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Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks

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NOTES

Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks

ABSTRACT

Every day in the United States and around the world, patients and research participants at hospitals and doctors' offices give biological samples, whether in the form of surgically removed cancer tissue or a routine blood sample. Many of these patients are entirely unaware that their tissues were not thrown out as hazardous waste, and instead used by scientists for the development of new drugs and therapies. The courts in the United States in Moore v. Regents of the University of California, Greenberg v. Miami Children's Hospital Research Institute, and most recently Washington University v. Catalona have determined that a patient does not retain rights to his tissues once they are removed, regardless of whether the patient consented to this forfeiture of rights.

This Note argues that the United States' regulations and common law developments are simply inadequate to achieve the appropriate balance between protecting patients' autonomy and further promoting scientific research. Sweden, Iceland, and Denmark have made greater strides in protecting these basic human tenets in the context of tissue banks through the implementation of comprehensive national policies. The United States should look to these nations for guidance in forming its own uniform national policy, as our current legal landscape

regulating tissue banks will remain fragmented so long as it develops out of sporadic common law precedents. A legislatively enacted nationwide legal structure would help ensure a uniform approach among courts addressing tissue bank issues and aid in striking an appropriate balance between the recognition of patients' rights and the promotion of scientific research.

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I. INTRODUCTION

Patients and research participants at hospitals and doctors' offices around the world give biological samples every day, whether in the form of surgically removed cancer tissue or a routine blood sample. According to a recent report, more than 307 million tissue samples from more than 178 million people are stored in the United States, and the number of samples is growing by 20 million each year.¹ The number of samples from patients around the world is surely even greater, although the exact number is presently unknown.² Doctors and scientists perform every type of imaginable research from these samples of human tissue, often extracting the DNA from the cells for examination.³ There is nothing that defines a person at a more basic level than his or her specific genes. Many of these patients, however, are entirely unaware that their tissues were not thrown out as hazardous waste.⁴ Although every hospital requires patients to sign some type of informed consent form, these forms are not uniform and are virtually unregulated. Thus, patients are generally left with little, if any, information about how their samples will be used or who might be using them.⁵ Scientists depend on these tissues to develop new drugs and therapy techniques, and without these samples would not be able to do so.⁶

Only a limited number of cases in the United States have addressed the issue of whether a patient or research subject retains any right to his tissue once it has been removed at a doctor's office or hospital. *Moore v. Regents of the University of California*,⁷ *Greenberg v. Miami Children's Hospital Research Institute*,⁸ and most recently *Washington University v. Catalona*⁹ have implemented the standard that a patient does not retain rights to his tissues once they are

1. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., Apr. 16, 2006, at 38 (citing a 1999 RAND study). Skloot further explains that these samples are taken from "routine medical tests, operations, clinical trials and research donations." *Id.*

2. *Medicine's New Central Bankers*, ECONOMIST, Dec. 10, 2005, at 29.

3. Skloot, *supra* note 1, at 2.

4. *See id.* (noting that this lack of awareness is particularly true in regard to the after-life of blood samples and other excised tissues).

5. *See id.* at 10 ("Some institutions . . . ask permission to keep tissues and let patients specify what research their samples will be used for. But others don't.").

6. For example, not only drug companies want human tissue samples to aid in drug discovery, but public health officials, epidemiologists, and disease advocacy groups hope to use such tissue samples to more efficiently identify disease patterns and aid in research for beneficial disease-specific therapies. *See Medicine's New Central Bankers*, *supra* note 2, at 29.

7. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

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

9. *Wash. Univ. v. Catalona*, 490 F.3d 667 (8th Cir. 2007).

removed, regardless of whether the patient consented to this forfeiture of rights.¹⁰ In *Catalona*, the District Court for the Eastern District of Missouri found that Washington University owned all the human tissues in its possession.¹¹ The judge determined that neither Dr. Catalona nor his patients held any proprietary or ownership rights to the patients' tissues, basing this decision primarily on *Moore* and *Greenberg*.¹² This decision eroded patients' rights to their tissues more than the existing case law in two important ways: (1) in discounting the importance of informed consent, the *Catalona* court also stripped patients of any real right to withdraw their sample from research; and (2) the hospital merely held the samples without using them, and yet this was sufficient to give the hospital full property rights to the samples.¹³ These legal bases restricting patients' interests became even more entrenched in recent months, as the Eighth Circuit affirmed the District Court's judgment in *Catalona*.¹⁴

The issues that arise in the context of tissue rights, namely ownership, informed consent, patient autonomy, and a patient's right to withdraw, have otherwise remained mostly untouched by the United States courts and state and federal legislatures. The federal regulations governing the collection of human-subject tissues for research provide guidance as to informed consent, but leave many questions unanswered regarding a subject's right to withdraw or otherwise control her tissue samples after the samples are taken.¹⁵

In contrast to the United States government's relative inaction, many countries have addressed issues surrounding human tissue-banking through developments in their emerging common law and through the legislative process. These developments provide model mechanisms for the appropriate allocation of property rights and informed consent requirements for patients who either knowingly or unknowingly provide tissue samples.¹⁶ Sweden, for example, places high value on the patients' rights and autonomy. For example, it is one of the only nations with specific tissue-banking regulations, and

10. Although neither *Moore* nor *Greenberg* are binding on the 8th Circuit, both the district court and 8th Circuit court cite to these cases for support and use the same reasoning to reach very similar conclusions. See *id.* (citing *Moore* and *Greenberg*).

11. Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006).

12. *Id.* at 995.

13. See Lori Andrews, *Who Owns Your Body? A Patient's Perspective* on Washington University v. Catalona, 34 J.L. MED. & ETHICS 398 (2006) (comparing *Catalona* to *Moore* where at least the doctor and university used and developed the samples in some way and the patient claimed a right in the resulting cell line the doctor had derived).

14. See *Catalona*, 490 F.3d 667 (affirming the district court's decision, which limited patients' interests).

15. See *infra* Part II.A (discussing the current federal regulations governing human tissue collection and treatment of human subjects).

16. See, e.g., *Medicine's New Central Bankers*, *supra* note 2, at 29 (discussing the use of biobanks).

its consent requirements are very strict.¹⁷ Additionally, Denmark allows individuals who gave required blood samples at birth to demand the return of their tissue samples.¹⁸ In Iceland, both the courts and the legislature have addressed human tissue-banking, requiring that the source of the human tissue retain an interest in her tissue and maintain control over its future use, even if the tissue is given anonymously or at any point is changed to an anonymous sample.¹⁹ Furthermore, various international bodies, such as the Council of Europe, have adopted lower standards than the nations described above, yet still offer innovative solutions to these issues of ownership, consent, and autonomy.²⁰

Parts II and III provide a comprehensive background of both the regulations and common law decisions addressing patients' rights to their removed tissues, and the way in which informed consent requirements have played a role in these rights. Part III emphasizes the current landscape of these issues in the United States as revealed by the *Catalona* decision, and the potential policy implications of that particular common law development. Part IV analyzes the approaches to patients' legal rights to their tissue samples in Sweden, Iceland, and Denmark. Part IV also discusses the perspective of the Council of Europe, an international regulatory body.

Part V argues that current United States property law and analyses of informed consent are ill-equipped to adequately address a patient's claims to her excised tissues held in a tissue bank, arguing that *Catalona* should have been decided on grounds broader than the narrow property analysis used and affirmed by federal courts in the Eighth Circuit. In order to further patients' rights, the United States should adopt national regulations incorporating aspects from the models of property rights, informed consent, and tissue withdrawal protocols from countries around the world. Part V reveals the greatest problems in the current system and potential deficiencies that may arise should various models be adopted in the United States. Finally, this Part suggests a charitable trust model as a

17. *Sweden Takes Steps to Protect Tissue Banks*, 286 SCI. 894 (1999).

18. Nordic Committee on Bioethics, *Biolaw Update: Legislation on Biotechnology in the Nordic Countries*, Table 7: Biobanks, <http://www.ncbio.org/biolawupdate/table7.pdf> (last visited Feb. 16, 2008) [hereinafter Nordic Table 7].

19. See, e.g., Remigius N. Nwabueze, *The Concept of Sepulchral Rights in Canada and the U.S. in the Age of Genomics: Hints From Iceland*, 31 RUTGERS COMPUTER & TECH. L.J. 217 (2005); J. Wolter Oosterhuis et al., *Tumour Banks: Well-guarded Treasures in the Interest of Patients*, 3 NATURE REV. 73 (2003).

20. Barbara Indech, *The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts*, 55 FOOD & DRUG L.J. 343 (2000).

potential solution to protect tissue providers' dignity, autonomy, and self-determination.

II. BACKGROUND OF REGULATIONS AND GUIDELINES IN THE UNITED STATES REGARDING PROPERTY RIGHTS TO HUMAN TISSUES AND PATIENTS' INFORMED CONSENT

Doctors and researchers obtaining tissues from patients and volunteer subjects must follow a number of federal, state, and professional requirements. Several federal agencies have adopted a set of regulations known as the "Common Rule," which provides mechanisms to ensure that the necessary informed consent is obtained from human research subjects.²¹ These regulations apply to any recipient of research funds from any one of eighteen federal agencies and also to any recipient of private funds directed toward clinical research on federally regulated drugs or medical devices.²² Furthermore, several states require additional protections for human research subjects either through legislation or court rulings.²³ Professional guidelines and legal frameworks provide a final layer of regulation of human tissue collection and patient informed consent.²⁴

A. Federal Regulations

The Federal Policy for the Protection of Human Subjects, referred to as the "Common Rule," regulates any federally funded research involving human subjects.²⁵ The requirements of the Common Rule attach to research funding received from eighteen different federal departments and agencies.²⁶ This federal rule requires that two mechanisms be implemented to ensure appropriate human-subject research: (1) informed consent and (2) Institutional Review Boards (IRBs).²⁷ Informed consent allows patients and research subjects to be supplied with all the relevant information

21. Paul E. Kalb & Kristin Graham Koehler, *Legal Issues in Scientific Research*, 287 J. AM. MED. ASS'N 85 (2002).

22. *Id.* at 87.

