

STATEMENT

OF THE
AMERICAN MEDICAL ASSOCIATION

Submitted to the
Food and Drug Administration

Re: Laetrile

FDA Docket No. 77N-0048

March 23, 1977

The American Medical Association takes this opportunity to submit its views on the Notice of a Rule Making Hearing on the substance laetrile by the FDA.

The proceeding is being conducted pursuant to a Notice published in the Federal Register on February 18, 1977 announcing the intent of the Food and Drug Administration to receive written testimony and to hold public hearings for the purpose of establishing an administrative record to determine 1) whether laetrile (also known as Vitamin B-17 and Amygdalin) is a "new drug" (i.e., is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective" for its recommended uses) pursuant to the definition found in the Federal Food, Drug and Cosmetic Act, and 2) if laetrile is in fact a "new drug" whether it would be exempt from the pre-marketing approvals otherwise required for a "new drug" (i.e., whether it would qualify as either a pre-1938 drug or as a pre-1962 drug).

According to the FDA, the proceeding itself is being held "solely because the agency was directed to do so" in response to an order of the U.S. Circuit Court of Appeals of the Tenth Judicial Circuit. In the case of Rutherford v. United States

were obtained from using laetrile (a common name for a beta-cyanogenetic glucoside named amygdalin) in the treatment of advanced cases of cancer. At that time, Krebs derived laetrile from apricot kernels. This substance was considered too toxic for general use, even by Krebs, Sr. When orally administered, hydrogen cyanide is formed when laetrile reacts with the gastric juices. It was not until 1952 that Dr. Krebs's son (E. T. Krebs, Jr.) announced that he had developed a substitute which was "safe" for general use when injected. However, in neither form was laetrile viewed by the scientific community as effective.

It was originally hypothesized by its proponents that laetrile is hydrolyzed by beta-glucoside enzymes which release glucose, benzaldehyde and hydrogen cyanide, which is lethal to cancer cells. Supposedly, cancer cells contain more of these enzymes than do normal cells and thus receive a larger dose of cyanide. Normal cells are also said to contain another enzyme rhodanese, which detoxifies the cyanide and therefore prevents unwanted destruction. A second theory that has been put forward by the supporters of laetrile is that cancer is a manifestation of Vitamin B-17 deficiency and that laetrile is this magic Vitamin B-17 which cures and prevents cancer. Neither theory is supportable. In addition, there is no proven natural substance identified as Vitamin B-17.

Furthermore, we believe that the weight of scientific evidence and view is that laetrile is not generally recognized as effective.

For example, in 1953, the Cancer Commission of the California Medical Association investigated laetrile as a treatment for cancer in human beings. In conclusion of its report, the Commission stated in part:

"The Commission has collected information concerning 44 patients treated with laetrile, all of whom either have active disease or are dead of the disease, with one exception. Of those alive, with disease,

results of this single set of tests could never be reproduced under similar conditions. To our knowledge, no valid clinical studies have been conducted which document the efficacy of laetrile.

The American Cancer Society has long pointed out, through its continuous review of the scientific literature, that laetrile is not a proven or generally recognized treatment for cancer.

In 1976, the AMA at its Clinical Convention adopted the following resolution pertaining to the profession's view of laetrile:

RESOLVED, That the American Medical Association continue to inform the public of the danger of delay in the diagnosis and treatment of malignancies by methods not generally recognized by the medical profession as beneficial and effective; and be it further

RESOLVED, That the American Medical Association inform the public that the safety and efficacy of amygdalin for the treatment or palliation of malignancies is unproven and that the use of amygdalin in such cases exploits the victims of malignancies and their families by preying upon the emotions of the hopelessly ill, in some cases for the profit of the unscrupulous.

"New Drug" Exemptions

In order for a "new drug" to receive an exemption from the otherwise applicable requirements of the law, it must either be a pre-1938 drug (a drug which was marketed prior to 1938 and was subject to the Food and Drug Act of 1906 and was marketed under labeling containing the same pre-1938 representations concerning the conditions of its use) or is a pre-1962 drug (a drug that on or before October 9, 1962 was marketed in the United States and which was "generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe" for use under the conditions prescribed, recommended or suggested in the labeling thereof).

We know of no evidence that indicates that laetrile was marketed prior to 1938 under the prescribed conditions in the law or that laetrile was marketed on

freedom of choice as to treatment. These groups have argued that the "medical establishment" is trying to "cover up" and "suppress" material and research which would prove the effectiveness of laetrile. Such a contention is simply not true and is an example of the technique used by these advocates to press their point. Unfortunately, the real recipients of such harmful techniques are those patients who are misled into seeking a useless treatment.

Those who proselytize laetrile often do so through undocumented testimonials of cures and remissions. These reports are anecdotal and testimonial in nature. Such reports do not establish the effectiveness of laetrile. These reports provide no evidence as to whether the "cured" individual had cancer in the first place or whether the person was enjoying a spontaneous remission or whether the person was simultaneously receiving accepted treatment for cancer while participating in a laetrile regimen. The type of evidence offered by the proponents of laetrile is of a type which is wholly unacceptable to medical science, as it provides no control and no documentation as to conditions under which the so-called treatments had taken place.

CONCLUSION


In conclusion, we believe that laetrile should be considered a "new drug" and thus be subjected to the requirements of the law for approval. We believe that it is clear that laetrile is not generally recognized by experts qualified to evaluate the safety and effectiveness of drugs as safe and effective. Furthermore, we do not believe that laetrile qualifies as a pre-1938 drug nor for any other exemption from the otherwise applicable requirements for marketing a "new drug".

The AMA wholeheartedly supports the efforts of the Food and Drug Administration to require drugs distributed in interstate commerce to comply with the requirements

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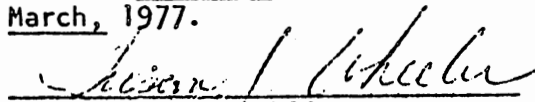
CERTIFICATION

I, James H. Sammons, M.D., Executive Vice President of the American Medical Association, hereby certify that I am authorized to submit on behalf of the AMA the foregoing statement in response to the Food and Drug Administration Notice of Administrative Rule Making Hearing as published in February 18, 1977 in the Federal Register, 41 F.R. 10066-10069, Docket No. 77 N 0048. The statements contained therein are true and correct to the best knowledge and belief of the Association.


James H. Sammons, M.D.
Executive Vice President
American Medical Association

Dated: March 24, 1977

Subscribed and sworn to before
me this 24th day of
March, 1977.


Notary Public

My Commission Expires:

6/2/80