

Politics and Science in the Laetrile Controversy

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Abstract:

In an analysis of the dispute between the proponents of Laetrile and those opposing the substance, the impact of both knowledge and value factors is explored. First, six related knowledge disputes are considered, with an emphasis on the difficulties of conflict resolution. It is suggested that when Laetrile supporters failed to obtain a favourable adjudication within the scientific community, they expanded the scope of the conflict through the use of the courts, state legislatures, and the freedom of choice appeal. Government regulatory bodies and leading members of the American medical community have tried to limit the scope of the conflict through claims of specialized knowledge and expertise. Finally, the concept of 'adjudication' is introduced to place the Laetrile dispute in an intellectual context which emphasizes the role of both knowledge and value factors in scientific controversies.

Article:

We generally say that a patient who has clinical cancer will be regulated or controlled with 50 grains of laetrile. That is about 17 to 20 injections of three grams each.¹

John Richardson, MD

The use of Laetrile rather than known, effective cancer treatments is the cruelest of all frauds.²

Robert Eyerly, MD

*(Chairman, the Committee on Unproven Methods of Cancer Management,
The American Cancer Society)*

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...³

Lewis Thomas

(President, Memorial Sloan-Kettering Cancer Center)

At no time in American history has there been a more effective challenge to medical expertise and authority than that mounted by the contemporary Laetrile movement.¹⁴ Despite opposition from the US Food and Drug Administration (FDA), the American Medical Association, the American Cancer Society and virtually all of the American medical community, support for this purported cancer cure and/or preventive continues to grow. Seventeen states have now legalized its use, and a 1977 Harris poll revealed that three-quarters of all Americans had heard of Laetrile, and that two-thirds favoured enactment of pro-Laetrile legislation in their states.⁵

The efficacy of Laetrile has been debated for 25 years. Not only has the controversy not been resolved, it 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? In order to understand controversies in science some scholars have focused on knowledge disputes⁶ while others have emphasized value disputes.⁷ While the knowledge-value dichotomy is analytically useful, reliance on one or the other may produce an incomplete picture of science. What is needed is to study the interactions between knowledge and value domains. Though Blume does not focus on the knowledge component we agree with him that:

Controversies in science seem to offer a research focus permitting concurrent exploration of cognitive and broad social structural factors ... epistemological conflicts always, inevitably, have a political aspect. In trying to understand epistemological conflicts, therefore, exclusive focus either (as is common) upon the cognitive dimension, or upon the political dimension, is seen as inherently wrong.⁸

In this paper we examine the process of scientific decision-making by focusing in detail on one controversy. First, we summarize the knowledge aspects of the Laetrile dispute, with special emphasis on areas of disagreement and the difficulties of conflict resolution. Next, we emphasize the role of values in the dispute. Finally, we set forth a concept of 'adjudication' which emphasizes the interaction between knowledge and values in scientific decision-making.

Knowledge Factors

Amygdalin is a substance which is found naturally in the seeds and kernels of many fruits (most notably apricots) and grains; it was first isolated from bitter almonds in 1830. Laetrile is a compound first extracted from apricot kernels by Ernst Krebs, Jr.⁹ In all of the Laetrile literature, the terms 'amygdalin' and 'Laetrile' are used synonymously. It now appears that they are related but different substances. Moreover, preparations of Laetrile contain varying amounts of amygdalin.¹⁰ This distinction confuses an already complicated story. In all but the most recent scientific work, it is difficult to know which substance was actually studied, making evaluation all the more problematic. The FDA asserts that this confusion is purposeful deception.

The confusion about the term Laetrile is long-standing and may in part be the result of a desire on the part of promoters to continue the use of drugs containing amygdalin while justifying the use of the drugs by theories associated with the Laetrile of Krebs, Jr.¹¹

The Laetrile controversy actually involves several related issues: theoretical, biochemical, pharmacological and clinical.¹² First, the nature and cause of cancer is at issue. Laetrile advocates explicitly reject the theories of contemporary oncology. Rather, they postulate a 'unitarian' or 'trophoblastic' theory of cancer. According to orthodox embryology, the trophoblast is the outer layer of the early developing embryo; it destroys uterine tissue to enable implantation, without which the embryo is not viable. As early pregnancy continues, the trophoblast is sloughed off and destroyed.

Scientists in the Laetrile movement dismiss this view and assign a central role to the trophoblast. In the theory first formulated by John Beard in 1902 and refined by Krebs Jr. in 1950, trophoblasts are seen as primitive, undifferentiated, *separate cells* which may survive early pregnancy and lodge in various tissues of the body. Cancer is not the result of unnatural invasion, but of trophoblasts gone wild — destroying body tissues as they once destroyed uterine tissue.

Laetrile scientists offer no direct histological evidence to confirm the presence of trophoblasts in adults.

The second issue in the debate is the detection of early cancer. Laetrile scientists claim that early cancer mimics early pregnancy in some ways and can therefore be detected by urine analysis. The Beard Anthrone Test (BAT) which measures the level of Human Chorionic Gonadotropic Hormone (HCG) in urine, 'has become the primary measuring rod for Laetrile cancer therapy'.¹³ The efficacy of the test has been denounced by official medicine; the California Department of Public Health¹⁴ found that the BAT 'is an insensitive and non-specific test and is completely unreliable and of no value in the diagnosis or prognosis of cancer .' Furthermore, California law forbids any person from claiming that the BAT detects cancer. Recently, however, cancer researchers not connected with the Laetrile movement have found that many types of cancer tumours secrete measurable levels of HCG.¹⁵

The relationship between clinical cancer and HCG is still not understood. But it is clear that the importance of this debate goes beyond biochemistry. Supporters of Laetrile, believing in a trophoblastic interpretation, claim that a positive BAT indicates an otherwise *undetectable* cancer. Medical orthodoxy defines an early cancer very differently. Therefore the data collected by each side in this debate may not be comparable.

