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Lori Andrews
Recent criminal cases have revealed a grisly new business: The sale of body parts—whether from corpses or from living people in the form of organs, blood, and other human tissue—is profitable, and some purveyors are not squeamish about how they get them. Even well-respected doctors and researchers sometimes use human tissue without a donor’s consent. The law is seeking to define who owns a person’s body.

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Even when patients clearly express their wishes for end-of-life care, disputes between health care providers and patients or their advocates may erupt. Doctors may continue unwanted life-sustaining measures; others may stop treatments even if the patient or his or her family requested them. Courts across the country have come to differing conclusions as they grapple with the question of when life should end—and who should end it.

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George J. Annas
In 1999, the Institute of Medicine issued a report warning that medical errors were harming, even killing, too many hospital patients. Since then, hospitals have done surprisingly little to implement better safety practices. Litigation that focuses on deficient patient-safety systems in hospitals, instead of on errors committed by individual doctors, can move the courts toward accepting the idea of patient safety as a legal right.

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Susan L. Crockin, Gail H. Javitt, Susannah Baruch, and Elizabeth M. Bloom
Genetic testing technology has brought new hope—and reproductive options—to would-be parents. But when a testing error occurs or the results are misread or miscommunicated, children may be born with severe, lifelong disabilities. Attorneys can help families of disabled children get the compensation they need to secure their future.
The battle over the body

Some uses of human tissue, donated before or after death, go beyond the donors’ consent. In the worst abuses, tissue marketers steal and sell body parts. Courts are being asked: Who owns the human body?

Lori Andrews

On February 23, 2006, four men were arraigned before Brooklyn State Supreme Court Judge John Walsh on a startling series of charges: Prosecutors claimed that the men, who worked for a company called Biomedical Tissue Services, had engaged in a modern form of body-snatching.

According to the indictment, they had paid $1,000 per body to 30 or 40 funeral homes in the New York and Philadelphia areas. Then—without consent of the families of the deceased—they used scalpels, mallets, scissors, and saws to remove the organs, tissue, and bones, which they sold for transplant, research, and medical education.

The indictment also alleges that the men misrepresented the age, cause of death, and health status of the corpses. After mining the bodies for valuable parts, they sent them off for cremation. If a funeral was intended, they inserted PVC plumbing pipe in place of the bones and sewed the body back up.

The state charged the four men with crimes that included enterprise corruption, body-stealing, opening graves, unlawful dissection, and forgery. They were also hit with lawsuits: Their actions created potential risks for tissue and organ recipients and resulted in 11 class actions on behalf of thousands of patients who received skin and bone grafts from Biomedical Tissue Services.

An exceptionally ghastly example of unscrupulous business practices, the Biomedical Tissue Services scandal is also just one instance of legal problems related to the collection and distribution of human tissue. Every day, abuses of rights occur in the tissue industry—some at elite universities or prominent pharmaceutical companies. Often the blood, organs, and other tissues come from living people who desperately need legal representation.

Few lawyers are prepared to handle cases that might cross so many areas of law: tort, property, gift, bailment, constitutional rights, and federal regulation. And some judges—blinded by defendants’ claims that they were acting to further medical progress—refuse to protect the people whose tissue is used, even when the law is clearly on the victims’ side.

Unethical practices in the tissue industry have grown, just as the value of human tissue, from both living and dead donors, has increased dramatically in the biotech era. A human egg can be worth tens of thousands of dollars. A single cadaver can be mined for medical and research uses—its skin is worth $36,522, its bones $80,000, its tendons $21,400, and so forth. The value of a particularly interesting human gene can be billions of dollars. Is it any wonder that courts are now faced with cases that involve biotheft?

The legal system is beginning to address how human tissue is acquired, what it is used for, and how to protect people who receive it—whether as a transplant, a transfusion, a bone graft, an embryonic stem cell line, a gene therapy, or even a biotech pharmaceutical product.