23. See discussion *infra* Part II.B.

24. See discussion *infra* Part II.C.

25. Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J. LEGAL MED. 119, 121 (2006).

26. See *id.* at 120 (explaining that although the FDA has not implemented the Common Rule, the FDA regulations and the Common Rule impose the same requirements in research involving human subjects and when individuals knowingly contribute their tissues to research specifically).

27. Daniel S. Strouse, *Informed Consent to Genetic Research on Banked Human Tissue*, 45 JURIMETRICS J. 135, 136 (2005).

they need to make an autonomous decision to participate in the research.²⁸ IRBs must be put in place so as to review and monitor the human-subject research at each IRB's respective institution.

Pursuant to the Common Rule, each IRB is responsible for monitoring proper administration of the informed consent process, ensuring risk to human subjects is minimized, and determining that the benefits of the research outweigh the potential risks to the research subjects.²⁹ Prior to the start of any given research pursuit, the IRB must determine that the research is ethically permissible.³⁰ Additionally, it is within the scope of the IRB's obligations to continue to monitor the conduct of ongoing research even after it has been approved by the research subject with the appropriate informed consent.³¹ Thus, the IRB ensures both adequate substantive research as well as an appropriate consent process.

In addition to the IRB requirements, the Common Rule also sets forth the elements necessary for adequate informed consent. Notably, the Common Rule requires scientists to inform human research participants that their participation is voluntary, and that they may withdraw from the research procedures at any time.³² The information must be given to each research subject in language understandable to her.³³ Furthermore, "[n]o 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 release the investigator, the sponsor, the institution or its agents from liability for negligence."³⁴

Not only does the Common Rule require the exclusion of exculpatory language from an adequate informed consent, but the Rule also requires an explanation of the risks, nature, purpose, and duration of the research.³⁵ Another element of informed consent is the research subject's ability to withdraw from the research.³⁶ Under the Common Rule, "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the

28. See *id.* at 138 ("The cardinal value advanced by informed consent to research is regard for autonomy.")

29. 45 C.F.R. §§ 46.101–46.409 (2007); see also Jon F. Merz et al., *IRB Review and Consent in Human Tissue Research*, 283 *SCI.* 1647 (1999) (discussing "the degree to which published studies involving human tissues document IRB approval and informed consent").

30. 45 C.F.R. § 46.111(a)(1)–(2).

31. *Id.* §§ 46.109(e), 46.111(a)(6).

32. *Id.* § 46.116(a).

33. *Id.* § 46.116.

34. *Id.*

35. *Id.*

36. *Id.* § 46.116(b)(4).

subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.”³⁷

Despite the Common Rule’s stringent requirements for obtaining appropriate informed consent of the subject, a few exceptions are also set forth. Consent from the subject may be waived where the IRB determines the research poses only a minimal risk to human subjects and does not adversely impact subjects’ rights, when the research could not be performed without waivers.³⁸ As an additional exception to the Common Rule requirements, researchers may anonymize the human tissue samples taken from the research subjects in lieu of obtaining informed consent as described above; anonymous tissues are exempt from the requirements of the Common Rule.³⁹ A tissue is anonymized if all identifiers and links to the specific subject are removed.⁴⁰ However, there is evidence that not all research practitioners skirting Common Rule requirements through the above exceptions do so properly. One study found that researchers using human tissue samples without consent or IRB approval were more likely to use samples in an identifiable form rather than in the proper anonymized form.⁴¹

The Common Rule sometimes lacks clarity and is not without areas of weakness. The first significant problem with the application of the Common Rule is that it is intended to govern humans, not their excised tissues.⁴² Thus, it is unclear whether it should even apply to human tissues. Second, the Common Rule does not address a research participant’s right to physically possess his samples on termination of further involvement in the research. Nor does the Rule mention whether a subject has the right to direct or transfer samples.

The United States Food and Drug Administration (FDA) may require a tissue donor’s informed consent where the Common Rule does not require it.⁴³ Since research that may have initially been governed by the Common Rule could ultimately result in therapies or treatments which require FDA approval, studies and the resulting data may fall short of the FDA’s informed consent requirements.⁴⁴

37. *Id.* § 46.116(a)(8).

38. Merz et al., *supra* note 29.

39. See 45 C.F.R. § 46.116 (describing informed consent).

40. See *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 992 n.10 (E.D. Mo. 2006) (“To ‘anonymize’ a sample, all links to the [research participant’s] personal identifying data is removed and the sample is no longer ‘linked’ to a particular [research participant].”).

41. See Merz et al., *supra* note 29 (revealing that of “13 studies performed without consent or IRB approval, only 3 . . . used nonidentified samples”).

42. See 45 C.F.R. § 46.116 (describing informed consent, which demonstrates that the Common Rule’s focus is on making sure a human knows his or her rights).

43. Evans & Meslin, *supra* note 25, at 121.

44. *Id.*

For research on products regulated by the FDA, researchers must comply with informed consent and IRB review set forth in FDA regulations, which do not contain an exemption for anonymized tissues akin to that of the Common Rule.⁴⁵

B. State Laws

Although individual states must adhere to federal regulations, many states have enacted additional protections for patients and their rights to their banked tissues.⁴⁶ New York, Maryland, and Virginia have extended the Common Rule to any research performed within their respective state borders.⁴⁷ Therefore, researchers in these states must comply with the Common Rule's requirements for informed consent and IRBs not only when their research is federally funded, but also when the research is state or privately funded.

A few states have even created laws that establish a tissue donor's express property right in her tissue.⁴⁸ In response to the California Supreme Court's ruling in *Moore*, Colorado, Florida, Georgia, and Louisiana enacted laws making genetic information personal property of the individual, even though the *Moore* holding is not binding outside of California.⁴⁹ Taken one step further, it is possible that if a patient has a property right in her genetic information, she may therefore retain a right in any extracted tissues placed in a tissue bank for research. Oregon decided to make genetic information the private property of the person who provided the tissue in its Genetic Privacy Act of 1999.⁵⁰ The state legislature, however, rescinded this new property right in 2001 because scientists became increasingly concerned that such a right would negatively impact the progress of research in the state.⁵¹

45. 21 C.F.R. §§ 50.1, 56.101 (2007).

46. See 45 C.F.R. § 46.101(f) (permitting state laws to impose additional duties).

47. A.J. Baeyens et al., *The Use of Human Biological Samples in Research: A Comparison of the Laws in the United States and Europe*, 5 *BIO-SCI. L. REV.* 155 (2003).

48. Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 *JURIMETRICS J.* 153, 160 (2005) ("A few states have enacted laws that expressly recognize the property rights of a DNA donor.").

49. Baeyens et al., *supra* note 47; see also Marchant, *supra* note 48, at 160–61 (describing state laws that have been enacted in Oregon, Colorado, Florida, Georgia, and Louisiana).

50. See Marchant, *supra* note 48, at 160 ("Oregon's Genetic Privacy Act of 1999 was the first to declare that genetic information was the private property of the individual from whom the DNA was taken.").

51. *Id.*

C. Professional and Legal Guidelines

In deciding who owns a patient's tissues once they are excised, courts may look to professional and legal guidelines for direction, as precedent on the issue is sparse. The American Medical Association (AMA), the largest association of medical doctors in the United States, seeks to promote medicine, science, and the improvement of public health.⁵² In its guidelines on the Commercial Use of Human Tissues, the AMA has stated that the "rapid growth of the biotechnology industry has resulted in the commercial availability of numerous therapeutic and other products developed from human tissue."⁵³ The AMA proposes that doctors obtain informed consent from patients in order to use patients' tissues in clinical research.⁵⁴ Additionally, the AMA prohibits use of human tissue for commercial purposes without the patient's informed consent, allowing for profit sharing between patient and doctor should there be a lawful contract.⁵⁵ These guidelines, however, do not necessarily fill in the gaps left under the Common Rule regarding a research participant's relationship and rights to any excised tissues.

The Restatement (Second) of Property provides a donor the right to give personal property to another person (donee) as a gift and yet retain some reversionary interest in the property.⁵⁶ This section of the Restatement allows the donor to retain such an interest by "delivering the property to the donee, or to a third person for the donee, with the manifest intention that the donee acquire an ownership interest in the property that terminates [] after the passage of some specified period of time or upon the occurrence or nonoccurrence of some event or condition."⁵⁷ According to this provision, a patient who "donates" his tissue for use in research may convey less than the entire interest in the property, retaining a reversionary interest in the donated tissue.⁵⁸

According to the Corpus Juris Secundum (CJS), the elements of an inter vivos gift are: (1) the donor's intention to make a gift to another person; (2) delivery of the property by the donor to the donee or a third party for the donee; and (3) an acceptance by the donee

52. See American Medical Association, AMA Mission, <http://www.ama-assn.org/ama/pub/category/1815.html> (last visited Feb. 16, 2008) (noting specifically the AMA's pursuit to unite medical professionals across the nation to shape public policy surrounding medical issues).

53. American Medical Association, *E-2.08 Commercial Use of Human Tissue*, <http://www.ama-assn.org/ama/pub/category/8427.html> (last visited Feb. 16, 2008).

54. *Id.*

55. *Id.*

56. RESTATEMENT (SECOND) OF PROPERTY (DONATIVE TRANSFERS) § 31.2 (1992).

57. *Id.*

58. *Id.* cmt. a.

which completes the gift.⁵⁹ CJS also explains that an inter vivos gift must be absolute with respect to the immediate vesting of ownership in the donee once the elements have been met.⁶⁰ However, "a condition or qualification, not inconsistent with the vesting of title, does not necessarily render a gift invalid."⁶¹ Therefore, although a research participant may not donate her tissue reserving the right to revoke it entirely, it is possible to permissibly attach conditions to the giving of her tissue.

