Nos. 06-2286 & 06-2301

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

WASHINGTON UNIVERSITY
Appellee-Plaintiff,

v.

WILLIAM J. CATALONA,
Appellant-Defendant,

and

RICHARD WARD, et al.
Appellants-Defendants.

On Appeal from the United States District Court for the
Eastern District of Missouri, Central Division
The Honorable Stephen L. Limbaugh, District Judge

BRIEF OF *AMICUS CURIAE* PEOPLE'S MEDICAL SOCIETY IN SUPPORT OF APPELLANTS-DEFENDANTS RICHARD N. WARD, THOMAS A. MCGURK, JR., LUIS GARCIA, ANTONIO CASTRO, PHILLIP WILAND, IVAN PARRON, JAMES D. ELLIS, AND MIKE MISSIOS AND REVERSAL OF THE DISTRICT COURT'S DECISION

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CORPORATE DISCLOSURE STATEMENT

In accordance with Fed. R. App. P. 29(c) & 26.1, counsel for *amicus curiae* People's Medical Society ("PMS") submit that PMS has no parent corporation and issues no stock.

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STATEMENT OF ISSUES

Amicus curiae the People's Medical Society respectfully joins in the Statement of Issues submitted by Appellants Ward, McGurk, Garcia, Castro, Wiland, Parron, Ellis, and Missios.

STATEMENT OF INTEREST OF AMICUS CURIAE PEOPLE'S MEDICAL SOCIETY

Pursuant to Federal Rule of Appellate Procedure 29, the People's Medical Society respectfully submits this brief, *amicus curiae,* in support of Appellants Richard N. Ward, Thomas A. McGurk, Jr., Luis Garcia, Antonio Castro, Phillip Wiland, Ivan Parron, James D. Ellis, and Mike Missios. The parties in this case have all consented to People's Medical Society filing this *amicus curiae* brief.

The People's Medical Society is an Internal Revenue Code Section 501(c)(3) nonprofit organization. It is the largest patients' advocacy group in the United States and is a recognized authority on health care issues, including issues related to medical research.[1] The People's Medical Society is regularly consulted by government agencies (such as the Federal Department of Health and Human Services), health care institutions, and pharmaceutical companies. Its current president, Charles Inlander, is a member of the Medical Error and Drug Safety Committee of the National Academy of Sciences, Institute of Medicine. The People's Medical Society has participated as an *amicus curiae* in numerous cases,

[1] Since 1983, the People's Medical Society has released over 100 books, as well as hundreds of articles, fact sheets, and newsletters. Its books have received awards. *Medicine on Trial* was honored as Book of the Year by the American Nursing Association's *American Nursing Journal*. *The Men's Health and Wellness Encyclopedia* (MacMillan Publishing Company, 1998) and *The People's Medical Society Health Desk Reference* (Hyperion Books, 1996) were honored as reference books of the year by the New York Public Library.

including *Moore v. Regents of Univ. of California*, 51 Cal. 3d 120, 793 P.2d 479 (Cal. 1990) and *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. __, 2006 U.S. LEXIS 4893 (2006). In *Moore*, the California Supreme Court adopted the logic of the People's Medical Society brief and found that the patient had a claim for breach of fiduciary duty and breach of informed consent when a researcher used the patient's tissue in research to which the patient had not consented. Since the *Moore* case, the American Medical Association amended its ethics code to require doctors to inform patients when they plan to use patients' tissue for research or commercial purposes. AMA Code of Ethics 2.08, Code of Medical Ethics: Current Opinions with Annotations (Chicago: AMA, 2000).

The People's Medical Society's voice is crucial here because the case's unusual procedural history disadvantaged the patients involved, the Research Participants ("RPs"). Appellee Washington University ("WU") filed its complaint on August 4, 2003, naming only Appellant William Catalona, M.D. as a defendant. WU, in part, sought to establish that it was the owner of the tissue the Research Participants had provided to Dr. Catalona for prostate cancer research. On February 11, 2005, the district court *sua sponte* decided to hold a permanent injunction hearing to determine the sole issue of who owned the Research Participants' tissue. Less than two weeks later, the RPs filed a motion to intervene.

The court joined the RPs as necessary parties on March 14, 2005, and refused to extend the hearing date, scheduled for less than one month later, April 11, 2005. The court limited both the subject matter and the number of testifying patients/research participants. (Order at 3, Feb. 11, 2005.) The Research Participants, therefore, did not have a full opportunity for discovery and had limited time to prepare for the hearing. Moreover, in assessing the potential policy implications of its decision, the lower court relied entirely on an *amicus* brief filed by the Association of American Medical Colleges on WU's behalf, without hearing from any national patients' group.

