REJECTION OF THE NEED FOR INFORMED CONSENT IN PROSTATE TISSUE SAMPLE RESEARCH

WILLIAM HANES*

INTRODUCTION

According to Michael Crichton, "[i]n Robert Louis Stevenson's day, body snatchers dug up corpses in the dead of night. Modern body snatchers take tissue from the living, and they do it in daylight."[1] After last year's decision in *Washington University v. Catalona*, he may not be too wrong.[2]

Today, many people believe that we should have absolute control over our bodies. Intuitively, our bodies and body parts should be the most personal of property. While this may be largely true as long as the parts are still connected to the body as a whole, as soon as a part is removed there is a different story. Our right to direct the use of our tissues, whether removed for diagnostic purposes or donated to research projects, has been slowly whittled away ever since *Moore v. Regents of the University of California*.[3] This trend finally came to a head in *Catalona*, where the judge essentially destroyed any meaning of informed consent and left donors wondering exactly what they donated their tissues to.

The last few decades have seen exciting new advances in science. We now know more about the human body than ever before. The human genome has been sequenced in its entirety and many diseases have been controlled or eliminated.[4]

---

* J.D. Candidate, Benjamin N. Cardozo School of Law, 2008, B.A. (Microbiology) Miami University, 2002. I would like to thank my wife for all of her support.

[1] Michael Crichton, *Body Snatchers*, WALL ST. J., Dec. 14, 2006, at A20.

[2] Washington Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. MO 2006).

[3] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (CA, 1990). The history of property rights may indeed go back even farther historically. In England, even though courts said people had no property rights to their body, until 1804 creditors apparently had such rights since they could arrest dead bodies for a debt. For example, the poet John Dryden's body was arrested as it was being transported for burial. In feudal times, it was a crime to maim oneself because this rendered one less able to fight for the king. Thus, the common law basis for preventing people from voluntarily transferring their body parts (which was later interpreted to prohibit even gratuitous organ donation) may not have its roots in the view that the body is sacred and that people should not be objectified as property. Rather, it may arise from the notion that people's bodies were the property of the Crown. Lori Andrews, *Two Perspectives: Rights of Donors: Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona,* 34 J.L. MED. & ETHICS 398, 401 (2006) (citing Note, Dale Oesterle, *The Sale of Human Body Parts*, 72 MICH. L. REV. 1182, 1182-1243 (1974) and Bernard Dickens, *The Control of Living Body Materials*, 27 U. TORONTO L.J. 142, 142-164 (1977)).

[4] Debra Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the*

However, many of these advances require a constant supply of tissue samples in order to develop new areas of biotechnology. The uses of these tissues are numerous: surgically removed tumors can help researchers map the progression of cancer at the molecular level;[5] blood samples can be matched to clinical profiles in order to investigate the role of genes and other factors in disease;[6] and hospital patients may be approached to provide tissues for study, leading to further understanding of their disorders.[7] While these studies can be done for research purposes only, increasingly they result in commercial developments that produce substantial financial rewards for researchers and biotechnology companies. Unfortunately, the individuals providing tissue rarely receive any portion of the resulting profits.[8]

The *Catalona* case is particularly troubling because there is a profound need for available prostate samples in order to advance prostate cancer research. Dr. Catalona himself made many advances in the development of a prostate specific antigen (PSA) test that is used to detect early stages of cancer. Without continued access to tissue samples, prostate cancer research may stall, leaving men vulnerable to the disease. This loss of tissues may arise as a result of biorepositories such as Washington University refusing access to samples, or by a lower pool of donors, scared off by the fear of misuse of their tissues.

The discussion below examines the loss of control of our tissues and the loss of the importance of informed consent, especially in light of the recent decision in *Washington University v. Catalona*. Part I summarizes the legal history of the loss of personal property rights over tissues. This line of cases includes John Moore and his tissue samples, which were extracted by fraud, and the ensuing immortal cell line that granted profitable returns, but not for Mr. Moore. It also involves a group of families suffering from Canavan, a genetic disease who approached a researcher to donate tissues to develop a test, only to find that the test was later patented and their use was restricted. In another case, the Havasupai tribe donated tissues for diabetes research without knowing the researchers were also using the samples to examine schizophrenia, inbreeding, and population migration. Finally, Part I discusses the recent *Catalona* decision, in which patients found that their primary tissues could not even be used for the initial primary purpose of donation—nor could they be destroyed. Instead, they were shanghaied into being used for any purpose Washington University deemed suitable and potentially excluded from Dr. Catalona's prostate cancer research, for which they had initially been donated. Part II analyzes the *Catalona* decision in an attempt to ascertain where it went wrong, and Part III outlines several recently proposed alternatives to

---

Patenting of Human Genetic Material, 15 ANNALS HEALTH L. 213 (2006).

[5] Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J. L. & MED. 77 (2002).

[6] *Id.*

[7] *Id.*

[8] *Id.*

denying research participants a property interest in their tissues while still promoting research activities.

PART I: THE HISTORY OF INFORMED CONSENT AND TISSUES AS PERSONAL PROPERTY NO LONGER

A. John Moore's Spleen

The view that participants in research studies have no property rights in their tissues or commercial products derived from them has its beginnings in *Moore v. Regents of the University of California*.[9] Mr. Moore's story begins simply enough. After becoming ill, Moore was diagnosed with hairy-cell leukemia and sought treatment at the Medical Center at the University of California at Los Angeles in October 1976.[10] Moore's attending physician, Dr. David Golde, confirmed his diagnosis after "withdrawing extensive amounts of blood, bone marrow aspirate, and other bodily substances."[11] Golde recommended that Moore have his spleen removed in order to "slow down the progress of his disease," and the splenectomy was successfully performed.[12]

Unbeknownst to Moore, Golde and his research assistant, Shirley Quan, had more than his best interests in mind. Golde had realized earlier that Moore's tissue had a tendency to overproduce proteins known as lymphokines, some of which have therapeutic properties.[13] The tissue could be used to isolate genetic material associated with the protein, and later be exploited through the use of recombinant DNA techniques to manufacture large quantities of these lymphokines.[14] Golde asked Moore to return to UCLA Medical Center at least twelve times between 1976 and 1983, even though Moore had moved to Seattle.[15] Each time, Moore was told that additional sampling was required to ensure his health and gave consent to withdraw "blood, blood serum, skin, bone marrow aspirate, and sperm."[16] Golde utilized the excessive production in the tissue to identify the related genetic material and developed an immortal cell line to manufacture the protein.[17] The cell line led to a patent which covered "various methods for using the cell line to produce lymphokines," and named Dr. Golde and Ms. Quan as the inventors of the

---

[9] *See Moore*, 793 P.2d at 497 (denying Moore's cause of action for conversion).

[10] *Id.* at 481.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Moore*, 793 P.2d at 481.

[15] *Id.* Golde would not allow Moore to be treated by a doctor in Seattle.