Why do some people contract cancer while others do not? This is the third issue in the Laetrile controversy. Laetrile scientists claim that cancer is a vitamin deficiency disease, analogous to scurvy, beri beri, pellagra, rickets, and the like. When an inadequate amount of vitamin B-17 is ingested, a complex process causes the trophoblast to develop into cancer. According to the *Physicians' Handbook of Vitamin B-17 Therapy*,¹⁶ ten raw apricot kernels per day will effectively prevent cancer.

The issue of whether or not Laetrile is a vitamin has legal and economic implications far beyond the immediate empirical debate. Here we briefly outline the biochemical and epidemiological arguments. Greenberg defines a vitamin as a 'nutritional component of organic composition required in small amounts for the complete health and well-being of the organism.'¹⁷ The usual methodology of vitamin determination studies is long-term exclusion of the substance from the diet with histological and medical follow-ups — an elaborate and expensive procedure. Laetrile scientists have offered no such evidence to show that Laetrile is a vitamin. However, Richardson claims that the absence of amygdalin may 'produce headaches, anorexia, bizarre muscular pains, skin changes, anemia, *sense of impending doom* . . . high blood pressure, sickle cell anemia and finally, tumefaction'.¹⁸ Studies of rats suggest that Laetrile is not a vitamin for some nonhuman systems,¹⁹ and the Committee on Nomenclature of the American Institute of Nutrition ... finds no scientific evidence that Laetrile has nutrient properties or is in any way of nutritional value for either animals or humans.²⁰

Laetrile advocates counter these claims with epidemiological data. Most often cited are the Hunzakut tribe who live in the remote Karakoram mountains of northern Pakistan. Apparently it is not uncommon for these people to live 100 years, and their longevity is attributed to their diet which is rich in nitrilosides (a category of organic substances including Laetrile). This claim has some establishment support from Charles Percy, a US Senator:

We began curiously to observe the life style of the Hunzakuts. Could their eating habits be a source of longevity? ...Some Hunzakuts believe their long lives are due in part to the apricot. Eaten fresh in the summer, dried in the sun for the long winter, the apricot is a staple in Hunza, much as rice is in other parts of the world. Apricot seeds are ground fine and squeezed for their rich oil, used for both frying and lighting.²¹

In addition, Laetrile scientists claim that there has never been a case of cancer among these people. At this time the connection between diet and cancer is difficult to prove or disprove. The Hunzakuts are extremely isolated and little is known of them. However, a 1955 expedition by scientists at Kyoto University examined 277 Hunza and found incidences of cancer, heart disease and appendicitis, diseases which were previously unreported in this population.²²

The fourth issue in the dispute is the biochemical mechanism of Laetrile in cancer therapy. The theory is as follows: cancer cells contain high levels of beta-glucosidase, an enzyme which selectively cleaves Laetrile into harmless sugar and hydrocyanic acid. The cyanide then poisons the cancer cell to complete the cycle. Establishment scientists challenge every step of this proposed mechanism. For example, a 1959 study showed only trace amounts of beta-glucosidase in experimental tumours, far less than is found in human kidney.²³

Recent argument has focused on the efficacy of cyanide as an anti-cancer agent. David Greenberg concludes that cyanide has no value in cancer treatment.²⁴ As evidence, he maintains that Brown and his colleagues 'administered cyanide along with anesthetic to patients with uterine tumors directly to the tumor and observed no improvement.' However, this statement misrepresents or confuses the animal and human studies of Brown's group.²⁵ In fact, these authors concluded that 'suggestive evidence is presented that differential tumor toxicity is obtained and is manifested by a prolongation of survival time.'²⁶ Only then do they extremely low doses of cyanide on human cancer produced no results.

Many substances effectively inhibit or reduce the growth of malignant tumours, but only at the cost of poisoning or even killing the host. In fact such chemicals (for example, 5-FU, methotrexate) are part of standard cancer chemotherapy. Laetrile advocates claim that while Laetrile is nontoxic, most chemotherapeutic agents are toxic and of little value in the treatment of cancer; on the other hand some establishment scientists claim that Laetrile is highly toxic. This latter claim is the fifth issue in the Laetrile controversy.

Recent studies on mice indicate that high doses of amygdalin may be toxic.²⁷ At a dosage of 5,000 mg/kg per day, four of 20 animals died after four days; at a dosage of 2,000 mg/kg per day, one animal died within the same time period. The authors of this study acknowledge that the drug was administered parenterally (directly into the body cavity), whereas in humans the drug is administered in other ways. And, similarly, Ovejera and his colleagues found that '200 mg of DL-Amygdalin plus 5 mg of B-glucosidase was highly toxic; all four mice were dead two days after the first injection.'²⁸ However, other researchers have found that, except for oral administration, large doses of amygdalin are not highly toxic.²⁹

Other animal studies show that apricot kernels taken orally may be toxic. The FDA claims that 100 kernels could constitute a lethal dose.³⁰ Again, the method of preparation as well as the way

the drug is administered may determine the toxicity of Laetrile. When apricot kernels are blended into a slurry and stored at room temperature, enough cyanide is released to kill rats and monkeys.³¹

