FDA Mounts Aggressive Push to Regulate Stem-Cell Clinics

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The Food and Drug Administration has launched a nationwide crackdown on stem-cell clinics, issuing letters of warning and threatening civil actions that could shut them down if they refuse to comply with FDA regulations.

On Wednesday, the FDA sent correspondence to 20 clinics around the country, putting them on notice that they must seek FDA review and approval for their procedures.

Over the past 12 months, the FDA has sent "regulatory correspondence" to 45 clinics, according to The New York Times, which refers to them as "rogue stem-cell clinics."

The regulatory crackdown is a paradigm change for more than 700 stem-cell clinics nationwide that have largely gone unregulated by federal authorities for over a decade.

The procedures being scrutinized include those that concentrate a patient's own stem cells and re-inject them into that patient to treat a wide range of painful, debilitating illnesses such as herniated disks, joint pain, reproductive issues, Parkinson's disease, multiple sclerosis, and several others.

The FDA has filed civil actions against two clinics, one in Florida and another in California, in a bid to force them to comply with FDA regulatory regimes applied to major drug manufacturers. That would likely be unsustainable for small practices.

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The clinics maintain that because many of the treatments involve harvesting a patient's own stem cells - known as autologous stem cells - and then re-injecting them into trouble spots in that patient's own body, they should not be subject to FDA regulation.

Stem cells are undifferentiated, meaning they have the potential to grow into multiple types of bodily tissues. The clinics that use them in treatments maintain they reduce inflammation and promote healing.

Stem cells, they say, have been successfully used to treat thousands of patients, while critics point to cases where patients had adverse reactions - including three Florida seniors with macular

generation who reportedly suffered "severe vision loss" after stem-cells were injected into their eyes in a clinical trial, as reported in a March 2017 article in the New England Journal of Medicine.

One factor in the growing controversy: The question of when a procedure involving one's own tissues comes under the purview of federal regulators. Libertarian-minded medical ethicists argue the government should not be empowered to regulate patients' decisions about their own medical treatment when it involves materials taken from, and reintroduced into, their own bodies.

Dr. Jeff Singer, a general surgeon in Phoenix who also serves as a senior fellow at the libertarian Cato Institute think tank, tells Newsmax that the FDA refrains from regulation in what's known as "same surgery," when a tissue is removed from one part of the body and introduced somewhere else in the same patient. A skin graft would be an example.

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But if the tissue is manipulated in some way, it begins to attract the FDA's attention, in part due to the concern the tissue could be somehow contaminated during the handling process.

"If it's what they call not the 'same surgery' - for example you take it and process it and then later on reinsert it into the patient - they consider that sort of a creation of a drug, and they claim to have regulatory authority over it," Singer says.

This demarcation is particularly relevant in the case of adipose stem-cell treatments -- that is, stem cells that are derived from fatty deposits in the human body.

The procedure can be performed in just two hours under local anesthesia. An amount of fat approximately equivalent to a stick of butter is removed from the body. Enzymes are added to help the stems cells detach from the fat cells. The fatty material is then spun in a centrifuge to separate out stem cells, which are then collected and re-injected into the treatment areas of the patient.

Singer comments: "The FDA considers that sort of like creating a medicine, and therefore it needs to come under their regulatory jurisdiction before it's approved - that's their position on it."

Singer would like the FDA to limit itself to certifying whether an autologous procedure has been proven to be safe and effective.

"For example," he says, "if the FDA wanted to say, 'We haven't certified that this process is safe, proceed at your own risk,' I'm ok with that. But I still want to be able to make my own decision."

Of course patient safety is very important to Singer, but he points out federal regulators are hardly beyond making errors of their own. And he says the principle that the patient, not the government, must ultimately decide his or her own care also must be protected.

As Singer tells Newsmax: "If I want to take my own tissue - my own, not someone else's - prepare it a certain way, and then put it back in my own body, that's as sacred as my right to free speech. From a medical ethics standpoint, it's a patient autonomy question."

That the FDA sees things differently has become increasingly evident in recent years. Last December, for example, it issued a news release that warned: "Time is running out for firms to come into compliance during our period of enforcement discretion. We'll be increasing our oversight related to cell-based regenerative medicine as part of our comprehensive plan to promote beneficial innovation while protecting patients."

Perhaps no one in the stem-cell regenerative medicine business has come under greater scrutiny than Dr. Kristin Comella, chief science officer of U.S. Stem Cell, a firm that operates three clinics in South Florida.

