. Opinion of Judge Volterra, January 22, 1979, Custody of a Minor, Mass. Superior Court Docket No. 78-6816 pending appeal, Massachusetts Supreme Court (slip opinion).
55. Custody of a Minor, on January 8, 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 "Bohannon affidavit" attesting that Chad does have terminal cancer. On January 9, 1979, Dr. Bruce Halstead of California made the same statement.

Arthur L. Caplan

6. When Liberty Meets Authority: Ethical Aspects of the Laetrile Controversy

Should the Ethical Issues in the Laetrile Dispute Be Taken Seriously?

It is no accident that many of the arguments concerning the use of laetrile to treat cancer in afflicted individuals have been couched in ethical and moral language. Ethical language has a good deal of authority and power in contemporary American society. The invocation of language concerning 'rights,' 'freedom,' 'coercion' and 'autonomy' is a powerful chip to play in policy debates. Such language seems unassailable and definitive in arguments about controversial matters of public moment. Once someone has claimed 'a right to choose a mode of treatment' or the 'freedom to care for one's body as one sees fit,' there seems to be little ground for further discussion and debate. Ethical language is often used to stake out the limits or boundaries of policy argumentation -- the point beyond which further discussion is pointless.

In addition to this topographical duty, moral terms often serve powerful rhetorical and political purposes. Disputants in policy debates in all areas of American life have been quick to recognize the hortatory and political force of talk about morality and ethics. Recent debates about civil rights for blacks and women, abortion, school desegregation, affirmative action, and nuclear power have all been couched in the language of ethics and morality. Nothing seems to work as effectively to rouse adherents of all persuasions and positions concerning various controversial policy issues to action as a rousing dose of ethics.

The difficulty posed by the rhetorical or political uses of ethical language is that it is not always possible to discern the pivotal ethical arguments and value commitments of those engaged in a controversy amidst all the

verbiage that passes for public debate. Nor is it always possible to decide whether an argument is raised in a policy debate as a matter of politics. The decision not to 'dignify that argument with a response' can be a sign that an argument is weak, incoherent, or logically fallacious. But, it can also be a sign that an argument phrased in ethical terminology is being interpreted as a mere smoke screen -- perhaps to divert attention away from the real issues in a debate, or, perhaps to disguise what is in reality a political, religious, or empirical belief.

All of these problems of interpretation and legitimacy surround the assessment of the ethical issues involved in the use and regulation of laetrile. It is not always clear which ethically grounded claims are mere rhetoric and which represent real, reasoned value differences among individuals. The situation is made more complex by the fact that ethical language is used by proponents and critics of laetrile to delineate the scope and boundaries of the issues open to debate concerning laetrile. This topographical use of ethical terminology in arguments about laetrile has the consequence that the focus of ethical argumentation is constantly shifting as the parties to the debate attempt to maneuver argumentation toward issues more favorable to their goals. It is not a particularly easy task to try and decide which ethical issues are central in talking about laetrile when the priorities and weights assigned to various ethical issues are so open to the pulls and tugs of the disputants (1).

The delineation of the central or 'real' issues which characterize disputes about laetrile is made even harder by the fact that laetrile has served as a rallying point for disputing camps concerning matters of ethics and political theory that have nothing to do with the pecularities of the use of laetrile to treat cancer victims. Laetrile is at the tip of a very large iceberg of difficult questions concerning the appropriate role of government in interfering for any reason whatsoever with the lifestyles and liberties of individual citizens. The nature of governmental authority, the expertise of governmental and professional groups, the legitimacy of governmental sanctions, penalties and rules -- are all issues of long standing concern for ethics (2). Unfortunately, most of the debates about these complex issues have taken place within the context of pressing policy issues such as the controversy over laetrile; contexts in which the half-life of abstract but nonetheless important issues regarding the nature of democracy, political authority, and scientific methodology is very, very short.

The fact is that there are actually two main types of

ethical issues that swirl around the use of laetrile. One set of issues concerns general policy issues about the appropriateness of government control and regulation of individual behavior and activity. The other set of issues concerns ethical arguments unique or particular to the use of laetrile as a drug to palliate or cure cancer. While the former set of issues constitutes the heart of distinctively ethical disagreements about laetrile, the latter type of issues tend to dominate the rhetoric and pamphleteering of the actual debate about laetrile. Much more has been written by those active in the laetrile controversy about the correct chemical composition of laetrile and the adequacy of clinical trials of this substance than has been written about the proper role of government in regulating pharmaceuticals or policing the medical marketplace (3). Indeed, the only way of dissecting substantive matters of ethics from mere rhetoric regarding laetrile may be to inquire into the general set of moral issues raised by laetrile use and then to use this moral taxonomy to assess the actual moral claims concerning laetrile that are specific to this controversy.

One final general comment about the ethical issues involved in the laetrile debate deserves mention. It might be argued that any attempt to assess the ethical claims made in the context of arguments about laetrile is doomed to irrelevancy at the outset since these kinds of considerations are not (and perhaps never are) likely to be determinative of the outcome of the debate. Law, politics, economics, luck, and emotion are all more plausible candidates to serve as explanatory variables regarding the course of the laetrile controversy than are ethical concerns. Debates about scientific or medical matters may begin over ethical disagreements, but, money, power and chance eventually take over center stage in understanding and explaining the course of such controversies (4).

The difficulty with this sort of worry about taking ethics seriously in controversies in science is that when taken to extremes it leads to the conclusion that reasoned argument plays no role at all in arguments about policy issues involving science and medicine. The fact is that while the ethical proclamations of various parties to the laetrile debate may fall on a wide variety of deaf ears, the disputants still feel motivated and obligated to engage in this particular variant of debate. And there is no reason to dismiss the fruits of their moral labors out of hand. Ethical arguments may not be the best vehicle for understanding the course of a scientific or policy controversy. But they are certainly important elements within controversies such as the laetrile debate. Thus, their

evolution and resolution ought to occupy the minds of those attempting to assess such controversies even if they are not always foremost in the minds of disputants involved in the actual give and take of controversy.

Who Needs Government Regulations?

One of the key issues raised by the laetrile dispute is the issue of the legitimacy of governmental regulations of the behavior of ordinary citizens. The specific issue concerns the moral legitimacy of allowing governmental officials or representatives to decide for individuals what drugs they will be able to buy, from whom, why, when they will use them, and, what they will be told about them. There are a host of ethical problems involved in this area of governmental authority and regulation. However, in large measure, many of these issues are directly contingent upon our understanding of the nature of the individuals involved as the subjects or beneficiaries of regulations.

Laetrile proponents tend to depict the consumers of laetrile as independent, autonomous, tough-minded agents who choose, on the basis of their values and interests, to use laetrile for the treatment or prophylaxis of cancer (5). Critics of laetrile tend to depict these same consumers as hapless pawns just waiting to be tricked, duped, and deceived at a time of grave emotional turmoil by money-hungry quacks and charlatans (6). One need not be a devotee of the view that the truth lies at the mean to recognize that such polarized views are unlikely to lead to a consensus about the legitimacy of regulating the sale and use of laetrile.

One way of beginning to get a handle on the appropriateness of these characterizations of citizen consumers of medical expertise and pharmaceutical paraphernalia is to see whether certain classes of people might reasonably be excluded from one polar characterization or the other. For example, even the most vociferous proponent of the autonomous agent model of medical consumerism would be forced to admit that fetuses, infants, the retarded, the comatose, and children up to a certain age (say sixteen) are not the strongest contenders for classification as independent, autonomous agents.

What is interesting about this group is that the number of individuals in it is not small, and, that the members of this group have a number of things in common. They are, as a class of people, especially dependent upon others for their existence and survival. They do not have or may have lost their full capacities and powers to function optimally as

rational agents. They lack the ability to indicate and protect their interests (7). That is, they cannot always say what they want or need and, even if they can, they have only the vaguest idea of how to go about getting what it is they want or need.

If we look to these traits it is not hard to think of other categories of people who might swell the ranks of the likely non-autonomous even further. The insane, the seriously ill, the senile, some of the illiterate, some of the alien or newly emigrated, some of the handicapped, some of the drug-addicted, and, some of the institutionalized are all prima facie candidates. This means that the percentage of the general population likely to be excluded from the proposed anti-regulation census of autonomous agents is quite probably larger than those included in such a group. And this result is obtained without even trying very hard, i.e., no ideologues, milquetoasts, sloths, sluggards, or compulsives have been included.

The question then arises as to whether anyone can satisfy the minimal requirements of agency requisite for the kind of autonomy and independence laetrile proponents have in mind. This brings us to a consideration of the portrait drawn by proponents of regulation and protectionism regarding medical consumers.

Much is made in this portrait of the fact that persons who believe or have been told they have cancer (or other serious illnesses) are paralyzed by fear. A fear issuing from both the knowledge of the disease and its dreaded prognosis, and, the knowledge of the pain and cost of the standard treatments for serious disease. The fear, anxiety, and loss of hope surrounding the cancer victim are presented as being totally incapacitating -- the patient is too emotionally disturbed to think straight, and is rendered irrational by the trauma of the diagnosis of cancer (8).

Moreover, persons who believe themselves to be seriously ill are depicted by the anti-laetrile standard bearers as particularly vulnerable to manipulation and propaganda. Desperate people are likely to grasp at any straw of hope, even if the straw is as flimsy as treating cancer with apricot pit extract. On this view the only way of explaining the appeal of laetrile among many persons is by dismissing their behavior as mindless, irrational or desperate. The choice of laetrile therapy becomes sufficient evidence for classifying an individual as emotionally incapacitated or brain-washed.

The difficulty with this picture of the medical consumer as 'vulnerable' agent is that it runs the risk of assigning all persons to the class of vulnerable medical consumers in need of regulation and protection. It is no doubt true that many persons are traumatized to the point of complete mental paralysis by a diagnosis of cancer. It is also true that many people, ignorant of science and pharmacology, will choose to use laetrile as a therapy in desperation. But, since there are many trying emotional circumstances in everyday life that can traumatize people and lead them to acts of desperation, these facts would not appear to be sufficient for declaring an individual incompetent to govern his or her medical life. The death of a parent or child, the experience of war, bankruptcy, divorce, unemployment and other awful experiences too numerous to list can traumatize even the sturdiest souls. Yet, our society seems to feel no moral obligation to legislate special governmental protection and medical regulations for people confronted with these emotionally trying experiences. This is due to the fact that the 'picture' of the cancer victim is conceptually muddled.