III. ANALYSIS: UNITED STATES COMMON LAW DEVELOPMENTS

While federal and state guidelines attempt to address the adequacy of informed consent by implementing regulations such as the Common Rule, it is the courts that have been left the task of allocating property rights in patients' excised tissues. Although many of the common law developments regarding tissue rights draw on the property law frameworks described above, the unique factual context of excised human tissue has resulted in a separate body of law all its own. By tracing the property rights to one's body parts from a historical perspective through the most recent developments in *Catalona*, the inadequacies in the U.S. approach become apparent.

A. Historical Property Rights in One's Body Parts

The concept that one owns her property and has the right to restrict another's access to that property is deeply rooted in the framework of property law.⁶² A property interest is commonly viewed as a "bundle of rights" that the owner retains with respect to the property, defining the ways in which an owner can include or exclude others from her property interest.⁶³ When a person's tissue is still a part of her body, it is clear that the individual owns that tissue.⁶⁴ However, the courts have struggled throughout history to define the

59. 38A C.J.S. *Gifts* § 11 (2007); see also *Washington Univ. v. Catalona*, 493 F.3d 667, 674 (8th Cir. 2007) (relying on these same elements as adopted in *Clippard v. Pfefferkorn*, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005)).

60. 38A C.J.S. *Gifts* § 37.

61. *Id.*; cf. 38A C.J.S. *Gifts* § 40 ("The reservation of a power of revocation is inconsistent with the absolute character of a gift inter vivos, and a gift with such reservation is void.").

62. See, e.g., Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 751-52 (2004) (emphasizing the power to restrict others as an important aspect of the evolution of property law).

63. *Id.* at 752.

64. Skloot, *supra* note 1, at 2.

set of rights given either to a person who has voluntarily parted with her tissue or to the person or entity that holds another's tissue.⁶⁵

In the early twentieth century, English and Australian common law provided only a limited set of rights to people claiming they had a property interest in a human body after death.⁶⁶ An Australian court in 1904 established that a man in a traveling freak show owned the two-headed stillborn child he had acquired for display in the show.⁶⁷ Although the police had confiscated the child's body, the man claimed in court that the body belonged to him, and the judge agreed, determining that if a corpse or body part had been altered for science or medicine, then it necessarily acquired value as property.⁶⁸ The judge came to this conclusion because he realized that if he found that this man had no right to own the stillborn child, museums, archaeologists, and medical schools would similarly have no right to own the bodies they had acquired.⁶⁹

In England, however, other people could hold property rights to a person's body despite the fact that a property right in one's own body did not exist under the law.⁷⁰ For example, one dead man's body was arrested while being transported to his funeral and given to his creditors as payment for his debts.⁷¹ Moreover, in the feudal era, it was a crime to mutilate one's body parts because this left an individual less capable of fighting for the king.⁷² Lingering hesitation to commodify tissues persists today because of the worry that people would then be reduced to an economic value, which many consider morally unacceptable in modern society.⁷³

In addition to the historical notion of a property interest in human bodies and body parts, informed consent has always been a fundamental principle in scientific research and ethics.⁷⁴ People can always refuse to participate in research, no matter how small the risk to them and how great the potential benefit to the community.⁷⁵ When patients choose not to participate in research, they retain the rights to their tissues, making the property claims of others clearly

65. *Id.*

66. Lucinda Hahn, *Owning a Piece of Jonathan*, CHI. MAG., May 2003.

67. *Doodeward v. Spence* (1908) 6 C.L.R. 406 (Austl.).

68. Hahn, *supra* note 66.

69. *Id.*

70. Andrews, *supra* note 13, at 400.

71. *Id.*

72. *See id.* (explaining that such understandings likely were based upon the idea that one's body and parts belonged to the king rather than the concept that the body is sacred).

73. *Cf.* Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 27 (2005) ("In mainstream U.S. culture, however, there are already precedents for payment for tissue and no cultural ban against it.").

74. *See id.* ("A basic tenet of research law and ethics is that research should not be undertaken without the subject's consent.").

75. *Id.*

illegitimate. Problems emerge here, however, when the situation involves pieces of tissue that the patient parts with intending to have them tested in a pathology lab. In such a situation, the patient has relinquished her tissue for a broad purpose, likely without having contemplated the scope of future uses.⁷⁶

B. Moore v. Regents of University of California

The United States court system first addressed the notion of a patient's property interest in his donated tissue sample when the California Supreme Court ruled in *Moore v. Regents of University of California* in 1990.⁷⁷ This landmark case arose after John Moore was diagnosed with "hairy-cell leukemia, a rare cancer that filled his spleen with malignant blood cells."⁷⁸ Moore's doctor, a cancer researcher at U.C.L.A., removed Moore's spleen, blood, and other tissue to eradicate the cancer.⁷⁹ The doctor used Moore's rare cells to develop and subsequently patent a valuable cell line without Moore's knowledge.⁸⁰ Moore alleged that the doctor did not inform him that his excised cells would be used for commercial purposes, nor did Moore give his consent to his doctor for such uses.⁸¹ Moore argued that he retained a property right in his tissue samples, and consequently, in the cell lines derived from those tissues.⁸² This property claim over human tissue was the first such claim ruled upon in the United States court system.⁸³

On appeal, the California Supreme Court determined as a matter of law that Moore retained no property interest in his excised tissues and resulting cell line.⁸⁴ Any property interest Moore had in his tissues disappeared when the doctor removed the tissue, despite the fact that Moore had not given consent for the doctor's research.⁸⁵ The court worried that if patients had a property right in their

76. See generally Strouse, *supra* note 27 (identifying the problem of how researchers can possibly obtain fully informed consent of the patient where possible future research uses of the patient's tissue are unknown at the time the tissue sample is taken).

77. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

78. Skloot, *supra* note 1, at 3.

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

80. *Id.* at 481-82; see also Skloot, *supra* note 1, at 4 (revealing that the doctor had entered into agreements with a biotech company to further develop the cell line and the market value of this cell line was predicted to near three billion dollars).

81. Moore further claimed that the researchers acted in unethical and misleading ways in order to continue obtaining more tissue samples for this research without telling Moore. See Marchant, *supra* note 48, at 156-57.

82. *Moore*, 793 P.2d at 487-95.

83. Skloot, *supra* note 1, at 4-5.

84. *Id.* at 5.

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

removed tissues, it would impede scientific progress because of the burden placed on scientists to ensure every cell line used in their research had the appropriate consent.⁸⁶ According to the court, a ruling in favor of Moore could potentially “destroy the economic incentive to conduct important medical research,”⁸⁷ and that as a result, “with every cell sample, a researcher purchases a ticket in the litigation lottery.”⁸⁸

The court determined that Moore had a valid claim that the researchers had failed to obtain his informed consent because the researchers had not disclosed their interest in his cells for research and potential financial gain.⁸⁹ Furthermore, the court found that a patient does, in fact, have some limited right to his tissues because so long as he is fully informed, he may withhold consent for the research if he does not approve.⁹⁰ However, the court did not find that this right extended to a patient’s retention of a comprehensive property interest in the resulting cell line.⁹¹ Instead, the court encouraged the legislature to determine the patient’s property interest in his removed tissues, admitting the current lack of regulation regarding consent and ownership.⁹²

The impact of the decision in *Moore* leaves patients without any ownership rights to their excised tissues, even if a court finds the patient’s consent to particular future uses inadequate. Although the California ruling is not binding in any other state, *Moore* is often cited outside California for the legal standard that courts will not recognize a property right for tissue donors.⁹³ In the two decades since this decision, no court has found that donors hold a property right in their genetic material, though courts have rarely had the opportunity to address the issue.⁹⁴ The irony in the impact of this decision is that the policy concerns the *Moore* court set forth to bolster its reasoning—namely, that giving a tissue donor property rights in her tissues would inhibit medical research because donors would limit researchers’ access to their tissues—has had quite the opposite effect.⁹⁵ Instead of preventing tissue commodification, “[the *Moore*

86. *Id.* at 493–95.

87. *Id.* at 495.

88. *Id.* at 495–96.

89. *Id.*

90. *Id.* at 491–92.

91. *Id.* at 494–96.

92. *Id.* at 496.

93. Skloot, *supra* note 1, at 7.

94. *See, e.g.*, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006); *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

95. Skloot, *supra* note 1, at 6.

decision] just took patients out of the equation and emboldened scientists to commodify tissues in increasing numbers.”⁹⁶

C. Greenberg v. Miami Children’s Hospital Research Institute

The Greenbergs were the parents of two children who had Canavan disease, a rare inherited brain disorder that kills the child within the first several years of life.⁹⁷ In 1987, the Greenbergs persuaded a genetic researcher to locate the Canavan gene, and they routinely provided samples of their children’s blood and tissues for this research over the next several years.⁹⁸ Yet the parents never once gave any form of written consent during a decade of this research.⁹⁹ The parents hoped that if the Canavan gene was found, the result would provide affordable access to the research, widespread prevention and screening techniques, and ultimately a cure for the disease.¹⁰⁰ According to the Greenbergs, the researcher eventually located the Canavan gene and patented the gene without informing them.¹⁰¹ The Greenbergs sued the researcher and his affiliated institution for unlawful conversion of their property, lack of informed consent, unjust enrichment, and fraudulent concealment of the patent.¹⁰² However, the court dismissed all claims except the unjust enrichment claim.¹⁰³

Similar to the ruling in *Moore*, the Federal District Court for the Southern District of Florida dismissed the conversion of property claim.¹⁰⁴ The *Greenberg* court found that because a tissue donor no longer retains a property right in her tissue samples once she voluntarily gives the sample to a third party, the Greenbergs retained neither a property right to the tissues nor any rights to the research derived from the tissues.¹⁰⁵ According to the court, researchers had

96. *Id.*

97. Kevin L.J. Oberdorfer, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources’ Research Interests*, 93 GEO. L.J. 365, 373 (2004).