Comella has helped train over 700 practitioners in her company's adipose stem-cell methodology, and U.S. Stem Cell has been recognized as a leader in its industry. Comella says the FDA's bid to regulate what patients choose to do with their own tissues is a case of regulatory overreach.

She's currently fighting a federal lawsuit that accuses U.S. Stem Cell of "openly violating the law" by not submitting to the FDA's authority to regulate stem cells as if they were a drug. She maintains she fighting not only for her company's rights, but for the rights of the patients being treated.

"Unfortunately," she says, "many other countries have embraced regenerative medicine and stem-cell technology far above what the United States has done."

U.S. Stem Cell has performed thousands of procedures, and several of its patients report near-miracle cures. One of them is Luisa Rufin.

Her personal descent began in early 2017. Rufin started to notice a sharp leg pain when getting in and out of her car - something she does a lot in her career as a Florida realtor.

A daily gym-goer dedicated to good health, Rufin says she thought, "Oh, I must have pulled a muscle, pulled a ligament."

But the pain grew steadily worse. She saw several board-certified doctors, including a neurosurgeon, and was diagnosed with two herniated discs in her lower back.

Unwilling to submit to the usual course of treatment - therapy, painkillers, and spinal surgery - she instead embarked on alternative treatments.

Chiropractic adjustments, physical therapy, acupuncture, decompression, cryotherapy - she tried them all.

Nothing worked, and over the months that followed she says the pain on a scale of 1 to 10 become an 8.5 or a 9 - every single day.

"I seldom cry," she recalls. "I've been married for 24 years. There were a couple of nights that I cried myself to sleep, and my husband was alarmed, first of all, to hear me cry, and second to hear me cry because I was in such pain."

With the constant pain came a sense of hopelessness, she says. She fought hard to keep the darkness from closing in.

"I had to tell myself every day, 'You are going to get through this because you are a warrior, a fighter,'" she says.

Her chiropractor suggested she consider the emerging field of regenerative stem cell treatment. Injecting her body's own stem cells into the damaged area, she was told, could turbocharge the body's natural ability to heal itself.

Rufin met with a spine-pain physician certified in anesthesiology and pain medicine, associated with the Florida-based U.S. Stem Cell Clinic.

By then, Rufin was using a cane and her condition had deteriorated to the point that Dr. Daly doubted just two herniated disks could be the cause.

Daly ordered a complete MRI body scan and the results were shocking: Rufin's body was a war zone. A gymnast in her youth, she had a total of nine herniated disks up and down the length of her spine.

On Oct. 23, 2017, Rufin underwent a regenerative adipose stem cell treatment. "Adipose" is the medical term for fat, and fat is where a great number of the versatile, inflammation-reducing stem cells are found.

Could those special cells, when concentrated and injected back into her body, kick start her body's natural healing process?

Rufin recalls that just before the cells were injected back into her own body, she asked, "May I see my cells?"

A member of the medical staff held up a tube of fluid.

"These are your cells," they told her.

She knew whether she would ever be healthy again depended on those cells.

Within just a few days of the procedure, Rufin says she was was able to get rid of the cane and walk on her own. She also got rid of the back brace she'd used for a year.

Today, she says she feels like she has her old life back. She's even resumed going to the gym every day to work out -- although she's very careful to protect her body.

"I can't articulate," she says, "I can't tell you ... there aren't sufficient words to tell you that the stem cell procedure made such a difference in my life that if that right were taken away from me, I just can't put it into words."

Comella recognizes the need for regulations, as long as they don't go too far. "In many ways," she says, "regulations are good. Unfortunately, when we are crippled by regulations, and there's this over regulating, it sometimes prevents the forward movement of technology and new therapies and science. So it's no longer serving its purpose to protect, because we're missing out."

She warns that if the FDA succeeds in its regulatory push, it could put the procedures out of reach for the average patient. "What it does is it forces patients to leave the country to get these

therapies," she says. "It then becomes a therapy that is only available to those that are able to travel and that have the financial wherewithal to do so."

Now Comella, the FDA, and the entire stem-cell industry are waiting to see whether a federal judge in Fort Lauderdale will agree the FDA has the authority to regulate stem cells as a drug cells when they are injected back into a patient's own body. If the government loses, the FDA would be limited in its oversight unless Congress opted to pass additional legislation.

For Singer, the surgeon in Arizona, the case spotlights a fundamental principle.

"I own myself," he insists. "At the end of the day, it's my body, it's my decision."