Medical institutions and physicians have a strong pecuniary and academic interest in asserting an unprecedented claim of ownership of tissue used in research because they can sell the tissue to other researchers and can profit from any new discoveries. In contrast, the People's Medical Society has no such pecuniary interest and thus can raise fundamental legal and policy considerations that will not otherwise be addressed.

ARGUMENT

I. PUBLIC POLICY SUPPORTS A REVERSAL IN THIS CASE.

The People's Medical Society felt compelled to enter this case because upholding the district court's opinion below will do serious damage to medical research in this country. The district court ruled below that Appellee Washington University, a research institution, is the owner of human tissue samples that the Appellant Research Participants, and tens of thousands of others who are not represented by counsel in this action, provided to Appellant Dr. William Catalona for use in prostate cancer studies. The district court misunderstood how the research enterprise operates and the policies that undergird that system. As a result, the court failed to correctly apply state and federal law.

Human research is a multi-billion dollar business in this country.[2] However, it is unlike any other industry in the United States. The raw material is not widgets, but people. These people altruistically give of their time and provide the use of their body parts, such as blood and tissue. The most important protection for them is the legal assurance that research is not a matter of conscription. People

[2] Washington University claimed net assets of over five billion dollars in its 2003 Form 990 (the latest form publicly available). Its highest paid physician/researcher received over one million dollars in compensation that same year. Washington University, Compensation of the Five Highest Paid Employees, Form 990, Schedule A, Part I for the Fiscal Year Ending June 30, 2004. WU holds over 500 patents.

cannot be forced to participate in research. They – and their tissue – cannot be used for research unless they consent. Consequently, research participants have inviolable rights to choose what research they are willing to allow on themselves and their tissue and to withdraw from research at any time for any reason. 45 C.F.R. § 46.116 (regarding informed consent); 45 C.F.R. § 46.116(a)(8) (regarding right to discontinue participation in research).

The federal regulations protect people in this way because people have strong feelings about what types of research should be done on their tissue.[3] Some individuals have religious beliefs about what research should be done; for example, some people oppose embryonic stem cell research and would not want their tissue used in that research. Moreover, research on tissue creates psychological and financial risk for people. For example, people have lost their health insurance based on their participation in genetic research.

The federal agency charged with enforcement of the federal regulations, the Office for Human Research Protections ("OHRP"), cautions that care must be

[3] Consent is also central to other statutes that deal with human tissue, such as the Uniform Anatomical Gift Act, Mo. Rev. §194.200 *et seq*., under which the person has a right to choose what is done with his organs and other tissue after his death. He may choose not to authorize any use of his organs and tissue (even though it might be better for society if he donated his organs). Mo. Rev. Stat. § 194.220(1); *accord* Mo. Rev. Stat. §194.220(3) (donee cannot accept organ or tissue if she knows the donor did not consent to the donation). The person may choose to provide his organ or tissue after his death to a particular named recipient (a friend who needs an organ, for example) (Mo. Stat. Ann. §194.230(4)), or to a particular researcher (Mo. Stat. Ann. §194.230(1)).

taken to protect people's rights (including the right to control what research is done on their tissue) because the information generated about an individual through genetic research can be harmful to the individual. U.S. Dept. of Health and Human Services, Office for Human Research Protections, Protecting Human Research Subjects: Institutional Review Board Guidebook, Chapter 5: "Biomedical and Behavioral Research: An Overview," Section H: "Human Genetic Research," (hereinafter, "OHRP Guidebook").[4] Often, the circumstances surrounding participation are imbued with inherent conflicts of interest on the part of the researcher or research institution. This is precisely the type of situation where a right of rescission is warranted and thus protected by the federal regulations.

This legal scheme not only makes good moral sense, it also makes good practical sense. More people are willing to participate in research when they can choose the type of research in which their tissue is used and can stop participating if they no longer desire to. Since many types of research require tissue from people with the particular disease being studied, it makes sense to encourage people to provide their tissue for research that affects them and their families. We would not have had a breakthrough in AIDS treatment if AIDS patients had not been able to choose the type of research that was done on them and their tissue. We would not have learned about the devastating disorder sickle-cell anemia if

[4] *Available at* http://www.hhs.gov/ohrp/irb/irb_chapter5.htm.

African-Americans had not been allowed to choose to provide their blood for research on that particular disease.

