



STATE OF KANSAS

Office of the Attorney General

1st Floor, State Capitol Bldg. (913) 296-2215 Topeka, Kansas 66612

August 18, 1977

Curt T. Schneider
Attorney General

ATTORNEY GENERAL OPINION NO. 77- 270

Mr. James E. Hill, M.D.
Secretary, Board of Healing Arts
503 Kansas Avenue - Suite 500
Topeka, Kansas 66603

RE: Food and Drugs - New Drugs - Laetrile

SYNOPSIS: Laetrile is a "new drug" as defined in the Federal Food and Drugs Act, 21 U.S.C. § 1 *et seq.*, and as such, must meet certain statutory and regulatory requirements before it may be put into interstate commerce. While the sale of Laetrile is presently prohibited, the matter is under consideration by the federal courts and it is possible that the court could overrule the FDA prohibition and allow general distribution of the drug.

*

*

*

Dear Dr. Hill:

You have asked for my opinion regarding the legal status of the drug Laetrile in the State of Kansas. In part, the answer to your question depends on missing factual information. However, I will review for you recent legal developments in the area and offer tentative conclusions as regards the legal status of this highly controversial drug.

Laetrile is a substance claimed to have certain curative effects on cancer when used in conjunction with a strictly supervised diet. It is known by a variety of other names including, amygdalin, prunasin, and "Vitamin B-17". The substance was reportedly discovered by accident in 1920 during attempts to improve bootleg whiskey. In 1952, the substance was supposedly improved by E. J. Krebs, Jr., the son of the man who originally discovered the substance.

Dr. Hill
Page Two
August 18, 1977

The threshold question in determining the legal status of Laetrile is whether it is a "drug" as defined in the Federal Food and Drugs Act, 21 U.S.C. § 1 *et seq.* Every court which has considered that question has reached the same conclusion - Laetrile is a drug. Certain individuals have argued that Laetrile is a food or vitamin and thus exempt from drug regulations. However, the broad statutory definition of the term allows a substance to be both a drug and a food. The determining factor is the use for which it is marketed. The word "drug" is defined in 21 U.S.C. § 321(g) (1) as including:

. . . (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .

Noting the above-quoted definition, United States District Judge Larson reached the following conclusion in *Hanson v. United States*, 417 F.Supp. 30, 35 (D. Minn. 1976) *aff'd* 540 F.2d 943 (8th Cir. 1976):

. . . In short, the use intended by these commercial distributors for the product is unquestionably the 'diagnosis, cure, mitigation, treatment, or prevention of disease in man.'

The conclusion reached in *Hanson, supra*, is supported by two recent cases, *Gadler v. United States*, 425 F.Supp. 244 (1977); and *Rutherford v. United States*, 542 F.2d 1137 (10th Cir. 1976).

Once a substance is classified as a "drug", then the United States Food and Drugs Administration acquires jurisdiction and the drug must then meet certain requirements including a demonstration that it is "safe" and "effective". If a drug was in existence and was generally accepted prior to the adoption of the statutes, then it is "grandfathered" and many regulations do not apply. On the other hand, if the substance is considered a "new drug", then a host of regulatory procedures must be followed before it may be legally marketed.

The FDA has long considered Laetrile to be a "new drug" as defined in the Code. The effect of the FDA position is that Laetrile may not be marketed until a party submits an application for approval. Proponents of Laetrile argue that it is not a "new drug" and no FDA application is needed. The federal courts which have considered the problem are somewhat split in their conclusions.

Dr. Hill
Page Three
August 18, 1977

In *Hanson, supra*, the Eighth Circuit Court of Appeals has upheld the FDA position and ruled that Laetrile is a "new drug" within the meaning of applicable legislation. Before the drug may be marketed, some person or corporation must apply to the FDA for permission and must demonstrate that Laetrile is a safe and effective medical substance. In *Hanson*, the court was concerned with whether commercial enterprises should be allowed to sell Laetrile.

The Tenth Circuit Court of Appeals was faced with a somewhat different question. Glen Rutherford of Conway Springs, Kansas, filed suit in the United States District Court for the Western District of Oklahoma. Mr. Conway alleged that he was a terminally ill cancer patient and that every conventional mode of treatment had proved unsuccessful. However, he had now begun treatment using Laetrile and it had proved effective. He asked the court for permission to import Laetrile from Mexico solely for his personal use.

Judge Luther Bohannon enjoined the Department of Health, Education and Welfare from interfering with Mr. Rutherford's use of Laetrile. *Rutherford v. United States*, 390 F.Supp. 1208 (W.D. Okla. 1975); *aff'd* 542 F.2d 1137 (10th Cir. 1976); *mod'f* 424 F.Supp. 105 (W.D. Okla. 1977). It was the rationale of the Tenth Circuit that the FDA's determination that Laetrile is a "new drug" must be supported by an adequate administrative record. No such record existed. The Tenth Circuit remanded the case for further proceedings in accordance with its opinion. District Judge Bohannon then remanded the case to the FDA for public hearings on the question and ordered a report to be made to him within 120 days of December 30, 1976. In checking with Judge Bohannon's office, it is our understanding that the report has been filed and his opinion will be forthcoming.

In addition, Judge Bohannon certified the suit as a class action. Thus, a person who wishes to use Laetrile may receive court permission if the following requirements are met: one, a doctor certifies the patient is suffering from terminal cancer; two, all conventional modes of treatment have failed; and three, the patient is voluntarily requesting Laetrile treatments. Special forms are available from Judge Bohannon's office to request this privilege.

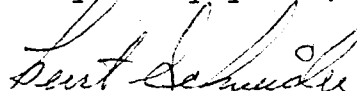
It should be noted that Judge Bohannon's opinion only applies to a strictly limited class of citizens. No court, absent special legislation, has allowed the sale of Laetrile for any purpose.

Dr. Hill
Page Four
August 18, 1977

The foregoing legal discussion applies to Laetrile which is involved in interstate commerce. Absent such involvement, the federal legislation is inapplicable. Theoretically, it is possible that Laetrile could be manufactured, sold and used entirely within the borders of Kansas. If that were the case, the Kansas Food, Drugs and Cosmetics Act would apply. K.S.A. 1976 Supp. 65-619 *et seq.* The act is nearly identical to its federal counterpart. It is my opinion that essentially the same issues would be involved in the application of the Kansas law as are involved in the federal law. I should emphasize that it is the federal legislation which applies to the vast majority of situations involving Laetrile.

It is therefore my opinion that except for a limited class of terminally ill cancer victims, Laetrile is a drug which has not met federal or state licensing requirements and cannot, therefore, now be marketed in Kansas. However, the matter is pending in the United States District Court for the Western District of Oklahoma and that Court's decision could have considerable effect on this subject. I am presently monitoring the situation and will inform you if there are further developments.

Very truly yours,



CURT T. SCHNEIDER
Attorney General

CTS:PAH:ksn