[16] *Id.*

[17] The "Mo" cell line. *Id. at* 482. Primary cells, those taken directly from the human body, only reproduce a few times, and then die. Through various techniques, scientists can create immortal cells from the primary cells that can reproduce indefinitely, creating an ideal medium for research purposes. *Id. at* 481.

cell line and the Regents as the assignee of the patent.[18] Agreements were made with two private companies yielding several thousand shares of common stock and payments of at least $440,000 over three years.[19]

During the treatment, Moore had no idea that his tissues were being used for research purposes.[20] The researchers did not inform him until seven years after the initial surgery, and after a patent application had been filed, that they were engaged in medical experimentation, and even then the doctors assured him that this research was purely scientific rather than commercial.[21] Mr. Moore further asserted that, despite his express inquiries about the potential financial benefits flowing from their research, defendants repeatedly denied that his biological materials possessed any commercial value.[22] On his last visit, in September 1983, Moore was presented with a consent form asking that he "voluntarily grant to the University of California any and all rights [he or his heirs] may have in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained by him."[23] Moore circled "I do not," signed, and returned the form.[24] Later that day, he received a phone call from Golde, who stated that Moore must have "missigned" the form.[25] A few days later, Moore received a package at his home that contained a new consent form with a large sticker and arrow saying "Please circle 'I do.'"[26]

Moore grew suspicious of the doctor's persistence to perform so many tests after the initial splenectomy and his insistence that Moore sign the form, and consulted a law firm.[27] His lawyer located an online article co-authored by Golde about his research on the tissue of a "37-year-old white male from Seattle, Washington," who proved to be John Moore.[28] Moore filed suit against Dr. Golde, Ms. Quan, the Regents of the University of California, and the two private companies, alleging, among other things, conversion, lack of informed consent, and breach of fiduciary duty.[29] Moore based his conversion claim on the theory that the tissue removed from his body was his tangible personal property, that he was entitled to direct its use, and that he never consented to its use in commercial

---

[18] ROBERT WEIR & ROBERT OLICK, THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE, 157 (Oxford University Press, 2004).

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *Moore,* 793 P.2d at 485-86 (defendants "repeatedly and affirmatively represented to [him] that there was no commercial or financial value to his Blood and Bodily Substances").

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Moore,* 793 P.2d at 485-486.

[28] V.S. Kalyanaraman, *A New Subtype of Human T-Cell Leukemia Virus (HTLV-II) Associated with a T-Cell Variant of Hairy Cell Leukemia,* 218 SCIENCE 571, 572 (1982).

[29] *See* Moore v. Regents of Univ. of Cal., 249 Cal. Rptr. 494, 498-99 (Cal. App. 2 Dist., 1988.).

research.[30] Therefore, the unauthorized use of his cells constituted conversion, and he claimed a proprietary interest in the products developed from his cells or the cell line.[31] Moore sought compensatory damages in the form of a share of the proceeds of the products.[32] By the time his case reached the California Supreme Court, most of the claims had been dismissed or consolidated, leaving only the questions of 1) whether Golde's failure to disclose the research and commercial interests violated Moore's right to make an informed decision about permitting his tissue to be used in this manner and 2) whether use of Moore's tissue for research and commercial reasons violated his property rights in the removed tissues.[33]

The court found that Dr. Golde had a duty as a physician-researcher to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment" in connection with procedures he recommends to patients.[34] A reasonable patient in Moore's position would have found Golde's research and economic interests relevant to the consideration of granting consent.[35] Golde therefore breached his fiduciary duty owed to Moore as his patient and his duty to provide informed consent. However, in a five-to-two opinion, the California Supreme Court found that Moore's claim for conversion failed.[36] It based this finding on the view that society's need for advancement of medical products outweighs the interests of research participants—otherwise the emerging biotechnology industry would suffer.[37] The court stated that, in order to maintain an action for conversion, the plaintiff must show "actual interference with his ownership or right of possession."[38] Because Moore had no expectation of retaining possession of the removed tissues, his claim must rest on an ongoing ownership interest in the removed tissue.[39] The court found that the claim failed because California statutes had limited patients' continued property interest in removed cells and because the cell line and products were found to be distinct, factually and legally, from Moore's own cells, meaning they could not be considered his property.[40] The court was attentive to the fact that conversion is a

---

[30] *See id.* at 501.

[31] *Moore*, 793 P.2d at 487.

[32] *Id.* at 482.

[33] *Id.* at 482-83.

[34] *Id.* at 483.

[35] *Id.*

[36] *Moore*, 793 P.2d at 498, 506.

[37] *Id.* at 495-96 (the court stated that "[i]f the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery").

[38] *Id.* at 488.

[39] *Id.* Moore would likely have assumed that the tissue would be discarded. *Id.*

[40] *Id.* at 489-90. For example, California's medical waste law, which directs disposal of human tissues, remains, and waste "following conclusion of scientific use" effectively destroys the property rights of the original host by restricting the use of removed tissues and destroying them. Additional laws concerning the collection and distribution of blood products treat these actions as services, not sale of goods. These laws, and others like them, convinced the court that excised human biological materials are "objects *sui generis*," and that ownership of biological materials should not be governed by general laws of personal property. *Id.* at 492-93 (finding that the patented cell line had properties sufficiently

strict liability tort, applying liability to every party in possession of cells, regardless of whether they knew of the deception.[41] The court further stated that "[i]f the scientific users of human cells are to be held liable for failing to investigate the consensual pedigree of their raw materials, we believe the Legislature should make that decision."[42]

B. The Canavan Patients

More recently, a similar situation arose involving families in which a family member was afflicted with Canavan disease.[43] These families contacted a noted researcher, Reuben Matalon, to help develop a genetic test for the disease using their tissue samples.[44] Matalon successfully developed a test and obtained a patent for the gene.[45]

The families were later devastated to find out that the test was being marketed with an extremely high royalty charged for each administered test.[46] The families stated that they had donated their tissues for the good of society, that they were never informed that there would be a patent and that they wanted the hospital to administer the test for free.[47] The families also objected because the Canavan Foundation was forced to stop offering free genetic screening, after being advised that it would have to pay royalties and comply with other licensing terms.[48]

Some of the families that had provided tissues for the research study filed suit against the researcher in the Southern District of Florida.[49] The complaint alleged breach of fiduciary duty and breach of the duty of informed consent when it was not disclosed to the patients that the researchers planned to patent the gene and market a test for Canavan.[50] They also alleged that the defendants converted their

---

different from those taken from Moore's body, and because a patent was issued for the line, it was legally "the product of human ingenuity" and "inventive effort").

[41] *Moore*, 793 P.2d at 493 ("The second important policy consideration is that we not threaten with disabling civil liability innocent third parties who are engaged in socially useful activities, such are researchers who have no reason to believe that their use of a particular cell sample is, or may be, against the donor's wishes.").

[42] *Id.* at 496.

[43] *See* Greenberg v. Miami Children's Hosp. Research Inst. Inc., 264 F. Supp. 2d 1064, 1066 (S.D. FL 2003). Canavan disease is a "rare genetic disease that occurs most frequently in Ashkenazi Jewish families." One in 6400 Ashkenazi Jewish children is affected by the disease, which is caused by a chromosomal mutation that leads to a deficiency of the enzyme aspartoacylase, gradually destroying the central nervous system; Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCIENCE 1062 (November 10, 2000).

[44] *Greenberg*, 264 F. Supp. 2d at 1066.

[45] *Id.*

[46] Joyce Boyle, *To Pay or Not to Pay, That is the Question: Finding an Intermediary Solution Along the* Moore *Spectrum*, 7 MICH. ST. J. MED. & L. 55, 65 (2002).

[47] *Id.*

[48] Marshall, *supra* note 44.

[49] *See Greenberg*, 264 F. Supp. 2d at 1066.

[50] Donna Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 260 (2004).

personal property by using the donations to reap economic benefits instead of promoting testing for the Canavan gene in conformity with the plaintiffs' wishes.[51] The complaint alleged that if the families had known of the researcher's intent to patent the Canavan gene, they would have restricted the use of the material to prevent commercialization or would have donated their tissues to researchers who had the same end goals of available testing.[52] In addition, the plaintiffs alleged fraudulent concealment, unjust enrichment and misappropriation of trade secrets.[53]

Following *Moore*, the Florida district court found that the plaintiffs retained no personal property right in their tissues, and thus dismissed all of the claims except one.[54] The court found that the unjust enrichment claim might be valid because the defendants had benefited from plaintiffs' contributions to their research, and it would be unjust enrichment for the researchers to profit from expansion of the scope of the research beyond the terms of plaintiffs' consent.[55] In the end, the parties reached a settlement agreement that became effective August 6, 2003.[56]

C. The Havasupai Tribe

In another case emblematic of the problems associated with tissue donation, members of an Arizona Native American tribe, the Havasupai, contested the use of their donated tissues.[57] The tribe has one of the highest incidences of type 2 diabetes anywhere in the world: over half the women and more than one third of the men have it.