This legal scheme for human research echoes those we have in place for other types of altruistic behavior. Courts assure that when a decedent has designated in a will which people and which causes will receive his property, those designations are honored. When a person donates money to a charity for a particular purpose, that money cannot be used by another charity or for another purpose. It does not matter that it would do more good for society if a decedent's estate or a gift to a charity were used for another purpose. We do not eliminate people's right to choose merely because the possibility exists that people might make choices that conflict with other public policy goals.

Because human research has such important continuing implications and risks for the individual, federal research regulations recognize the ongoing role of participants in human tissue research and provide *additional* rights to them, even beyond the protections given other forms of altruistic behavior. For example, the federal research regulations preclude research participants from agreeing to give up ownership of their tissue. (*See* Section II B, *infra*.) Under the federal regulations, research institutions are allowed only to ask research participants for permission to *use* the research participants' tissue. And research participants have a continuing right to withdraw from the research.

The federal research regulations prohibit the researcher or research institution from obtaining "fee simple" legal ownership of a patient's tissue. With legal ownership of a person's tissue, the institution could undertake research on a person by subjecting his or her tissue to research without his or her consent, no matter the risk or how much the research violated the person's beliefs.

In this case, the documents and testimony clearly indicate that the RPs agreed to a particular use of their tissue: prostate cancer research undertaken by Dr. Catalona. In a move unprecedented in all of human research – and in contravention of the federal research regulations – WU went to court seeking a declaration that it owned the Research Participants' tissue and could use the RPs' tissue for whatever purpose it wanted. The sheer audacity of this move was astonishing. It means that WU could take tissue provided for prostate cancer research by Dr. Catalona and use it for any research it wants. It could use it for research that the patient objected to on religious grounds, such as embryonic stem cell research, research that WU's administration and researchers enthusiastically support,[5] but that some RPs may find objectionable. WU could take tissue provided for prostate cancer research and sell it to a biotech company.[6]

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[5] *See* Judy H. Watts, *Stem Cells Hold Great Promise*, Wash. U. St. Louis Magazine, Spring 2005, http://magazine.wustl.edu/Spring05/StevenTeitelbaum.htm.

[6] Evidence in the record demonstrates WU seeks pecuniary gain from biotechnology companies for RPs' samples. With respect to 2000 samples on

The legal principles in this case are straightforward – the federal research regulations set forth the inviolable rights of research subjects to choose what research they want undertaken on their tissue and the right to change that choice. Research subjects are also protected by well-established state laws, including Missouri gift, bailment, property, and contract law.

If this case dealt with any other item, WU would not have been able to claim ownership of that item based on the evidence it produced. However, because this case deals with an unfamiliar item – human tissue, the district court deprived the people from whom the tissue was removed of basic legal protections that would have applied in all other instances.

If the district court's decision is upheld, the precedent will not only disrupt medical research, but other important transactions because:

1. Patients and research participants can no longer rely on the promises made by physicians and research institutions in informed consent documents

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which Dr. Catalona wanted to undertake the research to which RPs had consented, a WU employee wrote: "[T]his should be worth nearly $100,000 to the university. The only consideration Hybritech is offering is the potential for Catalona to get a publication. It is my opinion this is an unacceptable proposal." (E-mail from Jon Kratochvil, Business Development Director to Theodore Cicero, Vice-Chancellor for Research, Washington University. (Nov. 27, 2001) (Tr. 3:33)). This language of "cost recovery" is deceptive. The typical cost for sharing samples is a half-hour of a lab technician's time to pack them and the postage charge of shipping a liquid nitrogen tank of samples. The costs of obtaining the samples by blood prick or surgery and storing them were already paid for by either the National Institute of Health grants regarding the tissue or the patient himself or his insurer (in the case of surgery).

because such documents are "inconsequential" and can be ignored as a matter of law (Mem. Op. 20);

2. Research participants will lose the right to stop research on their tissue when a research institution materially changes the nature of the research being performed, because the right to withdraw means only the right to stop providing new tissue (Mem. Op. 23);

3. Research institutions will reformulate "informed consent" documents to contain waivers of research participants' rights because that is what the industry understands the rules to be (Mem. Op. 20-21) and the administrative interpretations of the regulations to the contrary are merely guidance entitled to no deference (Mem. Op. 20-21);

4. *Inter vivos* donors of kidneys to relatives will find the donated organ instead goes to a person chosen by the hospital, because allowing individuals to choose a specific type of recipient is against public policy (Mem. Op. 27);

