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## Price high, stakes higher. Stem cell therapy beats slow death, advocates contend

May 20, 2007

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Richard Rzaca's journey to extend his life began on a Tuesday morning two weeks ago at a Bonita Springs cardiologist's office.

His heart, damaged in a near-fatal heart attack in 2003, was getting weaker all the time. Doctors had already performed bypasses and put in stents and prescribed medications to keep his condition in check. They could offer nothing more.

Rzaca, 79, was not ready to die.

The start of the journey has to be timed precisely, so shortly before 8 a.m. nurse Sara Billings shooed Rzaca into an exam room where she and the cardiologist, Dr. Zannos Grekos, drew about 1 cup worth of Rzaca's blood, sealed it in a pouch, placed the pouch in an insulated bag, nestled the bag in a cardboard box, and then thrust the box into the hands of a waiting courier. The courier would speed the parcel across Alligator Alley in time to put Rzaca's blood on a 1:30 p.m. plane from Miami to Israel.



Registered nurse Sara Billings helps cardiologist Zannos Grekos draw blood from patient Richard Rzaca Tuesday, May 8, 2007.

Israel?

That's just the beginning.

At an Israeli lab, scientists would comb through Rzaca's blood looking for stem cells. These are adult stem cells, cells that circulate through the body and help it heal. They are not to be confused with the embryonic type.

The scientists would find the ones particular to the cardiovascular system, extract them and multiply them.

Meanwhile, Rzaca and his wife, Eleanor, would board a plane from Fort Myers to New York, and then from New York to Bangkok, Thailand.



By the time Rzaca arrived, rested, and underwent his pre-procedure exams, the blood would have arrived from Israel, ready for use. Thai doctors would inject his heart with the multiplied stem cells — millions of them — and let the cells work their magic.

If Rzaca's results were anything like those of Grekos' other patients, the cells would force the heart tissue to renew itself.

The repaired muscle would start pumping harder and Rzaca, who loathes idleness, could go back to enjoying his Marco Island retirement.

It's the kind of trip that makes some U.S. medical researchers shudder. The procedure is not approved for use in the United States, but Grekos and Billings believe it holds promise for patients with no other options.

"The procedure's a snap," Billings reassured Rzaca back at the office. "Everyone says that."

Her patient wasn't worried. He had nothing to lose.

"I'm not going to live forever, but another five years and I'll be happy," he said. "I just want to stick around as long as the good Lord allows me to."

### How it started

In the past few months, Southwest Florida has become an exporter of sick patients desperate to try a treatment that's not available in the United States. About a dozen patients from this area

have gone; others from places including Wisconsin, Utah, Texas, Connecticut and California also have worked with Grekos. It costs about \$40,000, plus airfare, and is not covered by private or government insurance.

Grekos started the surge.

He had learned about TheraVitaе, the company that developed the procedure, from a Naples man who had persuaded Grekos to accompany him to Bangkok last November.

The company, a biotechnology firm, had developed the procedure just two years ago. So far, only about 250 patients worldwide have undergone it. TheraVitaе claims about 80 percent of those treated show improvement for conditions such as coronary artery disease, congestive heart failure and cardiomyopathy.

Grekos, a University of South Florida-trained doctor who bills himself as an "innovative invasive cardiologist," was intrigued by TheraVitaе's use of stem cells. The therapy's premise made sense; American doctors have used the stem cells extracted from bone marrow for about 30 years to treat blood disorders, Grekos said.

"I went over a skeptic and came back a believer," Grekos said. "The science is very real."

He agreed to serve as the company's cardiology director in the United States, a role somewhat akin to a consultant. Grekos said he's not on the TheraVitaе payroll. He bills the company for services rendered — such as shipping the patients' blood and running diagnostic tests. He said he does not collect a fee for referring patients to TheraVitaе.

"I saw there was a huge need here to get people ready for the trip... and when they come back to follow up with them," said Grekos, who plans to study these patients long-term to track their heart function.

Grekos grabbed a copy of a patient's test results.

In imaging tests, the heart looks like a multicolored doughnut. The red and yellow areas show functioning heart muscle; the green patches are dead. On this particular scan, the patient's healthy tissue looked like islands in a sea of damaged muscle.

Three months after treatment, the red and yellow areas had expanded. Six months later, the islands of healthy tissue had reconnected in parts — precisely the result Grekos had hoped to see.

No one is claiming this is a cure, but Grekos said the improvement is clear.

"It's undeniable," Grekos said.

His opinion is not universally shared. Researchers elsewhere say stem cells hold great promise, but they don't believe there's enough evidence to embrace their use on cardiac patients.

Stem cell expert Dr. Carl Pepine, chief of cardiovascular medicine at the University of Florida's College of Medicine, said stem cells appear to be associated with the regeneration and preservation of cardiac muscle. But he said there's no evidence of long-term benefits.

"It's basically unclear," he said.

#### **'A slow death'**

The patients who see Grekos and Billings, his clinical care director, may not have the time to wait for more studies.

"It's hospice or this," Billings said of the choice some of her patients face.

A diagnosis of heart failure is a death sentence, she said.

There are about 5 million Americans living with congestive heart failure. About half will die within five years of their diagnosis.

When heart attacks kill part of the heart muscle, the rest of it starts working harder. Even so, it can't eject the blood through the body with the same force. Eventually, the overworked muscle starts to burn out, Billings explained.

As the heart declines, the patients grow weaker and weaker.

"It's a slow death. It's a very slow death," Billings said.

#### **Not ready to die**

Technically, Rzaca died once. Five minutes after his wife rushed him to Marco Island's urgent care clinic in 2003 he went into cardiac arrest. Medics revived him.

"The good Lord didn't want me. The devil wouldn't take me," he said with a grin.

He's still not ready to go.

"This is what I want to live for," he said, admiring the view from his waterfront home.

He wants to stick around Eleanor, his wife of 56 years.

The two still croon like teenaged sweethearts.

"Happy wife, happy life," Rzaca decreed.

Rzaca was born to Polish immigrants in Pittsburgh where his father was a sausage maker. Rzaca worked for the family business for a time and then branched out on his own, building an 86-employee company, Silver Star Meats. A framed, yellowed Pittsburgh Post-Gazette article declares "The King of Kielbasa is a bit of a ham."

Rzaca's sense of humor hasn't diminished, but his body is fast breaking down.

"He doesn't have the energy. He's tired all the time," Eleanor Rzaca said.

The entire trip will cost the couple about \$50,000.

"What good is the money if I'm laying in a box?" he said.

Because the procedure is not FDA approved, no government or private insurance plan will cover it.

Grekos said he plans to start a nonprofit foundation and a sponsorship program so those of more modest means can have the procedure.

"This is so new that the established nonprofits don't have a category for stem cells," Grekos said.

What upsets Grekos and Billings — and Rzaca for that matter — is TheraVita's procedure can't be done here. FDA approval for stem cell use in cardiac patients is still some years away.

Billings pointed to the heart catheterization lab at the Bonita Springs office.

"If it was FDA approved, we could do it right here," she said.

*NOTE: The Rzacas will return from Bangkok this week. Grekos will measure Richard Rzaca's heart function every few months.*