Some doctors view their patients as treasure troves, taking tissue from them without their consent. When physicians who were also researchers were developing contraceptives from fertilized eggs, their employees would encourage women to have unprotected sex in their fertile periods before getting pelvic surgery. In one study, these doctors recovered 34 fertilized eggs from women

Lori Andrews, a professor at Chicago-Kent College of Law, has served as pro bono counsel for patients in body cases. She is the author of Sequence (St. Martin’s Minotaur, 2006), a mystery novel featuring a female geneticist and a military lawyer.
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undergoing hysterectomies, tubal ligations, and other pelvic surgeries who apparently did not realize they were pregnant. One of the doctors joked about how he “poached” eggs—piercing patients’ ovaries and aspirating their eggs while they were having pelvic surgery for other reasons.4

Whose tissue is it, anyway?

In another case familiar to everyone who has graduated from law school since 1990—a Seattle man named John Moore had surgery for hairy cell leukemia, after which the doctor repeatedly asked him to fly back to Los Angeles to provide samples of blood, sperm, bone marrow, and other tissue.

Every day, abuses occur in the collection and distribution of human tissue—some at elite universities or prominent pharmaceutical companies.

Without Moore’s knowledge or consent, his doctor created a cell line from Moore’s tissue, patented it, and then sold rights to the cell line to a biotechnology firm.5

When Moore found out that he was patent number 4,438,032, he felt violated and sick: “What the doctors had done was to claim that my humanity, my genetic essence, was their invention and their property. They viewed me as a mine from which to extract biological material. I was harvested.”6

Moore sued his doctor and the case ultimately went before the California Supreme Court, which ruled that Moore could not sue for conversion but could sue for breach of fiduciary duty and lack of informed consent. The majority ruled that physicians must tell their patients if they have a personal interest, whether a research or an economic one, that might affect their judgment. “A physician who adds his own research interest to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient,” the court said.7

But Justice Stanley Mosk, dissenting, would have gone further, finding that Moore had a property right in his own tissue. Mosk expressed concern about giving companies “the right to appropriate and exploit a patient’s tissue for their sole economic benefit—the right, in other words, to freely mine or harvest valuable physical properties of the patient’s body.”

Without a property interest in their tissue, people are not adequately protected.9 If, for instance, you store blood before surgery or place your in-vitro embryos in clinic storage for future use, you have little recourse if the blood bank or clinic negligently destroys the tissue or gives it to someone else. Your ability to collect damages for emotional distress will be thwarted in jurisdictions that require physical injury to accompany that distress. Some courts have recognized the problem and held that, in those circumstances, human materials can be considered property that is the subject of a bailment.10

Parallel legal issues arise when the tissue source (that is, the person) is dead. At the Saginaw Community Hospital in Michigan, Armando Herrera was an assistant to the pathologist who conducted autopsies. Herrera’s job was to open up the bodies and then, after the pathologist had finished work, sew them back up. But Herrera had another job: He owned and operated the Central Michigan Eye Bank and Tissue Center. So when the autopsies were over, and without informing anyone, he would remove the deceased’s eyes and sell them.11

Relatives of Herrera’s deceased victims later sued, but the trial court dismissed their claims because a relative’s interest in a next of kin’s body was not a “property interest” under the Fourteenth Amendment’s Due Process Clause.12 The Sixth Circuit, however, was clearly troubled that people might not be protected if their bodies could not be considered property. If a woman’s husband died in a neighbor’s yard, one justice asked, should the neighbor simply be able to keep the body? To the appellate court, the answer was clear. Unanimously, the court ruled for the first time that next of kin have “a constitutionally protected property interest in the dead body of a relative.”13

Problems with patents

In jurisdictions where courts have found that people have no property right in their own tissue, plaintiffs have had to seek other legal remedies when their tissue was used in a way they did not intend.

