

Athletes' stem cell use gaining wider appeal

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When ailing hockey legend Gordie Howe received stem cells grown by the San Diego company Stemedica, the story attracted international attention. But while Howe's status made his case seem exceptional, this once-exotic therapy is increasingly being adopted not only by athletes, but also the American public.

Athletes, whether playing or retired, have a special need for the regenerative abilities that stem cells might provide. They break bones, strain ligaments, bang knees and wear out cartilage. If their restorative capability is proven, stem cells could be considered the latest form of sports medicine.

Since Howe's treatment in late 2014, two other athletic legends have received Stemedica's cells - former quarterbacks Bart Starr and John Brodie.

And the rest of the population, especially aging baby boomers, isn't far behind.

But while acceptance of stem cell therapy has grown, so have controversies surrounding its use. While clinical trials authorized by the U.S. Food and Drug Administration are proliferating in this country, so have treatments outside the regulated system. Patients are going to unauthorized stem cell clinics or seeking treatment in other countries where the rules are less restrictive.

It's not cheap: The expense can run into the thousands or even tens of

thousands of dollars. Stemedica said Howe's treatment, provided for free, would have cost about \$30,000.

For its part, the FDA is stepping up oversight.

Last year, it issued draft guidelines to clarify what types of human cell therapy it regulates. The short answer: Most of them, with "limited exceptions," according to an FDA email sent in response to questions from The San Diego Union-Tribune. These exceptions include cells or tissues that are "minimally manipulated," not given with any other product and perform the same function in the donor as in the recipient.

All other stem cell therapies are seen as involving human cells, tissues and cellular and tissue-based products - also known as HCT/Ps - regulated by the FDA's Center for Biologics Evaluation and Research.

"We understand that determining the appropriate regulatory path for HCT/Ps can be challenging, and the FDA is working diligently to develop guidance to help sponsors and physicians understand how to apply federal regulations to this complex and emerging field," the agency said.

The FDA will have its hands full.

In January 2015, University of California, Davis stem cell researcher and blogger Paul Knoepfler estimated that more than 100 unauthorized stem cell clinics were operating in the United States. Later that year, he increased that estimate to up to 200.

Then on May 6, he wrote on his blog: "We are seeing a flood of professional athletes getting stem cell treatments in the past few years. Just recently, it was (Cristiano) Ronaldo and now Boris Becker, too. Before that, (Rafael) Nadal had one. Gordie Howe. Bart Starr."

Athletes and others who want these treatments chafe at what they call cumbersome, time-consuming regulations in the U.S. The situation can be urgent for seriously ill patients, as Howe's case demonstrates.

Howe, then 86, was apparently close to death after suffering a stroke. After undergoing stem cell therapy in December 2014, he recovered enough to attend a tribute dinner in Saskatoon, Canada, in February 2015. This March, he attended a Red Wings game in Detroit.

While it hasn't been proven that the stem cells enabled his recovery, by all indications his health has improved significantly.

Howe was given two types of stem cells - [neural stem cells](#) and mesenchymal stem cells. The second type, derived from bone marrow, has anti-inflammatory properties and secretes chemicals that promote healing.

Some researchers such as Knoepfler criticized the manner in which Howe received his treatment. Howe was treated in Tijuana at a clinic operated by Novastem, a Mexican company that buys Stemedica's cells and then administers them under Mexico's clinical-trial guidelines. This arrangement avoids the FDA's stricter oversight, the critics said.

Howe's family said given his precarious post-stroke condition, it would have taken too long to obtain authorized treatment in America.

And Stemedica said it obeys all laws in the countries where it has business dealings. (Besides Mexico, the company provides its cells for use in Kazakhstan.)

Stemedica also conducts several clinical trials with its cells in the United States, and all of these tests are authorized by the FDA.

Howe's free treatment was a special case, said Stemedica spokesman Dave McGuigan, who previously worked for the Red Wings and received career help from Howe. The therapy was provided out of gratitude, he said.

While Howe's condition has improved by all accounts, he may have benefited from a change of care apart from the stem cells, said Jeanne Loring, a stem cell scientist at The Scripps Research Institute in La Jolla. She was referring to media reports that Howe was dehydrated shortly before his stem cell treatment and began improving after he was given more fluids.

Stemedica agrees that one case doesn't prove effectiveness, McGuigan said, and that's why it's conducting clinical trials in the United States. Besides stroke, the company is testing its cells for treatment of heart disease and sun-damaged skin.

Demonstrating its confidence in Stemedica's work, Howe's family recently partnered with the company and the Ohio-based health care system ProMedica to launch clinical trials of Stemedica's cells to counter traumatic brain injuries. The deal was spearheaded by Dr. Murray Howe, a ProMedica radiologist and a son of Gordie Howe.

While some [stem cell therapies](#) are progressing through the American clinical trial system, very few have been approved.

Bone marrow transplantation was the inaugural one, but that procedure was performed long before scientists managed to isolate stem cells.

The first therapy to be explicitly approved by the FDA as a stem cell treatment was Hemacord, which contains [blood-forming stem cells](#) taken from umbilical-cord blood. Hemacord was cleared for use in 2011.

With some new classes of therapies, such as monoclonal antibodies, initial FDA approvals pave the way for streamlined regulations as the agency gains familiarity with each technology. But that hasn't happened with stem cells, Loring said.

For example: Mesenchymal stem cells differ in their powers from individual to individual, and researchers generally don't check for those properties.

In addition, companies frequently make their stem cells with proprietary methods, and that means other companies can't benefit from the discovery process.

"Each trial is an entity in itself, with those particular cells," Loring said. "You can't generalize that to other cells."

Given the overall uncertainty, the FDA said its draft guidelines are intended to bring some clarity. Comments from the public on these guidelines are welcomed, the agency said.

"The comment period for all four draft guidances is open until September 27, 2016, to allow interested stakeholders to provide critical input across the full scope of the FDA's thinking in these areas," the agency said in its emailed response.

The agency plans to hold a public meeting to discuss the guidelines on Sept. 12-13 in Bethesda, Md. More information can be found at j.mp/fdastemcomments.

Also, the agency has scheduled a public meeting for Sept. 8 on how to evaluate scientific evidence for human cell and tissue products. More details regarding that meeting, to be held in Silver Spring, Md., are available at j.mp/fdacells.

Stemedica entered the field of stem cell therapy after its co-founders, Roger and Maynard Howe (no relation to Gordie Howe), encountered Russian stem cell science, McGuigan said.

A close relative, Arlene Howe, had been taken to Moscow about a decade ago for treatment after a vehicle accident. She was nearly paralyzed but was able to walk again after her therapy.

"She had what the family regards as a miraculous response," McGuigan said. "Our founders started taking two or three patients once a quarter to Moscow to find out if Arlene's response was an anomaly or a pattern."

They determined the latter, and that a business could be formed around the pursuit of stem cell treatments. So they established Stemedica in 2005.

While this was going on, the nascent company took a patient to Moscow who happened to be a friend of John Brodie, the former quarterback who recently received Stemedica's cells. Brodie was severely debilitated from a stroke, and his friend told him of the therapy.

Brodie, now 80, got his first stem cell therapy in Moscow in 2006.

The other athletes likewise came to Stemedica after hearing of the company through word-of-mouth. McGuigan said.

"We have not by strategy or design ever tried to develop a marketing outreach program at all, especially using celebrities," he said.

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