

Nos. 06-2286 & 06-2301

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

WASHINGTON UNIVERSITY, PLAINTIFF-APPELLEE,

v.

WILLIAM J. CATALONA, APPELLANT-DEFENDANT,

AND

RICHARD WARD, ET AL., DEFENDANTS-APPELLANTS

**On Appeal from the United States District Court
for the Eastern District of Missouri, No. 4:03-CV-1065
The Honorable Stephen L. Limbaugh, District Judge**

**BRIEF OF *AMICUS CURIAE* US TOO INTERNATIONAL
IN SUPPORT OF REVERSAL
IN FAVOR OF DEFENDANTS-APPELLANTS**

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
STATEMENT OF IDENTITY AND INTEREST.....	1
ARGUMENT.....	2
I. Failing to Enforce Promises Made to Prostate Cancer Victims Will Deeply Undermine Their Willingness to Participate in Research.....	3
II. Enforcing Promises Made to Prostate Cancer Victims, As Required by Federal and State Law, Will Fortify Patients’ Willingness to Participate in Prostate Cancer Research.....	4
CONCLUSION.....	7
CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32 (a)(7) and 8 th Cir. 28 A (d).....	8
CERTIFICATE OF SERVICE.....	9

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES:

Greenberg v. Miami Children's Hospital Research Institute, Inc.,
264 F. Supp. 2d 1064 (S.D. Fla 2003).....5, 6

STATE CASES:

Moore v. Regents of the University of California,
51 Cal.3d 120, 271 Cal. Rptr. 146 (Cal. 1990).....5, 6

STATUTES, RULES, AND REGULATIONS:

46 C.F.R. §46.116.....4

42 U.S.C. § 289.....5

42. U.S.C. § 201 *et seq.*, as amended by the Health Research Extension Act of
1985, Pub. L. No. 99-158 (Nov. 20, 1985).....5

Fed. R. App. P. 29(a), (c)(3).....1

INTEREST OF *AMICUS CURIAE*¹

Us TOO International. Headquartered in Chicago, *Us TOO International* was founded by prostate cancer survivors to support prostate cancer patients and their families. *Us TOO International* communicates timely and reliable information to individuals with prostate cancer, enabling them to make informed choices regarding detection and treatment of the disease. *Us TOO International* also publishes a newsletter that keeps patients informed about the latest findings in prostate cancer research and opportunities to participate in clinical trials. Finally, *Us TOO International* educates the public about detection and treatment of prostate cancer. *Us TOO International* accomplishes these goals by identifying, enlisting and supporting a national team of prostate cancer volunteer advocates from men with prostate cancer, their friends and loved ones, and concerned others. A non-profit charitable organization, *Us TOO International* has more than 320 chapters worldwide.

Both *Us TOO International* publishes information and statistics about prostate cancer, and prostate cancer research, that help place this case in perspective:

- Every year more than 200,000 men are diagnosed with prostate cancer, and nearly 30,000 die of their disease. If detected early, prostate cancer is often curable.

¹ *Amicus curiae* is authorized to file this brief by the consent of all parties to this case, as reflected by a letter on file with this Court. See Fed. R. App. P. 29(a), (c)(3).

- One of every six men in the United States is diagnosed with prostate cancer during his lifetime.
- A man with one close relative with prostate cancer has double the risk. With two close relatives, his risk is five-fold higher. With three, the chance is ten-fold higher.
- Two men every five minutes are diagnosed with prostate cancer.
- African American men have a prostate cancer incidence rate 60% higher than white men and a death rate that is 200% higher. Every 100 minutes an African American male dies from prostate cancer.
- Prostate cancer is the most commonly diagnosed non-skin cancer in American men today.
- Prostate cancer is the third-leading cause of cancer death in men in the United States.
- There is no curative treatment for advanced prostate cancer, and new treatments are urgently needed.

Us TOO International is interested in this case because, as *amicus* will explain, preserving the rights of prostate cancer patients and research participants to their bodily tissues is critical to achieving the best, most personalized treatment for prostate cancer victims and their families—which is the heart of *amicus*'s mission.

ARGUMENT

Amicus submits that the district court's decision that Washington University has complete ownership of tissues held in tissue banks not only contradicts Missouri case law and federal regulations as Defendant-Appellant's have argued, but it threatens the viability of the entire prostate cancer research enterprise. Accordingly, *Amicus* maintains that the patient—not the university and not the

research investigator—must have the ultimate say as to his continued participation in research.

I. Failing To Enforce Promises Made To Prostate Cancer Victims Will Deeply Undermine Their Willingness To Participate In Research

If prostate cancer research is to go forward, promises made must be promises kept. The district court concluded that “[m]edical research can only advance, if access to these materials to the scientific community is not thwarted by private agendas.” Def. Add. 27.² This gets it backwards. When research participants volunteer and sign agreements as to their understanding of what will be done with their bodily tissues, including their blood and tumor samples, their wishes should be respected by researchers and institutions collecting specimens—and by the courts.

