LAETRILE

BACKGROUND INFORMATION

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PREFACE

An alleged cancer remedy called Laetrile has recently become the focus of great public interest and controversy. This substance is also known by its generic chemical name amygdalin. It is one of a group of closely related chemicals occurring in nature, that Laetrile advocates have grouped together under the name nitrilosides. Its proponents have also recently been calling it Vitamin B-17. Manufactured versions of the substance bear the names Cyto H-3, Kemdalin, and other trade names. (2, 4, 56)*

There is no evidence that Laetrile has any effectiveness as an anti-cancer agent. It has been more extensively tested than any similar substance showing such consistently negative results. Those tests have demonstrated that Laetrile does not cure, control or alleviate human cancer.

Promotion of Laetrile has had at least four results:

1) Campaigns, literature, films, and lobbying efforts for the substance have misinformed many persons about the nature, causes, and proper treatment of cancer.

2) Promotion of the ineffective substance has resulted in very substantial financial gains for backers. (47)

3) Legislation which legalizes the sale and/or manufacture of the ineffective substance has weakened the fabric of consumer protection against medical exploitation and fraud. (see chapter 4)

4) Promotion and use of Laetrile have resulted in a tragic sacrifice of human life by diverting substantial numbers of persons having cancer from seeking proper and effective medical treatment. (see chapter 3)

The American Cancer Society receives many inquiries about Laetrile from members of the public, and from journalists, researchers, and public officials. This document summarizes information on Laetrile contained in the Society's files.

*Numbers in parentheses correspond to numbers in Bibliography.
Amygdalin, the generic chemical name for Laetrile, is a substance that occurs naturally in the pits of apricots, peaches, and plums. Closely related substances occur in many other foods and grasses.

Laetrile's advocates claim that the substance can do one or more of the following things:

1) If taken by persons who do not have cancer, it can prevent cancer from occurring;
2) It can cause cancer and its symptoms to be controlled, to be ameliorated, or to disappear;
3) If it causes cancer to be ameliorated or to disappear, continued use can prevent reoccurrence of the disease;
4) It can relieve the pain of cancer; and
5) In terminal cases, it can prolong life.

Two theories have been offered by Laetrile's advocates to explain how it works:

1) For a number of years it was alleged that an enzyme present in cancerous tissue would break Laetrile down chemically, liberating cyanide, which would destroy the cancer.
2) More recently, it also has been alleged that amygdalin is a vitamin, and that cancer is a disease caused by deficiency of this vitamin in the body.

Both theories are sometimes propounded simultaneously.

The Cyanide Theory

Amygdalin is one of a number of substances that are known as cyanogenic glycosides. In the presence of an enzyme called beta-glucosidase, amygdalin breaks down into a sugar -- glucose -- and a substance called mandelonitrile. This latter substance, in turn, decomposes into benzaldehyde and cyanide.

Laetrile proponents allege that cancerous tissue is rich in beta-glucosidase. Therefore, when Laetrile comes in contact with cancerous
tissue, the reaction described above supposedly takes place, and the cyanide thus released supposedly attacks and destroys the malignancy.

According to the theory, non-cancerous tissue are protected from a similar fate because they contain another enzyme called rhodanese. This enzyme converts the cyanide to thiocyanate, which will not destroy tissue. (19)

The drawings and text below, which are reproduced from literature disseminated by the Committee for Freedom of Choice in Cancer Therapy, a pro-Laetrile group, show how the theory is explained by this group to its members and to the public. As is increasingly the case, Laetrile is here called "Vitamin B 17." (45)

HOW VITAMIN B-17 FIGHTS CANCER

THE VITAMIN B-17 MOLECULE CONTAINS TWO UNITS OF GLUCOSE (SUGAR), 1 UNIT OF BENZALDEHYDE, AND 1 UNIT OF CYANIDE...

The BZD and CYD locked in Vitamin B-17 can not harm normal cells which contain the enzyme "Rhodanese!"

S S BZD
Vitamin B-17

Benzaldehyde and cyanide are poisons that are naturally "locked-in" the cell so as to be harmless!

John Beard and the "Trophoblast" Cell

The word "trophoblast" appearing in the above cartoon after the word "Cancer" is a reference to an older theory that many Laetrile advocates endorse. In 1902 an embryologist named John Beard, who lived in Edinburgh, Scotland, set forth his theory that a cell produced in pregnancy called the trophoblast cell, and the cell more commonly known as the cancer cell, are one and the same.

According to Beard, the mission of the trophoblast cell is to invade the uterine wall to form the placenta and umbilical cord. With this accomplished, its work is done. The pancreas then produce an enzyme called trypsin that, under normal conditions, stops the creation of more of these cells and kills off the existing ones.
Beard stated that if for any reason the pancreas malfunctions or fails to produce enough trypsin to kill all the trophoblast cells, these cells circulate through the body of both mother and infant, making them both vulnerable through life to cancer.

In adopting this thesis, Laetrile advocates state that amygdalin kills the trophoblast cells where the trypsin has failed.

"Vitamin B-17"

During the 1970's Laetrile theories have taken a new and additional tack. Its advocates state that they have discovered it to be a vitamin, which they have named Vitamin B-17. Cancer, according to this new theory, is a deficiency disease arising from lack of Vitamin B-17 in the diet, and this substance can serve the dual roles of treatment and prevention. Laetrile, according to one spokesman, "is the specific vitamin that provides the body's essential backup defense against cancer --- the incidence of cancer is epidemic in many civilized countries because some natural vitamins have been removed from processed foods."

Along with this shift in theory, there has been a shift in emphasis in claims made for the substance. The word "cure" appears less frequently, and claims such as "prevention", "relief of pain," "slows the cancer," and "stops its spread" are more frequently used. It is still claimed, however, that Laetrile "destroys" cancerous tissue.

Typical claims based on the theory that amygdalin is a vitamin, appears in the audio tape accompanying the film strip World Without Cancer, produced by Laetrile advocates and shown widely throughout the country:

"Vitamin B-17 does control cancer in human beings with an effectiveness approaching 100 percent."

"... a patient can have his cancer destroyed by Vitamin B-17 and still die from the irreversible damage already done to his vital organs."

"Of those with early diagnosed cancer, at least eighty percent will be saved by vitamin therapy. And, of those who presently are healthy with no clinical cancer to begin with, close to one hundred percent can expect to be free from cancer as long as they routinely obtain adequate amounts of Vitamin B-17".

(18, 45, 58)
"Vitamin B-13" and "Vitamin B-15"

Laetrile proponents also claim to have discovered that two other common chemicals are vitamins. One, orotic acid, they have named "Vitamin B-13", and the other, pangamic acid, they have named "Vitamin B-15." Both substances are being promoted, along with Vitamin B-17, as useful in cancer control and treatment.

(27, 35-37, 49)

The Big Tumor - Little Cancer Theory

Along with the major theories associated with Laetrile, a number of subsidiary theories have been evolved. One of these is the belief that the size of a tumor provides no index to the magnitude or progress of the disease. The position is that not all cells in a malignant tumor are cancerous, and the number or proportion of malignant cells bears no direct relation to the size or increase in size, of the growth.

The theory has two corollaries:

1. Conventional studies showing Laetrile to be ineffective have no value, according to Krebs, because they proceed on the assumption that the size of the growth is related to the progress of the malignancy; and

2. A patient who takes Laetrile and finds that the size of his cancerous tumor is increasing, need not necessarily worry. The Laetrile is dealing with the malignant cells, and the rest are harmless, however big the growth may become.

