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When Catalona tried to block the National Cancer Institute from using samples from the repository, Washington University filed suit for control of the material and accused the doctor of making misleading statements to patients in his effort to take it back.

On Friday, U.S. District Judge Stephen Limbaugh ruled in favor of the university, declaring it the sole owner of the disputed tissue samples and granting it permission to use the samples for appropriate research, and the authority to transfer the tissues to other institutions. "I do think it is a big setback for patients' rights," said Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law.

She said the ruling could mean that universities have the power to use samples for studies even over patients' objections. "The fact that the informed consent form was on Washington U. stationery means the university can do anything it wants with (the samples)," she said.

But the university raised another issue, suggesting that otherwise, transplant or blood donors might be able to refuse certain recipients. It would have "horrible implications," the university said in a prepared statement. It also warned that researchers would be reluctant to start long-term projects under such conditions.

Catalona complained that the ruling negates consent agreements and damages patients' trust in researchers. "If this ruling is to stand, it sort of effectively prevents patients from withdrawing from a research project if they want to," Catalona said. "This is not a used car or a television. It's somebody's genetic information," Catalona said. "The higher issue is in respecting what the patients want." Catalona and Burton Shostak, an attorney for several patients named as defendants, say they will appeal. Shostak said his clients donated their blood and other tissues to Catalona directly because they wanted him to conduct the research. "They went to Dr. Catalona, not to Washington University." Washington University uses the repository as a recruiting tool to attract faculty and research funds, Shostak contends. "What the school doesn't want to give up is the money (it) makes from research."

That's something Washington University strongly disputes. "The University has never profited a nickel from the repository, although it spent hundreds of thousands of university dollars and federal research dollars to create and maintain the repository and conduct research using it," the university said in a question and answer form posted on the Internet at [prostatecure.wustl.edu](http://prostatecure.wustl.edu).

Andrews said the university is not content to use the material for academic research. She said the university wants to sell it to biotech companies. "This is going to turn patients into treasure-troves rather than partners in research," Andrews said.

The university flatly denies it is out to make a profit. "No, we don't have these grand plans to sell the tissue," said Joni Westerhouse, a university spokeswoman. Other research universities that are approved to use the material pay shipping fees, and for-profit companies would be charged a fee in order to recoup costs of establishing and maintaining the repository, she said. "This is a money-losing game," Westerhouse said. "The university is not out to make a profit. We're trying to advance science."

None of the samples has been available for research since the dispute began in 2003. The judge asked that none be used for at least 10 days, but the university said it really would be months before any researchers would have proper authorization. "I don't want

to hold up research, but I'm also not for running roughshod over the rights of patients," Catalona said. "You can't start infringing on the rights of research subjects. You can say it's for the good of society, but that's what Hitler said when they started throwing people in ice water and seeing how long it took them to die. . . . When you start saying that the good of society supersedes the rights of the individual, I think you're treading on thin ice."

③ Doctors should be allowed to respect the wish of patients<sup>11</sup>

A federal judge in St. Louis has ruled in favor of Washington University in a high-profile case that centered on ownership of a vast collection of blood and tissue specimens at the research institution.

The case, in which research participants claimed ownership of their specimens so they could follow a prominent prostate surgeon who was leaving St. Louis, has national implications.

"If left unregulated ..." U.S. District Judge Stephen Limbaugh wrote, "these highly prized biological materials would become nothing more than chattel going to the highest bidder. "Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay." An appeal is planned.

Limbaugh ruled Friday that Washington University is the "true and rightful owner" of the blood, tissue and DNA samples that have been collected since the late 1980s by Dr. William Catalona, a renowned prostate cancer researcher, and his colleagues at the university. The collection, which is among the largest in the nation, is kept in 20 liquid-nitrogen freezers at Washington University. It includes more than 270,000 blood and tissue samples from 30,000-plus donors and has been used for groundbreaking work. Catalona used it to show that PSA was a first-line screening test for prostate cancer, which he reported in the *New England Journal of Medicine* in 1991.

Catalona worked at Washington University from 1976 to February 2003, when he left over what he viewed as restricted access to the very samples he had collected. A year earlier, the university had established a peer-review mechanism to determine who could use the samples. Catalona said he eventually was able to use samples but always after a delay.

When Catalona decided to resign to accept a post at Northwestern University, he announced his move and plans to continue research in Chicago to 10,000 of his former patients. He gave them the opportunity to have their biological materials transferred to his care and research at Northwestern.

About 6,000 donors signed forms indicating they wanted to transfer their specimens. A few weeks later, Washington University filed suit in federal court, wanting to settle the ownership issue. Research on the specimens was effectively halted while the lawsuit played out for three years.

Limbaugh cited two earlier cases in which courts found that donors do not own tissue they donate. He also expressed concerns for the "great potential for prejudicial influences into medical research," if donors could redirect their samples for their own reasons. The St. Louis case is the first involving a university, tissue donors and a researcher asserting that donors have the right to reclaim their tissue and send it to him, university spokesman Don Clayton said.

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<sup>11</sup> Cheryl Wittenauer. "Ruling on ownership of specimens has national implications". April 17, 2006. The Associated Press State & Local Wire.< Nexis>

Washington University said it was pleased with the ruling, which the school noted allows it to make the specimens available to researchers, including Catalona.

"We are looking forward to resuming research with these samples that is consistent with the expectations under which the donations were made, that is, to make discoveries about how cancer develops and can be treated," Clayton said in an e-mail Monday. Catalona, who plans to appeal, said he regrets that Limbaugh made it "a fairly narrow case of property law," when a higher issue, "patient autonomy" and the need to respect the wishes of research subjects, is at stake. He said he is not willing to concede that Washington University unconditionally owns the samples.