The attempt to portray all cancer victims as vulnerable and incapacitated runs afoul of two conceptual confusions. While it is true that people are rendered incompetent by a variety of experiences, it is also true that most people are able to adapt and accomodate themselves to the most traumatizing of experiences. Vulnerability and incompetence can be either transient or permanent states (9). If a person is permanently vulnerable or incapacitated (i.e. retarded, senile) legislation seems appropriate as a possible protective measure for many types of activities including health care. But transient vulnerability is an entirely different matter. It is harder to assess, difficult to endure, and impossible to prevent. Some cancer victims may be rendered permanently vulnerable and defenseless by their disease and their fears. But others, and my guess is that this is the majority of patients, are traumatized for shorter times. The only way this sort of vulnerability could be assuaged at a governmental level is through legislation. But this would pose both impossible problems of classification, and swell the ranks of the vulnerable beyond reason since, as was noted above, cancer is not the only nor even the most powerful cause of vulnerability.

That government should protect through law, rule, and sanction the weak, the vulnerable, the incapacitated and the traumatized is a political obligation whose standing seems secure (10). But, given the reality of human experience and human adaptability, a certain amount of vulnerability, weakness, trauma, and incapacity is the lot of us all. It is

the degree and the transience of these states that must be used to legitimate government concern and intervention.

It is not sufficient grounds for intervening in peoples' lives to say that they are incapacitated. Nor is it sufficient, as many laetrile critics seem to think, to say that a person is ignorant. Ignorance may be relevant to deciding whether a person is an ignoramus about a particular subject, field, or discipline, but it is not a sufficient condition for incompetence. Nor is the use of laetrile sufficient evidence of ignorance since ignorance is being hypothesized as the most plausible explanation for the selection of this chemical therapy. Besides, ignorance is often a reversible state of mind. This being so, regulation and protectionism would have to take a drastically different tack from their present course relative to laetrile if consumer ignorance were the major reason motivating the anti-laetrile camp.

Where does all this leave us then regarding the issue of who needs government regulation of laetrile? It should be obvious that there is a fairly large segment of the population who do need some sort of protection regarding the sale and use of medications. These individuals will not be helped by simply making information concerning disease and medical therapies available. For one reason or another this significant segment of the population will need scientific guidance and protection in selecting a therapy for life-threatening diseases such as cancer.

On the other hand not everyone in society needs the protection of federal or state government in deciding what to do about a diagnosis of cancer. Even those persons who are initially devastated by this dreaded diagnosis may eventually adapt to the reality of their situation and be in a position to regulate their medical affairs without the benefit of bureaucratic counsel. The anxious and the ignorant may be manipulable, but since this is true of most people under all sorts of trying circumstances, the permanence as well as the severity of disablement must be ascertained in determining the need for governmental help and advice.

Harm, Paternalism, and Protectionism

The argument has been made that the percentage of individuals in America likely to be in need of help, protection, or regulation regarding pharmaceuticals in general and medical therapies for cancer in particular is not small, but is not one hundred percent either. One might then reasonably ask exactly what are those who are manifestly vulnerable being protected from? The answers given to this question are

important since, if the harms and risks faced by vulnerable persons are either small or impossible to ameliorate, the legitimacy of regulating laetrile, despite the existence of a vulnerable group, would be greatly weakened.

There would seem to be two types of harms facing those who choose to use laetrile or other exotic therapies to treat their diseases. These people may harm themselves or they may cause harm to others.

There are many ways in which persons may cause harm to themselves by using laetrile. They may worsen the state of their disease by delaying standard medical therapies. They may put themselves at some risk to the toxic side-effects of the drug. They may risk psychological harm in the disappointment that may result from the failure of the drug to palliate or cure the disease. And they run the risk of harming their social and economic security by spending large portions of their financial resources on a dubious therapy.

There are a number of harms that may befall others as a consequence of laetrile use. Children or dependents may be denied access to medical care in favor of laetrile therapy. The confidence of the public in medicine and health care may be weakened by the bad example set by laetrile users. Medical research on cancer could be slowed by narrowing the pool of cancer patients available for research. And by delaying in availing themselves of traditional medical therapies, cancer patients may increase the social burden of paying for their medical care when they do finally fall within the purvue of medical science (11).

On one reading both types of harm are significant. The risks of increased morbidity and mortality, or financial ruin, of a loss of public confidence in scientific medicine, posed to a rather large proportion of the general population are nothing to snicker at. On the other hand, the risks involved are no worse than are encountered in many other areas of medicine and daily life. Strikingly similar cases could probably be mounted with little effort against candy, soda pop, guns, automobiles, bathtubs and lawnmowers -- none of which seem to have commanded the rapt attention of government in the way laetrile and other pharmaceuticals have.

Nor is the protection against harm to the manifestly vulnerable rationale strengthened when the grim prospects awaiting the cancer victim are added to the harm ledger. The risk of morbidity and mortality among persons afflicted with various cancers is high regardless of the therapy that is elected (12). And the efficacy and toxic side-effects of

available medical interventions leave much to be desired. And the psychological and financial costs of the standard medical regimens for cancer -- surgery, radiation, chemotherapy -- can be as great as any posed by the use of laetrile.

The usual justification for restricting the sale of laetrile is that such a restriction is the public's best interest. The moral foundation for drug regulation is that the public needs some assurance of the safety and efficacy of medicinal drugs. Without such legislative protection quacks and charlatans would be free to bamboozle a gullible public into the purchase of all sorts of odd chemicals and treatments. There is a long and distinguished history of medical charlantry available for anyone to study who doubts the scope of human greed and gullibility (13). And one need only look to contemporary abuses in fields such as weight control, nutrition, and psychotherapy to see that the phenomena of medical quackery is far from being a thing of the past.

The typical response of proponents of laetrile to governmental protection is 'thanks but no thanks.' Government legislation is seen as restrictive of the individual's right to choose those therapies deemed most useful and efficacious in treating an individual's ailments. The freedom of choice in all matters of personal behavior, including the selection of therapies and medical treatments, is taken as a central value and right of each citizen. Not all proponents of laetrile want to deregulate the drug in order to profit from its sale. For many the issue is one of defending personal freedom against the heavy bureaucratic hand of the state. The cost of that freedom in terms of the pain and suffering caused by bad choices is seen as far more preferable than the burdens imposed by a heavy-handed government bureaucracy.

In some ways laetrile is a particularly nasty battle which represents a preliminary skirmish in a broader social conflict over the value of personal freedom in contemporary America. Both sides recognize the slippery slope dangers lurking about the laetrile debate. Those favoring government regulation of the marketplace see laetrile as a first step toward returning America to a libertarian caveat emptor existence. Laetrile's advocates also see the legalization of laetrile as the first step toward removing governmental authority from daily life. With so many other issues available as topics for this debate, it is ironic that a rather harmless drug should wind up being cast in such a pivotal political role.

Freedom and Paternalism

The arguments for any sort of governmental regulation in the public interest are aimed at countering worries about the loss of free choice by the benefits to be garnered from protection. This involves regulation proponents in arguments which debunk the freedom of choice (14) ('Freedom is of little use when you're dead,' cancer patients are incapable of free choices, no one is free to kill themselves, etc.), while simultaneously defending the legitimacy of various forms of paternalistic governmental interventions in the daily lives of citizens. The issue of regulating the sale and use of drugs for medical purposes is thus metamorphised into a debate about freedom versus paternalism.

Those in favor of regulating the availability of drugs such as laetrile do not particularly care to be labelled as paternalistic. The notion of paternalism, especially governmental paternalism, has very negative connotations in our society. Paternalism is barely tolerated by its traditional subjects -- the poor, the retarded, and children -- so it is difficult if not impossible to see how anyone might reasonably expect fully mature rational adults to accept any sort of paternalistic meddling by government for any reason or purpose (15).

The central philosophical reasons underlying the general distaste for paternalism felt by many persons would seem to be (1) that paternalistic behavior is seen as an unwarranted restriction on the freedom of choice resulting from the interference of one person or group of persons with the behavior of another and (2) that people generally think they are the best judges of what is in their own best interest. No one likes to be told what to do or how to act, and it is certainly true that no one relishes being forced or coerced into behaving in certain specified ways. The awkwardness of the regulator's moral stance is patent; either an argument must be made that what looks like a restriction upon personal freedom, the buying and use of a particular drug, is not, or, that in certain cases paternalism is justified.

Philosophers traditionally approach the question of freedom by drawing a distinction between positive and negative freedom (16). Negative freedom indicates the absence of external coercions, restrictions, or hindrances. Physical force or threats of harm are paradigm examples of external coercion. A person who is under compulsion or coercion cannot be said to be free. But the absence of restrictions or coercions is not sufficient for insuring freedom.

A person must have viable distinct options to pick among, or a variety of courses of action available if freedom is to be meaningful. Positive freedom is meant to capture this aspect of freedom. Without real choices, freedom would simply not exist. A man standing naked in the heart of the Sahara desert may be free from compulsions, coercions, and restraints, but his freedom is, nonetheless, severely limited since his options for choice and action are severely limited.

The problem confronting those who want to argue that the regulation of the sale and use of laetrile does not restrict or abrogate freedom is that it clearly does. Regulation, in the form of legal constraints and trade sanctions, almost always constitutes an obstacle to negative freedom. It is simply silly to deny this fact. But it is also silly to think that negative freedom is sufficient for personal freedom. It is not since options, choices, and alternatives are at least as important as the absence of shackles, threats, and laws. Positive freedom is as important as negative freedom in establishing meaningful personal freedom for any individual.