More to the point, there is mounting evidence that Laetrile may be toxic to humans. In 1977 a ten-month-old girl died, purportedly after swallowing five of her father's 500 mg Laetrile tablets. The medical examiner attributed her death to 'extensive anoxic brain damage due to acute cyanide poisoning due to amygdalin ingestion.'³² However, according to a pro-Laetrile journal, the father of the girl claims that his child never ingested Laetrile tablets.³³

One study claims to have documented 37 cases of poisoning and 17 deaths from Laetrile and cyanide-containing fruit kernels;³⁴ another claims that Laetrile ingestion may produce symptoms ranging from itching, dizziness and headache to vomiting, diarrhoea and high fever.³⁵ On 9 August 1977, the Surgeon General of the United States asserted that:

As our experience with Laetrile grows, we are finding that it is not harmless. Quite to the contrary, we are finding that Laetrile is a potentially dangerous substance, especially in its oral form. Enzymes present in the human digestive tract can break down the drug to release deadly cyanide.³⁶

Epidemiological data also show that amygdalin may be toxic. In Turkey, certain varieties of wild apricots have a high content of amygdalin. According to Sayre and Kaymakcalan, children there are regularly poisoned by ingesting apricot kernels.³⁷ Finally, Jukes argues that in certain parts of Africa, where cassava — a rich source of amygdalin — is regularly consumed, chronic cyanide toxicity is observed.³⁸

Laetrile advocates, on the other hand, claim a long history of safe use of amygdalin by thousands of people. According to Griffin, Laetrile is less toxic than aspirin, or even sugar, let alone traditional modes of cancer therapy.' And Binzel claims that: 'I have personally given nearly 4,000 intravenous injections of Laetrile using doses up to 9 grams without any adverse reaction, period.'⁴⁰

The final, and most important, issue in the controversy is: does Laetrile cure or control cancer? After all of the physiological, biochemical and epidemiological arguments, can Laetrile save a person's life? The appropriate and official protocol of tests to adjudicate this question are extremely expensive, involving both animal trials and clinical testing. Therefore Laetrile scientists have relied on two sources of data — foreign studies and personal testimonials — to argue their cases.

To date 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.'⁴¹ Clinical corroboration of these findings comes from Ernesto Contreras, founder and Director of Centro Medico Del Mar in Tijuana, Mexico.⁴² Dr Contreras has treated thousands of Americans with Laetrile and is a hero of the movement. The FDA claims that it has repeatedly asked Contreras for clinical documentation of his success. In 1971, according to

Kennedy, Contreras supplied only 12 case studies.⁴³ The FDA claims that five of these histories were incomplete and that the other seven patients had all received orthodox treatment (surgery, chemotherapy or radiation) before, after or concurrently with Laetrile therapy. In Germany, Hans Nieper has written that Laetrile cures or controls various cancers:⁴⁴ and in the Philippines, Manuel Navarro has reported positive results with Laetrile therapy.⁴⁵ The FDA has not evaluated this work.

The most dramatic evidence comes from individual case histories and testimonials. Laetrile advocates cite case after case of almost miraculous recovery.⁴⁶ For example:

When my father was taking orthodox treatment, afterwards he came home and I recall visiting him one day while he was laying in bed. He referred to himself as a sack of pulp and he was right, ladies and gentlemen, he was a sack of pulp. His body was battered and bruised and he had been made an addict of pain pills. I recall a few weeks later I went to visit him down in Mexico after he had been taking Laetrile for about a week and he had been on the diet. I saw my father walking around and laughing. And he even began to tease me. And in a daughter and father relationship, teasing is a pretty good sign.⁴⁷

I spent three months in Huntington Hospital there vomiting constantly, couldn't hold any food in my stomach. I was bleeding internally and I was near death for the three months. The doctors told the pastor it was just a miracle that I was still alive. They'd put a tube in my side to get rid of the bile because my common duct was blocked and bile was flowing into my cavity and was just putting me off into a jaundiced situation. I don't have the tube anymore, it's gone. I have proper bowel movement, my stool is the right color. And I'm eating well and my weight has stabilized. And I'm on Laetrile and intend to stay on it.⁴⁸

The FDA has sharply criticized the use of testimonials as evidence and has criticized the methods of many of the studies reporting case histories. For example, Donald Kennedy, Director of the FDA, attacked the sample of patients (62 out of 4,000) which Richardson reported on in his book, and observed that there was a shortage of cases involving five-year survival or longer.⁴⁹

Orthodox medicine has responded to the claims of Laetrile advocates with laboratory studies of mice. Laster and Schabel found that high doses of amygdalin 'did not demonstrate antitumor activity against . . . three tumor systems.'⁵⁰ According to Wodinski and Swinarsky, 'no anti-tumor activity was observed in any of four tumor systems tested with (amygdalin) alone or in combined therapy.'⁵¹ These conclusions are confirmed by Hill's group, who claim that amygdalin actually hastens animal death: fifty-three of 60 amygdalin-treated mice given 10^6 tumour cells died before non-treated tumour-received mice.⁵² In the most recently published study, a group of researchers at Memorial Sloan-Kettering Cancer Center reported that amygdalin was ineffective against one induced and ten transplantable tumour systems.⁵³ But these studies were all done on mice whose cancers, many argue, may not be analogous to human carcinoma. In order to achieve a better approximation and model of human cancer, Ovejera's team transplanted various human malignancies into mice. In these hybrid systems they concluded that 'amygdalin has no effect

against a human mammary carcinoma (MX-1) or colon adenocarcinoma (CX-2) xenograft in athymic mice.⁵⁴