In a lawsuit, members of the tribe alleged that researchers at the University of Arizona and at Arizona State University collected blood samples from them for diabetes research.[58] However, instead of using the tissues only for their intended purpose, the researchers also used them in unauthorized studies on schizophrenia, inbreeding, and population migration.[59] The plaintiffs claimed that the research on schizophrenia and inbreeding stigmatized them and that they would not have authorized the migration research because it conflicts with their religious beliefs.[60] The federal district court found that the Havasupai had claims for negligent and intentional infliction of emotional distress, civil rights violations, negligence, and

---

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id. at* 261.

55 Weir, *supra* note 18, at 164.

56 Gitter, *supra* note 51, at 261 n.14.

57 *See* Rex Dalton, *When Two Tribes Go to War*, 430 NATURE 500, 500-02 (2004); *See also* Tilousi v. Ariz. St. Univ. Bd. of Regents, No. 04-cv-1290 (D. Ariz. Mar. 3, 2005).

58 Lori Andrews, *The Battle Over The Body: Some Uses of Human Tissue, Donated Before or After Death, Go Beyond the Donors' Consent*, 42 Trial 22 (2006).

59 *Id.*

60 *Id.*

gross negligence. The plaintiffs voluntarily dismissed the federal claims and are litigating the issues of state law in state court.[61]

D. Washington University v. Catalona

The controversy in *Washington University v. Catalona* involved tens of thousands of tissue samples donated by patients for prostate cancer research.[62] The story began in the early 1980s, when a well-known surgeon and prostate cancer researcher at Washington University, Dr. William Catalona, began asking his patients to donate and let him use tissue, blood, and bone marrow removed during surgery for research.[63] He eventually obtained over 30,000 tissue samples and a large collection of research results.[64] Dr. Catalona developed the PSA test by 1986 and underwent further research in order to obtain Food and Drug Administration approval of the PSA.[65] Dr. Catalona later performed additional clinical trials to create an improved test with a ninety-five percent detection rate for prostate cancer.[66] Over the following years, approximately seventy-five percent of American men over age fifty underwent some form of the PSA test.[67]

Over time, Washington University saw that the tissue samples were not limited to prostate cancer research, but were also a potential capital resource for the university.[68] An e-mail, from a business manager at Washington University's office of technology to the vice-chancellor of research, concerning a request Dr. Catalona made to use tissues to test Hybertech's new prostate cancer assay stated, "Bill Catalona wants to send nearly 2,000 documented samples to Hybertech for free. Just from a cost recovery scenario, this should be worth nearly $100,000 to the University. The only consideration Hybertech is offering is the potential for Catalona to get a publication. It is my opinion this is an unacceptable proposal."[69]

While a publication would have been consistent with the wishes and consent of the patients and would potentially have resulted in additional research grants

---

[61] *Id.*

[62] *Catalona*, 437 F. Supp. 2d at 985.

[63] Andrews, *Two Perspectives*, *supra* note 3, at 398.

[64] *Id.*

[65] *Id.* (For information about Dr. William Catalona, *see* Dr. William Catalona's Bio, Urological Research Foundation, http://www.drcatalona.com/catalona_bio.asp (last visited Feb. 9, 2008); *see also* A. Scherzer, *Gala Honors Cancer Fight*, ST. PETERSBURG TIMES, November 4, 2005 ("Catalona led national studies to win FDA approval for a blood test to screen for prostate cancer"); *see also* I. Thompson, *Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level less than 4.0 ng per Milliliter*, 350 NEW ENG. J. MED. 2239 (2004)).

[66] Andrews, *Two Perspectives, supra* note 3, at 398 (citing Press Release, *Beckman Coulter, FDA Approves New Free PSA Blood Test to Aid in Battle against Prostate Cancer*, (March 1998), *available at* http://www.beckman.com/products/applications/diseasemgmt/pdf/FDAapproval.pdf .

[67] Andrews, *Two Perspectives, supra* note 3, at 398 (citing B. E. Sirovich, *Screening Men for Prostate and Colorectal Cancer in the United States*, 289 JAMA 1414, 1417 (2003)).

[68] *Id.*

[69] *Id. at* 398-399 (citing an e-mail from Jon Kratochvil, Business Development Director, Washington University in St. Louis, November 27, 2001 (read into the record, Tr. 3:33 (April 13, 2005))).

being given to the university, Washington University decided the samples would be better used as a source of capital for the institution.[70] Conflicts soon began to emerge between Dr. Catalona and the university administration, and he ultimately left for a position at Northwestern University School of Medicine in Chicago.

Dr. Catalona then contacted his patients to inform them of his transfer.[71] In these letters, sent to 10,000 patients who had donated blood, tumor samples and DNA for his research, Catalona stated that they could continue to receive health care at Washington University, or they could travel to Northwestern.[72] He also asked them to indicate whether they were willing to transfer their samples to Northwestern and to write to Washington University asking that their samples be transferred to Catalona.[73] Six thousand of his patients responded that they wanted their samples moved with Catalona from Washington University.[74]

Washington University, however, refused to transfer the samples and filed suit against Catalona for control over them. The university justified the claim by stating that since Catalona was an employee of the university at the time he retained the samples, the university, as his employer, had ownership of them.[75] In addition, the university claimed that his employment was conditioned on intellectual property policies that essentially prohibited taking samples without prior written approval from the Vice Chancellor for Research.[76] The university sought a declaratory judgment that it owned the tissue samples, valued at more than one million dollars, and asserted that it had the right to use them "in its sole discretion."[77] In response, Catalona alleged that since his employment and the initial formation of the tissue bank were initiated prior to the induction of these policies, they did not apply to him.[78]

After the university initiated the suit, a group of Catalona's patients interpleaded, claiming that they owned the samples and advocating for the transfer of the samples to Northwestern University.[79] The patients stated that their original intent was for Dr. Catalona to conduct prostate cancer research with the donated samples.[80] They also argued that Dr. Catalona's actions with the university should not affect their ownership rights.

---

[70] *Id.*

[71] *Id.*

[72] Tina Hesman Saey, *WU Gains Rights To Tissue Samples*, ST. LOUIS POST-DISPATCH, April 18, 2006 at A1.

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] Saey, *supra* note 72.

[78] *Id.*

[79] Andrews, *Two Perspectives, supra* note 3, at 399.

[80] *Id.*

Washington University counter-argued that the patients had no ownership rights in their samples since they were donated as a gift to the university.[81] The patients and Dr. Catalona responded that the samples had been given to the university on the condition that they be used for research by Dr. Catalona, and that failure or refusal to perform such a condition by the donee constituted grounds for revocation by the donor.[82] Moreover, the patients claimed they retained control of the tissue based on the informed consent forms they had signed. These forms gave the donors the right to withdraw from research or to have their samples destroyed.[83]

The university responded that "the right to withdraw from research did not include the right to withdraw the sample, and that the university should be able to make the samples anonymous and do whatever research it pleased with them."[84] Concerning the destruction of samples, the university stated:

> [W]hen somebody withdraws or discontinues participation [in a medical experiment], there are three things [the research institution] can do. It can keep [samples], it can destroy [samples], or it can anonymize [samples], which means take away all identification links so that you don't know where it came from anymore, and in those events, it is no longer considered human subject research and is no longer subject to regulation.[85]

Washington University's argument suggests that by anonymizing a patient's samples, a research institution enables itself to use the samples for any kind of research, whether or not it was consented to by the patient. This would hold true even if the patient withdrew from all studies at the university and specifically requested that his sample no longer be used for research purposes. The patients objected to this anonymization because it would diminish their contributions, inhibit research progress because the samples would be unlinked from future medical records, and prevent the donors from learning specific details about their individual tissue, which could be medically beneficial to them and their offspring.[86] The samples had been donated for the express purpose of furthering Dr. Catalona's research, not for the financial gain of Washington University.