Regulation is not necessarily incompatible with freedom. It is only when negative freedom is restricted without a proportionate increase in positive freedom that regulation and freedom can properly be seen as antithetical. Regulations or laws which do not increase the options available to citizens or promulgate circumstances under which real choices can be made are in conflict with personal freedom. This would not necessarily mitigate against the institution of such regulations or laws. But no amount of cosmetic argumentation will disguise the incompatibility that exists between such regulations and freedom.

If it is true that freedom of choice is quite compatible with certain types of laws and regulations, it is also not clear that all forms of paternalism necessarily conflict with personal judgments of self-interest. An action undertaken in behalf of another is not indicative of impaired judgement or superior insight on the part of the actor. Some actions are simply done in the interests of others as a consequence of the act being delegated or assigned by one party to another. Paternalism can only occur when an actor has not been authorized or delegated to act in the recipient's behalf.

Many persons who participate in democratic systems delegate all sorts of powers to others to act as their representatives or delegates. Large portions of governmental

activities and policies are not paternalistic simply by dint of the fact that government acts at the request of its citizens and not necessarily from a desire to benefit them. When the authority or license to represent a person is withdrawn from government then there might exist some basis for concern about unjustified paternalism. But when the legitimacy of representative government goes unchallenged, paternalism becomes a difficult charge to make or to prove.

There are situations in which individuals do not consent to others acting in their interest or in their behalf. Such cases are better candidates for being designated as paternalistic. But they are not necessarily unjustified simply because they are paternalistic. If the decision-making powers of an individual are impaired, if there is grave risk of serious and irreversible harm occurring, if the paternalistic act is easily reversible, or if there is no opportunity to ascertain the desires and aims of the actor at a particular moment, then a paternalistic action might be morally defensible (17). Children, the insane, and the ignorant can all be the subject of paternalistic behavior since they fulfill one or all of these general conditions.

If paternalism can be justified in some cases, and if not all legal regulation is compatible with freedom, what can be said about the morality of regulating the sale and use of laetrile? It has already been argued that there exists a substantial segment of the population who are in need of government protection and regulation for a variety of reasons. Positive freedom is not a realistic goal for many people and paternalistic action in their behalf seems reasonable and morally appropriate in many cases. However, for many other individuals in our society positive freedom is a viable and morally compelling value. Furthermore, despite their ailments and psychological ups and downs, these people often do not meet the criteria for legitimating paternalistic behavior. They are only temporarily impaired by disease, the harm that awaits them is often unavoidable under any circumstances, and there is ample opportunity to discern their judgments and feelings about the effect of laetrile use on their self-interest. Since it is hard to see how withholding laetrile from such persons could serve to maximize their positive freedom in a manner commensurate with the deleterious effect such action would have on their negative freedom, it becomes hard to see how the regulation of the sale, manufacture, and use of laetrile could be morally justified. Once the conditions and components of freedom and paternalism are explicated, the moral case for the anti-regulation proponents of laetrile looks quite strong. If the arguments about the morality of drug regula-

tion regarding laetrile are confined solely to questions of freedom, competence, paternalism, and harm, freedom will undoubtedly win out on moral grounds over authority (18).

Filling in the Gaps in the Laetrile Debate

At the beginning of this essay it was suggested that a general discussion about the moral issues involved in regulation and free choice might shed some light upon the laetrile controversy. When this analysis is conducted it turns out that, on grounds of freedom, competence, harms, or paternalism, there is little justification for asking mature adults to subscribe to a system in which laetrile is restricted for sale and use. This is an interesting conclusion since it would seem to imply that, if the laetrile debate is confined simply to these moral issues, regulation must give way to personal choice and the free market place. If it is true that laetrile is relatively harmless, that the knowledge of cancer does not render people automatically incompetent, that ignorance is an insufficient basis for restricting freedom, and that medical science cannot, in most cases, palliate or cure cancer, then regulation will have to give way as unjustified on grounds of freedom and paternalism.

Nonetheless, despite the fact that this conclusion seems to follow from my arguments, I think it may still be invalid. But this is only because there are other concerns besides freedom, harm, competence, and paternalism that must be appended to any discussion of laetrile. Since they are often omitted from present discussions about regulating this drug, this paper will conclude by alluding to two of the more central of these neglected topics.

First, laetrile regulation is only one tiny portion of the legislation that exists to guide and direct the daily lives and activities of persons and groups in various locales. Legislation, if it is to be effective, must be clear and universal in its intent. By this political theorists mean that people must be able to understand the laws and that the laws should not be *ad hoc* or weighted with exemptions and *ad hominem* provisos (19). Legislation cannot work if each person is a law unto him or herself.

If clarity and universality are vital components of legal and legislative efficacy then the arguments against regulating laetrile may founder on these requirements. Critics of laetrile laws do not argue for the legalization for manufacture, sale, and use of all drugs and pharmaceuticals. Rather, they argue that an exception should be made

for laetrile. But the argument for exempting or reclassifying laetrile does not hinge on the generic features of the drug. Proponents of laetrile argue that it is different because it has a 'special' history, a 'special' chemistry and 'special' composition. These arguments may make laetrile unique, but they also make it difficult to exempt from controls and sanctions. There is a slippery slope here down which many powerful and manifestly harmful drugs could slide if an exception were made for laetrile simply on the grounds that it is a unique or special drug (20).

Moreover, the legislation dictating controls over the sale and use of laetrile is motivated, in part, by a desire to control deception and fraud in commercial transactions. It is, admittedly, an empirical question as to what, if anything, laetrile can do to ameliorate or cure cancer. But if its curative powers are indeed limited, then laetrile, like any other item of commerce, falls under government control and authority not as an object of medical interest but as an item of commercial interest. The moral underpinnings of regulating laetrile have as much to do with promoting commerce and discouraging fraud as they do with freedom and benevolent paternalism.

The arguments for legalizing laetrile for cancer victims also run into problems with ad hoc legislation on the grounds that exempting a cancer patient from a law on the grounds of terminal illness being present looks suspiciously like an exemption that is indeterminate and specious. Laetrile proponents cannot have it both ways; either cancer victims are competent or they are not. If they are competent, then the type of disease they have would not in itself be grounds for an exemption from legislation including laws concerning drugs. Persons who are dying need certain special protections under law, but to be persons they require legal liability as well. And if this means discouraging fraud and encouraging responsible free trade, then this must be meant for all persons whether they are dying quickly or slowly, or, whether they discern their mortality or do not (21).

There is another issue in addition to the limits and requirements of effective legislation which must be added into the equation of the laetrile debate. In addition to freedom, harm, and benevolent paternalism, considerations of justice directly affect the regulation and control of drugs and pharmaceuticals.

Laetrile legislation can be seen as an example of broader legislation intended to protect the interests of a minority. There are many examples of laws in our society and

others which are intended to protect or benefit a minority of citizens rather than a majority. Tax incentives for businessmen, affirmative action programs, welfare programs and the voting rights act are all examples of legislation intended specifically for minorities and not majorities. If it is possible to establish a category of persons in this or any other society who are clearly vulnerable persons in the sense that they cannot actively and responsibly participate in the free market of commerce, then it may be necessary to enact legislation to protect or benefit such a group. It may be the case that a majority of persons do not require the benefits and protections afforded the minority by the regulation of drugs and medicinals. But it may also be the case that the effective protection of the minority can only be accomplished by burdening the majority with unneeded and unwanted legislation. Considerations of justice may, in fact, require that the majority be asked to suffer in order to assure the protection or benefit of a minority (22). This is especially so when the minority is at a particularly significant risk relative to the majority. The least well off in any society may have special needs and problems that demand unfair or unwanted legislative treatment of a majority.

One example where justice may result in the advancement of minority interests over majority concerns is the area of gun control. Most people may be able to deal competently and safely with guns. But there is a significant minority of the population who, for one reason or another, lack such competence. Thus gun control may be needed not to benefit society as a whole, nor to protect the best interests of the majority, but to protect and benefit a minority. The majority may not need gun control laws, but the minority, due to their vulnerability, may require them. Efficacy and justice can combine to produce moral grounds for legislation which the majority finds distasteful and even coercive.

It is difficult to state in the abstract the conditions under which a desire to benefit the least well off might morally legitimate infringing the rights and freedoms of the majority. My point is to simply note that this situation can arise and that it may be relevant to the moral arguments concerning drug regulation in general and laetrile laws in particular. The retarded, the senile, children, and the insane may require special protections from fraud and harm relative to the sale and use of any drug. Most citizens do not fall into one of these categories and do not, therefore, require such protection. But many people do and, if they are to be protected efficaciously and benefitted maximally, then this may entail broad legislative measures which sacrifice majoritarian rights for minority benefit.

It may be that laetrile legislation is paternalistic. It may also be true that laetrile regulation restricts negative freedom without any gain in positive freedom. But it does not have to be the case that the persons affected by this regulation are affected in the same way. The paternalism may only be extended toward the minority who clearly need it. The infringement of freedom may only befall a majority who could certainly do without this infringement. But justice and efficacy may dictate this disproportionate allotment of benefit and burden. Whether it does or does not can only be ascertained by correctly discerning the complexities involved in the moral arena of government regulation and personal freedom.

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7. Social Context of the Laetrile Phenomenon

In recent years Americans have witnessed a tremendous amount of conflict over Laetrile (1,2). Proponents of this purported cancer treatment have battled the Food and Drug Administration, the American Cancer Society, the National Cancer Institute, and other medical authorities in a variety of settings including the media, state legislatures, and the courts. Why has the dispute over Laetrile emerged as a major social controversy in the 1970s? How can we account for the impressive growth of the Laetrile movement during this period? How have the Laetrile proponents been able to achieve political victories in the face of prestigious and powerful opponents?

This chapter will attempt to answer these questions through an examination of the social matrix in which the Laetrile controversy is embedded. In approaching the dispute over Laetrile, we will consider three types of factors: scientific, contextual, and situational. Scientific factors focus on the philosophical and professional variables common to many controversies in medicine. Much of the enmity of the current debate is traced to social and subjective forces within science. Contextual factors include such basic American values as individualism, freedom and equality. Contemporary Laetrile appeals, such as freedom of choice and rejection of expertise, as well as opposing anti-Laetrile arguments, are rooted in such values. Finally, situational variables unique to the 1970s are examined. These include such factors as heightened frustration over the inability to cure cancer, the decline in trust in science and medicine along with the concomitant growth of self-help medicine, and changes in the Laetrile movement itself.

