

Saint Louis University Public Law Review

Volume 26

Number 2 *International Law, the Courts, and the Constitution* (Volume XXVI, No. 2)

Article 8

2007

Who Owns My Donated Tissue? The Public's Prostate Inflammation: A Casenote on Washington University v. Catalonia

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Recommended Citation

Gamber, Jeff (2007) "Who Owns My Donated Tissue? The Public's Prostate Inflammation: A Casenote on Washington University v. Catalonia," *Saint Louis University Public Law Review*: Vol. 26 : No. 2 , Article 8.
Available at: <https://scholarship.law.slu.edu/plr/vol26/iss2/8>

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**WHO OWNS MY DONATED TISSUE? THE PUBLIC'S PROSTATE
INFLAMMATION: A CASENOTE ON *WASHINGTON UNIVERSITY v.
CATALONA***

I. INTRODUCTION

“It’s been in there for a year, and it’s ghastly.”¹ Larry Johnson, former executive of Alcor Life Extension Foundation, was referring to the cryonically frozen head of former Major League Baseball player, Ted Williams. At death, Williams purportedly had his head and body frozen separately in the hopes that future technological advancements could resurrect him.² However, serious doubts exist as to whether Williams ever intended to be placed in such a facility.³ Further, one can be sure he never meant for someone to refer to his frozen, decapitated head as “ghastly.”⁴ Is there a remedy at this point? Does the Williams family have control over his body? Should Williams even be classified as dead?⁵ Instead, presume Williams donated his head for research (premised on grounds he might want it back someday), does it then follow that once the donation is made, he loses all ownership rights to that donation?

Ted Williams’ head is an abstract (albeit grotesque) analogy to *Washington University v. Catalona*, a case currently pending in United States Court of Appeals for the Eighth Circuit.⁶ The issue in *Catalona* is whether donors of prostate tissue samples for research purposes have any rights to those tissues once the physical donation has been made.⁷ *Catalona’s* importance cannot be understated. According to one observer, “[T]he *Catalona* case raises a series

1. Richard Sandomir, *Ted Williams Tale Gets Stranger by the Day*, N.Y. TIMES, Aug. 14, 2003, at D2 (quoting Larry Johnson, former Chief Operating Officer of Alcor Life Extension Foundation).

2. *Id.*

3. Tom Verducci, *What Really Happened to Ted Williams: A Year after the Jarring News that the Splendid Splinter was being Frozen in a Cryonics Lab, New Details, Including a Decapitation, Suggest that One of America’s Greatest Heroes May Never Rest in Peace*, SPORTS ILLUSTRATED, Aug. 18, 2003, at 66.

4. Sandomir, *supra* note 1.

5. *See Alcor Life Extension Found., Inc. v. Mitchell*, 9 Cal. Rptr. 2d 572, 575-576 (Cal. Ct. App. 1992) (The court did not rule out the possibility of revival of cryonically frozen bodies, but stated that “those persons who will then head our various branches of government will be far wiser than we and entirely capable of resolving such dilemmatic issues without our assistance.”).

6. *Washington Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006).

7. *Id.* at 987.

of questions whose answers will shape the evolving law of research on body tissue.”⁸ More importantly, this case’s outcome will affect more than just a handful of people. According to a 1999 report by the RAND Corporation, over 307 million tissue samples from more than 178 million people were stored in the United States, increasing by a rate of 20 million samples each year.⁹ The samples are collected from routine medical tests, operations, clinical trials, and research donations, such as the one presently in question.¹⁰ Thus, *Catalona* has the potential to be a “landmark” case in the field of property rights and biological materials.¹¹

In order to investigate *Catalona*’s potential impact, the case will have to be examined. First, the case’s basic facts will be laid out. Second, various property arguments will be examined including whether exclusive possession and control of a biological sample determines ownership and whether the donations were inter vivos gifts or bailments. Clarifying the property rights issues will be helpful but not determinative. Finally, the fact that tissue donations are biological materials further complicates matters because federal regulations will be implicated, at least to some extent, if the research involves human subjects. But does research involving stored tissue constitute research involving human subjects? Would severing any identifying informational ties linking the sample to the donor (a process called anonymization) eliminate the involvement of human subjects? If not, donors must give informed consent prior to participating in the research. However, it is often unclear as to what exactly they are consenting. Ambiguity also exists as to what should happen when participants decide to withdraw from the research. What happens to a donor’s unused samples? An examination of all of the above questions will hopefully clarify the case of *Washington University v. Catalona*.

8. Lori Andrews, *Who Owns Your Body? A Patient’s Perspective on Washington University v. Catalona*, 34 J.L. MED. & ETHICS 398, 399-400 (2006). In fact, Andrews’ article included a bit of the history of a patient owning his own tissue outside of his body. *Id.* at 400. She stated that the common law did not allow people to have property rights to their body. *Id.* Interestingly, she stated, “[T]he common law basis for preventing people from voluntarily transferring their body parts . . . may not have its roots in the view that the body is sacred and that people should not be objectified as property. Rather, it may arise from the notion that people’s bodies were the property of the Crown.” *Id.* If they maimed their body, they could not fight for the king. *Id.* That ended by 1804, apparently, as her research uncovered a story from England in 1804 where a creditor arrested a dead body for a debt. *Id.*

9. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr. 16, 2006, at § 6. Doing the math, there should be 467 million tissue samples in the U.S. by 2007. *Id.*

10. *Id.*

11. *Id.*

II. BACKGROUND OF *WASHINGTON UNIVERSITY V. CATALONA*—WHAT HAPPENED?

A. *Facts of the Case*

Washington University (WU) is a private research university with a medical school which includes the Division of Urologic Surgery.¹² William Catalona (Catalona), an urologist, surgeon, and researcher, worked in the Urology Division at WU from 1976 to 2003,¹³ and he was Chief of the Division from 1984 to 1998.¹⁴ Catalona's research focused on prostate cancer, and through thousands of surgeries at WU, he collected many research samples from the excised, cancerous tissues of patients.¹⁵ Some of those patients became research participants (RPs) and subsequently plaintiffs in the case at bar. The patients' samples were stored in the Genito-Urinary Biorepository (Biorepository), which Catalona was "instrumental" in establishing.¹⁶

The Biorepository is operated by WU and is used strictly for research purposes.¹⁷ WU employees administer it, and WU provides the majority of funding to operate and maintain it.¹⁸ The Biorepository holds "biological specimens of prostate tissue, blood, and DNA samples . . ." collected not only from Catalona's surgeries but also from other WU physicians and outside researchers, as well.¹⁹ Of the 30,000 research participants in prostate cancer studies, only about 3,000 were patients of Catalona, and those patients only donated a total of 3,500 prostate tissue samples.²⁰

WU has instituted a process to distribute samples from the Biorepository to outside researchers. In 2002, WU created a Peer Review Panel which handled all sample requests from the Biorepository, including those from researchers outside WU.²¹ Prior to leaving WU, Catalona submitted three sample requests that were approved, but he did not subsequently request any other samples via the Peer Review Panel.²²

12. *Catalona*, 437 F. Supp. 2d at 988.

13. *Id.*

14. *Id.*

15. *Id.* It is interesting to note that the research participants (RPs) in this case were patients of Catalona, and they referred to themselves collectively as "patients," not "research participants," in all of their briefs. However, since the district court referred to them as RPs throughout its opinion, that is how they will be referred to here.

16. *Id.*

17. *Id.* at 989.

18. *Catalona*, 437 F. Supp. 2d at 989.

19. *Id.* at 988-89.

20. *Id.* at 988-89.

21. *Id.* at 993.

22. *Id.* at 993-94.