For over a decade, Ashkenazi Jewish families of children with Canavan disease provided body tissue and money, and the Canavan Foundation and the National Tay-Sachs and Allied Disease Association provided money, to a geneticist so that he could sequence the genetic mutation that caused this devastating neurological disease. They intended the genetic sequence to be used to develop an affordable genetic test that doctors could use for both prenatal testing and to screen couples before they conceived children to determine if they were carriers of the disorder. The families had contacted this particular geneticist because he was active in using inexpensive Tay-Sachs screening to alert Ashkenazi Jewish families to their risk of having a child with that disorder.

But once the doctor identified the Canavan gene sequence, he and his hospital patented it without the knowledge or consent of any of the donors. The families and the nonprofit foundations convinced medical providers to offer free Canavan-gene testing, but the hospital—which now held the patent to the gene sequence, allowing it to control any testing or therapy related to the Canavan gene—demanded royalties for its use, raising the price of testing and forcing the free testing programs to close.14

The families and foundations sued. A
federal district court in Florida held that the plaintiffs had retained no property right to the tissue but that they could maintain a cause of action for unjust enrichment. "[T]he facts paint a picture of a continuing research collaboration that involved plaintiffs also investing time and significant resources in the race to isolate the Canavan gene," the court said.10

Unlike the plaintiffs in the Canavan case, most people whose tissue is mined for patentable genes do not even know they have been donors. When a person has a blood test or biopsy at a hospital, that tissue is often used for research or sold to biotechnology companies. Over 292 million archived and identifiable pathological specimens, from more than 170 million people, are currently stored in the United States. At least 20 million new specimens are added each year.

Some tissue samples are coded and not identified with specific individuals; others carry patient names or codes that allow personal identification. Virtually everyone has his or her tissue "on file."

It would not be surprising if, in the future, people whose tissue had been used for unauthorized purposes filed class actions for lack of informed consent, conversion, fraud, and unjust enrichment. Victims could allege several harms. Some people have lost their health insurance when their tissue was used for genetic research that indicated they had a higher-than-average risk of a particular cancer.11 And the royalties extracted by patent holders of people's tissues have added to skyrocketing medical costs. Some donors, had they been asked, might instead have chosen to give their tissue to researchers who would not have patented the genes.

Genetic tests where the gene has not been patented can cost less than $100. With a patent, the cost is significantly higher; for example, the tests for the BRCA 1 and 2 breast cancer genes cost around $3,000. The test is not much more expensive than others to perform, but the patent holder charges a royalty on top of the cost of performing the test, making it much
more expensive.

Already, one in four laboratories has stopped performing certain genetic tests because of patent restrictions or excessive royalty costs.26 Half have not developed any genetic tests for fear of running afoul of patent law.27 These problems are sufficiently troubling that the American College of Medical Genetics and the College of American Pathologists oppose gene patents as threatening medical advances and proper patient care.28

**Beyond consent**

Even when a person consents to a particular use of his or her tissue, doctors and researchers may go beyond what they've been authorized to do. Recently, members of an Arizona Native American tribe, the Havasupai, provided blood samples for research on diabetes. The Havasupai have one of the highest incidences of type 2 diabetes anywhere in the world. Over half the women and more than one-third of the men have it.

Members of the tribe alleged in a lawsuit that researchers at Arizona State University and the University of Arizona collected 400 blood samples from them for diabetes research, but also used those samples to perform unauthorized studies on schizophrenia, inbreeding, and population migration. The plaintiffs said the research on schizophrenia and inbreeding stigmatized them, and they claimed they would not have authorized the migration research because it conflicts with their religious beliefs.

A federal district court found that the Havasupai had valid claims for negligent and intentional infliction of emotional distress, civil rights violations, negligence, and gross negligence.29 The plaintiffs voluntarily dismissed the federal claims and are litigating the case in state court.

An appeal in the Eighth Circuit in *Washington University v. Catalona* also raises issues about research subjects' control over their tissue. Starting in the late 1980s, patients from all over the world came to Missouri to be treated for prostate cancer by renowned surgeon William Catalona and to participate in his research. The doctor collected tissue samples from thousands of patients for that purpose.

