

Tissue Banks Trigger Worry About Ownership Issues

Tissues have what a new generation of researchers need to fight cancer: molecular clues to disease origins and a wealth of potential targets for new drugs. But some National Cancer Institute leaders consider a potential shortage of human tissues the single greatest barrier to cancer research.

Now, with high-throughput, robotic systems analyzing tissue samples by the thousands, shortages have become even more acute. Tissue banks, also known as biorepositories, are emerging to meet growing demands, but their contents have become mired in a troublesome controversy over who really owns the samples that patients donate for research. Universities, patient advocates, and researchers are all asking if tissue banks should assume exclusive control over donated samples, or should patients retain property rights over their tissues—and the ability to determine who gets to use them and how?

As it stands now, tissue banks appear to have de facto ownership over sample inventories and the right to use them as they wish. But a small, vocal minority is trying to shift ownership back to the donors. The outcome could have major consequences for cancer research. If patient ownership is allowed, tissue banks might be crippled by administrative nightmares that impede research, some experts say.

But opponents of the status quo counter that patients must own their samples so that they can make informed choices about how the tissues will be used. Opponents of stem cell science, for instance, wouldn't want their tissues used for that type of research. And many wouldn't want their tissues going toward for-profit ventures.

So far, the question has been managed by the courts, because Congress has passed no legislation settling the issue.

The absence of congressional action has created a vacuum currently filled by

a body of case law that, according to the Association of American Medical Colleges, “unambiguously rejects the concept that individuals retain any property interest in their excised tissues.”

The Patients' Case

Proponents of patients' rights have yet to concede defeat, however. Many



William Catalona

now rally behind an appeal of their latest loss: The U.S. District Court for Eastern Missouri decided against patients seeking control over tissues that they donated to William Catalona, M.D., a urologist who was formerly at Washington University in St. Louis. Catalona—who popularized the widely used prostate-specific antigen test for prostate cancer—began collecting tissue samples in the early 1980s. Augmented by other Washington University researchers, the collection numbered in the thousands by 2006 when he decided to move it with him to Northwestern University School of Medicine, where he was taking a new job.

Six thousand of Catalona's patients petitioned the university to release the samples, claiming that they had donated the samples to him—not to the University. But Washington University refused, claiming that the collection had been maintained with university funds and, moreover, it had become a broader resource that Catalona couldn't exclusively claim.

The deciding judge agreed, writing in his March 31 opinion that the donors had relinquished their rights to the samples: “Medical research can only advance if access to [tissue samples] is not thwarted by private agendas.” To

this, the judge added, “If left unregulated and to the whims of [donors], these highly prized biological materials would become nothing more than chattel going to the highest bidder. . . . Selling excised tissue or DNA on e-Bay would become as commonplace as selling your old television on e-Bay.”

In this case, the patients sought rights to move their samples from one repository to another, and they have appealed the Missouri court ruling. But this isn't the first case where patients have sought control over their tissues. A leukemia patient named John Moore tried unsuccessfully to obtain royalties from the University of California for a commercial cell line derived from his bone marrow. And in another milestone case, parents of children with Canavan disease tried in vain to block business ventures arising from gene patents derived from their children's tissues by the Miami Children's Hospital Research Institute.

Who Should Control Samples?

Reduced to a fundamental level, patient control over donated samples amounts to little more than their right to “withdraw” from a study by having their donated tissues removed or destroyed—neither Catalona's patients nor any other patients seeking tissue ownership have sought to have their samples physically returned, which is prohibited by hazardous waste laws. But even this simplification gets distorted when receiving tissue banks deliver samples to a different institution. According to P. Pearl O'Rourke, M.D., director of Human Research Affairs Partners HealthCare System in Boston, Mass., a patient's ability to block her sample's use by a secondary institution varies by the state she donated in, the language in the signed informed-consent form, the policies and procedures of the bank itself, and the extent to which the samples can be traced to the original donor.

With the Catalonia appeal going forward, some people wonder about the consequences for research if patient ownership was eventually rewarded. Would medical progress be stifled, as some propose? Or would patient ownership foster a greater willingness among individuals to give of themselves for research?