District Judge Stephen Limbaugh ruled in favor of Washington University, declaring it the sole owner of "all biological materials, including but not limited to blood, tissue, and DNA samples" and granting the university permission to use the samples for appropriate research and the authority to transfer the tissues to other institutions.[87] He also found that "neither Dr. William Catalona nor any research

---

81 *Id.*

82 *Id.*

83 *Id.*

84 Andrews, *Two Perspectives, supra* note 3, at 399 (citing Washington Univ. v. Catalona, Trial Tr. 1:24, Apr. 11, 2005).

85 *Id.* (citing Washington Univ. v. Catalona, Tr. 1:24 (April 11, 2005)).

86 *Id.* (citing Wash. Univ. v. Catalona, Trial Tr. 1:64,Apr. 11, 2005) (testimony of Dr. Catalona)).

87 *Catalona*, 437 F. Supp. 2d at 1002.

participant in connection with any research protocol conducted under the auspices of Washington University has any ownership or proprietary interest in the biological samples."[88] Finally, he declared the "Medical Consent & Authorization" forms void, essentially removing any last bit of possible control patients had over their tissues.[89]

Judge Limbaugh came to this decision after looking to the substantive law of Missouri, which defines an *inter vivos* gift as "a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction."[90] The requirements of the gift in Missouri are: (1) present intent of the donor to make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee, whose ownership takes effect immediately and absolutely.[91] Judge Limbaugh also relied upon *Moore* and *Greenberg* as persuasive precedents.[92] He essentially adopted Washington University's argument that the right to withdraw from the experiment merely meant the right not to contribute more tissues.[93] The right to have the tissues destroyed meant only that the samples would be used anonymously.[94] The guarantee that tissues would only be used for prostate research could be ignored, and Washington University was free to use the tissues for any purpose.

Judge Limbaugh looked at the fact that Washington University alone bears all the legal, regulatory, and compliance risks with respect to research done in connection with the tissues. He also weighed the fact that the university's Intellectual Property Policy states that any tangible research property, including biological materials, belongs to the university if significant university resources were used in obtaining it or, when funding came from an external sponsor, if the property was obtained in relation to a research project administered by the university.[95] However, Judge Limbaugh gave the most weight to the facts that the informed consent forms were printed on Washington University letterhead and that the samples were meant to be gifts to the university.[96] The forms used the words "donate" and "gift" and often stated that subjects would not be able to claim ownership of property that resulted from the research performed with the materials.[97] In light of these considerations, Judge Limbaugh found that the patients had made an irrevocable *inter vivos* gift and given up all control over the

---

[88] *Id.*

[89] *Id.* at 1003.

[90] Pilkington v. Wheat, 51 S.W.2d 42, 44 (Mo. 1932); *see also* Wills v. Whitlock, 139 S.W.3d 643, 653 (Mo. Ct. App. 2004).

[91] *See* Clippard v. Pfefferkorn, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005).

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Clippard*, 168 S.W.3d at 1003.

[97] *Id.* at 997.

samples, and that Washington University maintained complete dominion over the samples to the exclusion of Dr. Catalona.

The 8th Circuit has heard oral arguments and has affirmed the lower court's decision.[98] As of this writing, an appeal has been filed in the Supreme Court, however, no decision has yet been made regarding acceptance for review.

PART II: ANALYSIS OF THE *CATALONA* DECISION

Judge Limbaugh presumably decided the way he did to protect the interests of research institutions and projects. The common fear among researchers is a scarcity of available tissues, or that the available tissues are so restricted in their use that no useful research can be done on them. Research, especially on tissues, is a vital part of the advancement of society and must be protected.

However, Judge Limbaugh's ruling may have frightening consequences. He has managed to single-handedly destroy any remnant of control we have over our tissues. He not only declared that universities may be able to do whatever they want with tissues, he also essentially rendered the need to obtain patients' consent unnecessary if the consent forms can simply be disregarded. By doing so, he may actually negatively affect tissue donation, as potential donors will be unwilling to donate tissues if they fear that they will be used in a manner against their wishes. When considering how to approach the fine line between protecting donors and researchers, it is necessary to look at informed consent, specifically, what the understanding and intent of the patient are.

At one point in his opinion, Judge Limbaugh refers to a brochure given to the research participants entitled "What if you change your mind?"[99] The brochure states, "To request that your tissue no longer be used for research, you should call the investigator listed on the consent form. Your tissue will be identified and destroyed upon request. Any research results already obtained cannot be destroyed or recalled."[100] He reads the sentence "Your tissue will be identified and destroyed upon request," and observes "Nowhere in the brochure does it state anything about a [research participant] withdrawing his/her sample or a [research participant] requesting that his/her sample be transferred to another facility."[101] He managed to twist the words to their breaking point to find that the patients should have known that "your tissue will be destroyed" meant, "we will continue to use your tissue, but erase your name from the database."

---

98 Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2006). A recording of the oral arguments is available at http://www.ca8.uscourts.gov/oralargs/oaFrame.html (search for case number 062286)(last visited Feb. 1, 2007). Briefs on behalf of Dr. Catalona and the patients are available at http://www.drcatalona.com/litigation.asp (last visited Feb. 1, 2008). Briefs filed on behalf of Washington University can be found at http://prostatecure.wustl.edu/ (last visited Feb. 1, 2008).

99 *Id.* at 990.

100 *Id.*

101 *Id.*

By ignoring the brochure, Judge Limbaugh disregarded a major consideration in determining patient intent. While the patients did not all receive the same consent form allowing them to withdraw from the study or have their tissues destroyed, they did all receive the brochure. It must be acknowledged that the patients might have taken the ability to have their tissues destroyed into account when making the decision to donate them to the study. The mere existence of such a brochure written by Washington University implies that it recognized that patients might change their minds about participating in the study and would want to know what options they had at that point. What was the point of Washington University writing such a brochure if there were no options for the participant? By giving consideration of the brochure such short shrift, Judge Limbaugh does the reasoning behind his decision a disservice.

Some patients also retained a personal interest in the samples after they had been donated. The stored tissue indicates the condition of the cancer when the tissue was removed, and can be used to compare to current tissue samples to ascertain the progression or development of cancer. This can be of utmost importance to patients in detecting changes in their health. Under Washington University's logic, if they are even given the full options outlined in the brochure, patients can either have the tissue destroyed/anonymized, or allow potentially objectionable research to be done with their tissues, with no way to stop it. The patients are left with no way to protect their vital health interests and at the same time protect moral and privacy concerns.

In addition, Judge Limbaugh seems to ignore the fact that Washington University is a federally funded program. The Health Research Extension Act of 1985 requires federally funded institutions to establish institutional review boards to establish an ethical guidance mechanism.[102] Pursuant to this Act, the Federal Policy for the Protection of Human Subjects, known as the Common Rule,[103]

---

[102] 42 U.S.C. § 289.

[103] 45 C.F.R. § 46 (2007). See *generally,* Weir, *supra* note 18, at 129-46. This policy is referred to as the "Common Rule" due to its widespread adoption by regulatory agencies. The Common Rule does not create a private right of action, but instead provides regulatory guidance for informed consent requirements. While it requires a minimum set of mandated disclosures that a researcher must provide to a potential patient, it does not preempt state law, which must also be comported with. These state laws are normally more expansive and thus where the majority of disputes arise. *Id.* The Common Rule states, in part:

> [N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. §46.116 (2007).

requires researchers to tell people if they are participating in research, as well as inform them that the research is voluntary and that they can withdraw from the project at any time without penalty.[104] These research regulations forbid researchers and research institutions from forcing patients to waive their legal rights and require that participants be given an opportunity to make an informed decision.

