

Stem cell treatments are dominating science

TIJUANA, MEXICO

Clinics are popping up offering unproven regimens for a price

BY LAURA BEIL

Maggie Alejos arrived here in June from St. Anne, Illinois, 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.

Doctors from 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 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 operators offer creative variations on the theme, like cells from sharks and sheep.) In July, for example, a former pathologist at the University of South Carolina pleaded guilty to illegally processing and shipping stem cells for treatment without approval from the university or the U.S. Food and Drug Administration.

The number of clinics and products has reached the point that scientists fear repercussions for their own work. Hesham Sadek of the University of Texas Southwestern Medical Center in Dallas, who is studying heart muscle regenera-

tion, 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.

Even though Tijuana has perhaps 20 clinics offering adult stem cell therapy, Javier Lopez, the founder of the Regenerative Medicine Institute, said it was 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 said 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 are not convinced. Leigh Turner, a bioethicist at the University of Minnesota, said 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 money to travel and their financial investment may amplify an already strong placebo effect.

Dr. Lopez said that scientists in Mexico lack the government research support available in the United States, leaving institutes like his no choice but to charge patients. He agreed that many stem cell clinics are dubious, and said he works with the Mexican authorities to try to establish uniform standards.

Even in the United States, it is easy to conduct business outside government oversight, said 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.

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 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, and financing could be affected, said Dr. Sadek, the heart cell scientist in Dallas.

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 in Davis, said the lack of data was 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 said 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?"

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," said its public policy chairman, Jonathan Kimmelman, a bioethicist at McGill.

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 in Asia and Latin America who were willing to treat her. Close to home, Mexico felt comfortable.

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. "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."

ONLINE: HEALTH, SCIENCE AND MORE

For a collection of blogs and podcasts, visit: global.nytimes.com/science