Our approach to the Laetrile phenomenon is guided by Bloor's call for the "strong program" in the sociology of knowledge (3). Bloor contends that the sociology of scienti-

fic knowledge should be causal, impartial, and symmetrical (4). While sociologists would not want to argue that social factors are the sole cause of beliefs, they should be concerned with the social conditions producing belief or states of knowledge. Furthermore, the strong program demands an approach which is "impartial with respect to truth and falsity, rationality or irrationality, success or failure" (3, p. 5). Explanations in this approach should be symmetrical; the same types of cause may explain true and false beliefs. As Bloor has observed, scholars of science have too frequently sought causes to explain error or deviation while assuming that logic, rationality, and truth were their own explanation.

For these reasons we take an impartial -- perhaps agnostic -- position on Laetrile. We will not be concerned here with whether or not Laetrile controls cancer. Further, we will approach both sides of the Laetrile controversy in a similar manner. We do this not because we wish to suggest that both sides have an equal legitimacy, but because an explanation of the phenomenon should be symmetrical. The causes of the behavior of both sides of the controversy come from the same social matrix. Both must be understood to appreciate the controversy's social and intellectual foundations.

Schattschneider's (5) work on contemporary American political movements is our theoretical exemplar. Though Schattschneider outlines a conflict theory of politics, his work has implications for disputes which are not exclusively political -- such as the Laetrile controversy. Consistent with the strong program, his analysis is causal, emphasizing the role of audience and other resources in the resolution of conflicts. This focus remains unchanged, though the initial winners of a conflict may become the eventual losers. Moreover, the analysis is impartial with respect to the truth claims of both sides. Schattschneider's analysis is also symmetrical, meaning that both sides of a controversy are likely to use similar tactics and strategies, depending on the strength of their initial and developing positions.

Schattschneider asserts that the scope of a conflict determines its outcome. Disputes are won or lost depending on the extent to which the audiences are mobilized to participate in the conflict. The main struggle -- and most important strategy -- in politics is over the scope of conflicts. At any level the likely winners of a conflict will try to limit the scope of the dispute while potential losers will work to expand it. As Schattschneider observes, "it follows that conflicts are frequently won or lost by the success that the contestants have in getting the audience involved

in the fight or in excluding it, as the case may be" (5, p. 4).

One cannot, then, forecast the outcome of conflicts by simply estimating the strength of the original contestants. The weaker side in a dispute may have great potential strength if it can be aroused. Changes of scope contain a bias since it is highly unlikely that both sides of a dispute will be evenly reinforced as additional combatants enter the arena. Though the losing side generally tries to expand the conflict, there is always a risk in so doing: the new publics involved may be strong enough to wrest control from the original combatants. In mobilization, then, contestants on one or both sides may lose control of the shape of the conflict.

Schattschneider maintained that ideologies which emerge in conflict are best understood as strategic and tactical attempts to manipulate the scope of a dispute. Rather than viewing controversies as value conflicts, Schattschneider viewed political disputes as mediated through the successful appeal to values. Ideas such as individualism, localism, and privacy and economy in government have frequently been used to try to restrict the scope of conflicts, while equality, consistency, justice, liberty, and freedom are often used as means of broadening the scope of disputes.

Bloor and Schattschneider pose a set of strategic and tactical questions for this inquiry: which interest groups have militated for and against Laetrile? What audiences have they attempted to mobilize? Which ideologies have they invoked? And has each side maintained control of its own tactics? In our consideration of the way contextual, scientific and situational factors have shaped the Laetrile controversy, we shall address these questions.

Scientific Factors

Both advocates and opponents of Laetrile have used scientific arguments as tactical and strategic resources in the controversy. Supporters of Laetrile have sought to expand the controversy by attacking the philosophical assumptions of modern medicine and positing an alternate system of holistic medicine. In turn, orthodox medicine has attempted to restrict the controversy in two ways: by attacking the professional credentials and qualifications of Laetrile advocates, and by sponsoring animal studies to show that Laetrile is not efficacious. How each of these tactics and strategies have affected the controversy is considered in this section.

The history of Western medicine can be viewed as a struggle between the empirical and the naturopathic philosophy of medicine (6). The empirical tradition, from which modern medicine developed, stresses the mechanistic nature of the organism and the foreign nature of disease. Viewing the patient as a complex machine (e.g., the heart as a pump), the physician treats localized symptoms and repairs or excises defective parts. Illness is an external imposition on the patient. Sickness is combated with drugs, and little emphasis is placed on nutrition. Consistent with this philosophy, orthodox medicine has taken no strong role in shaping the American diet. There are lip-service appeals to avoid junk foods and recommendations concerning balanced diets, but these concerns are generally peripheral to the physicians' primary work of treating disease. In the empirical tradition the decisive factor in treatment is the physician himself, while the role of the patient in treating his or her own disease is down-played.

Opposing the empirical tradition is the naturopathic philosophy of medicine. Here disease is viewed as "a general fact which strikes the whole organism and has its origins in a perturbation of natural harmony" (6, p. XI). Traditional naturopathy has nearly disappeared in the United States but two modern versions, holistic medicine and orthomolecular medicine, are currently receiving considerable attention. Both emphasize the role of natural substances -- organically grown foods, vitamins, minerals and herbs -- in the maintenance of health; and the growing popularity of health and organic foods attests to the vigor and broad popular base of the movement.

> Holistic medicine maintains that
>
> (1) you take responsibility for your own health; (2) that you see your physical health as part of an entire life-style, (3) that you choose a doctor who sees you as a total human being (7, p. 21).

As an alternate philosophy of medicine, holism has made inroads into, or perhaps has been coopted by, orthodox medicine. Recently, for example, several branches of the National Institutes of Health sponsored a conference on "Holistic Health: A Public Policy." In one of the conference courses, "Health Through Nature and Cosmos," a native American Indian "explores the powers of transformation in re-establishing a relationship with Mother Earth, The Female Energy" wherein the student learns "to use touch (vibration), color, crystals and sound as healing instruments to alleviate suffering and prevent illness" (8).

Whereas holism seems to reflect popular, or even religious and mystical culture, orthomolecular medicine has its roots in the experimental sciences. Linus Pauling, twice a Nobel Prize winner, has created and organized the new health discipline which he defines as "the preservation of good health and the treatment of disease by varying the concentrations in the human body of substances that are normally present in the body and are required for health" (9). Various researchers have recently claimed success with orthomolecular strategies (10) and articles in the Journal of Orthomolecular Psychiatry purport that schizophrenia can be controlled and reversed by dietary supplements.

The historical roots of the Laetrile movement seem to be distinct from holism or orthomolecular medicine. Nevertheless Laetrile advocates use these contemporary movements as intellectual resources in their battle with orthodox medicine. The most important holistic claim of the movement is that Laetrile is a vitamin, known as B-17, which is necessary for the maintenance of health and prevention of cancer. Absence of Laetrile, according to one advocate, may: "produce headaches, anorexia, bizarre muscular pains, skin changes, anemia, sense of impending doom ... high blood pressure, sickle cell anemia and finally, tumefaction" (11, p. 465). Thus cancer is not a tumor disease; rather it is a metabolic disease in which the tumor is merely an obvious symptom. Just as it takes Vitamin B-12 as well as iron to cure pernicious anemia and proper diet as well as insulin to control diabetes, Laetrile supporters maintain that Vitamin B-17, described by one supporter as the "crown jewel in a total diadem of treatment" (11, p. 353), and diet will prevent or control cancer. In fact, in public speeches Dr. John Richardson, a leading Laetrile proponent, now calls cancer "fulminating avitaminosis."

Even so, and consistent with the holistic view of medicine, cancer is seen as a naturally occuring, degenerative phenomenon. Undetected and undetectable cancer is a part of normal life:

> Sub-clinical cancer is developing all the time. It may occur many times in a lifetime. But natural factors in the body itself keep it under control. Only when these natural factors do not keep it under control does the final "gross manifestation," usually characterized by tumefaction, or lumps and bumps, occur (12).

All of these claims are seen as part of a scientific doctrine, and Laetrile advocates claim the prestige of a

science, albeit an officially condemned science. The notion of vitamin deficiency is seen as part of an elaborate theory of cancer, known as the trophoblastic or unitarian thesis (13). Compared with orthodoxy this thesis calls for a different interpretation of cause, of symptoms, of the relationship between theory and practice and of the role of the physician (6, p. XV) -- in short, a different philosophy of medicine.

Several participants at the 1977 FDA Hearings on Laetrile recognized the philosophical differences between holistic and orthodox medicine. According to one opponent:

> ...The Laetrile system is indeed a total medical system...with its own biology and biochemistry which is different from that of standard science, but which is credible enough...that modern day sophisticated people will regard it as credible, reasonable and something worthwhile to try (11, p. 121).

While a Laetrile proponent argues for the concept of holistic medicine which treats:

> ...the whole man as a single entity, the sum of his parts. And once again a light year removed from the specialized, fragmented, crisis medicine whereby the patient is shuttled from dermatologists to internists to gastrologists to oncologists to psychiatrists (11, p. 352).

The new sensitivity toward, and popularity of, holistic and orthomolecular medicine have certainly served as a strategic resource to the Laetrile movement. No longer seen as an isolated product with its own separate history, Laetrile now appeals to many people seeking alternatives to orthodox therapy. To this strategic thrust medical experts and authorities have responded with tactics consistent with the empirical tradition. They maintain that the practice of medicine is exceedingly complex and can be mastered only by persons with extensive training. The best guarantee of competent and even life-saving therapy is the professionalized and highly certified physician. Others, whether well-meaning or quacks, are clearly acting against the best interest of the patient.