Consent forms must explain what the research is, how long it will last, any possible risks, and whether participants will be compensated.[105] In enforcement actions pursued by the U.S. Department of Health and Human Services, these rights have been interpreted to include patients' property rights to their own body tissue.[106] The *Catalona* opinion attempts to preempt the Common Rule and essentially render it ineffective. The opinion holds that the patients in this case waived *all* of their rights in their tissues even though they expressly reserved substantial rights in those tissues. The Common Rule was written and adopted in an attempt to protect research participants from harmful research studies and potential subterfuge. If this opinion is correct and the consent forms can be manipulated to the extent suggested, the Common Rule has lost its meaning.

The Common Rule does allow for "[r]esearch, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."[107] However, this exception is not pertinent to the instant case. First, this exception specifically applies to "pathological specimens" or "diagnostic specimens."[108] These specimens are materials produced by medical intervention, such as left over blood samples or tissues excised for histological examination. The majority of the tissues in the *Catalona* case, by contrast, were donated. Second, as noted earlier, research regulations are not limited to the Common Rule; it is only a starting point. [109] Here, the patients granted consent to their tissues being used in a certain manner that did not include anonymization. Washington University violated the consent agreement by refusing to destroy the tissues. The tissues were also identified at the time of donation and therefore were not "anonymous" samples. The Common Rule only allows use of anonymous samples; it does not permit the anonymization of

---

104 Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAGAZINE, Apr. 16, 2006, at 38, *available at* http://www.nytimes.com/2006/04/16/magazine/16tissue.html?pagewanted=1&ei=5070&en=770c3bcb5412effe&ex=1170392400.

105 *Id.*

106 Andrews, *The Battle Over The Body, supra* note 59, at 22 (citing Office for Protection from Research Risks (OPRR), Cooperative Oncology Group Chairpersons Meeting, *"Exculpatory Language" in Informed Consent* (Nov. 15, 1996), http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm).

107 45 C.F.R. § 46.101(b)(4).

108 *Id.*

109 *See supra* note 107.

them. Finally, Washington University was able to reach the participants to obtain consent for further studies, one of the primary concerns in prohibiting truly anonymous samples from being used—that it would be impossible to obtain consent.

Judge Limbaugh misapplied the laws of Missouri here and found the donations of the patients to be a "gift" to Washington University.[110] While the elements of a gift in Missouri are "1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3) acceptance by donee whose ownership takes effect immediately and absolutely[,]"[111] the court did not acknowledge that a donor must relinquish all "dominion and control" over the gift.[112] Therefore, a gift is not valid unless it is given unconditionally. "Language, written or spoken, expressing an intention to give does not constitute a gift unless the intention is executed by a complete and unconditional delivery of the subject matter or a delivery of a proper written instrument evidencing the gift."[113] A writing by the donor indicating that he did not plan to surrender all rights would refute any contention that the donor intended to give a gift.[114] In this case, the consent forms that the donors signed and the brochure given to them indicated that they could withdraw from research at any time and that their tissues would be destroyed.[115] This expressly placed a condition on the tissue donated and therefore, it could not be considered a gift.

Because the patients retained an interest in what was done with their tissues, this donation may be more like a bailment than a gift. A bailee/bailor relationship was found in *York v. Jones*, where a couple sought the release and transfer of a pre-zygote from an in-vitro fertilization program to a hospital. They had signed an informed consent form, which outlined procedures for freezing the pre-zygote and detailed the couple's rights to the fertilized eggs.[116] This consent form allowed the couple to withdraw from the program at any time. The physician in charge of the program later refused to allow the couple to transfer the pre-zygote claiming that the couple could only cease participating and either permit him to continue using use the pre-zygote for research, destroy it, or give it to someone else of the physician's choosing—the same argument as made by Washington University. The court in *York* found a bailor/bailee relationship created by the consent form between the plaintiffs and defendants, even without intent to create such a bailment

---

110 *Catalona*, 437 F. Supp. 2d at 994 ("It is well-settled that exclusive possession and control of personal property is *prima facie* evidence of ownership, and anyone else claiming such property bears the burden of proof." (citing Foltz v. Pipes, 800 S.W.2d. 14, 15 (Mo. App. 1990); State v. Patchen, 652 S.W.2d. 265, 267 (Mo.App. 1983))).

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

112 Ridenour v. Duncan, 246 S.W.2d 765, 770 (Mo. 1952).

113 *Id.* at 769.

114 *In re* Estate of Simms, 423 S.W.2d 758, 762 (Mo. 1968).

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

116 York v. Jones, 717 F. Supp. 421, 425 (D.Va. 1989).

based on the usage in the consent forms of the term "our pre-zygote."[117] Like *York*, the interests of Dr. Catalona's patients could be established through the language of the informed consent form, which consistently refers to patients as having a possessive interest in their tissue–"your genes," "your blood samples," "your pathological specimen[.]"[118] The ability to withdraw from research and destroy tissues upon request illustrates their ownership claims, the same as the *York* agreement allowing the release of the pre-zygotes from storage with "the written consent of both plaintiffs."[119]

Moreover, while this opinion purports to follow the *Moore* and *Greenberg* decisions, it in fact goes further. *Moore* and *Greenberg* both involved samples that were later converted into derivative products. *Moore* concerned a cell line that was patented and *Greenberg* dealt with development of genetic tests from DNA samples. Unlike in these cases, where the ownership issue was complicated by the fact that researchers "transformed the samples and obtained patents,"[120] in the *Catalona* case Washington University did not do anything innovative to those samples; it simply stored them.[121] *Moore* and *Greenberg* involved an element of intellectual property that is not present in *Catalona*.

Additionally, in *Moore,* the California Supreme Court found that a person had no absolute right to profit from a commercial venture utilizing his tissues because he has no property interest in them.[122] However, *Moore* still imposed a fiduciary duty on the physician, requiring him to grant enough information to his patient to enable him to make an informed decision.[123] The information that the tissue sample could potentially be used for economic gain was determined to be necessary for a reasonable patient to make a decision.[124] The *Catalona* case lowers and possibly even eliminates this requirement. No longer is the researcher required to disclose to potential donors that their tissue may be used for research studies not connected in any way with the initial reason for donation. In addition, it may not even be necessary to disclose that the samples could be used for commercial applications. Washington University is now allowed to do whatever it wants to do with tissue samples, regardless of what the initial donors were told. This allows the role of tissue administrator, which is normally a physician or researcher, to be supplanted by university board members who may know nothing of the scientific method and have no regard for the donor's original intent. This substitution is

---

117 *Id.* at 425-27.

118 Andrews, *Two Perspectives*, *supra* note 3, at 404.

119 *Id.* (citing *York*, 717 F. Supp. at 425).

120 *See, e.g., Moore,* 793 P.2d at 492-93.

121 Skloot, *supra* note 108.

122 *Moore,* 793 P.2d at 492-93.

123 *Id.* at 483. The court specifically noted that the research patient did not need a property right in his tissues to protect from their misuse because his interests were adequately protected by actions for breach of fiduciary duty and lack of informed consent. *Id.* at 491.

124 *Id.*

dangerous because a fiduciary duty is imposed only in the doctor-patient relationship—the university has no duty to act in the patients' best interests.