The studies referred to above were all done with transplantable tumour systems. With this methodology, a tumour is excised from one animal, chopped-up, and surgically planted into a genetically identical animal. Rejection of the tumour demonstrates the efficacy of the drug. Some scientists maintain that the transplantable tumours produce a malignancy which is not analogous to human cancer. Writing in *Science*, Culliton maintains that:

... There are many scientists who are beginning to question the virtue of [transplantable tumor systems] as the sole method for detecting new approaches, saying that transplantable tumors may be quite unlike any natural or spontaneous ones, that they may possess special enzyme systems which control their response to chemical agents, and that they may be anything but representative of tumors in man.⁵⁵

To overcome these difficulties, researchers may test drugs against spontaneous tumour systems. Here, special strains of mice spontaneously develop tumours 8 to 10 months after birth. A drug is deemed effective if it prevents the tumour. These systems may be a better approximation to human cancer, but the excessive time and cost of the systems prohibit their regular use.

In the most thorough tests to date, the Memorial Sloan-Kettering Cancer Center claims that amygdalin is inactive against spontaneous tumour systems. While the authors acknowledge that one member of their team, Kanematsu Sugiura, found positive results by macro-visual observation when mice with lung metastases were treated with 1,000-2,000 mg/kg/day of amygdalin, they suggest that

the significance attributed to those early observations is seriously challenged by the negative findings of three independent investigators, by two out of three negative cooperative experiments in which Sugiura participated and by the blind experiment in which he and others under blind readings found no anticancer activity.⁵⁶

The researchers also reported that amygdalin was found ineffective against spontaneous mammary adenocarcinomas in Swiss albino mice and against spontaneous leukemia in AKR mice.

Laetrile advocates, however, have generally rejected the findings of the animal studies on both theoretical and methodological grounds. On theoretical grounds some Laetrile proponents deny the basic analogy between animal and human systems. According to this logic, the success or failure of an anti-neoplastic agent in mice is of little use in assessing its efficacy in humans. In addition, Laetrile supporters reject the notion that cancer is a tumour disease; rather they view it as a metabolic disease in which the tumour is merely an obvious symptom. Just as it takes Vitamin B-12 as well as iron to cure pernicious anaemia, and proper diet as well as insulin to control diabetes, Laetrile supporters maintain that Vitamin B-17 cannot be tested and evaluated in the absence of megavitamin therapy and proper diet. Laetrile was described by one supporter as the 'crown jewel in a total diadem of treatment.'⁵⁷ In fact one small experimental study using a 'wholistic' strategy purported to show that Laetrile effectively inhibited mouse tumours.⁵⁸

Much of the criticism of experimental studies has been methodological. First, is efficacy assessed by the growth rate of a tumour, or by its size, or by whether it spreads to new locations? Should tumours be identified by gross examination or by newer techniques, such as 'bioassay', which are purportedly more sensitive? One criterion of efficacy important for humans, the relief of pain, cannot be used in animal studies.

Second, what kind of tumour system should be used? Most of the Laetrile studies were done on transplantable tumour systems, but, as we have noted, such systems are frequently criticized as not analogous to human cancer. Research on Laetrile which has used the more costly and time-consuming spontaneous tumour systems has not ended the controversy because of yet another area of dispute: which strain of mice should be used in a given experiment? In some strains, known anti-cancer agents test negatively; other strains may incorrectly indicate the efficacy of an agent. Similar problems face the researcher in choosing the site of the cancer, with choices ranging from tumours of various organs to non-tumourous leukemias. Different sites show varying and selective sensitivities to different drugs.

Value Factors

Proponents of Laetrile maintain that their ideas are scientific; opponents have characterized the controversy as a political (or 'value') dispute, often accusing the opposition of deception and quackery. In this section we show that the beginnings of the Laetrile controversy had a knowledge focus and context; only later did the dispute move into the value arena. Using the work of E. E. Schattschneider, we then show how proponents and opponents of Laetrile have politicized the controversy.

The early Laetrile debates took place largely within the traditional scientific community. In 1946 Krebs and Gurchot wrote two letters to *Science* outlining experiments (though showing no data) in support of the trophoblastic theory of cancer.⁵⁹ Furthermore, the 1950 paper by the Krebs and Beard was published in *Medical Record*;⁶⁰ and Morrone's on Laetrile's efficacy for humans was published in a reputable journal, *Experimental Medicine and Surgery*.⁶¹ Even as late as 1970, the McNaughton Foundation sought official approval from the FDA to test Laetrile.⁶² The important point here is that this activity preceded the social movement and social turmoil that developed in the 1970s.

Laetrile advocates were unsuccessful in their attempts to obtain a favourable evaluation within the scientific community. The articles by the Krebs, Beard, Gurchot and Morrone were largely ignored. Furthermore, the Cancer Commission of the California Medical Association issued a report in 1953 which rejected the claims made by the proponents of Laetrile. In 1963 a report which led to the banning of Laetrile in cancer treatment was issued by the Cancer Advisory Council to the Director of California's Department of Public Health. Finally, the federal government has successfully prosecuted Laetrile advocates for interstate shipment and smuggling of Laetrile.

