

No. _____

In the Supreme Court of the United States

WILLIAM J. CATALONA, *ET AL.*, PETITIONERS

v.

WASHINGTON UNIVERSITY, RESPONDENT.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Department of Health and Human Services regulations prohibit federally funded institutions from obtaining consent for medical research on human subjects by using “*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,” 45 C.F.R. § 46.116 (emphasis added), including (according to the Department’s authoritative interpretation) the statement that “[b]y consenting 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” (emphasis added). Exculpatory Language in Informed Consent, Office for Human Research Protections.

The question presented is whether these prohibitions bar contractual language requiring relinquishment of human subjects’ ownership rights, and thus preempt state law to the extent it would otherwise work a forfeiture of those rights.

PARTIES TO THE PROCEEDINGS

Dr. William J. Catalona and his patients Antonio Castro, James D. Ellis, Luis Garcia, Mike Missios, Ivan Parron, Richard N. Ward, and Phillip Wiland were appellants in the court below. Washington University was the appellee in the court below. There are no other parties.

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INTRODUCTION

This case is about ownership of irreplaceable human cancer tissues provided to researchers according to the federal “Common Rule,” a regulation so-called because it commonly applies to all federally funded research on human subjects. Petitioner Dr. William J. Catalona was Head of Urology at Respondent Washington University for more than a decade. When Dr. Catalona moved to another institution, thousands of patients who provided cancer tissues for his studies asked the University to send their tissues to Dr. Catalona. The University responded by suing Dr. Catalona to establish that it owned the tissues “pursuant to applicable federal and state regulations.” Pet. App. 35a. After joining eight of Dr. Catalona’s patients as defendants, the District Court held that the University owned the tissues with no strings attached under state and federal law. The Eighth Circuit disagreed that the patients relinquished all rights in their tissues, but agreed that the University ultimately owned them. In so doing, the Eighth Circuit improperly chose not to address the question whether any transfer of ownership was barred by the Common Rule, which precludes ownership transfers.

By refusing to recognize the Common Rule’s preemptive effect, the Eighth Circuit’s decision conflicts with the decisions of Maryland’s highest court and another federal court, which hold that the provision of the Common Rule at issue here trumps state common law. Review is needed to settle this conflict, and to address the immense, immediate risk to millions of research participants across the country whose identifiable genetic information may now be consumed, published, used for ethically objectionable research, or simply sold to the highest bidder.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eighth Circuit is reported at 490 F.3d 667 and reprinted at Pet. App. 1a-18a. The opinion of the United States District Court for the Western District of Missouri (Limbaugh, D.J.) is reported at 437 F. Supp. 2d 985 and is reprinted at Pet. App. 21a-54a.

JURISDICTION

The court of appeals entered its judgment on June 20, 2007. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND REGULATORY PROVISIONS INVOLVED

The Supremacy Clause of the U.S. Constitution provides that “[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof * * * shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, § 2. The relevant federal regulation is reprinted at Pet. App. 58a-62a.

STATEMENT

1. From approximately 1976 to 2003, Petitioner Dr. William Catalona provided medical care and conducted research at Washington University in St. Louis, Missouri. Pet. App. 4a. Dr. Catalona is one of the preeminent urologists in the country, and while at Washington University he performed thousands of surgeries, including prostate cancer surgeries. *Ibid.* Dr. Catalona is also a leading researcher. In 1983, he spearheaded the creation of a “biorepository” for the collection and storage of biological research materials

relating to prostate cancer research and related areas of inquiry. *Ibid.* This dispute centers on ownership and other rights in the materials in that biorepository.

2. The District Court stated that “[t]here are approximately 3,500 prostate tissue samples in the * * * Biorepository * * * [and] approximately 100,000 serum samples.”¹ Pet. App. 23a. The Eighth Circuit noted that Dr. Catalona “was instrumental in establishing the GU Biorepository for the collection and storage of biological research materials.” Pet. App. 4a. Dr. Catalona established research protocols for the cancer research studies and appointed other members of the urology division to specific research projects. Tr. 1:47; App. 39.²

Among those whose tissue samples are housed in the biorepository are the eight patient-Petitioners in this case (the “research participants” or “Patients”). All eight research participants are patients on whom Dr. Catalona performed prostate cancer surgery.

The prostate tissue samples Dr. Catalona obtained from the research participants and others are “linked” samples—that is, the samples are matched via a computer database to the identity of the research participant. Tr.2:111-112; App. 111. The database contains demographic information linked to each participant, including specific medical informa-

¹ For ease of reference, this application will refer to all of the samples provided to Dr. Catalona as “tissue samples.”