The court erroneously relied on the *Greenberg* decision as well. Florida law, on which *Greenberg* was based, did not recognize property rights in the body.[125] Missouri common law, on the other hand, does recognize a property right in bodies, body parts and bodily tissue.[126] In *Mansaw v. Midwest Organ Bank*, the U.S. District Court for the Western District of Missouri found that Missouri law granted a father a property interest in his son's dead body and that this property interest covered the right to control the removal of tissue and organs from the body.[127] In fact, the *Greenberg* court considered *State v. Powell* and ultimately rejected it.[128]

This decision purports to protect scientific advancement—"Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas."[129] However, this decision will potentially create the opposite effect. Donors have an interest in how their tissues are used—genetic information is very private, as it can tell so much about a person. Genetic information can be harmful in so many ways. Even Washington University's forms acknowledge this—according to the university's forms, "[i]f this information were to become known outside of th[is] research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or terminated from your current employment." [130] When donors begin to realize that their privacy has no protection, they will cease to donate. The research community will experience more losses of tissue sources if people simply cease donating than it would if they were simply not allowed free reign on any tissue samples that were ever donated. There is a real danger that the public will begin to "perceive that researchers obtain scientific inputs from them for free and then charge them for the commercial outputs."[131] If the public thinks that researchers are taking advantage of them, they will cease to contribute.

The decision also ignores the fact that people have moral and religious objections to use of their tissues in certain manners. The tissue could be used for human cloning, stem cell research, or commercial gain. If a donor is against the use of stem cells in research, it cannot be right that his opinion no longer matters as

---

[125] *Greenberg*, 264 F. Supp. 2d at 1075 (The court in *Greenberg* relied on *State v. Powell*, 497 So. 2d 1188 (Fla. 1986) where "the Florida Supreme Court refused to recognize a property right in the body of another after death." It also stated that, in a conversion action, "the property right in blood and tissue samples evaporates once the sample is voluntarily given to a third party.").

[126] *See, e.g.*, Mansaw v. Midwest Organ Bank, No. 97-0271-CV-W-6, 1998 U.S. Dist. LEXIS 10307, at *16 (D. Mo. July 8, 1998).

[127] *Id.*

[128] *Id.* at *15-16.

[129] *Catalona*, 437 F. Supp. 2d at 1002.

[130] Brief of Us Too, International as Amici Curiae Supporting Defendant-Appellants, Washington University v. Catalona, No. 06-2286, at *3 (8th Cir. Dec. 13, 2006), *available at* http://drcatalona.com/Amicus_Brief_of_Us_TOD6D7F.pdf.

[131] Gitter, *supra* note 51, at 341.

long as the tissues are rendered anonymous. It is too much to ask a person willing to donate tissue in the name of advancement of science to give up all personal beliefs. Going this far beyond patient consent will surely cause potential donors to think twice about giving in the future.

PART III: ALTERNATIVE APPROACHES TO THE CONSENT AND OWNERSHIP ISSUES

The answer to the problem of how to obtain a sufficient supply of tissue samples cannot be as simple as allowing biorepositories to do whatever they want with donated samples. The rights of donors need to be addressed as well. For donors to continue to contribute to research efforts, they must be given some sense of control and privacy. Several commentators have suggested possibilities for addressing these problems, which are outlined below.

A. The Human Genome Trust

The establishment of an organization that would hold the human genome in trust has been proposed by some commentators.[132] "Promoting proper dissemination of genetic information, protecting intellectual property rights, and implementing regulatory guidance for genetic research could best be served by the establishment of an international body to hold in trust the human genome as it is discovered."[133] The components of the system would include a board that would oversee Human Genome research and hold gene sequences in trust. The board would also grant licenses for researchers, including potential exclusive license rights (which would alleviate any economic concerns about companies becoming reluctant to invest money on public source projects). This system would increase international compatibility as most of the European Union opposes patenting of genes as they fall under the definition of body parts.[134] Unfortunately, this type of system has inherent difficulties, and may prove impossible to integrate.[135] While it could potentially promote more universal knowledge, it still does not protect donors and their tissues.

---

[132] *See, e.g.*, Patricia A. Lacy, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 804-05 (1998).

[133] *Id.* at 804-805; *see also* Barbara Looney, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POL'Y INT'L BUS. 231, 268 (1994) ("To ensure proper dissemination of genetic information, protection of intellectual property rights, and regulatory guidance for genetic research, an international body should be established to hold in trust the Human Genome as it is discovered, granting rights for continuing research that may culminate in inventions able to meet legal definitions of patentability.").

[134] Looney, *supra* note 133, at 263.

[135] *Id.* at 269 (noting, "Potential problems with establishment of such a governing body include administrative bureaucratic waste, lack of expertise, imbalance of power, and political tension. For example, creating such an agency raises bureaucratic concerns of waste--administrative, monetary and time--and political tension.").

B. The Harrison Hybrid Donative/Liability Model[136]

The Harrison Hybrid Donative/Liability Model was proposed by Ms. Charlotte Harrison, a former Fellow in Medical Ethics at Harvard Medical School in 2002. While its main goal was to allow donors to share in remuneration for commercial products developed from their tissues, it also addresses some of the inherent problems with the current system, such as lack of transparency, common purpose or priorities in the treatment of donated tissues. She proposed retaining the general rule of tissue donation with an emphasis on obtaining the patient's consent, and a nonmarket mechanism for compensating research participants when researchers have used their tissues to produce commercial products.[137]

Her solution includes remuneration of the research participants where the tissue proves of significant commercial value, and utilizes objective third parties that would aid in the determination of the award value, including an administrative agency, an arbitration panel, or a tribunal.[138] Where donors cannot be linked to the source tissue, or where the donor does not wish to receive compensation, the company utilizing the tissues would be required to pay the remuneration to a charitable purpose, such as "non-profit biomedical research or the provision of healthcare to the uninsured."[139] This approach would discourage the companies from "accidentally" losing the patients' records or persuading the donor against collecting his share. It also promotes maintenance of "links" between the research participant and the tissue sample, in both academic and commercial settings.[140] This proposed system would theoretically "enable the acquisition and study of tissue to go forward without the delays, commodifying tendencies and other disadvantages of up-front negotiations."[141] The system "would operate evenhandedly after the fact of use,"[142] and "could be applied uniformly to blood samples taken in private physician offices or through internet appeals, as well as to the full range of tissues collected in hospitals anywhere in the world."[143]

While this model could protect donors like Mr. Moore, who are seeking a portion of the profits realized through utilization of their tissues, the model does not address potential noneconomic interests, such as those in the *Greenberg* and *Catalona* cases.[144] These interests can include the right to participate in licensing decisions, such as those sought in the *Greenberg* case, and ownership rights,

---

136 Harrison, *supra* note 5, at 77.

137 *Id.* at 88.

138 *Id.* at 96.

139 *Id.* at 98.

140 *Id.* at 83 n.39.

141 *Id.* at 78.

142 Harrison, *supra* note 5, at 78.

143 *Id.*

144 *See id.* at 87 ("[T]he extent of protection afforded to a tissue contributor's non-economic interests is a public policy question that goes beyond the scope of this article.").

addressed in the *Catalona* case.[145] This model is a viable starting point, but it must be further expanded to cover the modern issues that have arisen in the past few years.

C. The Gitter Hybrid Property Rights/Liability Model

Donna Gitter proposed legislation for Congress to address current shortcomings, pointing out that "legislatures may be in the best position to design and institute appropriate remedies."[146] This is a view proposed by the *Moore* court as well—"If the scientific users of human cells are to be held liable for failing to investigate the consensual pedigree of their raw materials, we believe the Legislature should make that decision."[147] The Gitter plan proposes that:

> Congress implement a hybrid property rights/liability model that: (1) recognizes that individuals possess property rights in their tissue and therefore have the right to exchange it for valuable consideration, or to waive such rights if they prefer to make a gratuitous donation; and (2) permits individual research participants to maintain an action for conversion of their tissue in the event that: (a) they were not informed that researchers were using their tissue for commercial purposes; or (b) they did enter into an agreement regarding the use of the tissue that is voidable under the doctrines of fraud, duress, undue influence, or mutual mistake.[148]

Gitter points out that federal jurisdiction over research would be proper. Under the Common Rule, federal law already provides for regulations concerning the treatment of human research participants involved in federally sponsored research.[149] Certain research programs that involve experimental drugs, biological products, and medical devices are subject to FDA approval.[150] Finally, Congress grants property rights in "intangible intellectual property created by human ingenuity" in the form of patents, copyrights, and trademarks.[151] It therefore can create a similar incentive to supply tissue by granting research participants a continued property interest in their donations.

