

RISKING IT by Sarah McCoy OVERSEAS

The FDA doesn't allow stem cell therapies to be performed in the U.S., but for many Americans, these treatments are their only hope and available abroad

During a heart attack, approximately a billion cells are suffocated and killed. Doctors can give you drugs to decrease the viscosity of blood and surgically clean out the arteries wired to the heart to help reduce the force the heart needs to circulate blood from head to toe, but it doesn't change the fact that a large part of the heart muscle is dead, sitting in the chest like an indolent stone, and there is no approved treatment in the United States that can repair this damage. For many people, the damage is so severe it's like trying to run a marathon after having a significant portion of your quadriceps muscle removed.

However, there are treatments outside the Food and Drug Administration's jurisdiction that attempt to replace lost heart tissue for patients in the United States who aren't satisfied with their options. But with such esteemed medical facilities in the United States, we wonder why anyone would want or need to go abroad. The problem is not the quality of current American medicine, but the access to new procedures. Patients are often unable to obtain cutting-edge treatments because of government limitations.

"The business of health care has taken health care away from patients and physicians," says Dr. Zenno Grekos, director of cardiology and vascular disease at Regenocyte Therapeutic, a center based in Naples, Fla.

Since 2006, Grekos has escorted nearly 400 patients to Thailand and the Dominican Republic to perform life-saving cardiac and vascular stem cell therapy. Grekos is a University of South Florida-trained cardiologist and an innovator in the field of adult stem cell therapy, a treatment developed by the TheraVita Company, but not currently approved by the FDA.

"It all started when a friend of mine, Neim Malo, had a heart attack and sustained heart damage," Grekos says. "He was in his late 40s and was quite symptomatic with his heart failure. One day, he bumped into a man who told him how the doctors sent him home to die, claiming his heart condition was untreatable. Then his kids saw a special on National Geographic about the stem cell work they were doing in Thailand. So they packed him up and took him there for the treatment and now he leads a relatively normal life. So this

friend of mine contacted me about it, and I said, 'You want to do what? Where?' I was skeptical, but I spoke with the physicians in Thailand, and looked at their science and articles. It was very real. Much more real than a lot of the stuff going on in other places."

Grekos went with Malo to Thailand and toured the facility, met the staff and oversaw the procedures. "It was incredible. A lot of the doctors had been working in the United States for years and were board certified. One of them started at the Minneapolis Heart Institute. Another was the director of cardiology at the Bronx Hospital for 10 years. They were Thai and had returned to Thailand to continue practicing," Grekos says.

Malo was equally impressed. "At first I was nervous about the whole Third World country aspect, but the hospital was amazing. They treated me like a king," he says.

Many Americans may fear foreign medicine, but many of today's most popular treatments were being performed across the globe for

“It all started when a friend of mine, Neim Malo, had a heart attack and sustained heart damage...One day, he bumped into a man who told him how the doctors sent him home to die, claiming his heart condition was untreatable.”

years before they were deemed safe and reliable in the United States.

"As far as cutting-edge procedures and discoveries, they typically come from somewhere else—like LASIK eye surgery. They were doing that in Europe years before we got it. So everything cutting edge is tried outside and then brought to the United States because you want to be 100 percent certain it works before you spend \$200 million on (getting FDA approval)," Grekos says.

Meanwhile, people in the United States are unable to have these medical procedures and could possibly die without these vital treatments. But with a passport, a plane ticket and a doctor willing to explore every lifesaving method, there are alternative possibilities.

"I'm an advocate for every patient I treat. I'll try to provide them with what is available here in the United States. What's not available, I'll find a way to get them to it," Grekos says. "Even though we've been using adult stem cells in cancer patients for 40 years, it'll be at least seven to 10 years before the FDA approves them for cardiac and vascular use. Am I supposed to sit back and watch my patients die waiting? I can't. I won't."

While doctors complain about the slow process of approving new medical technologies, the FDA defends its cautiousness stating on its Web site: "The FDA's main priority is to ensure safe human cellular therapy studies. It does not want to stand in the way of progress that may lead to effective treatments but recognizes that new therapies may have unknown risks, even as they provide benefits to patients."