Dr. David Korn, senior vice president of the Association of American Medical Colleges, which had filed a "friend of the court" brief in the case, praised the ruling, saying any other decision would have hurt medical research. A tissue sample collection is like a great research library, he said. "If, at any time, book donors or their heirs could walk into the library and take out volumes, it would be awfully hard to maintain a library of any scholarship value," he said.

### 1-2-3 University

*The following are the key arguments made by this group in support of their view:*

- *Dr. Catalona lied while obtaining consent forms from patients.*
- *University control is required for long term research.*
- *University makes sure that the tissues are not wasted due to poor quality research.*

*The next paragraphs describe the above arguments in greater detail.*

#### ① Dr. Catalona lied while obtaining consent forms from patients<sup>12</sup>

Dr. William Catalona, a researcher who pioneered PSA testing to spot prostate cancer, said Wednesday that he was forced out of the Washington University School of Medicine and will fight to take thousands of tissue and blood samples with him.

The school is suing him in federal court, seeking to keep hold of the cancer study material and accusing Catalona of making misleading statements to patients in his effort to take it away.

Catalona denies making any false statements, and says the suit is the result of a bitter dispute that led to his leaving a urology department that he helped build into a major force in research on prostate cancer.

Catalona worked at Washington University for 27 years before resigning in February. He said his urology practice had thousands of patients, and that he has operated on celebrities like New York Yankees manager Joe Torre.

As many as 36,000 men in the St. Louis area participated in the PSA study program. It was shut down in 2001, Catalona said, at the behest of Dr. Timothy Eberlein, chairman of the school's department of surgery. "All I can say, to put it nicely, is that he really made it difficult for me to continue doing my research, and basically squeezed me out," Catalona said in an interview. He said he did not know what motivated Eberlein. "The excuse he used was that he did not like my management style," Catalona said. Eberlein could not be reached for comment.

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<sup>12</sup> Peter Shinkle. "WU, RESEARCHER ARE FIGHTING OVER STUDY SAMPLES". August 7, 2003. St. Louis Post-Dispatch. < Nexis >

Don Clayton, a spokesman for the medical school, said he could not elaborate on the allegations of the suit. But he responded to Catalona's statement that Eberlein "squeezed" him out. "Dr. Catalona was a tenured faculty member. He was not forced to leave the university," Clayton said. "He was told on several occasions that he was welcome to remain and continue his research at Washington University."

In February, as Catalona prepared to become director of the prostate cancer program at Northwestern University in Chicago, Catalona sent about 10,000 letters to notify patients and research participants. Each asked the patient to sign a consent form permitting release of his tissue or blood samples to Catalona or Northwestern University. Since then, more than 6,000 people have sent in signed forms, he said. "We have consent forms coming in every day." Catalona said he now wants to use the scientific treasure-trove for research with other scientists to try to uncover which parts of the human genetic makeup make men vulnerable to prostate cancer.

But for now, the samples, known as the "GU Biorepository," sit at Washington University, in freezers. The dispute has reached the National Cancer Institute in Bethesda, Md. In June, Catalona said, he called the institute and objected to its use of 400 blood samples that Washington University had sent there without his knowledge. As a result, the institute suspended its use of the samples. Dr. Lance Liotta, chief of the laboratory of pathology at the cancer institute, said he spoke with Catalona, who told him "he wanted the material sent back to him."

Liotta said he is not sure where the samples, which were to be used in genetic research, are now. "I think they're packing it up," he said. He said he knows little about the dispute at Washington University. But under federal law, he said, "The patient directs what happens to their tissue."

In the suit, filed Monday in U.S. District Court in St. Louis, Washington University says Catalona's consent forms have no legal effect because they were obtained through the use of "fraudulent" or misleading statements or omissions of fact. The university asks a judge to issue an order declaring that the samples belong to Washington University. The university contends, among other things, that Catalona's letter failed to mention that the university has repeatedly asserted ownership.

Catalona replied that he didn't think it was necessary to tell the patients what the university had claimed. "They've asserted a lot of things," he said. "I think that the ultimate decision about those samples should lie with the patient," he noted. The university says the recipients of the letters had signed earlier consent forms that were not consistent with the new forms sent out by Catalona in February.

A patient under the university's care who is having surgery must sign a form that "consent[s] to the disposal, use or examination of any bones, organs, tissues, fluids or parts which it may be necessary to remove," the suit says. The university also says that Catalona's letter suggests that patients need to sign the forms to receive continued care from him. "It's just not there," Catalona said. "I didn't say it was necessary for me to have this." Catalona noted that his letter even offered to help patients find another urologist.

## ② University control is required for long term research<sup>13</sup>

THE RESEARCHER "If this ruling is to stand, it sort of effectively prevents patients from withdrawing from a research project if they want to." -- Dr. William J. Catalona  
THE UNIVERSITY Without institutional control, donors might be able to refuse certain recipients and researchers might be reluctant to start long-term projects, WU said.

<sup>13</sup> Tina Hesman Saey . "WU gains rights to tissue samples". April 18, 2006 . St. Louis Post-Dispatch. < Nexis>

A federal judge in St. Louis has ruled in favor of Washington University that donors of tissue samples for medical research surrender control over who uses them. The ruling is a setback for a prominent urologist who left the university and fought in court for access to the samples -- and potentially a setback for donors who want to direct their samples to particular projects.

