

First of six chapters

## The trial of their lives

### A Hopkins doctor's vaccine offers a hope of survival for four women with terminal breast cancer (excerpt)

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Dr. Leisha Emens, the 46-year-old Hopkins oncologist who devised the treatment, sits stiffly in a desk chair, a thick medical file in her hands.

Emens believes she can train the body's immune system to attack cancer cells. For now it is an experimental treatment for the sickest of patients, but the research she is doing, while a long shot, could lay the groundwork for a vaccine to prevent breast cancer. Despite all the progress that has been made, once the disease spreads, there's no cure. About 40,000 American women die of it every year.

Therapeutic vaccines are the new frontier for researchers of many forms of cancer, a tool to add to the long-standing arsenal of chemotherapy, radiation and surgery. Vaccines have been developed to prevent infection from most strains of the virus that causes cervical cancer. But no one has yet been able to develop a vaccine that would thwart other kinds of cancer that are not caused by viruses. Roughly 100 clinical trials for cancer vaccines are under way, including several at Hopkins for cancers of the pancreas and prostate as well as leukemia and others.

The stakes are high. The breast cancer patients in Emens' trials are the "almost dead," as one puts it. And the odds are against this new therapy they have pinned their hopes on. Most experimental drugs never make it to market.

Yet this is how new medicines are developed. And at the heart of each trial is an extraordinary bargain between researcher and patient.

For joining Emens' study, for submitting to the pain of many injections, the sometimes-daily blood tests and the terrifying uncertainty of it all, women receive one more chance to extend their lives. Want to be around to see your kids and grandkids grow up? Try this vaccine. Maybe it will hold off your cancer.

#### No promises

Emens is careful not to promise anyone a cure. She knows this disease too well. When she was a teenager, her mother died of it. For Emens, the payoff from this study won't be measured in the number of women who live longer than most with metastatic breast cancer - on average, one to two years. It will be measured in the lab, in blood tests that detect a specific immune system response to the vaccine. Even if that response is insufficient to prolong life, it gives Emens something to build on in future research.

Future versus present, the long arc of scientific progress versus the shrinking life span of a woman with aggressive cancer; Emens and her patients have been brought together by hope, but there they part company.

They've been on different paths and will end this journey in different places.

For the past six months, the doctor and several of her patients have offered a rare and intimate look inside a clinical trial. At times, the women are optimistic; at others, despondent. They face

their fears and draw on their faith. Some manage to find one another despite procedures designed to discourage that, sharing information that can comfort and sometimes hurt.

All the while, Emens and her vaccine inspire and frustrate them. They have questions she can't or won't answer. Some mice were cured when they were injected with the same substance, but there is no way to know whether it will work in humans.

The consent form the women sign to join the trial tells them explicitly: "It is unlikely that you will be cured of your cancer if you join this study." What they hear is: "This is your chance to be the rare one who survives terminal breast cancer."

Emens started her first study in February 2004, injecting 28 women with the vaccine and with varying doses of chemotherapy meant to prime the immune system to attack. Siple is part of a second trial that began in December 2006 and still needs to enroll more women. The women receive the vaccine, a low dose of chemo and another drug - Herceptin - known to fight a certain form of aggressive breast cancer.