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HEALTH

Stem Cell Treatments Overtake Science

By LAURA BEIL SEPT. 9, 2013

TIJUANA, Mexico — Maggie Alejos arrived here in June from St. Anne, Ill., with her husband, her daughter and a cashier's check for $13,500, payable to the Regenerative Medicine Institute.

Rail-thin, with an oxygen tube anchored above her upper lip, Ms. Alejos, a retired Army nurse, has coped with emphysema for a dozen of her 65 years. Once she came close enough to a lung transplant that doctors prepared her for surgery, only to discover that the donor lung was unfit.

At a hospital here, doctors affiliated with the institute extracted about seven ounces of fat from her thighs, hoping to harvest about 130 million stem cells and implant them in her failing lungs.

Across the Internet — where Ms. Alejos learned about the Tijuana institute — adult stem cells are promoted as a cure for everything from sagging skin to severed spinal cords.

On the surface, the claim is plausible. Scientists have discovered that fat, bone marrow and other parts of the body contain stem cells, immature cells that can rejuvenate themselves, at least in the tissue they are naturally found.

But it has yet to be proved that these cells can regenerate no matter where they are placed, or under what conditions this might occur. Moreover,

questions about safety remain unanswered.

These sober realities do not appear to have slowed the rise of an international industry catering to customers who may pay tens of thousands of dollars in cash for their shot at a personal miracle. (Some foreign operators offer creative variations on the theme, like cells from sharks and sheep.)

Domestic providers, too, can push the limits. In July, for example, a former pathologist at the Medical University of South Carolina pleaded guilty to illegally processing and shipping stem cells for treatment without approval from the university or the Food and Drug Administration.

The number of clinics and products has reached the point that scientists fear repercussions for their own work. Dr. Hesham Sadek of the University of Texas Southwestern Medical Center in Dallas, who is studying heart muscle regeneration, worries that the marketing deluge now makes it hard for patients to tell science from swindle, and all that lies on the spectrum in between.

"It really has the potential to undermine the legitimacy of the whole field," he said.

Trial or Treatment?

Even though Tijuana has perhaps 20 clinics offering adult stem cell therapy, Dr. Javier Lopez, founder of the Regenerative Medicine Institute, says it is his that has become "the poster company to knock down."

Born and educated in Tijuana, he has lived and worked across the border, in San Diego, for more than 30 years, mainly as a health care administrator. He became inspired by stem cells after accompanying a physician friend to a conference in Palm Springs, Calif., in 2008.

"It was eye-opening," he said. "I immediately thought, 'This is the future of medicine, and I want to be a part of it.' "

He says he runs the institute within the accepted framework of clinical trials: Patients sign consent forms acknowledging that the treatment is experimental. Studies are registered with the National Library of Medicine in the United States.

Being accepted for treatment requires more than cash. Protocols and procedures are approved by the institutional review board, or I.R.B., at Hospital Angeles Tijuana, and are administered by physicians at the hospital. “The focus of our trial, from Day 1, has been safety,” Dr. Lopez said.

Still, skeptics in the United States are not convinced. Leigh Turner, a bioethicist at the University of Minnesota, says the Regenerative Medicine Institute blurs the boundary between trial and treatment.

The institute’s patient consent form “would not pass muster with a competent American I.R.B.,” Dr. Turner said, and the testimonials on its Web site place the emphasis squarely on results.

Moreover, studying patients who pay undermines the trials’ scientific validity, Dr. Turner said. The patient sample is skewed toward those with the means to travel, and their financial investment may amplify an already strong placebo effect.

Dr. Lopez says that scientists in Mexico lack the government research support available in the United States, leaving establishments like his no choice but to charge patients.

He agrees that many stem cell providers are dubious, and says he works with the Mexican authorities to try to establish uniform standards. As for his own institute, he said, “I’m very proud of what we are doing,” and added, “I get upset when people start talking trash about what is done south of the border.”