(35-37)

The Laetrile Theories and Modern Science

Acceptance of one of the Laetrile theories can subject the others to embarrassment. The vitamin theory states that cancer is caused by a deficiency of the "vitamin" Laetrile, while the trophoblast theory states that cancer arises from a deficiency of the enzyme trypsin. The cyanide theory attributes the efficacy of Laetrile to its ability to generate a substance that attacks and destroys tissue. The Society is not aware of any vitamin which gives its benefits to the body through destruction of tissue. The latter function, if indeed it occurred, would make Laetrile a chemotherapy agent and not a vitamin.

However, there is no evidence that the various Laetrile theories, separately or in combination, have any foundation in modern medical science, knowledge, and research.

To begin with, they proceed from a common underpinning of error—namely, that cancer is a single disease susceptible to a single "cure." Actually, cancer is a name given to a group of some 100 or more
different human conditions. Any given substance is effective against only one, or at best a few, of these numerous conditions. (86, 93)

In addition, each of the theories is specifically erroneous in its operating beliefs and assumptions.

1. The Cyanide Theory

The operating propositions of the cyanide theory are set forth below, along with the corrective facts of modern chemistry, and biology.

Proposition I: Cancerous tissues contain far greater quantities of beta-glucosidase than healthy tissues, causing cancerous tissues to release cyanide from amygdalin on a selective basis.

No evidence supports this proposition. Only traces of this enzyme are found in any animal tissues, and no more is found in cancerous than in healthy tissues.

Proposition II: Healthy tissues are protected from the action of the cyanide because they contain the enzyme rhodanese, absent from cancer tissue, which converts the cyanide to the harmless substance thiocyanate.

No evidence supports this proposition. Healthy tissues do not contain any more of the enzyme rhodanese than cancer tissues.

Actually, to the extent that there is any detectible difference in the levels or the enzyme beta-glucosidase in various tissues of the body, experimental evidence suggests that there is less in cancerous tissues than such organs as the liver, kidney, and spleen. If Laetrile behaved in the body in accordance with the proponents' theory, the first casualties would probably be various vital organs. Similarly, thiocyanate, the product of the interaction of Laetrile and the enzyme rhodanese, is a thyroid inhibitor and can cause goiter. All goitrogens are potentially carcinogenic, and if Laetrile operated as its proponents state, it would be a possible cancer-causing substance.

Laetrile, however, does not operate in the body as the theory states. In the words of one expert, David M. Greenberg, Ph.D., Chairman and Professor of Biochemistry Emeritus at the University of California, School
of Medicine, Berkeley and San Francisco, "The tissues of the body contain such minute amounts of the enzyme beta-glucosidase, the only enzyme that can decompose laetriles, that these compounds probably are not extensively broken down when introduced parenterally (i.e. by injection) and are probably excreted mainly intact in the urine." Thus, the only apparent difference between injected Laetrile and tap water as a treatment for cancer, is in the cost.

(19, 35-37)

Oral ingestion of Laetrile, it should be added, is a different matter, and may be dangerous. (This is discussed in Chapter 4.)

2. The Vitamin Theory

The term "vitamin" applies to a certain group of substances with the following characteristics:

1. They are externally-supplied organic substances that are required in small amounts for the health and well-being of the organism.

2. They function to promote a physiological process or processes vital to the continued existence of the organism:

3. Their absence causes certain clearly defined diseases to afflict the organism. These diseases arise only because of the absence of the vitamin, and are entirely cured by supplying the vitamin.

Laetrile advocates claim that they have discovered that the substance is a vitamin. However, "Vitamin B-17" as it has been renamed, fails to meet any of the above criteria.

-- No evidence exists that Laetrile is an essential nutrient

Laboratory animals have been kept alive and healthy for generations without having any of it in their diets.

-- No evidence exists that Laetrile promotes any physiological process vital to the existence of any organism.

-- No evidence exists that any specific disease state
has been linked to the lack of Laetrile in any animal, including man.

-- With specific regard to cancer, no evidence exists that it results from lack of Laetrile, or is arrested or cured by supplying Laetrile.

In a recent statement, the National Nutrition Consortium said, "The Committee on Nomenclature of the American Institute of Nutrition finds 'no scientific evidence for the existence of a nutrient identified as B-17. This terminology is neither recognized nor used by qualified nutritionists.' Cyanogenic glucosides are not vitamins in any sense of the word ... All available evidence indicates that Laetrile is not an effective treatment of cancer, and that there is no recognized Vitamin B-17 or any possible need for the substance so named." Member societies of the National Nutrition Consortium include the American Dietetic Association, the American Institute of Nutrition, the American Society for Clinical Nutrition, the Institute of Food Technologists, the Society for Nutrition Education, the American Academy of Pediatrics, and the Food and Nutrition Board of the National Academy of Sciences - National Research Council.

The classification of orotic acid as Vitamin B-13 and pangamic acid as Vitamin B-15 is equally spurious. There are no medically accepted or recognized B vitamins with a number higher than B-12.

It can be added that, not only are these three substances without value in treating cancer, but the same is true of recognized vitamins. There is no evidence that cancer is a vitamin deficiency disease.

(4, 19, 34, 94)

3. The "Big Tumor - Little Cancer" Theory

Contrary to the statements of certain Laetrile advocates, there is a direct and lethal relationship between the size of a malignant tumor, on one hand, and the number of malignant cells and the progress of the disease on the other. Not only do larger tumors contain more malignant cells, but the number of malignant cells grows in almost geometric ratio to the growth in size of the tumor.

(35-37)

The "Big Tumor - Little Cancer" theory has been used to reassure patients taking Laetrile, that they are actually getting better while their cancer grows. The
opposite is usually the case - that is, as the size of a tumor increases without proper treatment the cancer usually proceeds from an operable to an inoperable state.
Chapter 2

SCIENTIFIC STUDIES OF LAETRILE

The attempt to settle the question of Laetrile's value as a cancer remedy, has not been limited to pointing out the errors in the proponents' theories. Laetrile has been painstakingly and exhaustively tested by numerous leading research centers and institutions at great public and private expense. The results of these numerous tests were summarized in a report issued by the National Cancer Institute of the National Institutes of Health.

Letter and Report on Amygdalin From the National Cancer Institute to the American Cancer Society

This 1973 report stated that both alone and in combination with the enzyme beta-glucosidase no evidence of activity was exhibited against any of the tumor systems tested with Laetrile by the NCI or its contractor, the Southern Research Institute.

In addition to formal tests, numerous other efforts have been made to subject the claims made for the substance, to scientific verification. In no instance has it ever been possible to secure scientific confirmation of these claims.

The National Cancer Institute

The National Cancer Institute (NCI) conducted five separate tests of Laetrile between 1957 and 1975. Each test came up negative.

"In each of the tests," NCI states, "the compound failed to produce a reproducible anti-tumor effect." The animal systems used in the test, according to Dr. Frank J. Rauscher, then Director of the Institute's National Cancer Program" are those which have detected the active properties of the scores of drugs which, unlike Laetrile, have proven to be of demonstrable value in patients with many forms of cancer."

The results of each tests, summarized by NCI in its own words, are as follows:

1957: Amygdalin was tested with three transplanted mouse tumor systems used at the time by the NCI Cancer Chemotherapy National Service Center (CCNSC) to screen compounds for anti-cancer activity.
Amygdalin produced no significant inhibition or growth of the carcinoma 775 or sarcoma 180 tumors, and produced no significant increase in the life-span of mice with leukemia L1210 tumors.

1960: Material from a different source was tested against the same three mouse tumors. The compound failed to show anti-tumor activity.

1969: Amygdalin was tested alone and in combination with beta-glucosidase against leukemia L1210 in mice. Amygdalin was inactive against the tumor, alone and in combination with the enzyme. Toxic side effects increased when the drug and enzyme were given together.