In general the promotion of Laetrile -- and most of the pro-Laetrile research -- has been carried out by individuals outside the scientific community or by foreign physi-

cians who fall outside the medical certification system of the United States. For example, Ernst Krebs, Jr., widely regarded as the major theoretician of the Laetrile movement, describes himself as a biochemist. However, the FDA has frequently criticized his credentials. He was expelled from Hahnemann Medical School but later completed a B.A. at the University of Illinois. While he is referred to in the movement as 'Dr. Krebs,' his doctorate is an honorary one from American Christian College in Tulsa, Oklahoma (14).

Similarly the FDA has been critical of Andrew McNaughton, son of a former President of the United Nations Security Council and one of the earliest financiers of the Laetrile movement (15). Ernesto Contreras, a physician and founder of a Tijuana clinic which purportedly treats 150 patients per day with Laetrile, has acknowledged the problem of credentialism:

> Since the beginning, amygdalin (Laetrile) was handled in a non-professional way and it was put in the hands of general practitioners or chiropractors. This produced an initial prejudice from the oncologists and cancer research centers (16).

A few of the leaders of the movement do, however, have strong establishment credentials. For example, among the advocates of Laetrile are Dr. Dean Burk. At the 1978 meetings of the American Association for the Advancement of Science he was characterized as someone who had "spent time" at the National Cancer Institute (17). In fact, until retirement he was head of the cytochemistry section at NCI. Another scientist who has evaluated Laetrile favorably is Dr. Kanematsu Sugiura of the Memorial Sloan-Kettering Cancer Center.

Even so, the FDA claims that few of the researchers and clinicians active in the movement have any "special training in oncology or in the evaluation of drug safety or effectiveness" (18, p. 39785) and that they publish their results in books and pamphlets rather than in scientific journals with peer review. The tactics of the medical establishment are clear: only specialists operating through professionally approved channels should have the ear of the scientific community. Lack of qualification or evasion of procedure severely damages the credibility of the antagonist.

From this point of view only highly qualified scientists are capable of making decisions about cancer diagnosis and therapy. Such a decision on Laetrile was rendered 25 years ago. In 1953 the California Medical Association con-

cluded that "no satisfactory evidence has been produced to indicate any significant cytotoxic effect of Laetrile on the cancer cell" (19). And in 1973, NCI concluded that Laetrile showed no efficacy against a variety of tumor systems in mice (20).

The debate, according to the cannons of empirical medicine, should have ended at this point. Research procedures are based on logical and mechanistic hierarchies; clinical testing is reserved for drugs which show promise in non-human screening systems. Even so, Laetrile proponents pressed for clinical trials. Medical authorities countered that Laetrile was given a fair chance but failed in the laboratory. Based on research done between 1969 and 1973 the National Cancer Institute concluded that it "certainly has not ignored Laetrile. After extensive study, there is, in our view no sound basis for recommending clinical trials" (21).

Since that time the Laetrile movement has become highly politicized, and the pressure for clinical trials has continued to mount. During the same time period the medical establishment has been adamant in its opposition to Laetrile therapy. Nevertheless, throughout the mid 1970s the NCI sponsored laboratory research on Laetrile at Arthur D. Little, Inc.; the Southern Research Institute; Washington University; the Battelle Memorial Institute and Sloan-Kettering Memorial Cancer Center (22). In each of these studies, and to the surprise of no one, Laetrile was found to be inactive against various types of tumors in mice.

We view laboratory studies as another strategic and tactical resource to control the Laetrile controversy. As the pressure for clinical testing and legalization of Laetrile increased, establishment scientists turned to the milieu that they knew best -- the laboratory. Here training and skill could be applied to confirm researchers' suspicions that Laetrile had no efficacy. Here evidence could be gathered for use in other settings -- legislatures, courts and regulatory agencies. And here, the medical establishment hoped, the controversy could be restricted to the logic and method of empirical science.

Laetrile advocates have attacked the animal studies both theoretically, from a holistic position, and methodologically, from an empirical stance. Seen from the holistic position, mouse studies make little sense. Mice take no responsibility for their own health and presumably do not see health as a spiritual issue. Moreover they cannot report the more subjective aspects of experimentation such as

the alleviation of pain. Furthermore, mouse tumor systems, whether spontaneous or transplanted, are not identical to the naturally occurring cancers of human beings.

Every mouse study has also been attacked on methodological grounds. The appropriate strain of mice, the choice of tumor system and the assessment of efficacy -- in other words, all of the ambiguities of any experimental design -- have been examined at length in the Laetrile literature. In fact, the Sloan-Kettering experiments came under criticism not only from anti-establishment groups such as Second Opinion (23) but also from the official publication of the New York Academy of Sciences (24).

Laetrile advocates have not conceded the experimental domain to the scientific establishment. Rather, their empirical counter-attacks have confused an already incredibly complex debate. As the esoterica of mouse studies is publicly debated, experimental data of any sort takes on a certain amount of legitimacy. In 1977 a Loyola biologist purported that Laetrile, as part of a megavitamin regimen, effectively controlled mammary tumors in mice (25). Despite the fact that the paper was first read in a non-scholarly setting, that the paper was only two pages long, and that the experimental design lacked certain controls, the paper received national media attention. Now at last Laetrile advocates had their own mouse studies to use as a tactical resource.

Contextual Factors

In 1977 approximately 310,000 Americans died of cancer. In the U.S. in the 1970s there will be an estimated 3.5 million cancer deaths, 6.5 million new cancer cases and more than 10 million people under medical care for cancer. Once cancer is contracted, the death rate is fearfully high. Of the 700,000 people who were diagnosed as having cancer in 1977, only about one-third are expected to be alive by 1982; and many additional thousands presumably will die of their cancers in the years thereafter. If present rates are maintained, some 54 million Americans now living, or one in every four, will eventually die of cancer (26).

Over the years cancer will strike in approximately two of three families. Thus, few Americans will avoid watching the death of a friend or family member by cancer. Given the debilitating nature of the disease and the severe nature of its treatment, cancer may be a disease with a unique social, as well as clinical, character. Cancer is by far

the most feared of illnesses (27). Just as tuberculosis used to be associated with a romantic metaphor, according to Susan Sontag, cancer has now come to mean repression, violence and death (28). Against this backdrop one prominent physician has characterized the fear of cancer as cancerophobia, "a disease as serious to society as cancer is to the individual -- and morally more devastating" (29).

One way of viewing the Laetrile phenomenon is that it is a response to the clinical and social nature of cancer. In fact, both sides of the controversy seem to agree on this causal sequence. However, medical orthodoxy emphasizes an irrational, even phobic, fear of cancer as the explanatory intermediate variable:

> the answer lies in the fear that cancer engenders -- and that proven therapies for cancer engender -- and the need of patients and families for hope in a situation where the hope offered by the legitimate therapies is often modest (18, p. 39797).

Laetrile advocates, on the other hand, see the movement's popularity as a scientific response to the "cancer epidemic." As an alternative to surgery, irradiation and chemotherapy ("Slashing, burning and poisoning"), believers are offered a simple and painless way to prevent or control our most dread disease.

An accurate causal model of the Laetrile phenomenon must consider several complex factors. For though Laetrile is a response to cancer, the pathway is not direct. Among those variables that intervene are several dominant American values. By a value we mean:

> those conceptions of desirable states of affairs that are utilized in selective conduct of <u>criteria</u> for preference or choice or as <u>justifications</u> for proposed or actual behavior (30, p. 442).

Focusing on values as justifications we do not view the Laetrile controversy as a value conflict per se. Rather it seems that each side of the controversy has appealed to basic American values as a means of strengthening a position. Laetrile advocates have attempted to open and expand the controversy to new publics by appealing to the values of freedom and equality; medical orthodoxy, on the other hand, has tried to close and restrict the debate through an appeal to the values of expertise and scientific and secular rationality.

Americans have always asserted their freedom in health issues. They choose their own physicians, but they also choose tremendous quantities of non-prescription drugs to treat everything from common colds to declining sex appeal to some rather serious diseases (31). Some also assert their right to attempt cancer prophylaxis and treatment. Laetrile, they claim, is non-toxic (32). Yet the Federal Government bans its interstate sale. From the advocates point of view this ban makes little sense, especially in light of the legal status of known carcinogens such as tobacco and saccharin. Even if Laetrile were not efficacious, they argue, neither are many of the non-prescription drugs sold in such huge quantities throughout the United States. This so-called freedom of choice theme is the most powerful and strategically successful appeal of the Laetrile movement. It is also a device for expanding the scope of the conflict. In fact, the demand for freedom has served as a bridge between the Laetrile movement and both the holistic medicine movement and the radical right -- especially the John Birch Society.

The appeal to freedom, and against arbitrary control, is depicted as a constitutional as well as a personal issue. On this issue alone, many writers, though not endorsing Laetrile as therapy, have sided with the aims of the movement. As one physician, writing a letter to a professional journal, stated:

> I hold no brief for Laetrile, but I do insist that a sane person has the constitutional right to treat himself in any manner he chooses, regardless of what you or I or the FDA may say or wish (33).

In a similar vein, conservative columnist James J. Kilpatrick has argued that the real point of Laetrile controversy is not its efficacy:

> The point is freedom. We loose it by chunks, by bits, by grains. Daily we yield more authoritarian control to the state and to the experts (34).

These arguments, so deeply rooted in the American experience, must be tactically countered. Medical authorities contend that freedom of choice is a slogan used to promote a cynical and cruel hoax. On constitutional, professional and personal grounds they attack this slogan. At a constitutional level, the FDA maintains that the act of

forming a government necessitates the exchange of some freedoms in order to gain others. In the Commissioner's view:

> Congress indicated its conclusions that the absolute freedom to choose an ineffective drug was properly surrendered in exchange for the freedom from the danger to each person's health and well-being from the sale and use of worthless drugs (18, p. 39803).

