A Muted Victory for the Biotech Industry

A California court has ruled that patients don't own tissues removed from their bodies—but questions of consent remain

IN A LAWSUIT that kept the biotechnology industry on pins and needles for 6 years, the California Supreme Court last week ruled that a patient does not own tissues removed from his body or have rights to profits from products researchers derive from those tissues. But the court also ruled that a patient may sue if the physician who removed the tissues failed to obtain informed consent to do research on them.

The California high court's decision partially overturns a 1988 appeals court ruling that a patient has the right to share in profits derived from surgically removed tissues. If the supreme court had concurred, it would have been "disastrous" for the biotechnology industry, says Pamela Bridgen, executive director of the Association of Biotechnology Companies. "It would have caused major problems with doing any research on human tissue, and probably would have resulted in a slew of lawsuits that would interfere with research and development and getting products to market."

But the court's decision was not entirely a victory for the status quo, since the ruling on informed consent is likely to force changes in how hospitals and medical researchers obtain consent from patients. Those changes could "have a chilling effect on those who practice medicine in the same area that they do research," says Allen Wagner, the University of California attorney who represented the defendants in the case.

The plaintiff in the California case was John Moore of Seattle, who was diagnosed as having hairy cell leukemia by UCLA hematologist David Golde in 1976. His cancer-swollen 16-pound spleen was removed at the UCLA Medical Center. After surgery, Golde—whose research interest is in lymphokines, proteins that stimulate the growth and differentiation of white blood cells—established a permanent cell line, called Mo, from Moore's leukemic cells.

The Mo cells, Golde discovered, produced large amounts of several lymphokines, including one called colony-stimulating factor, or CSF—a substance with potential commercial application as an immune-system booster. That potential spurred the university to seek a patent on the Mo cell line, which was granted in 1984. In 1982, scientists at the National Cancer Institute found that the Mo cells carried a new human retrovirus, HTLV-II. Golde asked Moore to become a subject for research on HTLV-II. Moore agreed, signing a consent form.

But according to his lawyer, Sanford Gage, Moore did not know what kind of research he was participating in. Furthermore, there was a line in the consent form asking him to relinquish his rights to any cell line or potential product derived from his blood, making him suspicious that Golde was turning a profit from his cells.

Moore was right to be suspicious, says attorney Gage, because, unbeknownst to Moore, UCLA got $440,000 in research funds from the Cambridge biotech company Genetics Institute, in exchange for use of the Mo line for cloning CSF. At the same time, Golde became a member of the scientific advisory board of Genetics Institute, getting stock options that later became worth $3 million. When Moore learned of the Genetics Institute agreement, he filed suit, laying claim to a share of the profits.

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> —The California State Supreme Court

Golde maintains that his position as a scientific adviser was not in payment for the cells but simply for his expertise. He also says he told Moore before surgery that researchers might study his spleen. During Moore's periodic visits for check-ups, Golde says he kept Moore abreast of any information that had a bearing on his medical case, such as the establishment of the Mo cell line and the discovery of HTLV-II.

Moore and Gage may appeal the tissue ownership decision to the U.S. Supreme Court. They also plan to go to trial in state court on the issue of whether informed consent was obtained from Moore. Gage says that if they establish that Moore was not adequately informed of the research to be done on his spleen, they will try to recover as damages the profits made by UCLA, Golde, and Genetics Institute, as well as Sandoz Pharmaceutical Corporation, to whom Genetics Institute licensed the production of recombinant CSF.

Regardless of the specific outcome of the lawsuits, the case could alter relations between patients and physician-researchers. Although consent forms must be obtained from patients who are to become research subjects themselves, it is not current practice in research hospitals to obtain consent for research to be done on removed tissues. But in its decision the court called for such consent as a way of protecting the patient from a conflict of interest on the physician's part. "[A] physician who [has] a preexisting research interest might, consciously or unconsciously, take that into consideration in recommending [a surgical] procedure," the judges wrote.

UC attorney Wagner says the court's concern for informed consent is unlikely to have any bearing on the common practice of placing removed tissues in pathology labs, where any researcher has access to them. But in cases where the treating physician intends to do research himself on the removed tissue, Wagner says the court has made it clear that patients have a right to know. And that means research hospitals will have to modify their consent procedures. Wagner says it is likely that all patients of researcher-physicians will be asked for consent to do research on their removed tissues.

Such consent forms are likely to raise some patients' suspicions that they are being used for profit. "I would suppose [it] would cause some patients to say, 'Well, I think I want a second opinion,' " Wagner speculates. And that reaction might delay vital treatment, a possibility that the California judges noted in their opinion. Preoccupation with a physician's motivations, they wrote, "may corrupt the patient's own judgment by distracting him from the requirements of his health." But that possibility, the court concluded, does not override the patient's right to the information.

Golde agrees consent forms to cover research on removed organs will probably become standard. Furthermore, he warns, the consent procedure may give many patients the false impression that they are walking gold mines. Golde says he has already received a letter from a woman with hairy cell leukemia who was shopping around for a researcher who is willing to buy her spleen. ■ MARCIA BARINAGA