The decision "runs roughshod on patients' rights," said Dr. William J. Catalona, the prostate cancer researcher who collected the disputed samples. Catalona was a faculty member at the university for 27 years. He established a tissue bank, known as the GU Biorepository, that now includes samples from more than 30,000 men. When he left to become director of the prostate cancer program at Northwestern University's Feinberg School of Medicine in Chicago, Catalona sent letters to 10,000 patients who had donated blood, tumor samples and DNA for his research. The letters asked patients to write to Washington University and ask that their samples be transferred to Catalona. More than 6,000 men told Washington University that they wanted Catalona, not the university, to possess their samples.

When Catalona tried to block the National Cancer Institute from using samples from the repository, Washington University filed suit for control of the material and accused the doctor of making misleading statements to patients in his effort to take it back.

On Friday, U.S. District Judge Stephen Limbaugh ruled in favor of the university, declaring it the sole owner of the disputed tissue samples and granting it permission to use the samples for appropriate research, and the authority to transfer the tissues to other institutions. "I do think it is a big setback for patients' rights," said Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law. She said the ruling could mean that universities have the power to use samples for studies even over patients' objections. "The fact that the informed consent form was on Washington U. stationery means the university can do anything it wants with (the samples)," she said.

But the university raised another issue, suggesting that otherwise, transplant or blood donors might be able to refuse certain recipients. It would have "horrible implications," the university said in a prepared statement. It also warned that researchers would be reluctant to start long-term projects under such conditions.

Catalona complained that the ruling negates consent agreements and damages patients' trust in researchers. "If this ruling is to stand, it sort of effectively prevents patients from withdrawing from a research project if they want to," Catalona said. "This is not a used car or a television. It's somebody's genetic information," Catalona said. "The higher issue is in respecting what the patients want." Catalona and Burton Shostak, an attorney for several patients named as defendants, say they will appeal. Shostak said his clients donated their blood and other tissues to Catalona directly because they wanted him to conduct the research. "They went to Dr. Catalona, not to Washington University." Washington University uses the repository as a recruiting tool to attract faculty and research funds, Shostak contends. "What the school doesn't want to give up is the money (it) makes from research."

That's something Washington University strongly disputes. "The University has never profited a nickel from the repository, although it spent hundreds of thousands of university dollars and federal research dollars to create and maintain the repository and conduct research using it," the university said in a question and answer form posted on the Internet at [prostatecure.wustl.edu](http://prostatecure.wustl.edu).

Andrews said the university is not content to use the material for academic research. She said the university wants to sell it to biotech companies. "This is going to turn patients into treasure-troves rather than partners in research," Andrews said.

The university flatly denies it is out to make a profit. "No, we don't have these grand plans to sell the tissue," said Joni Westerhouse, a university spokeswoman. Other research universities that are approved to use the material pay shipping fees, and for-profit companies would be charged a fee in order to recoup costs of establishing and maintaining the repository, she said. "This is a money-losing game," Westerhouse said. "The university is not out to make a profit. We're trying to advance science."

None of the samples has been available for research since the dispute began in 2003. The judge asked that none be used for at least 10 days, but the university said it really would be months before any researchers would have proper authorization. "I don't want to hold up research, but I'm also not for running roughshod over the rights of patients," Catalona said. "You can't start infringing on the rights of research subjects. You can say it's for the good of society, but that's what Hitler said when they started throwing people in ice water and seeing how long it took them to die. . . . When you start saying that the good of society supersedes the rights of the individual, I think you're treading on thin ice."

### ③ University makes sure that the tissues are not wasted due to poor quality research<sup>14</sup>

The Catalona Collection sounds like a line of designer clothes, or perhaps an assortment of fine fragrances. Maybe a stash of Spanish paintings. It is anything but. The Catalona Collection is a repository of blood and tissue samples taken from some 10,000 prostate-cancer patients and their relatives. The specimens sit in a dozen-plus freezers at the Washington University School of Medicine, where administrators have a less romantic name for one of the largest such banks in the world. They call it the GU (short for genito-urinary) Biorepository. It may hold the key to a cure, or at least improved treatment, for a disease that's the second-biggest cause of cancer deaths in U.S. men. As such, it may be worth millions of dollars. And the university wants to keep it.

Dr. William J. Catalona, the collection's former curator, says the university has no right to the samples he began gathering in the 1980s. After 26 years in St. Louis, Catalona left Washington University in February, convinced that he was no longer wanted by the institution that once held him up as a genius. He's now director of the clinical prostate cancer program at the Robert H. Lurie Comprehensive Cancer Center at Northwestern University, just outside Chicago. He says the proper name for the samples is the Catalona Collection, and he wants them back.

Washington University sued Catalona in August, asking a federal judge to settle the ownership question. In October, Catalona countersued, requesting a jury trial. Not only do donors want him to have their tissues, the doctor says, but the law requires it. Besides hiring some of the best legal talent in St. Louis, both sides have brought in attorneys from outside Missouri. That this has turned into a big case is no exaggeration.

Behind the bickering are thousands of men who've undergone surgery and untold thousands yet to be diagnosed whose fates may hinge on who wins this court battle. The case is the latest in a series of disputes throughout the United States over ownership of human body parts used in research, and the ramifications could be felt in laboratories across the nation.

"I think the issue is: Who owns your DNA?" says Gregory Piche (pronounced pee-SHAY), one of Catalona's lawyers. He accuses Washington University of less-than-noble motives. "Our belief is it's all about money," Piche says.

William J. Catalona has long been a urologist to the stars. His patients include Joe Torre, manager of the New York Yankees, and Cardinals great Stan Musial. Former U.S.

