

Who Owns Your Body? A Patient's Perspective on *Washington University v. Catalonia*

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This article and the one that follows are two perspectives on the issue of rights of owners.

In 1890 a man sold the rights to his body after death to the Royal Caroline Institute in Sweden for research purposes. Later, he tried to return the money and cancel the contract. In the subsequent lawsuit, the court held that he must turn his body over to the Institute and also ordered him to pay damages for diminishing the worth of his body by having two teeth removed.¹

Today, it would be an anathema for a person's body to be used against his wishes and for a research subject not to be allowed to withdraw from a study. In fact, the Uniform Anatomical Gift Act allows people to change their minds and withdraw a previous agreement to donate organs and tissue after their death² and the federal research regulations allow people to withdraw from studies without penalty or loss of benefits.³ Yet the law is murky regarding research on a living person's tissue outside of his body, and some research institutions today emulate the Royal Carolina Institute and stake their claims on materials from people's bodies. A pending federal lawsuit in Missouri raises questions about the ethics and legality of the current practices governing research on human tissue.

The controversy in *Washington University v. Catalonia*⁴ revolves around tens of thousands of tissue samples that patients provided for research purposes. The journey to the point of litigation began in the early 1980s when Dr. William Catalonia, an internationally known prostate cancer surgeon and researcher at Washington University, began asking his patients if they were willing to let him use the tissue removed during their surgery, blood, and other tissue for research. Over the years he amassed over 30,000 tissue samples and an enviable set of research results. Dr. Catalonia developed the PSA (prostate-specific antigen) test in 1986 and undertook the research necessary to obtain approval of the PSA test by the US Food and Drug Administration.⁵ Dr. Catalonia later led clinical trials for an improved test that detects ninety-five percent of prostate cancers.⁶ About seventy-five percent of American men over age fifty have had a PSA test.⁷

Over time, Washington University began to see the tissue samples not solely as a resource for prostate cancer research advances, but additionally as a capital resource for the university. An e-mail from a business manager at Washington University's office of technology management to the vice-chancellor of research at the university, concerning a request Dr. Catalonia made to send out tissues to test Hybertech's new prostate cancer assay stated, "Bill Catalonia wants to send

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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.”⁸ While a publication enriches the scientific community, is consistent with the wishes and consent of the patients, contributes to the progress of medicine by furthering research, and in some cases may bring grant money into the university, Washington University instead preferred to use the samples to bring money directly into the institution.

As conflicts escalated, Dr. Catalona decided to leave Washington University for a new position at Northwestern University School of Medicine in Chicago. He began to write to his patients, telling them that he was transferring to a new institution. He said that they could continue to get their health care at Washington University, or he could see them at Northwestern. He also asked them to indicate whether they were willing to transfer their samples to Northwestern. Six thousand of his patients wrote that they wanted their samples to move with him.⁹

Washington University refused to transfer the samples and sued Dr. Catalona to prevent him from moving those samples and from contacting his other patients for permission to transfer their samples.¹⁰ Washington University alleged that since Catalona was an employee of the university, his employer had a right to the samples. The university also claimed his employment was conditioned on its intellectual property policies which prohibited taking samples without prior written approval from the Vice Chancellor for Research. However, according to Dr. Catalona, his employment (and the initial formation of the tissue bank) pre-dated any such policies, so they arguably would not apply to him. Washington University requested a declaratory judgment that it owned the tissue samples, which it said were worth more than one million dollars, and asserted that it had the right to use them as it wished “in its sole discretion.”¹¹

After Washington University sued Dr. Catalona, a group of patients were added as necessary parties to the case.¹² The patients claimed that they owned their tissue samples and advocated transferring them to Northwestern to effectuate their original intent of having Dr. Catalona undertake prostate cancer research on the samples. They indicated that Dr. Catalona’s actions *vis-à-vis* the university should not affect their ownership rights.

Washington University argued that the patients had no ownership rights to their tissue since it was a gift – a donation – to the university. The patients and Dr. Catalona disputed that depiction, claiming that the

tissue samples had not been given unconditionally to the University, but were instead provided to Dr. Catalona for a particular use. The patients also claimed that they had retained rights to control the tissue since the informed consent forms they had signed gave them the right to withdraw from research and, in some versions of the form, the right to have their samples destroyed.

Washington 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.¹³ Concerning samples, Washington University’s counsel stated,

the research institution, when somebody withdraws or discontinues participation, there are three things it 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 any more, and in those events, it is no longer considered human subject research and is no longer subject to regulation.¹⁴

Under this reasoning, an institution could anonymize a patient’s samples and use them for a type of research that was never contemplated or consented to by the patient, even if the patient withdraws from all studies and specifically requests that the research not be conducted on his sample.

Catalona’s patients objected to anonymization, because it would reduce the value of their contributions by limiting the type of prostate cancer research that could be done (since it would unlink the samples from ongoing medical records)¹⁵ and because it would prevent the patients from learning specific details of what the research had shown in their own tissue (which might be helpful to them or their children medically).¹⁶ Moreover, they felt they had given the samples for Dr. Catalona’s prostate cancer research – not to be sold to the highest bidder by the university.