5. Mothers who store cord blood in private tissue banks will find that they cannot direct that the cord blood be used for transfusions for their children because they had no expectation of return (Mem. Op. 25) and the bailment agreement was "inconsequential" (Mem. Op. 20);

6. Institutions with biorepositories will be free to sell tissue to the highest bidder, conduct any type of research on the tissue and generally treat the

tissue as their own property free of the rights of the person from whose body the tissue was obtained (Mem. Op. 27-28);

More generally:

7. All businesses will be required to comply with hazardous waste laws regarding storage and transportation of items such as computers and batteries, even when such items are brand new inventory because the requirement that such items be "waste" before such rules apply has been read out of the law (Mem. Op. 25);

8. Consignees who sell the goods and keep the money in violation of the consignment agreement will use a new defense: the agreement is inconsequential and the consignor had no expectation of return of the goods (Mem. Op. 25).

Respectfully, we submit that this Court does not need to break new ground in its decision to reverse the judgment of the district court. By applying established legal precedents, this Court will be furthering the important policy goals of advancing research, while still protecting research participants.

II. THE FEDERAL REGULATIONS REQUIRE A REVERSAL OF THE DISTRICT COURT'S JUDGMENT AND MANDATE A JUDGMENT ON BEHALF OF THE RESEARCH PARTICIPANTS.

The Nuremberg Code, the Declaration of Helsinki, and the Belmont Report set forth the ethical guidelines governing research. WU has publicly declared that

it follows these ethical standards for all its human research studies, regardless of the funding source.[7] The first principle of the Nuremberg Code is that the "voluntary consent of the human subject is absolutely essential." Thus, WU promises not to perform research on a person without his or her consent. But WU has gone to court to do just that. (Pl.'s Post Trial Br. 21-23, Doc. 140.)

A. Research Participants have a right of informed consent.

The federal research regulations similarly preclude research on an individual and on an individual's tissue without that individual's consent. 45 C.F.R. §§ 46.101(b)(4), 46.116.[8] The requirement of informed consent in medical research is designed to provide people an inalienable, continuous choice about what is done with their bodies and their tissue, even if there is no physical risk to them.

The research regulations protect research participants even in instances where a physical touching of the person will not occur. They protect people whose identified tissue is used because, when that tissue is subjected to research, including genetic research, the research results could lead to psychological or

[7] Washington University, "Institutional Statement of Commitment to the Protection of Human Participants in Research at Washington University," Rev. 5/31/04.
[8] The federal regulations are binding on Washington University. WU has provided an assurance (45 C.F.R. § 46.103) to the OHRP that it will comply with the federal regulations in both its federally-funded research and its non-federally-funded research. Washington University, "Institutional Statement of Commitment to the Protection of Human Participants in Research at Washington University," Rev. 5/31/04.

financial harm. Even the Genetics Brochure written by WU recognizes that research on a Research Participant's tissue poses significant risks to him, including the risks of employment discrimination and insurance discrimination based on the research. (Genetics Brochure at 2, Add. 34.)

Because research on tissue presents risks, 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." Committee on Human Genome Diversity, Commission on Life Sciences, National Research Council, *Evaluating Human Genetic Diversity* 65 (National Academy Press, 1997).

Because choice and consent are the central and continuing rights in human research, the federal regulations provide that research participants must be informed if there are any changes in the research that might affect their willingness to continue to participate. 45 C.F.R. § 46.116(b)(5). The chance to make a subsequent decision about continuing participation is consistent with the regulations' view that the research participant has granted the research institution the right to *use* the tissue for a specific purpose, not a grant of ownership. In this case, the RPs had specifically provided their tissue for research on prostate cancer in studies directed by Dr. Catalona. As required by the regulations, Dr. Catalona informed participants of his change of institutions which could affect their

willingness to participate. Over 6000 RPs requested that their tissue be transferred to him at Northwestern University.

The RPs' tissue contains their genetic material and any further research performed on their tissue, other than prostate cancer research by Dr. Catalona, is research that is performed on them without their consent. The district court's holding, which grants WU fee simple title to the RPs' tissue, thus contravenes the federal research regulations. (Mem. Op. 27-28.) This is reversible error.

The district court's misunderstanding of the consent requirements is underscored by the court's statement, "[a]llowing an RP to choose who can have the sample, where the sample can be stored, and/or how the sample can be used is tantamount to a blood donor being able to dictate that his/her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or a man." (Mem. Op. 27.) Existing laws clearly *do* protect people's rights to make these very decisions. People must be given sufficient information about a research project to make an informed decision about whether to participate and they can refuse to participate for *any* reason. *E.g.* 45 C.F.R. § 46.116(a)(8). Accordingly, they can choose which researcher to entrust their sample to and how it can be used. Moreover, living donors of organs can

choose who receives their organs (such as livers and kidneys), and 85% specifically designate a spouse or relative,[9] a decision which is legally protected.

