

Laetrile: Focus on the Facts

The Editor interviews:
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Editor: *Dr. Eyerly, as Chairman of the American Cancer Society's Committee on Unproven Methods of Cancer Management, I'd like you to put in perspective some of the claims voiced so loudly by the proponents of Laetrile.*

Dr. Eyerly: I welcome the opportunity to discuss this most important and controversial issue. As you know, Laetrile, identified as the chemical amygdalin and produced from ground, defatted apricot kernels and concentrates of apricot and peach pits, is not a new discovery. For more than 20 years, the proponents of this drug have claimed that Laetrile can "cure" cancer. For more than 20 years, these claims have been refuted by, to name only a few: the Cancer Commission of the California Medical Association, the California Cancer Advisory Council, the American Medical Association, the National Cancer Institute, and the American Cancer Society. The Food and Drug Administration has also reviewed the subject of Laetrile on several occasions.

Editor: *What were the findings of the FDA?*

Dr. Eyerly: Legal action against the proponents of Laetrile began as early as 1962 when they were charged, and pleaded guilty to, violating the new drug provisions of the Federal Food, Drug, and Cosmetic Act. In March 1963, the FDA reported that it had found "no competent, scientific evidence that Laetrile is effective for the treatment of cancer," and in 1965, the proponents agreed to a permanent court injunction against further distribution of the

drug. A year later, the proponents pleaded guilty to violations of the injunction.

In April 1970, an Investigational New Drug Application to test Laetrile was awarded by the FDA, thus giving the proponents permission to obtain the drug for experimental and clinical studies. This was widely publicized and resulted in a resurgence of interest in Laetrile. However, the FDA review of the IND application disclosed a number of serious clinical problems and the IND was terminated in less than a month. Once again, in September 1971, an ad hoc committee of five oncology consultants independently reviewed and evaluated Laetrile and found "no acceptable evidence to justify clinical trials" of the drug. Shortly thereafter, the FDA prohibited the interstate shipment of Laetrile in the United States, until basic studies had been performed. The FDA *requested* that the proponents provide clinical records of patients treated with Laetrile. I believe four or five case histories were sent to the FDA, but they were completely unacceptable in terms of biopsy documentation and other scientific criteria.

Editor: *With all this evidence against Laetrile, why has the issue not been put to rest?*

Dr. Eyerly: Laetrile is still illegally available in the United States. In the spring of 1975, U.S. Custom officials uncovered an extensive international smuggling operation that imported contraband Laetrile into this country from Mexico and Germany.

Furthermore, in an attempt to circumvent the federal ban on Laetrile, the proponents have renamed it Bee-Seventeen, the "anti-neoplastic vitamin," and Aprikern. These oral preparations have been distributed to many health food stores across the country. However, the FDA has issued a public warning that they are misbranded and potentially dangerous; the ingestion of five capsules of Aprikern or two packets of Bee-Seventeen can be fatal in a child.

Despite such warnings, too many Americans have been or will be persuaded to use Laetrile through the propaganda of the proponents. To those of us who are deeply concerned with the welfare of cancer patients, the use of Laetrile rather than known, effective cancer treatments is the cruelest of all frauds.

Editor: *How is Laetrile promoted?*

Dr. Eyerly: Certain large underground agencies are extremely adept at promoting and publicizing Laetrile. They publish a journal, distribute leaflets, show films and hold conventions. Frankly, the promotion of Laetrile is an economically profitable business. In addition, the proponents have made it a "political" issue.

Editor: *In what sense?*

Dr. Eyerly We, the "medical monopoly," the "cancer establishment," are purportedly involved in the "cover-up" and "suppression" of material. The proponents claim that we do not want to find a cure for cancer. In this time of public suspicion, such accusations are unfortunately given attention. It is difficult to respond to such an irrational statement. I can only reaffirm the American Cancer Society's commitment to the cure and control of cancer.

Editor: *Do the proponents of Laetrile offer any evidence of its efficacy?*

Dr. Eyerly: The scientific rationale is that amygdalin, split by the enzyme beta-glucosidase, releases glucose, benzaldehyde (a mild anesthetic) and cyanide, which is lethal to cells. Supposedly, cancer cells contain more enzyme than normal cells and thus receive a larger amount of cyanide. Normal cells are said to contain another enzyme, rhodanese, that detoxifies cyanide and therefore prevents unwanted destruction. However, there are many flaws in this hypothesis.

Editor: *Such as?*

Dr. Eyerly: Studies have shown only traces of beta glucosidase in animal tissues, and even less in experimental tumors. Furthermore, there is no pronounced difference in the level of rhodanese between normal and cancerous tissue.

Amygdalin administered parenterally is probably excreted almost intact in the urine. Taken orally, it is decomposed in the intestinal tract by beta-glucosidase into highly lethal hydrogen cyanide. Laetrile is 40 times more toxic when taken orally than parenterally.