In April 2005, Missouri federal district court judge Stephen Limbaugh held a hearing solely to determine who owns these tissue samples. The answer to that question will determine the extent to which people can direct what is done with their tissues outside of their body. In the interest of time, the judge requested that only a few representative patients testify for the group. At present, the judge has not yet ruled, but the briefs from both sides and the testimony from the patients and other witnesses provide a colorful and poignant picture of a research enterprise gone awry. Twenty-five years after the landmark case *Moore v. Regents of the University of California*,¹⁷ the Catalona case

raises a series of questions whose answers will shape the evolving law of research on body tissue. In *Moore*, the Supreme Court of California held that patients had stated a cause of action for breach of fiduciary duty and lack of informed consent, but not for conversion of the patient's property after researchers patented a cell line and associated products using a patient's cells without his permission. The *Catalona* case will revisit the issue of whether patients have a property interest in their tissue. This pending case is worth exploring in detail since most court cases dealing with research on tissue samples – including the famous *Moore* case – are settled before trial and thus the patients' voices are not heard in the legal record.

Can a Patient Own his Tissue Outside of his Body?

The notion that other people may own a patient's body parts while the patient may not – the holding in the *Moore* case – has an historical basis. 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.¹⁸ In feudal times, it was a crime to maim oneself because this rendered one less able to fight for the king.¹⁹ 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.

In 1998, a British court re-examined the early cases which had been thought to hold that a person did not have any property rights to their own tissue, and noted that this legal doctrine had a "very poor legal pedigree." In fact, the prosecutor in the 1998 case argued that the "no property in a body" rule had been the result of an erroneous interpretation of a 1614 case where the defendant had disinterred corpses to steal their burial clothes. "Generations of lawyers" then perpetuated the error. The modern British court indicated that, in the medical and scientific realm, there may be good reason to view a body as the person's property. "This may be so," wrote the court, "if, for example, they are intended for use in an organ transplant operation, for the extraction of DNA, or for that matter as an exhibit at trial."²⁰

In *Washington University v. Catalona*, the university relied on two cases, *Moore v. Regents of University of California*²¹ and *Greenberg v. Miami Children's Hospital Research Institute*,²² to support its assertion that patients have no ownership rights in extracted tissue.

However, these cases are not analogous to *Catalona* because they dealt with patients/research subjects objecting to the patenting of products derived from their body tissue (cell lines and gene sequences) and thus trying to control the products made from their tissue, not patients who claimed ownership of their own tissue itself. Equally important, neither case involved an informed consent form setting forth the intent of the parties, as did *Catalona's* form.²³ The courts in *Moore* and *Greenberg* could assume a gift was made, or that the tissue was abandoned, because there was no document reserving any rights on the part of the patients. In the Missouri case, research informed consent forms existed in which the patients reserved not only the right to withdraw from the research studies in question, but also the right to destroy their tissue if they so chose.

In *Moore*, a patient's doctor took blood and other tissue from the patient's body and created a commercial cell line out of it. The court held that the physician/researchers and their institutions had duties under the doctrines of fiduciary duty and informed consent to allow patients to control what is done with their tissue. The *Moore* court specifically noted that it did not need to give the patient/research subject a property right since his interests were thought to be adequately protected by the causes of action for lack of informed consent and breach of fiduciary duty.²⁴ Moreover, even in *Moore*, the court stated that "...we do not purport to hold that excised cells can never be property for any purposes whatsoever..."²⁵ Indeed, a subsequent California case cited *Moore* and found that a person had a property interest in his tissue where – as in *Catalona* – a contract existed that showed that the person providing the tissue had an "expectation he would in fact retain control..."²⁶

In fact, since the 1990 decision in *Moore*, numerous courts have held that human tissue outside the body can be considered the property of an individual or the next of kin.²⁷ In addition, Missouri common law recognizes property interest in bodies, body parts and bodily tissue.²⁸ In *Mansaw v. Midwest Organ Bank*, the U.S. District Court for the Western District of Missouri held that a father's property interest in his son's dead body is granted by Missouri law and that this property interest covers the right to control the removal of tissue and organs from the body.²⁹

Do the Hazardous Waste Laws Preclude a Patient/Research Subject from Having a Property Right in their Tissue?

Washington University also asserted that the existence of a hazardous waste statute negates any property interest patients might have in their tissues.³⁰ But every court that has addressed this issue has held that such

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a statute was not intended to, nor does it, negate the property rights of the individual from whom the tissue was taken or his designee.³¹ In fact, the *Mansaw* case in Missouri found that the existence of significant state regulation regarding the handling of dead bodies did not negate a property interest.³² The courts are clear that the hazardous waste statute may not be used by an institution “to permit ‘scientific use’ contrary to the patient’s expressed wish.”³³

Even Washington University recognized that restrictions on use do not negate the characterization of something as property, saying that “even radioactive materials, such as plutonium, are acknowledged to be property and thus capable of being owned – notwithstanding the strict regulation of use of such material.”³⁴ Additionally, patients in *Catalona* were not asking to take their samples home with them. Rather, they were asking to have them transferred to another reputable research institution that would likewise be bound by the hazardous waste laws.

