

# Lured by promise of stem cells, Americans head abroad for medical treatment

February 9 2009, By Maria M. Perotin

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A quadriplegic since she was 14, Jessica Grimm learned long ago how to work around her body's limitations. She lives alone, uses a computer, has a job, even drives a car. But the Arlington, Texas, student must rely on a coterie of assistants to help her dress, cook and get through each day.

Now 27, Grimm is eager for more independence. So much so that she traveled to Costa Rica last month for a controversial stem cell treatment that's unavailable in this country.

Grimm and her family raised about \$20,000 to cover her trip to the Institute for Cellular Medicine, where doctors injected her with adult stem cells.

"I was actually able to take a few steps on my own before I left, which I've never done," she said. "My mom was crying. Then my physical therapist started crying."

The feat thrilled Grimm, who previously had some mobility in her legs and hand. But she still has no idea whether the treatment actually succeeded.

Doctors told her it could take months to see results. And it's possible that the real credit for her footsteps should go not to the cell injections, but to the strenuous physical therapy she did in Costa Rica.

"I don't know if it was the physical therapy or the stem cells. But it

definitely showed me I need to get back into physical therapy," Grimm said. "If I can build more muscle, there's no telling."

That kind of ambiguity troubles some U.S. researchers, who worry about a rise in "stem cell tourism" as foreign clinics promote treatments for multiple sclerosis, Alzheimer's disease and a host of other illnesses. They contend that doctors from Ukraine to Mexico are pitching risky procedures on the Internet to vulnerable patients, with no science to back up their claims.

It's unclear how many people are traveling abroad for stem cell therapy or even how many clinics offer the treatments. But one biotech company, which boasts 24 hospitals in China, claims to have treated more than 3,000 patients at its facilities alone.

The promise of stem cells, which are found in embryos and in various body tissues, comes from their ability to develop into many different types of cells in the body.

Proven stem cell treatments exist for only a handful of conditions, mainly affecting the blood and immune system. But advocates believe that the cells can be used to repair damaged or diseased tissue in many parts of the body.

Laurie Zoloth, who directs the Center for Bioethics, Science and Society at Northwestern University, said legitimate researchers worldwide are experimenting with stem cells, using a methodical approach to scrutinize the safety and effectiveness of their treatments.

Without such controlled trials, stem cell clinics have no evidence that their treatments work, she said.

"They're not doing science. They're selling a product and making claims.

But they have no way to test it, no way to make it safe," Zoloth said. "It's just on the basis of pure trust."

A study published recently in the journal *Cell Stem Cell* raised similar concerns.

Researchers from the University of Alberta who reviewed 19 Web sites found that stem cell clinics portray their treatments online as "safe, effective, and ready for routine use in a wide variety of conditions."

Yet they found little clinical evidence - and sometimes none at all - that stem cell therapies can treat Alzheimer's disease, multiple sclerosis, Parkinson's disease, spinal cord injuries or strokes.

In December, the nonprofit International Society for Stem Cell Research released guidelines for developing stem cell treatments aimed largely at addressing "rogue clinics" that market treatments directly to patients.

In its accompanying patient handbook, the organization - of which Zoloth is a member - urged patients to ignore claims based solely on patient testimonials.

Dr. Fabio Solano, who is medical director of the stem cell institute in Costa Rica, dismissed the criticism and said opponents "are generally speaking out of ignorance."

Solano said he warns patients of potential risks and accepts only those who stand to benefit from his treatments.

"I do not make any promises of results to patients," he said in an e-mailed statement.

Solano treats patients with stem cells derived from umbilical cords or

with cells harvested from their own bone marrow or fat, he said.

He cited several examples of successful cases and insisted that his treatments are similar to natural processes in the body.

"Your dog and your horse can get treated with fat stem cells in the U.S., but not your brother," Solano wrote. "If a critic asks me 'How can I do this?' my answer is, 'How can I not?' "

One believer is Fort Worth police Sgt. Preston Walker.

Walker, who was diagnosed with multiple sclerosis in 2001, underwent stem cell therapy last May at Solano's clinic in San Jose, Costa Rica.

Before the treatment, he grappled with memory loss, depression and fatigue so severe that he was exhausted by 8 every night. Now, Walker said he's virtually free of symptoms.

He has lots more energy. And he has given up three prescription drugs that he used to take routinely.

"I really believe I'm a walking testament to what they're offering," Walker said. "It was a big, big leap in faith."

Zoloth acknowledged that some patients, like Walker, do show improvement after treatment.

But unless stem cell clinics conduct meticulous studies that experts can review, she said, there's no way to explain those results or to tally how often therapy succeeds.

"That sort of trial is the only way to know if something works," Zoloth said. "I know the desperation of patients. I know the desperation of

people who look at their child and just wish it could be fixed. ... But we really can't know the answer until we take it through the course that, since the Enlightenment, science has used to try to find truth. And that's the experimental method."

Of course, that approach can take many years.

Walker said he wasn't interested in waiting while his symptoms worsened.

He never hung his hopes on the Food and Drug Administration approving stem cell therapy. And he wondered what the price would be if American physicians offered stem cell therapy someday.

"So many people have expressed some concern about going to a Third World country," Walker said. "Just looking around, and seeing just what's happening in the United States and people dragging their feet, I knew I was going to have to go. So I prepared myself for an overseas visit."

Walker spent upward of \$20,000 on his visit to Costa Rica, where he got a combination of physical therapy, spinal injections and IV treatments.

He began to sense improvement after the second injection and felt significantly better by the time he flew home, Walker said.

The changes have endured so far, although Walker said he experienced one particularly miserable day after the treatment and still has trouble with short-term memory.

Walker, who now knows about 30 people who have had treatment at the Costa Rica clinic, concedes that some of them haven't seen much relief.

"I wish I could say this is going to be the same for everybody, but it's apparently not," he said. "I definitely took a gamble."

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## WHAT TO CONSIDER

Considering stem cell therapy? Here are some questions to ask before getting treated:

- Have preclinical studies been published and reviewed by other experts?
- Is the provider approved by the appropriate regulatory agency?
- What's the scientific evidence that this treatment works for my condition?
- What are the possible benefits I can expect?
- How will this be measured and how long will it take?
- How is the procedure done?
- What's the source of the stem cells?
- How are they delivered to the right part of the body?
- What are the risks and side effects?
- Whom do I contact for emergency care?
- Who's the doctor in charge? What training does the physician have?

- What are my rights if I'm injured?
- What are the costs of treatment?
- What are the costs of emergency care if something goes wrong? Who pays for that?

Source: International Society for Stem Cell Research patient handbook

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## SOME WARNING SIGNS

- Claims based solely on patient testimonials
- Numerous different diseases that all are treated with the same cells
- Unclear documentation about how the treatment will be performed
- High or hidden costs

Source: ISSCR patient handbook

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