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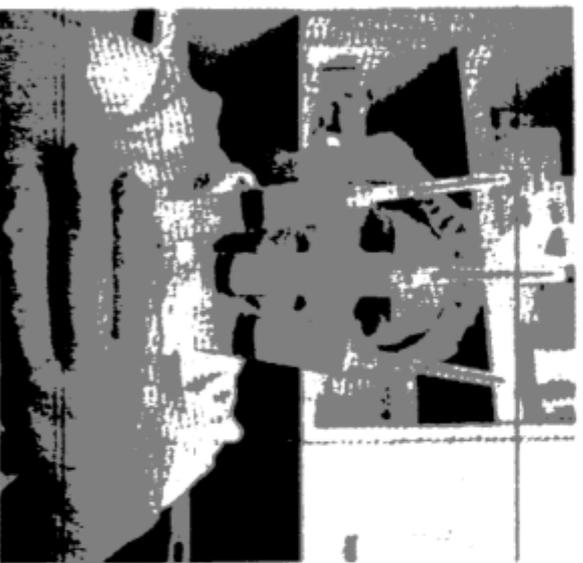


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'Soup' therapy promises healing

STEVE ANNOBILI, USA TODAY SPORTS
Clinical specialist Lisa Santia-go works in Florida for Joseph Purita, who has a history of helping athletes heal with stem cell treatments.



Treatment touted as surgery alternative amid effectiveness and legal concerns

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For a minimum price of \$15,000, several professional athletes recently received a curious new medical treatment in New York.

It's called "The Soup" — a mixture of human cells that includes stem cells derived from a patient's own fat. If it works the way they hope, "The Soup" can help repair injuries that otherwise might require surgery — damaged



STEM CELLS AND SPORTS

knees, elbows, hips, necks and more.
"Traditional medicine and traditional drugs do not work for a lot of patients," said

Steven Victor, founder and chairman of "The Soup's" manufacturer, IntelliCell Biosciences. "This kind of cellular therapy can really be a savior to them."

It's an exploding field. Just a

▶ **STORY CONTINUES ON 6C**

Combo of cells potential alternative to surgery

► CONTINUED FROM 1C

few years old, IntellCell's technology already has served various active and former pro athletes, including Merrill Hoge, a former NFL player who says he was blown away by how quickly his elbow injury healed after being treated last year. James Andrews, the most prominent sports doctor in America, even agreed to serve as a consultant to the company and was issued 18 million shares in company stock as compensation, according to recent government filings.

But here's the catch: Nobody knows if this type of treatment really works or if it's even legal under U.S. Food and Drug Administration (FDA) rules, according to experts consulted by USA TODAY Sports. The same can be said about a rapidly increasing number of American clinics that have been offering stem cell therapies to help a wide variety of health concerns, ranging from arthritis to Alzheimer's disease.

Stem cell clinics in the USA have quadrupled in the last five years to nearly 200, according to an estimate by Paul Knoepfer, a stem cell expert at the University of California-Davis.

"It really does feel like a big experiment, and people are paying a lot of money to be part of this," Knoepfer said.

The sports clientele is a driving factor, along with Baby Boomers looking for alternatives to surgery.



Steven Victor, founder of IntellCell BioSciences, harvests adipose tissue from a patient at Regen Medical in New York.

ANDY WARREN, USA TODAY/SPORTS ILLUSTRATION

"As the number of professional athletes getting stem cell treatments continues to climb ... I think the number of ordinary people is likely going to continue to climb, too," Knoepfler said.

Such growth is a concern, experts say, because the market for these clinics appears to have rocketed beyond the boundaries of government regulation and established science.

Take IntellCell, for example. The company's recent history shows the risks of operating in this vast new medical frontier, where the law has been vague and treatments haven't been scientifically proved.

In March 2012, the FDA issued a warning to Victor, saying IntellCell's product violated the law and should be considered a new drug — a designation that would require long and expensive clinical trials to determine whether it's safe and effective for public consumption.

Former IntellCell employees also recently filed two federal lawsuits against the company, accusing Victor of making false statements about his product and manipulating data to boost its prospects — accusations he says are bogus.

Meanwhile, financial problems have increased. Last year, IntellCell — which is publicly traded — reported an accumulated deficit of \$64 million.

Yet Victor isn't backing down. Unlike other cellular therapy clinics, Victor says his company is doing things the right way, according to the law, because his lab is registered with the FDA.

"If you look at other (stem cell clinics), they're kind of winging it," said Victor, a cosmetic dermatologist and self-described mad scientist. "They don't really follow the FDA rules."

But because it's such a new and rapidly evolving field, it's hard to tell who's right, what works and what doesn't.

to prolong their careers.

