UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY, Plaintiff, v. WILLIAM J. CATALONA, et al., Defendants.	)	Case No. 4:03 CV 01065 SNL

PLAINTIFF'S POST-HEARING REPLY BRIEF

(a) Defendants' Cases Are Inapposite.

Defendants cite many cases they have never bothered to mention before. All of them are way off the mark. Chief among those cases are the frozen sperm and embryo cases like York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989), Hecht v. Superior Court, 16 Cal. App. 4th 836, 20 Cal. Rptr. 2d 275 (1993), and Kass v. Kass, 96 N.Y.2d 554, 696 N.E.2d 174 (1998). On their face, those cases recognize how they are different from Moore and Greenberg. "Unlike the facts in Moore, a contract with the sperm bank purports to evidence decedent's intent and expectation that he would in fact retain control over the sperm following its deposit." Hecht, 16 Cal. App. 4th at 846. Not surprisingly, therefore, the agreement in York contained specific bailment language preserving the property interest of the husband and wife against claims by the research institute. 717 F. Supp. at 424-25. Defendants fail to grasp the clear distinction between someone contributing reproductive, life-giving material and someone else contributing their excised tissue for medical research. Greenberg recognized the difference, noting that York involved a couple granted property interests in their frozen embryos and "do[es] not involve voluntary donations to medical research." 264 F. Supp. 2d at 1075.

Our case has nothing to do with whether the next of kin have the right to possess a dead body for the sole purpose of conducting a burial, the issue in Mansaw v. Midwest Organ Bank,

1998 WL 386327(W.D. Mo.). It has nothing to do with the disposition of dead bodies, the subject of the Uniform Anatomical Gift Act. It does not involve a fight over a Stradivarius violin, where documentary evidence revealed that the claim of a gift was based on "fantastic interpretations." Rabinof v. United States, 329 F. Supp. 830, 840-41 (S.D. N.Y. 1971). It is not a tax case in which the issue was whether payments received for the sale of plasma were taxable income. Green v. Commissioner, 74 T.C. 1229 (1980). There is no issue here, as there was in U.S. v. Arora, 860 F. Supp. 1091 (D. Md. 1994), that the biological material is property capable of being owned. Indeed, while defendants cite several of these cases for the undisputed proposition that biological specimens constitute property capable of being owned, that is not the point. Although Moore confirms that excised biological materials can be owned, the Court there concluded that the research participants themselves do not retain any ownership interest in what was excised after it was excised. 51 Cal.3d at 136-37, 154-55. It is simply absurd to rest on these cases but to reject Moore and Greenberg, the only precedents dealing with the ownership of excised bodily material turned over to a research institution for research purposes.

(b) The Clinical Use Theory Is A Fabrication.

In an attempt to avoid the clear guidance of Moore and Greenberg and to somehow confer a continuing personal interest in the physical samples upon the research participants, defendants attempt to transform the GU Biorepository from a research tool into a repository for clinical use. They are wrong as a matter of fact and of law. Defendants mention one statement of Dr. Andriole out of context but neglect to mention the rest of what he said:

> "Q. [H]ave there been any occasions when you have been asked to use a research sample for clinical purposes?
>
> A. Relative to this repository, no. Actually, not even relevant to any others that I know of, no.
>
> Q. Never in your 19 years here; is that correct?
>
> A. No." (Tr. 2:141)

There is a clear and recognized distinction between research and clinical care. All the informed consent documents told the research participants that the samples would be used for research purposes.[1/] Not a word was said about use of the samples for clinical care. Dr. Catalona has emphasized repeatedly throughout this case that he needs the GU Biorepository to conduct prostate cancer research. He brought this very motion so that WU could not use the samples in its research and so that he could use it for his own research. Defendants now seek to deny the whole purpose for which the samples have been collected and retained.

The clinical purpose theory is as self-defeating as it is wrong. The excised biological materials from a clinical patient who declined to become a research participant are thrown away without the patients' consent (Tr. 1:135-37; 1:194). In other words, the clinical subject has no proprietary rights to the specimens that come from his body. The specimens were not retained for clinical purposes and, as Dr. Andriole testified, have not actually served any clinical purpose (Tr. 2:141). Finally, since Dr. Catalona was not the treating physician for most of the research participants whose samples he seeks, clinical considerations cannot be the motivation for the attempted transfer to Northwestern. (Again, many were not patients of anyone).[2/]

[1/] The consent form for "The Genetics of Prostate Cancer" research study specifically said: "Also, if you have had any surgery you will release the pathologic specimen (if any) from the hospital where said surgery was performed so that your genes (DNA) can be tested. Please be aware that this might use up all of your pathologic specimen at the hospital where you had surgery, but ordinarily this specimen is not used for any clinical purposes after surgery." See e.g., (Pts. Exh. 59). The patient defendants incorrectly suggest (Br. at 10) that this language recognizes a right on the part of the patient to have samples transferred. In fact, this language applies only to samples taken at other institutions and not yet donated for medical research, and it asks the patient to give his sample to WU precisely because it is not needed for any future patient care.

[2/] Defendants repeatedly speak about "the patients" as if the eight who joined in this case represented all research participants. These eight defendants have neither sought nor obtained class certification. Nor is there any evidence that these eight (only three of whom testified) speak for anyone but themselves. In fact, because the vast majority of research participants failed to sign and return Dr. Catalona's "Medical Consent & Authorization," it is especially misleading to suggest that Messrs. Ellis, McGurk, and Ward are speaking for the group of research participants at large. These eight defendants are cherry-picked patients of Dr. Catalona, who are grateful for his services.

