WHO Owns My Tissue?

When it comes to biological materials, personal property does not get any more personal. Or, does it?

J. Mark Waxman, Esq.
Foley & Lardner LLP

Recent court decisions could make it more difficult for scientists to individually secure usage rights for research involving the study of human biological materials, as patients and clinicians have begun to question exactly what is granted—and to whom it is granted—when a patient signs an informed consent agreement.

These court decisions deal largely with questions of ownership and commercial gain, and have not led to changes in existing federal guidelines for research involving human biological materials, which focus on ensuring ethical practices and protecting patient privacy rights. Indeed, there exists a delicate line between information that is scientifically valuable and information that potentially violates a patient's right to privacy. There is a concern that the research use of genetic information could infringe upon an individual's privacy and, if misused, could result in trauma or discrimination (e.g., paternity findings or diagnosis of incurable genetic disease). Researchers must be aware that patient concerns focus not only on privacy, but on questions of ownership, particularly as the commercial potential of donated biological materials is closer to being realized.

Where is the focus of any inquiry? The case law reveals that it involves a careful analysis of the substance and scope of informed consent. When must a specifically-defined, informed consent be obtained from subjects whose biological materials are to be donated to or stored in a biorepository?, What parameters must be specified within that consent document?

In general, written, informed consent should be obtained, without coercion, from each donor-subject whose data will be entered into the database, in accordance with the Department of Health and Human Services regulations at 45 C.F.R 46.116.

The applicable regulations mandate that the basic elements of informed consent should include "clear descriptions" of:

- the operation of the cell repository;
- the specific types of research to be conducted;
- the conditions under which data and specimens will be released to recipient-investigators; and
- procedures for protecting the privacy of subjects and maintaining the confidentiality of data.

Regulations also advise that informed consent documents not include any exculpatory language through which subjects are made to waive or appear to waive any legal rights, and that written descriptions of the nature and purpose of the research be as specific as possible.

But these guiding provisions, however comprehensive, fail to take into account the human and potentially emotionally-complicated relationship between a donor and his or her donated cells or tissues. In our age of biotechnology, of pharmacogenomics and "designer" embryos, patients are well aware that one's biological materials are truly personal and uniquely one's own. And for researchers to retain control of these unique materials and to preserve the integrity of their research, patients must understand the nature of their research participation and must be informed. Case-by-case judicial activity is now defining the standards of what constitutes and what is given by informed consent.

Washington University v. Catalona (2006)

Dr. William Catalona, developer of the prostate-specific antigen (PSA) test for prostate cancer, was employed by Washington University (WU), St. Louis, Mo., from July, 1976 through February, 2003. There, he was instrumental in developing a biorepository for the collection and storage of biological research materials—specimens of prostate tissue, blood, and DNA samples—for prostate cancer research.

The importance of informed consent should not be minimized.

When he left WU for a research position at Northwestern University, Dr. Catalona attempted to reclaim from WU those samples that had been collected from his own patients by mailing letters to his patients, asking them to request from WU that their tissues be transferred to another institution, for his use. Roughly 6,000 of the 10,000 patients whom Dr. Catalona solicited responded as he suggested. In response, WU filed suit for ownership of the samples, in August, 2003.

The 2006 decision from the US District Court in Missouri, ruled that the samples belong to WU, and Dr. Catalona's patients have no rights to relocate them. This decision was upheld by the Eighth Circuit Court of Appeals in 2007, and is consistent with laws governing property ownership and donation. The case of *Washington University v. Catalona* highlights the reality, that researchers themselves have limited rights over their own work, and provides a focal point by which to explore the question: In granting a researcher the right to explore our biological materials in the name of science, do we resign all rights to something that is uniquely our own?

The district court found, among other things, that WU had, at all times, exercised undisputed and exclusive possession over the samples in question, demonstrating *prima facie* evidence of ownership. The court ruled also that the samples had been donated to WU as gifts. Dr. Catalona appealed the decision.

The Eighth Circuit recently upheld the lower court's decision and affirmed that patients who make an informed donation of their biological materials for the purposes of medical research have no ownership interests in those materials and no ability to direct their transfer to anyone or anyplace else. The court found material support for its decision in the text of the signed informed consent documents, which bore the WU logo, characterized the patients' participation as a voluntary donation and indicated that the research would be conducted by Dr. Catalona or one of his colleagues. [Editor's note: Additional analysis can be found on *www.dddmag.com*]

Precendent: The question of ownership, and the value of consent

In deciding *Catalona*, the district court relied on two other well-publicized cases: *Moore v. Regents of the University of California* (1990) and *Greenberg et al. v. Miami Children's Hospital Research Institute, Inc., et al.* (2003). In both cases, patients sued researchers for patenting a cell line or gene isolated from samples without the donors' knowledge, and the challenges similarly revolved around the scope of informed consent.

Moore v. Regents

John Moore, a hairy-cell leukemia patient, sought treatment at the University of California Los Angeles (UCLA) Medical Center under the care of Dr. David Golde. In the course of Moore's clinical treatment, Dr. Golde extracted samples of blood, bone marrow, and other tissues; Moore also underwent a splenectomy. Without Moore's express consent, Dr. Golde eventually derived and patented a cell line derived from Moore's tissues.

Moore sued Dr. Golde, the Regents of the University of California (to whom the patent was assigned) and the patent licensees alleging among other things that his extracted cells had been used in commercially valuable research without his permission and that Golde had breached his disclosure obligations as a physician.

The California Supreme Court agreed that Moore did have a claim for breach of fiduciary duty and lack of informed consent because Dr. Golde had failed to disclose the extent of his research and his economic interest in Moore's cells. The court stated in its decision, that an adult of sound mind should have the power to decide whether or not to submit to lawful medical treatment. For that power to be effective, the court stated, a patient's consent must be informed consent.

Greenberg, et al. v. Miami Children's

In *Greenberg, et al.*, the "Greenberg" group of individuals and nonprofit institutions collaborated with Dr. Reuben Matalon to identify the gene responsible for Canavan disease. The individual members of the Greenberg group were parents of children afflicted with Canavan disease, who had collected blood and tissue samples from other Canavan families for the purposes of Dr. Matalon's research. Using these samples—and the information contained in a clinical and medical information database, also created by the Greenberg group—Dr. Matalon and his research team successfully isolated and patented the sequence of the Canavan gene.

The Greenberg group alleged that the commercial patent limited public access to potential therapies and sued Dr. Matalon and his institution.

The plaintiffs claimed, among other things, breached duty of informed consent and unjust enrichment. The Florida district court did find that Matalon and his group had unjustly benefited from the licensing fees negotiated under the commercial patent. However, the Florida court found no breach of duty of informed consent—because, as Dr. Matalon was not a treating physician to the Canavan patients or their families, the case involved no patient-physician relationship.

Implications and Regulations

Patients must be made to understand that their donations are just that: donations, over which they can exercise no future control beyond their de-identification. Hence, the realities of the right to withdrawal, and the use of anonymized samples, should be explicitly explained to patients. The possibilities of commercialization and restrictive patents should be discussed broadly—to make patients aware that profits might ultimately be realized but not shared.

The importance of informed consent should not be minimized. A careful review of the informed consent document and an extended conversation with a potential donor might prevent legal trouble and negative press for both researcher and institution.

J. Mark Waxman is a partner in the Boston office of Foley & Lardner LLP. He is the leader of the firm's health care industry team and a member of the white-collar defense and corporate compliance practice group.