

Subject's head says evaluations were biased

Worthiness of U of L vinyl

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A \$2.4 million, federally financed program at the University of Louisville dealing with the health effects of vinyl chloride on workers at the B. F. Goodrich Co. is ending under a cloud of controversy.

The controversy stems from a highly critical evaluation of the program by an independent group of scientists last September. Four of the 11 scientists recommended the program be terminated immediately, while five of them voted to let the project continue until its contract expired June 30 and two said the project should be extended.

Some of the reviewers said U of L was failing to fulfill some of the terms of the government contract, financed by the National Cancer Institute.

The three-year contract called on the university to develop early-warning tests for workers facing the danger of a rare liver cancer believed to be caused by exposure to vinyl chloride — an ingredient in the making of plastic.

U of L also was to develop a program for educating workers on the problem and for providing counseling to workers with liver cancer. Those programs were to be something that could be used in other industries.

The contract went into effect June 26, 1975, in the midst of expectations that there would be a rash of cases of vinyl chloride-related liver cancer (the possibility came to light in 1974 when two cases were noted).

During the project, only one case showed up (a total of three occurred between 1974 and the time the contract went into effect).

Besides saying the terms of the contract were not being met, one of the scientists in the review — Dr. Samuel Epstein, a professor of occupational medicine at the University of Illinois — charged that U of L had a conflict of interest by receiving money from chemical industries, as well as the government, to conduct vinyl chloride projects. He said the university put out false or misleading information downgrading the health dangers to Goodrich workers.

Although another committee of inde-

pendent scientists later decided to allow the contract to continue until it was scheduled to end in late June, the critical evaluation found its way into the hands of U.S. Rep. David R. Obey, a Wisconsin Democrat with close ties to labor.

Epstein said he tipped off a high-ranking union official at the national AFL-CIO about the reports and said Obey's office was "a friend."

Obey questioned officials of the National Cancer Institute about the reports of some of those scientists during appropriation hearings in March on the institute's budget. He read sections of the reports that contained such statements as "this is a dangerous program which should be terminated as soon as possible."

Dr. Diane Fink, director of the cancer institute's Division on Cancer Control and Rehabilitation, which is responsible for the contract, replied by saying the contract was being phased out.

Dr. Carlo Tamburro, a nationally known liver specialist who heads the vinyl chloride project, said some of the scientists in the review were biased. He said members of his group were not allowed to give full presentations to the committee.

He noted that other independent committees of scientists had previously given the project high marks. And he pointed out that a group of experts from the cancer institute, sent to Louisville after the critical evaluation, had delivered reports apparently softening the scientists' criticism.

However, Ben E. Acton, special assistant to Dr. Fink at the National Cancer Institute, said the critical evaluation by non-government scientists carries more

weight than the later reports of the institute's team.

That is because, he said, "there is interest for us always to make it (evaluation) as good as possible because it is our program (financed by the cancer institute). I think the independent objective review by an outside group certainly does carry a great deal of weight."

Acton said the independent scientific evaluation of the final report, which U of L group still must prepare, will be crucial.

If the evaluation is favorable, a negative report will disappear," he said.

However, the U of L group has been unable to deliver its final report on time. It was due at the end of last month. The group is expected to ask and to receive a 30-day extension to prepare the report.

Verbal approval of an extension was given late last month during a Washington meeting of Tamburro and two other members of the U of L Cancer Center. Louisville union official, U.S. Rep. Romano Mazzoli, D-3rd District, and officials of the National Cancer Institute.

Meanwhile, Tamburro's request for an 18-month contract extension and additional funds of more than \$300,000 was rejected, according to James J. Vanagh, the cancer institute's contract officer who is handling the U of L project.

Sheldon W. Samuels, director of health, safety and environment for the AFL-CIO industrial union department in Washington, said Louisville unions involved in the project had asked whether the AFL-CIO should use its influence

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A page of background,
interpretation and commentary

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vinyl chloride project questioned

get more funds. However, he said that, from what he had heard, there were problems with the U of L project and he would do nothing until a final report had been received.

Samuels, who was on the original committee that approved the U of L contract, was in Louisville Friday to discuss with union leaders what the AFL-CIO should do about testing workers, because the U of L project is being phased out. (Goodrich, which has a chemical plant on Bells Lane, is required by law to perform certain health tests on workers.)