98. Hahn, *supra* note 66; Oberdorfer, *supra* note 97, at 373.

99. In 1994, the hospital sent the Greenbergs an informed consent form, but nowhere in this consent form did the researcher disclose his intent to use the tissue samples for potential commercial purposes by patenting the Canavan gene. *See* Hahn, *supra* note 66.

100. *See* Oberdorfer, *supra* note 97, at 375 (pointing out that no evidence exists demonstrating that the Greenbergs ever actually conveyed this vision to the researchers).

101. *Id.* at 375–76.

102. *Id.*

103. The Greenbergs won on the unjust enrichment claim because they invested time and significant resources into the research. *See* *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003). The Greenbergs received an undisclosed settlement from this lawsuit. Skloot, *supra* note 1, at 7.

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

105. *Id.*

no continued duty to disclose all information to patients who at one time submitted tissues because such disclosure would impede science, similar to the court's policy-based reasoning in *Moore*. The court simply considered the tissue as donations to research without any expectation for return at a later time, and therefore determined that the Greenbergs retained no right in the tissues.¹⁰⁶

According to the *Greenberg* court's reasoning, no liability should attach for a doctor's failure to disclose to the patient her commercial intentions of tissue sample research. This analysis effectively restricts patients' rights to a greater degree than the *Moore* decision.¹⁰⁷ Furthermore, although the *Greenberg* decision is not binding, it has been used in subsequent decisions such as *Catalona*, demonstrating the emerging nationwide acceptance of this framework to determine researchers' rights to removed tissues and patients' loss of rights to those same tissues.

D. *The Latest Development: Washington University v. Catalona*

Washington University v. Catalona represents the latest common law development in tissue rights. Drawing heavily from the *Moore* and *Greenberg* decisions (which were merely persuasive and not binding authority on the court), the case was questionably decided with regard to both the property interest ruling and the informed consent ruling. Nonetheless, after the Eighth Circuit affirmed the District Court ruling in June, 2007, *Catalona* stands as the preeminent decision regarding tissue rights in the United States.

1. The Story of Six Thousand Loyal Patients

This unique lawsuit arose from Dr. Catalona's continued commitment to cancer research and to his patients, who in turn remained loyal to their doctor and researcher. Dr. Catalona, a preeminent surgeon and researcher of prostate cancer at Washington University in St. Louis, Missouri, had helped to establish a tissue bank at the University to collect and store biological research materials he obtained from his patients in his prostate cancer surgeries.¹⁰⁸ Over several years, Dr. Catalona had collected over thirty thousand tissue samples from patients willing to help him in

106. *Id.*

107. *Cf. Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (finding that Moore's physician's failure to disclose his research and economic interests violated Moore's rights to make an informed decision).

108. *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006). The tissue bank held biological samples of prostate tissue, blood, and DNA for the purpose of prostate cancer research. *Id.*

this endeavor.¹⁰⁹ In 2003, Dr. Catalona accepted a prostate cancer research position at another university and informed his patients of this transition.¹¹⁰ He asked them for permission to transfer their samples to the new university for his continued research, and six thousand patients wrote back to him stating explicitly that they wanted their samples to transfer with him.¹¹¹ Notably, Dr. Catalona also informed his patients in this correspondence that he would continue to provide care to them in his new position should they desire.¹¹²

Washington University refused to transfer the tissue samples and sued Dr. Catalona to obtain a permanent injunction to prevent further attempts by Dr. Catalona or his patients to transfer tissues.¹¹³ Washington University contended that because they held the samples over several years, the school—rather than the doctor who was merely their employee—owned them.¹¹⁴ Washington University claimed that it legally owned the patients' extracted tissues because the patients had donated them as gifts when they signed the University's informed consent forms.¹¹⁵ However, Dr. Catalona and the patients argued that the patients had not given their tissues unconditionally to the University.¹¹⁶ Rather, several of the patients testified during the trial that they had signed forms at the time the tissue samples were taken with the original intention of giving Dr. Catalona—not Washington University—their donated samples.¹¹⁷

Furthermore, the patients claimed that the informed consent forms they had signed did not demonstrate the giving of unconditional gifts because the forms gave patients the right to withdraw from the research at any time and have their samples destroyed.¹¹⁸ The patients understood this right to include “the right to continue control over the use and location of their excised biological materials.”¹¹⁹ Therefore, the patients argued that Dr. Catalona

109. See Andrews, *supra* note 13, at 398 (emphasizing Dr. Catalona's consistent successes in his research including the FDA approval of the commonly used PSA (prostate-specific antigen) test and improvement on existing tests for the detection of prostate cancer).

110. *Id.* at 399.

111. Transcript of Record at 1:26, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. Apr. 11, 2005) (No. 4:03CV1065SNL).

112. *Id.*

113. *Catalona*, 437 F. Supp. 2d at 985.

114. *Id.* at 986.

115. Andrews, *supra* note 13, at 399.

116. Post Hearing Brief for Defendant at 7–11, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV1065SNL) [hereinafter Post Hearing Brief].

117. *Id.*

118. *Id.*

119. *Catalona*, 437 F. Supp. 2d at 999.

should be allowed to take the samples with him to his new university because they retained a right to direct where their tissues should go.

Washington University responded that each patient's right to withdraw from the *research* did not include the right to withdraw the *sample* itself, and researchers had the right to simply anonymize the samples if consent was withdrawn.¹²⁰ The University explained that there were only three things that could happen when a patient decided to terminate participation: "(1) [the University] may destroy the sample; (2) [the University] may store the sample indefinitely without any further use; or (3) [the University] may remove all identifying markers and use the sample in exempt 'anonymized' research."¹²¹ The process of anonymizing a sample consists of stripping the sample of any identification, thus removing all connections to any human being.¹²² According to Washington University, transferring or returning the sample to the patient who has withdrawn participation in the research is not a recognized option.

2. The District Court's Findings

The district court ruled in favor of Washington University, finding that the University owned all the patients' "donated" tissue samples, and that neither Dr. Catalona nor his patients held any proprietary interest in these samples.¹²³ In regard to the issue of ownership, the court positioned the primary issue in the case as whether the research participants retained rights to direct or transfer their biological tissues to a third party after having "donated" the tissue to a research institution.¹²⁴ The court held that the University owned all the tissues in their tissue bank because they housed them in their facility, paid for the tissue bank's maintenance and administration, and raised the necessary funding to hold the tissues.¹²⁵ Because the patients never had access to their tissues once put in the tissue bank, the court determined that the University had exclusive control over the tissues.¹²⁶ The court acknowledged the lack of legal precedent guiding the court in its decision, yet based its finding entirely on the non-binding decisions of *Moore* and *Greenberg*,

120. See *id.* at 990 ("[T]he typical WU informed consent form states that '[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.' Some forms use the phrase 'withdraw my consent and discontinue participation.'").

121. *Id.* at 999.

122. Andrews, *supra* note 13, at 399.

123. *Catalona*, 437 F. Supp. 2d at 1002-03.

124. *Id.* at 997.

125. *Id.* at 994-95.

126. *Id.*

both of which “concluded that research participants retain no ownership of biological materials they contribute for medical research.”¹²⁷

The court further agreed with Washington University in regard to informed consent and the patients’ autonomy. The court considered the patients as “donors” giving their tissues as *inter vivos* gifts.¹²⁸ To constitute an *inter vivos* gift under the law, only the elements of donative intent, delivery, and acceptance are required.¹²⁹ Despite patient testimony indicating intent to give tissue to Dr. Catalona specifically,¹³⁰ the court discounted Dr. Catalona’s argument that the patients’ intent was to retain rights in their tissues, not donate them to the University, at the time they signed the consent form.¹³¹ Nonetheless, the court held that the patients had apparently intended to donate their tissues because the forms stated the word “donation” multiple times and listed the University as the owner of donated materials.¹³² The court regarded the patients’ heartfelt testimonies describing their intent to give their tissues to the doctor who had saved their lives as merely “afterthought[s] of regret” rather than the intent the patients claimed.¹³³

Finally, with respect to the issue of the patients’ right to withdrawal from the research, the court agreed with Washington University that under the consent forms, the patient simply retains the right to withdraw himself at any time from further participation in the research, not that the patient retains any right to control the sample itself.¹³⁴ The court found it sufficient that when a patient withdraws from the research, her sample may be destroyed, stored indefinitely, or anonymized, as such practices were acceptably implemented in research at the University at the time.¹³⁵

The court briefly addressed the policy concerns behind the decision in favor of the University. First, the court recognized that professional standards and “checks and balances” govern the

127. *Id.* at 995.

128. *Id.* at 997.

129. *Id.*

130. See Post Hearing Brief, *supra* note 116, at 17 (referring to patients’ trial testimony that they intended the tissue samples to go to Dr. Catalona, not the University specifically).

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

132. *Id.*

133. *Id.* at 999 (citations omitted).

134. See *id.* at 1000.

The Court finds that the right to discontinue participation in a research project means nothing more that the [patient] has chosen . . . not to make any more *inter vivos* gifts of donated biological materials to [Washington University]. Nothing more can or should be read into this right possessed by the [patients] at all times.