1973: Amygdalin was tested alone and in combination with beta-glucosidase against the Walker 256 carcinoma in rats and against the following 4-tumor mouse screen currently in use by NCI: leukemia L1210, lymphoid leukemia P388, B16 melanoma, and Lewis lung carcinoma. Amygdalin was completely inactive against the four tumors, alone or in combination with the enzyme.

1975: Amygdalin was tested alone and in combination with beta-glucosidase against three transplanted mouse tumors; lymphoid leukemia P388, Lewis lung carcinoma, and Ridgeway osteogenic sarcoma. In these tests, Amygdalin had no anti-tumor activity.

In May 1977 the National Cancer Institute announced that it is considering clinical trials of Laetrile on human subjects. Dr. Guy Newell, acting director of the Institute, said that the possibility of a clinical trial was being "seriously considered" because a growing number of states are legalizing the substance (See Chapter 5). He stated that there had been no change in the Institute's position on Laetrile, that it is ineffective as a cancer treatment.

Independent Research Centers

During the period 1973 - 1977, the Sloan-Kettering Institute for Cancer Research of the Memorial Sloan-Kettering Cancer Center carried out the most extensive animal tests ever conducted on Laetrile.

In a press release dated June 15, 1977, the Memorial Sloan-Kettering Cancer Center stated that, "Laetrile was found to possess
neither preventive, nor tumor-regressant, nor anti-metastatic, nor curative anti-cancer activity." The full findings of the Sloan-Kettering test series are scheduled for near future publication in the Journal of Surgical Oncology, and are now in press.

(75, 97, 98)

A preliminary study in the Sloan-Kettering series had suggested that animals treated with Laetrile fared better than the control animals. Raw data from this study were leaked before the results could be checked by further tests, and caused a furor among Laetrile groups. Actually, subsequent efforts to duplicate the original findings under adequate controls, in which the researcher in question participated, entirely failed to duplicate the original findings.

(32)

Four additional animal studies were undertaken by Southern Research Institute in Birmingham, Alabama under NCI auspices. Laetrile was tested against Ridgeway osteogenic sarcoma, Lewis lung carcinoma, and leukemia P388. Of these types of cancer, Ridgeway osteogenic sarcoma has been shown to be particularly sensitive to anti-tumor chemical agents. But neither it nor any of the other forms of cancer was in any way affected by the Laetrile.

(7)

Similar experiments were conducted by Arthur D. Little, an independent testing laboratory in Cambridge, Massachusetts, with leukemia L1210 and P388, melanoma B16 and Walker 256 carcinosarcoma. No results were achieved, either through use of amygdalin alone or in combination with beta-glucosidase.

(8)

The McNaughton Foundation's Application for an Investigational New Drug Exemption for Laetrile

The Federal Food, Drug, and Cosmetic Act requires that all drugs marketed in the United States for human medical use must meet two standards. They must be safe, and they must be effective. Unless and until they meet these two standards, they cannot be transported or sold in interstate commerce.

(16)

Proof of safety and effectiveness must be established through precise procedures. Initial tests are made with animals. If they show a possibility of promise, the sponsors of the studies can file an application for an Investigational New Drug Exemption (IND) with the Food and Drug Administration. This application must summarize the results of the animal tests and must describe the applicant's plan to test the drug on human subjects. If FDA approves the IND application, then clinical testing with human volunteers can proceed. Quantities of the substance sufficient to conduct the tests can move in interstate commerce, and the substance can be legally sold and administered in connection with the tests. (16, 22)
In 1970 the McNaughton Foundation of California applied for Investigational New Drug status for Laetrile. The IND (No. 6734) was granted. The McNaughton Foundation submitted various data, which were reviewed by FDA and found to be incomplete and defective. FDA asked the Foundation to supply missing data on two questions about manufacturing controls, seven questions on preclinical tests, and four medical questions on data the application had mentioned but had not submitted.

The ten-day period allotted for a response to such requests for additional information passed without a reply from the McNaughton Foundation. The Foundation's IND for Laetrile was thereupon terminated by FDA.

Four months later, the McNaughton Foundation sent some additional data.

To ensure fairness, FDA took a step not required by law. The agency appointed a special committee of nationally recognized non-governmental experts to review the entire Laetrile data file. Members of the committee were:

Albert Segaloff, M.D., Oschner Foundation, New Orleans
Melvin J. Krant, M.D., Tufts University Medical School, Boston, Mass.
David B. Rall, M.D., Ph.D., National Institute of Environmental Health Sciences, Research Triangle Park, N.C.
Michael B. Shimkin, M.D., University of California, School of Medicine, San Diego
Julian L. Ambrus, M.D., Roswell Park Memorial Institute, Buffalo, N.Y.

The Committee studied the materials and even interviewed McNaughton, to give him a full opportunity to respond to the FDA's questions about the Foundation's IND and to other questions about Laetrile.

In its report, the Committee stated that no evidence exists to warrant or justify experimentation with amygdalin in humans.

Dr. Morrone's Article

In 1962 an article favorable to Laetrile appeared in a publication called Experimental Medicine and Surgery. The article, by John A. Morrone, M.D. of Jersey City, N.J., is entitled "Chemotherapy of Inoperable Cancer: Preliminary Report of 10 Cases Treated With Laetrile." The article has received wide circulation at the hands of Laetrile
The paper by Dr. Morrone contains such statements as:

"In a review of 17,000 papers on malignant neoplasms and related biological subject, the trophoblast was described as the sine qua non of cancer."

"The malignant lesion is characterized by a high focal concentration of beta-glucuronidase, which is a beta-glucosidase."

"Rhodanese, the cyanide-detoxifying enzyme, is absent or relatively deficient in malignant lesions but present in normal tissues."

Dr. Morrone also stated that:

"The use of Laetrile (1-mandelonitrile-beta-glucuronoside), a beta cyanogenetic glucoside, intravenously in 10 cases of inoperable cancer, all with metastases, provided dramatic relief of pain, discontinuance of narcotics, control of fetor, improved appetite, and reduction of adenopathy. The results suggest regression of the malignant lesion."

Dr. Morrone is now deceased.

The Journal of Experimental Medicine and Surgery has discontinued publication.

Articles in Foreign Journals

Medical Journal articles favorable to Laetrile are known to have appeared in foreign publications. These publications may not necessarily always maintain the same standards of reporting and valid research data required by standard medical and other scientific journals in the United States.

A substantial number of all these foreign medical journal articles are by a single author, Manuel D. Navarro, M.D., of the Philippine Islands. Navarro is a Laetrile advocate who treats numerous patients with the substance. 
The book, entitled The Laetriles -- Nitrilosides -- in the Prevention and Control of Cancer, cited above, contains a bibliography on Laetrile, consisting of 26 references. A check of these referenced by the American Cancer Society showed that two were in manuscript, one was in the press, one was a paper read before the Osteopathic Internists convention at Philadelphia, in 1954, and one was Dr. Morrone's article. The remaining 21 were all published in foreign journals and of these, 18 were by Dr. Navarro. Many of Dr. Navarro's articles contained only a single case report.

(44)

The Sloan-Kettering Research Series

As noted above, the first study in Sloan-Kettering's series conducted by Dr. Kanematsu Sugiura, indicated that Laetrile had an inhibitory effect on the development of lung metastases in a breeding colony of laboratory mice. Dr. Sugiura's raw data were leaked to the Committee for Freedom of Choice in Cancer Therapy. This group, in a Press Release published September 5, 1975, alleged that Sloan-Kettering was trying to "cover up" Dr. Sugiura's results, as part of a larger conspiracy to prevent Laetrile's value from being known.

