



THE AUDACITY OF IMAGINATION...Dr. Stephen DeFelice, left, and Dr. Michael Maroules will pioneer a promising study to treat ovarian cancer.

Ovarian Cancer: A Promising New Clinical Study

By MICHAEL J. POLLACK

Specially Written for The Westfield Leader and The Times

WESTFIELD – Dr. Stephen DeFelice, equal parts physician and poet, has dedicated his life to advancing medical discovery. After exhausting countless concepts on reticent editorial boards, politicians and supposed intellectuals, only to be thwarted by red tape and indifference, his latest hypothesis, one which could lead to a new approach in treating ovarian cancer, may have been accelerated through sheer dumb luck and an inclination to entertain – both himself and others.

Enjoying Chinese food at Cathay 22 in Springfield one evening, the doctor overheard the celebration of a woman's 100th birthday. Not missing an opportunity to put on the charm, he moseyed over and began to sing to the lucky centenarian.

As fate would have it, the doctor was singing to the mother-in-law of Dr. Ernest Federici, program director of the Seton Hall Internal Medicine Residency Program, and fellow Westfield resident.

The M.D.s began talking shop, and Dr. DeFelice floated an idea: administering carnitine – a naturally occurring substance that transports fatty acids into the mitochondria, where they are metabolized to produce energy – to those with late-stage ovarian cancer.

During the Vietnam War, Dr. DeFelice had worked with a cardiovascular pharmacologist at the Walter Reed Army Institute of Research (WRAIR), where they conducted animal studies that showed that carnitine dramatically reversed myocardial ischemia (lack of oxygen to the heart.) At WRAIR, Dr. DeFelice also postulated and later experienced that incorporating carnitine with Adriamycin (doxorubicin), an anti-cancer drug, upped its cancer-fighting properties. He was excited by the “dual-mechanism action” that carnitine possesses; it can increase Adriamycin's tumor-kill capacity as well as decrease its toxicity.

This unfortunately, for 30 years, was where the story ended for Dr. DeFelice, who was stymied in any efforts to find a company or organization to sponsor a clinical trial to determine whether this premise would hold true in human cancer patients.

For a man who examines life, in all its physicality, down to a molecular level, Dr. DeFelice employs heavier doses of art and metaphysicality into his thought processes. The words of the philosopher John Dewey are rather apropos. He once said, “Every great advance in science has issued from a new audacity of imagination.” While imagination is not a scarce resource for the doctor, good fortune had been.

Then about a year ago, a 24-year-old hostess at the Plainfield County Club was stricken by ovarian cancer.

“This bonafide tragedy really hit me hard, and I decided I had to give it one more try,” Dr. DeFelice said. “I arranged for a study at Vanderbilt University to test the drugs on their cell-killing effect on human ovarian cancer culture cells. The results were unexpectedly dramatic. Not only did carnitine increase the kill capacity of Adriamycin, but it also had its own impressive cell-killing effect. With my batteries recharged, I tried, without success, to find a company to sponsor the clinical study. I was about to call it quits when I ran into Dr. Federici at Cathay 22.”

Who knew that potential scientific breakthroughs begin after a course of dumplings and fried rice on Route 22?

Dr. Federici was more than receptive to Dr. DeFelice's idea, putting him in touch with members of the fellowship program on hematology (blood) and oncology (cancer), which is run between three area hospitals – St. Michael's, St. Joseph's and Trinitas.

Dr. Federici told *The Westfield Leader* and *The Scotch Plains-Fanwood Times* that he does not mind being a “catalyst” for a breakthrough. He said Dr. DeFelice's concept of using carnitine in conjunction with Adriamycin, an anti-cancer drug used in chemotherapy, to limit the toxicity to the heart has a “realistic possibility” of making headway.

“It's probably very worthwhile,” he said.

If the tests provide evidence that toxicity can be limited through a regimen that in-

cludes carnitine, Dr. Federici has hopes that patients might become responsive to higher doses of Adriamycin – sans the unpleasant side effects.

As a cardiologist, Dr. Federici said he treats patients who were given previously-considered “safe” doses of Adriamycin much earlier in their lives, and still, they have experienced toxicity to the heart later.

“There became no safe haven, no safe dosage that could be given,” he said.

Calling the study a possible “significant breakthrough,” he said it might have application in treating other cancers such as lymphomas and breast cancer.

Dr. Kashif Ali, chief hematology/oncology fellow, will run the study at St. Joseph's Regional Medical Center. Dr. Ali, who trained under Dr. Federici, said the study is approved, and they are ready to start accruing their first patients. The search for patients, however, is quickly becoming the “hurdle.” The goal, according to Dr. Ali, is to have 20 before results can truly be interpreted.

The study is designed for patients in the late Stages III – IV of ovarian cancer who have become resistant to both platinum and taxane therapy.

Dr. Ali, age 33, is enthused about being on the precipice of medical discovery.

“I'm definitely excited. There's evidence this (carnitine) could work with other chemotherapy agents. There is a wide scope of uses to expand to when thinking about toxicity and chemotherapy. I believe it will reduce toxicity and increase the kill capacity. If this comes true, we will have a different approach to treating cancer.”

He also is certain that nothing potentially harmful could come of the study.

“What Dr. DeFelice is doing is already standard; we're not giving patients anything less,” Dr. Ali said. “All that's proposed is adding carnitine.”

He compared taking carnitine to taking a vitamin, and he said it is quite tolerable.

Doctors will monitor patients and determine whether the combination can reduce tumor size over a period of six months. If tumor size remains the same or is reduced, then the patient will continue to receive the therapy for as long as the beneficial effect continues. Intravenous carnitine therapy will be given along with Adriamycin approximately every four weeks. Oral carnitine will also be taken daily. The results of the study will be compared to historical controls.

The study's principal investigator and chairman of the hematology/oncology department at St. Joseph's, Dr. Michael Maroules, whom Dr. DeFelice considers a “patient-oriented physician,” said everything to do with the ovarian-cancer study will “filter” through him. He said he has hopes that carnitine, which he too considered “innocuous,” can lower toxicity and increase the efficacy of chemotherapy.

Dr. Maroules took a layered approach when speaking of his prognostications.

“I'm extremely confident we won't see an increase in toxicity, moderately confident we will see cardiac toxicity go down, and reasonably confident it will be as effective as other treatments out there.”

Dr. Maroules also issued the “bottom line.”

“If patients have been unresponsive or failed standard treatments,” Dr. Maroules said, “it's mostly not curable. There's a chance this is probably not worse than what's available, and, who knows, it may help future patients.”

When asked what would happen if the study results were positive, Dr. DeFelice smiled and said, “The very good news is that both drugs are FDA-approved and available to doctors, and patients could be immediately treated.”

Screening of patient volunteers will be conducted exclusively by Dr. DeFelice, not the hospital. Those interested in participating should consult their physicians, who then can contact Dr. DeFelice through e-mail at application@carnitine-cancerpromise.com or by phone at (908) 272-1600. For more information on carnitine, including the clinical protocol, visit carnitine-ovariancancerpromise.com.

It is hoped that some idea of the effectiveness of the combination will be known by mid-2010.