135. *Id.* at 999.

institutions collecting human tissues for research to ensure proper adherence.¹³⁶ According to the court, private interests and agendas would only corrupt such standards, allowing monetary agendas to trump the interests in public health.¹³⁷ The court believed that “[i]f left unregulated and to the whims of a [research patient], these highly-prized biological materials would become nothing more than chattel going to the highest bidder.”¹³⁸ Following the court’s reasoning down its proposed slippery slope, one might imagine a world where patients would soon be selling excised tissue on E-bay, threatening the integrity of all human tissue banks because patients could simply move their samples from one bank to another.¹³⁹ Secondly, the court found “[m]ore alarming . . . the great potential for prejudicial influences into medical research,”¹⁴⁰ as such prejudices violate the medical profession’s ethical codes, which attempt to promote health benefits to the greater public rather than benefits to selective groups or individuals.¹⁴¹

3. The Eighth Circuit Affirms the District Court

In December 2006, Dr. Catalona’s appeal reached the Eight Circuit Court of Appeals.¹⁴² Reviewing the District Court’s ruling under an abuse of discretion standard, the court affirmed the lower ruling on June 20, 2007.¹⁴³ Considering the novelty and importance of the issue as well as the lack of governing precedent in the context of tissue rights, the Eighth Circuit deferred to the District Court’s “well-reasoned opinion and judgment” to a surprising degree.¹⁴⁴ The Eighth Circuit echoed the reasoning of the District Court and labeled the patients’ donations *inter vivos* gifts under Missouri law.¹⁴⁵ In its only true departure from the District Court opinion, the Eighth Circuit pointed out that at no point were patients ever informed of any right to “physically withdraw or request the return of their biological samples.”¹⁴⁶ In fact, the court determined that under both

136. *Id.* at 1002.

137. *Id.*

138. *Id.*

139. *See id.* (“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.”).

140. *See id.* (analogizing the concern to a blood donor dictating his blood must be transfused into an individual of a particular ethnicity and a kidney donor requiring the recipient to be of a particular gender).

141. *Id.*

142. *Wash. Univ. v. Catalona*, 490 F.3d 667 (8th Cir. 2007).

143. *Id.* at 677.

144. *Id.*

145. *Id.* at 673–74.

146. *Id.* at 676.

federal regulation and Missouri statutes, restrictions on the handling of hazardous wastes meant that such donated samples could not be withdrawn or returned.¹⁴⁷ This aside only amounts to dicta, however; the Eighth Circuit affirmed the District Court's ruling on the basis of the same flawed property theory applied by the lower court.

4. Faults in Both Courts' Reasoning

Although the *Catalona* court relied heavily on the *Moore* and *Greenberg* decisions, deeper analysis reveals significant factual differences in those cases which render *Catalona* distinguishable. First, in *Catalona*, the tissues themselves are the property at issue, not the cell lines or gene sequences derived from those tissues.¹⁴⁸ As the patients and Dr. Catalona stated themselves, "contrary to *Moore* and *Greenberg*, Patients are not accusing [Washington University] of improperly converting their property, nor are they attempting to profit from or control the commercial use or exploitation of new products developed from their Tissue Samples."¹⁴⁹ The patients recognized that they voluntarily gave their tissues to Dr. Catalona, not to the University, for use in the doctor's specific research, and they reserved the right to withdraw their tissue samples at any point.¹⁵⁰ Conversely, neither the *Moore* patients nor *Greenberg* patients specifically reserved any rights, allowing the court to assume a gift was made unconditionally.¹⁵¹

Furthermore, unlike the researchers in *Moore* and *Greenberg* who put effort into developing something from the genes for many years, Washington University did nothing to the patients' tissues but store them. The *Catalona* court's reasoning that whoever pays to house tissues therefore owns them unnecessarily expands the prior tissue ownership doctrine.

Notably, as the patients and Dr. Catalona revealed to the court, "nowhere in *Greenberg* and *Moore* is it apparent that the extracted samples at issue in those cases were important [or] even relevant to the plaintiffs, or their families, future health care [and] follow-up."¹⁵² The *Greenberg* court emphasized that the patients' tissue samples had no therapeutic purpose to the patients, and that the doctors

147. *Id.*

148. See Andrews, *supra* note 13, at 400 (noting that the patients in *Moore* and *Greenberg* were "trying to control the products made from their tissues, not patients who claimed ownership of their own tissue itself" as in *Catalona*).

149. Post Hearing Brief, *supra* note 116, at 16.

150. *Id.*

151. See *id.* (citing *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003), and *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 488-89 (Cal. 1990)).

152. *Id.* at 17.

obtaining the samples were solely researchers, not clinical doctors.¹⁵³ The court in *Moore* found that the samples were used “strictly [for] academic and purely scientific medical research,” and that the patient’s excised tissues were not important in his future clinical treatment.¹⁵⁴ In *Catalona*, the court similarly found that the tissues in Washington University’s tissue bank were used strictly for research purposes but not for patient clinical or follow-up care.¹⁵⁵ Yet this stance overlooks the claims of several individuals and experts who testified at trial that the samples were used for patient care, not only for research.¹⁵⁶ Importantly, each sample was “linked” to the individual from whom it was taken, further demonstrating the possible future uses to each patient’s clinical care as knowledge in research progressed.¹⁵⁷

Finally, the *Catalona* court’s decision refused to take into account the potential ramifications of discounting the value of informed consent and a patient’s option of withdrawal from research as stated in the informed consent form. If a patient participating in Dr. Catalona’s research decided to withdraw, Washington University could simply anonymize that patient’s tissues, allowing further research to be done without being bound by regulation, as the patient’s identity would essentially be erased in regard to his sample. However, the court failed to address the fact that tissue can never truly be anonymous because the tissue still holds DNA. Additionally, there are further drawbacks to anonymization from both patients’ and researchers’ perspectives. The patient who anonymizes her banked tissue risks that the tissue will be used in research with which she disagrees. Additionally, the patient and her descendents will never know the results from research done on the tissue, and thus cannot benefit from any personal connection to that unique DNA. The researcher also suffers as a result of tissue anonymization because the patient’s individual characteristics beyond her genetic material can no longer factor into any research analysis.

IV. INTERNATIONAL REGULATORY AND COMMON LAW DEVELOPMENTS

Many nations around the world have enacted regulations or are currently preparing future regulations to regulate individuals’ rights to their tissues once they have been excised and stored in tissue banks. Expanding biomedical research has recently resulted in the

153. *Greenberg*, 264 F. Supp. 2d at 1070.

154. *Moore*, 793 P.2d at 485–86.

155. *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 989 (E.D. Mo. 2006).

156. Post Hearing Brief, *supra* note 116.

157. *Id.* at 17.

increased value of tissue samples, and several countries have recognized the importance of protecting the dignity, autonomy, and self-determination of patients who provide their tissues to their medical professionals and subsequently to tissue banks. Laws have been promulgated in response to this expansion not only at the institutional and local levels, but also at regional, national, and more broadly at international levels.

A. Sweden

Sweden is just one of the many countries that have been collecting human blood and tissue samples from its citizens for generations.¹⁵⁸ Specifically, the Karolinska Institute in Stockholm, one of the largest medical universities in Europe, has been running one of the world's oldest human tissue banks.¹⁵⁹ The Karolinska Institute itself claims that the "Swedish health care system is well-integrated and has a long tradition of storing medical data," and that its biobanks contain "millions of samples of tissue, blood, serum, plasma, DNA and other human biological specimens."¹⁶⁰ Using the tissue bank, researchers plan to follow 500,000 Swedes for thirty years to gather valuable information about depression, cancer, and heart disease.¹⁶¹

Furthermore, in 1975 Sweden's government established one of the first nationally-run biobanks,¹⁶² which now contains blood and/or tissue samples from almost every Swede born since its establishment.¹⁶³ Interestingly, this tissue bank is not anonymous, meaning that each of its samples remains linked to the person from whom it was taken.¹⁶⁴ These biobanks, therefore, contain not only samples, but an abundance of relevant data about the people from whom the samples were obtained.

Sweden is one of the few countries to institute specific tissue-banking legislation aimed at governing biobanks such as the one

158. See *Medicine's New Central Bankers*, *supra* note 2, at 29 (mentioning that not only Sweden but also Iceland, Quebec, and Japan have been collecting human tissues for many years).

159. *Id.*

160. Karolinska Institutet, World Class Source of Knowledge, <http://ki.se/ki/jsp/polopoly.jsp?d=7121&a=14493&l=en> (last visited Feb. 17, 2008).

161. *Medicine's New Central Bankers*, *supra* note 2, at 29.

162. *Id.*

163. *Id.*; see Mattias Karen, *In Sweden, Biobank Becomes Detective's Tool for Identifying Bodies in Thailand*, Feb. 2, 2005, <http://www.signonsandiego.com/news/world/20050203-0126-tsunami-dnadetectives.html> (last visited Feb. 17, 2008) (describing the privacy concerns surrounding Sweden's use of the tissue samples in its biobank to identify bodies of citizens who died in the Asian tsunami).