<sup>14</sup> Bruce Rushton. "Gland of Opportunity". November 19, 2003 .Riverfront Times .< Nexis>

Senator Robert Dole is an honorary trustee of the Chesterfield-based Urological Research Foundation (URF), which has Catalona as its medical director and [www.drcatalona.com](http://www.drcatalona.com) as its Web address. The nonprofit foundation has raised millions of dollars for prostate-cancer research, and some has gone to fund Catalona's work. Anthony Sansone Sr., URF president and one of the region's most prominent real estate developers, says he would have traveled anywhere to be cured by Catalona when he was diagnosed with prostate cancer thirteen years ago. Even though he's one of the wealthiest men in St. Louis, Sansone says Catalona didn't treat him like a celebrity. He says he was put on a waiting list like everyone else. The doctor's bedside manner, Sansone says, equals his skill as a surgeon. "They come from all over the world for this man to operate on them," Sansone says. "I thoroughly enjoyed the gentleman. He had a great deal of compassion. As far as I was concerned, he couldn't have made me feel more at ease."

Citing advice from his attorneys, Catalona declined to be interviewed for this story. But his praises have been sung all the way to Congress. "Even though he practices medicine at Washington University in St. Louis, Missouri, he mailed to us videotapes and pamphlets, as well as calling Bob on the telephone several times," Carol L. Watson, wife of former Houston Astros baseball star Bob Watson, told the U.S. Senate Special Committee on Aging in 1997. "We were both very well informed about the possibilities of incontinency and impotency and about the time, energy and effort on both of our parts that aftercare would encompass."

Catalona specializes in delicate operations that remove diseased prostates while preserving nerve bundles that surround the walnut-size gland, which produces seminal fluid. The tiny nerves control erections, meaning that a scalpel that wanders a millimeter or two can result in impotence. Nerve-sparing surgery, which costs as much as \$30,000, is considerably more expensive than the standard operation that removes the prostate and often damages nerves. But men who undergo the painstaking procedure say the extra money is worth it, given that some experts say impotence rates are as high as 90 percent in men who undergo the less-precise operation. Catalona, who has performed more than 3,600 nerve-sparing surgeries, claims nearly 80 percent of his patients retain their ability to achieve an erection. Nerve-sparing surgery is also less likely to result in incontinence, another common side effect of prostate removal.

Besides being a top surgeon, Catalona is one of the premier prostate-cancer scientists on the planet. He's best known for demonstrating that prostate cancer may be detected with a blood test. The test measures prostate-specific antigen, or PSA, an enzyme produced by the prostate that, in theory, should only be present in semen. In reality, some finds its way into the bloodstream, although experts can't say exactly how or why. High PSA levels in blood are a red flag for cancer, according to a landmark study Catalona published in the *New England Journal of Medicine* in 1991.

Almost immediately, PSA tests became de rigueur for men who are at risk for prostate cancer. Celebrities who survived cancer, including Dole, former financier Michael Milken and General Norman Schwarzkopf, touted PSA tests in television, newspaper and magazine interviews and credited blood tests for saving their lives. Less fortunate victims, including rock musician Frank Zappa, LSD guru Timothy Leary and actor Telly Savalas, succumbed.

In short, the prostate gland, an organ that was once taboo, came out of the closet. It was OK for a former presidential candidate to talk about his prostate while endorsing Viagra, a drug that can help reverse post-operative impotence. Research money skyrocketed, both in the private and public sector. In 1992 the federal government spent \$31.4 million on prostate-cancer research. By 2002 the amount had zoomed to \$278.4 million. Milken, who became as zealous a philanthropist as he was a financier, established the Association for the Cure of Cancer of the Prostate (CaP CURE), a private foundation that

has raised more than \$100 million for prostate-cancer re-search since 1994 and distributed it on a streamlined basis to scientists who once had to wait months or years for government funding.

Catalona became a darling of the mainstream press, with interviews in the New York Times, the Wall Street Journal, USA Today and other publications. His research had mushroomed in 1991, when he began enrolling St. Louis-area men in a long-term study designed to fine-tune PSA testing and further prove its efficacy. Over time, about 36,000 men enrolled in the study and received regular PSA tests. Based on mass screenings supervised by Catalona, the Food and Drug Administration in 1998 approved a new form of the PSA test manufactured by Hybritech, a San Diego biotech company that helped fund the doctor's work. (The test is not without its critics. For more, see accompanying sidebar.)

In 1983, Catalona claims, he started saving blood and tissue from patients to help investigate the causes of prostate cancer and potential treatments. Eventually the doctor expanded the collection to include specimens from relatives of prostate-cancer patients that could prove instrumental in determining the disease's genetics and finding a cure. Although more than 200,000 men are diagnosed with prostate cancer annually in the United States and about 30,000 die each year, collections of research-quality tumor tissues are as rare as Rembrandts. Approximately 10,000 men have donated samples now stored at Washington University. Besides being big, the collection preserved at minus 70 degrees Fahrenheit may be the oldest in existence. As such, it is coveted by researchers looking for telltale markers of prostate cancer on chromosomes or proteins within the bloodstream.