Further research institutions have procured research samples from the Biorepository, subject to Material Transfer Agreements (MTA).²³ The MTAs were required for studies which occurred either outside of or in partnership with WU.²⁴ Seven MTAs, signed by Catalona himself, acknowledged WU as the owner of the samples.²⁵ In one instance, Catalona attempted to change the MTA to assert co-ownership of the samples with WU, but when WU refused to alter it, Catalona signed it nonetheless.²⁶

WU had an Intellectual Property Policy, which stated:

[A]ll intellectual property (including . . . tangible research property) shall be owned by [WU] if significant [WU] resources were used or if it is created pursuant to a research project funded through corporate, federal, or other external sponsors administered by [WU] . . . [G]enerally, creators and research investigators will retain custody of tangible research property while at [WU].²⁷

As defined, “tangible research property” includes biological materials, owned by WU per the agreement.²⁸ Both the Intellectual Property Policy and the MTAs were used as evidence to show that WU had held the property rights to the samples, not the RPs or Catalona.²⁹

RPs in WU studies had to sign “informed consent” forms, which bore the WU logo.³⁰ The forms stated that the RPs could not claim ownership rights to any product resulting from the research.³¹ The forms further stated that the biological donations were “a free and generous gift of [blood, tissue, and/or DNA] to research that may benefit others.”³² The forms also provided for withdrawal from research, stating “you may choose not to participate in this research study or withdraw your consent at any time.”³³ The forms were silent on the issue of whether RPs could withdraw their previously-donated samples or transfer them to another facility.³⁴ However, testimony at trial showed that once RPs chose to withdraw from participation, WU had three options concerning the previously-donated tissue: destroy the samples, store them indefinitely, or “anonymize” them.³⁵

23. *Id.* at 989.

24. *Catalona*, 437 F. Supp. 2d at 989.

25. *Id.*

26. *Id.* at 995.

27. *Id.* at 989 (quoting Plaintiff’s Exhibit 17, § 1.3(a)).

28. *Id.* at 995.

29. *Id.*

30. *Catalona*, 437 F. Supp. 2d at 990.

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 992. In anonymizing a sample, all information linking the donor to the sample is destroyed. *Id.* at 992, n.10.

In addition to the informed consent forms, RPs were also given (purportedly to sign) a “WU Genetic Research Brochure,” which stated that if an RP decided to withdraw, “you should call the investigator listed on the consent form, [y]our tissue will be identified and destroyed upon request,” and “any research results already obtained cannot be destroyed or recalled.”³⁶ Like the informed consent form, the brochure was silent as to whether RPs could withdraw their previously-donated samples or transfer them to another facility.³⁷

In early 2003, Catalona left WU to continue his prostate cancer research at Northwestern University.³⁸ Prior to doing so, he sent letters to 60,000 RPs, even those that were not his patients, informing them of his intent to leave WU.³⁹ Catalona asked the RPs to sign an attached “Medical Consent & Authorization” form, which purportedly allowed all samples to be released to Catalona.⁴⁰ Six thousand RPs returned a signed form.

B. Procedural History

WU filed a declaratory judgment action in the United States District Court for the Eastern District of Missouri to settle the ownership dispute over the samples.⁴¹ Catalona was the original defendant, and the RPs later intervened.⁴² Concerning the issue of ownership, the district court held a preliminary injunction hearing that included all parties, including the RPs, in April 2005.⁴³ A decision on the injunction was issued on March 31, 2006⁴⁴ and is currently on appeal in the Eighth Circuit.⁴⁵ Oral arguments concerning the appeal were heard on December 13, 2006,⁴⁶ and an opinion is expected in the summer of 2007.

III. DISTRICT COURT’S CONCLUSIONS

The district court stated that the sole issue in the case was ownership, and asked whether “[T]he research participants retain ownership rights in such materials in that they can direct said materials’ use and transfer to third-

36. *Catalona*, 437 F. Supp. 2d at 990.

37. *Catalona*, 437 F. Supp. 2d at 990.

38. *Id.* at 993.

39. *Id.*

40. *Id.*

41. *Id.* at 987.

42. *Id.* at 989 n.5.

43. *Catalona*, 437 F. Supp. 2d at 988.

44. *Id.* at 985.

45. The case numbers are No.06-2286 and No.06-2301.

46. Oral arguments are available for listening online at the United States Court of Appeals for the Eighth Circuit’s website, <http://www.ca8.uscourts.gov/tmp/062286.html> (last visited Jan. 21, 2007).

parties.”⁴⁷ The court concluded that WU owned the tissues because it had exclusive possession and control over them, and the RPs had not produced sufficient evidence to overcome that.⁴⁸ With WU having ownership, the RPs retained no right to transfer.⁴⁹ Further, the court found that the WU obtained the samples via *inter vivos* gifts, not as bailments as the RPs had suggested.⁵⁰ However, the issues in this case were clouded because there were special considerations concerning biological materials, such as informed consent forms and a RP’s right to discontinue participation in research.

IV. PROPERTY ARGUMENTS: DOES EXCLUSIVE POSSESSION AND CONTROL DETERMINE OWNERSHIP? DID WU ACQUIRE SUCH POSSESSION VIA INTER VIVOS GIFTS OR BAILMENTS?

The sole issue in *Catalona* is whether WU or the RPs own the tissue samples, and to what extent. The fact that the samples in question are biological materials will cloud the analysis of ownership and control, but a proper analysis begins by first examining the issue as if the samples were general personal property. Next, the issue of how property is transferred via an *inter vivos* gift will be examined. The last property-based argument to be discussed is an alternative legal explanation that the samples instead were bailments, with WU as bailee.

A. *Property Ownership, Generally*

Property ownership is relatively straightforward. In Missouri, where the events in *Catalona* occurred, a *prima facie* case of ownership is established by meeting both requirements of a two-part test: (1) exclusive possession and (2) control of the personal property.⁵¹ The non-possessor bears the burden of establishing ownership by a preponderance of the evidence.⁵² For example, in *Foltz v. Pipes*, two brothers argued over the ownership of a coin.⁵³ Since the defendant brother had exclusive possession and control of the coin, the court held he had *prima facie* evidence of ownership.⁵⁴ The plaintiff could not meet his burden of establishing ownership by a preponderance of the evidence.⁵⁵

In *Catalona*, the court framed the issue as whether the RPs retained ownership rights of their samples to such an extent that they could transfer

47. *Catalona*, 437 F. Supp. 2d at 994.

48. *Id.* at 997.

49. *Id.*

50. *Id.* at 997, 1001.

51. *Id.* at 994 (citing *Foltz v. Pipes*, 800 S.W.2d 14, 15 (Mo. Ct. App. 1990)).

52. *Id.*

53. *Foltz*, 800 S.W.2d 14 (Mo. Ct. App. 1990).

54. *Id.* at 15.

55. *Id.*

them to third parties.⁵⁶ The court noted that Missouri law governs the substantive issues of property ownership, and followed the two-part test of exclusive possession and control.⁵⁷ The court concluded that WU had been in exclusive possession of the samples, and that this point was undisputed.⁵⁸ Further, WU owned, maintained, and funded a majority of the Biorepository.⁵⁹ The court also concluded that WU had control over the samples, too.⁶⁰ WU controlled who had access to the samples and bore “all legal, regulatory, and compliance risks,” and WU was responsible for complying with all federal and state laws and regulations.⁶¹

The court stressed that WU had continually asserted its ownership in the samples, first in its Intellectual Property Policy (IPP) and again in its MTAs.⁶² The IPP stated that tangible research property “shall be owned by [WU] if significant [WU] resources were used.”⁶³ The MTAs also acknowledged WU as the owner of samples, and WU refused Catalona’s request to assert co-ownership over them,⁶⁴ Catalona signed the MTAs, nonetheless.⁶⁵ Thus, WU’s strongest claim was possession,⁶⁶ and the court concluded that WU had exclusive possession and control over the samples.⁶⁷ Having possession and control established, the next issue was how WU acquired the samples—were they *inter vivos* gifts or bailments?

B. *Inter Vivos Gifts*

The next issue discussed in *WU v. Catalona* was whether the samples constituted an *inter vivos* gift from the RPs, and if so, to whom.⁶⁸ In Missouri, an *inter vivos* gift of personal property requires three elements: 1) the donor’s present intention to make a gift; 2) delivery of the property by the donor to the donee; 3) acceptance by the donee.⁶⁹ Upon acceptance, the donee takes ownership “immediately and absolutely.”⁷⁰ The donee has the burden of proving ownership with clear and convincing evidence, which can be

56. *Catalona*, 437 F. Supp. 2d at 994.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 994-95.

62. *Catalona*, 437 F. Supp. 2d at 995.

63. *Id.* at 989.

64. *Id.* at 995.

65. *Id.*

66. Andrews, *supra* note 8, at 402.

67. *Catalona*, 437 F. Supp. 2d at 997.

