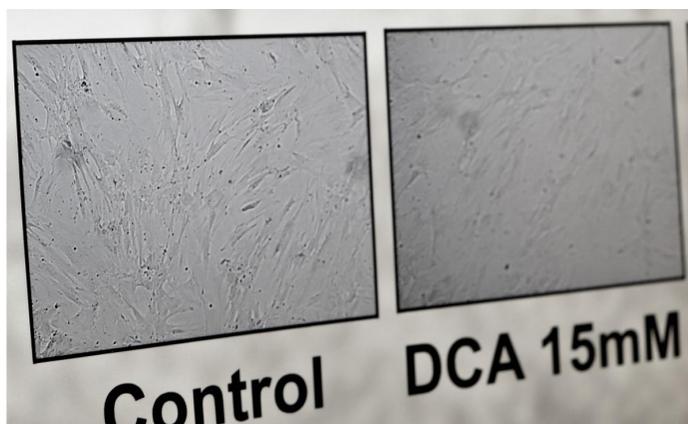


Stem Cell Clinics Could Face Crack Down

By [ROBBIE GAFFNEY](#) · Feb. 25, 2020



FSU's College of Medicine displays this poster of stem cells in one of its labs.

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Stem cell research has shown both promise and peril. The technology is advancing faster than the government's ability to regulate it. That's led to problems, such as a [2017 case](#) where three women went blind after receiving stem cell injections to cure a degenerative eye disease. Since then, the federal government has taken measures to regulate stem cell clinics. Florida has been trying to follow suit.

Stem Cell Basics

These cells can renew themselves for long periods and turn into other types of cells. That could be a fat cell, bone cell, and more. Researchers say that ability could help the body heal itself. However, there are two different types of stem cells: [embryonic and adult](#). Each has pros and cons, but adult stem cells are the most commonly used in clinical trials.

How Stem Cell Clinics and Therapies Are Regulated

The federal Food and Drug Administration (FDA) clarified some of its [regulations](#) on stem cell practices in 2017. It gave clinics a three-year grace period to comply with federal rules, which ends this November. Florida currently does not regulate stem cell clinics.

Proposed Changes

Sen. Travis Hutson (R-Palm Coast) wants to create state [rules](#) for clinics that offer stem-cell products and treatments. "There's kind of a black market going on out there because there's no real patient safety and protection," Hutson says.

His proposal would require such clinics to be licensed by the Florida Agency for Healthcare Administration (AHCA). This agency would be responsible for deciding how these clinics collect, manufacture, store, and use products containing stem cells.

Hutson's bill would also require stem cell clinics to appoint a medical director who can make sure the business complies with the rules. Any practitioner who works in a stem cell clinic without proper authorization can be penalized by regulatory boards. That could include fines and suspension of a medical license. The proposal would not apply to organizations like hospitals and ambulatory surgical centers - or to medical schools and pharmacies if they meet specific requirements.

Is More Regulation Needed?

"I think that regulation is very important here," says Cathy Levenson, a professor at Florida State University's College of Medicine who studies adult stem cells. "We do not want people that are underprepared for using this technology injecting these cells into people."

The type of stem cells commonly used in clinical trials usually want to turn into fat or bone cells.

"If we're going to use these clinically, we have to absolutely ensure that people are being treated with what we think they're supposed to be treated with, and not cells that have become something else in the process of growing them," Levenson says.

According to a 2017 report in the [New England Journal of Medicine](#), it's possible the three women who went blind earlier that year after being treated with stem cells from their own fat, did so because the stem cells reverted.