Dr. Gerald Andriole, head of urology at Washington University's medical school, says the frozen tumor tissue and blood may one day help patients decide whether they should undergo surgery, radiation or any treatment at all, given that prostate cancer often poses no risk to a man's life because many tumors have slow growth rates. "Right now, based on what we know about prostate cancer, it's literally a coin toss: You could choose surgery or you could choose radiation," Andriole says. By analyzing samples from the repository, researchers may be able to determine that men with certain markers were cured by radiation that didn't work for patients who had different markers. "It could be a genetic marker on a chromosome, it could be a cell-surface marker, which is usually a protein, it could be combinations of different types of markers," Andriole says. "If we knew that all the men who had x, y, z [markers] responded well to radiation, then you could say, 'If my tumor is x, y, z, I want to have radiation.' Some men are destined never to die of prostate cancer. Wouldn't it be terrific if we could call you up and say, 'Gee, you have prostate cancer, but guess what? We've done these marker studies and guys who have the marker profile that you have, they almost never die of prostate cancer.'"

Catalona and Andriole, who wants the tissue bank to remain at Washington University, agree on at least one thing: The stash is special. "The repository is unlike any other repository, in the sense that it's been collected over a long period of time, so people can go back now and look at these tissue samples and see if the markers are present," says Gregory Piche, Catalona's attorney. But the specimens don't last forever, the lawyer notes: "These samples are not stable. When you use them [for research], you consume them." That's one reason the university wants to guard them, Andriole says. "Some of this material -- the tissue, the DNA, for example -- you use it once, adios amigos: It's lost," he explains. "You don't want to let somebody with some half-baked, not completely thought-through concept just use your repository."

The value and rarity of the repository is reflected in how much CaP CURE has spent to build up the nation's stock of prostate tissue. After Milken founded the group nine years ago, one of his first steps was donating money to collect and maintain specimens at three universities, including Washington University, which received \$500,000. According to a



1999 article in the journal *Science*, the private foundation was doling out \$800,000 a year to support the banks.

Catalona has drawn on the bank in studies aimed at pinpointing causes of prostate cancer. His work in St. Louis resulted in scores of articles in medical journals publicized by Washington University. "Research-ers Home In on a Gene That Could Play a Major Role in Prostate Cancer," trumpeted a press release in 2000, when Catalona announced he'd found a link between prostate cancer and a specific chromosome. By then, the doctor's career at Washington University was drawing to a close.

According to Catalona, the beginning of the end came in 1998, when Dr. Timothy Eberlein, chief of surgery at Washington University and director of the Alvin J. Siteman Cancer Center (which is run by the university and Barnes-Jewish Hospital), arrived in St. Louis from Harvard. Within a year of Eberlein's arrival, Catalona was replaced as head of urology at the medical school. One of world's top urologists was no longer top dog at his own university. "You have a change in administration, and that change leads to an apparent lack of respect for everything that you've done," Piche explains. "You find that you're losing financial support through the university, you're losing office space, you're losing staff to the point where it's interfering with your research and what you're doing. It doesn't take long to figure out you're not wanted." None of this, Piche adds, is part of the legal case, and he won't go into detail about conflicts between Catalona and his superiors at the medical school. "Dr. Catalona doesn't want to go down that line -- what was done to him," the attorney says. "He has the ability to stand on his own."

Eberlein directed inquiries to the medical school's media-relations office. "Dr. Eberlein had let Dr. Catalona know he was welcome to remain here and conduct his research," says spokesman Don Clayton in an e-mailed response to questions from the *Riverfront Times*. "So did Dean [William] Peck." Joni Westerhouse, another medical school spokeswoman, says personalities are irrelevant. "We're not viewing this as a personal war," Westerhouse says. "It's all about tissue." The tissue tug-of-war broke out two years ago, when Catalona was on the verge of leaving for the University of Virginia. Dr. Robert Carey, dean of the University of Virginia School of Medicine at the time, says Virginia wanted a big name. In return, Catalona would return to a position of prestige at a respected academic medical center. "He's among the top five names in prostate cancer in the country," Carey says. "We have an outstanding urology department, but we don't have what you would call a national leader in prostate disease on our faculty. Dr. Catalona would have answered that. Particularly on the clinical side, Dr. Catalona's name carried a lot of weight. His cadre of patients from all over the country was a big asset. We thought, also, he could help us with some of the logistics of patient care, because he does it so smoothly and so effectively. I certainly think his reputation is outstanding, so that reputation might spill over into some other areas, some other programs, some other opportunities."

Virginia came so close to landing Catalona that the medical school issued a press release in 2001 announcing that the doctor had been named to lead the school's Mellon Prostate Cancer Research Institute. Washington University also issued a press release stating that the doctor would be "pursuing other opportunities and challenges." But the deal fell through. In court papers, Catalona alleges that Peck (who stepped down as dean of the Washington University medical school this past June) agreed to let the specimen bank move with Catalona. Only when Eberlein ordered otherwise did the transfer hit a stone wall, the doctor claims.

It wasn't that simple, counters Clayton. "In an attempt to resolve the dispute without resorting to the courts and in a way that would allow research to continue at both institutions, we and UVA eventually reached a mutually acceptable split of the repository," the Washington University spokesman writes in an e-mailed response to the RFT. "We compromised. However, splitting the repository was unacceptable to Dr.

Catalona and the deal fell apart. Now, Dr. Catalona seeks to have it all transferred to his personal authority."

Dividing the tissue bank was impractical, Piche argues. "How do you divide this stuff?" Catalona's lawyer asks. "These things are frozen." Once the Virginia deal disintegrated, Washington University "seized" the samples and demanded that Catalona surrender donor lists and databases, the doctor claims in court documents. Previously, he had been the collection's curator and gatekeeper.

According to its lawsuit against Catalona, the university established a committee to decide who should have access to the specimens. The aim, says Clayton, was to make the bank open to researchers nationwide, including Catalona. "We're more than willing to receive proposals from Dr. Catalona," Clayton says. "We want to preserve access to the resource. Keeping it available for research is our goal."