68. *Id.*

69. Duvall v. Henke, 749 S.W.2d 714, 716 (Mo. Ct. App. 1988).

70. *Id.*

determined not only through specific language, but also by examining the circumstances surrounding the action.⁷¹

In *Catalona*, the court found the circumstances surrounding the donations constituted clear and convincing evidence that the RPs made inter vivos gifts to WU.⁷² First, the court found that the informed consent forms showed the RPs had the present intention to make a gift.⁷³ The forms, bearing the WU logo, did not state that Catalona would have sole possession of the samples, and they included language that the research would be conducted by “Catalona and/or colleagues.”⁷⁴ Moreover, the forms used the term “donation,” and at least some of the forms referenced a waiver of claims to the samples.⁷⁵ Thus, present intent to make a donation was clear, and since a completed inter vivos gift cannot be revoked, the RPs’ desires to later transfer the samples were merely “afterthought[s] of regret.”⁷⁶ Thus, the court found the RPs had the present intent to make a gift.⁷⁷ Second, it was undisputed that the RPs “delivered” the property, presumably since they had possession of the samples before surgery, and following surgery WU had possession. Lastly, the court found that WU accepted the samples by placing them in the Biorepository and claiming ownership.⁷⁸ Thus, the court concluded that the RPs donated their samples as inter vivos gifts, which could not be revoked.

The RPs had a counterargument, though. First, the RPs that testified denied making an unconditional gift, and Catalona denied receiving an unconditional gift.⁷⁹ The RPs argued that conditions attached to the donation that afforded the RPs additional rights in the samples.⁸⁰ Thus, the RPs argued that even if the donations were characterized as gifts, they were conditional gifts whose conditions would not be satisfied with WU as the owner.⁸¹ The RPs claimed they went to WU merely to see Catalona; as such, the gifts were made on the condition that Catalona and his designees would use the samples,

71. *Id.*

72. *Catalona*, 437 F. Supp. 2d at 997.

73. *Id.*

74. *Id.* (emphasis added).

75. *Id.* at 999.

76. *Id.* at 999. The court showed some empathy for the RPs attempt to help Catalona retrieve their samples, but then the court discredited their testimonies by implying a bias due to a “deep personal connection to Dr. Catalona” because he saved their lives. *Id.*

77. *Id.* at 998. However, the court noted that the informed consent forms were “inconsequential” because a gift does not require written documentation; federal regulations required it here, though, because it concerned a biological material. *Id.* Curiously, the court’s opinion suggested that the finding of intent was based mostly on these “inconsequential” informed consent forms, restating no other evidence.

78. *Catalona*, 437 F. Supp. 2d at 998.

79. Andrews, *supra* note 8, at 402.

80. *Id.*

81. *Id.* at 403.

not WU.⁸² With Catalona gone, WU could not meet that condition.⁸³ The RPs supported their argument by noting that Catalona was an “internationally known prostate cancer surgeon and researcher.”⁸⁴ A brief glance at Catalona’s website confirmed his notoriety; he developed the PSA screening test for prostate cancer.⁸⁵ It would be absurd to question his skill or accomplishments as a surgeon and researcher. But did Catalona’s skill mean that the RPs wanted only him to use their tissues in research, as opposed to WU? One observer believed so, analogizing that “just because a person trusts his son to drive his car, despite the fact that the son might get in an accident, does not mean that the person has given up ownership of the car or that the person is indifferent to who drives his car.”⁸⁶

C. *Bailment*

The RPs, however, did not believe they made inter vivos gifts to WU. Instead, they argued the samples were bailments, not gifts, and WU was merely a bailee.⁸⁷ A bailment is “a contract resulting from the delivery of goods by bailor to bailee on condition that they be restored to the bailor . . . [once] the purposes for which they were bailed are answered.”⁸⁸ In other words, a bailment occurs when one party hands possession of personal property to another with the expectation that it will be returned in the future.⁸⁹ A bailment can be expressed or implied.⁹⁰ The RPs have since made the analogy (during oral arguments on appeal) to the United Parcel Service, noting that with packages, there is a bailment relationship even though the customer has no expectation of return.⁹¹ If the donations were bailments, then the RPs could retain ownership rights of the samples even after WU took possession.

The District Court rejected the RPs’ bailment argument, noting that they had no expectation of having the samples returned, nor was any evidence

82. *Id.*

83. *Id.*

84. *Id.* at 398.

85. Dr. Catalona – Prostate Cancer, PSA Study, and Nerve Sparing Prostate Surgery, <http://www.drcatalona.com> (last visited Jan. 31, 2007).

86. Andrews, *supra* note 8, at 401.

87. *Catalona*, 437 F. Supp. 2d at 1001.

88. *Seitz v. Lemay Bank & Trust Co.*, 959 S.W.2d 458, 461 (Mo. 1998).

89. SANDRA H. JOHNSON, PETER W. SALSICH, JR., THOMAS L. SHAFFER & MICHAEL BRAUNSTEIN, *PROPERTY LAW* 30 (West Group 2d ed. 1998).

90. *Id.* at 31. The authors gave an example of a person tossing car keys to another. *Id.* Although not expressed, a court would imply a bailment, guessing that there was a change in possession with the expectation to have the car returned. *Id.*

91. Recordings of Oral Arguments, *Washington Univ. v. Catalona*, No. 06-2286, 06-2301 (8th Cir. Dec. 13, 2006), *available at* <http://www.ca8.uscourts.gov/tmp/062286.html> (last visited Jan. 21, 2007).

presented to that effect⁹² The court concluded the sample donations were not bailments.⁹³ However, the RPs were not finished arguing for ownership or recognition of a bailment, addressing the elephant in the room—that these samples were not simple personal property but instead biological materials.

V. FEDERAL REGULATIONS AND BIOLOGICAL MATERIALS: IF THE RESEARCH INVOLVES HUMAN SUBJECTS, THEN RESEARCHERS MUST OBTAIN INFORMED CONSENT AND ALLOW THE PARTICIPANT TO HAVE THE RIGHT TO WITHDRAW FROM THE STUDY

A wide range of special considerations exist in cases involving biological materials. These include the protection of human subjects, informed consent, and the right to discontinue participation, each of which is subject to some form of federal regulation. The U.S. Department of Health and Human Services (DHHS) oversees the protection of human research subjects, issuing federal regulations known informally as the “Common Rule.”⁹⁴ The Office of Human Research Protection (OHRP) is responsible for enforcing these DHHS regulations by investigating complaints and conducting audits.⁹⁵ The OHRP has a duty to protect volunteers in research supported by DHHS.⁹⁶

Federal regulations are important in research. A Consensus Statement printed in the *Journal of the American Medical Association* stated, “[M]uch weight is given to federal regulations regarding the protection of human subjects both because they are legally enforceable and because they are the embodiment of an attempt to strike a balance between the desire to increase knowledge and the protection of individual interests.”⁹⁷ Although the court’s decision had an emphasis on property law, federal regulation played a role in that decision. First, however, it must be determined that the federal regulations apply in this case. Following that, specific federal regulations will be

92. *Catalona*, 437 F. Supp. 2d at 1001.

93. *Id.* at 1001.

94. BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, *BIOETHICS: HEALTH CARE LAW AND ETHICS* 420 n.1 (5th ed. 2004).

95. *Id.* at 421 n.7.

96. OHRP Fact Sheet, <http://www.hhs.gov/ohrp/about/ohrpfactsheet.htm> (last visited Jan. 21, 2007).

97. Ellen Wright Clayton et al., Consensus Statement, *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 *JAMA* 1786, 1787 (Dec. 13, 1995). The article clarifies the authors of the article, “A WORKSHOP consisting of scientists, ethicists, lawyers, and consumers was convened jointly by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) on July 7 and 8, 1994, at the NIH to develop recommendations for securing appropriate informed consent when collecting tissue samples for possible use in genetic research and for defining indications for additional consent if samples in hand are to be used for genetic studies. The analysis that follows represents the consensus of the individuals listed . . . (although not all signers agreed with every point) and is not the official policy of the NIH and the CDC.” *Id.* at 1786.

examined, including those on informed consent and the right to discontinue or withdraw from participation in research.

