Photo by Eric Poggenpohl

Arthur C. Upton

and because "a retrospective study is not the way to go. It is not scientific." Instead he called for a clinical trial.

At least three other pro-Laetrile groups also boycotted the study: the Cancer Control Society, the International Association of Cancer Victims and Friends, and the Richardson Clinic of Albany, California. The complaints from these groups ranged from "poor protocol" to the fear of harassment by federal and local authorities if the names of physicians and patients using Laetrile were made public.

The only known pro-Laetrile group to pitch in was the Committee for Freedom of Choice in Cancer Therapy, claimed to be the largest pro-Laetrile organization in the country with about 60,000 active and inactive members, 3000 of them being physicians. Its chairman, Robert W. Bradford, was the sole pro-Laetrile voice on the NCI "protocol review panel" that formulated the case-review study. "We didn't like the way they were going about it," he says. "We didn't like their selective process. But we felt that if anything at all positive came out of it, however slight, at least we'd have our foot in the door."

By Bradford's standards, the door has now been thrown wide open. A panel of 12 NCI cancer specialists judged the 67 cases, and to avoid charges of an anti-Laetrile bias, an equal number of conventional cancer cases were mixed in. Results appeared in the 7 September issue of the *New England Journal of Medicine*. One case was judged twice, since the patient took Laetrile on two separate occasions. Of the 68 Laetrile cases, the panel threw out 11 that had "insufficient data" and 35 others that were "non-evaluable" (because, for instance, anticancer drugs had been given along with Laetrile). This left 22 cases to be judged—out of the 93 that had originally been sent to NCI. Seven of the 22 showed progressive disease. Nine showed stable disease. Two cases showed complete disappearance of all cancer and four showed shrinkage of tumors by 50 percent or more. Says Bradford: "I'm very happy with the report. You've got a couple of clear-cut cases of remission. Here for the first time we have the National Cancer Institute coming out and saying, hey, we've really got to look at this stuff."

To the researchers, however, no clear conclusions can be drawn from the study. Normal variability or spontaneous remissions could account for the recoveries, they say. And since the study looked only at positive responses, a balanced view is not yet available. "In fact," says Ellison, "although we only asked for cases of a positive response, we received replies from 220 physicians who claimed to know more than 1000 patients who showed no beneficial response to Laetrile."

Another ambiguity, and an unavoidable weakness of any after-the-fact study, is that improvement by other factors cannot be ruled out. Patients treated with Laetrile almost always use it as part of a program of "metabolic therapy," including a vegetarian diet, supplementary vitamins and enzymes, and chelated minerals, some of which may, according to the report's authors, "be regarded as immune stimulants." The report also said that improvement could be brought on by "the unmeasurable ingredient of hope."

The solution? Shelve the whole thing or attempt a clinical trial. If it achieved nothing else, at least the retrospective study seems to have weakened some of the ethical objections to a clinical trial. Last November John C. Fletcher, assistant for bioethics at the NCI Clinical Center, coauthored a letter to the *New England Journal of Medicine* that said a clinical trial of Laetrile would come as a "devastating blow" to the established canons of medical ethics. Now he is not so sure. "There are," he says, "some scientific problems with the retrospective study, but there is also a small signal there that needs to be heard. I am now more open to the possibility of a clinical trial. We have to take this evidence seriously."

Even though NCI's Decision Network Committee has made its toss-up recommendation, the ultimate decision rests with Arthur C. Upton, director of the institute. His decision, expected within 1 week, does not have to follow the Network Committee's recommendation. And even if a decision to test Laetrile is made by Upton, NCI still needs an Investigational New Drug (IND) permit from the FDA. Commissioner Donald Kennedy is said to not think kindly about the idea.

It is no small irony that in the midst of making the long-put-off decision, NCI director Upton will be rubbing shoulders with some militant pro-Laetrile company. The Committee for Freedom of Choice in Cancer Therapy, of Los Altos, California, is holding its "First International Conference on Laetrile, Metabolic Therapy, and Cancer" at the Bethesda, Maryland, Holiday Inn, just a couple of blocks down from NCI headquarters. They expect 125 physicians, pharmacists, and nurses to attend. Says Vincent Oliverio, chairman of NCI's Decision Network Committee: "I thought this whole thing was dying down. But here they are, camped right on our front doorstep."—WILLIAM J. BROAD

Erratum: Due to a printer's error, the word "nitrite" was altered to "nitrate" in two instances in the article, "Ever so cautiously, the FDA moves toward a ban on nitrites," (8 September, p. 887). The lead sentence should read, "The hazard to animals and man of eating excessive amounts of nitrates and nitrites. . . ." The first sentence in the fourth paragraph should read, "These circumstances . . . the existent but unquantified hazard of adding nitrites to food." Nitrites—not nitrates—are deliberately added to foods.