That's Catalona's aim, too, according to his attorney, who says the doctor has shared the repository with other researchers and would continue to do so. "He has continually engaged in collaborative ventures with other people in the use of the samples," Piche says. "And I don't think he's ever turned down a viable research project that would be useful in developing the body of knowledge."

While the university contends that three scientists on the repository's gatekeeping committee evaluate proposals and decide who gets samples, Catalona is skeptical. His attorneys say he tried on several occasions to obtain samples by submitting written requests to Andriole, who had succeeded him as chief of urology. Responses, in the form of e-mails or notes, arrived after considerable delay, Piche says. "If there is a committee, [Dr. Catalona] doesn't know who he's talking to," Piche says. "We actually think [Andriole] is the committee."

Andriole says he knows of no instance in which Catalona was denied access to samples he requested. He also says Catalona never waited very long before his requests were granted. "That's a very subjective thing," Andriole says. "Some people don't like to wait in line for five minutes at the bank." Catalona's concerns go beyond asking permission and waiting for specimens. "These are samples that he's put together, and if you carve the best samples out and give them to somebody else, that interferes with what he's doing," Piche says.

While Andriole and Clayton say Catalona is welcome to use the tissue bank, as is any other researcher with a valid proposal, Piche says his client's work has been impeded by the dispute. "He, on a regular basis, gets requests to do extensions of his research with somebody else," Piche says. "All those kinds of things have been on hold."

The fight has also affected work at the National Cancer Institute in Maryland. The federal government's main cancer-research division returned 400 samples of frozen serum, a blood component, to Washington University after Catalona called federal researchers in June and told them they had no right to use the material.

Piche sees the return of the samples as evidence that the feds, who haven't officially weighed in on this fight, agree with his client. But Catalona may have more powerful friends than the federal government. Five days before Catalona left Washington University for Northwestern, he sent new consent forms to every donor. The forms are brief and to the point: "Please release all my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects." So far approximately 6,000 donors have signed the forms, according to Catalona. Piche insists that his client isn't claiming ownership of the samples. Rather, Catalona is a trustee, and

the university should honor the wishes of donors who signed new consent forms, Piche says.

Washington University officials contend Catalona improperly accessed patient lists when he mailed out the revised consent forms. Furthermore, the university claims, the tissues are no different from lab notebooks and other work products created with university funds. As far as the university is concerned, donors gave their tissue to the institution, not Catalona, and they gave up their rights when they signed original consent forms, which state: "By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate." (The forms also say donors can withdraw their consent at any point, at which time their specimens will be destroyed.)

While Washington University says it spent hundreds of thousands of dollars to collect samples and maintain the repository, Catalona says government and private grants paid for the collection. As lead researcher for those grants, he contends the samples should be under his control. It's a legal quagmire with few road maps. While blood and tissue donors elsewhere have sued after their specimens were used to produce valuable medical products, this may be the first time a court will decide who owns tissues before any profitable discovery has been made.

Courts have usually decided that blood and tissue donors have no right to share profits made possible by their specimens. There's no better example than John Moore, a Seattle man who sued his doctor and the University of California, which had patented cells produced from rare antibodies in his blood. The university, along with Moore's physician, sold the cell line to two biotech firms for \$440,000, plus stock worth more than \$3 million. Moore had gone to UCLA for treatment of leukemia in 1976. He became suspicious that something more than his health was at stake when his doctor insisted that he return repeatedly to California for checkups that included taking samples of his blood, skin, bone marrow and sperm. The trips continued for seven years before Moore hired a lawyer, who discovered that big bucks were behind the exams the physician had said could be done only at UCLA. "Specifically, defendants were conducting research on Moore's cells and planned to benefit financially by exploiting the cells and their exclusive access to the cells by virtue of the ongoing physician-patient relationship," wrote the California Supreme Court in a 1990 ruling.

Moore claimed he should profit from discoveries that wouldn't have been possible without him. But a divided state supreme court ruled he had no property rights to cells that he'd surrendered. Otherwise, the court reasoned, research that could save lives might grind to a halt.

Justice Armand Arabian concurred with the majority, but he was clearly torn. "Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue for profit," Arabian wrote in a separate opinion. "He entreats us to regard the human vessel -- the single most venerated and protected subject in any civilized society -- as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much. Whether, as plaintiff urges, his cells should be treated as property....is not, in my view, ours to decide. The question implicates choices which not only reflect, but which ultimately define our essence. A mark of wisdom for us as expositors of the law is the recognition that we cannot cure every ill, mediate every dispute, resolve every conundrum."

The U.S. Supreme Court declined to review the case, which is widely considered the compass that guides similar lawsuits across the nation. More recently, families whose children are afflicted with Canavan disease, a deadly genetic disorder, settled a federal lawsuit against Miami Children's Hospital in Florida, which used donated tissue to find and patent the gene responsible for the disease. Researchers at the hospital subsequently created -- and licensed -- a screening test so that couples considering

parenthood would know whether their offspring would be susceptible to the disorder. Families were angry that the hospital restricted access to the test to selected laboratories and physicians.

Exact terms of the settlement announced in September are confidential, but the parties say that the plaintiffs have agreed not to further challenge the hospital's ownership and licensing of the patent, and the hospital can still collect royalties from the test.