(35)

In fact, however, efforts in the ongoing series to reproduce the results of Dr. Sugiura's first tests, were unsuccessful. The tests were rerun at New York's Catholic Medical Center by a two-man team consisting of Dr. Sugiura and Dr. Daniel S. Martin, who maintains the special breeding colony of mice used by Dr. Sugiura in his first experiment. The conditions of the experiment were identical with the conditions of Dr. Sugiura's first test, with the exception of two changes introduced to decrease the possibility of subjectivity in the results.

(38)

(1) In the original test, according to an article in the N.Y. Daily News, May 9, 1977, Dr. Sugiura knew which animals were receiving Laetrile and which were not. The second test, conducted with Dr. Martin, was done "blind" -- that is, neither Dr. Sugiura nor Dr. Martin knew which animals were receiving Laetrile and which were receiving a placebo.

(96,97,98)

(2) In determining the presence of cancerous tissue, personal observation of the researcher, and histologic evaluation by the pathologist, both of which were used in the first test and both of which introduce subjective elements, were supplemented by bioassay. This consists of transplanting the whole lung of an experimental mouse to a fresh host. In the recipient animal healthy transplanted tissue disappears but malignant cells proliferate. The animal itself therefore determines whether or not cancer cells are present; and human impression are eliminated.

(38)
It proved impossible, in these subsequent tests, and in others in the series, to duplicate Dr. Sugiura's initial results. In 1975 Dr. Sugiura wrote a memo to the director of the Walker Laboratory of Sloan-Kettering Institute, in which he works, stating that his joint experiment with Dr. Martin "indicates that amygdalin did not have an inhibitory effect on the development of lung metastases in mice."

(38, 92)

Studies in Israel

It has been reported that experiments with Laetrile have recently been made in Israel. During hearings on a bill in the Nevada Legislature to legalize Laetrile in that state, the publisher of the Las Vegas Sun, wrote in a column in his newspaper, "The foremost medical researchers in the state of Israel have been experimenting with Laetrile in cancer treatment and although no positive results have been printed, I do know from personal knowledge that a breakthrough is not far away." During the hearings another witness claimed that Hadassah Hospital in Jerusalem was using Laetrile with startling results.

(78)

Further information on the status of Laetrile in Israel is given in Chapter 5.

Testimonials: Anecdotal Reports; Incomplete Case Histories

By far the largest body of "evidence" offered for the effectiveness of Laetrile consists of testimonials, anecdotal reports, and "case histories" unsupported by full documentation or medical records.

In medical terminology, testimonials are statements made by the persons themselves, that they used the product or treatment, and, in their opinion, it helped them. Anecdotal reports are descriptions of single cases, by someone other than the person who was treated, that are lacking in scientific methodology, full data, full medical records, or controls. "Neither type of evidence is accepted by the scientific or research community, as evidence that any substance or treatment is medically effective." Modern scientific progress has been achieved only by the meticulous study of verifiable objective data. Testimonials and anecdotal reports, the traditional promotional techniques of all forms of quackery, cannot be considered scientifically acceptable.
This principle has been upheld by the U.S. Supreme Court.

(68, 110, 113)

Among testimonials for Laetrile is that of Glen Rutherford, a cancer patient who has secured a court order allowing him to import Laetrile for his own use, and who is a party in a suit in which a Federal Judge required the Food and Drug Administration to hold hearings on FDA's position that Laetrile is a new drug, subject to the procedures required for new drugs (see chapter 5). "If I lose my Laetrile," Rutherford stated at the FDA hearings, "you will read my obituary in 8 to 10 months."

The following account of Rutherford's medical history appeared in the same proceedings.

"Rutherford was diagnosed as having rectal cancer on December 3, 1971. The cancer was a polyp. The diagnosis is not in doubt. The magazine Medical World News, with Rutherford's permission, had slides of the polyp tissue examined in 1976 by two eminent pathologists. Both confirmed cancer.

"Rutherford refused surgery in 1971 and went to Mexico for Laetrile. He told the FDA hearing he received no other therapy but the drug. Yet last year he told Medical World News and confirmed for the Observer after his testimony last week, that the polyp was cauterized by Mexican surgeons 15 days after he began Laetrile treatments. Five-year survival rates among people who have had cancerous rectal polyps removed runs as high as 90 percent" (105)

Typical of anecdotal reports allegedly showing the effectiveness of Laetrile are the following two cases from the chapter entitled "From Death's Door: The Laetrile Recoveries," in Michael L. Culbert's book Vitamin B-17: Forbidden Weapon Against Cancer. The identities of the patients as given by Culbert have been changed, but the material is otherwise directly quoted.

"Mrs. Jones had first met Contreras when she took her father-in-law to see the Mexican medic. Frank Jones was suffering from rectal cancer. Mrs. Jones had previously lost her parents and a brother to the disease, and now her father-in-law had been given three weeks to live by American doctors. Frank Jones underwent the Laetrile treatment and died eighteen months later, but of a heart attack. During that time, Mrs. Jones swears, the Laetrile seemed to bring his cancer under control.
"Mrs. Jones, originally told in October 1966 that she had a tumor in the uterus cervix, was examined in Tijuana. Dr. Contreras used the urine test for cancer - denounced by American medicine - and informed her that she should start taking Laetrile capsules. She continued taking the little yellow pills during 1967, finally attaining two negative readings. In June 1968 she returned to Tijuana, where Contreras judged her tumors now to be non-malignant. She underwent a hysterectomy and a "quart of tumor" was removed.

"She told me that the operation, regarded by her American doctors as excellent had buoyed up her spirits. Too much. Because, now overconfident, she believed the problem was over. She went off Laetrile, and was all right for months until she started having abdominal pains. A loss of eighteen pounds in two weeks told her all she needed to know. It was my own fault, she said. Back in Tijuana in October 1969, she began "massive injections" of the substance. Since that time, she believes, her cancer had been controlled. She was still healthy and controlled" in January 1974."

The information required to assess the value and role of Laetrile in these cases is not present in this account. The report on Mrs. Jones contains --

1. No data from her medical records on her diagnosis, treatment, and laboratory tests;

2. No data from her medical records while she was under his care;

3. No explanation of the meaning of the phrase "two 'negative' readings" used to describe her condition after taking Laetrile in 1967;

4. No indication on the type of data or tests by which Dr. Contreras determined that her malignancy had disappeared in 1968; and

5. No data relating to her illness and treatment during the follow-up period 1968 - 74.

Information on her father-in-law's case is more meagre still. There are no data.

The scientific research community has been much interested in securing the full documentation underlying such accounts but has found it difficult to get. Patients, often at the urging of their Laetrile practitioners, usually refuse to grant access to the information.
Where it has been possible to secure adequate case records for review, such records have never in any instance shown that there was any value in the use of Laetrile. Groups of records of patients treated with Laetrile in Canada, the U.S., and Mexico have been analyzed by the Food and Drug Administration and by scientists from the California Cancer Advisory Council. In many of these cases, there was no documented evidence that the patients had cancer in the first place. In other cases, in which cancer patients showed improvement, they had received a variety of standard treatments in addition to Laetrile, and it was not possible to document which treatment had produced which results.

In 1953, the Cancer Commission of the California Medical Association, after reviewing the records of 44 patients treated with Laetrile, reported that in none of the cases was there any evidence of anti-cancer activity.

In 1962, the Cancer Advisory Council of the California State Department of Public Health, after an investigation that extended over two years and included a review of the case records of 144 cancer patients who had been treated with Laetrile, announced its conclusion that the substance was valueless.