After The Courier-Journal made a request under Kentucky's Open Records Law for the project evaluations, Tamburro made available a copy of a summary of the critical evaluation, other more favorable reports, letters of support from unions and Goodrich management, memoranda from the cancer institute's team of experts, and a letter favorable to the project from Dr. Irving J. Selikoff, the well-known Mount Sinai School of Medicine physician who has studied the health effects of asbestos on workers.

But Tamburro refused to release the individual reports from the team of scientists. He said, in part, that the release of the individual reports would "add more confusion than clarity. ... They are like table notes. They are not the official report."

Some cancer institute officials said the reviewers thought that projects to develop tests to detect disease should not be undertaken unless it can be shown lives can be saved. There was little proof of this in the vinyl chloride project, the reviewers said.

From reading the available reports and interviewing scientists, labor and government officials, here is a summary of the criticisms and U of L's response to them:

The computer

The team of scientists said that massive amounts of information about workers and medical tests had been put into the U of L study's computer but not analyzed. There were questions about whether the information system had been properly designed.

The information was to be used for determining which tests were not good at picking up health problems from vinyl chloride, so the tests could be eliminated, and to identify which workers had higher risks of disease.

Tamburro said the information was analyzed during the last six months. He said some of the medical-test evaluations could not be done until the last

the team had refused to listen to a lengthy presentation on the subject and, thus, was mistaken in its evaluation.

A computer specialist who came with the later cancer institute team said he thought no member of the first team of scientists had "a particularly strong (if any) background in either data processing or information management."

The scientist who did much of the questioning on the computer system was Dr. Gary Cutter, a University of Texas statistician who is the deputy director of a program using computers to monitor thousands of people with high blood pressure.

Dr. Richard A. Greenberg, the epidemiologist with the vinyl chloride project, said the analysis was slowed because the U of L group was forced to switch from one computer to a larger, better one in the middle of the project.

However, he said medical histories and test results for individual workers were quickly available if the worker's physician requested it.

It was difficult to evaluate how good the medical tests were because only one person came down with the liver cancer during the three years of the project, he said. The university had expected an "epidemic" of cancers, he said.

Even so, the computer system was successful in developing a way to keep track of the health effects of worker exposures to 22 chemicals, he said.

However, new funds are necessary to continue this project, he said. Even though the computer system was successful, he said, there is no money to continue the project.

The reviewers also said the sample size for testing the effects of vinyl chloride on heart problems may have been too small.

Health education

The team of scientists and a health education specialist with the cancer institute who visited U of L later criticized the effectiveness of the efforts to inform workers about the health programs. U of L was to develop and institute a health education model that could be used by other industries.

Part of the problem, according to the cancer institute specialist, was that the first director of health education was not effective in doing his job.

Later, the efforts improved, but no good system had been established for proving which methods were the most effective, Dr. Ruby N. Isom said.

Counseling, psychological help

had not been developed, according to the evaluation. But Tamburro pointed out that only one worker had come down with the cancer. He said a better project would be to develop a system for helping workers deal with living under the threat of cancer.

Conflict of interest

Epstein, the University of Illinois occupational medicine specialist, said his report had noted that U of L had a conflict of interest for accepting hundreds of thousands of dollars from Goodrich and the Manufacturing Chemists Association, an organization financed by the chemical industry.

He said U of L had kept the grants a secret, although U of L officials said they had publicized them.

After the evaluation, a cancer institute investigator checked whether U of L had mixed the institute's funds with industry funds and concluded that the school had not.

Epstein claimed the money made the university biased toward the company, rather than the workers. He said some workers had told him they felt this way.

He said this resulted in putting out newsletters understating the threat from vinyl chloride.

Dr. Arthur H. Keeney, dean of the U of L School of Medicine, said project officials had tried to reassure workers while remaining concerned about the problem.

George French, a business representative of one of four unions involved in the project, Pipefitters Local 522, and active in the vinyl chloride problem, said he did not believe the university favored management.

However, he said some men might have felt that way because they interpreted Tamburro's testimony in a workmen's compensation case involving liver cancer a few years ago as favoring management.

Epstein contended that the contract required the school to emphasize finding ways to keep workers from being exposed to vinyl chloride. Instead, he said, the university spent much of the time "subjecting workers to a wide range of investigations (tests), many of which seem to have doubtful values to the workers, although they may have had some academic interest."

Keeney said the tests could be beneficial, because they might identify workers who had greater risk of developing disease.

Officials of the vinyl chloride project said they were not required to regulate exposures to vinyl chloride and could