Purita declined to name the NFL player who received treatment in July. Many of them have wanted to keep such treatments secret, largely because team management might disapprove of such alternative medicine.

"This can affect their contract negotiations and all kinds of things, and so some guys come without the team even knowing," Purita said. "They don't want the team to know, so we just kind of keep it quiet."

Victor says his sports clients also didn't want to be named but adds that teams have become more accepting of this treatment in recent years. IntellCell's list of medical advisers includes doctors for the Oakland Raiders, New York Rangers and Andrews, who had planned to use the IntellCell product at a lab in Florida. Andrews didn't return several messages seeking a comment.

He and others have said they think cellular therapy is the cutting edge of sports medicine, a way to avoid surgery and heal faster more naturally. Hoge, the former running back, says a ligament in his right elbow was 50% torn but healed in six weeks after receiving IntellCell's stromal vascular fraction cells, the scientific name of "The Soup."

After fat tissue was extracted from his side in New York, sound waves were used to separate the cells from the fat. The cells were injected into his elbow in a bid to help it regenerate and heal.

"Stem cell therapy is your body healing yourself," Hoge said. "For me, it worked out beautifully, and I avoided a surgery. I avoided a six-month rehab process. I was completely better in six weeks versus six months."

FDA SHUTDOWN

Yet questions persist about this and similar treatments because they have not undergone enough rigorous testing to determine their safety and effectiveness.

MORE ON

At sports.usatoday.com: Stem cell injections treat skin rejuvenation, but are the claims pure hype?

outside the country — in Bogota, Colombia.

"The FDA made me sign an agreement that I wouldn't do that anymore in the United States," Williams said.

He says the FDA had an issue with him using fat-derived cells for these purposes.

"We were doing the same thing everybody else was doing. I think," Williams said, referring to similar clinics using fat-derived stem cells. "It's just that we became kind of known a little more quickly than some of these other clinics."

The FDA declined to comment on the case, leaving questions unanswered about how this clinic was manipulating stem cells differently than other U.S. clinics that offer similar fat-derived stem cell treatments.

'I CAN'T DEFINITELY SAY'

McClain isn't the only athlete who can't say for certain if the stem cells worked or if other factors helped instead.

Former pitcher C.J. Nitkowski says he paid about \$2,200 to get an injection of his own fat- and bone marrow-derived stem cells at Purita's clinic in 2011. In an effort to revive his career, he also used other treatments involving platelet-rich plasma from the blood, along with aggressive shoulder rehabilitation.

"I tell people that the combination of those things led to me having the ability to pitch again," Nitkowski said. "I can't definitely say that stem cells helped heal

the tear in my rotator cuff and allowed me to pitch again. The science behind it makes sense to me, but you'll find no shortage of people that debate it."

complicated ... "There's a lot that we don't know about this area of biology. It's why it's a hot research area. It's a new frontier. We know that there's a lot of interesting, potentially beneficial work to be done, but we haven't done it yet. We don't know enough."

MANIPULATING GAME

The kinds of stem cells being offered in U.S. clinics these days are different from other, more controversial types of stem cell treatments that have been in the news in recent years. These aren't stem cells that come from embryos or the kind that hockey great Gordie Howe received in Mexico after suffering a stroke: stem cells that were derived from a fetus and another person's bone marrow.

Instead, these U.S. clinics are offering autologous stem cells — stem cells that come from an adult patient's own body, usually bone marrow or fat, and are reinserted into the same patient to help regenerate and heal the body. Such autologous cells aren't OK for clinics to use in the USA if they've been more than "minimally manipulated."

This term is critical. After being taken out of the body, U.S. clinics typically use a centrifuge or other methods to purify and concentrate the cells.

"That's the whole crux of the matter," Purita said. "What is minimal manipulation?"

If the cells are more than minimally manipulated, the treatment is going beyond FDA regulations and should be regulated as a new drug candidate.

Some clinics that clearly exceed the manipulation threshold operate in other countries instead.

In 2011, NFL quarterback Peyton Manning went to Europe to receive adult stem cell treatment for his ailing neck, according to media reports. Manning hasn't publicly commented on this treatment, and it's not clear how well it worked because he later

concerns. They also say processing that isolates cells from fat tissue is "generally considered more than minimal manipulation."

The guidelines even say stromal vascular fraction cells — like those used by IntellCell — involve processing that generally exceeds minimal manipulation.

"It seemed like a warning shot to the clinics," Knoepfler said. Yet there's time and room for debate. Victor says his company doesn't "use anything but sound waves and water" and thinks his process does not violate regulations.

"Whether it's a drug or a cell from your own body under minimal manipulation, that's a long debate we're going to have," he said. "It's a scientific debate and a regulatory debate that's going to go on for who knows."