Did the Patient/Research Subjects Provide their Tissues to the Research Institution or the Researcher?

Dr. Catalona’s patients said they sought him out specifically because of his excellent credentials and reputation in the field of prostate cancer. “That’s where Dr. Catalona was, so that’s where I was,” testified Richard Ward, a Kansas resident and long-time patient of Dr. Catalona who now travels to Chicago to see him. “I was looking...for the best to do my surgery, the best in the world if I could find them and they were available to me. I was willing to wait for him if I could get him.”³⁵

Patients had good reason to choose Dr. Catalona: he is an expert in performing the “nerve-sparing” radical prostatectomy that can preserve sexual potency. Patients have come from as far as Asia, the Middle East, South America and Europe to be seen by him.³⁶ “Their intent is to work with the investigator, not with the institution,” testified patients’ expert Ellen Wright-Clayton, a Vanderbilt University Law and Medical School professor, practicing pediatrician, and Director of the Rosalind E. Franklin Chair in Genetics and Health Policy.

The patients chose to participate because of the type of research Dr. Catalona was performing and the fact

that Dr. Catalona would be the one leading the studies. According to one of the patients, James Ellis:

I have six grandsons and the one thing I want to do is what I can do to make certain they don’t go through what I’ve gone through, and my family’s gone through, for the last fourteen years. And I [can’t] think of anybody that I would have more faith in to do the kind of research that might help my grandsons on my samples, my tissues, my body parts, than Dr. Catalona and as far as I’m concerned, that’s really my interest in this whole case. I want to see, I think everybody does, a cure, but I want to see it for my six grandsons, so I care about the kind of research he does.³⁷

Washington University countered that, even though the informed consent forms said that the tissue was being provided for research by Dr. Catalona (and, in some informed consent forms, Dr. Catalona and colleagues or assistants), the patients were actually giving the tissue to the university since the forms were on university stationery.³⁸ However, if a woman donated her kidney to her brother, after signing an informed consent form on a university’s letterhead, she could reasonably expect that the kidney would be given to her brother, not used by the university for whatever purpose it chose.

Patients provided tissue to Dr. Catalona for a specific research use because they trusted Dr. Catalona and because, as a physician, he had certain fiduciary duties. He was a known individual whom they respected, not an amorphous institution. The fact that they allowed him to make decisions about whether the tissues would be consumed or destroyed in furtherance of the agreed-upon research is consistent with a grant of use, and certainly does not negate patients’ interests nor give rights to Washington University. Just because a person trusts his son to drive his car, despite the fact that the son might get in an accident, does not mean that the person has given up ownership of the car or that the person is indifferent to who drives his car.

Was the Tissue from the Patient/Researchers an Unconditional Donation?

Washington University argued that it owns the patient tissue because patients “donated” it free of restrictions

to the University.³⁹ Yet under the informed consent forms signed by patients, which incorporated many provisions required by federal research regulations, as well as some provisions that seem out of compliance with the federal regulations, the patients/research subjects retained substantial rights with respect to the tissue.

Washington University's strongest claim to the tissue is one of possession. Patients transferred possession of their tissue to Dr. Catalona for limited purposes, and Dr. Catalona stored it on the premises of the university. Washington University now claims that the transfer constituted a complete unconditional gift and claims that it now "owns" the tissue samples.⁴⁰ However, the patients testifying at the hearing denied making an unconditional gift of their tissue to Dr. Catalona.⁴¹ Dr. Catalona denied receiving an unconditional gift.⁴²

Other cases have held that informed consent forms constitute contracts.⁴³ In the Catalona case, the informed consent forms (which have slightly different language depending upon the time period in which the patients entered the study) are contracts governing the terms of the transfer of possession of the tissue. Each form is an invitation to participate in a research study conducted by Dr. William J. Catalona and/or "assistants" (or, in some cases, "colleagues"). The purpose of the study is stated. The participant's role is set forth – for example, he is required to provide a family history and a blood sample.

Some forms state that if the participant has had any surgery at any hospital, the participant "will release the pathologic specimen (if any) from the hospital where said surgery was performed" to Dr. Catalona. Because many of the patients transferred tissue from other institutions to Dr. Catalona at Washington University in the first place, it would seem reasonable for them to have thought they had the right to compel Washington University to transfer it to another institution in the future.

Some of the forms provided that the patients would receive no monetary compensation or ownership rights to any medical or scientific products developed from research conducted using their tissue. Notably, these forms did not say that patients could not claim ownership of the tissue itself.

All of the forms provided for patients' withdrawal from the research at will. No form stated that Washington University "owns" the patient tissue or that the patient tissue would become the property of Washington University, or that, upon withdrawal of the patient, the patient tissue would remain with Washington University.⁴⁴

One form stated that "by agreeing to participate in this study, you agree to waive any claim you might have

to the body tissues that you donate." But that form also gave the patient the right to require destruction of his tissue if he "changes his mind." Arguably, if the patient has the right to require destruction of the patient tissue, he has not "waived any claim [he] might have to the body tissues." No informed consent document expressly provided that a patient could not require Washington University to transfer his tissue to another institution. Finally, many informed consent forms repeatedly refer to the patient tissue as "your tissue." Nowhere was it stated that the patient tissue was Washington University's tissue. Any person seeing repeated references to "your tissue" in a document of this type would reasonably conclude that he had retained substantial rights of ownership, including the right to require the transfer of the tissue to another custodian.