In 2002, Catalona moved from Washington University (WU) in St. Louis to Northwestern University in Chicago. Six thousand of his research subjects asked him to take their samples with him so that he could continue the research. But when he tried to transfer the tissue to Chicago, WU sued him, claiming that the tissue was the university's property.

Some of the research participants joined the case, arguing that they had given their tissue not to WU but specifically to Catalona for a particular purpose. They pointed out that the informed consent documents the signed reserved all sorts of rights to them, including the right to withdraw from the research and the right to order WU to destroy their samples. The documents specified that they were providing the tissue to Catalona for a study on the genetics of prostate cancer.

The patients also noted that federal research regulations forbid researchers and research institutions from forcing patients to waive their legal rights. In enforcement actions pursued by the U.S. Department of Health and Human Services, these rights have been interpreted to include patients' property rights to their own body tissue.30

But in April 2006, the federal district court for the Eastern District of Missouri ruled that the university owned the tissue and could do whatever it wanted with it. The court held that the patients' informed consent documents were "inconsequential." The case is currently being appealed.31

The judge seemed to say that people have fewer rights regarding their tissue than they would have with respect to any other item. The research subjects contend that the opposite is true: that people should have more, not less, to say about what happens to their own tissue.

Human tissue is irrevocably tied to a person. DNA profiling can always determine from whom that tissue came. Anything learned about the tissue is learned about the person. Therefore, tissue should never be used in a way that goes beyond the donor's consent.

The unwitting recipient of a hu-

**Existing U.S. laws do not require doctors to tell patients if their treatments are made from body tissue, and these treatments are not subject to the same FDA approval standards that drugs are.**
ovulate were not told that the injections came from the pituitary glands of human corpses. Now, some of those women are dying of CJD.28

**Poor oversight**

Existing U.S. laws do not require doctors to tell patients if their treatments are made from body tissue, and these treatments are not subject to the same FDA approval standards that drugs and medical devices are. European law is far stricter. A European Commission document recommended that the use of certain tissue, such as dura mater and auditory ossicles, be “banned or at least limited” because valid tests are not available to ensure that the tissue is disease-free.29

The FDA imposes tissue regulations through its Center for Biologics Evaluation and Research.30 As of 2005, tissue banks must comply with the FDA’s “current good tissue practice requirements.”31 These require facilities to test nearly all transplantable tissue for HIV and hepatitis, document their procedures, track the tissue’s distribution, and permit FDA inspections.32 Tissue processors must also prevent the “introduction, transmission, or spread of communicable diseases.”33 The problem, as some commentators have noted, is that the FDA does not have the resources to ensure compliance.34

Lawyers fighting on behalf of people who have received harmful tissue run into a number of stumbling blocks. Some states have shield laws that treat the provision of blood or tissue as a service and thus prohibit strict liability claims against blood banks or tissue banks.35 Plaintiffs in those states could bring negligence claims, although it might be hard to establish the appropriate standard of care. The American Association of Tissue Banks (AATB) has crafted standards for the industry, but accreditation is voluntary, so tissue processors have little incentive to comply with the association’s standards.36

Courts in some cases involving contaminated blood have used the American Association of Blood Banks’ standards and FDA regulations to establish a standard of care.37 Some professional organizations, such as the American Academy of Orthopaedic Surgeons, endorse the AATB’s standards for other tissue beyond blood.38 Based on their support, courts may be convinced

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*When someone has a blood test, that tissue can be used for research—or sold to biotech companies.*

Notes


7. Moore, 793 P.2d at 484.

8. Id. at 515-16 (Mosk, J., dissenting).


12. Id.

13. Id. at 1116.


15. Id. at 1072-73.


21. Id.


(8th Cir. May 16, 2006).
27. Id.
34. See Vangness et al., supra n. 30.

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