A. *Threshold Issue: Do Federal Regulations Apply to Catalonia?*

Both WU and the research itself must meet certain criteria in order for the Common Rule, concerning research on human tissues, to apply. The requirements for application of the Common Rule can be found directly in the Code of Federal Regulations, which states:

[T]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.⁹⁸

Relative to *Catalonia*, two particular aspects need to be examined. First, was WU's research "conducted, supported or otherwise subject to regulation by any federal department or agency" (i.e. is WU subject to federal regulation?), and second, did the research conducted on stored prostate tissue samples involve human subjects?

1. Is Washington University subject to the Federal regulations?

Technically, the Common Rule only applies to research either funded by the federal government or subject to federal regulation.⁹⁹ Often, however, as a condition of receiving any federal funding, an academic institution must agree to apply the Common Rule to all academic research.¹⁰⁰ This is done using a formal agreement called an assurance, which requires institutions (like Washington University, for example) to comply with the Common Rule.¹⁰¹ The academic institution makes the assurance to the DHHS (via the OHRP).¹⁰² In the assurance, the institution agrees to follow DHHS regulations in all research, even projects not federally funded or otherwise subject to federal regulation.¹⁰³ The OHRP has the authority to take action in response to violations of the assurance, but in *Catalonia*, it took no action against WU.¹⁰⁴ Neither WU nor the RPs directly objected that the Common Rule did not apply to WU.

98. 45 C.F.R. § 46.101(a) (2005).

99. FURROW ET AL., *supra* note 93, at 420 n.1.

100. *Id.*

101. OHRP Fact Sheet, *supra* note 95.

102. FURROW ET AL., *supra* note 93, at 420 n.1.

103. *Id.*

104. *Catalonia*, 437 F. Supp. 2d at 992.

2. Does research on stored human tissue involve “human subjects?” If so, does severing the informational link between a sample and its donor change the result?

In order for research to be subject to federal regulation, it must involve “human subjects.”¹⁰⁵ It would be difficult to deny that the RPs were not human subjects at the time the tissue was removed and donated, especially after hearing their testimony in this case. However, an indirect, unstated argument laid beneath the surface. In testimony at trial, WU stated that one option it had concerning the previously-donated tissue samples was to “anonymize” them.¹⁰⁶ In anonymizing a sample, all identifying information linking the donor to the sample is destroyed.¹⁰⁷ The argument is that once identifying information was removed, the sample no longer involved a human subject because it could not be traced back to any particular person.¹⁰⁸

This indirect argument that anonymizing a sample would exclude it from the Common Rule¹⁰⁹ has some basis in the Code of Federal Regulations:

- (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories *are exempt from this policy*:

....

- (4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or *if the information is recorded by the investigator in such a manner that subjects cannot be identified*, directly or through identifiers linked to the subjects.¹¹⁰

Thus, two criteria exist for the use of anonymous samples.¹¹¹ First, the samples must already exist at the beginning of the research; second, identifiers linking the subjects to their samples must be removed.¹¹² If both elements are met, then a human subject is no longer involved.¹¹³ The effect is that the Common Rule would not apply, and informed consent would not be required.¹¹⁴ The National Bioethics Advisory Commission (NBAC), created

105. 45 C.F.R. § 46.101(a) (2006).

106. *Catalona*, 437 F. Supp. 2d at 992.

107. *Id.* at 992, n.10.

108. NATIONAL BIOETHICS ADVISORY COMMISSION, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 15 (1999).

109. *See Andrews*, *supra* note 8, at 398 n.1.

110. 45 C.F.R. § 46.101(b)(4) (2006) (emphasis added).

111. Clayton et al., *supra* note 96, at 1787.

112. *Id.*

113. NATIONAL BIOETHICS ADVISORY COMMISSION, *supra* note 107, at 15.

114. *Id.*

by former President Bill Clinton,¹¹⁵ seemed to agree, stating that as long as those two requirements are met, the Common Rule permits researchers to take and use samples, even without a subject's consent.¹¹⁶

It is not clear how complete the severance must be, though. Some claim that it must be "impossible under any circumstances to identify the individual source" of the sample, and that even the institution must not have the ability to do so.¹¹⁷ However, this may be an extreme view. New guidance from the OHRP suggested that when the sample has been coded and the researcher does not have access to the key, then it would no longer involve a human subject.¹¹⁸ The OHRP's guidance on the subject stated:

OHRP does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

115. Exec. Order No. 12,975, 60 Fed. Reg. 52,063 (Oct. 3, 1995). The NBAC's functions included:

(a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters: (1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and (2) applications, including the clinical applications, of that research. (b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles. (c) NBAC shall not be responsible for the review and approval of specific projects. (d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

60 Fed. Reg. at 52,063-64.

Incidentally, the current NBAC was created in 2001 by President George W. Bush as the President's Council on Bioethics, advising him on bioethical issues that emerge "as a consequence of advances in biomedical science and technology." Exec. Order No. 13,237, 66 Fed. Reg. 59,851 (Nov. 28, 2001). The Council does not oversee regulations for government agencies; its purpose is solely to advise the President. *Id.* The NBAC was renewed through September 29, 2007 by Exec. Order No. 13385, Fed. Reg. 57989 (Sept. 29, 2005).

116. National Bioethics Advisory Commission, *supra* note 107, at 16.

117. Clayton et al., *supra* note 96, at 1787.

118. Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J.L. MED. & ETHICS 15, 16 (2005).

(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

- (a) the key to decipher the code is destroyed before the research begins;
- (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
- (c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- (d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

This guidance applies to existing private information and specimens, as well as to private information and specimens to be collected in the future for purposes other than the currently proposed research. The following are examples of private information or specimens that will be collected in the future for purposes other than the currently proposed research: (1) medical records; and (2) ongoing collection of specimens for a tissue repository.¹¹⁹

The OHRP guidance also states that when analyzing whether the research involves a human subject, one must focus on what the researcher is obtaining.¹²⁰ “If the [researchers] are not obtaining . . . data through intervention or interaction with living individuals . . . then the research activity does not involve human subjects.”¹²¹ In interpreting the above OHRP’s guidance, Ellen Wright Clayton affirmed that the Common Rule does not apply to “investigators who receive only coded information so long as they do not have access to the key” because the research would not involve human subjects.¹²²

Whether the samples in *Catalona* would be excluded as research on human subjects based on the OHRP’s guidance remains unclear. At least some samples were not collected specifically for the current research, but rather for the Biorepository. If the identifying information were severed from the sample, an argument could be made that the research no longer involved human subjects.

119. Office for Human Research Protections (OHRP), *Guidance on Research Involving Coded Private Information or Biological Specimens*, available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf> (last visited Jan. 21, 2007) (emphasis in original).

120. *Id.*

121. *Id.*

122. Clayton, *supra* note 117, at 16.

Even if the research did not involve human subjects, some argue that it would be ethically wrong to acquire and anonymize samples without consent because researchers would have had the opportunity to get consent; they just failed to do so.¹²³ Further, Lori Andrews, a professor of law and Director of the Institute for Science, Law and Technology,¹²⁴ stated that some of the RPs objected to anonymization because they claimed that severing the samples from identifying information would “reduce the value of their contributions by limiting the type of prostate cancer research that could be done and because it would prevent the patients from learning specific details of what the research had shown in their own tissue.”¹²⁵ Andrews later argued that patients agreed to participate in Catalonia’s research with the hope of benefiting “future generations of cancer sufferers . . . including family members unlucky enough to inherit the genetic risk of developing the disease.”¹²⁶

A conclusion on this point has not been reached.¹²⁷ Nonetheless, regarding the Biorepository, WU might be permitted to anonymize the samples without consent of the donors, but that argument is closely tied into the basic argument in *Catalona*—that WU has control over the samples.

3. If a participant dies, does the research still involve a human subject?

There is one last issue to address stemming from the human subject requirement of the Common Rule.¹²⁸ The Common Rule’s definition of a human subject begins with “a living individual . . .”¹²⁹ A Consensus Statement in the *Journal of the American Medical Association* might shed light on the subject; although the Consensus Statement concerned genetic research, it could be applied to other forms of research.¹³⁰ The authors of the Consensus Statement noted that any use of samples from deceased patients is not covered by the federal regulations.¹³¹ The authors were also quick to point out that with genetic research, information could be revealed that “may pose psychosocial risks to living relative,” but “[t]he absence of risks to living people may justify the use for genetic research of anonymous samples.”¹³²

123. Clayton et al., *supra* note 96, at 1788.

124. Andrews, *supra* note 8, at 398 n.2. Andrews’ career has “focused almost exclusively on genetic rights and tissue issues. She has written 10 books and more than 100 articles and legal briefs; she has advised Congress, the World Health Organization, the National Institutes of Health and 14 foreign countries.” Skloot, *supra* note 9, at § 6.