Researchers, however, will be able to use the Canavan gene without a license from the hospital. Researchers have prevailed over universities in at least two disputes over tissue banks, though neither case got far enough for a judge or jury to make a call. In 1999 the University of Texas agreed to ship the world's largest breast-cancer tumor bank to Baylor University, which had successfully recruited Dr. Kent Osborne, a prominent breast-cancer specialist, and virtually his entire research team. While there was a disagreement over where the samples should be kept, the matter didn't result in a lawsuit. "Initially they wanted to keep them," Osborne recalls. "There wouldn't have been anyone there who would have used them much, since the whole breast-cancer program, except for one or two people, were moving with me to Baylor. I think they would have liked to keep them just in the possibility that someone would have come along someday [and used them], and they initially verbalized resistance to moving them. But the National Institutes of Health intervened on our behalf."

Because the tumor bank had been established and maintained with government funds that came in the form of NIH grants, Osborne says, the NIH argued that the government owned the tumors and the tumors should move with the researchers and their ongoing federal grants. A closer parallel to the dispute at Washington University may be found in a lawsuit brought against Texas Tech University by families of patients with Alzheimer's disease. The plaintiffs dropped the case in June, after the university shipped brain tissue and other donated specimens to the University of Georgia, where Shirley E. Poduslo, the repository's creator, had gone after leaving Texas Tech.

Floyd Holder, attorney for the families and Poduslo, says Texas Tech released the samples rather than risk public embarrassment. "What I did down here is I sued Texas Tech and said, 'By keeping these, you're violating a public trust,'" Holder recounts. "By being selfish and keeping them from my client, who went to the University of Georgia, what they're doing is forsaking their duty as trustee. I said, 'It's a breach of their duty, and the remedy is to appoint a new trustee.' And the judge said he jolly well would do it if he found they're not in a position to continue the trust." Though the university argued that it should not be stripped of its trusteeship, Texas Tech moved many of the samples, rendering the lawsuit moot, Holder says.

Suzanna Martinez, spokeswoman for the Texas Tech University Health Sciences Center, says the school shipped the samples after receiving new consent forms from donors or their legal representatives authorizing the transfer. "The fight was more about Poduslo needing to get new consents, because those people never consented to take those wherever they wanted," Martinez says. "Once she received those new consents, that's why we allowed her to take them. Because then, legally, we could give them to her." Holder says donors should decide who gets their tissues. "If the [donors] really want it, let's move them," the attorney says. "What's the point in fighting over it? What good does it do? There's only one common-sense thing to do. In the words of the immortal Rodney King: Can't we all get along?"

Apparently not. Dr. Eric A. Klein, a prostate-cancer researcher at the Cleveland Clinic Foundation in Ohio, notes that consent forms used by researchers there and at Washington University state that samples will be used by researchers, or destroyed if a donor withdraws consent. Transferring jurisdiction isn't discussed. "Those are the only options," Klein says. "There's not an option up front for the patient to have the samples transferred elsewhere. This is just my opinion, now, but I don't think that a university or

some other medical system could be compelled to do that if the only options that were presented to them in the consent form was: Either let us use them or they'll be destroyed."

Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania, says he's never heard of a case like the one between Catalana and Washington University. He says he doubts the original consent forms give legal custody to the doctor. "Normally, a doctor can't handle them," Caplan says. "You've got to give them to the school. The doctor can say, 'I'm going to use them,' or, 'I'm going to have exclusive control over them,' or whatever. It's very hard for someone to donate tissues to an individual doctor." Legalities aside, Caplan says the focus should be on ethics.

"Ethically, I'd like to see them honor these requests," Caplan says. "People make these gifts -- and they are gifts -- and certainly you can say, 'I made the gift contingent on the fact that this doctor's going to work with these tissues. I know that Wash. U. has control, but I really gave them because I like this doctor. If he's moving and he wants them, he should have them.' I think, ethically, the school should honor that, if they want to keep getting people to give tissues to them." Normally, when pushed, a school would probably say, 'OK, take it,'" Caplan adds. "I'm suspicious that there's something unique or valuable here that they're fighting over." Even run-of-the-mill tissue is worth a lot of money. While it's illegal under federal law to sell human body parts for transplant purposes, tissue, eyes, limbs, hearts and almost anything else may be bought or sold if the goal is research. In its lawsuit against Catalana, Washington University says it would take well over \$1 million and several years to replace the prostate-tissue repository. And a formerly rarefied field is now crowded, owing to advances in genetic research that have created a huge market for all sorts of tissue and body parts that once were thrown away. Private companies that collect tissue for research have cut deals with hospitals for surgical leftovers, sometimes paying cash, sometimes offering free access to their collections in return for specimens. One such company is Massachusetts-based Ardaïs Corp. According to a 2002 story in the Boston Business Journal, Ardaïs, which was founded in 1999, spent \$40 million compiling a bank with tissues from at least four medical centers and is making a profit. "The tissue samples in and of themselves have value, even without a gene discovery," notes Laurie Rosenow, a Chicago attorney who recently helped negotiate the Canavan disease settlement on behalf of plaintiffs. "It's really expensive to get the tissue. A researcher can go online and see what's available. There are catalogs where, for money, you can say, 'I need 10,000 samples of such-and-such cell line.'" In its lawsuit, Washington University claims that it is the "true and legal owner" of the tissues and can use or transfer them without asking anyone's permission. In his counterclaim, Catalana says donors have the right to know that Washington University might sell their tissues.

