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## CTI MAKES PET ITS MISSION

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### POSITRON EMISSION

#### TOMOGRAPHY

**Caption:** Terry Douglass, president of CTI Inc., sits behind one of the positron emission tomography scanners the company builds at its West Knoxville plant.; P.E.T. SCANSCTI Inc. is the worldwide leading manufacturer of PET equipment. Their factory, shown here, is on Innovation Drive in West Knoxville.; P.E.T. SCANSPhotos by J. Miles Cary/News-Sentinel staffSharon Fields prepares crystals for one of the bonding steps at the CTI Inc. manufacturing plant. J. Miles Cary/News-Sentinel staff; P.E.T. SCANS

**Illustration:** photo (3)

**WYNNE BROWN, NEWS-SENTINEL STAFF WRITER**

In 1973, Terry Douglass took a telephone call that changed the course of his life.

He was technical director for life sciences at EG&G ORTEC in Oak Ridge. The caller was Mike Phelps of Washington University in St. Louis. "He wanted some help on detectors and electronics and just happened to get me," Douglass recalled. "He began to talk about this idea of positron emission tomography -- at the time it didn't even have a name."

Phelps was the originator of this new technology, and the call was the beginning of CTI Inc., now a \$40 million company based in Knoxville.

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Positron emission tomography, more simply known as PET, is similar to MRIs and CTs in that it's a noninvasive way of looking at the body. But unlike magnetic resonance imaging and computed tomography, which are pictures of structures, PET is a picture of how the body is functioning.

Phelps explained to Douglass that while traditional imaging methods can show doctors what has already happened to the body, PET could show them what biochemical changes were happening at that moment.

"The more he talked about it, the more I thought it had a lot of potential," Douglass said. "It just sounded like fundamentally it was the right thing to do.

"So we started working with him, and we spent about three years developing a prototype. We decided in 1976 that we would commercialize this at EG&G ORTEC, and we produced the first commercial PET scanner."

Douglass went on to become the president of EG&G ORTEC and said he became focused on other projects -- until in 1983 it became his responsibility to sell off the PET business since it didn't fit with the rest of the company.

It was like selling a child, he said. "That was one that I had started and one I felt strongly about . . . So I left ORTEC as president and formed CTI with four other partners, including Mike Phelps."

Twenty-five years later, the privately held CTI Inc. holds 70 percent of the world market for commercial PET products and 60 percent of the U.S. market.

"We are the center of the universe for commercial PET," Douglass said.

That universe hasn't always been a friendly place for PET. Stumbling blocks have included the newness of the technique and its high cost. In addition, regulation and reimbursement issues have challenged the company: Because the Food and Drug Administration has not been willing to approve the most commonly used radioisotope for PET, Medicare and insurance companies aren't willing to reimburse hospitals for the procedure.

Douglass said one of the first goals of CTI was to make PET less expensive.

"When we first started doing PET at CTI, 2 to 2 1/2 million (dollars) of cyclotron and 2 to 2 1/2 million (dollars) of scanner is what you had to have to get into it."

Ward Digby, vice president of marketing for CTI, said the cyclotrons needed to make the radiopharmaceuticals now cost

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around \$1.3 million, and the scanners range from just under \$1 million to about \$2 million. A clinic or hospital putting in a new PET center would face a cost of about \$3 million, depending on how much site preparation is required.

Once installed, the equipment requires technicians and chemists -- and more money. Curtis Curley, the University of Tennessee Medical Center's vice chancellor of business and finance, estimated it will cost \$900,000 to run UT's PET center this year.

A PET scan of the brain costs about \$1,500 and a whole-body scan is \$2,000. In comparison, an MRI scan is \$1,240. The problem for patients comes with the bill. Most MRIs are automatically covered by insurance. The most commonly used tracer in PET is FDG, or flouro-deoxy-glucose, and after 20 years, the FDA has not yet approved its use because the agency is still not completely convinced of the tracer's safety.

What this means to the patient is that many insurance companies will refuse to reimburse the hospital for the cost of the PET scan.

This has been a thorn in the side of CTI.

"Our whole strategy, whole approach has been we just simply think PET should be reimbursed when it's demonstrated that it's clinically effective and cost-effective," Douglass said. "It's hard to argue with that. There's so much regulatory uncertainty that only the large institutions were going to buy PET. But even when you consider all the problems they had to face, we still have 70 institutions in the U.S. that have PET and 150 worldwide."

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Douglass admitted the company has a lot to lose in the U.S. if the Food and Drug Administration does not approve FDG. That's why he's been working with Sen. Bill Frist, R-Tenn., and Sen. Ted Stevens, R-Alaska, helping with their efforts to draft legislation to force the FDA to approve the radiopharmaceuticals used in PET and ease reimbursement. Lee Rawls, chief of staff in Frist's office, said progress of the section of Senate Bill S 830 called "PET Compounding and Reimbursement Act of 1997" has been good. The first hurdle, the "mark-up" phase of the bill, has been cleared with the PET section intact. The next step is the Senate floor on July 21.

Meanwhile, an increasing number of private insurance companies are willing to pay. "If it's not an emergency, patients can call their insurance company and many will be approved on a case-by-case basis," said CTI vice president Digby.

Douglass said the next push for the company is establishing sites where FDG will be manufactured and then distributed to area hospitals with scanners. Because of the rate at which FDG decays, the hospitals need to be within a 2 1/2-hour commute of their source of radiopharmaceuticals.

"A major part of our strategy is to be able to increase the number of our distribution centers," Douglass said. CTI has distribution centers in Phoenix; Los Angeles, Sacramento, Palo Alto or San Francisco, Calif.; Omaha, Neb.; Chicago; Peoria, Ill.; Nashville; Tampa, Fla.; New York; Atlanta; and Detroit.

Douglass said it is likely that a distribution center will be added at UT Medical Center.

Where does he see this trend going?

"I think there needs to be 100 distribution centers," he said. "If you look at where PET's application is, a million studies per year in the U.S. would not be an exceptional number of studies to be done. There are 14 million conventional nuclear medical studies done per year. To penetrate 7 or 10 percent of that market is not unreasonable for PET.

"To do that, though, requires about 100 distribution centers, one in just about every significant metropolitan area in the United States. I see no reason, other than capital and personnel, why one would not be able to do that."

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CTI Inc. is the parent company for four affiliates:

\* CTI Cyclotron Systems -- production, marketing, sales and service of the cyclotrons, which are mini-particle accelerators where the radiopharmaceuticals are synthesized.

\* CTI PET Systems Inc. -- scanner research and development, production, marketing, sales and service.

\* CTI Services Inc. -- sources, infusion systems and PETNet FDG Distribution Systems.

\* CTI Detector Systems -- detector (used in the scanners) research and development, production, marketing and sales.

Seventy-two percent of the shareholders in the parent company are officers and employees of CTI. Siemens holds 3 percent, Mitsui 10 percent and others 15 percent. The affiliated company CTI PET Systems Inc. is jointly held by Siemens, 49.9 percent, and CTI, 50.1 percent.



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