

ARE THERE PROPERTY RIGHTS IN HUMAN TISSUE?

*The Law “Lacks” Definitive Answers**

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INTRODUCTION

The popularity of a recent nonfiction book about a woman whose cancerous cells refused to die has generated renewed interest in the subject of human tissue ownership. In *The Immortal Life of Henrietta Lacks*,¹ science writer Rebecca Skloot tells the compelling story of Lacks; her battle with cervical cancer; the scientific mystery surrounding the fact that a specimen of her cervical cancer removed in 1951 has remained viable in tissue culture ever since, providing a substrate for innumerable studies of cancer; and her children’s difficulty in reconciling her death with the continued life of her cells, which famously bore the first two letters of her first and last names, “HeLa.” The book has been a *New York Times* bestseller, was selected by National Public Radio as one of the top five books of the summer of 2010, and Oprah Winfrey has agreed to produce a movie version for Home Box Office. Immortal indeed.

But the publicity surrounding the story of a poor African American woman whose tumor cells were removed and used without her consent, overshadows the complex legal questions presented by Skloot’s narrative, which are far from black-and-white. Although never litigated, the Lacks case presents a useful framework for analyzing the legal issues that may arise when human tissues are used in medical research. It will also undoubtedly prompt questions and concerns from patients and their families, as well as physicians and their counsel.

In this article, I will provide an overview of the law governing the rights of patients and duties of physicians with respect to the use of excised human tissues. In Part One, I focus on the settled legal issues—principally, the federal statutory protections dealing with informed consent and patient privacy that have been enacted since Lacks’s death in 1951. In Part Two, I focus on the legal issues that are unsettled,² including the complex question of whether a property or other ownership “right” actually remains for tissues after they are removed from the body. Finally, in Part Three,

I provide some guidance for physicians who may be unsure of the extent of their obligations to discuss these complex issues with their patients.

I. FEDERAL STATUTES GOVERNING INFORMED CONSENT AND PATIENT PRIVACY

Of the many legal, ethical and moral issues presented by the Lacks case, two concerns seem to have amplified the volume of outrage directed by readers and reviewers toward Johns Hopkins University (“JHU”), whose hospital managed her care. The complaints are first, that Lacks never specifically consented to providing samples of her cervical tissue for research, and second, that JHU released her name and medical records to third parties without her or her family’s permission. Today, such conduct would violate two federal laws that govern patients’ rights to informed consent and that guarantee the privacy of their medical and other personal information. These laws include the Federal Policy for Protection of Human Research Subjects (also known as the “Common Rule”), and the Health Insurance Portability and Accountability Act (HIPAA).

The Common Rule is triggered whenever a patient (or even non-patient) participates as a human subject in federally funded medical research.³ It should be emphasized that the gravamen of the complaint against JHU’s treatment of Lacks does not involve her treatment as a *patient*, but rather her treatment as a *human subject*, that is, as a participant in medical research involving the human body or its parts. The primary purpose of the Common Rule is to ensure that human subjects participate voluntarily in medical research and provide their informed consent for any treatment they receive. Federal regulations spell out the specific duties and responsibilities of both the medical professional and the entity sponsoring the research. In particular, had the Common Rule been in place when Lacks’s tissue was removed and cultured in 1951, it would have prevented JHU from using her initials to identify her cells.

*This article is intended to provide general information only and should not be construed as legal advice. Physicians and other readers who seek additional guidance in this area should consult with their own legal counsel.

Another relevant legal development since Lacks's death was the passage of HIPAA in 1996. This federal statute applies to physicians, hospitals and other health care providers that electronically transmit health information with individual identifiers.⁴ HIPAA protects the privacy of a patient's medical records and requires disclosures to patients of any limitations on privacy rights, including, for example, disclosure to insurance companies for purposes of reimbursement. Author Skloot mentions HIPAA's protections in the *Afterword* to her book: "Because of [HIPAA], there is now clear federal law in place to prevent the kind of privacy violation that happened to the Lacks family when doctors at Hopkins released Henrietta's name and her medical records."

A third federal law that has relevance in this area but would not have been an issue in the Lacks case is the Genetic Information Nondiscrimination Act (GINA), enacted in 2008. GINA prohibits employers and insurance carriers from using a person's genetic information to deny employment, a benefit, or a health insurance or workers' compensation claim. It also requires consent to the removal or use of any genetic information. GINA issues come into play in this area when researchers are examining populations of patients with a particular illness or abnormality, or other discrete groups, such as Native Americans. The recent settlement between the Havasupai Indian Tribe and Arizona State University, discussed in the next section, illustrates the conflicts that may arise when biological materials are used for genetic research.

II. LEGAL DECISIONS REGARDING HUMAN TISSUE "OWNERSHIP"

There are very few reported legal opinions on the question of whether an individual retains an ownership interest in her tissues after they have been removed from her body. There is no binding legal precedent in Pennsylvania, or in the adjoining states of Delaware, Maryland, New York, or New Jersey, though every state or federal court that has considered the issue has rejected this notion.