125. Andrews, *supra* note 8, at 399.

126. *Id.* at 403.

127. Clayton et al., *supra* note 96, at 1788.

128. 45 C.F.R. § 46.101(a) (2005).

129. 45 C.F.R. § 46.102(f) (2005).

130. Clayton et al., *supra* note 96.

131. *Id.* at 1790.

132. *Id.*

The article did not further clarify, but presumably the psychosocial risks would involve the fact that donors would not want any genetic disease publicized. In *Catalona*, the research was not genetic in nature. However, similar psychosocial risks could arise as long as the samples remain linked to a specific donor. Although the Common Rule, on its face, seems to exclude samples from deceased donors, the issue has not been decided.¹³³ It is plausible that a court would treat the disposition of tissues no differently than those from living subjects: destroy them, store them indefinitely, or anonymize them.

B. Two Particular Provisions of the Common Rule: Informed Consent and the Right to Withdraw From Participation

Since federal regulations (including the Common Rule) apply, two provisions of particular importance are present in *Catalona*: informed consent and the right to discontinue participation.¹³⁴

1. Informed consent. Is it necessary? Are there flaws? Is exculpatory language permitted, relieving the researcher from liability?

a. Informed consent is necessary

The Common Rule provides a basis for the requirements of informed consent, indirectly providing a definition, stating:

[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective *informed consent* of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.¹³⁵

Thus, prior to conducting research on human subjects, a researcher must provide potential subjects with information about the risks and benefits that accompany it.¹³⁶ Potential subjects can then make an informed decision whether to expose themselves to any health and safety risks, in the name of research.¹³⁷ Informed consent had its legal origin in cases involving serious physical injury or death; if potential participants fully knew of the risks, they

133. *Id.*

134. *Catalona*, 437 F. Supp. 2d at 990 (referring to 45 C.F.R. § 46 (2005)).

135. 45 C.F.R. § 46.116 (2005) (emphasis added).

136. Clayton et al., *supra* note 96, at 1787.

137. *Id.*

may have shied away from participating in the study.¹³⁸ In *Catalona*, there was no question that informed consent forms were signed by the donors.¹³⁹

b. Informed consent has its flaws

There are concerns with the doctrine of informed consent, however. When there are no physical risks, the scope of informed consent is in question.¹⁴⁰ One court analyzed this by splitting research into two categories: nontherapeutic and therapeutic.¹⁴¹ The court, in defining the categories, stated:

At least to the extent that commercial profit motives are not implicated, therapeutic research's purpose is to directly help or aid a patient who is suffering from a health condition the objectives of the research are designed to address—hopefully by the alleviation, or potential alleviation, of the health condition. Nontherapeutic research generally utilizes subjects who are not known to have the condition the objectives of the research are designed to address, and/or is not designed to directly benefit the subjects utilized in the research, but, rather, is designed to achieve beneficial results for the public at large.¹⁴²

With regard to nontherapeutic research, informed consent is necessary.¹⁴³ By contrast, however, much of the risk is eliminated with therapeutic research because the primary purpose is to benefit the patient.¹⁴⁴ Further, in research involving tissue samples obtained from surgeries, nearly all of the risk is eliminated because the patients needed the surgeries anyway.¹⁴⁵ Requiring informed consent in cases with little or no physical risk might seem pointless, notwithstanding other types of risk.¹⁴⁶ In fact, the NBAC stated, “[W]hen important research poses little or no risk to subjects whose consent would be difficult or impossible to obtain, it is appropriate to waive the consent requirement.”¹⁴⁷ Research that poses little or no risk to subjects is rare, if it exists at all, but research on stored tissue might come close. In *Catalona*, the excision of a donor's cancerous tissue could be seen as therapeutic, and the resulting tissue sample as merely a by-product. Health risks, with respect to

138. Clayton, *supra* note 117, at 18.

139. *Catalona*, 437 F. Supp. 2d at 997.

140. There are other types of risks in research, such as psychological, social, economic, and legal. For further discussion on these, see CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 245 (2005).

141. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 811-12 n.2 (Md. 2001).

142. *Id.* at 811.

143. See *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1472 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987) (where the court held that for nontherapeutic research, there is a duty to inform the participant of all risks that are reasonably foreseeable).

144. *Grimes*, 782 A.2d at 811 n.2.

145. Clayton et al., *supra* note 96, at 1788.

146. See COLEMAN ET AL., *supra* note 139.

147. NATIONAL BIOETHICS ADVISORY COMMISSION, *supra* note 107, at 66.

the research, would be eliminated as the patients' cancerous excisions would have occurred anyway.

Informed consent has also been questioned when obtaining consent is impracticable.¹⁴⁸ A Consensus Statement in the *Journal of the American Medical Association*, concerning informed consent for stored tissue samples, noted that there has been little litigation concerning informed consent and impracticability in research.¹⁴⁹ The statement stressed, though, "[C]onsent cannot be waived on the simple assertion that seeking it would be tedious, burdensome or costly."¹⁵⁰ Instead, a balancing test was suggested where the burden and cost of obtaining consent would be weighed against the possibility that the research might not go forward.¹⁵¹

Even when informed consent is required, concern exists that the consent forms may be inadequate.¹⁵² Donors are usually not informed that their samples can be retained and used for other studies.¹⁵³ In fact, the samples may be used in research for unrelated purposes at other institutions.¹⁵⁴ Some argue that an informed consent form should specify whether it includes permission to store (and later use) tissue in a biobank.¹⁵⁵ Not only would the form enable an individual to decide whether to accept certain risks, but it would also "honor" the contribution the donor is making.¹⁵⁶ However, others argue there is some question as to whether a donor should be allowed to give such "blanket consent for future research," given that it may be impossible to make an informed choice.¹⁵⁷

c. The prohibition of exculpatory language in an informed consent form

The RPs argued one additional caveat of the Common Rule. They challenged the validity of the informed consent forms in *Catalona* because they contained exculpatory language prohibited by the Common Rule.¹⁵⁸ The Common Rule states:

No informed consent, whether oral or written, may include any *exculpatory language* through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to

148. Clayton et al., *supra* note 96, at 1789.

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.* at 1787.

153. *Id.* at 1787.

154. Clayton et al., *supra* note 96, at 1787.

155. Clayton, *supra* note 117, at 19.

156. *Id.*

157. *Id.* at 19-20.

158. *Washington Univ. v. Catalona*, 437 F. Supp. 2d 985, 998 (E.D. Mo. 2006).

release the investigator, the sponsor, the institution or its agents from liability for negligence.¹⁵⁹

The court, however, concluded that prohibition of exculpatory language applied only to waivers of legal rights due to negligence, not to the property issue in *Catalona*.¹⁶⁰ Curiously, though, the OHRP listed guidance on its website which provides examples of exculpatory language.¹⁶¹ Two improper examples are:

1. I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
2. By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.¹⁶²

These two examples, the second in particular, seems to refute the court's conclusion that the prohibition on exculpatory language does not apply to property rights. The discrepancy has not been resolved, and researchers are still left with the question as to whether informed consent forms can affect property rights. Another Common Rule provision remains to be examined, however: the right to discontinue participation.¹⁶³

2. Right to discontinue participation—what happens to prior donated samples?

The Common Rule states that one of the requirements of informed consent is to provide each subject with information including a statement that “participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefit,” and it also states that the RPs must be provided with information concerning “[t]he consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.”¹⁶⁴ In *Catalona*, the informed consent forms also provided for withdrawal from research, stating that an RP “may choose not to participate in this research study or withdraw your consent at any time.”¹⁶⁵

159. 45 C.F.R. § 46.116 (2005) (emphasis added).

160. *Catalona*, 437 F. Supp. 2d at 998.

161. Office for Human Research Protections (OHRP), “*Exculpatory Language*” in *Informed Consent*, <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm> (last visited Feb. 7, 2007).

162. *Id.* (emphasis added).

