

# Doctors question Perry's stem cell back treatment

MARILYNN MARCHIONE - AP Medical Writer - Associated Press

He calls it innovative. Others call it a big risk. In any case, the stem cell procedure that Texas Gov. Rick Perry had last month was an unusual experiment to fix a common malady: a bad back.

Perry, the newest GOP presidential candidate, has access to the best possible care and advice. Yet he and his doctor chose a treatment beyond mainstream medicine: He had stem cells taken from fat in his own body, grown in a lab and then injected into his back and his bloodstream during a July 1 operation to fuse part of his spine.

The treatment carries potential risks ranging from blood clots to infection to cancer and may even run afoul of federal rules, doctors say. At least one patient died of a clot hours after an infusion of fat-derived stem cells outside the United States. It's not clear how much of this Perry might have known.

His doctor and friend, orthopedist Dr. Stanley Jones, could not be reached for comment despite repeated requests to the spokeswoman for his Houston-area hospital. Jones told the Texas Tribune that he went to Japan for a stem cell treatment that helped his arthritis and that he had never before tried the procedure he used on Perry. He also said it had no side effects or risks.

However, some top scientists are questioning the safety and wisdom of Perry's treatment, especially because it was not part of a clinical trial in which unproven therapies are tested in a way that helps protect patients and advances medical knowledge.

Perry "exercised poor judgment" to try it, said Dr. George Q. Daley, of Children's Hospital Boston and the Harvard Stem Cell Institute. "As a highly influential person of power, Perry's actions have the unfortunate potential to push desperate patients into the clinics of quacks," who are selling unproven treatments "for everything from Alzheimer's to autism."

Daley is past president of the International Society for Stem Cell Research, a group of 3,000 scientists and others in the field. He consults for several biotech companies and favors stem cell research. But of Perry's treatment he said: "I would never in a million years accept for one of my family members to undergo this."

On the campaign trail Thursday in New Hampshire, Ray Sullivan, Perry's chief of staff, said: "The governor consulted with his physician and decided the best course of action for him. He's very pleased with the results of the surgery, with the rapid recovery and with the procedure that he had. And he feels like that is certainly his right to determine the best course of treatment for him."

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Perry's treatment was first reported by the Texas Tribune. The procedure was done by Jones, who works at Foundation Surgical Hospital — a private, doctor-owned orthopedics center in suburban Houston — but Perry spokesman Mark Miner would not say where it took place.

"The governor chose this procedure to repair a reoccurring back ailment" and has confidence in the team that did it, Miner told The Associated Press. "The governor believed in this innovative approach."

It used Perry's own "adult" stem cells — not embryonic stem cells, a controversial technology that involves destroying an embryo, which the governor opposes. Adult stem cells have long been used to treat cancers such as leukemia and lymphoma — it's what doctors are using when they do bone marrow transplants. The 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.

Some orthopedic surgeons, including Dr. Christoph Meyer at Jones' hospital, are experimenting with stem cells to help bones heal. The cells usually are taken from bone marrow and injected or implanted in the trouble spot, such as a knee or shoulder. The theory is that these "master cells" will follow cues from cells around them and form bone or cartilage, though scientists worry they also might spur unwanted growth and cancer.

Perry, however, had an even more experimental procedure: stem cells from fat removed by liposuction and grown in a lab for some time before they were put into his spine and bloodstream.

"It's a new technology that doesn't have the track record of the older ones," Meyer said. "Doctor Jones and Governor Perry made a bold move but that's how all advances in medicine have been made. I think it says a lot about Governor Perry that he was willing to try something like this that was new and untested. I mean that in a positive way."

However, Dr. George Muschler, an orthopedic surgeon at Cleveland Clinic, said fat-derived stem cells are "an unusual choice" because they don't form bone as readily as those from marrow.

Using them as was done for Perry is "quite experimental and it's quite controversial because there isn't good evidence yet, at least in the medical literature, that fat cells work better or even work at all in repairing bones," Muschler said. "It's out there, a little past the edge of what mainstream medicine would generally accept."

The Cleveland Clinic has three patents on cell-related technologies Muschler developed, and he has consulted for Medtronic Inc. and the federal Food and Drug Administration.

Dr. Thomas Einhorn, orthopedics chairman at Boston University, has tested some experimental stem cell therapies himself. He said one concern is that Perry's cells

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were grown in a lab dish with other ingredients where there is more of a risk they will transform into cancer and any breach in sterility could lead to an infection once they were put into a vein.

He also took issue with infusing the cells into Perry's bloodstream. "I can't think of any reason to do that. I wouldn't want to cause a blood clot."

It also enters a gray area with the FDA, which does not regulate how doctors practice medicine but does oversee medical products. Growing the cells in culture and possibly mixing them with other substances may make these modified cells a product. The FDA got an injunction barring a Colorado company from growing marrow-derived stem cells in this way; lawsuits over that are pending.

FDA spokeswoman Shelly Burgess said that the agency could not comment on Perry's treatment and that each case must be evaluated individually.

Besides safety concerns, little is known about whether such cell therapies work.

Patients may believe cells helped them, but there's no way to know they did unless a study is done comparing those who did and did not receive such treatment, said Dr. Scott Rodeo, an orthopedic surgeon at the Hospital for Special Surgery in New York. He was a physician to the USA Olympics Teams in 2004 and 2008 and is associate team physician for the New York Giants football team.

Perry still wears a back brace sometimes now on the campaign trail, but he wasn't available for an interview Thursday. On July 12, less than two weeks after his surgery, he told an AP reporter: "Every day has been better. Not quite ready to go run a marathon in July but I feel great, wear a little brace and good to go. Everything is awesome."

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Associated Press writers April Castro in Austin, Texas, and Steve Peoples in Dover, N.H., contributed to this report.

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