papers in the archives, the total number of which may be as high as 60,000. And Professor Stachel has also been able to contact many of those who were in correspondence with Einstein, asking for their comments on copies of letters which have been sent to them.

But there the matter rests. Mr Herbert Bailey, head of the university press, admits that the project has had "problems", and does not accept that it has gone into abeyance. "We have a lot of reasons to think that the project, on which we are as keen as we have always been, will go forward" he said last week; however he declined to reveal how the project will proceed after the NSF grant money, and Professor Stachel's contract, run out in the summer.

Dr Nathan is equally adamant that claims that the trustees have placed unworkable restrictions on how the editing work should proceed are "nonsense", and that the trustees "are being maligned" if such charges are being made.

He says that since a few days after Einstein's death the estate has been attempting to get a complete edition of the physicist's writings published, but that he has been "blocked again and again", and that he feels that "at the moment we do not know where we are going".

Historians of science are hoping that the stalemate can be resolved by some means (there are rumours of possible litigation, but these cannot be confimed). No one disputes that the collected works, when they are eventually published, will be a major contribution to twentieth century scholarship, helping to provide a far greater understanding of Einstein's role in the development of both modern science and the modern world; but few do not express frustration at the current impasse.

"When completed it will be—or should be—what historians and philosophers of science, and others, have been waiting for since Einstein died", Dr Jeremy Bernstein, professor of physics at Stevens Institute of Technology, and author of a biography of Einstein, wrote recently. "Not all this material is of great interest . . . but what matters is that it should be available." □

FDA scientists dispute ethics of testing laetrile

A SCIENTIST with the Food and Drug Administration has filed a "citizen's petition" against his agency in an attempt to prevent it from giving approval to clinical trials which the National Cancer Institute is planning to carry out on the controversial anti-cancer drug laetrile.

Dr Robert Young, a clinical oncologist with the FDA, echoing concerns which have already been expressed and debated within the NCI, claims that such trials would be in violation of accepted ethical codes since no firm scientific evidence yet exists that the drug has any beneficial effects.

Both the FDA and the US medical establishment maintain stiff opposition to the use of the drug, which is derived from apricot kernels and is currently taken by thousands of cancer patients in the nation. The agency has issued notices warning that laetrile is "worthless" and that its cyanide content in particular is potentially dangerous.

However despite this uncompromising stand, FDA commissioner Dr Donald Kennedy, previously professor of human biology at Stanford University, has come under pressure from those who argue that although previous studies do not provide any conclusive evidence that laetrile has a beneficial effect, neither is there sufficient evidence to rule out such an effect.

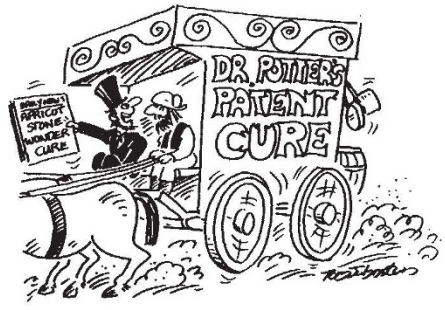
The clinical trials have been proposed by the NCI following a retrospective study of laetrile patients which the institute, having frequently rejected the idea in the past, agreed to carry out last year.

Over 90 cases claiming evidence of a beneficial effect of laetrile treatment were submitted in response to a nationwide appeal, and a detailed study of 67 of these by a panel of oncologists revealed six patients who had received laetrile as their primary treatment, and were judged to have had a clinical response.

Announcing the results of the study last autumn, the NCI said that these would not normally be sufficient to suggest that a drug merit clinical tests over other candidate drugs. However it added that "because of widespread public use and interest in laetrile, the NCI will proceed with plans to evaluate the drug".

Subsequently the institute filed an "investigational new drug application" (IND) with the FDA in December. And although the agency has taken considerably longer than normal to approve the application—there have been detailed discussions with the NCI both about the protocol for the experiment, as well as on technical details about the quality, stability and purity of the substance to be tested—this is expected to be granted within a few weeks.

Dr Young's objection to granting approval is that "there is not adequate scientific data that would justify the test of the drug in human beings." In an interview with *Nature* last week he cited in particular the lack of evidence, accepted by the NCI, of the drug's efficacy in animal tests; and even the retrospective tests, he says, provides "no scientific data from which you can responsibly conclude that it was the taking of the drug that mitigated the disease".



"To the nearest apricot farm!"

In his petition, which Dr Young says reflects the feelings of a number of laboratory staff in the agency, he requests that laetrile should not be exempted from the provision of the Food and Drug Act, which require reports "adequate to justify the proposed clinical testing". And he criticises the agency for using a "sociopolitical argument", rather than a solid scientific case, to justify the trials.

If the FDA approves the cancer institute's IND, a six-month study will be carried out involving between 150 and 300 patients with different types of cancer; participation will be restricted to patients in whom all known therapies have been attempted.

Meanwhile the Supreme Court has agreed to rule on whether the FDA has the right to bar the use of laetrile as an anti-cancer drug, following the decision of a lower court that the need to show a drug is both "safe" and "effective" before being approved for sale or distribution does not apply to drugs used by terminally ill cancer patients.

In appealing the decision to the Supreme Court, the FDA has claimed that this ruling seriously limits its power to protect the public from unsafe and ineffective drugs, adding that it would be "virtually impossible to restrict the use of laetrile to the terminally ill".

David Dickson

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