At the professional level, medical authorities have tried to restrict the controversy by appealing to an ideology of elitism and expertise. They emphasize that medical decisions and policies must be made by highly trained experts. The Acting Director of the National Cancer Institute has stated the elitist position well:

> The average citizen in this country does not have the resources and technical skills necessary to select, develop and test materials for the treatment of disease. Neither does he have the background that will enable him to make enlightened decisions concerning the selection and use of therapeutic agents. The selection, development, testing, evaluation, marketing, prescribing and administration of materials for disease treatment is an area in which large institutions and skilled professionals are uniquely qualified to take the measures necessary to protect the interests of the public (35).

An elitist position logically leads to government control: those who are expert should not only advise but protect. At the Kansas City Laetrile hearings a professor of medicine at the Mayo Clinic asked "Do we want a government which permits the strong to take advantage of the weak, or do we want a society that protects the consumer?" (11, p. 185).

The strongest attack against the freedom of choice slogan is at the personal level. The FDA claims that cancer victims and their families let emotion, rather than intellect, lead them to uninformed choice. As one expert asserted, "the emotional trauma of a cancer diagnosis severely impairs the patients' and families' ability to engage in rational decision-making" (18, p. 39804). Others, in even stronger language, characterize the patient's irrationality as childlike. Thus: "The gullible, like children, should be protected from those who would exploit them" (36). This theme, comparing Laetrile advocates with children, was

developed at the Kansas City hearings where a psychiatrist declared that:

> Freedom of choice...is the same argument that my seven-year-old daughter tells me, when she takes matches and says to me, "Daddy, I am grown up enough to use these matches, and don't worry. I won't burn myself" (11, p. 62).

This attempt to restrict the Laetrile controversy, as one restricts the behavior of a child, has produced an angry and emotional response from advocates. Thus:

> You people in authority consider all the rest of us a bunch of dummies... You set yourself up as God and Jesus Christ all rolled up into one. And we don't have any rights"....Patrick Henry said: "Give me liberty, or give me death." Glenn Rutherford says "let me choose the way I want to die. It is not your prerogative to tell me how. Only God can do that" (11, pp. 308, 315-316).

Medical experts have reserved their strongest criticism not for the followers, but for the leaders of the Laetrile movement. They claim that Laetrile has not been investigated in a scientific way -- in short, that it is quackery.

This attack on the movement, appealing to the American value of "science and secular rationality" (30), is probably the strongest strategic resource of orthodox medicine. Indeed, from this perspective reason and rationality seem to be on the wane. The government says that saccharin causes cancer and people continue to consume it; the government says that Laetrile does not cure cancer and people continue to consume it. Other substances, such as Gerovital in Nevada and DMSO in Oregon, have been legalized despite FDA opposition.

Summarizing the claims and frustration over this issue, Lewis Thomas, the President of Sloan-Kettering, has mused "These are bad times for reason, all around. Suddenly, all of the major ills are being coped with by acupuncture. If not acupuncture, it is apricot pits..." (37).

Situational Factors

While scientific and contextual factors are important in understanding the dynamics of the Laetrile movement, four

more immediate situational factors may help to explain the phenomenal growth of the movement in the 1970s. These situational factors are heightened frustration over the inability to control cancer, a decline of trust in science and medicine, the growth of the medical self-help movement, and changes within the Laetrile movement itself.

For the past 200 years medical scientists have cured one deadly disease after another. From smallpox in the 1790s to polio in the 1950s, determination and dollars led to the prevention and cure of a variety of maladies. By the 1970s the primary target of medical research was cancer. In his 1971 State of the Union address, President Richard M. Nixon declared "war" on cancer and proclaimed:

> The time has come in America when the same kind of concentrated effort that split the atom and took man to the moon should be turned toward conquering this dread disease. Let us make a total commitment to achieve this goal (38).

This commitment to cure cancer, now embodied in the National Cancer Act, led to great optimism (or "overpromising" (39) in the words of the FDA Commissioner) in the professional and lay literature. For example, the American Cancer Society claims that: "Cancer is one of the most curable of the major diseases in this country" (40). Throughout the early 1970s, however, five-year survival rates did not go down; in fact, with a few exceptions, they remained constant (40,41). By the mid 1970s, the National Cancer Act and the bureaucracy which administered it had come under attack (38). J.D. Watson, the Nobel laureate, has assailed the war on cancer as scientifically bankrupt, therapeutically ineffective and wasteful (42). "By comparison with the fight against polio," now asserts the FDA Commissioner, "the war on cancer is a medical Vietnam" (39).

Throughout the cancer establishment there is considerable disagreement over everything from theory to therapy (43). Recent debate has focused on the efficacy of surgery for early breast (44) and prostate (45) cancer, combined radiation therapy for cancer of the bile duct (46) and chemotherapy for a variety of gastrointestinal cancers. In particular the use of 5-fluorouracil for chemotherapy has been sharply criticized: "To insist on 5-FU as standard therapy for advanced gastrointestinal cancer offers precious little to today's patient and is a distinct disservice to tomorrow's patient" (47); or: "with this large mass of evidence, one can only hope that the good judgment of the American physician will dissuade him from treating thousands

of post-operative cancer patients with this toxic drug" (48).

Despite these problems, clinical research in chemotherapy, radiation and other traditional modalities continues to be funded at high levels while nutritional and environmental research on cancer is funded at much lower levels (49). Finally, even programs for the early detection of cancer have come under attack with the revelation that X-ray screening procedures may be carcinogenic (50).

In the midst of this official disappointment, acrimony and controversy, the Laetrile movement grew. Pro-Laetrile magazines often paraphrase cancer statistics and official disagreements over treatment. As doubt is cast on conventional therapy, with its debility and disfigurement, the promise of simple and painless treatment and prophylaxis becomes politically, as well as personally, attractive.

The past decade has also been a period of declining trust in the leaders of major institutions. In 1976 Louis Harris observed that "public confidence in major U.S. institutions is at its lowest point since the Harris Survey began making such measurements ten years ago" (51). By 1976 only 11 percent of the public had "a great deal of confidence" in the leaders of the executive branch of government, a drop of 30 percentage points from the 1966 level (51). In this environment of distrust, it is no wonder that the pronouncements of the Food and Drug Administration and other government agencies are frequently met with skepticism or disbelief. This atmosphere has made it much easier for Laetrile proponents to convince people that the government is part of a conspiracy to suppress a new and effective treatment of cancer.

The degree of public confidence in medicine and science continues to be high relative to other institutions. Even so, there has been a dramatic decline in trust in these sectors in the past decade. Public confidence in the leaders of science was substantially lower in 1971 than it had been in 1966. Though confidence levels generally increased from 1971 to 1974, they have since begun to decline again. Confidence in medical leaders follows the same pattern -- declining from 1966 to 1972, increasing, and then declining after 1974 (52). Data from the Gallup Poll (53) reveal that this decline continued through 1977. By 1977 only 39% of Americans had a great deal of confidence in medicine even though in 1966 some 73% of the public had a great deal of confidence in the leaders of medical institutions (51). In recent years and especially since 1974, Laetrile advocates

have been able to attack orthodox medicine before an even more receptive audience composed of persons whose level of confidence in medicine was no longer very high.

Associated with this distrust is the development of the medical self-help movement. While self-help is not new, in recent years an amazing variety of organizations have emerged which espouse the self-help approach. Some observers have viewed the self-help movement as a virtual revolution in health care.

> Some people have seen us moving toward a 'self-help society.' Others have hailed self-help as the third revolution in mental health, as fulfilling functions in late-twentieth-century life that were once served by the family, the church and close-knit communities, as a sign of an evolving more democratic society, as a reification of the aspirations of the Founding Fathers, as an indication that we are entering an era of self-determination, as the emerging church of the twenty-first century, and as a great many other things as well (54).

Many self-help organizations are critical of, and sometimes hostile toward, health professionals. The competence and compassion of physicians comes under special scrutiny, probably because of the "personal and social adaptive problems of chronic patients" (55). As the data on public confidence in leaders of major institutions indicate, such attacks on the competence of professionals are not confined to physicians. In fact, the medical self-help movement may be closely linked to a more general social movement by outsiders and consumers (56). This movement has developed partially as a result of the perceived failure of societal institutions "to provide nurturance and social support for the needy, the stigmatized, the socially isolated or nonconformist" (56) and partially as a result of a convergence of theory and practice which has emphasized the importance of involving the client in decision-making about his or her destiny.

Pro-Laetrile organizations show most of the properties which have been cited as being characteristic of self-help organizations and they may be viewed as such by a significant proportion of members. One study (57) of a local chapter of the Cancer Control Society found that two types of meetings were held each month. While one was a general public meeting where information about Laetrile was distributed, the second was aimed at active members and cancer

patients. At these meetings testimonials were given, nutritional matters were discussed, and social support was provided.

The journals published by pro-Laetrile organizations also have a strong self-help flavor. All contain a large number of short items that provide information on various cancer therapies. Most of these presentations are quite uncritical and frequently advocate questionable practices, such as fasting, coffee enemas, color therapy, and raw juice therapy. The journals also contain large numbers of news items about legislative or legal victories for Laetrile. The Choice and Cancer Control Journal frequently reprint newspaper stories or editorials about Laetrile.

A common type of article recounts personal victories over cancer with titles such as "How I Controlled Cancer Using the Holistic Approach," "Metabolic Therapy Did It For Him," "Beating Leukemia With Laetrile," and "I Would Have Died If I Hadn't Gone to Mexico." Such testimonials appear to be most frequent in Cancer News Journal and The Choice but also are found in Cancer Control Journal. Testimonials seem to be a ubiquitous feature of self-help groups (58) and the major means by which experiential information is expressed and shared. Although most health professionals reject the utility of such statements (18, p. 39799-39800), testimonials continue to play a major role in the promotion of Laetrile by its supporters.

Other contents with a "self-help flavor" in the Cancer News Journal include discussions of herbal teas, health food recipes, and tips on how to stop smoking. The Cancer Control Journal also contains considerable information on nutrition and has examined the health benefits of raw fruit and vegetable juices. All three journals publish book lists that include works on various cancer therapies, health, nutrition, and vitamins. The Choice contains advertisements on a variety of products including apricot kernels, vitamins and enzymes, juicers and water distillers.

