



U.S. Halts Cancer Tests In Oklahoma

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Federal regulators have shut down all government-funded human medical experiments at the University of Oklahoma Health Sciences Center in Tulsa amid evidence that researchers there broke multiple rules designed to protect patients and then tried to cover up their lapses by withholding information from university overseers and patients.

Among the concerns that led to the unusually severe disciplinary action were that dozens of cancer patients may have been injected with experimental cancer-fighting vaccines contaminated with dangerous bacteria or viruses; that 11 of the first 18 patients to get the vaccines were not eligible for the study; and that the informed-consent form given to volunteers overstated the possible benefits of the experiment and understated the risks.

University officials said yesterday they were looking into the lapses but had found no evidence that any patients had been harmed.

The research suspension, which affects about 75 studies on campus, represents the first major disciplinary action by the newly constituted federal Office for Human Research Protections (OHRP). Health and Human Services Secretary Donna E. Shalala created the office in the past month in response to a growing recognition of the need for enhanced federal oversight of human clinical studies.

Michael Carome, OHRP's chief of compliance, sent a 17-page letter to University of Oklahoma officials on June 29, outlining a plethora of patient protection failings. Most were related to a study of the experimental cancer vaccine, which had been approved for use in 40 patients with advanced melanoma--a deadly form of skin cancer--but which was actually injected into at least 90 patients. The study was led by Michael McGee, who was vice chairman of the university's department of surgery until recently, when he was relieved of that status.

According to OHRP's letter, first described yesterday in USA Today and obtained by The Washington Post, McGee's department asked a private consulting group to conduct an independent audit of the work early this year.

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Among that group's March findings: The university researchers making the cancer vaccine were not qualified to do so; the techniques used could not ensure that the vaccine doses were produced free of contamination; the vaccines were being shipped to remote locations for injection into patients without proper assurance that they remained cold enough and were administered properly; and there was no reliable system for determining whether illnesses experienced by vaccine recipients--indeed, whether any of the 26 deaths that occurred among those patients--were due to the vaccine.

The auditors recommended that the experiment, which they said suffered from "egregious" lapses, be discontinued immediately, "since adequate precautions to protect the safety of patients have not been taken." The auditors also noted that "liability and public relations issues could surface as a result of this trial," according to a subsequent memo from McGee's boss, the chairman of surgery, to the university's dean.

But certain key details of that report, including the possibility that patients may have been harmed by the vaccine, were not immediately forwarded to the university's Institutional Review Board (IRB), which is responsible for ensuring patient safety in clinical studies, or to surviving patients, as is required by federal regulations and international principles of human medical research.

Instead, in an April 10 letter to participating researchers and surviving patients, and in a May 17 report to the IRB, McGee wrote that the study had been suspended because so many patients had expressed interest in the study that they had run out of vaccine. McGee also wrote that there "are no significant safety issues."

In a telephone interview yesterday, Ken Lackey, president of the university's Tulsa campus, said the school had recently hired consultants to review each patient's medical chart and look for evidence that any may have been harmed by the vaccine. "It certainly appears from that review that all the deaths were from the natural consequences of their diseases," he said.

As for the vaccine samples themselves, he said, "they were all tested and found to be free of contamination."

This past weekend, fulfilling one of OHRP's "required corrective actions," the university sent out new letters to doctors involved in the study, the surviving participants' primary care physicians and the closest known relatives of deceased patients, explaining the truth about why the study was suspended.

Lackey said he had disbanded the university's IRB and relieved two high-ranking research oversight officials of their administrative duties while the university completes its own internal investigation and

prepares to come back into compliance with federal regulations.

Staff researcher Alice Crites contributed to this report.

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