The district court judge seemed to believe that the creation of a large biorepository was so important that the laws and regulations protecting patients' right to informed consent to research and right to withdraw could be ignored. (Mem. Op. 27.) The district court's logic was wrong. First, biorepositories are not protected by law; research participants are. People can choose not to give tissue to biorepositories in the first place. They can require that their tissue samples be destroyed, thus they already have the clear right to diminish the number of samples in the biorepository. In fact, in this case, WU induced the RPs to participate in research by promising them the right to destroy their tissue if they no longer wanted to participate (*e.g.* Genetics Brochure at 3, Add. 34; Patients' Ex. 10, Ex. App. 8), which would inevitably diminish the value of the biorepository. WU is acting with extreme audacity to now claim that it is against public policy to deplete the biorepository. (WU Pre-Hr'g Br. 17.)

In fact, the best way to keep the biorepository intact is to transfer the tissue samples to Dr. Catalona. If WU persists in not obeying transfer instructions of the 6000 patients, those patients will probably exercise their right to destroy their samples. Effectuating such a transfer will also give people who participate in

[9] OTN/SRTR Annual Report, *Living Donor Characteristics, 1995-2004*, *available at* http://www.ustransplant.org/annual_reports/current/208_don_rel_ty_dc.htm.

research across the country confidence that when they choose to participate in a particular type of research with a particular researcher, that choice will be honored. This will lead to greater participation in research, and larger biorepositories at all institutions.

Second, any purported need for unfettered access to samples in research cannot override the property rights and informed consent rights of research subjects. 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 v. Midwest Organ Bank*, No. 97-CV-0271, 1998 U.S. Dist. LEXIS 10307 (W.D. Mo. July 8, 1998) (unpublished opinion) at *26-27, the court acknowledged that the need for donated organs was great and that many people died waiting for them. However, the need for donated organs did not justify interfering with a person's or next-of-kin's property rights in his or her tissue.

B. Research Participants have a right to continued ownership of their tissue.

The federal regulations also prohibit research subjects from waiving their legal rights to their tissue. Section 46.116 of Title 45 of the Code of Federal Regulations provides:

> 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.

This regulation prohibits the very action WU sought in this case: requiring research participants to give up rights to their tissue. In this case, informed consent documents given to a subset of RPs contained the language: "[b]y agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate." (*E.g.*, Patients' Ex. 10, Ex. App. 8.) WU has been unable to point to any statute, regulation, or written document which supports its claim to the RPs' tissue besides this one sentence. However, the language in this sentence is forbidden by the federal research regulations set forth above, which state that a participant in research cannot be made to waive any of his or her legal rights, which the relevant agency has interpreted to prohibit research institutions from asserting ownership over research participants' tissue.

The OHRP has alerted research institutions of what is forbidden exculpatory language under 45 C.F.R. § 46.116, including: "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." In contrast, acceptable language under 45 C.F.R. § 46.116 is, "[b]y consenting to participate, you authorize the *use* of your

bodily fluids and tissue samples for the research described above" (emphasis added).[10]

The OHRP has enforced § 46.116 by taking action against universities whose informed consent documents for research contain language virtually identical to WU's, such as: "By your consent to participation in this research study, you give up your property rights that you may have in your bodily fluids, substances, or tissues."[11] The OHRP determined this language was exculpatory in violation of 45 C.F.R. § 46.116 because it made a subject "waive, or appear to waive" his or her legal rights.

Contrary to the district court's assertion of what the "research community consistently understood" (Mem. Op. 20), the OHRP's stance on exculpatory language is widely endorsed and is (as it must be) followed by the medical research community. Major research institutions such as Stanford University follow the federal research regulations and the OHRP's guidance, prohibiting

[10] Office for Human Research Protections, *Exculpatory Language in Informed Consent*, *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm.

[11] Letter from Carol J. Weil, Compliance Oversight Coordinator, Division of Human Subject Protections, Office of Human Research Protections, to John C. McDonald, Chancellor/Dean, Louisiana State University Health Science Center Shreveport (Jan. 25, 2006) (On file with the PHS FOIA Office) *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR06/jan06a.pdf.

informed consent document language that waives research participants' property rights in their tissue.[12]

The informed consent form used by the National Cancer Institute for all of its cancer research on tissue similarly asks research participants for a grant of *use* of their tissue and does not seek to own the tissue. Moreover, the NCI informed consent form states that "If you now decide that your tissue can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue."[13]

The fact that the entities that undertake the most cancer research in the country recognize that they cannot own the patients' tissue renders ludicrous WU's admonition that recognizing RPs' ownership rights in tissue will sound the death knell for research. It is only WU that has the audacity to claim it should not be bound by the federal rules.