Purita says fat-derived stem cells are "old technology" and he "doesn't have any fights with the FDA." He's instead using other cells, including those derived from bone marrow.

The FDA says there was no time frame to finalize these guidelines.

"This is a complex issue, and the agency needs to carefully consider all comments and the developing science prior to finalizing this guidance," the FDA said in a written statement.

WHAT'S LEGIT AND NOT?

In the meantime, the industry might continue to grow as the debate rages about whether it really works and whether it should be subject to more oversight.

IntellCell's Victor thinks his Soup will be allowed but predicts other clinics will be banished because they are not registered with the FDA to manufacture cellular products.

The purpose of this law is to help ensure that these establishments are safe, sterile and subject to inspection.

Victor says IntellCell registered its lab with the FDA, part of

SURGING POPULARITY

An NFL defensive back recently needed medical help with a tendon tear above his kneecap. Training camp was starting in a few weeks, and he wanted the injury to heal faster.

So in early July, he visited the clinic of Joseph Purita, a doctor in Florida with a history of helping athletes heal with stem cell treatments derived from bone marrow. In 2010, baseball pitcher Bartolo Colon received his treatment and credited it with helping revive his arm from the brink of collapse.

"A good bellwether of whether these really work or not are your pro athletes," Purita said. "You have people who are making millions of dollars a year. They're going to do their research — them and their agents. They're not going to do something that's bogus and doesn't work. Why do you think athletes have embraced this? Because they know it works. It's as simple as that."

Purita says the cost of his treatments ranges from \$4,000 to \$7,000 — a small price to pay for athletes who might be desperate

One expert questioned whether many clinics are even using effective stem cell populations. Adding to the confusion are unclear regulations from the FDA, which is tasked with helping ensure the safety and effectiveness of new drugs in the USA.

Consider the case of Precision Stem Cell, a clinic in Alabama that treated current and former NFL players with their own fat-derived stem cells, including linebacker Rolando McClain. Now with the Dallas Cowboys, McClain used it to treat a high ankle sprain after the 2011 season.

"I don't know if it was the actual stem cells or just mentally, but overall I felt better from it," McClain told USA TODAY Sports recently. "The best thing about it was that I healed up faster than what was expected."

The clinic's doctor, Jason Williams, says positive reviews about this treatment had spread after he treated other patients connected to the University of Alabama. But the FDA later took a more negative view of these treatments. It barred them from competing Williams to offer them

He says he tried it because he wasn't ready to retire and "the mentality of the athlete is generally that we'll try almost anything to stay on the field."

There's no proof it didn't work. There's no proof it did work, either. To really know if such treatments work by U.S. standards, it would need to be treated like a new drug candidate. In the USA, a new drug doesn't receive approval from the FDA for widespread use until after long and expensive clinical trials to determine its safety and efficacy.

The reason these clinics aren't required to go this route is because they say these cells aren't drugs but rather cells that come from a patient's body. They say such treatments are essentially surgeries performed in a medical office, which isn't subject to FDA regulations.

"People would require more evidence from their auto mechanics than they do from these clinics," said Larry Goldstein, professor and director of the Sanford Stem Cell Clinical Center at the University of California-San Diego. "Human biology is really

had neck surgery.

Goldstein adds another note of skepticism about U.S. clinics. If these stem cells are more than minimally manipulated, they're not legal in these U.S. clinics. But if they're not more than minimally manipulated, he questions whether they're producing pure, effective stem cell populations.

"There could be some exception out there, but, realistically, it's unlikely," he said. "It's unlikely in the extreme that these minimally manipulated methods are producing a stem cell population that is therapeutically beneficial. There's just no evidence for it."

WARNING SHOT

The FDA recently issued draft guidelines to help bring some clarity to the field — recommendations that didn't seem to bode well for the many U.S. clinics that harvest their cells from adipose or fat.

The proposed guidelines say that using cells from fat tissue to treat bone and joint disease appears to go beyond what nature intended for those cells, exceeding regulations and raising safety

a complicated and expensive compliance process. "That's what makes our stuff so expensive," he said.

By contrast, Victor says almost all stem cell clinics are not regulated because they say it's not necessary. Such clinics argue they are not "manufacturing" and instead are performing a surgical procedure not subject to FDA rules.

A big question is how the FDA can keep up with the labs and technology, helping patients know what works and what doesn't, what's safe and what might not be. It won't be easy.

"It's hard to write good law and regulation that allows legitimate work to proceed as rapidly as possible while prohibiting illegitimate work," said Goldstein of UCSD. "Part of the problem is it is a new area of medicine where the regulations didn't anticipate this sort of thing. The regulators on the ground in the field, they themselves don't have adequate background to tell what's legit and what's not. It's hard."

Contributing: Jarrett Bell