The first and still the leading case in this area was decided in 1990. In *Moore v. Regents of the University of California*,⁶ a patient sued his physician and the physician's university employer after learning that samples of his tissues had been used to develop a profitable cell line without his knowledge. The patient, John Moore, had been treated for hairy cell leukemia and consented to a therapeutic splenectomy performed by his physician, Dr. David Golde. Dr. Golde used portions of the excised spleen tissue to develop a cell line that led

to a patent and substantial profits for the university. As part of his medical research and unrelated to the patient's care, he also took additional blood samples from Moore that had no therapeutic purpose.

In contrast to the Lacks case, Moore expressly consented to the removal of his tissues. He contended in the lawsuit, however, that Dr. Golde should have disclosed his "preexisting research and economic interests in the cells before obtaining consent to the medical procedures by which they were extracted." The court agreed with this argument under settled California law that a "reasonable patient would want to know whether a physician has an economic interest that might affect the physician's professional judgment."⁷

Although holding that Dr. Golde breached his fiduciary duty to disclose a commercial interest in Moore's excised tissues, the court rejected Moore's argument that Dr. Golde had committed the tort of 'conversion.' A cause of action for conversion is recognized when the plaintiff alleges that the defendant committed an unauthorized act that denied the plaintiff of his property—in this case, samples of Moore's own blood and spleen. The court rejected this theory of liability, distinguishing between Moore's legitimate and well-established interests in protecting his *privacy* and his "novel claim" that his tissues were his *property*. The cell line developed from Moore's tissues, the court concluded, is not Moore's property.

In reaching this conclusion, the court expressed the need to balance two competing interests: 1) that physicians recognize a "competent patient's right to make autonomous medical decisions;" and 2) that the courts "not threaten with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is, or may be, against a donor's wishes."⁸ The court also noted, "If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery."⁹ In short, Moore lost on his "novel" conversion theory. Instead, the court concluded that he had "donated" his tissues.

The *Moore* decision has guided other courts to the same conclusion. In the most recent case, decided in 2006, the only issue before the court was the legal ownership of samples of tissues that had been removed from the plaintiffs following therapeutic prostatectomies performed by their physician, Dr. William Catalona. At the time, Dr. Catalona was an employee of Washington University in St. Louis, Missouri. Unlike Moore and

Lacks, the patients in *Washington University v. Catalona*¹⁰ had expressly consented, in the form of a written agreement in compliance with the Common Rule and university policy, to the use of their excised tissues for medical research. The wrinkle in this case, however, was that these patients believed they had authorized the use of their tissues *solely for Dr. Catalona's research*. When he sought authorizations from these patients to take these tissues with him to another research center, Washington University sued to stop him under the theory that Washington University, and not the patients owned the tissues. The university claimed that the informed consent form signed by the patients established the university's contractual right to the tissues; it did not recognize or create property rights on behalf of the patients.

Although tissue rights advocates believed *Catalona* would establish, for the first time, an ownership right in human tissue, Washington University won, with the court applying Missouri law. While a decision of the California Supreme Court is not binding on Missouri, the *Catalona* Court found *Moore's* reasoning "persuasive." Echoing *Moore's* concerns about a "litigation lottery," the Court also asserted the following public policy rationale to support its holding:

*Medical research can only advance if access to [biological] materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a [research participant], 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.*¹¹

On public policy grounds more than on the basis of settled law, the *Moore and Catalona* decisions elevated the societal interest of promoting medical research over an individual's claim to ownership of her tissues. And the law generally has never recognized an ownership right even to one's own body – much less to one's excised tissues and cells. But many issues in this area remain unresolved.

In a case decided several years before *Catalona*, a federal district court applying Florida law rejected the claims of research subjects to a portion of the royalties earned from a gene patent developed from their tissues.¹² While finding for the defendant hospital, the court also recognized that "the question of informed consent in the context of medical research . . . is a

relatively novel one in Florida."¹³ The same can be said for Pennsylvania and other states.

Finally, in *Moore* itself, the California Supreme Court cautioned, "we do not purport to hold that excised cells can never be property for *any purpose whatsoever*."¹⁴ The recent settlement between members of the Havasupai Indian tribe and Arizona State University¹⁵ suggests that defendants in this area—and their counsel—are taking *Moore's* qualifying language seriously.

In the lawsuit, the Havasupai alleged that ASU researchers had collected blood samples to study the prevalence of diabetes in the tribe, but subsequently used them to study genetic markers for other disorders, including schizophrenia and alcoholism. The Havasupai claimed ASU had used the specimens beyond the scope of their informed consent and that the resulting research findings damaged their reputation and conflicted with their cultural beliefs.¹⁶ As the *New York Times* reported, "The case raised the question of whether scientists had taken advantage of a vulnerable population, and it created an image problem for a university eager to cast itself as a center for American Indian studies."¹⁷ While we will never know how a court would have resolved the tribe's claims, ASU's decision to settle signals the university's uncertainty about its ultimate success in litigation, or at least the risks of letting the case go to trial.