The district court held that WU owned the RPs' tissue. (Mem. Op. 27-28.) This was reversible error.

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[12] *E.g.*, Stanford University, *IRB Guidance: Basic Research Consent Requirements*, http://humansubjects.stanford.edu/research/documents/ConsentGuidance.doc; University of Nevada, Las Vegas, Office for the Protection of Research Subjects, http://www.unlv.edu/Research/OPRS/consent-exculpatory-language.htm; Illinois State University, http://www.rsp.ilstu.edu/policy/informed_consent/exculpatory_language.shtml.

[13] First Generation Guidelines for NCI-Supported Biorepositories, Appendix 1 – NCI Sample Consent for Use of Tissue for Research, 71 Fed. Reg. 25,184, 25,197 (April 28, 2006).

C. Federal research regulations give participants the right to withdraw and to discontinue participation in research.

The federal regulations also provide that participants have a right to withdraw from research and to discontinue participation at any time and for any reason. The research participant must be told that "the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." 45 C.F.R. § 46.116(a)(8). In this case, the informed consent documents provided by WU also state that "participation is voluntary" and that the RP can withdraw from the study. Contrary to the district court's holding, (Mem. Op. 10), WU does not have the discretion to destroy the samples, or attempt to anonymize the samples when an RP discontinues participation or withdraws from the studies.

No documents gave WU the right to destroy or anonymize any of the samples, nor did it prove it has that right on any other grounds. All documents that gave an express right to destroy or anonymize an RP's tissue gave that right to the RP, not to WU.[14] (*E.g.* Genetics Brochure at 1, 3, Add. 34.)

The only provision of the federal regulations that addresses anonymized samples deals with samples that have *already been* anonymized. 45 C.F.R. §

[14] While it is true that some samples might be totally consumed in the course of research, that is entirely consistent with the RPs' grant of use to Dr. Catalona. However, the RPs allowed that right only to Dr. Catalona and only for specific prostate cancer studies.

46.101(b)(4) exempts certain anonymized specimens from the informed consent rights otherwise accorded human research subjects. However, 45 C.F.R. § 46.101(b)(4) only applies to samples that were initially collected for "pathological" or "diagnostic" purposes. While the samples here could be used for the RPs' medical benefit, the samples were collected for research purposes.

Second, this section only applies to samples in which "the subjects cannot be identified, directly or through identifiers linked to the subject." 45 C.F.R. § 46.101(b)(4). The tissue in this case *can* be identified. The identities of the participants are linked to the samples. (WU Post-Trial Br. 10 ("Currently, the samples are still linked to the participants' identities"); *see also* Andriole testimony, Tr. 2:126-127.) Even WU's expert, Dr. Prentice, admitted that the regulations do not contemplate anonymization in these circumstances. (Tr. 2:224-225.) A non-applicable federal regulation that covers discarded, anonymous tissue does not apply to WU because it does not give WU a right to attempt to anonymize identifiable tissue in contravention of the express wishes of the RPs.

WU's own policy rules state that it cannot use anonymous samples except in limited circumstances which do not apply in this case: "If the samples are anonymous, it is possible for the investigator to obtain the samples without informed consent. Samples are anonymous only if it is impossible under any

circumstances for anyone to identify the tissue source."[15] The tissues at issue are identifiable, and are linked to the RPs' identities, and therefore this is not the type of research that is exempt from informed consent requirements.

Even if it were technically possible (which it is not, due to the possibility of identifying people through their DNA), anonymization would not only thwart the RPs' intent, but would also diminish the value of the tissue for research. When the person's identity is linked to the sample, the person can be recontacted for further information about his health. His samples can be linked to those of his relatives to try to identify genetic mutations that lead to particular diseases. Anonymizing the tissue would preclude the RP and his children from personally benefiting from the research. (Catalona testimony, Tr. 1:64.) This violates the language in the informed consent documents that the research could specifically benefit the RP and his family.

The district court held that WU has a right to destroy or anonymize the samples if an RP withdraws from a study. (Mem. Op. 22.) This was reversible error.