Genetic information about a patient’s disease risks is precious—and not just to prostate cancer patients. According to the University’s forms, “[i]f this information were to become known outside of th[is] research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or terminated from your current employment.” Def. Add. 35. Because of such risks, Dr. Ellen Wright Clayton testified that “if [patients] understand that when . . . you provide samples for research that you in

² For the Court's ease Amicus cites to the Joint Defendant-Appellant's Addendum and Appendix.

fact lose all control, that you have no right to withdraw at all . . . it will radically undermine the research enterprise.” Def. App. 58 (Tr.1:122).

In light of these risks, the Common Rule provides that “[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights.” 46 C.F.R. § 46.116. And, for the same reason, Washington University’s own expert testified that patients must be re-consented if their tissues are to be used for new purposes. Testimony of Dr. Ernest D. Prentice, Def. App. 146 (Tr.2:252). And, also to protect patients, the University’s forms promise that the Patients “will be informed of any significant (major) new findings developed” during research that “may have a bearing on my willingness to continue in this study.” Def. Add. 31.

By holding that the patients have *no* rights in their tissues, the district court breezed past these legal and ethical red flags. It is therefore the district court’s decision that poses the real risk to medical research. The best way to ensure that patients—including many of *amicus*’s members who have had prostate cancer surgery—are willing to participate in human research in the future is to enforce express promises made to patients today.

II. Enforcing Promises Made To Prostate Cancer Victims, As Required By Federal And State Law, Will Fortify Patients’ Willingness To Participate In Prostate Cancer Research

Not only does public policy require reversal in this case, the law does, as well. The district court's interpretation of the patients' agreement with Dr. Catalona and Washington University runs contrary to federal regulations protecting human research participants' rights in favor of cases from California and Florida that are singularly inapplicable here.

While Congress has established a regime for protecting human research subjects, the district court ignored that regime. The Health Research Extension Act of 1985 requires federally funded institutions (such as Washington University) to establish institutional review boards to establish an ethical guidance mechanism. 42 U.S.C. § 289.³ Pursuant to this Act, as noted above, the Common Rule prohibits research institutions from requiring patients to waive their rights before participating in research. Yet, the district court's decision flies in the face of the Common Rule, holding that the patients in this case waived *all* of their rights in their tissues—despite expressly reserving substantial rights in those tissues.

Rather than heed the requirements of the Common Rule, the district court erroneously relied on Moore v. Regents of the University of California, 51 Cal. 3d 120, 271 Cal. Rptr. 146 (Cal. 1990); and Greenberg v. Miami Children's Hospital Research Institute, Inc. 264 F. Supp. 2d 1064 (S.D. Fla 2003). These cases involved samples that later were converted to derivative commercial products. In

³ Public Health Service Act, 42 U.S.C. § 201 *et seq.*, as amended by the Health Research Extension Act of 1985, Pub. L. No. 99-158 (Nov. 20, 1985).

Moore, the sample was converted to a cell line that was commercialized. In Greenberg, DNA samples were used to develop a commercial genetic test for Canavan disease. In short, these cases pertain to intellectual property rights and are distinguishable from the case before the court.

In the present case, the samples have not been converted to any derivative product, and neither Dr. Catalona nor the patients are seeking monetary reward. The patients only seek to exercise their rights to withdraw from research at Washington University and to transfer their samples to Dr. Catalona to continue as the custodian of their samples and to conduct prostate cancer research for their benefit, according to their original wishes.

As Dr. Catalona's research in prostate cancer is publicly recognized as being of seminal importance by Washington University and is nationally acknowledged by many research awards and honors⁴, the patients' request is reasonable. Such movement of collections of samples is not unique. Indeed, Washington University's expert testified that samples have been transferred from one institution to another when the Principal Investigator changes institutions. Def. App. 146 (Tr.2:251). Under federal law, Dr. Catalona's patients—and *amicus's* members—must have that same right.

⁴ Amicus Add. 1-15.

CONCLUSION

For the foregoing reasons, *amicus Us TOO International* respectfully requests that this court reverse the decision of the district court and remand the case to the District Court with instructions to enter an injunction protecting the patients' tissues and declaring that the patients have the right to control disposition of those tissues.

Respectfully Submitted,

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**CERTIFICATE OF COMPLIANCE
WITH FED. R. APP. P. 32 (a) (7) and 8th Cir . R. 28 A(d)**

Pursuant to Fed. R. App. P. 32 (a)(7) and 8th Cir. R. 28 A(d), counsel for Amicus Us TOO International certifies that this brief conforms to the rules contained in Fed. R. App. P. 32 (a)(7) and 8th Cir. R.28 A(d) for an amicus curiae brief with proportionally spaced font and that the digital version of the brief is in PDF format and has been scanned for viruses and is virus free. Created in Microsoft Office Word 2003, the length of this brief is 1,360 words.

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CERTIFICATE OF SERVICE

Counsel for Amicus Curiae Us TOO International hereby certifies that on July 21, 2006, two copies of Us TOO International's Amicus Curiae Brief, as well as a digital version of said Brief, were delivered by U.S. Mail to the following:

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