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Clinical trials halted; patients endangered

By Edward T. Pound, USA TODAY

WASHINGTON — In a continuing crackdown on mishandled medical experiments, federal health officials have shut down all government-sponsored clinical trials involving human subjects at the University of Oklahoma College of Medicine in Tulsa. They acted, officials say, after concluding that a cancer study there endangered patients' safety.

A federal watchdog agency issued the suspension June 29 in a letter that accused university researchers and an oversight board of repeatedly violating federal regulations meant to protect patients in the three-year-old cancer trial. The letter was obtained by USA TODAY.

University officials say the study involved injecting vaccine into patients who were seriously ill with melanoma, a deadly skin cancer. Officials acknowledge that 26 patients died, but they say there is no indication that the vaccine caused their deaths. The study was canceled after an outside clinical research firm hired by the university sharply criticized the trial and its principal researcher, Michael McGee, who was vice chairman of the Department of Surgery during the trial. He declined comment.

The Office for Human Research Protections issued the suspension. That office recently was established in the Department of Health and Human Services. Its job: to protect the tens of thousands of people who enroll in medical experiments, many desperate to find a cure for their disease. Concern over clinical trials arose after Jesse Gelsinger, 18, died in September 1999. He had been a patient in a gene-therapy experiment at the University of Pennsylvania.

Officials at the University of Oklahoma say their biggest concern is patient safety. They say all 75 trials at the Tulsa campus have been suspended pending an internal review. Moreover, the university's president, David Boren, has set up a task force to ensure that all trials comply with safety regulations.

Ken Lackey, president of the Tulsa campus, says an internal review of the vaccine trial is underway. "We have to find out what happened here and make damn sure it does not happen again," he said in an interview.

The suspension letter was signed by Michael Carome, the chief compliance official in the federal human protections office. Carome criticized sharply the study's researcher, McGee, as well as the Institutional Review Board (IRB) established at the Tulsa campus to review all clinical trials. The IRB was supposed to make sure that risks were minimized for patients, but it failed miserably in the melanoma trial, Carome concluded. He said the chairman of the IRB, Daniel Plunket, must be replaced. The university has disbanded the IRB and removed Plunket from his administrative duties at the College of Medicine. McGee was removed as vice chairman of the Department of Surgery.

According to university officials, McGee made his own vaccine and headed the trial, which was conducted in Tulsa and at eight other sites, mostly physicians' groups across the country.

When the trial was put on hold in March, after an outside research firm issued highly critical reports, McGee "misrepresented the reasons for the suspension" in letters to surviving patients, Carome wrote. Carome said the outside firm had found that some vaccine had been made available for use without testing to ensure safety and compliance with government regulations. McGee, however, wrote patients that he was stopping injections because he no longer had adequate supplies, according to Carome.

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