[15]Washington University in St. Louis, *Policies and Procedures—Commercial Sale of Blood and Tissue Samples Policy*, http://www.wustl.edu/policies/bankedtissuesamples.html.

III. STATE LAW PROTECTS RESEARCH PARTICIPANTS IN THIS CASE.

A. The Research Participants did not make a gift of their tissue to Washington University.

The federal regulations are clear that state laws providing additional protection for research participants must be followed, even if they provide greater protection than the federal regulations. 45 C.F.R. § 46.101(f). One relevant state law precedent is that of the law of gift. Under Missouri law, a valid *inter vivos* gift requires 1) an intent of the purported donor to make a gift, 2) delivery to the donee and acceptance by the donee, and 3) relinquishment of all "dominion and control" over the purported gift. *Ridenour v. Duncan*, 246 S.W.2d 765, 769-70 (Mo. 1952). The party "claiming the gift has the burden of proving the gift by clear and convincing evidence." *Estate of Bean v. Hazel*, 972 S.W.2d 290, 293 (Mo. 1998).

The testimony and evidence in this case showed that the RPs did not intend to make a gift of their tissue; they did not deliver their tissue to WU; and they did not absolutely relinquish dominion and control of their tissue to anyone, especially not WU.

Each testifying RP stated he did not intend to give a gift of his tissue to WU but rather agreed to the use of their tissue in prostate cancer research conducted by Dr. Catalona with the understanding that they could withdraw at anytime. (Ward testimony, Tr. 2:71-72; Ellis testimony, Tr. 1:158-59, 161; McGurk, testimony Tr.

1:211.) The RPs indicated they had provided their samples to Dr. Catalona, not to WU. (Ward testimony, Tr. 2:71-72; McGurk, testimony Tr. 1:219.) Ellis said that he did not even initially know that Dr. Catalona was affiliated with WU. (Tr. 1:154.) The written documents accompanying the transfer of the RPs' tissue to Dr. Catalona nowhere state or imply that the RPs intended to give a gift to WU. In fact, the documents are so clear that the tissue is being provided to Catalona, and not WU, that they specifically require Dr. Catalona to ask the patients' permission if he wants to share the tissue with another WU researcher: "May I share your tissue and data . . . with investigators doing research in similar fields at Washington University . . . ?" (Patients' Ex. 10, Ex. App. 8.) This would not be necessary if WU owned the tissues.

Furthermore, the documents executed by the RPs when they provided their tissue to Dr. Catalona gave them continuing rights of dominion such as the right to anonymize and destroy their tissue. In fact, the right to exclude others (in this case, through destruction of the purported gift) is "one of the most essential sticks in the bundle of rights that are commonly characterized as property." *Dolan v. City of Tigard*, 512 U.S. 374, 384, 393 (1994) (quoting *Kaiser Aetna v. U.S.*, 444 U.S. 164, 176 (1979)).

The district court used the fact that the informed consent documents "typically bore the WU Medical Center logo," to show the RPs gave their tissue as

a gift to WU. (Mem. Op. 18.) However, not all of the RPs received informed consent forms with the WU logo on them. (For example, Appellant Ward's informed consent document did not have WU's logo on it. (Patients' Ex. 1, Ex. App. 1.)) Moreover, the presence of WU's logo in no way confers a gift of the tissue to WU. If a woman donated her kidney to her sister during a surgical procedure at WU, after signing an informed consent form on WU's letterhead, she could reasonably expect that the kidney would be given to her sister, not used by WU for whatever purpose it chose.

Because WU failed to meet its burden of demonstrating by clear and convincing evidence for each element that the RPs made a gift of their tissue to WU, the district court erred in finding WU to be the owner of the materials in the biorepository via an unconditional *inter vivos* gift. (Mem. Op. 17.)

B. Hazardous waste laws do not preclude a finding that the RPs owned their tissue.

The district court judge's failure to correctly apply the Missouri common law of gift and the federal research regulations appears rooted in his belief that there is something unseemly about human tissue. This is most evident in his erroneous view that the hazardous waste statutes would require the court to declare WU and not the RPs the owner of the tissue and to prevent the RPs from transferring their tissue to another institution.

However, every court that has addressed the effects of hazardous waste statutes on property rights in tissue has held that those statutes were not intended to, nor do they, negate the property rights of the individual from whom the tissue was taken or his designee. *Moore,* 51 Cal. 3d 141, 793 P.2d 479; *Hecht v. Kane*, 20 Cal. Rptr. 2d 275, 281 (Cal. Ct. App. 1993). Courts are clear that the hazardous waste statutes may not be used by an institution "to permit 'scientific use' contrary to the patient's expressed wish." *Moore*, 51 Cal. 3d at 141. *See also Hecht,* 20 Cal. Rptr. 2d at 281.[16] In *Mansaw,* 1998 U.S. Dist. LEXIS 10307, at *16, the existence of significant Missouri state regulation regarding the handling of dead bodies did not negate the next of kin's property interest in the decedent's organs and tissue.