One of the main parameters of this proposal is that research participants be able to negotiate openly with researchers and that they be fully informed of all risks of the research and any economic interests in order to reach a satisfactory informed consent agreement.[152] In order to protect themselves, "research participants should

---

[145] *See id* at 83 n.39 (acknowledging that the proposal does not address potential issues of "ownership and control").

[146] Gitter, *supra* note 51, at 339.

[147] *Moore*, 793 P.2d at 496.

[148] Gitter, *supra* note 51, at 339.

[149] *Id.*

[150] *Id.* (citing 21 C.F.R. §§ 50.1, 56.101 (2002) (describing the scope of the regulations)).

[151] Gitter, *supra* note 51, at 340 (citing 15 U.S.C. §§ 1051-1129 (2000) (setting forth the federal trademark statute); 17 U.S.C. §§ 101-1332 (2000) (setting forth the federal copyright statute); 35 U.S.C. §§ 1-376 (2000) (setting forth the federal patent statute)).

[152] Gitter, *supra* note 51, at 340.

possess the right to initiate an action for conversion... against any researcher who uses their tissue without informed consent."[153] Under this model, if an action for conversion were brought, remuneration would be limited to compensation "only if the researchers earned a profit from commercializing their tissue."[154] In doing this, the model views the donors as investors in the research project who donate capital and could potentially lose the value of their investment. The actual value of the tissue in the commercialization process would be considered the investment.

Gitter believes that this model will not increase the number of conversion lawsuits filed because litigants would expect a small damage award if they do not have unique tissue and therefore would only file lawsuits if they were sufficiently aggrieved.[155] She feels that this model will stimulate biomedical research, rather than restrict it. First, the potential for monetary compensation may encourage research participation by "individuals who might otherwise decline to behave altruistically while others profit."[156] Second, the possibility of a share in profits may induce medically affected individuals to report any scientifically significant phenomenon to researchers who may have an interest in their condition.[157] Third, threat of potential liability in the case of incomplete disclosure creates incentive for researchers to properly provide informed consent.[158] Fourth, this model purports to help tissues end up in the hands of the party that will put the tissue to its most valuable use by giving research participants the ability to bargain with researchers to meet a mutually beneficial agreement.[159] Finally, under notions of equity, research participants "who supply useful scientific raw materials, and encounter risks through their participation," should be entitled to share in the same economic gains as the researchers.[160]

D. The Tissue in Trust Proposal[161]

Joyce Boyle proposed a "trust system," in an attempt to offer a solution to the property rights debate. Like the liability models, this proposal attempts to offer a mechanism that promotes altruism while allowing individuals to receive compensation when they contribute a great deal to a research study. Unlike the liability models, which grant no property interest in the donor,[162] this solution

---

153 *Id.*

154 *Id.*

155 *Id.*

156 *Id.* at 340-41 n.377 (also pointing out that research participants who wish to make a truly altruistic donation may waive any rights to profits of biomedical research).

157 Gitter, *supra* note 51, at 341, 341 n.378.

158 *Id.* at 341, 341 n.379 (citing *Moore*, 793 P.2d at 494, in support of the proposition that the threat of a conversion claim may help enforce a patient's right of informed consent).

159 *Id.* at 341.

160 *Id.*

161 Boyle, *supra* note 47, at 74.

162 *See, e.g.*, Harrison, *supra* note 5.

attempts to confer a property interest, which may provide benefits to both the research subject and the research community as a whole.[163]

The first step in enacting this proposal would require the establishment of a federal commission authorized to regulate compensation for tissues used in research. "This commission would streamline the regulatory use of tissues in research by creating an efficient and uniform system."[164] The establishment of a uniform system with a single set of standards that researchers could look to would aid the distribution of tissues between research facilities.[165] Open and accessible policies would place the research subject on notice and may further assist in obtaining complete informed consent.[166] "As a result, people may be willing to contribute their tissues if they are fully informed of the process and procedures of donation."[167] This specialized federal commission would also be empowered to establish a compensation threshold amount.[168]

For example, if an individual contributed a tissue sample and the commercial gain to that individual would be one thousand dollars or less, the amount gained would be donated to a research foundation of donee's choice (*e.g.* AIDS research foundation, American Diabetes Association). If the product resulted in financial gain over the threshold amount, the person would be notified, the commission would review the individual case and determine whether compensation [was] appropriate.[169]

Boyle believes that this approach will "alleviate[] the tension in cases like *Moore* where researchers become millionaires and nothing is given to the individual who made a significant contribution."[170] By giving the donor both the ability to receive compensation for his donation and direct where the compensation goes, the incentive to act altruistically is increased. It also allows donors who contribute not only tissue samples, but also time and energy, to receive payments.[171]

Beyond compensation, Boyle's plan attempts to allow donors to retain a property right in their tissue samples. To do this, the commission would create an *inter vivos* trust at the time of donation.[172] An *inter vivos* trust is defined as a "trust created during lifetime of settlor and to become effective in his lifetime."[173] The term *inter vivos* refers to a property being transferred by conveyance by a living

---

163 Boyle, *supra* note 47, at 74.
164 *Id.*
165 *Id.*
166 *Id.*
167 *Id.* (citing Harrison, *supra* note 5, at 85).
168 Boyle, *supra* note 47, at 74.
169 *Id.*
170 *Id.* at 75.
171 *Id.*
172 *Id.*
173 Boyle, *supra* note 47, at 74.

person, as opposed to a gift made by succession or devise.[174] This trust would be created on behalf of the donee, on the chance that his tissue will have commercial value.

According to general trust law principles for creating an *inter vivos* trust, first, a settlor, or the person who creates the trust, would be determined.[175] Here, either the federal commission or an officer of the commission would be appointed the settlor. This settlor must properly manifest an intention to create a trust.[176] Then, the patient/donor would need to be named as the beneficiary of the trust.[177] Next, the federal commission would be appointed trustee of the trust to manage the trust, act in a fiduciary capacity, and hold title in the tissues in the interest of the beneficiary.[178]

Finally, the trust must be "funded" to become valid.[179] Here, the commission would fund the trust after deeming the case "worthy of compensation" by either conferring a token asset into the trust or larger assets, depending on whether "the market price or the compensation amount had yet been determined."[180]

In order to prevent complications and ensure uniformity, Boyle proposes a few rules: "1) the inter vivos trust would remain in the donee's name for the life of the individual; 2) transfer of property interests would not be allowed; 3) the trust would terminate upon death of the donee; and 4) the individual would not be able to contract for private sale."[181]

Boyle's system has the advantages of uniform application, the possibility of compensation for contributions to commercial products, and at least some form of property right. While the potential record-keeping costs could potentially be high, the uniform national system should reduce some of the complex recording issues. In addition, the ability to retain a legal right in the tissue, as well as a fiduciary duty imposed on the agency managing the samples, may encourage individuals to

---

174 *Id.* (citing BLACK'S LAW DICTIONARY 821 (6th ed. 1990)).

175 *Id.* (citing JOHN COHAN & GERALDINE HEMMERLING, INTERVIVOS TRUST PLANNING, DRAFTING AND TAXATION7 (Shepard's Citations, Inc., 1975)).

176 *Id.* (citing RESTATEMENT (SECOND) OF TRUSTS § 23 (1959) ("The manifestation of intent to create a trust may be spoken words, memorialized in writing or expressed through conduct. No specific language is necessary to constitute a manifestation of intent.")).