Patients testified that they interpreted the right to withdraw from the study as a way to retain some control over their tissue. "You don't have the right to withdraw if you've...given a gift, if you've donated in that sense. No one at that time or any time has asked me if I was transferring ownership of my tissues,"⁴⁵ said patient James Ellis.

Patients' expert Dr. Clayton testified that

Since they can withdraw the samples...they could direct them to another investigator who's doing the work....It's very clear to me that as between the patients' rights to withdraw the samples and Washington's rights to retain the samples with the objections of the patients, it's really clear to me who wins: The patients get to withdraw the samples.⁴⁶

In some documents, patients were specifically advised that they could not retrieve research results upon their withdrawal. But they were not advised that Washington University intended that the patient tissue would remain at the university after a patient's withdrawal from the study. The patients asserted that a document entitling them to withdraw at will implied they could withdraw their tissue as well. Patients' expert witness, Dr. Clayton, testified that the federal regulations, which indicate that "the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled,"⁴⁷ should be interpreted to allow patients to withdraw their samples.⁴⁸ Otherwise, the right to withdraw at will, protected by those regulations, would be meaningless.

Is it Possible for Patients to Reserve Rights when they Authorize the Use of their Tissue in Research?

The patients in the case pointed out that there was no "gift" language in the informed consent forms.

Plus, they argued that, if the Court decided the tissue sampling was a “gift,” it was a *conditional* gift and the conditions would not be met by allowing Washington University to keep the tissue.

Patients joined the Catalona studies hoping to benefit future generations of cancer sufferers including their sons, grandsons and other family members unlucky enough to inherit the genetic risk of developing the disease. Richard Ward, who was diagnosed with an aggressive form of prostate cancer, still remembers why he chose to participate in Dr. Catalona’s study. “It is very important to those of us who are cancer survivors and to our future generations to have these tissues used as we intended – to further the research.”

In the legal proceedings, Dr. Catalona’s patients relied on legal cases saying that if a gift is made upon a condition, a failure of, a violation of, or refusal to perform such condition by the donee constitutes grounds for revocation by the donor.⁴⁹ The donor of a charitable gift has a right to annex such conditions thereto as he deems proper, and a departure from those conditions works as a forfeiture.⁵⁰ Generally, the rule applicable to conditional gifts is that the person giving the gift may impose such conditions as he pleases as long as they are sufficiently definite to be enforced and are not impossible or illegal.⁵¹ A donation can be a conditional gift, and the condition “may be imposed by law or implied in fact in order to prevent unjust enrichment.” The decisive factor in establishing the kind of gift is the donor’s intention.⁵²

The patients argued that any donative intent was conditioned upon the continued use of their tissue for prostate cancer research by Dr. Catalona and colleagues he designated. Because these conditions could not be fulfilled at Washington University, they asked that their samples be transferred to Northwestern University.

The patients also pointed out that they had a personal medical interest in the samples. Some of the patients wished to have their follow-up treatment with Dr. Catalona at Northwestern University. For some, their stored tissue indicated the state of their cancer when their surgery was performed. Comparison to current tissue from a biopsy could be helpful to ascertain if they have further problems.

In its Pre-Hearing Brief, Washington University stated: “The informed consent forms [the patients] signed plainly state that the collection of samples is for medical research and not future care.”⁵³ However, the forms themselves contain language talking about “pos-

sible benefits to myself or to society from this research” and promising to notify the patient of “any significant (major) new findings developed during the course of my participation.”

When Dr. Catalona’s lawyer, Troy Doles, asked the Washington University doctor who is now asserting control of the samples whether he agreed that the tissue samples were very important to the patient with respect to their future health care, Dr. Andriole replied, “Absolutely. [I] agree with that wholeheartedly.”⁵⁴

Additionally, in an internal Washington University report to the head of the Department of Surgery, Dr. Andriole stated, “It is conceivable that new develop-

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ments in prostate cancer (or other diseases) may warrant evaluation of archived specimens at the request of the patient or to most properly care for him.”⁵⁵

Can the Provision of Tissue Samples be likened to a Bailment?

The fact that the patients cared about what was done with their tissue – and might wish to provide samples only for certain purposes – is consistent with other legal concepts, such as bailment. Human tissue may be the entrusted property in a bailee/bailor relationship.⁵⁶ In *York v. Jones*, the plaintiffs entered into an in-vitro fertilization (IVF) program where they signed a research informed consent form entitled “Informed Consent: Human Pre-Zygotes Cryopreservation.”⁵⁷ The form outlined the procedures for freezing their fertilized eggs, and “detailed the couple’s rights in the frozen pre-zygote.”⁵⁸ The research informed consent allowed the couple the right to withdraw from the research at any time. A year after a pre-zygote was frozen, they sought to have it transferred from the medical school where it was held in Virginia to another research institution in Los Angeles, California. The physician, on behalf of the Virginia Medical School, refused to allow the transfer. He argued that while the plaintiffs could withdraw, he could keep their pre-zygote and the plaintiffs were limited to letting him use the pre-zygote for research of his choosing, destroy it, or give it to someone else. In short, the physician in the *York*

case was making a similar claim to that of Washington University.