163. *Catalona*, 437 F. Supp. 2d at 998.

164. 45 C.F.R. § 46.116(a)(8) (1991); 45 C.F.R. § 46.116(b)(4) (1991).

165. *Catalona*, 437 F. Supp. 2d at 990.

However, as the *Catalona* court correctly noted: “The federal regulations do not address the matter of a RP’s ‘right’ to physically possess their samples upon termination of their participation in a research study; or, a ‘right’ to direct their sample[s] transfer to another institution or Principal Investigator.”¹⁶⁶ Indeed, the informed consent forms, too, are silent on the issue of whether RPs can withdraw their previously-donated samples or transfer them to another facility.¹⁶⁷

Catalona and the RPs argued that the right to withdraw from participation found in the Common Rule included the right to withdraw prior donated samples.¹⁶⁸ The RPs, in essence, were arguing that if property ownership was viewed as a bundle of sticks, then they would still hold at least one (the right to withdraw); therefore, WU would not have complete property rights over the samples. The court disagreed and concluded that the right to withdraw meant only that the RP could decide not to provide any more samples; it did not affect prior samples.¹⁶⁹ On appeal in the Eighth Circuit, during oral arguments, WU responded to the RPs’ argument by distinguishing the right to withdraw as a privacy right, not a property right.¹⁷⁰ The Common Rule would allow WU to either destroy the samples *or* anonymize them.¹⁷¹ Anonymizing the samples would protect the donor’s privacy, not a property right. Therefore, WU argued destruction of the samples must have the same purpose.¹⁷² Thus, the Eighth Circuit now has an additional argument to consider, but given that the district court found for WU, the conclusion should not change—the right to withdraw does not include the right to retrieve prior samples.

VI. LEGAL PRECEDENT INVOLVING TISSUES IN RESEARCH—SCARCE, ONLY TWO SIMILAR YET DISTINGUISHABLE CASES

Only two relevant cases exist concerning the donation of biological materials for research purposes. According to *Catalona*, there was a “scarcity of legal precedent to assist” in situations involving ownership of biological materials donated for research, and there were only two cases: *Moore v. Regents of the University of California* and *Greenberg v. Miami Children’s*

166. *Id.* at 992.

167. *Id.* at 990.

168. *Id.* at 999.

169. *Id.*

170. Recording of Oral Argument, *Washington Univ. v. Catalona* No. 06-2286, No. 06-2301 (8th Cir. Dec. 13, 2006), <http://www.ca8.uscourts.gov/tmp/062286.html> (last visited Jan. 21, 2007).

171. *Id.*

172. *Id.*

*Hospital Research Institute, Inc.*¹⁷³ With a dearth of cases concerning the issue, these two opinions must be carefully examined to ensure consistency with federal regulations, as the *Catalona* court did here.¹⁷⁴ In short, both cases found the RPs to be donors who lost all ownership rights in their samples once donated.¹⁷⁵ Likewise, the *Catalona* court was persuaded to apply the same reasoning, although the cases were easily distinguishable.¹⁷⁶

A. *Moore v. Regents of the University of California*

In *Moore*,¹⁷⁷ the court had to determine whether the plaintiff, Moore, stated a cause of action of conversion against Golde (the physician), Quan (a university researcher), regents (owners and operators of the university) and others.¹⁷⁸ Moore, diagnosed with the rare disease hairy cell leukemia,¹⁷⁹ went to Golde for treatment.¹⁸⁰ Golde told Moore “that he had reason to fear for his life,” and he proposed a splenectomy.¹⁸¹ Golde and Quan decided to take the excised spleen and use it for research purposes, without informing Moore.¹⁸² Further, Golde asked Moore to return to the medical center several times over the next seven years to give samples of blood, blood serum, skin, bone marrow aspirate, and sperm, under the guise that it was necessary for his health.¹⁸³ During this time, the samples were actually needed so that Golde could continue his research and exploit the cells.¹⁸⁴ Golde and Quan subsequently obtained a patent for a cell line created from Moore’s samples.¹⁸⁵

The opinion addressed two issues: 1) fiduciary duty and informed consent, and 2) conversion.¹⁸⁶ In the former, the court examined whether the physician had a duty to acquire the patient’s informed consent and whether the physician

173. *Catalona*, 437 F. Supp. 2d at 995 (referencing *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) and *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003)).

174. *See id.* at 995-97.

175. *Id.* at 997.

176. *Id.*

177. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990). For an in-depth overview of the case, see Skloot, *supra* note 9, at § 6.

178. *Moore*, 793 P.2d at 480-81.

179. The disease is called “hairy” cell leukemia because when examined under a microscope, the cells look hairy. National Cancer Institute, *General Information About Hairy Cell Leukemia*, <http://www.cancer.gov/cancerinfo/pdq/treatment/hairy-cell-leukemia/patient/> (last visited Nov. 14, 2006).

180. *Moore*, 793 P.2d at 481.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.* at 482.

186. *Moore*, 793 P.2d at 483, 487. Conversion is “a tort that protects against interference with possessory and ownership interests in personal property.” *Id.* at 487.

had a duty to disclose his research intentions and his economic interests prior to conducting the medical procedures.¹⁸⁷ In the second issue, the court examined the patient's conversion claim, where the patient argued that he continued to own his samples following removal, and that he never consented to their use.¹⁸⁸

1. Fiduciary duty and informed consent

The patient, Moore, alleged that Golde failed to disclose his research and economic interests before obtaining consent to use the samples.¹⁸⁹ A physician has a duty to disclose personal interests that may bias professional judgment, and a failure to do so results in a cause of action for performing medical procedures without informed consent.¹⁹⁰ Golde argued that the scientific use of cells already removed cannot affect the health of a patient.¹⁹¹ However, the court stated that a physician with a research interest may, perhaps subconsciously, recommend a procedure that might not be in the patient's best interest.¹⁹² The court held that a physician must, when obtaining informed consent, disclose personal interests unrelated to the patient's health.¹⁹³

2. Conversion

In his claim for conversion, the patient argued that he continued to own his samples following removal, and that he never consented to their use.¹⁹⁴ The patient further claimed that as a result of the conversion, he had a proprietary interest in each product ever created from his cells.¹⁹⁵ The court noted, however, that if the patient won the conversion argument, a duty would be imposed on researchers to investigate every human sample ever used in their research.¹⁹⁶ Further, since Moore did not expect to retain possession of his cells after removal, then in order to sue for conversion, he must have retained some other ownership interest in them.¹⁹⁷ However, the California Health and Safety Code dictated the disposition of human biological materials based on policy goals, not the law of personal property.¹⁹⁸ The policy goals were to ensure safe handling of hazardous waste materials, not to compensate donors;

187. *Id.* at 483.

188. *Id.* at 487.

189. *Id.* at 483.

190. *Id.*

191. *Id.* at 484.

192. *Moore*, 793 P.2d at 484.

193. *Id.* at 485.

194. *Id.* at 487.

195. *Id.*

196. *Id.*

197. *Id.* at 488-89.

198. *Moore*, 793 P.2d at 489.

once the policy goal is recognized, the practical effect is that what is left does not constitute a property interest for the purposes of conversion.¹⁹⁹ The *Moore* court concluded its conversion analysis by stating that the cell line cannot be the patient's property because it is "both factually and legally distinct" from his donated cells.²⁰⁰

3. Application of *Moore v. Regents to Washington University v. Catalona*

Moore can be distinguished from *Catalona* in several important respects. First, in *Moore* the facts involved a cell line created from donations, whereas *Catalona* involved the donations themselves. Next, unlike *Moore* where the physician did not disclose his research interests, in *Catalona* there was no question whether the RPs knew what would become of their tissue (although it may be cloudy as to whether they thought their tissues could still be used after they exercised their rights to withdraw). Further, although the *Moore* court stated that a physician might subconsciously recommend a procedure not in the patient's best interest, factual distinctions also exist between *Moore* and *Catalona*. In *Moore*, many of the procedures performed by Golde had no purpose other than research. In *Catalona*, however, there was no question that the RPs needed the surgeries for cancer treatment. Moreover, in *Moore* the physician and RPs were on opposing sides, whereas here *Catalona* and the RPs want the same thing.