In October 1971, Dr. Contreras, responding to an invitation from the Food and Drug Administration, sent the agency the names of twelve cases which, in his opinion, possessed outstanding value for documenting the effectiveness of Laetrile therapy. Of these cases, one could not be traced and two refused to cooperate in the study. Of the remaining nine, six are dead of cancer, one has progressive cancer, one died of another cause following cancer surgery and the ninth, still alive, had radiation and established chemotherapy treatment as well as Laetrile.
Chapter 3
PROBLEMS AND DANGERS OF USAGE

As has been previously stated, Laetrile is a cyanogenic glycoside. In the presence of the enzyme beta-glucosidase, it breaks down and releases cyanide.

Two things should be stressed. First, cyanide, produced in nature and through natural processes, is one of the most lethal substances known to man -- far more lethal than many of most man-made chemicals denounced by many Laetrile followers.

(3, 89)

Second, the safety of Laetrile, in whatever form and whatever way it is taken, has not been demonstrated by its advocates in proper clinical studies. This means that anyone taking it in any form and in whatever manner, does so at his own risk, and with the knowledge that one of its breakdown components is poisonous in even miniscule dosages.

(22)

With these caveats clearly in mind, it can be stated that, according to presently available evidence, nothing much appears to happen one way or another when Laetrile is injected into the human system. Contrary to the belief of Laetrile advocates, the amount of beta-glucosidase present in human tissues, cancerous or otherwise, is too small to cause Laetrile to decompose to any significant extent when it comes in contact with these tissues. As noted in Chapter 1, it appears to remain largely inert, and is excreted through normal bodily processes.

(21)

Oral ingestion of Laetrile, however, brings other bodily processes into play, and presents potential dangers. The problem is heightened because such leading Laetrile advocates as Ernst T. Krebs, Jr., Dr. Hans Nieper, and Dr. John A. Richardson, advocate or administer Laetrile by oral ingestion.

(35, 36, 37, 70, 87)

When Laetrile is taken orally, it can be decomposed by beta-glucosidase present in the microbe population of the intestinal tract or in other foods that have been ingested. If that should happen, cyanide poisoning can take place.

In cultures where the population regularly ingests food containing cyanogenic glucosides, extensive and chronic cyanide poisoning is the result. The vegetable cassava, for example, contains the glycoside linamarin, one of the closest chemical relatives of amygdalin. In Africa, Jamaica, and Malaya, regular use of cassava in the diet causes large numbers of persons to live in a state of chronic cyanide poisoning that frequently results in blindness. In these populations the cyanide also attacks the nerves of hearing and the spinal cord.

(4, 19)
It is interesting to note that Dr. John A. Morrone regarded oral ingestion of the substance as dangerous: "Laetrile is relatively non-toxic when administered parenterally (i.e. by injection), he wrote. "Orally it is extremely toxic due to the release of hydrogen cyanide on contact with the hydrochloric acid of the gastric juice." Another organization that has warned against the dangers of oral ingestion of Laetrile is the McNaughton Foundation of Canada. In a publication entitled "The Rationale & Clinical Evaluation of Laetrile Palliative Therapy in Cancer," the Foundation states, "CAUTION: Laetrile (1-mandelonitrile-beta-glucuroniside) is NOT TO BE TAKEN ORALLY. It is extremely toxic by this route of administration, since the gastric hydrochloric acid acts to hydrolyze the substance, with the release of hydrogen cyanide."

(26, 85)

Cases of poisoning in the U.S. through the Laetrile-amygdalin - "Vitamin B-17" craze are now being reported. Instances of such poisoning through ingestion of apricot kernels have been cited in the publication California Morbidity in 1972 and 1973. In one case, a man became violently ill after purchasing some apricot kernels from a health food store and using them in a milk shake. Symptoms included forceful vomiting, headache, flushing, heavy perspiration, dizziness, and faintness. He went immediately to a local emergency room, where further vomiting was induced by ipecac, and the symptoms subsided. The doctors who reported the case, one associated with the San Diego County Division of Medical Services and the other with the California State Department of Health, state, "The minimum number of seeds needed to cause disease or death is not known."

(21, 89)

The Wooing of Non-Terminal Patients

Although ingestion of Laetrile may pose dangers from cyanide poisoning, a greater danger posed by promotion for the substance, is the weaning of non-terminal patients from proven therapies.

In 1977, 115,000 people with cancer will probably die who might have been saved by earlier treatment. Of every six people who get cancer, two will be saved and four will die. But of the four who die, one might have been saved with earlier diagnosis and prompt treatment with proven therapies. This means that half of those who get cancer could and should be saved. Thus, the immediate goal of cancer control in this country is saving 345,000 lives, or half of those who get cancer each year.

(12)

A major thrust of Laetrile promotions is to persuade patients in early stages of the disease, not to take the established therapies available. Such therapies, however, may represent the hope for life.

(45)

One feature of this campaign is the allegation that no advance has
been made in treatment or cure rates of cancer for 30, 50 or 70 years, and/or that existing chemotherapy treatments are largely or wholly ineffective. "The so-called chemotherapeutic drugs -- have proved uniformly useless," Ernst Krebs, Jr. said in a recent speech. "... they have been found to interfere with the action of Laetrile -- we unqualifiedly condemn them for the management of any form of internal cancer." Some of the advances in cancer chemotherapy are shown in a recent paper by Irving Krakoff, M.D. and recent progress in cancer treatment is also discussed briefly by Dr. Jerry Lewis in the Western Journal of Medicine.

As will be described more fully in the next Chapter, the alleged failure to achieve progress against the disease, is often attributed by Laetrile advocates to a conspiracy in the field of medical research to prevent effective remedies from being discovered. If progress were truly the goal of the American Medical Association and the American Cancer Society," Cecile Pollock Hoffman, founder of the International Association of Cancer Victims and Friends, said in a keynote address to one of organization's annual conferences, "do you not believe that the billions of dollars of public monies pumped into the research empire reigned over by these two groups would find an answer (i.e. a cure for cancer) at once? The conclusion is inescapable, and it is damning: The cancer statistics get ever worse because of the conspiracy on the part of the 'Powers' to maintain the status quo."

The natural fears of cancer patients are played upon without compunction of reservation. The drawing below is from a leaflet disseminated by the Committee for Freedom of Choice in Cancer Therapy.

By contrast, Laetrile or "Vitamin B-17" is depicted as not only mild and benign, but as far more effective. The campaign makes use of the results of decades of health education, through which many persons have come to know that certain diseases arise through lack of certain
vitamins in the diet, and are cured by ingestion of these vitamins.
"Once Vitamin B-17 is as widely understood and available as other vita­
mins," says the narrator on the sound tract of the filmstrip World Without
Cancer, "Cancer will then be as rare as if scurvy or pellagra today."

The chart below appears in the same booklet from which the above
drawing was taken. It promises dramatic results for persons who have
detected their cancers early and take Laetrile instead of proved therapies.

---

**ARE YOU A GAMBLER?**

**COMPARE THE RESULTS BELOW...**

**ORTHODOX**  **VITAMIN B-17**

TREATMENT:  THERAPY AND

CUT, BURN, POISON  SOUND NUTRITION

$3/10\%$ LIVE  ADVANCED  $15\%$ LIVE

$15\%$ LIVE  EARLY  $80\%$ LIVE

$84\%$ LIVE  HEALTHY  $100\%$ NOW  NO CANCER

---

Progress Against Cancer

No single "cure" for cancer has been found. As has been explained
earlier, cancer is not a single disease, as Laetrile theory assumes, but
a large number of different diseases. There is little reason to believe
that a single "cure", whether it be laetrile or any other substance, will
ever be found. The scientific truth is that cancer is one of the most
complex of all medical and biological problems. Although progress is
being achieved, and although in certain areas it can even be described
as great, the overall picture is one of forward movement that is often
heartbreakingly slow. This probably accounts for much of the success
of Laetrile, whose advocates find no problem about promising results
that all available scientific evidence indicates cannot be achieved and
therefore, cannot ethically be promised.

