

## POWER PLAY

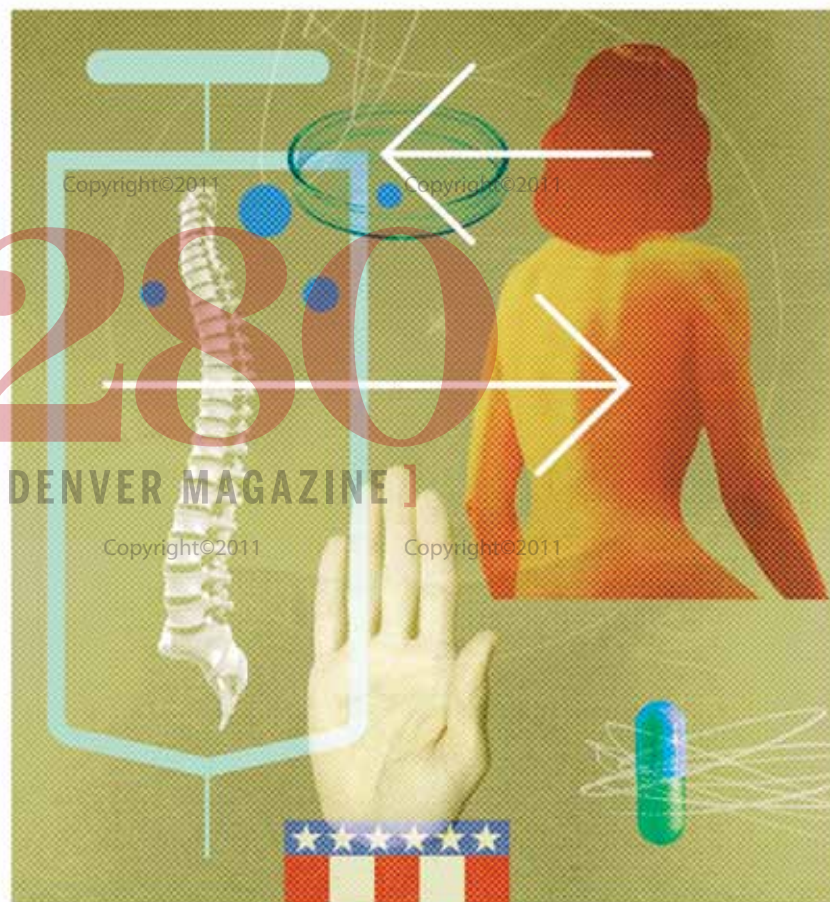
# A Front Range M.D. has developed a potentially revolutionary treatment for orthopedic injuries. So why is the FDA trying to stop him?

WHEN HE WAS 63 YEARS OLD, Joseph Maroon's doctors told him he needed an artificial knee. The diagnosis wasn't particularly remarkable for someone that age, but Maroon was a serious triathlete, and in the course of his post-diagnosis research, the University of Pittsburgh neurosurgeon read about a new orthopedic procedure. This potentially miraculous process, called Regenexx, relied on a patient's own stem cells instead of surgery and let orthopedic patients avoid the painful and possibly addictive minefield of steroid injections and prescription drugs. So in 2008, with the hope of saving his swim-bike-run lifestyle, Maroon traveled to Colorado to see the only physician in the United States capable of performing the procedure: Christopher Centeno of Regenerative Sciences and the Centeno-Schultz clinic in Broomfield.

Regenexx involves extracting stem cells from a patient's bone marrow, culturing them—growing the cells in a laboratory over a few weeks so they strengthen and multiply—and then injecting the super-charged regenerative agents into the damaged body part. The treatment helped Maroon's deteriorating knee cartilage repair itself, once again cushioning his bruised bones. With his pain significantly decreased, Maroon raced Ironman Hawaii six months later, at the age of 68. He's still racing today.

**SHARON MARTIN WASN'T SO LUCKY.** The 50-year-old Wyoming resident has hobbled around for 30 years thanks to a pair of degenerated discs in her lower back. Desperate for an alternative to surgery, she found the Centeno-Schultz clinic online. In 2009, she had the \$7,000 procedure done on one of her damaged discs; she says the procedure eradicated half her pain. However, when she tried to schedule an appointment to have the same procedure done on the other disc a year later, she learned that Centeno could no longer help her. By this time, the very formidable obstacle standing between Martin and relief from her back pain was the federal government.

Martin was denied because on August 6, 2010, the Center for Biologics Evaluation and Research, a division of the Food and Drug



Administration, had filed an injunction against Centeno, ordering his clinic to stop culturing his patients' stem cells. The FDA contends that extracting and culturing patients' tissue qualifies Regenexx as a "cultured drug product," like penicillin or the myriad other pharmaceuticals that must adhere to federal manufacturing, testing, and approval standards. Because it hasn't undergone the FDA's process, and the cells aren't properly labeled as a drug, the agency claims Regenexx could be unsafe. "FDA recognizes the importance of the development of novel and promising new therapies," Karen Midthun, M.D., acting director of the FDA's Center for Biologics Evaluation and Research, said in the agency's official statement. "However, when companies like

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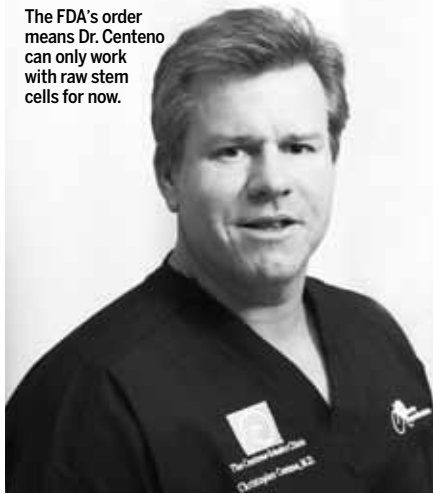
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Regenerative Sciences fail to comply with FDA laws and regulations, they put the public's health at risk."