Further, with respect to the conversion argument, similarities exist between *Moore* and *Catalona*. In *Moore*, the court noted that the patient did not expect to retain possession of the cells, just like the RPs in *Catalona*. Further, in *Moore* the court followed the California Health and Safety Code to determine the disposition of the samples, not general property law. Although the *Catalona* court followed similar federal and state (Missouri) health and safety codes, it placed more emphasis on the role of general property laws. In the end, the *Catalona* court took from *Moore* that a research participant/donor did not retain any ownership rights in the samples after the donation of the biological materials.²⁰¹

B. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*

In *Greenberg*,²⁰² donors of human biological materials sued physician/researcher Dr. Matalon (Matalon), who used the donated samples to isolate a gene which he then attempted to patent.²⁰³ The donors claimed the

199. *Id.* at 491-92.

200. *Id.* at 492.

201. *Washington Univ. v. Catalona*, 437 F. Supp. 2d 985, 997 (E.D. Mo. 2006).

202. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

203. *Id.* at 1067.

purpose of their donations was to further research of Canavan disease, hoping to lead to prenatal testing for the disease as well as carrier detection which would benefit the public at large.²⁰⁴ The donors' intent was not for the samples to be used for profit-motives that limit research.²⁰⁵ Matalon successfully isolated the gene and, unbeknownst to the donors, filed a patent application for his discovery.²⁰⁶ Once granted, Matalon (and other defendants) had the power to restrict any research related to that gene by any other researchers.²⁰⁷ In fact, Matalon exercised that right with threats, and then allowed access to the gene only through licensing agreements which charged royalty fees.²⁰⁸

The donors filed a complaint alleging, *inter alia*, lack of informed consent and conversion.²⁰⁹ The plaintiffs' argument for lack of informed consent revolved around the defendants' failure to disclose the intent to patent and profit off the donations.²¹⁰ The court disagreed and refused to extend informed consent in that manner.²¹¹

The plaintiffs' argument for conversion centered on their claim that the defendants deprived them of a property interest in their body tissue.²¹² The court disagreed, stating, "These were donations to research without any contemporaneous expectations of return of the body tissues and genetic samples, and thus conversion does not lie as a cause of action."²¹³ The court recognized that for a conversion claim, the plaintiffs must have had a property interest, which they lacked.²¹⁴ Further, the property right in biological tissue samples "evaporates once the sample is voluntarily given to a third party."²¹⁵ Thus, the court concluded that the donors had no claim for conversion.²¹⁶

An important factual distinction arises between *Greenberg* and *Catalona*. In *Greenberg*, the court recognized that the "patented result of research is 'both

204. *Id.* at 1066-67.

205. *Id.* at 1067. The defendants threatened other facilities that attempted to use the patented technology, and they also restricted public accessibility through licensing agreements and royalties. *Id.*

206. *Id.*

207. *Id.*

208. *Greenberg*, 264 F. Supp. 2d at 1067.

209. *Id.* at 1068. The plaintiffs also alleged breach of fiduciary duty, unjust enrichment, fraudulent concealment, and misappropriation of trade secrets. *Id.* Presumably, the district court in *Washington Univ. v. Catalona* did not discuss these since those have no direct application to the case at bar.

210. *Id.*

211. *Id.* at 1071.

212. *Id.* at 1074.

213. *Id.*

214. *Greenberg*, 264 F. Supp. 2d at 1074.

215. *Id.* at 1075.

216. *Id.* at 1076.

factually and legally distinct' from excised material used in the research."²¹⁷ In *Catalona*, however, the tissues were not altered—only stored—with no evidence of commercial intent²¹⁸ which, may limit the applicability of *Greenberg*. Nonetheless, in *Catalona*, the court followed the advice of *Greenberg*, asserting that the RPs were donors who voluntarily gave up ownership rights in their biological materials upon donation.²¹⁹

VII. PUBLIC POLICY CONCERNS—THE BATTLE BETWEEN THE PATIENT'S
RIGHT TO MAKE AN INFORMED DECISION AND THE RIGHT TO PROTECT
RESEARCH THAT FURTHERS SCIENCE AND SOCIETY

In *Moore*, the court analyzed the policy issues concerning donations of biological materials as a battle between two considerations.²²⁰ The first issue is the protection of the RP's right to make autonomous medical decisions.²²¹ Second, research must be protected; innocent researchers merely engaging in socially useful activities should not be threatened with "disabling civil liability" when they have no reason to believe their use of a sample is against the donor's wishes.²²² The *Moore* court stated that these two policy considerations must be balanced, but noted that it may be more important to remove uncertainty rather than necessarily finding the best balance.²²³ The two policy considerations must be examined.

A. *The Research Participant's Right to Make an Informed Medical Decision*

Individuals have the right to make informed decisions about their health. The Common Rule's informed consent provision states as much.²²⁴ It is doubtful that anyone would object to the idea that a person has a right to dictate what happens to their body, and that right is more important than conducting research. The Consensus Statement warned, "[D]espite the desirability of increased knowledge, research [must not] risk harming the individuals who are being studied."²²⁵ Logically, then, as the *Moore* court stated, a remedy should exist "when physicians act with undisclosed motives that may affect their professional judgment."²²⁶

However, the issue is clouded when instead of research on a person's own body, the research concerns a tissue sample that has already been excised and

217. *Id.* at 1074-75 (citing *Moore*, 793 P.2d at 492).

218. *Catalona*, 437 F. Supp. 2d at 989.

219. *Id.* at 997.

220. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990).

221. *Id.*

222. *Id.*

223. *Id.*

224. *See* 45 C.F.R. § 46.116 (2005).

225. Clayton et al., *supra* note 96, at 1787.

226. *Moore*, 793 P.2d at 493.

stored. For samples that were taken with a specific research purpose in mind, consent would be easy to obtain from the donor for that specific project. With stored tissue banks, although the donor was initially told about the purposes of the donation, as time passes, circumstances change. A different research project might need samples. Where else would a researcher look but to a biobank? Researchers may not be intentionally disobeying the donors' wishes, and they generally want to gather as much information as possible to advance research.²²⁷ However, in all the excitement, sometimes researchers do not think about the consequences.²²⁸ When researchers' activities do not correspond with the donors' expectations, the trust between researcher and donor is eroded. As Clayton put it:

More attention also needs to be paid to restoring the public trust in research. A greater commitment to seeking informed consent is one way, but so is a more far reaching and transparent discussion of the goals and benefits of research. Part of the distrust also results from public perception that someone else is making money out of something that is 'theirs.'²²⁹

Of course, some might argue that the tissue no longer belongs to the donor. It is clear, however, that the RPs have a right be informed of their rights prior to donating a sample.

B. Protecting Research: The Researcher's Right to Perform Important Medical Research

Undoubtedly, medical research is a good thing. As the Consensus Statement argued, "Increasing the fund of knowledge generally is . . . good both for society and for the individuals whose care is improved by more complete understanding. Society rightly values research and the contributions of those who participate as subjects in research."²³⁰ Thus, a researcher should have the right to perform such research, but some important caveats must simultaneously be recognized.

First, researchers must be allowed to use stored biological materials for medical research. A report from the NBAC noted, "Biomedical research routinely relies on the availability of stored human biological materials as well as the willingness of individuals to participate in research protocols by donating blood, tissue, or DNA samples to research."²³¹ Further, stored tissue is invaluable in cancer research:

[T]he availability of large archives of carefully documented and clinically correlated specimens has permitted researchers to apply directly new detection

227. Skloot, *supra* note 9, at § 6.

228. *Id.*

229. Clayton, *supra* note 117, at 19.

230. Clayton et al., *supra* note 96, at 1787.

231. NATIONAL BIOETHICS ADVISORY COMMISSION, *supra* note 107, at 19.

technologies to existing biological materials. This is a far more rapid and less expensive approach than initiating new prospective studies for each new promising candidate gene for many of the varieties of human cancer. Conducting such studies not only would be extraordinarily costly in terms of dollars and human effort, but would require study periods of many years, or even decades.²³²

Thus, there is a need for stored tissue samples.