A Gray Area

In the United States, too, it is easy to conduct business outside

government oversight, said Dr. George Q. Daley, who studies stem cells for blood diseases at Harvard Medical School. Close down one shady operation, he went on, and more seem to randomly pop up.

Even questionable publicity does not necessarily hurt business. Regnocyte, a company in Florida, posted an unflattering CNN report about it on its Web site under the heading "special coverage."

If the stem cell business continues to flourish without proper scrutiny, Dr. Daley and others fear research progress will suffer. Clinical trials depend on patients who are willing to sign on even though they know they might be given a placebo, while competing clinics are offering what seems to be a sure thing. In addition, patients who have already had stem cell therapy could be ineligible for trials.

And if too many patients try stem cells unsuccessfully, the public may come to see the entire field as a failure, said Dr. Sadek, the heart cell scientist in Dallas. Many comments on articles about his last paper, published in the journal Nature, "were skeptical and jaded," he continued. "One said, 'I've gotten stem cell therapy and nothing happened.' If the public loses faith in regenerative medicine in general, funding can be affected."

A Lack of Data

Beyond the online testimonials, there is little evidence to indicate whether adult stem cell treatments on offer are working. Paul Knoepfler, a stem cell researcher at the University of California, Davis, says the lack of data is vexing.

"There is absolutely no legitimate reason for such clinics to be not publishing their data," he wrote on his stem cell blog this year. "Yet they almost never do it."Stem cell businesses say they have other priorities. "I'm not that interested in doing a lot of research for publication purposes only," said Maynard A. Howe, the chief executive of Stemedica Cell Technologies in San Diego, which is developing a drug made from donated stem cells. Dr. Howe

and his brother Roger started the company in 2005 after a sister-in-law received stem cells in Russia for a spinal cord injury.

Dr. Howe says that his company publishes just enough data to meet F.D.A. requirements, but that he would rather his scientists spend their time getting a product to market.

He also defends the practice of foreign trials largely on economic grounds. Outside the United States, he said, "I can do a PET scan for $500," a fraction of the typical American rate. "Why wouldn't I do my clinical trial overseas?"

For his part, Dr. Lopez says he is trying to publish data from the 125 patients he has treated so far, but he faces a struggle. "Nobody wants to talk to us because we are from Tijuana," he said of medical journals. He has managed to get just a case description accepted for publication.

So for now, he does not have much to show in the way of science. He believes in stem cells — and in that, he and his critics share common ground. The challenge for scientists is to promote the promise of stem cells with both excitement and restraint. It can be a hard line to walk.

"I understand how difficult it is — how many years and sometimes decades it takes before you discover a new therapy," said Dr. Daley, of Harvard. "We have a tremendous enthusiasm about the potential of stem cell therapy.

"That said, these aren't magical agents that run around your body and fix things. It's frustrating to watch other people who, even well intentioned, aren't acting in their patients' best interest."

This week, the International Society for Stem Cell Research is to release a statement declaring the use of stem cells outside scientific settings to be "a threat to patient welfare, patient autonomy and to the scientific process," according to its public policy chairman, Jonathan Kimmelman, a bioethicist at

McGill.

This is the same group that once tried to offer an online guide to stem cell clinics, but the journal Nature reported that the effort was abruptly abandoned under threat of lawsuits.

Ms. Alejos says she accepts the uncertainty of her choice. She came to Tijuana because nothing else had worked. After her anticipated lung transplant fell through, she turned to Google and found stem cell doctors throughout Asia and Latin America who were willing to treat her. Close to home, Mexico felt comfortable.

She was well aware of the controversy over stem cell tourism. Even most of her family did not know where she was headed.

Back home in St. Anne a few days after the procedure, she had a brief bout of pneumonia over the summer, but generally feels no better or worse than she did before her treatment. She knows she will not be cured. Her dreams are modest, like being untethered from oxygen long enough to go out to a movie.

"I was an Army nurse for 30 years," Ms. Alejos said. "I know there is no such thing as a miracle in the world of medicine."

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