In recent years most pro-Laetrile scientific experimentation has been on the fringes of, or outside, the scientific community. For example, Harold Manner's articles on Laetrile have been published in the *Science of Biology Journal*, the *Journal of the Alternative Medical Association*, and the *Journal of Manipulative and Physiological Therapeutics*, all

obscure publications.⁶³ His well publicized paper (two pages in length) purporting to demonstrate Laetrile's efficacy was read at the annual meetings of the National Health Federation. Manner has been widely criticized by cancer researchers for presenting his paper in this setting rather than at a scientific meeting.⁶⁴

Schattschneider's work provides a useful framework for understanding the history and dynamics of the Laetrile controversy.⁶⁵ Schattschneider argues that the main struggle in politics is over the scope of the conflict because the outcome of every conflict is established by the extent to which the audience participates in it. He further asserts that the likely winners of a dispute will try to limit the scope of the conflict while the likely losers will try to expand the dispute. Thus many ideas and arguments which emerge in conflicts are best understood as attempts to manipulate the scope of the conflict and thus determine the outcome of the dispute.

Defeated, or at least stalemated, at the scientific level, pro- Laetrile forces have expanded the conflict into the ideological, legislative and political arenas. Laetrile advocates have adopted a populist ideology of medicine. Rather than treating cancer by the methods of experts — so called slashing, burning and poisoning — proponents urge a deprofessionalization of medical care. Individuals are encouraged to prevent and treat cancer through the use of natural substances and in the final analysis to be their own physicians. The populist position logically leads to a position that Laetrile advocates refer to as 'freedom of choice' in cancer therapy. They declare that cancer patients have a right to choose their form of treatment without interference by the medical community or the government. Freedom of choice is seen as a constitutional, as well as a personal issue. In a series of newspaper columns over a two year period, James J. Kilpatrick has argued that the real point of the Laetrile debate is freedom: 'The point is freedom. We lose it by chunks, by bits, by grains. Daily we yield more authoritarian control to the state and to the experts.'⁶⁶

The charge of arbitrary government added to the 'life-or-death' issue of cancer therapy has produced an angry, emotional and eloquent blend of populist and medical themes. At the 1977 FDA hearings one proponent asserted his freedom of choice: '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'.⁶⁷ To which he added: 'Patrick Henry said: "Give me liberty, or give me death". Glen 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.'⁶⁸

The 'freedom of choice' theme which Laetrile advocates have turned into the movement's major slogan is basically a device for expanding the scope of the conflict. The demand for freedom of choice has served as a bridge between the Laetrile movement and both the nutrition-megavitamin movement and the radical right — especially the John Birch Society. The Committee for Freedom of Choice in Cancer Therapy, probably the most effective of the pro- Laetrile organizations, was founded in 1972 to aid in the defence of Dr John Richardson, who was being tried for using Laetrile in cancer therapy. 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 Choice*, the official publication of the Committee, stated that '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'⁶⁹ Pro-Laetrile pamphlets and books

are frequently sold at John Birch Society bookstores and *American Opinion*, published by John Birch Society founder Robert Welch, has attacked the suppression of Laetrile. The Committee, which has about 500 local chapters with 8,000 members, describes itself as 'the nation's major leading advocate of the decriminalization of Laetrile.'

Joining the Committee to promote Laetrile has been the Cancer Control Society, with some 4,000 members, and the International Association of Cancer Victims and Friends, with approximately 8,000 members. All three organizations publish magazines designed to promote the movement. In addition the National Health Federation, with a broader 'health food' interest, has also recruited movement supporters through its journal, the *National Health Federation Bulletin*, and through its special project, the Fund to Stop Government Ban on Laetrile.

The freedom of choice issue, with its populist roots, has an appeal and following outside of right-wing politics. From the other end of the political spectrum an organization called 'Second Opinion' has been involved in the Laetrile controversy. It was founded in 1976 by members of the New York City Chapter of 'Science for the People', a radical-left group which has written and demonstrated on such issues as nuclear power, recombinant DNA and sociobiology. Second Opinion, which claims to represent the rank-and-file employees of the prestigious Memorial Sloan-Kettering Cancer Center, accuses the Center of racism, chauvinism, and imperialism in its policies and work. Their newspaper, *Second Opinion*, chastizes the Center for not emphasizing the prevention of cancer and for not being open-minded toward unorthodox cancer therapies. In 1977, Second Opinion issued a special report, 'Laetrile at Sloan-Kettering', which was highly critical of the Center. The report was co-authored by Sloan-Kettering's Assistant Public Affairs Director, who was subsequently fired for his role in its publication.⁷⁰

About 1975, Laetrile advocates began to use the courts to prevent the Food and Drug Administration from banning interstate sale of Laetrile. Cancer patients won permission to import supplies of Laetrile in cases before a number of federal judges. The most famous of these cases, *Rutherford v. United States*, a class action lawsuit, is another good example of the way in which the Laetrile controversy has expanded beyond the medical-scientific community. In the initial decision Judge Bohanon held that the plaintiffs, in being 'denied freedom of choice for treatment by Laetrile to alleviate or cure their cancer, were deprived of life, liberty or property without due process of law.'⁷¹

The FDA appealed the decision, and in October 1976 the 10th US Circuit Court of Appeals ruled in favour of Rutherford. According to the court, if Laetrile was used as a cancer drug before 1962, or if it was generally recognized as safe and effective at that time, then the FDA could not legally regulate its current use. The court stated, 'as it is, the FDA's record is grossly inadequate and consists merely of a conclusory affidavit of an official of the FDA which in effect declares that it is a new drug because the FDA says it is and thus is subject to all the statutory vagaries of such a designation.'⁷²