(10)

After every caveat about the complexity of the problem and lack of
swiping "cure discoveries" has been stated, it remains a fact that real
progress is being made. The alleged information in the pro-Laetrile
charts and quotations above, regarding the status of both medical pro-
gress and patient treatment in the field of cancer, is completely un-
supported. So are the statements regarding the efficacy of Laetrile as
compared to proven therapy. To begin with, the claim made by pro-Laetrile
forces that the incidence of cancer has increased in the United States,
is untrue. The claim appears in the statement by Cecile Pollock Hoffman,
quoted above. A booklet published by the Committee for Freedom of Choice in Cancer Therapy states, "With the decline of Vitamin B-17 rich foods in the American diet in the past 50 years cancer has increased." Actually, the overall incidence of cancer has decreased slightly in the past 25 years, and the decline would be notably more pronounced if it were not offset by the dramatic increase in the incidence of lung cancer, related to cigarette smoking. The death rate for lung cancer for men, who are heavier smokers than women, has increased 25 times in 45 years.

Cure rates, as well as incidence of the disease, have shown steady improvement. In the early 1900's few cancer patients had any hope of long-term survival. In the 1930's less than one in five were alive at least five years after treatment. In the 1950's it was one in four. Now the ratio is one in three. The gain from one in four to one in three translates into a net saving of 58,000 lives annually.

On the chemotherapy front, about 50 drugs - introduced since 1952, when administration of Laetrile to patients was beginning - are now being used effectively in treating cancer.

These drugs have controlled or cured at least eleven different types of cancer that were formerly considered incurable -- acute lymphocytic leukemia in children, advanced malignant melanoma, Burkitt's lymphoma, choriocarcinoma, embryonal rhabdomyosarcoma, Ewing's sarcoma, histiocytic lymphoma, Hodgkin's disease, retinoblastoma, testicular carcinoma, and Wilm's tumor. The drugs whose effectiveness against these cancer have been established, have time and again passed the scientific tests that Laetrile has invariably failed for twenty-five years.

An outstanding example of successful chemotherapy is the advanced treatment for Hodgkin's disease, a lymph cancer found in young adults, which involves a combination of four drugs. In less than 10 years the five-year survival rate for patients with this form of cancer rose from 68 to 90 percent for early cases and from 10 to 70 percent for advanced cases. In acute lymphocytic leukemia, which is predominantly a disease of childhood, survival for five years was rare as recently as 1960. Now the ratio of persons with this disease who survive for five years or longer is nearly 50 percent.

As outlined above, and contrary to the claims of the Laetrile proponents, substantial gains have been made by treating cancer with chemotherapy - with drugs that have been thoroughly tested, undergone clinical trials and have been approved by the FDA. A progress report on cancer chemotherapeutic agents was published in the May/June, 1977 issue of Ca-A Cancer Journal for Clinicians.

(12, 45, 86, 89)
The Human Cost of Laetrile

More people die of cancer that could have been cured or prevented than of cancer for which a cure has yet to be found. As has been noted, the twin keys in increased survival and cure rates are earlier diagnosis and prompt treatment with proven therapies. In their effort to discredit the second of these essential steps for survival, Laetrile promoters are achieving a significant measure of tragic success.

In a letter published in the New England Journal of Medicine, a physician associated with the Cleveland Clinic Foundation states, "Every three or four months I see a woman with an advanced and usually inoperable breast cancer that had been present for months or years while the patient was receiving no treatment except Laetrile." In a May, 1977, interview with a New York Times reporter, Dr. Vincent DeVita, Director of Cancer Treatment at the National Cancer Institute, said, "Every day I see or hear of patients who died because they took Laetrile instead of proven cancer treatment."

A typical case is that reported in the Summer, 1977, issue of Cancer News. The report states that in May 1972, a 58-year old California woman, Mrs. AB, was told by her physician that she probably had cancer of the left breast. A lump, which was possibly affixed to the skin, was shown by mammography to have characteristics of malignancy. The physician "strongly recommended biopsy, to be followed, if necessary, by surgery."

"It is highly probable that Mrs. AB's cancer was localized at that time and could have been successfully treated," the report states. But, according to her medical chart, "the patient sought alternative forms of therapy, and after reading about Laetrile... she went to northern California to get Laetrile treatments."

Mrs. AB visited a doctor and received Laetrile treatments, both intravenous and oral, for $50 each. However, following several episodes of bleeding at the tumor site, she again sought medical help in 1976.

It was too late. The tumor in her left breast had grown to the size of a cauliflower, and tumors subsequently developed in her armpits. The tumor, in its early stages in 1972, had progressed into an advanced cancer while she was treated with Laetrile. She has received radiation therapy, which has reduced the size of the tumor. However, according to the report, her prognosis is still very poor.
Chapter 4

"FREEDOM OF CHOICE" AND "CONSPIRACY" THEORIES

In the controversy over Laetrile, proponents of the substance have relied strongly on what they describe as the "freedom of choice" of cancer patients, or patients and practitioners consulting together, to decide on the therapies the patient will receive, regardless of whether the scientific community regards the therapy as effective, and without interference from the government. This argument has proved persuasive among many persons who do not necessarily believe in or support the substance itself. Carried into legislative halls, often by terminal cancer patients, it has won victories that the substance have never been able to win on its medical or scientific merits.

Laetrile advocates have also relied on the "conspiracy" argument, which states that the medical, scientific, and research communities are working together to prevent the riddles of cancer from being unraveled, and to prevent useful remedies and therapies from reaching the market.

Both of these arguments are discussed below.

"Freedom of Choice"

The "freedom of choice" argument has played a significant role in the passage of bills in a number of states that would legalize Laetrile within those states, and the enactment of such laws in several states. In a letter to the speaker of the state's house of representatives, explaining his decision to permit such a bill to become law without his signature, one governor said, "My decision not to veto the bill, in spite of the recommendation to do so by several physicians, hospitals and the Food and Drug Administration, is based on one strong conviction -- the individual's right to decide on a course of conduct or a mode of treatment, given the alternatives available. In my opinion, that right outweighs the shortcomings of the bill and the possible complications for the medical profession."

(117)

The American Cancer Society does not agree that an individual's "freedom of choice" can be the controlling policy consideration, in this area, where one person's exercise of such freedom can cause other persons substantial and perhaps irreparable harm. In a democracy, everybody's rights, not just the rights of a few, must be considered, and the civil rights of minorities unable to protect themselves, must be protected. With Laetrile and other substances proved worthless by the test of science, the right of certain persons to buy and use the substance, must be balanced against the right of myriad others to protection against being cheated, defrauded, and harmed, an inescapable consequence in a society in which worthless remedies can be marketed.
Securities offered for sale for investment purposes are strictly controlled in our society, although this represents a curb on the freedom of every citizen. In an area directly related to the demand of Laetrile proponents for "freedom of choice", Federal and State governments have long possessed and used injunctive and other powers to ban products from the marketplace which, through appropriate procedures prescribed by law, have been shown to be unsafe, mislabeled, or fraudulently advertised. Such laws represent a complete abridgement of the right of every practitioner and every citizen to exercise his freedom of choice, if consistently applied, would require that this entire body of consumer protection law, regulation, and judicial activity, would have to be repealed and abandoned.

Two questions are involved.

The first is whether the Government can and should protect the citizenry against exploitation by ineffective and unproven medicines and remedies.

