

A COMPLEX PROBLEM

Cancer patients, hospitals wrestle over ownership

By STACEY BURLING

The Philadelphia Inquirer

PHILADELPHIA — All Niki Perry wanted was pieces of her own brain, and she got angrier by the day as she tried to get them.

She needed samples of her brain tumor this spring to enter clinical trials she hoped might save her life.

What she got, she said, was delay and disappointment. Plus insight into what she sees as a new battleground: who controls what happens to tiny bits of tumor tissue saved after surgery. This tissue is growing more precious as scientists unlock its potential to target treatments to a specific person's cancer.

When Perry had surgery in September, she knew better than most patients how valuable the deadly cells in her tumor might be someday.

A frequent participant in brain-cancer message boards and an aficionado of new research, Perry knew she might want to

◆ SEE CANCER PAGE D2

enter a European cancer vaccine clinical trial or seek genetic testing that would require frozen pieces of her tumor. She said she asked her surgeon at Thomas Jefferson University Hospital to freeze some just in case.

Freezing tumor cells in a form that can be used for vaccines or advanced genetic testing is unusual. Doctors always put some of the tumor, preserved in formalin and embedded in wax, in slides and small blocks for diagnosis and later testing. Perry knew she would want that, too.

When in March she requested the frozen tissue and her slides, Perry said she ran into weeks of red tape and a Catch-22.

She says Jefferson balked at sending slides to another hospital until she was officially in a trial there.

But she needed the tissue to enter the trial. Jefferson finally mailed the slides at the end of May and she picked up the tissue blocks herself at the hospital. To her dismay, she learned there was no frozen tissue.

The 37-year-old South Philadelphia woman, who has had speech problems since the surgery and now communicates more easily by e-mail, wrote that she felt "helpless" and "enraged" as she fought for the tissue. She felt the hospital, which has said it will not comment on her individual case, got "in the way of my trying to save my own life."

Cancer surgeons at Jefferson usually do not freeze tumor tissue, and Peter McCue, who runs Jefferson's anatomic pathology laboratory, said he did not receive instructions to save frozen cells. He said Perry should not have had trouble getting slides.

Perry's experience is unusual, but she says she's seeing more complaints on message boards from patients having trouble getting tissue sent from one hospital to another.

Some doctors agree with her. They say problems with tissue-sharing likely will worsen as the era of "personalized" cancer treatment unfolds. Individualized care is spurring higher demand



for tissue, creating nascent tensions between research and treatment. That's making tumor cells a hot commodity, one that patients — bewildered and terrified by a life-threatening diagnosis — often give little thought.

Cancer treatment protocols already contain acronyms for biomarkers — HER2, EGFR, KRAS — that determine which drugs will be used. Memorial Sloan-Kettering Cancer Center does genetic profiling of most of its lung-cancer cases. Swedish Medical Center in Seattle routinely profiles brain tumors.

This is where cancer treatment is heading. The trend has huge fiscal, medical, and social implications. Instead of everyone getting the same chemo cocktail, patients will get treatments aimed at specific mutations in their cancer. They can avoid side effects from drugs that won't help them and can avoid paying for expensive treatments that won't work.

Gregory Foltz, a neurosurgeon who directs brain-tumor treatment at Swedish, says genetic profiling done with frozen brain-tumor tissue may identify the most aggressive forms of a disease that can kill in months. That will help patients make key decisions, like whether to quit a job or enroll in a riskier trial. Companies can justify drugs with smaller target markets. One lung-cancer treatment in development, for example, seems to work well, but only for 3 percent of patients.

Tumor tissue is the keystone of the new science, and its use is fraught with complex, unanswered questions. When cancer

patients have surgery, they usually sign consent forms allowing their tumor to be used for research, although hospitals say patient needs should trump science. Tumor tissue might not only save a patient's life — or the lives of other patients years later — but reveal scary genetic truths about him, his family, or his ethnic group. You can't legally sell tissue itself, but its secrets might help a drug company make millions.

