

2000 Walk to Cure Diabetes



Patient's Death In Gene Tests Not Reported

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Washington Post Staff Writers
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A Tufts University scientist failed to report the death of a volunteer in his gene therapy experiments and put other participants' lives at risk, including a patient with early signs of cancer that may have spread as a result of the treatment, federal officials charged yesterday.

Patients suspected of having cancer were supposed to be excluded from the study because it involves a treatment that fosters the growth of new blood vessels, which are known to feed tumors. Yet a volunteer diagnosed with a lung mass was enrolled anyway, and his tumor doubled in size within three months of treatment.

In another case, a volunteer had a heart attack after getting a gene infusion in her heart, and died from complications a few months later. But the scientist and his team waited months before revealing the problems to hospital officials overseeing the experiment's safety. And even then, only the complications and not the death were reported.

These and other alleged violations of federal research rules are detailed in a nine-page warning letter from the Food and Drug Administration to Jeffrey Isner, who led the research at St. Elizabeth's Medical Center in Boston.

The letter raises serious questions about the quality and safety of Isner's high-profile efforts to grow new blood vessels in patients with heart disease and other circulatory problems. Those efforts, which for a time seemed to offer a miraculous way to grow crucial blood vessels around blocked ones, have been stalled since late February, when the FDA ordered a halt to four human gene therapy experiments that Isner oversaw pending the completion of its inspection.

More generally, the new revelations come at a time when the field of gene therapy is trying to recover from a spate of bad publicity. The experimental approach, which tries to cure diseases by giving people new genes, has been under intense public and regulatory scrutiny since the death in September of a teenage volunteer in a University of Pennsylvania experiment. Federal regulators ultimately concluded that the Penn experiment and many others around the country were not in

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compliance with federal rules.

The Boston experiments were sponsored by St. Elizabeth's and by Vascular Genetics Inc. of Durham, N.C., a company that Isner cofounded to commercialize gene therapy discoveries.

Isner and other representatives of Vascular Genetics could not be reached for comment. But in March, Vascular Genetics President John Cumming said the company was complying with the FDA's request for information and was "very comfortable with the data."

According to the FDA letter, Isner's research team neither properly investigated the death of the volunteer late last year nor reported it to St. Elizabeth's institutional review board, a panel that is charged by law with safeguarding patients enrolled in experiments at the medical center.

The volunteer's heart stopped after receiving a direct injection of genetic material in June 1998, leading to multiple organ failure and, four months later, death, the letter states. The chief pathologist told FDA officials that he removed the heart and turned it over to Isner, who performed the autopsy even though he apparently didn't have hospital authorization or board certification to conduct autopsies.

In addition, Isner didn't inform the institutional review board that the volunteer had suffered any complications until 1999, the letter states. Even then, he only reported that the volunteer required a two-month hospital stay, without mentioning that the person died, the letter states. It is unclear whether the gene therapy caused the death.

In the other case, Isner's research team injected genetic material into a volunteer's heart in September even though X-rays taken at St. Elizabeth's just before the treatment showed evidence of a growth in his lung. Although at least two follow-up X-rays soon after the treatment again revealed the lung mass, there is no written indication that he or his private doctor was told about the problem, the letter states. It was only after the patient suffered chest pains in late October that his personal doctor told him he had cancer.

When the volunteer returned to St. Elizabeth's in December for a routine gene therapy follow-up, a new X-ray showed that the lesion had doubled in size.

"A reasonable possibility exists that circulating [gene material] contributed to the tumor growth," the FDA letter states.

Yet, the team didn't perform the necessary tests to determine if the genetic treatment might be contributing to the spread, according to the FDA letter. Moreover, records show that the enlarged tumor was initially deemed to be a "severe" adverse event, a class of complication that must be promptly reported to regulators. Later, however, someone changed the

word "severe" to "mild."

In addition, the letter states, other patients were enrolled who were not eligible to participate, and many volunteers never received the physical examinations or laboratory tests that the FDA-approved protocol had required before and after treatment.

The FDA letter gives Isner 15 days to respond with a plan for correcting the deficiencies.

Researchers found in violation of federal regulations face a range of possible punishments, including being barred from conducting federally funded research.

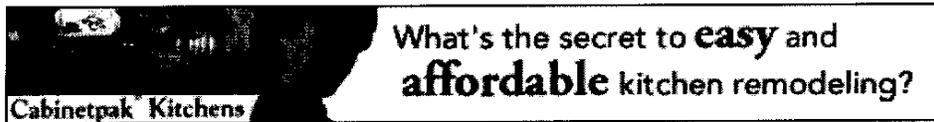
A hospital spokeswoman said officials there have been investigating the issues raised by the FDA but would have no immediate comment.

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