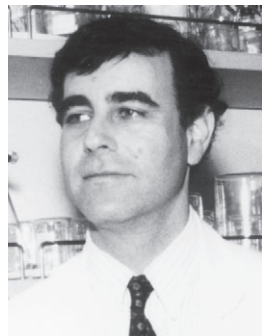
David Korn, M.D., senior vice president at the Association of American Medical Colleges, argues that any change could only harm research. "I look at tissue repositories the way people look at enormous research libraries," he says. "What if every book in the Library of Congress came with a conditional legal document that allows the donor, or the donor's heirs, to walk in and take the book back, or dictate who gets to read it? Just like a library couldn't operate that way, I have a hard time understanding how a tissue repository could function under those conditions."

Korn says that patient ownership might impede future research in ways that can't be anticipated today. "The idea that a donor can predict future developments and say 'you can do this but not that with my tissues' is nonsense," he says. "You really cripple the value of a research repository by putting these strings on it. Nobody can predict when certain types of tissues might be important to answer questions that couldn't have been asked when the tissues were collected."

Or patient ownership could lead to the advent of daunting informed-consent forms that might deter some individuals from donating samples, said Wayne Grody, M.D., a professor at UCLA School of Medicine and director of the school's molecular diagnostics laboratory.

"The forms would have to account for every eventuality," he explains. "And that might lead patients to worry about outcomes that don't pose a real threat. We think if you confront patients like this before surgery, and present them with these myriad options when all they're thinking about is what's going to happen to them, they're just going to opt out altogether."

But patient ownership advocate Lori Andrews, J.D., a law professor at Chicago-Kent College of Law, counters that individual control will produce the opposite effect. In her view, patients who control how their tissues are used will be



Wayne Grody

more likely to donate samples, not less. "If the patients in Catalonia have their tissues used without their consent and against their wishes by [Washington University],

it will be harder to persuade future patients to participate in cancer studies," she says.

Andrews points out that some groups react with anger upon finding their donated tissues are in research that they don't approve of. In a well-known example, members of the Havasupai Indian tribe were outraged to find that tissues they had donated to Arizona State University for diabetes research were also used in what they viewed as potentially stigmatizing studies of schizophrenia, inbreeding, and population migration.

Moreover, patients have grown increasingly worried that genetic information extracted from tissues could somehow be used against them, Catalonia adds. His own patients donated samples on the condition that their DNA wouldn't eventually wind up in the hands of those who could do them harm, such as insurance companies that might refuse coverage to the donors or their children on the basis of inherited disease susceptibility.

"Insurance companies wouldn't hesitate for a minute to get their hands on that information," he says.

For its part, Washington University offered to "anonymize" the samples in its repository so that the tissues couldn't be traced to the original donors. But Catalonia emphasizes that individuals can be identified by genetic sequences numbering just 75 base pairs of DNA.

What's more, some genetic data obtained from publicly funded research will be posted online, making it available to insurance companies and others who would use it to the donor's detriment.

"I see myself as the custodian of my patient's samples," Catalonia says. "The patients came to me, not to [Washington University]. They trust me, they know that I understand their problems."

Moving Forward ... for Now

Today, the Catalonia case remains under appeal, with its outcome uncertain. Some experts believe that the appeal will probably fail but Korn cautions, "Nothing in the court system is dead in the water ... it's hard to predict exactly what's going to happen."

Recently, congressional officials—including Rep. Joe Barton (R-Texas)—expressed concern that a lack of oversight leaves millions of tissue samples administered by the NIH "vulnerable to theft and abuse." According to Barton's investigation, drug companies and consultants had paid NIH investigators thousands of dollars for samples, leading some experts to call for better controls on the use of stored tissues. NCI officials contacted for comment on this issue and other questions regarding patient ownership declined to comment for this article.

In the meantime, the language that researchers are writing into tissue access proposals appears to be getting more "granular" with respect to donor rights, says Mark Sobel, executive officer at the American Society for Investigative Pathology.

"Investigators have been prompted to anticipate problems ahead of time," he says. "What happens if the investigator leaves? What happens to the samples when donors change their minds? There seems to be a lot more sensitivity now regarding individual rights. You don't want to do something that you know is against the desires of sample donors."

—Charlie Schmidt

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