² “App.” refers to the appendix to Petitioner’s brief in the court below; “Tr.” refers to the transcript of the three-day evidentiary hearing preceding the Court’s summary judgment decision; and “Add.” refers to the addendum to Petitioner’s brief in the Court below.

tion such as prostate-specific antigen (“PSA”) levels, disease diagnosis, past history of prostate cancer, and clinical follow-up data. Tr. 2:112-113; App. 111-112. The database also lists the identity of the treating physician for each research participant.

Linking the samples to the identity of their owner is important because cancer has a significant genetic component. If it were determined, for example, that a certain set of genetic variants predisposed an individual to cancer, it would obviously be important to inform the person from whom the tissue came that he was predisposed to cancer. But it would also be important to inform the relatives of that individual, when appropriate, because they too would be likely to have the same genetic predisposition. Tr. 2:124-126; App. 114-115.

Research participants could be harmed by the release of such information. As the University’s own genetics brochure states, “[i]f this information were to become known outside of the research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or be terminated from your current employment.” Add. 35 (emphasis added). The information, once known, could also cause public embarrassment. See Alan F. Westin, Institute of Medicine Privacy & Research Studies, at 8 (Sept. 11-18, 2007) (national public survey finding embarrassment among concerns if personally-identified health information were disclosed) (on file with Study Director at Institute of Medicine).

3. Washington University is a federally approved and regulated institution with respect to the human-subjects research based in the biorepository. Because

Washington University receives federal funds, it must comply with regulations issued by the Department of Health and Human Services and 16 other federal departments and agencies that govern the conduct of human-subjects research. See 56 Fed. Reg. 28,003 (June 18, 1991) (codified at 45 C.F.R. pt. 46). Because of their applicability across the agencies, these regulations collectively are known as the Common Rule. See *id.* (providing the “Text of the Common Rule”).

Among other things, the Common Rule protects participants by placing strict limits on what a research institution may seek consent to do:

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. § 46.116 (emphasis added). Interpreting this regulation, the Office for Human Research Protections (“OHRP”), the enforcement arm of the Department of Health and Human Services, has issued authoritative guidance barring waivers of the patient’s property rights in tissue samples provided for research. See *Exculpatory Language in Informed Consent*, Ofc. for Human Research Prot., available at <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm> (forbidding statement that “[b]y consenting 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”).

Moreover, to constitute informed consent under the Common Rule, a consent document must contain certain provisions, including “[a] statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and 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). Where “appropriate” the consent form must also state “[t]he consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.” *Id.* at § 46.116(b)(4).

Pursuant to the Common Rule, research participants were presented with consent forms and a brochure drafted by Washington University. Pet. App. 5a-6a. The forms provided that their tissue samples would be used for prostate and bladder cancer research and that “[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.” Pet. App. 6a. The forms did not state that Washington University (or Dr. Catalona) would own the tissue samples, but instead made clear—in a section entitled “**What if you change your mind?**”—that the patients retained significant ownership rights in their tissues, including the right to demand that their samples be destroyed upon their request. Pet. App. 27a (emphasis in forms and District Court opinion).

4. In early 2003, Dr. Catalona left Washington University to become a professor and director of the Clinical Prostate Cancer Program at Northwestern University in Chicago, Illinois. Pet. App. 7a. In February of that year, Dr. Catalona sent a form letter to his patients, the families of his patients, and all oth-

ers who participated in his research protocols at Washington University. The letter asked if the recipient would consent to having his tissue transferred from Washington University to Northwestern University. Pet. App. 7a-8a. Dr. Catalona also published his request in the medical newsletter *Quest*. Pet. App. 33a. The Petitioner-research participants, along with more than 6,000 other research participants, requested that the University withdraw their samples from research there and transfer the samples to Dr. Catalona. Pet. App. 8a.

The University refused to honor these requests and filed suit in federal District Court under state and federal law. Specifically, the University, which alleged jurisdiction based on diversity and federal questions, “argued that the [research participants] made voluntary donations . . . , and once these ‘gifts’ were delivered to [the University], [the University] became the sole owner with control as to use and storage (pursuant to federal and state regulations).” Pet. App. 35a. Dr. Catalona and the Patients countered that, among other things, the Common Rule prohibited using “exculpatory language” in informed consent forms, including language transferring ownership of tissues, and thus “*negates* the gifts.” *Id.* at 44a (emphasis added).

5. The District Court sided with the University, holding that the prohibition on exculpatory language merely barred the University from inducing patients to waive the University’s negligence. Pet. App. 45a. The Court rejected OHRP’s interpretation of the prohibition, which also bars transfer of ownership rights, on the ground that OHRP guidance was non-binding because it was not formally promulgated. *Ibid.* Declining to find federal preemption, the District Court