Patients have their own views. "I prob-



ably wouldn't be around if I had to wait for FDA approval," Malo says. "But they won't approve until they've seen 2,000 to 3,000 of us guys. Meanwhile people are dying. They say about 15,000 a year pass away from heart disease, and that's just heart disease, never mind all the other diseases that stem cell therapy could help."

But adult stem cell therapy is only a minute fraction of the progressive but unapproved treatments performed in other countries.

"Right now we're seeing a lot of people leaving the U.S. for cardiac surgery, orthopedic procedures—joint replacements—dental work, assisted reproductive technology, and a lot of plastic surgery," Grekos says.

Some medical insurance companies are even jumping on the bandwagon by offering incentives for people to have procedures done abroad.

"Our facility in the Dominican Republic is in the midst of contracting with U.S. insurance companies to provide medical care at significantly reduced rates than in the United States with equal or better quality. That way the insurance companies can save money and pass those savings along to their customers, and people are able to get all the treatments they need," Grekos explains.

For the time, however, most out-of-country medicine means out-of-pocket expenses. Grekos' Regenocyte Therapy runs patients \$33,500 to \$44,500. But for those given a death sentence, the price is comparatively small.

"It was all worth it," Malo says. "I'm living proof this works. People need to know there are alternatives. I believe in this. It's given me a second chance and now I want to help others."

Grekos and his Regenocyte patients are so committed to


“ I probably wouldn't be around if I had to wait for FDA approval. But they won't approve until they've seen 2,000 to 3,000 of us guys. Meanwhile people are dying. They say 15,000 a year pass away from heart disease...never mind all the other diseases that stem cell therapy could help. ”

making this and other non-FDA-approved therapies available that they're in the process of building a foundation to fund other patients' trips. Sara Copeland is one of the early benefactors. Diagnosed with cardiomyopathy and congestive heart failure at age 18, she is scheduled to undergo Regenocyte treatment in the Dominican Republic. The Mayo Clinic refused to treat her with adult stem cells, so she turned to Grekos.

"My very first cardiologist referred me to Mayo Clinic, saying I would eventually need a heart transplant. I've learned as much as I can about transplants, and the risks seem to outweigh the benefits. I've also learned about adult stem cell therapy. It's definitely something I want and something I am looking forward to," Copeland says.

For Copeland and all of Grekos' patients, leaving the country for medical care is their only hope for life. These overseas destinations offer what the United States cannot.

"To hear the responses from patients is truly amazing," Grekos says. "This is science at its best and it needs to be available to everyone."

For more information on adult stem cell therapy, visit regenocyte.com or theravita.com. 

ADULT *versus* EMBRYONIC Stem Cells

For many, the term "stem cells" evokes images of politicians and pro-life protestors. But let's be clear: Adult stem cells are not embryonic stem cells. The government has supported the use of adult stem cells in cancer treatment for the last 40 years. Food and Drug Administration clinical trials are being conducted for their use in other diseases: vascular, cardiac, neurological, orthopedic, etc. On the other hand, embryonic stem cell use is not sanctioned and all research is privately funded.

So what's the basic difference? According to the National Institutes of Health, adult stem cells are a natural part of each of us, found in the brain, bone marrow, blood, muscle, skin and liver. They are regenerative cells with the primary goal of maintaining and repairing our body's tissues. Scientists and physicians typically collect adult stem cells from a patient's blood or bone marrow, grow and reproduce them outside the body, then re-implant them to repair damaged/diseased tissue. The

body readily accepts these cells because they are its own.

These differ from embryonic stem cells, found in the inner cell mass of embryos. Unlike adult stem cells, which only regenerate tissues in the body of origin, embryonic stem cells can develop into any type of cell, offering vast possibilities in a wide range of disease treatments. The drawbacks: Harvesting these stem cells results in the destruction of the donor embryo and they're often rejected by the transplant's immune system.

