

Laetrile Brush Fire Is Out, Scientists Hope

National Cancer Institute study finds treatment ineffective; Laetrile proponents persist

There was less than a sliver of hope that Laetrile would prove to be an effective treatment against cancer. Animal models, good predictors of drugs that will fight cancer in humans, had shown Laetrile to be inactive. Nevertheless, given widespread public interest and a long and bitter dispute between Laetrile supporters and the scientific community, the National Cancer Institute (NCI) went ahead last July and began the first full-fledged clinical trial to determine the efficacy of the compound derived from the pits of bitter almonds and apricots. Last week the results were finally in, with researchers crossing their fingers that the controversy over Laetrile would be laid to rest.

"Laetrile has been tested and it is not effective," announced Charles Moertel, director of the Comprehensive Cancer Center at Mayo Clinic at the annual meeting in Washington, D.C., of the American Society of Clinical Oncology. Moertel is head of the four-institution group which conducted the research.

Laetrile's effectiveness to fight cancer or to relieve accompanying symptoms were roundly disappointing. Of the 156 patients analyzed, only one patient

ter, Minnesota, the University of Arizona in Tucson, Memorial Sloan-Kettering in New York, and the University of California at Los Angeles took pains to follow the protocols and special diets of fresh fruits, vegetables, whole grains, and little meat that are espoused as effective by pro-Laetrile groups.

To satisfy another regimen touted by other Laetrile proponents, the institute studied another 14 patients, given even larger amounts of Laetrile and huge doses of vitamins. One patient died of cancer. Of the 13 still living, nine patients have cancer spreading. Two are stable and two have yet to be evaluated. So even at higher doses, Laetrile appears to be inactive, Moertel said. The problem with such high doses is that cyanide levels soared dangerously high in some patients and treatment was stopped.

But even before the institute study got under way, one of the most vocal Laetrile advocates, Robert W. Bradford, president of the Committee for the Freedom of Choice for Cancer Therapy, filed for an injunction against the NCI, claiming that the researchers were planning to test a substance that was not in the form of Laetrile that he said had been used

from a West German company and then purified by American firms under contract with NCI.

The institute had planned another trial to test Laetrile's efficacy in a double blind, placebo trial. But given the current results, the institute and investigators will reevaluate the plans and decide within the next month to continue or not.

The Laetrile trial is apparently the first time the institute has tested a potential anticancer drug on humans that has previously shown no benefit in animal studies. Sidney Wolfe, director of the Health Research Group, a public interest organization in Washington, D.C., says that the NCI study was unethical. "It's possible that some of the patients might have benefited from other experimental drugs." The government tried to avoid conducting a clinical trial when, in 1978, it searched nationwide in a retrospective study to find cancer patients who had improved with Laetrile treatment. The search revealed only six people who possibly benefited from Laetrile, but the evidence was not clear.

Wolfe said the Laetrile trial "sets an unfortunate precedent" for other substances that may stir up comparable public attention in the future. The \$400,000 to \$500,000 that the federal government spent on the testing "was a waste of money."

On the other hand, the negative results of the study may be enough to cancel the hopes of some cancer patients in what appears to be quack medicine. But there is little doubt that many patients will continue to seek out Laetrile. As many as 70,000 Americans in the late 1970's turned their backs on potentially curative conventional cancer treatment for Laetrile, according to NCI estimates.

Moertel sadly predicts that there will be "more brush fires like Laetrile." When asked at a press conference by a member of Bradford's pro-Laetrile group whether patients should be free to choose their cancer therapy, Moertel quickly replied, "I agree with the freedom of choice but not with the freedom to exploit desperate cancer patients."

The Laetrile findings were disclosed at a cancer meeting where researchers reported a good measure of progress in the treatment of cancers, including osteosarcoma and breast cancer. But even as

After 8 months of study, 102 of the 156 patients analyzed have died.

showed partial remission. After 10 weeks, however, the patient suffered a relapse. After 8 months of study, 102 patients have died. Of the remaining 54 patients still alive—a survival rate that is no better than can be expected if all the patients received no treatment—cancer has spread in 49 individuals. Five are still stable. About one-fifth of the patients, whose cancers included breast, lung, and colorectal, reported that they felt some temporary improvement in symptoms of the disease such as loss of appetite. But placebo trials achieve similar results, Moertel noted. Two-thirds of the patients had not responded to standard chemotherapy. One-third had received no prior treatment with anticancer drugs. Most patients were in generally good condition and none were disabled.