Finally, changes in the Laetrile movement itself occurred during the 1970s, and these may be important factors in explaining the growth and success of the movement. Prior to 1970 the major voluntary organization active in the promotion of Laetrile was the International Association of Cancer Victims and Friends. This organization had been founded in 1963 by Cecile Hoffman, who believed that she had been cured of cancer by Laetrile. Schisms within this organization led to the formation of another major pro-Laetrile group in 1973, the Cancer Control Society. Other groups

which have broken off from IACVF include the Foundation for Alternative Cancer Therapies (1975) and the Cancer Federation (1978), both organizations which promote holistic approaches to cancer therapy. In the late seventies the National Health Federation actively began to promote Laetrile through such means as its "Fund to Stop Government Ban on Laetrile" and its newspaper Public Scrutiny.

Perhaps the most important of these organizational developments, however, was the founding of the Committee for Freedom of Choice in Cancer Therapy by Robert Bradford in 1972. The Committee was established to aid in the defense of Dr. John Richardson, who was being tried for using Laetrile in the treatment of cancer. The Committee, which today has about 500 local chapters and about 8,000 paid newsletter subscribers, has been very active in lobbying for pro-Laetrile legislation. In fact, it describes itself as "the nation's major leading advocate of the decriminalization of Laetrile."

Since its founding, the Committee has had ties to the radical right. Richardson was an active member of the John Birch Society, as are virtually all of the present officers of the Committee. The editor of the Committee's journal, Choice, has stated "there are a lot of us Birchers in the Laetrile movement because the John Birch Society has the guts to fight for what it believes in" (59). It seems likely that the slick promotional material, active political lobbying, and effective use of the courts which have characterized the Laetrile movement in the past few years may reflect skills gained by the radical right in earlier campaigns against fluoridation and sex education.

Conclusion

Many medical experts and government officials have been perplexed in the face of the phenomenal growth and success of the Laetrile movement. How could a small band of Laetrile promoters garner so much publicity, gain so much public support, and achieve so many legislative victories?

We maintain that the Laetrile controversy cannot be understood without an examination of its social and intellectual context. Our analysis of the controversy, following Bloor's strong program in the sociology of knowledge, seeks to locate causes of the phenomenon. We delineate three categories of causal factors: scientific, contextual, and situational.

Among the scientific factors that we find relevant are

the new interest in holistic and orthomolecular medicine, disputes over professional credentials, and ambiguities of experimental design and data. The primary contextual factor is fear of cancer, mediated through dominant American values. Advocates appeal to freedom and equality, while opponents appeal to expertise and the scientific and secular rationality. Finally, four situational factors -- heightened frustration over the inability to cure cancer, decline of trust in science and medicine, the growth of the medical self-help movement, and the organizational development of the movement -- are useful in explaining the recent growth of the movement. Our analysis is also impartial and symmetrical. For each of the causal factors we attempt to account for the behavior of both advocates and opponents of Laetrile. Both the orthodox and the heterodox arise out of the same social milieu.

In order to understand the dynamics of the controversy, we use Schattschneider's work as our exemplar. Thus, we focus on the strategies and available resources of the contestants. In so doing, we do not imply that an attempt to control the scope of the conflict is the sole motivation of the actors in the dispute. Rather we maintain that actions, however motivated, have real consequences for the scope of the conflict. Medical experts and authorities have tried to restrict the appeal and availability of Laetrile through a series of laboratory studies which cast doubt on the drug's efficacy. Proponents of Laetrile have countered by expanding the conflict into a broad-based social movement. Laetrile advocates, by involving a wide range of individuals and organizations, have created the most effective challenge to medical orthodoxy in American history.

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8. Discussion: Bias in Analysis of the Laetrile Controversy

Controversies, of course, have at least two opposing sides, and it is worth looking at the papers in this book to see if the authors have taken one side or the other in the Laetrile controversy, and if so, how it has affected their conclusions. I characterized each paper as pro- or anti-Laetrile, and then passed these judgements among the authors to check their perceptions against mine. Three papers are clearcut. Historian Young and Lawyer Monaco are easily recognized, and acknowledge themselves, as anti-Laetrile while sociologists Markle and Petersen have sought a neutral agnostic position and carried it off in the eyes of their colleagues. The two remaining papers are harder to classify. Smith is certainly critical of Sloan-Kettering but otherwise seems neither for nor against Laetrile, so I called him neutral. I read an anti-Laetrile bias into Rich's sympathetic treatment of the Food and Drug Administration (FDA) and particularly in his view of proponent positions, which I will take up later. There was agreement here among all the authors but one, Rich seeing his own paper as neutral and Smith's as pro-Laetrile. Taken together, the papers are skewed against Laetrile.

If Laetrile is a fraud, a purposive attempt to peddle a fake cure, then one can hardly fault an anti-Laetrile bias. But we do not know if the proponents of Laetrile are any more fraudulent than the median promoter of many orthodox cancer remedies, which have severe limits to their efficacy. If the Krebs are frauds, why did they take the trouble to refine amygdalin rather than sell some readily available material, as some Krebiozen promoters sold mineral oil? Why did McNaughton supply Laetrile to Sloan-Kettering for tests if he knew it to be worthless? Most recently, why did the Committee for Freedom of Choice in Cancer Therapy cooperate with the National Cancer Institute in its retrospective survey of Laetrile patients? These instances are reconcilable

with fraud, but with some difficulty. I think that the readiness of many of us to assume fraud comes from false "either/or" reasoning which says that if a cancer therapist is not orthodox, he must be a quack. There are other options. Laetrilists may be sincere believers in the drug's efficacy, whether or not it is indeed efficacious.

Given reasonable uncertainty about the motives of the Laetrile people, I am particularly concerned with the biases of analysis which come from a presumption of guilt. Therefore, the foci of this discussion will be the papers of Young, Monaco, and Rich, where I perceive an anti-Laetrile slant which seems to affect their conclusions.

Young's interesting history of Laetrile is useful for its broader discussion of other unorthodox cancer cures such as Krebiozen. But the historian, by definition, rarely relies on firsthand information, so he must maintain a healthy skepticism about the veracity of his data, particularly that which comes from distant or biased sources. Young is so completely convinced of Laetrile's quack status that he relaxes these standards. For example, Young supports his claim that Laetrilists exploit the cancer patient's panic by noting, "One physician testifying (to the FDA)...told of a patient who, within a day of having lung cancer diagnosed, received Laetrile advertising in the mail." First, we know that the U.S. mail is simply not that fast, but even if it were, one must suspect that exaggeration might have entered when the patient told that tidbit to his doctor, or when the anti-Laetrile doctor used it to bolster his testimony to the FDA. At another point, Young implies that Ernst Krebs, Jr. made unsubstantiated claims by citing, uncritically, this item, extracted from court testimony: "A widow testified that her (dead) husband, learning that he had lung cancer, (said Krebs told him)...that his chance of recovery (with Laetrile) would be one hundred percent." The court record <u>said</u> the widow <u>said</u> the husband <u>said</u> that Krebs <u>said</u> that. Did Krebs <u>really</u> say that?

The most provocative section of Young's paper is his ten-point profile of health quackery, which he applies to Laetrile. Six of these points seem to me to apply to many of the drugs and therapies which are promoted by completely orthodox sources:

Exploitation of fear.
Promise of painless treatment and good results.
One cause for the disease/one therapy.
Shifts in description and explanation of the therapy.
Reliance on testimonials.
Involvement of great sums of money.

One more--claims of a miraculous scientific breakthrough--seems common of particularly promising new therapies. I see no strong suggestion of quackery, or even unorthodoxy, in any of these seven points. An eighth point, that the promoter "distorts" the idea of freedom, is so subjective as to be meaningless. After all, who can say that someone else's notion of an abstraction like freedom is more or less distorted than one's own notion of it? What of Young's remaining two points?

One is that the quack cries that there is a conspiracy on the other side. But orthodox promoters also cry "conspiracy" when they encounter successful opposition. For example, after numerous communities voted against fluoridation, the public health establishment claimed that the opposition was orchestrated by the Klu Klux Klan and John Birch Society. Indeed, Young himself seems to sense, among the Laetrile proponents, a conspiracy to defraud. Perceptions of conspiracy are surely not limited to quacks.

Young's tenth point about quackery is the "Galileo ploy"--the quack compares himself to Galileo who was insulted in his own time but exalted by history. I think we do not lack orthodox physicians who have similar self images.

In sum, Young has listed ten points which may commonly occur in cases of health quackery, but I suggest that they occur in legitimate medicine as well. Young writes as if organized medicine is pristine, rationalistic and altruistic without elements of egoism, error, and foolishness. He assumes too readily that pique, paranoia, or greed are diagnostic of quackery, forgetting that members of the American Medical Association share these foibles. To Young, orthodoxy is righteous and the unorthodox are quacks. Laetrile is unorthodox, therefore, a fraud. This analysis convinces only those who share these biases.

Grace Monaco's excellent discussion of legal aspects was particularly interesting when she summarized Rutherford v. United States, the case which has been the greatest judicial victory for the Laetrilists (at least to this writing when it awaits review by the Supreme Court). But I entered that section of the paper well aware from earlier sections that Monaco does not like Laetrile, and so I was skeptical of her flat declaration that the district court which wrote the initial decision was incorrect. The court found, contrary to the FDA's claims, that Laetrile qualified for an exemption from the Food, Drug, and Cosmetic Act under a 1962 grandfather clause, because it has been commercially

available and generally regarded as safe prior to 1962. Monaco rejects this decision as improper, contrary to the evidence, and contrary to accepted principles of law. While the issue was apparently settled for her at that point, it was thrown open to me. How could the court have erred? What were the judge's errors of evidence and law? Unfortunately, we are given no hint of his faulty path, and no opportunity to agree or disagree that it was indeed a faulty path. The next we hear about the decision is that it was appealed and sustained! The appeals court made what Monaco assures us is another faulty decision, holding that the Drug Act's requirements to show safety and efficacy do not apply to a terminally ill cancer patient who wants Laetrile. To my mind, though not to Monaco's, there is indeed a problem in applying these requirements to a drug intended for patients known to be at great risk from cancer. If a man's cancer is not curable, then there is not much meaning in rating drugs by their efficacy of cure, or at least the meaning is very different from what it would be if the disease were curable. What is a "safe drug" (or for that matter, a "harmful drug") for a man who is already on the verge of death? Physicians routinely administer very dangerous treatments in desperate cases (for example, carcinogenic radiotherapy for cancer) on the principle that if the patient is saved, then the risk was justified; and if he is not saved, then he will not suffer from the treatment. Surely this is a different calculus than is used to evaluate treatments for benign conditions, where dangerous therapies are not routinely acceptable.