The court in *York* held that the research informed consent form had created a bailor/bailee relationship between the plaintiffs and defendants, even without intent to create such a bailment.⁵⁹ The court held that “under Virginia law, no formal contract or actual meeting of the minds is necessary....Rather, all that is needed ‘is the element of lawful possession however created, and duty to account for the thing as the property of another that creates the bailment...’”⁶⁰ The court stated that the defendants had recognized the plaintiffs’ proprietary rights to the pre-zygotes when the research informed consent form referred to the embryos as “our pre-zygote.”⁶¹

Washington University claimed that a bailment cannot exist between the patients and Washington University because the patients did not expect to get their tissue back.⁶² However, there are many legal instances in which a bailment can occur even if the bailor does not intend that the property be returned.⁶³ For example, a bailment is created if a company ships its materials to another company. Even if the first company does not expect to get those materials back, its rights are violated if the materials are used by the shipping company in a manner that the bailor did not intend.

As in *York*, the proprietary interests of Dr. Catalona’s patients could be established through the informed consent form.⁶⁴ Similar to the language in the *York* form, the informed consent documents in the Missouri case consistently refer to patients as having a possessive interest in their tissue (“your genes [DNA] can be tested,” “your blood samples,” “your pathological specimen”) (emphasis added). To be able to have “the tissue destroyed upon request” illustrates their ownership claims, similar to the *York* agreement allowing the release of the pre-zygotes from storage with “the written consent of both plaintiffs.”⁶⁵

Can a Research Institute Anonymize Patients’ Research Samples over their Objections?

Washington University asserts that 45 C.F.R. 46.101(b)(4) gives them a right to anonymize the samples.⁶⁶ This section exempts certain specimens from the protections otherwise accorded human research subjects. However, the provision does not apply to samples that were collected for *research* purposes, as the samples were here. By its terms, 45 C.F.R. 46.101(b)(4) only applies to samples that are “pathological specimens” or “diagnostic specimens,” the type of abandoned specimens that occur after routine medical interventions. Second, it only applies to samples in which “the subjects cannot be identified, directly or through identifiers linked to the subject.” The tissue in this case *can*

be identified.⁶⁷ The patients argued that Washington University was attempting to take a non-applicable federal regulation that covers situations of discarded, anonymous tissue and claim that it gives it a right to anonymize identifiable tissue in contravention of the wishes of the patients.

What are the Policy Implications of a Ruling in Favor of the Patients in this Case?

Both Washington University and the patients in the Missouri case make predictions about how a decision in the case will affect the research enterprise. The university’s lawyers argued at the hearing that, “the only way we can have effective human biological research in this country is if research institutions are able to collect, aggregate, and control the research samples.”⁶⁸ The patients responded that the need for convenience in the research world should not override the property rights and informed consent rights of research subjects. They pointed out that Missouri law recognizes that even an important and valid social purpose cannot trump an individual’s property rights in his tissue or his family members’ tissue. In *Mansaw*, the court acknowledged that the need for donated organs was great and that many people died waiting for them.⁶⁹ But that did not justify interfering with property rights absent clear informed consent to the contrary.

The patients noted that actual research practices today, as well as regulations, guidances, and ethical standards, gave considerable control to patients over the use of their tissue. Times had changed since the cases of *Moore* and *Greenberg*. Since those cases, the American Medical Association had amended its ethics code to require doctors to inform patients when they were planning to use their tissue for commercial purposes.⁷⁰ In apparent contravention of the code, there is no evidence that the doctors at Washington University informed the patient/research subjects about the University’s desire to sell the patients’ tissues to Hybritech. And, as a report of a committee of the National Academy of Sciences on genetic research noted, “it is not ethically or legally acceptable to ask research participants to ‘consent’ to future yet unknown uses of their identifiable DNA samples.”⁷¹

What the patients are arguing for in *Catalona* is in keeping with guidance from the National Institutes of Health Office for Protection from Research Risks interpreting the federal research regulations.⁷² In this guidance, explicated by an NIH Cooperative Oncology Chairpersons group, it is noted that acceptable language in an informed consent form allows patients to transfer to the researcher the right to *use* tissue. The examples of unacceptable language are instances in which patient/research subjects completely give up any

property rights to the tissue. The fact that oncology researchers have indicated this is how they conduct their research certainly undercuts Washington University's arguments that it would be harmful to research to rule for patients in this case.

