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Laetrile: Should the Dying Patient Decide?

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On July 1, 1980, at four major medical institutions across the United States, the National Cancer Institute began testing Laetrile on cancer patients on whom all other therapy has failed. The study calls for 200 patients to receive the drug, along with a natural food diet. Results should be known in two years, and should demonstrate once and for all whether or not Laetrile has any cancer inhibiting effects. The study was undertaken primarily because of the large amount of publicity proponents of Laetrile have generated over the past five years, rather than any independent evidence that Laetrile may be an effective anticancer agent. Its commencement, however, provides a useful opportunity to review the legal status of Laetrile, and to suggest a possible approach to the controversy it has caused.

Nurses, of course, spend more time talking to terminally ill cancer patients than any other health care professional. What, if anything, can they tell them about Laetrile? Certainly it is inaccurate and unethical to describe it as an "alternative treatment," since there is no evidence that it is either safe or effective. And one state nursing board has even gone so far as to suspend a nurse's license for six months upon a finding that she discussed Laetrile with a terminally ill leukemia victim at the patient's request. That decision was later reversed by the state's supreme court. The court concluded that engaging "in conversations with a patient regarding alternative treatments" could not be considered "unprofessional conduct" in the absence of a specific regulation that defined such conduct in a way that would put nurses on notice as to what was expected of them.[1] Before nurses decide what they should do when their patients ask about Laetrile, it is important that they understand the law as it currently exists.

Laetrile, labeled by most a quack remedy — akin to snake oil and mineral tablets — is a symbol. As a symbol, it has different meanings to different people. To some it symbolizes the struggle of the patient to obtain whatever substance he desires to introduce into his body; to others, especially the U.S. Food and Drug Administration, it symbolizes a battle to insure that all drugs marketed in interstate commerce in the United States are "safe and effective." One case has reached the United States Supreme Court, and suggests a possible compromise position that this article explores: making Laetrile (and other substances not proven "safe and effective") legally available only to terminally ill patients.

The leading case on Laetrile involves Glen L. Rutherford who, in 1971, developed cancer of the colon. His physicians recommended immediate surgery. Upset about the potential risks of surgery, Rutherford traveled to Tijuana, Mexico, where he was treated with Laetrile and had his tumor cauterized. His symptoms disappeared. He continued using Laetrile until 1975 when his supplier was arrested. Rutherford thereupon brought suit to enjoin the FDA from interfering with his procurement of Laetrile. The case was heard in U.S. District Court in Oklahoma by Judge Luther Bohanon. He found that the FDA had refused to "make a clear determination of whether the drug Laetrile should or should not be placed in commerce" even though thousands of patients had been using it for years. The Judge ruled that individuals like Rutherford were being "denied freedom of choice" as guaranteed by the United States Constitution. Accordingly, he entered an order granting the injunction.[2]

The United States Court of Appeals for the Tenth Circuit affirmed, but remanded the case to the District Court to determine if Laetrile was exempted from the "new drug" provisions of the Food, Drug and Cosmetic Act by virtue of the "grandfather" clauses of the 1962 amendments. To qualify, it would have had to have been marketed on October 9, 1962 as a cancer drug and been generally recognized as "safe," or have been used as a cancer drug under the same conditions as its current use sometime during the period June 30, 1906 to June 25, 1938. The FDA had presented no evidence on these questions, and therefore the court could make no decision regarding them.[3]

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