177 *Id.* (citing RESTATEMENT (SECOND) OF TRUSTS § 112 (1959) ("A trust is not created unless there is a beneficiary who is definitely ascertained at the time of the creation of the trust or definitely ascertainable within the period of the rule against perpetuities.")).

178 *Id.* (citing RESTATEMENT (SECOND) OF TRUSTS § *95* (1959) ("Pursuant to this section of the Restatement, the United States or a State has capacity to take and hold property in trust. Specifically, a State can administer a trust for any purpose unless restrained by provisions of the Constitution or laws of the United States or of the State. Here, the federal commission would set guidelines for each State in order to allow for administration of the trusts.").

179 Boyle, *supra* note 47, at 74 (citing Susan Porter, *How to Use Inter Vivos Trusts in Estate Planning, in* USE OF TRUSTS IN ESTATE PLANNING: DRAFTING TIPS, TAX CONSEQUENCES AND ETHICAL CONSIDERATIONS171 (Practicing Law Institute 2001)).

180 *Id.*

181 *Id.*

donate. Knowledge that there is accountability for mismanagement of their tissues will grant donors comfort.

E. A New Proposal

In determining the best approach to resolve such a difficult problem, it is vital to consider the needs of both the research community and the potential donors. This is the only way to incentivize efficient donation of tissues, while providing for the needs of the research community.

Researchers have several needs when it comes to tissue samples. First, a steady supply of tissues is necessary. The samples are used up in the course of study, and thus only a finite amount of research can be done with any one sample. In order to continue performing new studies, new tissues are required. In addition, for many projects, researchers need background data on the patient himself. These data are used to link tissue properties with a particular clinical background, such as a cancer patient. The use of these linked data allows researchers to look at the differences between the tissues of people without the ailment and the people with it. Therefore, the availability of at least some tissue that is not anonymized is crucial.

Donors, as well, have many concerns, some countervailing, that must be addressed. As discussed previously, privacy is a large concern, as are moral and religious objections, and continued access to excised tissue samples for health reasons—reasonably limited access may make it difficult for a company to dispose of materials. In order for donors to be willing to donate their precious tissues, they must be assured that their concerns will be addressed.

The best way to address privacy concerns would be to permit donors to maintain private rights of action based on information that is released or misused as a result of tissue use. This would include violations such as research linking the donor to an embarrassing disease, or leaked information that an insurance company can use. It would be the researcher's responsibility to see that the data collected is protected and presented in a manner that shields the donor. Essentially, this would create a bailment relationship, much like that in *York,* where the researcher would have certain legal responsibilities to the donor.[182]

Moral and religious objections, as well as unintended uses, can be addressed with a combination of sufficient disclosure and rescindable donations. While it is not feasible to allow every donor to negotiate the terms of donation, researchers must be explicit in outlining the sample's intended use, including whether the tissue may be used in other projects or in commercial use. The model release form promulgated by the National Institutes of Health would essentially allow a donor to transfer use of the tissue to a researcher.[183] In the case of a violation of the

---

[182] *York*, 717 F. Supp. 421.

[183] Guidance is available from the National Institutes of Health that interprets the federal regulation

patient's intent, as formed by the information given, at the time of donation, the donor would have the right to rescind the donation and have the tissue destroyed or sent to another researcher.[184] While this may seem like a harsh result, this outcome will only occur if the researcher does not make a complete disclosure at the outset of the relationship. The donor would be able to ask questions about potential uses, and let the researcher know if he has any objections to specific uses.

Finally, the donor should be able to have reasonable access to the tissue, even after donation, for health related reasons. As stated *supra*, a patient may have a need to access the tissue at a future point, such as to compare to current tissue samples in determining the course of a disease. It does not make sense that a person cannot have access to his tissues, if they still exist, merely because they have been donated. Maintaining this right of access for tissues would be costly to research organizations, and should only be limited to certain cases, such as when whole organs or other large samples are donated. It would be overly burdensome to require this right of access for small samples, as it would limit the amount of research that can be done with them, or with blood, which is used up quickly. It would also be necessary to set guidelines for when a researcher may dispose of a sample and how notice may be given to a donor so he may have the tissue transferred to another location if the original researcher no longer needs it.

It should be noted that this approach does not include any compensation for commercial products. A system that does not include compensation will partly offset the costs to researchers of maintaining the rights of donors, and reflects a view that donors should not be induced with monetary incentives. Providing compensation to all donors across the board would be unreasonable. First, it is impossible to judge the monetary worth of an organ, and therefore the contribution to an invention. In addition, to require compensation may also be detrimental to research, as only rich researchers will get tissue. It may also convince people to donate when they may not have fully considered the ramifications but are in need

---

governing informed consent documents, which prohibits exculpatory language requiring a subject to waive or appear to waive any of the subject's legal rights, or releases the investigator, the sponsor, the institution, or its agents from liability for negligence. Andrews, *Two Perspectives*, *supra* note 3, at 404 n. 72 (citing Office for Protection from Research Risks, *"Exculpatory Language" in Informed Consent, supra* note 106.).

The examples of unacceptable language are instances in which patient/research subjects completely give up any property rights to the tissue.

Examples of exculpatory language: By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances; I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items; By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research; I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of acceptable language: Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur; By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.

[184] The patient would not be able to receive the tissues back because hazardous waste laws, which would cover the donated tissues, prevent the tissues from being sent to an unlicensed party.

of money, making the determination of the donor intent difficult to establish. While this approach may rely on the altruistic nature of the human being, donors have historically not been compensated for donations and many have done so despite the lack of compensation.

While donors should not be directly compensated, situations such as the Canavan patient case should be avoided.[185] It is appalling that donors can donate tissues that are used to develop a treatment for an ailment they are afflicted with, only to find that they cannot receive the treatment, whether for monetary or licensing reasons. Donors should receive some form of benefit in this circumstance, either in the form of a reduction in price or a compulsory license in the product or treatment. This is would be a very fact specific determination, depending on the product at issue.

CONCLUSION

As Dr. Catalona asserts, "This is not a used car or a television. It's somebody's genetic information."[186] Our tissue is part of who we are. We can never be separated from our genetic material. Far too much can be learned about a person through the use of DNA profiling. Not only does everything we learn about the tissue relate back to the person who donated it, it also relates to that person's children, parents, siblings, and any other relatives.

In an age where insurance companies will refuse coverage based on genetic tests, too much information is dangerous.[187] If genetic information becomes too public, we may find our children unable to obtain insurance based on our genetic tests. The fact that a tissue sample is anonymized means nothing; our DNA imprint is locked into the genetic material and can never be removed. It is for precisely these reasons that research participants should have control over what happens to their tissues.

We are also in an age full of controversial research. The use of stem cells and human cloning has caused uproar and a continuing battle against science. Research has been done on the genetic link to homosexuality. Tissue samples are being researched for projects the donor might never have intended or agreed to, such as alcoholism and schizophrenia.

We may have lost our right to profit from use of our tissues in *Moore* and our property rights in *Greenberg*. *Catalona* takes the issue too far: it allows institutions to completely disregard the intentions of the donor when the donation was first made. It imposed no fiduciary duty on the research institution for using the tissues in violation of the patients' initial consent agreements. The Supreme Court now has the opportunity to correct the mistakes of the District and Circuit courts in

---

185 *Greenberg*, 264 F. Supp. 2d at 1064; *see discussion supra*, note 43.

186 Saey, *supra* note 72.

187 Skloot, *supra* note 108.

Catalona. There is a real danger that prostate cancer research will be stalled by an unavailability of tissues, both by bio-repositories controlling use of the tissues or by a lack of donors giving new samples out of fear of misuse. A lack of further research could lead to the deaths of many men at the hands of a preventable disease.