The investigators at Mayo, in Roches-

ter, Minnesota, the University of Arizona in Tucson, Memorial Sloan-Kettering in New York, and the University of California at Los Angeles took pains to follow the protocols and special diets of fresh fruits, vegetables, whole grains, and little meat that are espoused as effective by pro-Laetrile groups. The case, however, was dismissed on the grounds that Bradford would not suffer any potential harm if the testing continued, except possibly economic injury. Bradford sells Laetrile to the 23 states and 30 countries which allow the use of Laetrile. He is appealing the lawsuit.

The National Cancer Institute "sabotaged the trials to save face," Bradford said last week in a telephone interview. "The negative results mean nothing."

NCI maintains that it tested the same Laetrile used by proponents of the substance, only in purer form. The material for the institute's trial was purchased

Moertel concluded his speech in the cavernous ballroom at the Sheraton-Washington, an elderly woman, Gertrude Engel, stood up before hundreds of physicians to press her cause in support of Laetrile. "What about all the anecdotal

evidence that Laetrile works?" she demanded. "Doesn't that count for something?"

Moertel responded from the podium, "People have said that crocodile dung and leeching have helped to cure disease

based on anecdotal evidence. It is destructive information. We need scientific evidence and we now have it on Laetrile."

His remarks were met with a round of applause.—MARJORIE SUN

Watt Carves Up Strip-Mining Policy

The new Secretary of the Interior wants to hand it back to the states

One of the Reagan Administration's earliest reversals of environmental policy is occurring in the regulation of strip-mining. The Department of the Interior, under Secretary James Watt, is recasting virtually every rule written in the 4 years since Congress passed the Surface Mining Control and Reclamation Act, with the effect of drastically reducing federal involvement in the act's enforcement. Watt's plan is to give state authorities added discretion to interpret the law according to regional conditions, a decision that lets individual mine owners avoid some mining and reclamation procedures that they believe are too difficult and costly. At stake are millions of dollars in coal profits and some requirements that environmentalists had pursued for at least a decade.

A small group of officials from other federal agencies meets daily at the Office of Surface Mining to "streamline" the existing rules. "We've taken out a lot of the verbiage, a lot of the specific criteria for reclamation and mining operations," says Edward Johnson, an acting assistant administrator on loan from the Agriculture Department. "The idea is to accomplish great changes without a legislative fight."

As with much of Watt's agenda, the strip-mining plan has provoked strong opposition from the environmental community, as well as from farmers and ranchers in mining areas. Thomas Galloway, of the Center for Law and Social Policy, in Washington, D.C., threatens that some of the reforms will be challenged in court. Edward Grandis, of the Environmental Policy Institute, says, "they are developing a recipe for failure, leaving the program with high goals but no enforcement."

The industry, however, is excited at the prospect of operating under more flexible rules. Many of the regulatory changes have come directly from lobby-

ing groups such as the Mining and Reclamation Council of America, in Washington, D.C., whose members conduct 70 percent of the nation's coal mining. Additional suggestions have come from individual mine owners and state political officials, who say that their protests against stringent interpretations of the law's provisions had previously fallen on deaf ears. Joseph Porter III, vice president of the Garland Coal and Mining Company in Arkansas, is one of many to write the department in recent weeks, applauding the attitude shift. "For small companies such as ours, the benefit is incalculable," he wrote.

The wrangling that attended the law's consideration by Congress has never ceased. Its proscriptions against the gouging of mountainsides and the care-free dumping of mining spoil reversed long-standing industry practices and cost

millions of dollars. Operators complained that the Carter Administration started citing them for violations without even a short grace period to modify their practices. Federal officials took the attitude that requirements had to be spelled out in utmost detail or they would be circumvented. Last year, resistance to the rules was so great that the Senate voted to make the regulations "advisory" and not mandatory.

The opposition also found its way into the courts, where more than 100 provisions of the law and the subsequent regulations have been challenged. The result is a confusing patchwork of rules, some of which are in limbo and others in constant revision. The Supreme Court is expected to rule this spring on the decisions of federal judges in Virginia and Indiana that certain portions of the law violate states rights, due process, and



Office of Surface Mining

A mountainside littered by mining spoil

Kentucky argued to bar this completely last year, but only after a fight.