FDA may probe TX firm that held Perry's stem cells

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(AP) -- The Food and Drug Administration has received a complaint against a company that stored adult stem cells from Texas Governor Rick Perry for use in an experimental procedure to treat his back pain.

A University of Minnesota professor is calling on the FDA to investigate the safety and legality of services offered by CellTex Therapeutics, a company which banks patients' own stem cells for future use in medical procedures.

"I think there's a role here for the FDA to ensure that people are receiving safe and effective treatments," said Leigh Turner, an associate professor of bioethics, in an interview with the Associated Press. "I think a lot of these stem cell therapies seem like 21st century quackery."

Turner believes the Houston company's business model runs afoul of FDA regulations governing human stem cells, though the area is subject to multiple rules

A spokeswoman for the FDA declined Wednesday to comment on the letter or say "what, if any, investigation would take place based on the concerns submitted."

Turner said an agency official contacted him last month to say that the Feb. 21 letter is being "taken seriously." CellTex is only one of multiple U.S. companies offering to store stem cells for untested medical procedures, Turner said.

While pursuing the Republican presidential nomination last fall, Perry revealed that he had stem cells taken from fat in his body, grown in a lab and then injected into his back during a July operation to address back pain.

News of the procedure triggered criticism last November from medical experts who said untested stem cell treatments carry a host of potential risks, ranging from blood clots to infection.

Adult stem cells are being studied for everything from heart disease to diabetes, but it's too soon to know if these approaches are safe or effective. Perry's procedure used his own cells - not embryonic stem cells, which are more controversial because their use involves destroying human embryos.

The FDA has not approved any adult stem cell therapies for orthopedic use, but experimentation by doctors in the U.S. and abroad is common.

Perry's procedure was performed by his doctor and friend, orthopedist Stanley Jones, with stem cells allegedly stored by Houston-based CellTex Therapeutics. Last year the company paid $30 million to license technology from RNL Bio, another stem cell company with offices in the U.S. and South Korea.

"Have CellTex and RNL Bio provided to the FDA data concerning safety and efficacy of their adult stem cell procedures?" asks Turner in his letter, which was first reported by the Minneapolis Star Tribune.

In a March 9 letter to the FDA, lawyers for CellTex said the company operates within state and federal law. The letter stresses that CellTex does not treat patients using stem cells, a key distinction in FDA regulation.

"It is a lab that processes stem cells at the behest of independent physicians who diagnose and prescribe to their patients," states Jonathan Emord of Emord & Associates in Washington, D.C.

Procedures like Perry's highlight a gray area for the FDA, which does not regulate the practice of medicine but does oversee medical products. For years, some U.S. doctors have reportedly extracted adult stem cells from patients' fat for a variety of experimental uses, ranging from skin-smoothing facelifts to joint-strengthening injections. The agency has taken little action against these techniques because they usually do not involve commercial products marketed by a company.

But some experts say growing cells in culture and possibly mixing them with other substances may make these modified cells a product. The FDA brought an injunction barring a Colorado company from growing marrow-derived stem cells in this way. Court proceedings in that case are underway.