That, Clayton vows, isn't an option. "We will not sell these samples to anyone," the medical school spokesman says. "That just won't happen." But there are other ways to realize profits from the samples. Universities, hospitals, drug companies and biotech firms have patented scores of genes, proteins, amino acids and assorted molecules with links to prostate disorders. (The U.S. government, holder of patent number 5,489,525, controls the rights to an antibody that can signal prostate cancer.) Typically, these substances can be scrutinized to help detect cancer, according to claims filed with the U.S. Patent and Trademark Office. Once a patent is secured, researchers may be required to pay royalties to patent holders for studying genes and other substances found within the human body. "If they've got a patent on a chunk of DNA, anyone who wants to use it, to do research on it -- to do anything, basically -- has to get permission from the patent holder," explains Tim Holbrook, an assistant professor of law who specializes in patent issues at Chicago-Kent College of Law in Chicago. "Most likely that requires a license, so they'll charge some sort of fee for it."

Washington University holds just one patent directly related to prostates, according to patent-office databases, and that's for a genetically modified mouse that generates prostate tumors similar to those in humans. But the university possesses 417 other patents, including dozens for proteins, genes and DNA sequences. One is for mammaglobin, a protein associated with breast cancer that could prove useful as a marker for the disease. The university exclusively licensed the patent to Corixa, a biotech firm that hopes to create a cancer vaccine based on mammaglobin, according to a 2000 report by the company to the U.S. Securities and Exchange Commission. The company typically pays universities in cash or shares of stock for exclusive licenses and also covers research costs, according to the report.

Another Washington University patent is for proteins that may be useful in fighting a variety of infections, including HIV. Yet another is a protein-based test to determine a person's chances of contracting Alzheimer's disease. In most cases, the university's medical school, which collected nearly \$330 million in federal grants in the fiscal year ending June 30, doesn't have to dig into its own pocket to pay for these discoveries. And research is a growing business for the medical school, which received less than \$130 million in government grants a decade ago. Between government and private grants, the medical school has estimated it will soon be bringing in a half-billion dollars annually in research money.

Under Washington University policy, patents belong to the university, not faculty members. The university holds patents on more than 150 discoveries that were paid for with government grants, and about half of those have been licensed to private companies. Money from royalties and licenses are split three ways, with the faculty member getting 45 percent and the medical school receiving 40 percent. The remaining 15 percent goes to the university's Office of Technology Management, which markets discoveries to the private sector. Any transfer of research material from the medical school must go through the Office of Technology Management.

Catalona holds no patents registered with the federal government, nor is he listed as an inventor of anything with rights assigned to another individual or entity. In a 1998 interview with the St. Louis Business Journal, the doctor said he had not been "smart enough" to cut a profit-sharing deal with manufacturers of the PSA tests that became commonplace thanks to his research. If he had, Catalona told the Journal, he could have collected millions of dollars.

Piche chuckles at the notion that his client wasn't intelligent enough to realize the profit potential in his research. "I think that's an example of his humility, in the sense that he was smart enough, but that was not what he was thinking about," Piche says. "From everything I know about him, he's more interested in the product of the research: He wants to find a cure for cancer. I assume there's an ego element involved in that, but that's what drives him."

Piche allows that Catalona might realize royalties in the event he wins custody of the tissues and a profitable discovery is made from them. Northwestern University spokesman Charles Loebbaka declined to answer questions about the collection and who might have access to it if Catalona were to win his lawsuit, saying the university doesn't comment on pending litigation involving faculty members. Brenda Conger, who lives in upstate New York, learned from experience about squabbles over tissue and researchers who won't share. Conger's ten-year-old son Clifford suffers from cardio-facio-cutaneous syndrome (CFC), a rare genetic disease that causes mental retardation, skin disorders, facial disfigurement and heart problems. In an effort to help find a cure, she flew him all over the nation to various doctors who drew blood samples. She and her husband also donated blood. "I felt I was giving of my child and myself and my husband to promote research," Conger recalls.

Then she started thinking. "How many times can you tap into these frail bodies and do this?" Conger says. "I didn't know it was going to be, 'Well, the blood is here for research here.' I don't have the time to get into lawsuits -- I teach full-time and I raise this child as a normal child. I thought, 'What else can we do? What would be Plan B that would help everybody, would help researchers at a different facility?'" Plan B has turned into a specimen bank created and controlled by families whose loved ones suffer from CFC. Researchers with an interest in CFC must file proposals with the CFC Family Network, which reviews proposals with the help of independent doctors and decides which researchers will be granted access to specimens. So far the network has collected 42 samples -- a large number, considering CFC's rarity. "We are the database collection for the world for this disease," Conger says. "Our organization owns the samples."

Families touched by CFC aren't alone. On October 14 the Genetic Alliance Biobank, a fledgling blood and tissue repository owned by a consortium of disease advocacy groups (including the CFC Family Network), officially incorporated in Delaware. The consortium hopes to draw on disease advocacy groups that will contribute samples and share the cost of banking them. The samples will be distributed to researchers who file proposals with the individual groups and pass muster with each group's scientific advisory board. "The whole fight over human tissue as a commodity is not a good thing, obviously, because it isn't the way we want to think about human tissue," says Sharon Terry, president of the Genetic Alliance, a nonprofit umbrella organization for more than 600 disease advocacy groups. "But it's a very important part of research, and so definite lines need to be drawn, and ownership issues need to be taken care of." Terry doesn't care if researchers, universities or biotech companies get rich from donated tissue. "We have absolutely no problems with the motivations and incentives that are already built into the system," she says. "Industry's looking for a profit. Academics are looking for promotions and papers. What we want to see is acceleration of research to an endpoint."

And to do that, the system for distributing parts of human beings needs to change, she says. "It just made complete sense to us that if we are going to advance research, we should have the biggest lever in our hands, and that's blood and tissue."

## 別紙 4

## 研究成果の刊行に関する一覧表

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