164. *Medicine's New Central Bankers*, *supra* note 2, at 29.

described above.¹⁶⁵ Similar to the United States Common Rule's requirements of informed consent and IRB review for the acquisition of human tissue samples, Sweden requires informed consent and approval by an ethics committee.¹⁶⁶ The Swedish Biobanks Act of 2002 and the Swedish Ethical Review Act of 2003 expressly called for scientists collecting tissue samples to obtain donors' explicit informed consent.¹⁶⁷ More notably, the Biobanks Act adopts a strict approach where donors must consent to the storage of their tissue once it is no longer being used in clinical research. Thus, donors must give separate consent for each different research procedure in which their tissue may be used.¹⁶⁸ Additionally, any existing tissues in banks that were obtained without consent are destroyed unless retroactive consent can be obtained from the donor.¹⁶⁹ According to the Swedish government, the acquisition of this consent is so important that out-of-touch donors must be tracked down even if it requires advertising in the media.¹⁷⁰ If a particular tissue cannot be identified, however, the consent requirements of the Biobank Act and the Ethics Review Act do not apply.¹⁷¹

The Ethical Review Act also provides for ethics committees to perform a balancing test in an attempt to protect both the donor as well as the advancement of scientific research. This Act contains an important provision which only allows the ethics committee to approve research where the "risks it entails to the research subject's health, security, and personal integrity are counterbalanced by its scientific value."¹⁷² Such a balancing of risks and benefits, including protection of the donor's privacy and personal integrity, attempts to be more sensitive to the interests of the tissue donors.¹⁷³

165. Oosterhuis et al., *supra* note 19, at 76.

166. *Id.*

167. M.G. Hansson, *Building on Relationships of Trust in Biobank Research*, 31 J. MED. ETHICS 415 (2005).

168. Oosterhuis et al., *supra* note 19, at 75; *Sweden Takes Steps to Protect Tissue Banks*, *supra* note 17; see also INSTITUTO DE SALUD CARLOS III, OUTSTANDING LEGAL AND ETHICAL ISSUES ON BIOBANKS: AN OVERVIEW ON THE REGULATIONS OF MEMBER STATES OF THE EUROBIOBANK PROJECT, at 41, available at <http://www.eurobiobank.org/en/intranet/workflow/uploadDir/PDFmarcadoresEUROBI OBANK-ING.pdf> ("Tissue samples may not . . . be collected and stored in a biobank without the donor being informed about the aim and purpose or purposes for which the biobank may be used and thereafter giving his or her consent.").

169. *Sweden Takes Steps to Protect Tissue Banks*, *supra* note 17.

170. See *id.* ("[I]nformed consent is required for each new use of the blood, even if it means advertising in the press to track down donors who are out of touch.").

171. Nordic Committee on Bioethics, *Legislation on Biotechnology in the Nordic Countries—An Overview*, Table 7: Biobanks, <http://www.norden.org/pub/ovrigt/ovrigt/uk/TN2006506.pdf> (last visited Feb. 18, 2008) [hereinafter *Legislation Table 7*].

172. Hansson, *supra* note 167, at 415.

173. See *id.* (noting that because tissue samples will be coded, there is only minimal risk of violating the donor's privacy).

Furthermore, the same local ethics committee with publicly-elected members must approve each withdrawal.¹⁷⁴ Under the Biobank Act and Ethics Review Act, a tissue donor's withdrawal is unconditional and his samples may either be anonymized or destroyed.¹⁷⁵ Although withdrawal from research is directly addressed in the legislation, the situation of a donor wanting to take back his own tissue sample is not addressed.¹⁷⁶ If the biobank wants to permanently transfer any tissue samples, it must get approval from the National Board of Health and Welfare.¹⁷⁷

Many experts have been researching and commenting on Sweden's regulations of informed consent, withdrawal, and the banking of tissues generally. There is a strong sense of duty to promote the public good by donating one's tissues in Sweden. One recent survey of Swedish blood donors to a large biobank concluded that "a majority of the respondents were willing to waive their right to informed consent and leave the decision about what kind of research should be carried out on the stored samples to the ethical review board."¹⁷⁸ Swedish citizens appear to have a deep trust of their government, researchers, and ethical review boards. Such trust may be the reason why the issue of a donor wanting to take back his tissue sample has not yet presented itself. "The respondents were more concerned with the security of the procedures and that secrecy was maintained than in the kind of research for which their samples were used."¹⁷⁹

So long as citizens' privacy is maintained, the problem of who owns the tissues may remain unanswered. However, as more information is obtained from genetic research on these tissue samples and the results are made public, the donors may find themselves stigmatized. For example, if a particular group of individuals is found to be more likely to carry genes for a disease or disorder, those individuals may be treated differently by social groups or employers. In such situations, the citizens of Sweden may become interested in reclaiming their tissues.

174. *Id.* at 416-17.

175. *Id.*

176. An interesting comparison can be made to Denmark law where a donor who wants her tissue sample returned to her is entitled to such an interest so long as she has a justified reason for the return, such as treatment at another institution or religious concerns over the tissue's use in research.

177. *Id.*

178. *Id.* at 416.

179. *Id.*

B. Iceland

Similar to Sweden, Iceland is one of few countries to have specific tissue-banking legislation; however, Iceland's consent requirements are more relaxed than Sweden's requirements.¹⁸⁰ In 1998, Iceland's Parliament enacted legislation—the Act on a Health Sector Database (HSD)—which created a national centralized database of human tissue samples and accompanying personal health and genetic data of Iceland's citizens.¹⁸¹ The homogeneous nature of Iceland's citizens, a relatively isolated group of individuals, makes such a comprehensive tissue bank unique and incredibly desirable to the scientific community.¹⁸² The goal of establishing the HSD was to improve the health of Iceland's citizens through a database of “non-personally identifiable” health data.¹⁸³ The 1998 Act only regulates the information, specifically declaring that it does not govern the “storage or handling of, or access to, biological samples.”¹⁸⁴

The Act on Biobanks, enacted in 2000, regulates the storage and handling of the tissue samples.¹⁸⁵ The donor informed-consent and withdrawal provisions under this act represent a comparatively more relaxed “middle-of-the-road” approach to tissue-banking procedures, allowing for increased protection of donors while maintaining feasibility for scientific researchers.¹⁸⁶ In a non-clinical setting, the Act requires a donor's voluntary informed consent for any tissues collected for storage in a biobank.¹⁸⁷ The donor must be told about “the objective of the sample collection, the benefits, and risks associated with its collection, and that the biological sample will be permanently stored at a biobank for use.”¹⁸⁸

A donor may withdraw his consent at any time, and consequently, all of his stored tissues must be destroyed.¹⁸⁹ However,

180. Oosterhuis et al., *supra* note 19.

181. Alice Hsieh, *A Nation's Genes for a Cure to Cancer: Evolving Ethical, Social and Legal Issues Regarding Population Genetic Databases*, 37 COLUM. J.L. & SOC. PROBS. 359, 360 (2004).

182. *Id.* at 370.

183. Act on a Health Sector Database, No. 139/1998, art. 1 (1998) (Ice.), available at <http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/659#kafli1>.

184. *Id.* art. II.

185. Act on Biobanks, No. 110/2000 (2000) (Ice.), available at <http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/31> [hereinafter Act on Biobanks].

186. Oosterhuis et al., *supra* note 19, at 75.

187. See Act on Biobanks art. 7 (“In connection with collection of a biological sample for preservation in a biobank, the free, informed consent of the person giving the biological sample shall be sought.”).

188. *Id.*

189. *Id.*; see also Regulations on the Keeping and Utilisation of Biological Samples in Biobanks, No. 134/2001, art. 7 (2001) (Ice.), available at <http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/684> [hereinafter Regulations

"[m]aterial that has been produced from a biological sample by performance of a study or the results of studies already carried out shall . . . not be destroyed."¹⁹⁰ Although the data from such studies will not be destroyed, they must still be completely anonymized so that any samples or findings from the studies cannot be traced back to the donor.¹⁹¹

Furthermore, the Act on Biobanks declares that neither the biobank nor the specific individuals who take a donor's tissue own that tissue.¹⁹² The law specifically states that "[t]he [biobank] shall not be counted as the owner of the biological samples, but has rights over them, with the limitations laid down by law, and is responsible for their handling being consistent with the provisions of this Act, and of government directives based on it."¹⁹³ It then goes on to state that the biobank cannot "pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt."¹⁹⁴ These provisions offer donors a strong position from which to claim they retain a property interest in their donated tissues similar to the patients' claims in *Catalona*. If neither the biobank nor the doctor may transfer a tissue sample, such a choice may remain in the hands of the original donor.

Another interesting area of Icelandic biobank law surrounds the concept of presumed consent. The Biobank Act provides for a presumption of consent for storage and further research using the tissue samples collected from patients in connection with clinical testing or treatment.¹⁹⁵ However, a donor remains free to "opt out," withdrawing from this presumed consent.¹⁹⁶ Once a donor provides

of Biological Samples] ("A donor of a biological sample may at any time withdraw his/her consent for the preservation of a biological sample in a biobank and/or participation in a scientific study.")

190. Act on Biobanks art. 7; *see also* Regulations of Biological Samples, *supra* note 189, art. 7.

On withdrawal of informed consent, the biological sample shall be destroyed, i.e. samples of tissue, blood samples, cells and isolated genetic material (DNA/RNA), and it is not permissible to carry out further tests on the sample, whether the original biological sample or isolated parts of it, cells or genetic material.

191. Regulations of Biological Samples, *supra* note 189, art. 7.

192. Act on Biobanks art. 10.

193. *Id.*

194. *Id.*

195. *Id.* art. 7.

196. *See* Regulations of Biological Samples, *supra* note 189, art. 8.

Should biological samples have been gathered in connection with clinical tests or treatment, the presumed consent of the donor of the biological sample may be assumed . . . for the biological sample to be stored in a biobank, provided that this is stated in written information which is available to the donor of a biological sample where the sample is taken . . .

the requisite notice of withdrawal to the Director General of Public Health, tissue samples already collected from the donor can “only be used in the interests of the donor of a biological sample or by his/her specific permission.”¹⁹⁷ Therefore, the donor retains an interest in her tissue and has a say in its future use, even if her tissue is anonymized.¹⁹⁸

This same presumed consent provision applies to individuals whose samples were entered into the HSD.¹⁹⁹ Iceland justifies such presumed consent with the argument that donors’ privacy interests are protected because the information is coded and anonymized.²⁰⁰ However, such an argument does not hold up under scrutiny; although Iceland claims to be protecting the privacy of these donors, it fails to protect their autonomy. The right to choose whether or not one’s own tissue will be stored and potentially used is of paramount importance, and such a provision does not recognize that basic right to choose.

