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## Injections of Hope

Doctors Promote Offshore Stem Cell Shots, but Some Patients Cry Foul

By Brian Vastag  
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A vast human experiment is afoot. And no one is taking good notes.

Fueled by demand from desperate patients, dozens of companies around the globe are peddling stem cell injections for \$15,000 to \$50,000 and more. Based merely on the claims made by these companies, at least a few thousand patients from the United States have paid for stem cells overseas.

Patients dart across the border to Mexico or jet to the Caribbean, India, China and elsewhere for injections of stem cells from embryos, fetuses, umbilical cords and the patients' own fat, blood and bone marrow. These shots would be illegal in the United States, where the [Food and Drug Administration](#) has yet to approve any such treatments.

Online ads promoting this therapy target people with spinal injuries, Lou Gehrig's disease, heart failure and other tough-to-treat conditions, promising improvements and even cures.

"Diseases and conditions such as diabetes, multiple sclerosis, cerebral palsy . . . are all being successfully treated," claims one site, returninghope.com. When asked to support the claims, Brian Dardzinski, who operates the site from Bangkok and Hong Kong, provided one medical journal article describing the treatment of incontinence with muscle stem cells, an Austrian study now under investigation for possible ethics problems.

Dardzinski has no medical background and acts as a broker, matching U.S. patients with stem cell providers overseas. "Several hundred patient inquiries a month is not uncommon," he said. "I'm just a businessman trying to do some good."

Because the companies operate offshore, they are not subject to the FDA's strict safety regulations. And because they collect little, if any, data, it's impossible to assess whether their treatments work.

The business is drawing sharp concern from academic researchers.

"It's almost evil, because it preys on the fears and the hopes of the most vulnerable people," said Evan Snyder, a stem cell researcher at the Burnham Institute in La Jolla, Calif.

"There are a lot of scams out there," said Wise Young, a spinal cord injury researcher at [Rutgers](#), the state university of New Jersey. "People should be very careful."

Barbara Hanson and Jeannine Richardson discovered the risks after a trip to a stem cell clinic in Tijuana, Mexico, last year.

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The women, who met in an online support forum for people with chronic obstructive pulmonary disease, learned of a company called Stem Cell Biotherapy, which has offices in Agoura Hills, Calif., and advertised online. Hanson says one of the company's doctors, Burton Feinerman, told her he had taken 10 COPD patients to Tijuana and all had improved enough to discard their portable oxygen tanks.

Because Hanson and Richardson helped recruit patients for Stem Cell Biotherapy from the online forum, the company dropped its price from \$25,000 to about \$17,000 for each of them, the women said. Hanson borrowed the money from her mother, and Richardson took cash advances on her credit cards.

But a week after traveling to Tijuana at Feinerman's direction and getting injections, both women spiked fevers and developed flulike symptoms. Richardson was hospitalized for eight days after returning home to New Hampshire.

"It was like the worst pneumonia I'd ever had," said Hanson, who lives near Denver. "It was so bad I honestly thought I was going to die." Hanson believes the injections made her and Richardson sick; Richardson isn't sure.

Feinerman did not return calls asking for comment. But Casey Navabi, Stem Cell Biotherapy's chief executive, said Hanson and Richardson grew embittered after he decided not to use the women's printing business. (Hanson says that the company still owes her money.)

"They wanted our business, and we didn't give it to them," he said. "Now they're putting out a lot of negative comments about us. I view it as extortion."

About 25 patients from the forum eventually visited the Tijuana clinic, Hanson says, with Stem Cell Biotherapy acting as the broker. "None of us has gotten off of oxygen," Hanson said. She and Richardson say the injections might have slowed the course of their illnesses (they both rely on bottled oxygen less than before), but Hanson is furious. "I can't say I didn't get any [benefit]," she said. "But I sure didn't get my money's worth, and I sure didn't get what I was promised."

### **Patient Complaints**

That refrain is common among those who pay for stem cells. Nine years ago, Fia Richmond of Santa Barbara, Calif., took her brain-damaged 3-year-old son, Palmer, to a clinic in the Bahamas run by William C. Rader, a psychiatrist from Malibu, Calif.

Palmer was unable to walk or talk, and Richmond said she decided to take a chance on Rader, who offered to inject Palmer with fetal stem cells for \$25,000, telling her the cells might help her son.

When the pair returned home, Palmer began having seizures, Richmond said.

Rader disputes this. "The only communications from Mrs. Richmond [post-treatment] . . . were all very positive," he wrote in an e-mail.

Now 12, Palmer is still unable to walk or talk, his mother said.

"It was devastating to come back and for my son to not do well, to have a lot of seizures where he hadn't had seizures for years," Richmond said. She said she "had taken a step too far with my son being a guinea pig."

Another mother whose developmentally disabled child received Rader's injections, Dianne Caprio of Monterey, Calif., said: "There was no follow-up at all. He never called us. He did nothing but collect money." Caprio said her daughter Courtney received two rounds of injections, one in the Bahamas and

one at Rader's clinic in the Dominican Republic. "Initially we thought we saw some improvements, but nothing really substantial," Caprio said. "Looking back, it might have been wishful thinking. I think he's just preying on desperate people." Rader provided notes that show the Caprio family originally thought they saw some initial improvement in Courtney. The notes detail several phone calls from Rader's office to the family to arrange more cell injections.