III. GUIDANCE FOR PHYSICIANS

What guidance can be given to practicing physicians in this largely unsettled and rapidly changing area of law? First, physicians who do not engage in medical research but only order or perform surgical or other invasive procedures for therapeutic purposes must only obtain the patient's informed consent for the procedure. There is currently no duty, under federal or Pennsylvania law, to disclose to the patient what will happen to the removed tissues. In fact, Pennsylvania and most other states treat such tissues as biological waste and require its incineration or other method of disposal under strict environmental regulations.

Second, physicians who engage in medical research should principally be guided by the policies and procedures of their employing or sponsoring institutions. Lancaster General Hospital ("LGH"), for example, requires patients to sign a general consent form that includes the following statement: "I hereby authorize LGH to retain, preserve, and use for scientific or teaching purposes, or dispose of at its discretion, any

*According to LGH Associate General Counsel Christopher M. O'Connor, LGH physicians who are engaged in medical research must obtain written, informed consent from human subjects, which may also address tissue ownership.

specimens or tissues taken from my body during my care.”* Guided by *Moore* and other legal precedents, it is likely that a reviewing court in Pennsylvania would view this language as negating a patient’s claim to ownership of her removed tissues. On the other hand, this language limits LGH’s use of the tissues to “scientific or teaching purposes.” If LGH uses the tissues for a commercial purpose, could the patient claim a right to share in any royalties or profits derived from her tissues? While there is no definitive answer under Pennsylvania law, the *Moore* line of cases strongly suggest that no such right would exist outside a valid contract between the parties that expressly contemplated commercial use.

Another source of guidance for physicians derives from the medical profession itself and rests on ethical rather than legal concerns. In 1994, the American Medical Association issued the following guidelines regarding the commercial use of human tissue:¹⁹

1. Informed consent must be obtained for the use of organs or tissues in clinical research.
2. Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials.

3. Human tissue and its products may not be used for commercial purposes without the informed consent of the patient before a profit is realized on products developed from biological materials.
4. Profits from the commercial use of human tissue and its products may be shared with patients, in accordance with lawful contractual agreements.
5. The diagnostic and therapeutic alternatives offered to patients by their physicians should conform to standards of good medical practice and should not be influenced in any way by the commercial potential of the patient’s tissue.

The AMA Guidelines thus expand a physician’s obligation to obtain a patient’s informed consent for: 1) using the tissue in clinical medical research; and 2) using the tissue for commercial purposes. Interestingly, the Guidelines also recognize that the law of contract, not property, should govern arrangements between a physician and patient in this area. Of course, for a contract to be valid, both parties must be fully cognizant of the rights and obligations created by a written instrument. That will not always be the case, as the story of Henrietta Lacks, as told by Rebecca Skloot, should remind us.

REFERENCES

1. Rebecca Skloot, *The Immortal Life of Henrietta Lacks* (New York: Random House, 2009).
2. While the issue is beyond the scope of this article, the law has not even clearly resolved whether there is any ownership right at all to one’s body (whether living or dead) or its component parts. See e.g., Charo, R.A., “Body of Research - Ownership and Use of Human Tissue,” *N.Eng.J.Med.* 355:15 (Oct. 12, 2006).
3. The U.S. Department of Health and Human Services regulations implementing the “Common Rule” are codified at 45 C.F.R. §46.101 et seq. See 42 U.S.C. §1320d-1(a).
4. *Immortal Life* at p. 319.
5. 793 P.2d 479 (Ca. 1990).
6. *Id.* at 483.
7. 793 P.2d at 493.
8. *Id.* at 495-96.
9. *Washington University v. Catalona*, 437 F.Supp.2d 985 (E.D. Mo. 2006).
10. 437 F.Supp.2d at 1002.
11. *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*, 264 F.Supp.2d 1064 (S.D. Fla. 2003).
12. 264 F.Supp.2d at 1069.
13. 793 P.2d at 493.
14. See Amy Harmon, “Indian Tribe Wins Fight to Limit Research of Its DNA,” *New York Times*, April 21, 2010.
15. Published articles based on this research concluded that the tribe had experienced a high degree of inbreeding and that its ancestors came from outside North America—well beyond the Arizona canyon which the tribe believed had been its only home. *Id.*
16. *Id.*
17. For a more detailed legal perspective on this case and a proposed “tiered” approach to the complex issue of informed consent in medical research, see Michelle M. Mello and Leslie E. Wolf, “The Havasupai Indian Tribe Case - Lessons for Research Involving Stored Biologic Samples,” *N.Eng.J. Med.* 363:3 (July 15, 2010).
18. American Medical Association, *Opinion 2.08—Commercial Use of Human Tissue*, 1994 (reprinted with permission).

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