A 2003 Icelandic Supreme Court ruling, *Ragnhildur Guomundsdottir v. The State of Iceland*, held that the presumed consent provision did not apply universally.²⁰¹ In this case, the daughter of a deceased man argued that she had the right to prohibit the transfer of her father’s genetic information into the national tissue database.²⁰² The court admitted that the HSD Act contains no direct provisions giving relatives of a deceased individual the right to prevent information about him being transferred to the HSD or opting out of consent as described above.²⁰³ However, the court nevertheless found that an individual’s constitutional right to privacy includes genetic relationships, emphasizing the right to privacy and individual autonomy especially in regards to consent procedures.²⁰⁴ It was also noted that merely introducing the requirement that donor information must not be able to be tracked to that individual donor and the establishment of review boards does not ensure individuals’ privacy is protected in accordance with the country’s constitutional requirements.

197. Act on Biobanks art. 7.

198. C. Thomas, *The Use and Control of Heel Prick Blood Samples*, 24 MED. & L. 259, 261 (2005).

199. Hsieh, *supra* note 181, at 378.

200. *Id.* at 379

201. *Ragnhildur Guomundsdottir v. The State of Iceland* [Supreme Court] No. 151/2003 (2003).

202. *Id.*

203. *Id.*

204. *Id.*

C. Denmark

In Denmark, the legal requirements for tissue research and the related ethical issues are found in the nation's data protection law.²⁰⁵ Denmark also included new provisions for regulating tissue banks in the revised Act on Ethics Review in June 2003, and in the Patients Rights Act in September 2004.²⁰⁶ Unlike both Sweden and Iceland, where entirely new acts were passed, these updated provisions merely add to existing ethical standards and tissue bank laws.²⁰⁷ The Patients Rights Act's 2004 amendment included provisions for patients' self-determination in how their samples were used in connection with their care or samples stored or developed by private groups.²⁰⁸

Denmark has also increased protection of patients' informed consent rights with protections similar to those implemented in Sweden. Patients in Denmark must provide explicit informed consent for their tissue to be collected for a research tissue bank.²⁰⁹ However, if the tissue is going to a tissue bank for clinical work, the patient's consent is presumed and an opt-out system has been put in place.²¹⁰ Opt-out systems provide that patients be informed that their tissue may be stored in a tissue bank for continued research, and that the patients have a choice at that time to decline the option to have their tissue stored.²¹¹ Unlike the opt-out procedure, the requirements for consent if the tissue is going to a privately-owned tissue bank are much more stringent. In such cases, the patient and tissue bank must actually enter into a written contract setting forth each party's respective rights.²¹² Furthermore, patients in Denmark must also give their informed consent for any secondary use of their tissue, and each new research project that will use a patient's tissue must obtain approval from its respective ethics committee before it can proceed.²¹³

Denmark has even more stringent laws regarding the patient's right to withdraw her tissues after they have been put into a tissue bank with the patient's initial consent. The patient must be informed at the time her tissues are taken that she may withdraw her consent at any time.²¹⁴ If a patient later desires to withdraw her consent, she

205. Baeyens et al., *supra* note 47.

206. Legislation Table 7, *supra* note 171.

207. See *supra* Part IV.A-B.

208. Legislation Table 7, *supra* note 171.

209. *Id.*

210. Nordic Table 7, *supra* note 18.

211. See Oosterhuis et al., *supra* note 19, at 75 (explaining the opt-out procedure).

212. Legislation Table 7, *supra* note 171.

213. Baeyens et al., *supra* note 47.

214. Legislation Table 7, *supra* note 171.

may simply request that her sample be destroyed, and the tissue bank must comply with her wishes.²¹⁵ Unlike other nations such as the United States, where the *Catalona* court deemed anonymization an appropriate remedy for a patient who desired to withdraw consent, when a patient requests this destruction of the tissue in Denmark, anonymization is insufficient.²¹⁶ More notably, if the patient wants the sample returned to her rather than destroyed, the tissue bank must physically give it back to her so long as she has a justified interest in getting it back.²¹⁷ Such an allowance provides for extenuating circumstances where Denmark's lawmakers have concluded that self-determination is more important than any future interest in research that one particular tissue sample may offer. However, public or private interests may override the patient's right in having the tissue sample returned to her.²¹⁸ Thus, the system allows for the balancing of different interests rather than rigid rules.

Neonatal screening offers an example of how Denmark's nationwide requirements for the banking human tissue samples in clinical tissue banks are implemented, ensuring the parents and newborn child maintain their autonomy, privacy, and self-determination. Since 1982, all babies born in Denmark have a blood sample taken for screening that is subsequently stored in a tissue bank.²¹⁹ It is required under law for the parents to be provided with written as well as verbal information regarding the blood sample screening before any blood is taken from the baby.²²⁰ Furthermore, the purpose of the tissue bank where the blood sample will be stored must be explained both verbally and in writing to the parents at the same time.²²¹

Parents then have several options after becoming fully informed.²²² First, parents have the right at the time the sample is taken to opt out of their child's blood being stored at the tissue bank in the first place.²²³ However, should the parents opt out at this early stage, no future screening on the child's blood could be done without

215. *Id.*

216. *See* Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (finding that since anonymization was a result of withdrawal stated in some of the patients' consent forms, anonymization was an acceptable solution for patient withdrawal); *see also* Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (affirming the reasoning and findings of the district court).

217. Legislation Table 7, *supra* note 171.

218. Nordic Table 7, *supra* note 18.

219. Nanette Elster, *Future Uses of Residual Newborn Blood Spots: Legal and Ethical Considerations*, 45 JURIMETRICS J. 179, 185 (2005).

220. *Id.*

221. *Id.*

222. *See id.* (comparing the systematic nation-wide requirements of the Danish system to the fragmented regulations of newborn screening tissue samples in the United States where each state implements its own system).

223. *Id.*

taking another sample. Second, if parents do allow their newborn's blood to be stored, all further screening and diagnosis beyond the initial screening must be approved separately by the parents under their informed consent.²²⁴ This additional informed consent is required with each new use or test on the stored tissue.²²⁵ Finally, parents have the option to withdraw the physical blood sample at any time after it is stored.²²⁶ Such an option to take back the physical sample in the future implies that the child, and thus the parents as guardians, retain an interest in that sample despite the fact that they have allowed it to be stored at the tissue bank.²²⁷

D. *An International Proposal: The Council of Europe*

The Council of Europe promulgated guidelines in 2002 for the use of stored human tissues and informed consent in biomedical research.²²⁸ The Council of Europe, first established as a result of The Hague Congress in 1948, consists of forty-three countries, including many nations not in the European Union.²²⁹ The guidelines were built on principles of the Convention of Human Rights and Biomedicine as well as the Protocol on Biomedical Research, and assert the purpose of protecting human rights, dignity, and self-determination with respect to medical research which uses stored human tissues.²³⁰

The main principle of the proposal declares that tissues which remain identifiable (non-anonymized) cannot be used for any purpose other than that for which they were initially removed unless the patient's informed consent is obtained.²³¹ Thus, without the patient's consent, the tissue may not be used for any secondary research not

224. *Id.*

225. *See id.* (mentioning that approval by an ethics committee is also required in addition to the parents' consent for a new use or test on the sample).

226. *Id.*

227. Another example of the high protection of an individual's property rights in a neonatal blood sample is found in New Zealand. New Zealand requires every child born in New Zealand must have a "heel prick" blood sample test between 48 and 72 hours after birth, similar to Denmark's testing. Parents of these children, or even the children themselves when they become competent, have the right to demand the return of their sample. The number of requests for returned samples has risen from none in 1995 to 775 in 2003. *See generally* Thomas, *supra* note 198 (suggesting that the rights these individuals retain in their tissue samples demonstrate that such samples should be considered the property of the human sources from which they were excised and that research use of the samples without consent should be prohibited).

228. *Id.* at 273 (noting that the guidelines were released in October 2002 for public comment).

229. Baeyens et al., *supra* note 47, at n.18.

230. *See, e.g.*, Thomas, *supra* note 198, at 273; Baeyens et al., *supra* note 47.

231. Baeyens et al., *supra* note 47.

covered by the original informed consent.²³² However, the guidelines do not apply to anonymized tissues, allowing nations who ratify the guidelines to simply anonymize tissues in order to circumvent the requirements for obtaining the patient's informed consent.²³³

Although this approach intends to protect human dignity and self-determination, allowing the simple anonymization of tissue to evade the Council's substantive protections does not further such goals. Sweden, Iceland, and Denmark offer patients even greater protection of dignity, autonomy, and self-determination. However, it is important for the Council of Europe and other international bodies to continue putting forth proposals in this area and to encourage nations not only to comment publicly, but also to ratify the proposal to establish widespread international minimum standards.

V. PROPOSAL

The United States' regulations and common law development as described above are simply inadequate to achieve the appropriate balance between protecting patients' autonomy and promoting scientific research. The *Moore*, *Greenberg*, and *Catalona* decisions demonstrate that the courts are forging a path of precedent that consistently allows research to outweigh the patient's dignity, autonomy, and self-determination. Unfortunately, these rulings have yet to elicit a national response. Such a response is imperative if the United States wants to find a more reasonable balance between individuals' rights and the furtherance of scientific research. Both interests are important, and to strike this balance, new solutions must be implemented, looking to countries such as Sweden, Iceland, and Denmark for guidance.

The United States comprehensively regulates informed consent, and a patient must be informed of his right to withdraw from scientific research.²³⁴ However, this informed consent loses its value if the right to withdraw is restricted merely to refusing to give additional tissue samples to the research; the full right to withdraw or destroy the already excised tissue sample itself is necessary to provide individuals with the self-determination they deserve. The systems of Sweden, Iceland, and Denmark all place a very high value on the patient's rights, allowing the patient to destroy or anonymize any samples she has provided in the past. Each country provides a slightly different rule for a patient's decision to withdraw, but all the

232. Thomas, *supra* note 198.

233. *Id.*

234. See *supra* Part II.A (discussing requirements of informed consent and IRBs).

rules carry the same common theme: the patient retains an interest in his tissue, and thus may call for the return, destruction, or anonymization of that tissue at any time.