The American Cancer Society believes that the answer must be yes. ACS concurs with the opinion of Congress and President Kennedy, embodied in the 1962 amendments to the Federal Food, Drug and Cosmetic Act, requiring promoters of drugs to demonstrate their effectiveness before marketing them, that exploitation of the public by purveyors of worthless remedies is repugnant to the purposes and ideals of our society, and is a legitimate area in which government can act to protect the people where they cannot protect themselves.

The second question is, if the government's right and obligation to provide such protection is granted, can the power be exercised on a discriminatory basis, banning some remedies and protecting others, all of which have failed to meet identical scientific standards?

Discriminatory enforcement raises questions of the most serious kind relating to equal protection under law, and exposes the entire apparatus to ethical and legal assault, with the likelihood that it will not survive intact.

"If one such product could be sold," says the Food and Drug Administration, "untold numbers of others would appear, their promoters claiming immunity from the law on the same basis as Laetrile. The result would be chaos in medical care, with no one able to distinguish a valuable medicine from a worthless but well-promoted substance."

Cancer victims constitute a de facto minority in our society. Like all minority groups, they have a right not to be exploited. As with
other minority groups, our protection of this group has been built up over a period of time, as our society has become increasingly aware of the magnitude of the cruelty of the conditions to which the group is exposed, in the absence of government protection.

Under the guise of "freedom of choice", advocates of Laetrile are seeking to repeal our modern protection of this group's civil rights, and return us to an earlier era. Cancer victims would once again be exposed to the mercies of those who, either innocently or by design, will play on their emotions, their fears, and their special vulnerabilities to sell them products that are worthless, and to persuade them to abandon the therapies that science has shown to be their only realistic hope for life. The American Cancer Society believes that state legislators, governors, and other officials, should not assist in the achievement of this result.

It should be noted in this connection that laws protecting the rights of minorities and disadvantaged groups, historically do not require that a person violating these laws, be shown to have had any malevolent intent. It is the protection that counts, and it is the protection that the law provides, without concerning itself with the motivation of those who violate the rights involved. Thus, civil rights legislation does not differentiate between those who intend to harm minorities and those who do not. All are liable to the law. The same is true of the nation's food and drug laws. This was strongly affirmed by the U.S. Supreme Court in a November, 1943, landmark decision interpreting the Food, Drug and Cosmetic Act, according to Dr. W. G. Evans of the Food and Drug Administration.

In U.S. vs. Dotterweich, the Court set forth a view quite the opposite of the "freedom of choice" argument, namely, that it is the protection of a disadvantaged group that takes precedence over other considerations. This protection, said the Court, is paramount, and a person could be held accountable for transgressing it even though he had no intention of wrongdoing. The Court's opinion was put in memorable words by Mr. Justice Felix Frankfurter. "The purposes of this legislation," Frankfurter said, "thus touch phases of lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection... Such legislation dispenses with the conventional requirements for criminal conduct -- awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relationship to a public danger."

It has been argued that, at the very least, the terminally ill should have the freedom of choice to use Laetrile if they wish. Unhappily, ACS does not believe that this approach avoids the dilemmas.

The question must be raised first, if the state can associate itself with the selective fleecing of a certain group of persons, on the
ground that they are going to die anyway.

Second, such bills, instead of solving the problems arising under the doctrine of equal protection of the laws, seriously compound them. To discrimination in favor of one substance, is added discrimination in favor of one group. Further, the group is nearly impossible to define in objective terms. The net result is to widen the potential area of assault against the entire structure of national consumer protection against fraud, and against the rights of cancer sufferers.

The American Cancer Society does not doubt that this effort to turn the clock back on the rights and protection of cancer victims, springs from sincere if misguided belief on the part of many or most advocates of Laetrile. For many of those making substantial financial gains from Laetrile, however, the "freedom of choice" campaign comprises one more episode in the never-ending effort by promoters of valueless remedies, to relieve themselves of the responsibility that is properly theirs, and to place it instead on the shoulders of their victims.

The "Conspiracy" Theory

This theory appears frequently in Laetrile literature and publicity. A typical statement of the theory is that by Cecile Pollock Hoffman, quoted in the preceding chapter. Others, from pro-Laetrile literature, include:

"... the interests... would deny cancer victims their right to life..." (44)

"Powerful groups with vested interests have conspired to outlaw free speech and to persecute doctors who are dedicated to the practice of inexpensive life-saving vitamin therapy in the treatment of cancer in the U.S.A."

(45)

"Can you see why this relatively CHEAP vitamin (i.e., "Vitamin B-17) may tempt medical and drug groups to conspire with politicians to outlaw it?"

(45)

"It appears that the principal reason that organized medicine maintains this opposition is because they wish to protect and perpetuate perhaps the most lucrative monopoly in medicine today. At a reported average cost to die of $13,000 for each 335,000 cancer patients that die annually, the cancer business exceeds $4,000,000,000,000 ($4 billion) annually, or more than $10,000,000 daily -- $1,000,000 daily in California alone... It appears that organized medicine has intentionally planned a huge conspiracy to maintain their cancer monopoly and to do almost anything within their power to block any testing of the non-toxic therapies which many patients and doctors consider to be of such great potential value to the 900 people who die each day of cancer." (39)
To the unscrupulous manipulation of cancer patients' fears that is practiced by Laetrile promoters, the conspiracy theory adds a reinforcement of hatred. The dual formula of exploiting the fears of a group of people, and then providing them with a scapegoat, is one that has been used to destroy science and truth and promote totalitarianism in many places in the world in the Twentieth Century. Pressing of these forces into service to achieve the financial success of a medical remedy that cannot pass the test of science, is a development of which no American can be proud.

The tragedy of the use of these tools in lieu of scientific discourse is compounded because, to the extent that the conspiracy theory is believed, the parties who will be hurt will not be the doctors, scientists, and researchers who are being attacked, but innocent cancer patients whom the promoters of Laetrile are trying to reach without having to answer to science.

In view of the notorious inability of American society to keep secret arrangements secret -- so fully demonstrated in recent years with regard to secrets that Government officials, with many legal powers of secrecy, on their side, were unable to suppress -- the idea of a successfully-run health care conspiracy involving tens of thousands of active agents, is not likely to appeal to the sense of reality of thoughtful persons. A few of the more obvious considerations are set forth below.

(1) Doctors, scientists, biologists, chemists, professors, researchers, and elected officials -- and also officers and employees of the American Medical Association and the American Cancer Society -- all get cancer, and die of it. So do their fathers, their mothers, their sisters, their brothers, their wives, their husbands, and their children. The conspiracy theory requires one to believe that all these persons silently lay down their own lives and sacrifice their loved ones, in order that the conspiracy might live.

(2) Most doctors see relatively few cancer patients per year, and derive only a small portion of their income from treating them.

(3) If the health care community conducts conspiracies to suppress medical developments that might reduce the number of its patients, one might ask what happened to the functioning of the conspiracy in connection with such developments as the polio vaccine, penicillin, sulfa drugs, and cortisone? All of these advances have kept countless numbers of persons out of hospitals, clinics, and doctors' offices, for countless numbers of hours for which health professionals would have been reimbursed. The truth, of course, is that the health care community fostered all these developments, welcomed them, and rushed to make them available.

(4) Doctors, probably without exception, urge their patients to
reduce the risk of cancer by avoiding or quitting smoking, avoiding excessive sun exposure, having regular breast examinations, and undergoing regular Pap tests.

(10)

(5) Far from conspiring to prevent useful cancer therapies from being discovered, the Cancer Chemotherapy National Service Center of the National Cancer Institute was specifically organized with a mandate from Congress to seek out drugs that might be useful in treating cancer. From this and other programs have emerged about 170 currently-approved Investigational New Drug Exemptions (INDs), and through successful tests of drugs through the IND procedure, have emerged the effective new drugs whose role in the war against cancer is described in Chapter 2.