The patients argued that if Washington University prevails in this case, research in this country will be threatened. Patients will be unlikely to allow the use of their tissue if they have no control over how the tissue is used.⁷³

Under the logic of Washington University, tissue donated to a particular researcher (Dr. Catalona) for a particular use (prostate cancer studies) could be used for any research the university desired. In the hearing, Dr. Catalona testified,

Were those samples to be anonymized, they are totally outside of federal regulations. They could be licensed to a drug company, they could be licensed to a biotech company, they could be sold to another university, they could be used to study sexual predator behavior, alcoholism, criminal behavior, other diseases that these patients never intended to have their samples used for.⁷⁴

If Washington University's logic were followed, in contravention of a patient's wishes, the tissue could be used in research to create a human clone. It could be used for a type of research that violated a patient's religious beliefs, such as embryonic stem cell research. Or it could be sold to a biotech company for research for sheer commercial gain.⁷⁵ The specter of such possibilities will chill potential research subjects' willingness to participate in research.

The problems of doing research that goes beyond initial consent are illustrated by another lawsuit. In 2004, the Native American Havasupai tribe of Arizona filed a \$50 million lawsuit claiming 400 samples given to local universities for the purpose of diabetes research were used for studies on inbreeding, schizophrenia and ancient human population migrations to North America. The tribe asserted they were stigmatized by the schizophrenia and inbreeding research and would not have consented to the origins studies because they directly conflicted with the tribe's religious beliefs.⁷⁶

Conclusion

Tangible items are generally considered to be property. As new potential for body parts unfold in research, diagnostics, and therapy, the question arises – should they be considered property as well?

Increasingly, patients are interested in how parts of their tissue outside of their bodies are used. Some people store blood before a surgery to protect them-

selves from disease if they need a transfusion. Couples store embryos for future implantation. Many patients enter into specific research protocols because they trust the researcher or wish to see research undertaken on a disease or condition of particular interest to them. Courts must consider the patients' views as they deal with emerging and novel legal issues concerning the right of a patient to make decisions concerning the products of their own bodies for diagnostic treatment and research purposes.

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3. 45 C.F.R. § 46.116(a)(8).
4. *Washington University v. Catalona*, Case No. 4-03-CV 010655NL. Quotes in this article are to documents filed in the case and the transcript of the hearing in the case.
5. For information about Dr. William Catalona, see <http://www.drcatalona.com/catalona_bio.asp> (last visited February 17, 2006); 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"); I. Thompson, et al., "Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level less than 4.0 ng per Milliliter," *New Eng. J. Med.* 350 (2004): 2239-46, at 2239.
6. Press Release, "Beckman Coulter, FDA Approves New 'Free PSA' Blood Test to Aid in Battle against Prostate Cancer" (March 1998), at <<http://www.beckman.com/products/applications/diseasemgmt/pdf/FDAapproval.pdf>> (last visited February 17, 2006).
7. B. E. Sirovich, et al., "Screening Men for Prostate and Colorectal Cancer in the United States," *JAMA* 289 (2003): 1414, 1417.
8. E-mail from Jon Kratochvil, Business Development Director, November 27, 2001 (read into the record, Tr. 3:33 (April 13, 2005)).
9. *Washington Univ. v. Catalona*, Tr 1:26 (April 11, 2005).
10. Complaint at 16-17 (on record with the author).
11. Complaint at para. 14 and para. 53 (on record with the author).
12. Technically, the plaintiffs are thus considered to be defendants, although Washington University is not asserting a claim against them *per se*.
13. *Washington Univ. v. Catalona*, Tr. 1:24 (April 11, 2005).
14. *Washington Univ. v. Catalona*, Tr. 1:24 (April 11, 2005).
15. *Washington Univ. v. Catalona*, Tr. 1:64 (April 11, 2005) (testimony of Dr. Catalona).
16. *Washington Univ. v. Catalona*, Tr. 1:64 (April 11, 2005) (testimony of Dr. Catalona).
17. *Moore v. Regents of University of California*, 793 P.2d 479 (Cal. 1990).
18. D. A. Oesterle, "The Sale of Human Body Parts," *Michigan Law Review* 72 (1974): 1182-1243.