(c) The Proof Meets The Evidentiary Standard.

Because Moore holds that research participants never had an ownership interest in excised biological material after it was excised, 51 Cal.3d at 136-37, 154-55, there is no need even to reach the evidentiary standard for establishing a gift. There is, however, abundant evidence to satisfy the clear and convincing standard. Defendants do not challenge the proof of delivery and acceptance. The only issue they raise is the research participants' intent. But the evidence on that issue is overwhelming and compelling: (1) the research participants expressly acknowledged, by signing the informed consents, that they intended to provide their tissue and blood samples for research; (2) their intent was to benefit future generations, not themselves (Tr. 1:157; 1:210); (3) the samples could be completely consumed in the research (Tr. 1:135); (4) nothing prevented the researchers from destroying or discarding the samples at any time, as Dr. Catalona often did with excess samples (Tr. 1:87-89); and (5) the research participants did not expect to — and there are no circumstances consistent with the laws regulating hazardous medical waste in which they could — ever regain possession of the physical specimens (Tr. 1:134; 1:188-89; 2-78). All of this is *undisputed* clear and convincing evidence. Missouri courts have found clear and convincing evidence of a gift on proof far less compelling than this. See e.g., Schultz v. Schultz, 637 S.W.2d 1, 6-7 (Mo. Sup. 1982); In re Estate of Wintermann, 492 S.W.2d 763, 768-69 (Mo. Sup. 1973).

Two of the three research participants who testified at trial actually signed written instruments stating: "By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate" (Patients Exhs. 1 and 7). It is impossible to conceive of more clear and convincing evidence of donative intent. In fact, everyone concerned understood that the research participants had made a donation of their samples until Dr. Catalona, when he changed jobs, began looking for a way to take the GU Biorepository with him to Northwestern. The recent change of mind on the part of the defendant patients is irrelevant. Only

the intent at the time of delivery matters. Donnelly v. Donnelly, 951 S.W.2d 650, 653 (Mo. App. 1977).

In view of this compelling proof, defendants focus on a legal contention rather than on the evidence. They say "you can't made a donation" because that would be exculpatory. We will not repeat the extensive treatment of defendants' "exculpatory language" argument from our main post-hearing brief. Suffice it to say here that the research participants knew nothing about Dr. Catalona's recent "exculpatory" objection when they signed the informed consents. Their own intent was clear. They intended to donate their specimens, did so for the purpose of advancing medical research, and expressly relinquished any ownership of them through the informed consents.

(d) The Restricted Gift Theory Is Meritless.

Defendants also erroneously argue that the donation of samples was a conditional — and therefore incomplete — gift. In fact, WU's ownership of the physical specimens became absolute as soon as the specimens were received. The only conditions were on the future use of *intangible personal information* linked to these specimens. The tangible *personal property* was WU's to keep as of the time it received the samples, and the research participants attached no conditions allowing them to get that property back. In the ordinary course of research, WU was free to consume all of the specimens. Defendant's expert stated that "as a matter of law, institutions and investigators can throw samples away" (Tr. 1:135), and Dr. Catalona frequently did so (Tr. 1:87-89).

WU's unconditional ownership of the physical samples does not change if a participant decides to withdraw from the study. The regulations require that a participant be informed that he can discontinue his participation in research, but they say nothing about returning or transferring the physical samples. Defendants' expert agreed that, if a research participant elected to discontinue participation in research, WU could choose to destroy the samples or store them indefinitely (Tr. 1:194). Dr. Prentice explained that WU also could choose to remove personal information and continue to use the samples in research (Tr. 2:224). The Office of Human Research Protection

recently issued a guidance document explaining how anonymized research may continue on existing tissue collections without any further informed consent (Tr. 1:142-44). Although defendants disagree with *this* OHRP guidance document, Dr. Catalona presently uses a consent form at Northwestern that allows the institution to anonymize samples and continue to use them even when a patient withdraws (Pl. Exh. 16, Tr. 2:43-44). While the consent form for one isolated study did say that WU would destroy the samples if a patient were to withdraw and so request, any such destruction would fulfill WU's own promise rather than satisfy some inferred "condition" the participant allegedly placed on the donation.

(e) There Are Absurd Consequences To Defendants' Position.

Much of what defendants now say engenders absurd consequences. If research participants own and have the right to control all excised biological materials they contribute for research, the research institution would have an obligation to maintain those specimens in perpetuity, no matter the cost or lack of utility, unless and until the research participant (in his unfettered discretion) relieved the institution of that burden. Because biological waste laws prevent the participants from ever getting the specimens back (See Moore, 51 Cal.3d at 137, n.20), the research institution would be required to keep and maintain these materials until the research participant directs that they be sent elsewhere — something that may never occur. Any transferee researcher would bear the same burden.

It does not end there. Defendants argue that Missouri law imposes substantial evidentiary requirements on what must be said or done in order to make a gift. But they also argue that, because of the bar on "exculpatory language," federal regulations prohibit research participants from using the very language defendants deem necessary in order to make a donation of biological materials to research institutions! In the end, they are left with the nonsensical conclusion that the federal regulations make it impossible for research participants ever to donate excised biological materials for medical research.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 1st day of July, 2005, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following attorneys for the Defendant:

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