FDA
Consumer MEMO
CURRENT AND USEFUL INFORMATION FROM THE FOOD AND DRUG ADMINISTRATION

LAETRILE

An unapproved drug called Laetrile, derived from apricot kernels, is being promoted and sold to the public for the prevention or cure of cancer.

Cancer patients and their families are warned not to rely on Laetrile. Persons with cancer who accept Laetrile as a treatment, instead of consulting their physicians, run the risk of allowing their disease to progress beyond control. Cancer can be cured in many cases by prompt medical attention and proper treatment. Delay frequently means death.

Laetrile has been sold for treating cancer for around 25 years, yet there is still no sound, scientific evidence that it is either effective or safe. It is therefore classified as a "new drug." Under the Federal Food, Drug and Cosmetic Act, a new drug must be approved by FDA on the basis of scientific evidence, including tests on animals, before its use can be justified for experimental tests on humans. A new drug can be distributed commercially only if it has been approved by FDA as *safe* and *effective* after conclusive tests on both animals and humans.

Several attempts have been made to secure approval to distribute Laetrile in the United States. The most recent was by the McNaughton Foundation of California, which submitted an Investigational New Drug Application to FDA in 1970. An independent committee of cancer experts reviewed the application and supplemental data and interviewed Andrew R. L. McNaughton, who organized the foundation. The committee concluded there was no evidence adequate to justify human tests with Laetrile. It is FDA's position that until such evidence is presented, Laetrile may not be shipped within the United States for use on humans.

Laetrile has been identified as the chemical amygdalin. Amygdalin occurs in the seeds of many plants. It is abundant in the kernels of peaches, apricots, bitter almonds, and apple seeds. Seeds which contain amygdalin should not be eaten because amygdalin may break down into the toxic substance cyanide. Laetrile is sometimes referred to as vitamin B-17, but it is not a vitamin.

Laetrile was allegedly first used for treating cancer shortly after 1920 by Ernest T. Krebs, Sr., M.D., but it was supposedly too toxic to be safe. In 1951 Dr. Kreb's son, E. T. Krebs, Jr., a biochemist, claimed to develop a purified form safe for injection.

Recently, promoters have claimed it safe for oral consumption. Capsules of ground, defatted apricot kernels and concentrates of apricot and peach pits have been marketed as a source of Laetrile. FDA has seized such products and has charged that they are adulterated and misbranded. The court papers charge that the products Aprikern and Bee 17 contain a food additive that has not been shown to be safe, and provide no directions for safe and effective use in the treatment of cancer. A public warning issued November 27, 1973, stated that the products contain potentially dangerous levels of hydrogen cyanide and that five capsules of Aprikern or two packets of Bee 17 contain enough cyanide to be fatal to a child.

Backers of Laetrile

Some of the leading proponents of Laetrile are:

1. Ernesto Contreras, M.D., a physician licensed to practice in Mexico, who operates a hospital and clinic in Tijuana, where Laetrile is sold and dispensed in treatments for cancer.

2. International Association of Cancer Victims and Friends (IACVF). It was founded in 1963 by Cecile Hoffman. Although she believed Laetrile had saved her life, she died of cancer. The IACVF publishes the *Cancer News Journal* which often contains misleading articles related to unproven cancer treatments. It also sponsors conventions at which unproven remedies for cancer are promoted, and at which products such as apricot kernel capsules are displayed and sold. The IACVF continues to distribute information on the availability of unproven cancer remedies and makes arrangements for travel to Mexico for treatment.

3. Cancer Control Society. Founded by Betty Lee Morales, a former board member of the IACVF, it publishes the *Cancer Control Journal* and operates similarly to the IACVF.

4. The Committee for Freedom of Choice in Cancer Therapy, organized by Robert Bradford, a Stanford University physicist. It regards efforts to regulate Laetrile and other unproven cancer remedies as an invasion of privacy and unwarranted interference with individual freedom. The committee shows films and distributes literature about the value of Laetrile and makes travel arrangements for cancer victims to go to Mexico for treatment.

5. Several firms and individuals are or have been engaged in the illegal marketing of Laetrile, apricot kernel capsules, amygdalin, or related products sometimes sold in health food stores. General Research Laboratories, a Van Nuys, California firm, consented to a preliminary injunction which on January 28, 1974 prohibited them from distributing apriot kernel capsules (Aprikern) and a milk shake mix (Bee 17) containing amygdalin.

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6. Hans Nieper, M.D. Dr. Nieper operates the Silbersee Clinic in Hanover, West Germany, which offers cancer treatments with Laetrile. He is a proponent of the drug and has written a number of papers asserting the value of Laetrile.

7. Dean Burk, Ph.D. Dr. Burk, a biochemist, is a retired employee of the National Cancer Institute. He believes Laetrile is at the front of the chemotherapeutic attack on cancer. He is frequently a speaker at conventions where Laetrile and other unproven remedies for cancer are promoted. His views are not shared by the National Cancer Institute, the Department of Health, Education and Welfare, or the academic community, and they have not been supported by any known evidence from adequate, well-controlled scientific studies on Laetrile.

8. Ernest Krebs, Jr. Krebs, a biochemist, is the son of the discoverer of the alleged anticancer activity of Laetrile. He is said to have discovered the means of rendering the form of Laetrile, with which his father originally worked, non-toxic.

In 1961, Mr. Krebs, Jr., doing business with his father as the John Beard Memorial Foundation, and the Foundation, were both convicted of illegally promoting another drug—"Vitamin B 15"—for improving the performance of race horses. The U.S. District Court at San Francisco fined Mr. Krebs, Jr. and the Foundation $3,775 and put Mr. Krebs on probation for three years. As a condition of probation he was prohibited from shipping any new drug, including Laetrile, without first having it approved by the FDA.

9. Andrew R. L. McNaughton. Mr. McNaughton is the son of the late General A. G. L. McNaughton, former Commander of the Canadian Armed Forces and a President of the U. N. Security Council. McNaughton, a proponent of Laetrile, describes himself as a consultant specializing in international affairs. He is the founder of Biozymes International, Inc., a Canadian corporation established to manufacture Laetrile, and of the McNaughton Foundations of Canada and California, established to secure approval for the marketing of Laetrile.

Mr. McNaughton has appealed a recent conviction of conspiracy to misrepresent the value of a mining stock in Canada in which he was sentenced to a year in jail and a $25,000 fine. In Italy he has been charged with swindling investors in a plant to produce Laetrile.

10. Glenn D. Kittler, author. One means of publicizing the claimed effectiveness of Laetrile has been a paperback book, "Laetrile—Control for Cancer," claimed to be "the authorized story" and hailing it as a miracle product "which will be to cancer what insulin is to diabetes." Such promotion, not supported by any competent scientific evidence, is a fraud on the public.

It is argued that FDA should permit the use of unproven remedies like Laetrile despite the lack of evidence they are of value. But to do so would create false hope, interfere with effective treatment, and dangerously mislead those who must rely upon drugs to meet the standards of safety and effectiveness that Congress has enacted into law.

The public can be confident that any cancer remedy which meets sound scientific standards will swiftly be approved and made available to all Americans.

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