19. B. Dickens, "The Control of Living Body Materials," *University of Toronto Law Journal* 27 (1977): 142-164.
20. *Regina v. Kelly and Another*, 3 All ER 741 (Court of Appeals, Criminal Division, 1998). For a discussion of the case, see L. Andrews and D. Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York: Crown Publishers, 2001).
21. *Moore v. Regents of University of California*, 793 P.2d 479 (Cal. 1990).
22. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
23. See *Moore*, *supra* note 20; *Greenberg*, *supra* note 21.
24. See *Moore*, *supra* note 20, at 491.
25. *Id.*, at 493.
26. *Hecht v. Superior Court of Los Angeles County*, 16 Cal. App. 4th 836, 846, (Cal. Ct. App. 1993).
27. *York v. Jones*, 717 F. Supp. 421, 426 (E.D. Va. 1989) (finding that a couple can have a property interest in their pre-zygote that limits a clinic's rights as bailee); *Hecht v. Superior Court of Los Angeles County*, 16 Cal. App. 4th 836, 850 (Cal. Ct. App. 1993) (holding that sperm is property to be distributed by decedent's estate); *Whaley v. County of Tuscola*, 58 F. 3d 1111 (6th Cir. 1991) (next of kin have a "constitutionally protected property interest" in the dead body of a relative).
28. *Mansaw v. Midwest Organ Bank and Truman Medical Center West*, No. 90-0271-CV-W-6, 1998 U.S. Dist. LEXIS 10307 (W.D. Mo. 1998).
29. 998 U.S. Dist. LEXIS 10307, at *16. In contrast, the state law precedent in Florida which was applied in the Greenberg case was *State v. Powell*, 497 So. 2d 1188 (Fla. 1986) in which "the Florida Supreme Court refused to recognize a property right in the body of another after death." Greenberg, 264 F. Supp. 2d. at 1075.
30. Washington University Pre-Hearing Brief at 8-9.
31. See *Moore*, *supra* note 20, at 492; *Hecht*, *supra* note 26, at 847.
32. 1998 U.S. Dist. LEXIS 10307 at *16.
33. *Moore*, *supra* note 20, at 141; *Hecht*, *supra* note 26, at 847.
34. See Washington University Supplemental Memo, at 3.
35. Testimony of Mr. Richard Ward, *Washington Univ. v. Catalona*, Tr. 2:67-68 (April 12, 2005).
36. Dr. William Catalona's bio, Urological Research Foundation, available at <http://www.drcatalona.com/catalona_bio.asp> (last visited February 17, 2006).
37. Testimony of Mr. James Ellis, *Washington Univ. v. Catalona*, Tr. 1:168-69 (April 11, 2005) (on file with the author).
38. Plaintiff's Post-Trial Brief, at 13 (stating that "the consent forms they signed typically bore the WU Medical Center logo" as evidence of ownership).
39. Plaintiff's Proposed Findings of Fact and Conclusions of Law, at 16 ("The research participants intended to donate their prostate tissue and blood samples to Washington University for medical research").
40. "Possession of property alone and without explanation is evidence of ownership; but it is the lowest species of evidence. It is merely presumptive, and liable to be overcome by any evidence showing the character of the possession, and that it is not necessarily as owner." *Rabinov v. United States*, 329 F. Supp. 830, 840 (S.D. N.Y. 1971) (quoting *Manning v. Anderson Galleries, Inc.*, 222 N.Y.S. 572 [N.Y. Sup. Ct. 1927]). Moreover, under Missouri law, patients can maintain legal possession even if another entity has physical possession. See *State of Missouri v. Hughes*, 1985 Mo. App. LEXIS 4270, at * 7, 702 S.W.2d 864, 867 (1986).
41. Testimony of Mr. James Ellis, *Washington Univ. v. Catalona*, Tr. 1:158-59 (April 11, 2005); Testimony of Mr. Tom McGurk, *Washington Univ. v. Catalona*, Tr. 1:211 (April 11, 2005); Testimony of Mr. Richard Ward, *Washington Univ. v. Catalona*, Tr. 2:71 (April 12, 2005) (on file with the author).
42. Testimony of Dr. William Catalona, *Washington Univ. v. Catalona*, Tr. 1:93 (April 11, 2005).
43. *Dahl v. Hem Pharmaceuticals*, 7 F.3d 1399, 1404-5 (9th Cir. 1993) (similar informed consent forms found to be contracts and defendant's argument against such characterization found "almost frivolous"); *York v. Jones*, 717 F. Supp. 421, 425 (E.D. Va. 1989) (finding that the research informed consent constituted a bailment contract governed by the same principles as apply to other contracts); *Perna v. Pirozzi*, 457 A.2d 431, 441 (N.J. 1983) (Supreme Court of New Jersey determined that informed consent includes the right to choose the surgeon and to refuse to accept a substitute, and the substitution of one surgeon for another without the consent of the patient could be framed as a breach of contract between the surgeon and the patient).
44. Forms used in at least two of the studies at issue provide that "If you choose to participate in a study that uses code numbers to link participants to tissue and later change your mind, the tissue can be destroyed upon request. To withdraw your consent, call Dr. Catalona at 314-362-4241. Any research results already obtained cannot be destroyed or recalled." The studies in this case were "linked" studies.
45. Testimony of Mr. James Ellis, *Washington Univ. v. Catalona*, Tr. 1:158, 168 (April 11, 2005).
46. Testimony of Dr. Ellen Wright Clayton, *Washington Univ. v. Catalona*, Tr. 1:125-26 (April 11, 2005).
47. 45 C.F.R. 46.116(a)(8).
48. Testimony of Dr. Ellen Wright Clayton, *Washington Univ. v. Catalona*, Tr. 1:121-23 (April 11, 2005) ("I think the regulation[s] by saying that patient/participants have a right to withdraw have to include within that, in a study like this, the right to withdraw their samples and the right to withdraw their information. If it doesn't mean that, then there is no right to withdraw").
49. Post Hearing Brief of Patient/Defendants at 17. *Franklin v. Moss*, 1937 Mo. LEXIS 484, at *11, 101 S.W.2d 711, 714 (1937).
50. *Bredell v. Kerr*, 242 Mo. 317, 329, 147 S.W. 105, 108 (1912).
51. *Frey v. Huffstutler*, 1988 Mo. App. LEXIS 525, at *11, 748 S.W.2d 59, 63 (1988).
52. *Davidson v. Lane*, 566 S.W.2d 891, 892 (Tenn. Ct. App. 1978); *Stock v. Augsburg College*, C1-01-1673, 2002 Minn. App. LEXIS 421, at *15-17 (Minn. Ct. App. 2002) (donor had made a conditional gift for a building with his name, not a gift to a general building fund, and was entitled to a return of the money).
53. Plaintiff's Pre-Hearing Brief, at 6.
54. Testimony of Dr. Andriole, *Washington Univ. v. Catalona*, Tr. 2:126 (April 12, 2005). See also Testimony of Dr. Catalona, *Washington Univ. v. Catalona*, Tr. 1:40-41 (April 11, 2005) (stating, "some [patients] are destined to have a recurrence...we could possibly develop [a] new treatment to delay, control or prevent the recurrence in these patients").
55. Testimony of Dr. Andriole, *Washington Univ. v. Catalona*, Tr. 2:126 (April 12, 2005).
56. *York*, 717 F. Supp. at 425. "A 'bailment'...imports the delivery of personal property by the bailor to the bailee who keeps the property in trust for a specific purpose, with a contract, express or implied, that the trust shall be faithfully executed, and the property returned or duly accounted for when the special purpose is accomplished or that the property shall be kept until the bailor reclaims it" (emphasis added).
57. *Id.*, at 424.
58. *Id.*
59. *Id.*, at 425.
60. *Id.*, (citation omitted).
61. *Id.*, at 426-27.
62. Plaintiff's Pre-Hearing Brief, at 16. However, Washington University appears to misrepresent the law of bailment in its Pre-Hearing Brief at 9-10. The cases it cites for the premise that there must be an anticipation of return for a bailment to have occurred themselves say that there can be an expectation of return or an expectation of the bailee dealing with the goods according to the bailor's direction. See *Scope Enters., Ltd. V. United States*, 18 Cl. Ct. 875, 884 (1989); *Welding Metals, Inc. v. Foothill Capital Corp.*, No. 3:92CV00607, 1997 WL 289671, at *7 (D. Conn. 1997).
63. See, e.g., *Weinberg*, 1966 Mo. App. LEXIS 657, at *4-5, 402 S.W.2d at 599; *D&R Distributors, Inc. v. Caryl*, Civil Action Nos. 89-C-46, 89-C-47, and 89-C-48 (Cir. Ct. W. Va. 1992) (finding a bailment where Union Oil transferred possession of oil to D