Editor: *You have explained why Laetrile does not work in theory. Is there any evidence that it is effective in practice?*

Dr. Eyerly: Reports of Laetrile's ability to prevent, arrest or cure cancer are, in the main, anecdotal. For instance, a prominent entertainer will claim that his wife was "miraculously" cured of cancer with Laetrile, while failing to mention that she was also treated with surgery, radiation therapy and chemotherapy. For 20 years, we have asked the proponents of Laetrile for scientific documentation of efficacy, but it has not been forthcoming. Nonetheless, because of public pressure to begin clinical testing, Laetrile has recently undergone extensive experimental study by Sloan-Kettering Institute for Cancer Research and the Catholic Medical Center in New York, the National Cancer Institute in Bethesda, and Arthur D. Little, Inc., a research laboratory in Boston.

Editor: *What were the results?*

Dr. Eyerly: In 1973, Sloan-Kettering Institute conducted a preliminary ex-

perimental study which indicated that amygdalin had some inhibitory effect on the development of tumors and lung metastases in a strain of mice that develop spontaneous mammary cancer. Their findings were prematurely leaked to the press and received extensive publicity by the proponents of Laetrile. In an attempt to reproduce these initial results, two experiments were begun in 1974 at the Catholic Medical Center, using bioassay to verify data objectively. Researchers found no inhibition of primary tumor growth and no difference in the incidence of metastases between mice treated with amygdalin and controls.

Sloan-Kettering Institute has supported four additional studies of Laetrile. Two experiments attempted to entirely reproduce the conditions of the original study, even including the daily light cycle. Far from duplicating the initial findings, researchers discovered that the Laetrile-treated animals fared worse than the controls. Two later studies, which modified the original experiment, also had negative results.

Editor: *Did the other research institutes confirm these negative findings?*

Dr. Eyerly: Yes, they did. Extensive experimental studies at the National Cancer Institute found *no* evidence of activity using Laetrile in leukemia L1210 and P388, melanoma B16 and Walker 256 tumor systems. Four additional studies have been carried out under the auspices of the National Cancer Institute at a leading cancer research center in the South. They studied Laetrile in Ridgeway osteogenic sarcoma, Lewis lung carcinoma and leukemia P388. The osteogenic sarcoma system which is particularly sensitive to antitumor agents, did not respond to amygdalin, nor did the other animal systems.

Arthur D. Little, Inc. conducted a similar experiment using leukemia L1210 and P388, melanoma B16 and Walker 256 carcinosarcoma. They also found no evidence of any selective effect using amygdalin alone or in combination with beta-glucosidase.

Editor: *Is there any indication for clinical trials of Laetrile?*

Dr. Eyerly: No. Based on experimental studies, there is *no* scientific evidence to justify clinical trials.

Editor: *How do you respond to statements like: "the mere fact that a drug does not work in mice and rats does not necessarily prove that it will not work in man?"*

Dr. Eyerly: Each drug in use in the United States must undergo a protocol of experimental and clinical testing. While experimental studies can obviously only anticipate results in humans, they are essential to protect the public from worthless or harmful agents. The National Cancer Institute has many drugs that have shown no

antitumor activity in the laboratory, and therefore do not warrant a clinical trial. To make an exception for Laetrile, is to open the door to potions and snake oils.

Editor: *What's your reaction to those who advocate that Laetrile might at least help the patient psychologically?*

Dr. Eyerly: As Dr. George Rosemond, the past president of the American Cancer Society, has so aptly stated, the possible, slight psychological benefit of a worthless remedy to a patient with advanced cancer is far outweighed by the catastrophe of a potentially curable patient using Laetrile instead of a proven, effective treatment.

Editor: *What is being done to protect patients from Laetrile and other unproven methods of cancer management?*

Dr. Eyerly: Legal action has already been taken on the federal level by the Food and Drug Administration. In 1974, California passed legislation making medical quackery a felony rather than a misdemeanor. Anti-quackery laws are now in effect in Colorado, Illinois, Kentucky, Maryland, Nevada, North Dakota, Ohio and Pennsylvania. Every state should have similar laws.

Public and professional education is vital to the control of all unproven methods of cancer management. Increasing the public's understanding and knowledge of cancer and how it can be treated will help eliminate fear. Indeed, we've found that the major reason cancer patients use Laetrile is fear . . . fear that the disease is incurable, that surgery or other therapy is mutilating, and that the medical profession is not to be trusted. We need the assistance of the media and the profession, so that the public may know all the facts.

For this reason, the American Cancer Society has organized a unique, comprehensive collection of all pertinent data on unproven methods of cancer management. The National Office is the principal repository for such information in the world. In addition, the Committee on Unproven Methods of Cancer Management, comprised of physicians, lawyers, representatives from the National Cancer Institute, the FDA and other health agencies, meets twice a year to assess future professional and public educational programs, to recommend and encourage anti-quackery legislation, and to advise the American Cancer Society in its endeavors to more effectively control cancer quackery. Of course, our efforts require the active assistance of all physicians to fully and forcefully warn their patients against the dangers of unproven cancer "cures."

Editor: *Thank, you, Dr. Eyerly.*

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