cilities are either under construction or being planned—providing 5 million square feet of space at a cost of more than \$1 billion—at the same time that 4.5 million square feet of unoccupied space already exists in current facilities. No action was taken on the recommendations in the last report for cutting this apparent inefficiency, he noted.

The new report elaborates, revealing for example that the Defense Department is planning or building 31 new research facilities at a cost of \$593 million, at the same time it has more than 1 million square feet of unoccupied space in existing facilities. The Department of Health, Education, and Welfare is more modest: it is planning or building 12 new facilities at a cost of \$290 million, at the

## Briefing.

# NCI's Retrospective Look at Laetrile Seems Doomed to Fail

The laetrile movement is gaining momentum and with every pro-laetrile step forward, the National Cancer Institute (NCI) finds itself under increasing pressure to do something to affirm or persuasively refute persistent claims that laetrile fights cancer. It is estimated that 100,000 or more American cancer patients take laetrile, which has recently been legalized by several state legislatures. Yet, by all conventional scientific standards, it must be said there is no evidence that laetrile works.

It was in this milieu that NCI officials last fall began serious talks about conducting a clinical trial of the apricot-pit drug, in which some patients would receive laetrile, others a placebo. There is, at NCI, strong sentiment for going ahead with human tests of laetrile in the hope that doing so would put the issue to rest once and for all. But there is also strong opposition to testing laetrile on cancer patients on grounds that to do so would be unethical. One cannot ethically give a patient an agent that has not shown any anticancer effect in animal models, it is argued.

What to do? NCI officials came up with an imaginative scheme, a step removed from a real clinical trial, which they hoped would yield some information about whether laetrile has any biological activity in humans without putting the NCI itself in the position of actually giving the controversial agent to anyone. NCI decided same time it has 564,000 square feet of unoccupied space in existing labs. Even more space, amounting to 2.5 million square feet, is available in laboratory buildings owned by the National Aeronautics and Space Administration, which has suffered budget cutbacks in recent years.

The report assumes, but does not prove, that a significant amount of the unoccupied space could be used as is or modified for use in place of the new construction. The investigators' primary objective was simply to produce the inventory and point out its potential value. Apparently, this was difficult enough by itself. "It was unimaginable . . . the depths within a department that one had to descend before any semblance of a listing of laboratories could be contrived," they report.

In addition to listing such information, the authors—under chapter headings such as "Department and Agency Inaction" and "An Exercise In Futility" get down to the nitty gritty of who is at fault. Primarily, it turns out to be the GSA, which tried to set up an inventory of laboratory space but did it so poorly that only one-fifth of the laboratories in the earlier congressional study were included in the GSA list published 3 years later.

The reason that the agency missed so many labs, says the report, is that instead of using the congressional study as a starting point, GSA set up a task force to study how to formulate the inventory,

to try to exploit what deputy director Guy R. Newell called a "kind of clinical trial going on in the community, one that we have an ethical responsibility to look at."

Last January Newell and other NCI leaders announced that they wanted to study, without prejudice, the case records of patients who had been taking laetrile and who believed their tumors had regressed as a result. Declaring that "Our minds are not already made up," while acknowledging the institute was responding to public pressure, Newell outlined the ground rules of NCI's proposal to examine the "clinical trial going on in the community."

It was a long shot, with the institute betting that it could find 200–300 individuals behaving in real life as if they were part of a scientific study. If NCI could find that number of patients in whom there could be shown some evidence that laetrile has "any biological activity," whether it cures cancer or not, the institute would be on firmer ethical ground if it decided to conduct a rigorous human trial of its own.

Since January, NCI has been seeking data on patients who have (i) confirmed pathological diagnosis of cancer, with slides to prove it and (ii) measurable disease-a palpable lump or tumor that is apparent in an x-ray, for instance. These patients may well have received some standard form of anticancer therapy-indeed, it is likely, inasmuch as they would probably have first been treated by a conventional physician in order to have had scientifically valid diagnoses of cancer. But, to be eligible for NCI's retrospective review, they would also have to have had a "documented" interval of 30 days or more during which they took only

laetrile and after which their tumors either disappeared or shrunk. Through letters to physicians, articles in medical journals, and items in the general press, as well as pro-laetrile newsletters, NCI has been searching for these patients people who gave up on standard therapy in favor of laetrile but who have also kept in touch with their regular physicians, the ones NCI is hoping will have the necessary proof that something positive happened to their laetrile-taking patients.

No matter what happened with a retrospective study of this sort, one would never get definitive data, but in order to get any useful information at all, it is essential to get the records of those 200– 300 cancer patients. Almost three months ago, NCI officials optimistically predicted that getting patients to volunteer their records would be no problem, though the foundation for that optimism was shaky.

Now, it looks as if the whole compromise scheme is going to fail. Instead of having records from 200–300 patients, NCI has heard from only 45 or 50 and, according to Neil Ellison, who is handling the project, not all of them meet the criteria. For example, he noted that in some cases there was no adequate proof that the person actually had cancer and in others, the record showed that the patient was already in remission as a result of standard therapy before taking laetrile.