The government of the Bahamas closed Rader's clinic in 2000 after a critical television report. He moved to the Dominican Republic, where he meets and injects patients on weekends. In a phone interview, Rader said he gets his product from a lab in the republic of Georgia, where technicians extract stem cells from the brains and livers of aborted fetuses. Rader claimed in an interview to have injected more than 1,000 people with such cells since 1997.

Rader recruits patients from his Malibu office and via the Web site of his company, Medra Inc. Earlier in his career, he operated eating disorder clinics and reported medical news for a television station in Los Angeles.

During four hours of phone interviews, Rader described himself as a misunderstood pioneer. He said that he has tried to educate several physicians about the benefits of stem cell injections but that they refuse to accept that he has helped patients. Rader said his treatments have reversed Down syndrome, stopped intractable seizures in children, cured AIDS in at least two patients and boosted the immune systems of cancer patients undergoing chemotherapy. "If I'm telling the truth, it will change the face of medicine," he said.

Rader is not interested in talking to the FDA about conducting fully documented clinical studies. He said that if he opens his work to scrutiny, the FDA and the pharmaceutical industry will squelch him. "I trust no one," he said.

### **Short on Science?**

Quackwatch, a Web site devoted to outing doctors practicing unsafe and unproven medicine, highlighted Rader and other overseas stem cell providers in 2006. "Their theories and methods are simplistic; their treatments may have adverse effects; they offer no credible outcome data; and their promises go far beyond what is now possible," wrote the site's founder, Stephen Barrett.

Rader dismissed the criticism, questioning Barrett's credibility. He and other stem cell providers point to testimonials, posting videos and blogs from patients who say they've improved. Research from [Harvard University](#) and elsewhere on patient decision making shows this to be smart marketing: Patients pay far more attention to stories than to statistics.

But when determining whether a medical intervention really works, "testimonials mean absolutely nothing," said Snyder, the Burnham Institute researcher. "They're worthless."

One reason: They don't allow for the possibility of spontaneous recovery. A 2007 study in the journal *Spinal Cord* found that "almost all" spinal cord injury patients spontaneously regain some feeling and movement.

And then there's the placebo effect: If the brain thinks it's getting a treatment, the body often feels better. Medical journals are littered with descriptions of drugs and other interventions that displayed initial promise only to wilt under the rigors of placebo-controlled studies, where some patients get the intervention and some get a sugar pill or other non-treatment.

Clinical trials in Parkinson's disease offer perhaps the most stunning demonstration of the placebo effect. In the trials, doctors transplanted fetal cells into the brains of some Parkinson's patients, hoping the cells

would make the brain messenger dopamine, which diminishes with the disease. Other patients got holes drilled in their heads but no cells. Over a year, both groups showed some improvements, according to a 2004 report in the Archives of General Psychiatry. Further, of the patients who did not receive the cells, those who thought they had fared better than those who thought they had not.

In other words, believing makes the "medicine" work.

Likewise, patients who travel for stem cells are strongly motivated to feel better, said Jamie Heywood, founder of the online support network PatientsLikeMe. "If you spend so much money and sacrifice so much to do something, it's difficult to believe it didn't help," said Heywood, who tracks several offshore stem cell providers.

### **More Study Needed**

The disease that most interests Heywood is amyotrophic lateral sclerosis, or ALS, also known as Lou Gehrig's disease.

In 1999, after doctors diagnosed his brother Stephen with the fatal disease, Heywood organized the first human stem cell trial in the country for ALS. After Heywood won FDA approval for the safety study, his brother and two other ALS patients received spinal injections of stem cells from their own blood at Thomas Jefferson University Hospital in Philadelphia. None of the patients improved. Stephen died in 2006.

Since then, about 20 ALS patients from PatientsLikeMe have received offshore stem cell injections, Heywood said. None has shown lasting improvements, according to patient reports and surveys on the site. "The evidence to date is that the simple 'put them in and they will heal you' model isn't going to work" against ALS, Heywood said.

The only way to know if the injections help patients, academics say, is to subject them to fully documented, placebo-controlled studies. That's why the 2,500-member International Society for Stem Cell Research (ISSCR) is developing guidelines to encourage overseas stem cell companies to collect and share data. A draft of the guidelines says the society "condemns" injections of stem cells outside rigorous studies.

At the same time, a few academics voice regret about overplaying the promise of stem cells. Reams of evidence suggest various types of stem cells do possess healing properties, but figuring out how to harness that power will take years of careful human trials, they say. "There's been extremely high levels of hope and hype" surrounding stem cells, said Laurie Zoloth, a bioethicist at [Northwestern University](#).

"I take as much blame for creating this aura that stem cells can do anything as anyone else," Snyder said. He and other academics offer a rule of thumb: Avoid companies asking for money.

"There's a standard in clinical research: Patients don't pay for it," said George Daley, president of ISSCR and a researcher at the Harvard Stem Cell Institute. Snyder said this rule might screen out "some legitimate operations," but it will also weed out the scams. Legitimate clinical trials are usually funded by the government or by private companies, he said.

"At the beginning you think, 'I'm going to be cured for life, I'm going to get better every day,'" said Hanson, the lung patient who traveled to Tijuana. "Well, that isn't true."

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