(11)

(6) Far from conducting a conspiracy against Laetrile, the Federal government and private research organizations have invested substantially in testing it. Far from suppressing information on successful patient experience with Laetrile, the Food and Drug Administration has made substantial efforts to secure adequate medical records of patients who have allegedly been helped. As has been noted, information of this kind has been most difficult to obtain. In many or most cases it is withheld by Laetrile practitioners. (see Chapter 2.).

FDA wrote to both Dr. Hans Nieper and Dr. Ernesto Contreras, asking them for a selection of their cases that, in the view of these doctors, most clearly demonstrated the value and effectiveness of Laetrile. Dr. Nieper replied, saying that he would supply some cases, but he never did. Dr. Contreras supplied twelve cases. The results of FDA's review of these cases are given in Chapter 2.

(11, 56, 109, 110)
CHAPTER 5

The Legal Status of Laetrile

At the time of this writing, the legal status of Laetrile presents a complex picture, with activity on a number of fronts.

Laetrile has not met the requirements for safety and effectiveness specified under the 1962 amendments to the Federal Food, Drug and Cosmetic Act. Since 1963, its manufacture for, and distribution and sale in interstate commerce has been illegal in the United States.

In 1970 the McNaughton Foundation sought Investigational New Drug status for Laetrile. This status was granted briefly, but was withdrawn when the McNaughton Foundation failed to respond to FDA's request for additional information in connection with its application.

In recent years proponents of Laetrile have attempted, through a number of different approaches, to remove the substance from classification as a drug, so that it would not have to meet the requirements of the Food, Drug and Cosmetic Act.

One approach has been to allege that amygdalin is included in a list maintained by the Food and Drug Administration, called the "Generally Recognized as Safe," or "GRAS," list. Such substances may circulate in interstate commerce without having to comply with the procedures for demonstrating safety and effectiveness that are required for approval of new drugs.

Commenting on an article which stated that amygdalin is on this list, FDA's Bureau of Foods, said, "It is obvious that the article is absolutely false in stating that amygdalin is considered GRAS by the Food and Drug Administration."

According to the Bureau of Foods, the list "does recognize an essential oil extracted from the bitter almond as GRAS, provided that such essential oil is free of the toxic substance, prussic acid (Hydrogen cyanide)... The distilled oil must be rendered free of HCN before it can be used as a food flavoring... It is an obvious contradiction in terms to even attempt to equate the GRAS essential oil without hydrogen cyanide, with Laetrile or amygdalin or Vitamin B-17. Amygdalin is an identifiable chemical compound which includes the cyanide radical."

Another approach, described in Chapter 1, has been to allege that amygdalin is a vitamin, and is therefore not subject to the legal re-
quirements for new drugs. The Food and Drug Administration, however, has refused to classify the substance as a vitamin for regulatory purposes. "Laetrile", the FDA states, "is not a vitamin." (22)

Yet another approach has been to maintain that it is a food or food supplement rather than a drug. A company called General Research Laboratories, Inc., marketed two products, named "Bee-SevenTeen" and "Aprikern", containing ground apricot kernels. They were offered as foods or food supplements in health stores. Federal authorities sought an injunction against their sale. In his ruling on the case, the judge stated that the products could be regarded as both foods and drugs, and that, under either heading, they were illegal. As foods, he ruled, they were adulterated and unfit for human use because they contained hydrogen cyanide. As drugs, they had failed to meet the requirements of the Federal Foods, Drug and Cosmetic Act. On April 24, 1975, the Court issued a permanent injunction against the manufacture and sale of the two products.

(14)

In addition, Federal authorities have secured a number of court rulings against the activities of persons involved in the Laetrile movement and organizations with which they have been associated.

(33,35,36,37,68,87)

A number of individual cancer patients have gone to court, seeking orders allowing them to import sufficient quantities of Laetrile for their own personal use. In some cases the requests have been granted by the courts, and in others they have been denied.

One case, originally brought by a terminal patient, Juanita Stowe, who died during the proceeding, was continued by another patient, Glenn Rutherford. In this case, the court ruled that FDA should hold hearings, to establish an administrative record in support of FDA's ruling that Laetrile is a new drug, and therefore subject to new drug procedures. The hearings were held in Kansas City in May, 1977, and at this writing a ruling is pending.

(105,109,110)

At the state level, California and Illinois have laws patterned after the Federal Food, Drug and Cosmetic Act. In these two states no new drug may be introduced into medical practice until it has satisfied the requirements of the Federal law. In both of these states, as well as in many others, bills have been introduced into the legislatures which would legalize Laetrile. These bills vary greatly in their scope and provisions. As of July 20, 1977, eleven states had enacted laws legalizing Laetrile. The laws in Alaska and Florida in effect legalize its use, and Indiana has among other states, legalized its manufacture and sale as well as its use. The status of such state enactments as they relate to the Federal ban of the substance in interstate commerce, and their actual effect in making Laetrile available to patients in these states has not yet been determined.

(82,115,116)
In response to a query from the American Cancer Society, the Director General of the Israel Cancer Association responded that

"...no clinical trials with Laetrile have been or are being performed in these hospitals (i.e., Beilinson; Shiba Medical Center and Hadassah University Hospital, Jerusalem) and Laetrile is not being used for treatment of cancer patients in Israel.

"Both physicians - Dr. Rubin and Dr. Issahary, are no experts in oncology treatment and up to our best of knowledge are not giving treatment to cancer patients.

"Dr. Rubin approached some time ago, Prof. Z. Fuks, Head of Oncology Department, Hadassah University Hospital, Jerusalem and Prof. N. Goldblum, Head of Virology Department, University Medical School, Jerusalem, and asked them to perform trials with the above medicine. His request was totally rejected. He also contacted the unit for clinical trials at the Israeli Ministry of Health who confirmed as well, that no such clinical trials have been performed in Israel."

This information was confirmed in correspondence from the Scientific Counselor, Embassy of Israel in Washington, the Ministry of Health of Israel and from Dr. David Rubin.

(80, 100, 101, 102, 103, 104)

In Mexico, the Mexican Department of Health banned Laetrile in October 1976, in an action which would close down the manufacture of the substance by Cytopharma and Kem Laboratories. The manufacturers have made an administrative appeal of the Department of Health's ruling and at this writing a decision has not been made.

(77)

In a number of other countries, if Laetrile is distributed and used, it is not through specific approval achieved through scientific procedures or tests, but because these countries have no legislation or regulatory apparatus to differentiate effective from non-effective remedies.

Information recently obtained by the U.S. Department of State, suggests that in 14 countries Laetrile is unknown, in 10 countries it is either prohibited or not approved, in 38 countries it is neither registered nor available on the market, and in 2 countries its use is permitted.

Additional information has been requested from the U.I.C.C. Information is not available at present as to which of the countries mentioned have standards that are comparable to U.S. Food and Drug regulations on drugs. Informal information suggests that very few of them do.

(99)
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69. Letter from Prof. Dr. C.G. Schmidt, of the German Cancer Society re: Dr. Hans Nieper of Hanover, Germany, Aug. 18, 1971.


75. Memorandum from E.J. Beattie, Jr., Chief Medical Officer, Memorial Sloan-Kettering Cancer Center to Attending Staff, Memorial Hospital, June 16, 1977.


79. Telegram from the Israel Cancer Association to the American Cancer Society, with related materials attached, Apr. 21, 1977.


82. American Cancer Society, Inc.: Circular letter from Vice President for Professional Education on Status of Legislation on "Medical Freedom of Choice" Bills, April 1977.


100. Letter from D. Rubin, MD, Tel-Aviv, Israel, to the American Cancer Society, July 11, 1977.