- & R for delivery to the State of West Virginia with no expectation that the oil would be returned); *Home Indem. Co. v. Harleysville Mut. Ins. Co.*, 166 S.E.2d 819, 824 (S.C. 1969) (“Bailment has been defined as the delivery of a chattel for some express or particular purpose upon a contract, express or implied, that, after the purpose has been fulfilled, then the chattel shall be redelivered to the bailor, or otherwise dealt with according to his directions”) (emphasis added).
64. 717 F. Supp. at 425.
65. *Id.*, at 426.
66. Plaintiff’s Post-Trial Brief at 9 (“WU could choose to anonymize the samples and continue to use them in research”). However, WU’s expert, Dr. Prentice, admitted that the regulations do not contemplate anonymization. *Washington Univ. v. Catalona*, Tr. 2: 224 (April 12, 2005) (when asked whether the regulations contemplate anonymization, Dr. Prentice answered, “No, not specifically”).
67. WU Post-Trial Brief, at 10 (“Currently, the samples are still linked to the participants’ identities”).
68. See Opening Statement of Washington University Counsel, Mr. Wack, *Washington Univ. v. Catalona*, Tr. 1: 28 (April 11, 2005).
69. 1998 U.S. Dist. LEXIS 10307, at *26-27.
70. AMA Code of Ethics 2.08, *Code of Medical Ethics: Current Opinions with Annotations* (Chicago: AMA, 2000).
71. Committee on Human Genome Diversity, Commission on Life Sciences, National Research Council, *Evaluating Human Genetic Diversity* 65 (Washington, DC: National Academy Press, 1997).
72. The guidance in its entirety reads: “No informed consent, whether oral or written, may include any exculpatory language through which the subject 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 CFR 46.116. *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; This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research; This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.” Office for Protection from Research Risks (OPRR), Cooperative Oncology Group Chairpersons Meeting, November 15, 1996, “Exculpatory Language” in Informed Consent.
73. Testimony of Dr. Ellen Wright Clayton, *Washington Univ. v. Catalona*, Tr. 1:122 (April 11, 2005) (“If [patients] understand that when or if it becomes the law that when you provide samples for research that you in fact lose all control, that you have no right to withdraw at all...it will radically undermine the research enterprise”).
74. *Washington University v. Catalona*, Tr. 1:77 (April 11, 2005).
75. L. Andrews and D. Nelkin, *Body Bazaar: The Market For Human Tissue In The Biotechnology Age* (New York: Crown Publishers, 2001) (some universities and hospitals sell access to patient’s tissue to biotech companies).
76. R. Dalton, “When Two Tribes Go To War,” *Nature* 430 (2004): 500-02; *Tilousi v. Arizona State Univ. Bd. of Regents*, No. 04-CV-1290-PCT-FJM (March 3, 2005).