For all I know, Monaco is completely correct in her assessment of the decisions in Rutherford v. United States. However, the value of her paper would be heightened if she would explain this case to us from the perspective of the pro-Laetrile side, in the same effective manner in which she argues the anti-Laetrile viewpoint.

Rich's paper is the most difficult to treat because the bias I perceive, and the consequences which I assume flow from that bias, he denies. His view is as valid as mine, so I present these thoughts simply as an alternative view to consider.

According to Rich, opponents of Laetrile, particularly those within the FDA, define the Laetrile issue in two different ways. In one of these definitions, Laetrile is a purely scientific matter: Is it safe and effective, as determined by scientific testing? Opponents also define Laetrile as a quack cure to be put out of business.

The proponents of Laetrile also define the problem in two ways, according to Rich. To them, the Laetrile issue is primarily one of freedom of choice. "Laetrile is basically a convenient vehicle to help reach a larger and broader set of ends. The freedom of choice issues are at stake and not Laetrile qua Laetrile...This group does not make any particular claims for the efficacy of Laetrile." The proponents also define the problem as one of "big government" intrusion into private matters: "Laetrile is simply an example of a more general trend toward government interference in our lives."

Thus, while Rich characterizes the FDA as directly concerned with Laetrile per se--with its safety and effectiveness and promotion, he portrays the proponents as only incidentally concerned with the drug, using it as a convenient vehicle to promote a different goal: personal freedom from intrusion by big government.

Rich apparently denies that any of the Laetrilists have a sincere concern for the drug's fate, and for the cancer patients who might use it, quite apart from their concerns about government regulation. Even allowing that a portion of the Laetrile promotion may be fraudulent, it seems to me that there is no doubt that some of the proponents believe that the drug is beneficial. Surely a major problem, as defined by these people, is to make Laetrile legally available to cancer victims in the United States. Why else did Glen Rutherford, a cancer patient who used Laetrile himself, bring suit against the FDA to have the sale legalized? (See Young and Monaco for discussions of Rutherford v. United States.) His argument that the drug is exempt from FDA restrictions because of the 1962 grandfather clause of the Food, Drug, and Cosmetics Act, does not establish any general principle upholding freedom from government regulation. It is a specific exclusion for a particular drug: Laetrile. Yet Rich denies that in any important way, the proponents define their problem as one of making a beneficial drug legally marketable. That he grants the FDA the straightforward goal of reacting to the drug on its merits, and then denies the proponents a similar goal, is best explained by his own bias, in my view.

Any analysis of Laetrile must carry some bias; even neutrality is a bias. What, then, is the proper bias here? It seems to me that any bias will do as well, or as poorly, as another. The essential point is that the analyst must recognize his bias, he must recognize how it affects his perception and presentation of evidence, and he must recognize how it predisposes him to one or another conclusion.

He ought to consider how another analyst, coming at the same data with a different bias, might reach different conclusions. He should consider the degree to which his perceptions and conclusions depend on his particular bias rather than on "objective fact," and when he has eliminated from his work any major distortions due to bias, he should inform the reader of those routine distortions which remain.

9. Discussion: Science and Technology in the Pits

> Today's American ideologue is a middle-class man who objects to his dependence on science even when he accepts its norms. He is resentful of the superiority of the educated, and antagonistic to knowledge. His ideology...looks back to a more bucolic age of individuality and localism, in which parochial values of mind were precisely those most esteemed, to a simple democracy... (David Apter, *Ideology and Discontent).*

The papers in this symposium on the politics of the Laetrile controversy are linked by a common theme; namely that the dispute has less to do with the curative power of apricot pits than with the social and political implications of expert control over an area of personal health. In this sense I look at this dispute as but one of a whole series of controversies over quite different areas of science. Many different concerns have provoked such controversies: the fear of risk, the fear that a technology can be put to pernicious use, or that it may threaten traditional values. But an overwhelming source of conflict is the infringement of technology on individual rights and on freedom of choice. Indeed, the Laetrile dispute must be seen in the context of many other disputes--over the automobile airbag, over swine flu vaccination, and over FDA bans on saccharin and other food additives. Above all, the Laetrile dispute resembles the recent creation-evolution controversy, as creationists demanded equal time for teaching creation theory in public schools (1).

In each of these cases, the government has imposed certain regulations or mandated certain practices on the assumption that individual choices have social costs, or that individuals may fail to make enlightened choices on their own behalf. And in each case there are striking similarities

in the arguments developed during the controversies as well as in the dynamics and tactics of disputes. These protests all reflect a perception that government is intruding unnecessarily into daily life, and that the authority of expertise is intruding on individual choice. The creationists, for example, argue that government-organized biology curricula based on evolutionary assumptions violates their religious values. Students should, they claim, hear both sides--evolution and creation theory--and be free to make their own choice. "Sound educational practice requires teaching creation as an alternate theory so that students can decide what to believe for themselves." Those who oppose government constraints on the use of nitrites or the sale of saccharin want the freedom to make their own choices about risk. Indeed, they claim to have a constitutional right to maintain such freedom of choice. Curiously, in the case of the recombinant DNA dispute, it is the scientific community faced with the regulation of research which argues, in very similar terms, about the constitutional basis of freedom of scientific inquiry and the right to pursue scientific research.

The discourse in the Laetrile dispute that was laid out by Professor Young is also familiar to those of us who have studied other conflicts. Like the pro-Laetrile people, creationists use the "Galileo ploy," arguing that scientists may criticize us now but will honor us later. They too see the actions of the scientific establishment as a conspiracy, suppressing divergent ideas in order to maintain power and control. The arguments of creationists like those of the Laetrile group shift with agility to meet changing circumstances. Creationists skillfully maneuver around empirical data supporting evolutionary principles by accusing biologists of basing their findings on unproven assumptions--that is, on faith. Based on circumstantial evidence, they argue, evolution theory is but "a hallowed religious dogma that must be defended by censorship of contrary arguments."

Tactically, there are also striking similarities among these disputes, in particular in their mix of technical argumentation with appeals to basic values. Appeals to freedom, equity, and justice help to broaden the scope of controversy, attracting wide public sympathy; and engaging in technical debate provides legitimacy. The Laetrile folks have their own scientific expertise; the creationists call themselves "scientific creationists." Membership in creationist organizations requires a degree in natural science, although to be sure their credentials are often of dubious origin, as in the case of Laetrile's Dr. Krebs. And like the Laetrile experts, creationists also focus their argument on scienti-

fic issues, attacking what they perceive to be weaknesses in the scientific base of evolutionary theory. This helps to support their case in the state textbook commissions and local school boards. But the basic appeal to their constituency of fundamentalists lies in the perceived threat to religious values.

Similar tactics appear in the disputes over abortion and fetal research. Here the arguments revolve around the technical criteria that define the beginning of life, but these only provide legitimacy to the moral issues underlying the dispute. Similarly, those opposing the ban on saccharin focus on questions about the adequacy of animal tests and the validity of the FDA experiments.

In each case, taking part in technical arguments is a means to win legitimacy for views which counter the consensus of the scientific establishment. Indeed, a striking characteristic of all these debates is the pervasive belief, expressed in the behavior of the protagonists, that technical debate has more political credence than the expression of political and value concerns.

As it turns out, engaging in technical debate is a skillful tactic, for characteristically the science establishment falls into the trap by overreacting to the challenges to their expertise. Again there are striking similarities in the defensive response of scientists. First, they argue the necessity of expertise to ensure consumer protection: Cancer patients, children in public schools, automobile drivers are all vulnerable for one reason or another and not necessarily able to make informed or effective choices on their own behalf. The broad consensus of the scientific community--about the necessity of teaching evolution theory or the safety and effectiveness of new drugs--is seen as more important in such cases than individual freedom of choice. This argument, of course, reinforces the concern about professional paternalism.

Second, the scientific community responds characteristically by trying to limit the scope of arguments to the technical arena. But this seldom distresses the scientific creationists or pro-Laetrile types. For technical expertise can be found to support any point of view, and engaging in technical debate enhances the legitimacy of their arguments. They need not, after all, provide a full refutation, but only raise public doubts about the established scientific view.

Third, scientists in all these disputes dismiss the

opposition by debunking the credentials of their critics; they are "quacks," they "lack qualifications," or they have "marginal degrees." This too only exacerbates the debate, lending credence to the arguments about the closed and arbitrary nature of established expertise and its own vested interests.

Finally, scientists dismiss their critics for their political motivations, labeling them right-wing or ultra-conservative. This indeed seems to be the case in the Laetrile dispute and also in the creation controversy. Interestingly, in both cases important support for these movements comes from engineers and technicians in California's science-based industries. But the resistance to government authority extends beyond the ultra-conservative fringe. It is not only the right which opposes the airbag or the swine flu vaccine in the name of individual freedom. And certainly those who argue the right of women to seek abortion cannot be labeled conservative. There is in fact a strong convergence of liberal and conservative values pervading most of these disputes. Indeed the controversy over Laetrile is but one example of widespread ideological resistance to the rationality and reductionism epitomized by science, and broad political resistance to the pervasive influence of professional expertise in many areas of personal life.

Note

1. See Dorothy Nelkin (ed.), Controversy: Politics of Technical Decisions (Sage Publications, Beverly Hills, 1979); and Dorothy Nelkin, Science Textbook Controversies (MIT Press, Cambridge, 1978).

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