Second, unrestricted access to tissues is important.²³³ Some examples of restrictions include clauses such as, “you can use my tissues for this research, not that research,” or “don’t commercialize them, or do, and give me a cut.”²³⁴ As of now, researchers generally have the access they want, but they fear that restrictions might slow research.²³⁵ “Many scientists depend on access to tissues without the burden of restrictions that donors might make.”²³⁶ Of particular concern are financial restrictions by the donor, because they could threaten the sharing of tissue for research purposes by withholding access for money.²³⁷ Researchers worry that it could destroy their financial incentive to do research because donors would hold out for a large cut.²³⁸ Nonetheless, “a growing number of activists — ethicists, lawyers, doctors and patients — are arguing cases and pushing for federal regulations that would change the status quo by granting people rights to control their tissues.”²³⁹

The practical implications of granting donors more rights must be considered. At the time of a donation to a stored tissue bank, the research use of that tissue is unlikely to be known. Later, when the tissue is allocated for a particular research project, it would not be practical to disclose every research detail or every possibility of economic benefit to a potential donor—even if that donor could be found. The court in *Greenberg* noted that it would be “unworkable and would chill medical research as it would mandate that researchers constantly evaluate whether a disclosable event has occurred.”²⁴⁰ Similarly, when *Moore* was decided, lawyers worried that a victory for donors would “create chaos for researchers” and “[sound] the death knell to the university physician-scientist.”²⁴¹ Moreover, granting donors additional rights would give rise to a type of “dead-hand control that research subjects could

232. *Id.*

233. Skloot, *supra* note 9, at § 6.

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.*

238. *Id.*

239. Skloot, *supra* note 9, at § 6.

240. *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003).

241. Skloot, *supra* note 9, at § 6.

hold because they would be able to dictate how medical research progresses.”²⁴²

An additional concern is that perhaps the rights of donors have been overstated. As Skloot stated, “Scientists aren’t stealing your arm or some vital organ. They’re just using tissue scraps you parted with voluntarily.”²⁴³ Further, in *Greenberg*, the court stated that “these Plaintiffs are more accurately portrayed as donors rather than objects of human experimentation, and thus the voluntary nature of their submissions warrants different treatment.”²⁴⁴

In *Catalona*, the court had the last say involving policy concerns. The court noted:

The safety and welfare of human subject participants is protected through a variety of legal and professional standards administered by committees of persons schooled in the fields most privy to the needs of the medical/science community. Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a RP, these highly-prized biological materials would become nothing more than chattel going to the highest bidder. It would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most. Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. The integrity and utility of all biorepositories would be seriously threatened if RPs could move their samples from institution to institution any time they wanted. No longer could research protocols rely on aggregate collections since individual samples would come and go. Accountability would no longer exist since institutions would merely be warehouses filling purchase orders.

More alarming is the great potential for prejudicial influences into medical research. Allowing an RP to choose who can have the sample, where the sample will be stored, and/or how the sample can be used is tantamount to a blood donor being able to dictate that his/her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man. This kind of “selectiveness” is repugnant to any ethical code which promotes medical research to help all of mankind.²⁴⁵

Thus, the district court was concerned about private agendas—some financial—as well as the availability of samples in a stored tissue bank that could be relied on. In essence, the court was concerned that research could come to a screeching halt.

242. *Greenberg*, 264 F. Supp. 2d at 1071.

243. Skloot, *supra* note 9, at § 6.

244. *Greenberg*, 264 F. Supp. 2d at 1071.

245. *Washington Univ. v. Catalona*, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006).

VIII. DISCUSSION AND CONCLUSION

In sum, in *Catalona*, RPs who donated prostate tissue excised during cancer surgery at Washington University attempted to transfer that tissue to Northwestern University.²⁴⁶ The case revolves around ownership of these samples. The district court had no choice but to treat the tissue samples as personal property, with little discretion. The district court's decision in *Catalona* has been appealed to the U.S. Court of Appeals for the Eighth Circuit.²⁴⁷ The Eighth Circuit should surprise no one when it affirms. In fact, the opinion could be all of one sentence,²⁴⁸ stating, "We find WU to be the owner of these samples, as it had exclusive possession and control following the RPs voluntarily donations of the tissue samples."

WU unquestionably had exclusive possession and control over the samples, and the RPs could not meet their burden of showing, by a preponderance of the evidence, that they were the rightful owners. The RPs' best response—that the donations were merely bailments—borders on the absurd. A bailment, by definition, requires an expectation of return.²⁴⁹ Any analogy to a delivery service like UPS, Federal Express, or DHL is worthless because in those instances, the customer expects the package to be delivered *somewhere*. Also, the last time someone shipped a package via UPS, did they "donate" it? Of course not. Here, the RPs had no expectation that the samples were to be delivered or returned anywhere. Logic and reason support that conclusion—the RPs wanted to give away their tissue, with no further rights or obligations, in the hopes that someone would benefit. They knew, or should have known, that WU would become the new owner of the samples; the informed consent forms had the WU logo and used the term "donation."

Although federal regulations on biologic materials complicate these issues, the result will be unchanged. The most important purpose of informed consent is to protect the donor's health and safety. Here the health and safety concern is a minimal issue because the tissues were excised in a necessary surgical procedure for prostate cancer, and there are no significant non-physical risks (undoubtedly making this discussion quite narrow in scope). The RPs would have the surgeries regardless of whether the resulting tissue was donated for research or simply destroyed. Further, their "right to withdraw" should be read logically; it means that a donor has the right to stop donating more tissue at any

246. *Id.* at 994.

247. The case numbers are No. 06-2286 and No. 06-2301.

248. Of course, by convention the opinion will undoubtedly be much longer. At least with law review articles, there is hope. See, e.g., Erik M. Jensen, *The Shortest Article in Law Review History*, 50 J. LEGAL EDUC. 156 (2000); Grant H. Morris, *The Shortest Article in Law Review History: A Brief Response to Professor Jensen*, 50 J. LEGAL EDUC. 310 (2000); Thomas H. Odom, *A Response to Professors Jensen and Morris*, 50 J. LEGAL EDUC. 311 (2000); Erik M. Jensen, *Comments in Reply*, 50 J. LEGAL EDUC. 312 (2000).

249. *Seitz*, 959 S.W.2d at 461.

time, without regard to prior donations. Informed consent is a mechanism to protect the donor's health and safety, nothing more.

Moreover, the RPs are not really a party in interest; Catalona is using his patients to get access to tissues that he wants. Do the patients really care who uses the samples? Maybe a little, but it is probably not as much as their lawyers want people to think. The RPs want to eradicate prostate cancer so that those who come after them can avoid what they had to go through. Regardless of who owns the tissue samples, no one suggested that they would not eventually be used for research on prostate cancer. That use seems to fall in line with the RPs' wishes.

So, what is this case about, really? It is about money, or at least the future ability to earn it. True, no one argued that the RPs or Catalona had any financial motive for the lawsuit. But there are financial incentives to perform research. Successful research equals money, not only from private companies but also to obtain grants from the federal government. Further, it is not the RPs who truly want money; when they made their donations, they thought the tissues were valueless. They were right, of course; the tissues were valueless, and they will continue to be valueless until researchers find a way to utilize them. Sure, the donors might be tempted by greed once they see that their tissues were turned into a valuable product, but this is no different than selling paint to Picasso—it was worthless until he converted it into a masterpiece. Also, public policy dictates that the RPs should not be allowed to sell their tissue to the highest bidder. If they were allowed to do so, researchers could no longer count on the availability of samples collected. Further, the administrative hardship that it would create would be a disincentive to maintain biobanks for medical research, which is the opposite of the societal goal of medical research.

However, even a reversal would probably not rattle the research world as some suggest, leading back to the original question: Will this case “shape the evolving law of research on body tissue?”²⁵⁰ It will not. The holding in this case is not what makes it important; it will be easily distinguished, much like *Moore* and *Greenberg* were.

What makes the case so important is that it creates discussion about serious issues involving research in the 21st Century. Would the RPs have had a problem with the disposition of their samples if they knew ahead of time that WU would own them free and clear? Doubtful. The importance of this case is to teach researchers and institutions about the consequences of communication failures in respect to ownership of research samples. In theory, the rightful owner of the tissue samples should be the one who will best use them. This is not a question that a court can decide; it is a question best left to experts, like WU and Northwestern University. The universities could have collaborated to

250. See Andrews, *supra* note 8, at 399-400.

come up with mankind's best solution in a mutually profitable way. Instead, a lawsuit seemed more appropriate to them. Now, the RPs' outcry in this case has swelled more than their prostates ever did.

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