So who really owns this stuff and has the right to make decisions about it?

You might think the obvious answer is the patient. But that's actually not clear. C. Mitchell Goldman, a health care lawyer at Duane Morris L.L.P., expects more lawsuits as more uses for tissue emerge.

"There's not a body of settled law around this issue," he said. It's "fertile for litigation once it becomes clear that having control of this tissue for future use will become important."

Penn bioethicist Arthur Caplan thinks hospitals will have to reserve more tissue for patient use.

"The notion of 'I-might-want-it-myself' has just emerged in the last few years," he said. "There's no point in having personalized medicine and mapping the genome if you can't get your tissues shipped."

The bottom line, researchers said, is that patients who want vaccines that use frozen tissue either have to have surgery in a hospital that's doing the clinical trial or they have to ask for special treatment before the operation.

That's asking a lot of

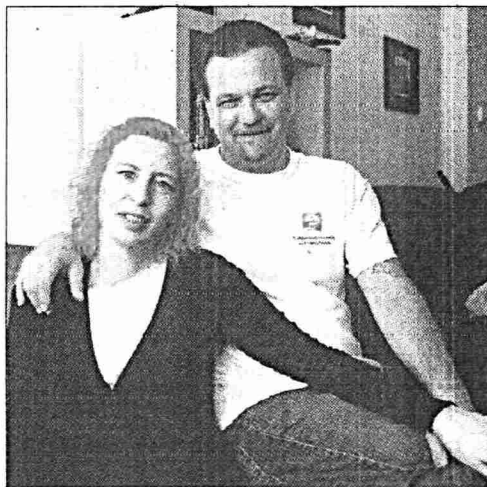
patients. "They're in a state of shock and they get rushed into surgery right away before they hardly know what hit them," said Linda Powers, an owner of Northwest Biotherapeutics, a Bethesda, Md., company that's testing a brain-cancer vaccine.

Perry is still steaming over avenues now blocked because there is no frozen tissue.

"I am utterly crushed by not having access to what I truly believe is the best, most amazing trial ever," she said, referring to a vaccine trial in Belgium. The trial that needed her slides rejected her because her cancer had spread.

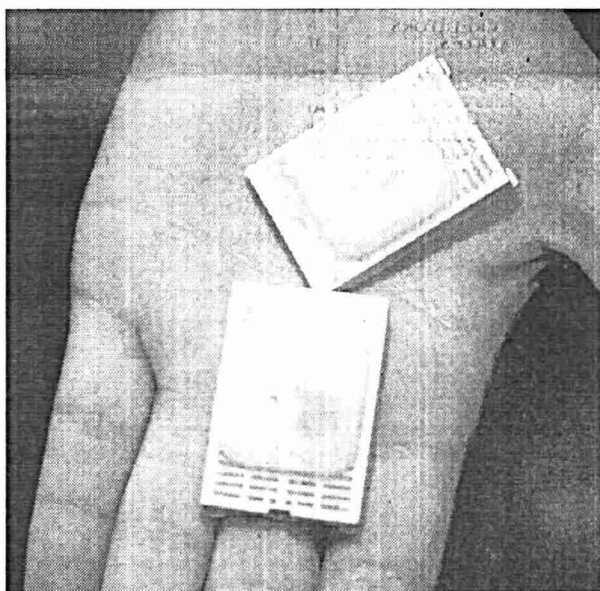
She's weighing less-appealing alternatives now.

"I'm totally freaking out day after day," she said, "desperately digging for something that holds promise."



ED HILLE/PHILADELPHIA INQUIRER

Cancer patient Niki Perry, left, sits in her Philadelphia home with her husband, Chris.



ED HILLE/PHILADELPHIA INQUIRER

Cancer patient Niki Perry holds tumor tissue blocks that she needed to get into a clinical trial at another hospital.