The United States should incorporate this theme into a national framework for regulating tissue banks. Furthermore, the United States should go a step beyond these nations by allowing only for return or destruction—not anonymization—of a patient's withdrawn sample. Anonymization of a tissue sample is simply insufficient to fully protect a patient's interests. There are three reasons why de-identification does not accomplish anonymity of the tissue. First, "anonymizing" tissue is a misleading term because although the anonymization process requires that the patient's name and identity no longer be linked with the sample, it cannot ever fully strip the tissue of its connection to the person from whom it was taken.²³⁵ The tissue contains the individual's unique DNA, the most basic level of human identity. As science and technology progress and scientists understand more about the details of each person's specific DNA strains, DNA will likely become even more closely identified with human identity.

Second, anonymization is insufficient as a solution to a patient's wish to withdraw his tissue sample because the patient's family members will be unable to have further access to the tissues once they are anonymized. For example, the research in *Catalona* dealt specifically with prostate cancer. If the tissues taken from the men with prostate cancer were anonymized, the patients' children, grandchildren, and other decedents would not be able to access information from the original tissue that might provide them important insight into their own future health. As scientific screening tests improve, such samples will become more important in informing family members whether they will be subject to the same disease or health problems of the patient who initially provided the sample.

Third, even if an individual's tissue is anonymized, a group or individual may still be stigmatized or offended if the nature of the research violates his intent in originally providing the sample. Often scientific research will examine a specific definable group or population, and even if tissues are not linked to any one individual, when the research results are released, they may have a negative impact on the group as a whole, and thus the individual who provided tissue as a member of that group.²³⁶ For example, the Havasupai

235. See Andrews, *supra* note 73, at 24 ("Now that DNA typing is available which can identify individuals, samples cannot ever be truly anonymized.")

236. See *id.* (describing potential discrimination against the tissue source not because of one's individual identity, but because of a characteristic revealed about him as a member of a group).

tribe has sued Arizona State University (ASU) for misusing the tribe-members' blood samples in their scientific research.²³⁷ The scientists claimed to collect the tribe-members blood samples for studies on diabetes, but in fact performed research on schizophrenia and inbreeding.²³⁸ Although the providers of the tissue samples in this case did not have their samples anonymized, the end result of the ASU research demonstrates the potentially stigmatizing effect of research results. The tribe-members suing ASU claim that such research was stigmatizing to them and that the research itself conflicted with their religious beliefs.²³⁹ Each member of that tribe is now linked to the findings of schizophrenia and inbreeding, even though they never wanted to participate in such research in the first place. Even if those tissues were not linked to any particular individuals, they remain linked to the group, which was subsequently stigmatized when the findings were released.

The United States must also implement a system of tissue bank regulation that prevents trust in the doctor/patient relationship from dissolving further. Maintaining trust in the doctor/patient or researcher/patient relationship is essential to the medical profession, yet as patients learn more about their surrendered rights to tissues, that trust begins to dissolve. Most patients are not even aware that the tissues they have donated will be used for purposes beyond diagnosis, instead assuming that they will be thrown out as hazardous waste. However, as court holdings such as *Catalona* emerge in the headlines, the public will learn that this is certainly not the case.²⁴⁰

Because of the nature of the medical profession, patients often place a great deal of trust in their doctor. Doctors hold all the pertinent specialized knowledge, while most patients have little or no knowledge about the medical and scientific consequences of their condition. The patient trusts that the doctor will act in her best interest, and if the patient later finds out this is not the case, that trust begins to erode. When patients sign informed consent forms just before undergoing surgery, allowing their tissues to be banked, they may not fully comprehend the potential issues that may arise in the future when they find out they have no right to declare how those

237. Nicole Saidi, *Tribe Files \$50M Suit Against ASU*, ASU WEB DEVIL, Mar. 22, 2004, <http://www.asuwebdevil.com/issues/2004/03/22/news/637571> (last visited Mar. 7, 2008).

238. Lori Andrews, *Havasupai Tribe Sues Genetic Researchers*, in WHO OWNS YOUR BODY: POLICY CHALLENGES FOR HUMAN RESEARCH AND BIOTECHNOLOGY 23 (Inst. on Biotechnology & the Human Future, 2006).

239. *Id.*

240. See Skloot, *supra* note 1, at 38 (referring to the RAND study which showed hundreds of millions of tissue samples are put into tissue banks every year in the United States).

tissues should or should not be used. A patient is at his most vulnerable and emotional just before surgery, and he may depend on the withdrawal language as a safeguard for his protection. That protection should not later be reduced to carry no meaning from the patient's perspective.

Furthermore, patients generally expect that medical professionals, hospitals, and research institutions will use their tissues for good purposes, but how each patient defines "good" may be slightly different. When the patient later realizes that her expectations have not been met, the patient may feel discouraged or even betrayed by the medical professionals who have used her tissue for purposes to which they may not have initially consented.

Such an erosion of trust would be unfortunate because it could result in patients becoming less willing to participate in medical and scientific research.²⁴¹ Research participation is important to the progress of medicine and often beneficial to public health, such as when new drugs and therapies are developed to treat diseases and harmful conditions. Therefore, in order to avoid this deterioration, certain safeguards must be put into place to protect patients' interests while also providing for the use of human tissues in the progress of scientific research.

One possible approach to protect patients' autonomy and self-determination, different from those used in Sweden, Iceland, and Denmark, is the use of a charitable trust framework as a legal solution for ensuring that patients retain some control over their tissues.²⁴² Black's Law Dictionary defines a trust as "[a] property interest held by one person (the *trustee*) at the request of another (the *settlor*) for the benefit of a third party (the *beneficiary*)."²⁴³ The property interest is conveyed to the trustee through the trust only "as a result of a manifestation of an intention to create it."²⁴⁴ Since the trustee of the trust has a legal duty to use the property in the interest of the beneficiary, the property remains protected.²⁴⁵ Thus, a patient who provides tissue to a research institution would be considered the beneficiary, and the research institution holds title to the tissue as trustee, subject to the obligation to use the tissue for the benefit of the patient beneficiary.²⁴⁶

241. See Thomas, *supra* note 198, at 276 n.49 (mentioning an example of lost trust in medical professionals in an organ retention scandal in New Zealand where children's hearts were banked without consent after their autopsies).

242. David E. Winickoff & Larissa B. Neumann, *Towards a Social Contract for Genomics: Property and the Public in the "Biotrust" Model*, 1 GENOMICS, SOC'Y & POL'Y 8 (2005), available at <http://www.lancs.ac.uk/fss/journals/gsp/docs/volume1number3/dwgspvol1no32005.pdf>.

243. BLACK'S LAW DICTIONARY 1546 (8th ed. 2004).

244. *Id.*

245. Winickoff & Neumann, *supra* note 243, at 10.

246. *Id.*

A charitable trust, a subset of the general category of trusts described above, must actually be "charitable," aiming at the benefit of the general public or charity rather than the benefit of an individual.²⁴⁷ Under this framework, as patients continue to provide their tissues for use in scientific research, these tissues would simply be held for the benefit of public health. Although charitable trusts require a class of individuals, not the general public, to be designated as beneficiaries,²⁴⁸ medical professionals and patients may be able to contract around this requirement in the conveyance of the tissues to the trust.

The charitable trust model would require that the tissue samples be used according to the terms of the trust, with the institution as the trustee enforcing this use. This model would allow the patient to retain some control over the use of the tissue, and the patient would potentially be able to withdraw the sample so long as the trust relationship is revocable.²⁴⁹ A revocable trust is one "in which the settlor reserves the right to terminate the trust and recover the trust property."²⁵⁰ Although the charitable trust structure may not solve all current deficiencies in tissue regulation and may present new areas of conflict, this structure would provide patients with the autonomy, security, self-determination, and trust that the current regulations fail to protect.

VI. CONCLUSION

The United States' regulations and common law developments in *Moore*, *Greenberg*, and *Catalona* are simply inadequate to achieve the appropriate balance between protecting patients' autonomy and further promoting scientific research. These courts' rulings are undervaluing the notions of individual autonomy and self-determination that the U.S. holds dear. Sweden, Iceland, and Denmark have made greater strides in protecting these basic human tenets in the context of tissue banks through the implementation of comprehensive national policies. The United States should look to these nations for guidance in forming its own uniform national policy, as our current legal landscape regulating tissue banks will remain fragmented so long as it develops out of sporadic common law precedents. A legislatively enacted nationwide legal structure would help ensure a uniform approach among courts addressing tissue bank issues and aid in striking an appropriate balance between the

247. BLACK'S LAW DICTIONARY 1547.

248. Winickoff & Neumann, *supra* note 243, at 10.

249. *Id.*

250. BLACK'S LAW DICTIONARY 1551.

recognition of patients' rights and the promotion of scientific research.

However, many issues must still be explored and analyzed. Most importantly, more information regarding human tissue samples and tissue banks must be provided to the public, allowing for increased awareness of individuals' rights, or lack thereof. The broader the public comprehension of tissue-banking, the greater the chance that patients will make truly informed decisions when giving informed consent to have their tissues banked. Other issues presently remain unanswered. What will be the impact of more restrictive regulation of tissue banks on future scientific research? Will individuals who provide tissues truly benefit if the tissue bank system becomes more strictly regulated? What practical administrative problems need to be overcome to implement the proposal of a charitable trust structure of tissue donation and are the solutions feasible? Looking to the future, however, these concerns should not prevent the United States from immediately implementing new regulations that will protect tissue providers' dignity, autonomy, and self-determination.

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