In response to the appeals court decision, Judge Bohanon gave the FDA 120 days to compile information on whether or not Laetrile is a new drug and gave the FDA an additional 30 days to file its conclusion. The FDA received about 5,500 pages of written testimony; in addition, 47

individuals made oral presentations at the hearing, which was held in Kansas City on 2 and 3 May 1977. More than 100 Laetrile supporters attended the hearing and frequently applauded and cheered Laetrile advocates and booed opponents of Laetrile. Thereafter the FDA commissioner issued a 50,000 word decision that Laetrile is not generally recognized by qualified experts as a safe and effective cancer drug and that Laetrile is not exempt from FDA regulation by virtue of the 'grandfather' provision of the act. Despite this report, Judge Bohanon issued a permanent injunction forbidding the FDA from restricting the importation and use of Laetrile. In the most recent appeal of that decision the US Court of Appeals ruled that the FDA may not prevent terminal cancer patients from receiving Laetrile injections. Further, the court stated that Laetrile can be considered 'as effective as anything else' in the treatment of terminal cancer patients.

The legal status of Laetrile remains tentative and confusing and further court rulings are likely. The importance of the Rutherford decision is that it restricts the authority of the FDA and thus should be interpreted as a political victory for the Laetrile movement.

The campaign to legalize Laetrile through state legislation may also be seen as an expansion of the initial conflict. In taking the dispute out of the medical-scientific community and into state legislatures, the proponents of Laetrile have achieved considerable success. In 1976, Alaska became the first state to legalize Laetrile. The FDA and other federal and state health agencies have opposed deregulating the use of Laetrile. Yet, to date, seventeen states have passed legislation — generally by wide margins — to legalize Laetrile. In most states the legislation includes provisions which protect physicians, permit manufacture, establish quality control and require informed consent. In a few states the bills protect pharmacists, require written records to be filed and reviewed, and declare Laetrile not to be a drug.⁷³

Concurrent with the attempts to expand the scope of the Laetrile conflict have been attempts to limit the controversy. Virtually all medical experts and authorities have labelled Laetrile advocates as quacks and frauds. Since Laetrile has been negatively adjudicated within the scientific community, they have attempted to restrict its political growth by arguing that governmental regulation is protective, and by accusing advocates of incompetence.

In responding to the demand for freedom of choice, the FDA asserts its role as a protection of innocent people:

The very act of forming a government . . . necessarily involves the yielding of some freedoms in order to obtain others . . . 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 wellbeing from the sale and use of worthless drugs.⁷⁴

Furthermore, expert testimony before the FDA asserted that the emotional trauma of a cancer diagnosis impairs the abilities of patients and families to engage in rational decision-making. A psychiatrist declared that Laetrile users are like children — not to be trusted with freedom: '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"'.⁷⁵

The FDA charges that few of the researchers and clinicians active in the movement are experts in oncology or in the evaluation of drug safety or effectiveness and that they publish their results in books and pamphlets, rather than in scientific journals with peer review. For example, the FDA has tried to discredit Krebs Jr., charging that 'while he is referred to as a doctor, he did not complete medical training and is a doctor only by virtue of an honorary degree.'⁷⁶

To summarize: Laetrile proponents used a populist ideology to expand the controversy into the political arena; opponents have tried to restrict the movement's growth by invoking an ideology of expertise. The government's position has been stated most clearly by the Director of the National Cancer Institute:

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.⁷⁷

Efforts at expanding and restricting the conflict may be concurrent and interactive. One case study shows the development of these themes and the richness and complexity of the controversy: Laetrile experiments at Memorial Sloan-Kettering Cancer Center. Sloan-Kettering, one of the most prestigious cancer centres in the world, first got involved in the Laetrile controversy in 1972. At that time its President said: 'This institution can answer the Laetrile question fairly quickly.'⁷⁸ But more recently the head of Sloan-Kettering has lamented: 'I sure as hell wish the Sloan-Kettering Institute had not taken on the testing. It has been such a bag of worms. It has nothing to do with science, it has to do with politics.'⁷⁹

The first mice studies were conducted by Kanematsu Sugiura, a well known cancer researcher. He found that Laetrile tended to inhibit the spread of new tumours (metastasis) in spontaneous breast tumours. He repeated the experiment twice, with the same findings. Though these experiments were completed in 1973, they were never published. According to Chester Stock, Vice-President of the Institute and in charge of later experiments: 'If we had published those early positive data, it would have caused all kinds of havoc.'⁸¹ But by 1975 these data were too controversial to hide. In a pamphlet entitled 'Anatomy of a Coverup', the Committee for Freedom of Choice in Cancer Therapy published Sugiura's data along with the following unsigned letter on Sloan-Kettering stationery:

Here are some of the results of Sloan-Kettering's continuing experiments with Laetrile. Due to political pressures these results are being suppressed. Please do your best to bring these important findings to the attention of people. Krebs' theory is very promising, and Laetrile should be tested clinically to see if it really holds water.⁸¹

Sloan-Kettering scientists claim that they have been unable to replicate Sugiura's early findings, though they now admit that some early follow-up experiments — in collaboration with the Catholic Medical Center — were flawed due to clumsy injection procedures. But in 1977, Sloan-Kettering completed the most thorough and comprehensive studies ever done on Laetrile. The findings: Laetrile is inactive against spontaneous systems.