Moreover, the hazardous waste statutes do not affect ownership. Under the Missouri Environment Control Solid Waste Management statute, when businesses are done with car batteries, they have to dispose of them according to certain rules. Mo. Rev. Stat. § 260.260. This does not change the fact that the businesses "own" the batteries until they decide to dispose of them.

WU produced no evidence at the hearing, nor has WU argued, that the tissue was in any sense "waste." While at first it may seem counterintuitive to think of

[16] The district court misstates the California law on the subject (Mem. Op. at 16-17), saying the hazardous waste law precluded property interests in *Moore*, when the opinion holds just the opposite. *Moore*, 51 Cal. 3d at 141.

human tissue as valuable personal property, that is the very point of this case. All parties, including WU, which asserts that the tissue in the biorepository is worth more than $1 million, concede that the tissue is valuable. (WU Compl. at ¶ 14.) All parties want this supposed "waste." Moreover, the RPs want the tissue to be used by Dr. Catalona in productive research, not discarded. Nothing in the hazardous waste laws or regulations cited by the district court prevents a person from authorizing the transfer of his or her tissue for research at another institution which would also be governed, when appropriate, by any applicable hazardous waste laws. The RPs were told in their informed consent documents they could transfer tissue from other institutions to WU, and a number did. (Tr. 1:82.) Some RPs transferred tissue out of the biorepository for their use at other institutions by calling Dr. Catalona. (Tr. 2:16-17.) There is no law, policy or contractual provision that precludes RPs from transferring their tissue to Dr. Catalona or Northwestern University. In holding that the hazardous waste laws precluded RPs' ownership and authority to transfer their tissue, the district court committed reversible error. (Mem. Op. 10, 17, 25.)

CONCLUSION

This case began as a simple employment dispute between a researcher and a research institution, but it has expanded into a case where the future of medical research in this country is at stake. The case raises issues of national importance: Is an informed consent document laying out the rights and responsibilities of researchers and research subjects worth the paper it is printed on – or is it, as the district court held, merely "inconsequential?" Is predatory behavior by an institution excusable merely because the institution makes the argument that such behavior is somehow for the public good? And should existing laws, regulations, and ethical principles be set aside by a court merely because the item at issue is something unfamiliar to most judges: human tissue?

If affirmed, the district court's judgment will inhibit future medical research because patients will not agree to participate in studies when they learn that promises made to them in informed consent documents can be disregarded. They also will not participate in research if they have no control over who has their tissue, how that tissue is used, and what types of research are performed on their tissue. Taking this one step further, it is even possible that people will not seek out medical care if they cannot trust that their tissue will not be taken and used in medical research against their will. This is especially a concern for minority individuals, who have been shown to be less likely to seek medical care for

existing conditions due to apprehension about what an institution will do with their tissue. Rayna Rapp, *Refusing Prenatal Diagnosis: The Uneven Meaning of Bioscience in a Multicultural World*, 23 Sci., Tech., and Human Values 45 (1998).

For these reasons, *amicus curiae* the People's Medical Society respectfully urges this Court to reverse the district court's decision, to declare the Research Participants to be the owners of their tissue samples, and to order Washington University to transfer the samples to Dr. Catalona's care at Northwestern University, as directed by the Research Participants.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE FOR BRIEF

This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B) because this brief contains 6779 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in 14 point Times New Roman.

Respectfully submitted,

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July 21, 2006

CERTIFICATE OF COMPLIANCE WITH EIGHTH CIRCUIT RULE 28A(d)

A PDF version of this *amicus curiae* brief, excluding the unpublished opinions, has been furnished on a CD-ROM and produced to this Court. This brief is the only document on the CD-ROM. The file was scanned for viruses using the AVG Virus Scan program and was virus free.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of July 2006, I sent 10 printed copies and one electronic copy on CD-ROM of *amicus curiae* People's Medical Society's brief to the St. Louis office of the Clerk of the Court via Fed Ex, postage prepaid. I also certify that two printed copies and one electronic copy on CD-ROM of *amicus curiae* People's Medical Society's brief were sent via Fed Ex, postage prepaid, to the counsel listed below:

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