At this stage, it is not clear what NCI will do next. The pressure for an NCIsponsored clinical trial continues, and it looks as if the institute is going to have to make the hard go-no go decision without relying on the false comfort that its retrospective analysis was meant to give. and waited 2 years to begin. Ultimately, the agency's officials decided to restrict the inventory reports of unoccupied space to lots of 10,000 square feet or more. Also, only laboratories operated by the federal government were required to respond (many labs are owned by the federal government but operated under contract). When the report form was finally devised, it was watered down enough to create "further havoc on what was destined to become a diluted and meaningless inventory" according to the subcommittee. "Succinctly stated, the GSA reaction was 'a day late and a dollar short.' '

Wallace McCoy, the assistant to the assistant commissioner for space management at GSA, contests the charge. "We limited the report requirements to large blocks of space because we perceived those to be the most valuable for one agency to borrow from another," he said. "Also, labs operated under contract from the federal government are more difficult to transfer from one agency to another."

However good or bad, once the form was sent out, other agencies had an opportunity to share in the debacle. "The Department of Defense, for all intents and purposes, was totally unresponsive," the subcommittee report states. NASA submitted 15 forms, but GSA claimed it received only six. Neither agency made any attempt to find the missing ones. The Department of Energy submitted inventory forms on only 8 of its 41 laboratories, and, when confronted by the subcommittee investigators, acknowledged that it had not been totally responsive. The Department of Agriculture was one of the few that complied with the GSA requirement on deadline, according to the subcommittee report, "but this can hardly be considered an accomplishment." The submitted forms reflected only 30 percent of the department's laboratories. HEW also submitted inaccurate totals, claiming later that it had never understood the requirements in the first place.

The subcommittee report attributes part of the inaccuracy to a reluctance by several of the agencies to report unoccupied space. "Coincidental or not, when figures pertaining to 6 U.S. Army facili-

Briefing

#### March of Dimes Denies Giving In to Antiabortionists

For several years, antiabortion forces have been trying to convince people not to contribute to The National Foundation-March of Dimes because of its support of "genetic services programs" through which pregnant women may have amniocentesis. Amniocentesis, as far as "right-to-life" groups are concerned, is the next best thing to abortion because if the procedure' reveals a defective fetus, it is more than likely that the mother will opt to abort. Antiabortionists are unimpressed by arguments that in 97 percent of cases, amniocentesis reassures women that the fetus is healthy and the mother carries it to term.

**Opponents of The National Foundation** have not been successful in hampering fund raising (contributions more than doubled from \$25 million in 1970 to more than \$57 million in 1977), but they are this year claiming a victory of sorts because the foundation is reducing its support of some of its genetic services programs. (There will be no reduction in its support of basic research in genetics.) Foundation officials, who insist that a number of 5-year projects are merely coming to a natural end, are so concerned about appearing to have given in that they have sent statements explaining their case to March of Dimes staff and volunteers, as well as to the press. "... contrary to what you may have heard, we are neither terminating our support of genetics programs nor submitting to pressures by antiabortion forces to alter our policies and programs," Foundation president Charles L. Massey says. In fact, in 1979, the Foundation will continue to support 80 genetic services programs to the tune of \$2.3 million and is accepting applications for new ones.

### MIT Scientist to Head FDA's Bureau of Foods

When Donald Kennedy became commissioner of the Food and Drug Administration (FDA) a year ago, he declared that one of his principal ambitions was to attract first class scientific talent to the agency to belie its reputation as a place where no imaginative researcher would want to work. In hiring Sanford Arthur Miller, professor of nutritional biochemistry at the Massachusetts Institute of Technology (MIT), to head FDA's bureau of foods, Kennedy seems to have taken a step in the direction of remaking the agency's image.

Miller, who has been at MIT since 1959, enjoys a reputation as one of the country's leading nutrition researchers. His areas of specialization include the interaction between nutrition and development in the infant (including the effects of food additives) and oral biology (including the relationship of diet and vitamins in the etiology of periodontal disease).

In a telephone interview with *Science* Miller discussed his reasons for taking the FDA job, prominent among them the fact he'd be working with Kennedy whom

#### he calls "the single most impressive person I've met in 20 years of dealing with the federal establishment." "I suppose," he said, "I should say that I come screaming all the way, but really I'm just interested." In a number of ways, Miller's associates and MIT as an institution pushed him to go to FDA. "For 20 years, I've been firing off polemics against the FDA," Miller said. "One of my colleagues told me it was time to 'put up or shut up.' And one of my students said that the American people had been supporting me for 20 years while I had a good time. Service at FDA gives me a chance to repay that." And, less philosophically, Miller added, "I also have reached the right stage in my career for a move like this. I guess I have the 20-year itch."

Miller also credits MIT with his decision to accept. MIT which, he says, "has a long tradition of supporting this kind of thing," has granted him a 3-year leave of absence. On the one hand, this reduces the risk he takes—if he and FDA do not seem fit for each other he can just return to Cambridge. On the other, it puts him in a position to speak out without having to worry about his rise up any bureaucratic ladder.

And Miller promises to speak out, even if it means locking horns against his outspoken boss. But suddenly about to become an insider, he is reluctant to comment on particular issues. "Around here I always say, 'Never quote me tomorrow on what I said today,' "Miller quipped, while acknowledging that in a federal agency, where decisions are "quickly engraved in sandstone, if not in granite," one has an obligation not to shoot from the hip.

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