In the normal course of science the Sloan-Kettering experiments might have been definitive and squelched the opposition. But Laetrile proponents have a long record of resiliency; within months of the press conference at which Sloan-Kettering released their unpublished findings, serious objections were raised about that research. Now the fight was led by Second Opinion, which in 1977 published a special report charging that Sloan-Kettering suppressed findings which showed Laetrile to be efficacious, and that they rigged their experiments to show that Laetrile was inactive. One example of the first charge is the work of Dr Elizabeth Stockert, a Sloan-Kettering scientist. In preliminary research done in 1973 she found some evidence suggesting Laetrile's efficacy. Chester Stock, principal author of the recent studies, claimed that Stockert's work was not cited because he did not know of the work. Yet Second Opinion (January 1978) has printed a memo to Dr Stock which summarizes the work in question. Second Opinion also cites other instances where data were purportedly covered up.

The other major criticism made by Second Opinion has been corroborated by the New York Academy of Sciences through its official publication, *The Sciences*. According to a press release of the Academy, the recent Sloan-Kettering experiments were done on 'the most drug resistant of experimental cancers, and that many drugs that are effective against cancer in human patients have never been tested on them.'⁸² As a result of the Academy's investigative work, Sloan-Kettering had to alter its manuscript which was forthcoming in the *Journal of Surgical Oncology*.

In the Sloan-Kettering debacle it seems obvious that authorities under-estimated the ability of their adversaries because, at least initially, they did not understand the political nature of the dispute. The behaviour of these cancer researchers is reminiscent of the actions of scientists in the controversy with creationists over the content of science textbooks. As Nelkin has observed, the scientific community is poorly equipped to deal with external political pressures and thus scientists 'often take refuge in reasserting the neutral character of their work and the irrelevance of political, social, or religious considerations.'⁸³

Adjudication

Contemporary scholars disagree on how to account for controversy in science. On the one hand, Merton and his followers study the social system of science — or more specifically, the way scientists act and relate to one another. They do not study the substance of science. In fact, these scholars view substantive issues within science as insulated from sociological forces. The ethics and norms of *how* scientists work are studied, while the work itself is not. Thus: 'Merton confines himself to explaining how the procedural rules or scientific method become *morally* binding; he does not consider the question of how and with what consequences their views of the world become *intellectually* binding.'⁸⁴ In this sociology of science, controversies are manifested as normative disputes which may be settled by the redistribution of status and reward. But the basis of a dispute is empirical and should be falsifiable.

Thomas Kuhn and his followers, on the other hand, emphasize the history and sociology of falsification. Crucial to the creation or resolution of controversy are the theories and methods involved in falsification procedures:

Scientists must, for example, decide which statement to make 'unfalsifiable by fiat' and which not. Or dealing with a probabilistic theory, they must decide on a probability threshold below which statistical evidence will be held 'inconsistent' with that theory. Above all, viewing theories as research programmes to be evaluated over time, scientists must decide whether a given programme at a given time is 'progressive' (whence scientific) or 'degenerative' (whence pseudoscientific).⁸⁵

Much of the activity of the Laetrile movement may be seen as attempts at paradigm creation and revolutionary science — or, at least, as the emergence of an 'embryonic paradigm'. In discussing Velikovsky's ideas, Dolby uses the concept of 'embryonic paradigm' to emphasize the existence of 'a coherent scientific world view incommensurable with that of the physical sciences'. Whether or not the Velikovsky, or any, embryonic paradigm will develop fully depends on its treatment of new evidence:

If . . . the community was only able to keep its central dogma alive by continually modifying it so as to escape falsification by the new facts the community produced, it would soon die out as a science . . . It might continue to survive at a more popular level, however. Many failed sciences have managed to perpetuate themselves by continuing to satisfy some social need: astrology and phrenology are clear examples.⁸⁶

Masterman has argued that full-fledged paradigms must meet three criteria: the 'new science' must develop its own metaphysics, history and sociology.⁸⁷ In a metaphysical sense Laetrile theory seems to be based on a naturopathic philosophy of medicine which stresses the use of natural substances to aid nature. Rather than treating cancer by 'slashing, burning and poisoning', Laetrile theory emphasizes 'natural' treatment such as vitamins (in fact, John Richardson, a leading physician in the movement, calls cancer 'fulminating avitaminosis') and nutrition. Laetrilists have also constructed a revisionist history of medicine. It begins with John Beard who, in 1902, formulated the trophoblastic theory of cancer, and celebrates the 1950 article by Ernst Krebs, Jr, his father and Howard Beard.⁸⁸ To meet the sociological criterion of paradigm building, Masterman demands both theoretical and methodological consensus. Here it might be argued that the Laetrile literature — whatever its source — shows remarkable similarity: the same problems are encountered repeatedly; the same solutions are inevitably proposed.

Most opponents of the Laetrile movement do not view it as an alternative scientific system; they view it as pseudo-science and quackery. First and foremost they claim that Laetrilists do not research and thus do not engage in attempts at falsification — and that they have, moreover, simply ignored all laboratory evidence showing Laetrile to be inactive. Laetrilists are also accused of changing the rules of the game to suit their own needs. For example, the whole notion of vitamin deficiency was not mentioned in the original Krebs' article, but was added later. At issue is whether this addition was designed to appeal to health food people or whether it was a legitimate addition to Laetrile theory. As seen by the critics, the Laetrile debate is just another example of an illegitimate challenge to scientific rationality. Pro-Laetrilists, however, claim that there have been both laboratory experiments and human studies showing Laetrile's efficacy. Moreover they charge that studies done by prestigious laboratories have either misinterpreted data or covered up positive findings.