Centeno rejects this claim and contends that adult stem cells are body parts, not cultured cell products. He says their use is medical, not pharmacological, and therefore his work lies outside the FDA's jurisdiction. (The culturing procedure is similar to the process of cultivating a woman's eggs during fertility treatments. The FDA doesn't regulate that, although it does regulate the drugs and devices used in the procedures.) Centeno understands how maddening it is to have a doctor prescribe an invasive surgery that won't necessarily work, or a pill or shot that will provide only temporary relief and may have unwelcome side effects. "You go to a doctor, you expect to get fixed," Centeno says. "And as a doctor, you want to provide a fix, not an experiment or a Band-Aid."

**OVER THE PAST DECADE**, the U.S. government's view of stem cell research has been contentious. Citing pro-life factors, President George W. Bush banned federal dollars from being used to create new embryonic stem cell lines, causing research to sharply decline after 2001. (The Obama administration has

The FDA's order means Dr. Centeno can only work with raw stem cells for now.



since lifted the ban.) Back then, Centeno's work was unaffected, because he operates exclusively with adult stem cells in a privately funded clinic.

This didn't stop the FDA from investigating. Although Centeno says he has "no idea" what first triggered the agency's interest, FDA officials visited the clinic so many times over the past several years—they were poking around his medical lab "as if it were a mass drug manufacturing factory," Centeno

says—that he eventually filed temporary restraining orders against the agency.

It was a strategic move by Centeno. Until the agency officially decided what it wanted to do about the clinic, Centeno had no legal grounds to question the visits. The multiple restraining orders, filed simultaneously in Denver and Washington, D.C., finally spurred the FDA to issue its injunction against the clinic, after which Centeno dropped the restraining orders and countersued the FDA for unduly interfering with his business.

Centeno has wondered if the government has bottom-line reasons for wanting to shut him down. Regenexx has the potential to eliminate the need for steroid injections and pain medication, and Centeno estimates that if people used their own stem cells to repair orthopedic ailments, it could reduce Americans' reliance on prescription pain medication by two-thirds—and jeopardize the FDA's control of a more than \$300 billion market. "With this type of medicine, we can move from managing pain to actually curing the injured tissue," Centeno says. "Imagine knees, hips, backs, all fixed. No more pain. No more surgery. No more meds. All you need are your own stem cells. Doctors would start actually curing disease

COURTESY OF CENTENO SCHULTZ CLINIC

# HAVE YOU BEEN INJURED BY A DEFECTIVE PAIN PUMP?

**Are you the victim of a pain pump misapplication?** A pain pump is a medical device that provides for the continuous infusion of an anesthetic medication into a shoulder or other joint space following surgery. The medication is infused from the pain pump into the joint via a catheter which is surgically implanted following an arthroscopic surgery. Research now indicates that pain pumps used in this manner can cause an agonizing condition called **Chondrolysis (PAGCL)** which results in the permanent degeneration of joint cartilage. Most affected patients ultimately must consider some type of glenohumeral arthroplasty (i.e. prosthesis).

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instead of prescribing drugs to manage disease, and that's a groundbreaking paradigm shift."

That may be hyperbolic, or it might actually be the case. Right now we can't know for certain because Centeno has stopped culturing stem cells in compliance with the FDA injunction. Although he can't help patients like Sharon Martin, Centeno still can treat injuries in areas—such as knees, shoulders, and ankles—that receive enough blood flow through normal movement to accept a raw stem cell reinjection. For those, stem cells get harvested from one part of the body and immediately injected into the damaged joint. But culturing is critical for body parts, particularly spinal discs, that receive less blood flow and thus lower amounts of oxygen. "Unfortunately, in many cases, it's the clients suffering the most that we can't treat now," says Centeno, who empathizes with their plight: As a post-M.D. resident in Texas in 1992, a car accident broke two bones in his back. The doctor has suffered chronic pain ever since.

The 46-year-old physician has built his practice around alleviating the frustrating agony patients like Martin experience every day. One of the few practitioners in the world with this expertise, Centeno has authored

*"All you need are your own stem cells. Doctors would start actually curing disease instead of prescribing drugs to manage disease, and that's a groundbreaking paradigm shift."*

most of this country's research on using stem cells in orthopedics on human patients (as opposed to lab animals). He's spent more than \$500,000 testing his procedure and performed it more than 1,000 times. He'll present his latest findings at a Vatican-sponsored stem cell conference in Rome this fall, and the International Cellular Medicine Society he founded now includes members from 35 countries and six continents. The physical therapists and doctors who attend his global lectures have

called him a genius. "This technology represents the wave of the future as another adjunct to repairing knees and other joints," says Maroon, the neurosurgeon from Pennsylvania. "It requires more research, more studies, and Dr. Centeno is leading that effort."

The FDA's Center for Biologics Evaluation and Research declined to comment for this story. Regardless of the agency's motives, the question of whether adult stem cells should be considered body parts or drugs could be a landmark trial if it reaches federal court in Washington, D.C., which may not be until 2013. But Centeno says the discovery period later this year will enable him to figure out why the FDA has targeted his work and could result in a pre-trial settlement. "That's when things will get interesting," Centeno says.

Meanwhile, Sharon Martin calls the clinic once a month to check on the progress of the case. "It's devastating to be so close to getting relief, to finally have hope, and then to have things come to a standstill," she says. "And to think of all the people they could have been helping." ▲

JAYME MOYE is the managing editor of *Elevation Outdoors* in Boulder. Email her at [letters@5280.com](mailto:letters@5280.com).

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