We find Kuhn's approach useful in understanding the dispute between Laetrile advocates and opponents because it emphasizes the metaphysical and ideological nature of the adjudication process. Thinking of Laetrile as an embryonic paradigm we can trace the path from theory to

specific empirical disputes. Several participants at the 1977 FDA hearings conceptualized Laetrile as an embryonic paradigm. 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.⁸⁹

The claims of an embryonic paradigm are particularly difficult to adjudicate: problems are conceptualized differently, defined differently and may be unanswerable in terms of currently known experimental techniques and instrumentation. Lacking an empirical basis for adjudication, opposing parties — each convinced of the validity of their claim — may do battle in the political arena.

Here, however, the Kuhnian approach has limitations for studying Laetrile since it virtually ignores external factors. Kuhn assumes an almost total independence of the shape of cognitive structures, or the content of concepts, from either institutional structures or the broader societal processes and structures.⁹¹ To truly understand scientific controversy we need a 'socially constructed epistemology's' which considers both knowledge and value factors, and their interactions, in influencing scientific decision-making.

Our concept of adjudication ought to meet Bloor's criteria for a 'strong programme' in the sociology of knowledge — that is, it should be causal, impartial and symmetrical.⁹² The previous two sections of this paper present evidence for knowledge and value causality. This controversy has been shaped by mouse studies and testimonials as well as judicial rulings and regulatory actions. Our position is impartial, or perhaps even agnostic: we are not directly concerned with whether or not Laetrile cures or controls cancer. Rather, as in an analysis of the Velikovsky conflict, our interest is in 'the methodological significance of the affair,'⁹³ or 'the methods which are actually used to distinguish those knowledge claims which are "true" from the rest.'⁹⁴ Both sides of the controversy warrant examination. Finally, by giving equal time to both sides of the controversy, we are not suggesting that both sides have similar legitimacy. Rather, our explanation of the phenomenon is symmetrical, meaning that the behaviours of both sides must be understood if the controversy is to be understood.

By using the term 'adjudication' we construct an analogy with the legal system. This analogy was first used by Popper: 'The verdict of the jury . . . like that of the experiments is an answer to a question of fact . . . By its decision, the jury accepts, by agreement, a statement of factual occurrence . . .'⁹⁵ Though Popper admits that the jury may be wrong, he maintains that the verdict is reached by a formal set of rules designed to result in the discovery of truth. He allows for 'subjective convictions' or even 'subjective biases' but sees both of these as psychological aberrations. Pursuing the legal analogy, Popper asserts that science is more like a judge's, rather than a jury's, verdict. Whereas a jury's decisions can only be challenged on procedural grounds, a judge's ruling may be challenged on logical grounds.

This legal analogy has merit in understanding Laetrile as a scientific controversy. However, in developing our concept of adjudication, we would like to qualify and elaborate Popper in three ways. First we see adjudication as a process rather than as a single event. According to Bloor, Popper's 'decisions can be construed as points rather than processes; as things without structure

or history; as momentary events. Seen in this way they can function as discontinuities which terminate inquiry.⁹⁶ Moreover scientific procedures designed 'to reach conclusions are thus not well suited to laws needed to make decisions⁹⁷ at a particular point in time.

Second, sociologists of law distinguish between the 'declared' law and the 'living' law. The former relates to formulated rules while the latter describes the law as it is lived and applied in courts. According to King, Merton's (and presumably Popper's) scientist plays by the rules (also known as 'the scientific method'). Disputes are settled within the fixed framework. But Kuhn's revolutionary scientist resembles the judge of living law and acts as 'a man engaged in the interpretation, elaboration, modification and even on occasions overthrow of a professional tradition.'⁹⁸ Given our interest in causal rather than ideal explanations, we incorporate the idea of living law into our concept of adjudication.

Finally, we note that Popper's judge may suit our needs, but not in the way he intended. Law is blatantly political, and no more so than in the election or appointment of judges. Moreover judges often disagree; and in the US Supreme Court, for example, such disagreement may be predictable from the political ideology of the judge. In reality the judge, like the scientist, may find it difficult to separate the abstract merits of a case from his or her own political beliefs.

Conclusion

Medical experts and government authorities view the Laetrile phenomenon either as a purely political movement or as the latest fad in a long tradition of cancer quackery. The political conceptualization focuses on the conspiratorial nature of the movement, particularly its right-wing connections. Viewing the movement as quackery stresses the exploitation of useless substances for monetary gain and the irrational or uninformed behaviour of gullible citizens. Laetrile proponents, on the other hand, claim that Ernst Krebs, Jr is a scientific genius whose work has been unjustly ignored by a conspiracy of physicians, government officials and pharmaceutical firms.

We believe that none of these views is adequate for understanding the Laetrile phenomenon. We interpret the beginnings of the Laetrile controversy as a knowledge dispute. Only later did value factors come to dominate the debate. By developing the concept of adjudication and linking it to Schattschneider's model of political dynamics, we seek to emphasize both knowledge and value factors, and their interactions, in decision-making about Laetrile. Today we find that proponents of Laetrile, attempting to expand the controversy, and opponents of the movement, trying to limit the dispute, move back and forth between the laboratory and even more explicitly political realms.

NOTES

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