Ownership of Biological Materials

Jill E. Anderson, Esquire
Moses & Singer LLP
Boston, Massachusetts

Many research institutions customarily bank biological tissue samples supplied by patients participating in research at the institution. There has historically been controversy among institutions, researchers, and patients over rights in the patients’ biological samples provided for research. This ownership issue is crucial because it dictates the use by the institution of such samples for future research. The U.S. Court of Appeals for the Eighth Circuit recently issued an important decision regarding this issue in Washington University v. William J. Catalona, et al. The court upheld a lower court ruling that Washington University (Washington) was the exclusive owner of all biological samples and associated data contained in a tissue repository maintained by the University, and neither the researchers nor research participants have ownership rights in the biological samples and associated data. While previous cases have addressed commercialization rights to biological samples, the Catalona decision is the first to address ownership rights in biological samples. Dr. Catalona filed with the U.S. Supreme Court a petition for a writ of certiorari, so the next step is for the Supreme Court to decide whether it will review the case.

The facts of this controversial case began in 1983, when Dr. William Catalona, a well-respected prostate cancer researcher at Washington University, developed a large biorepository for biological samples collected for prostate cancer research (the Biorepository). This Biorepository is located on Washington property, and Washington contributes most of the funding to support the Biorepository. The contributed biological samples came from research participants who signed the required informed consent form. The Biorepository contained tissue samples and genetic information of thousands of research participants, of which approximately 10% were Dr. Catalona’s. The remaining research participants were patients of other Washington physicians, relatives of those patients, or volunteer participants who were not Washington patients.

In 2003, Dr. Catalona left Washington for a position at Northwestern University. To further his prostate cancer research at Northwestern University, Dr. Catalona intended to take with him all the patient tissue samples contained in the Biorepository. Prior to leaving Washington, Dr. Catalona sent to the research participants a letter and release form directing Washington to release their biological samples to Dr. Catalona at Northwestern University. Approximately 6,000 research participants returned signed release forms to allow the transfer.

Washington filed an action against Dr. Catalona to establish Washington’s ownership of the Biorepository and its samples. Dr. Catalona argued that the biological samples belonged to the patients and Washington did not have a legal interest in
the samples. Washington argued that the patients had signed consent forms and willingly donated the tissue samples to Washington and, as such, Washington owned the samples. Eight of Dr. Catalona’s patients joined Dr. Catalona as co-defendants, asserting that they had intended their samples to remain in Dr. Catalona’s possession.6

The central issue in the case was whether patients who voluntarily contribute their biological materials to a research institution for research retain ownership rights in those materials. The Catalona court ruled that they do not.7 Cases to date have ruled that once consent is given by a patient to participate in a research study, the patient loses all property rights to the biological samples and any information obtained from research conducted on the samples.8 As a result, there is a consensus among institutions that biological samples and the data derived from the samples are the property of the institution.

As part of its analysis, the Catalona court relied upon Missouri law to determine that the research participants had donated their biological materials to Washington as inter vivos gifts. In reaching this decision, the court concluded that the research participants intended to make an irrevocable and absolute gift of their biological materials to Washington.11

The court closely examined Washington’s policies, procedures, and forms in rendering its decision. Specifically, the court reviewed Washington’s intellectual property policy, material transfer agreements (MTAs), and the informed consent forms taken from the subjects as part of the research studies. The court found it significant that the consents bore Washington’s logo, used the term “donation” to describe the transfer of biological samples to Washington, and included language that the biological samples may be used for future purposes by researchers at other institutions or companies.12 The only rights the court found the research participants retained in the samples were the options to stop participating in the study; stop donating samples, and not allowing their materials to be used for further research. If the research participant requested that his samples no longer be used for research, those materials would be destroyed. Beyond that, the research participant did not have a right to dictate how, where, or for what purposes the materials would be used.13

The court also noted Dr. Catalona’s past practices at Washington in its analysis. While employed at Washington, Dr. Catalona had executed a number of MTAs transferring the materials to researchers at other institutions—the MTAs all explicitly stated that Washington owned the biological materials. In addition, Dr. Catalona had consistently ordered the destruction of some biological materials in the Biorepository to free up more space. He did not obtain additional consent from the research participants prior to destruction, thereby reinforcing the court’s view that the research participants gave up all rights in the materials.14 Research institutions can take several points away from the Catalona decision in order to safeguard their rights in biological samples and the associated data. Institutions should carefully review their intellectual property, research, consent, and authorization policies, procedures, and forms to secure the institution’s ability to use the biological samples and data for future research purposes.

Because the Catalona court placed great emphasis on the language in the informed consent forms, institutions should ensure that their consent forms capture key concepts. Institutions may want to put the consent forms on the institution’s letterhead and indicate in the consents that the study participants are donating the biological materials to the institution, that the materials may be used for future research, and that researchers outside the institution may conduct research on the materials. The consent forms should clearly state that the research participant may withdraw consent at any time and, upon request, their biological samples will be destroyed. Institutional policy would then need to address destruction of the materials. Both institutional policy and the consent forms should also indicate that any data already obtained from the materials cannot be destroyed or recalled.

Washington’s consent forms contained exculpatory language stating that the research participants agree to waive any claim they may have to the biological materials that they donated. While the Catalona court did not address the validity of this waiver language,15 the Common Rule prohibits consent forms from containing exculpatory language.16 The Office of Human Research Protections (OHRP) has issued guidance on examples of prohibited exculpatory language, including language similar to that in Washington’s consent forms.17 As such, institutions should be cautious about incorporating exculpatory language into their consents.

Institutions need to also keep in mind additional HIPAA18 and Common Rule concerns regarding the collection, storage, and use of biological materials. For example, the creation of a tissue repository is considered a research activity under the Privacy Rule and thus requires a separate HIPAA Authorization (or waiver). In addition, institutions should be cautious about including language in the consent or authorization stating that the biological materials may be used for future, unspecified research. NIH guidelines and HIPAA commentary have made it clear that a future research use is a research activity under HIPAA and therefore requires a separate consent.19

Institutions should have a clear intellectual property policy indicating that the institution owns all intellectual property, including tangible research property, and data used or created during all research administered by the institution. The intellectual property language in every research agreement, licensing agreement, and MTA should mirror this policy. Institutions need to be especially cautious about language in translational or clinical research agreements in which the sponsor has requested access to biological materials. In addition, institutions should have with each researcher an agreement that transfers to the institution all intellectual property rights that he/she may have as a result of conducting research at the institution. This is particularly important if the researcher is not an employee, but rather an affiliate or contractor of the institution. In order to maintain oversight over research conducted on materials at the institution, institutions may want to establish a main repository for biological materials that will be used only for research purposes. Institutions should
then mandate that all researchers deposit into this repository materials to be used for research.

The Catalona decision emphasizes the importance of having clear and consistent institutional policies and procedures related to intellectual property and the informed consent process. Provided they take appropriate measures to secure their rights in biological samples, institutions that maintain tissue repositories can consider the decision a victory for the advancement of medical research.

Jill E. Anderson, Esquire, is an attorney with the law firm of Moses & Singer LLP and Counsel to the firm’s Healthcare Practice. Email janderson@mosessinger.com

1 See e.g., Moore v. The Regents of the University of California, et al., 51 Cal. 3d 120 and Greenberg et al. v. Miami Children’s Hospital Research Institute et al., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
2 490 F. 3d 667 (8th Cir. June 20, 2007).
3 51 Cal. 3d 120 and 264 F. Supp. 2d 1064.
4 Id. at 3.
5 Id. at 4.
6 Id. at 5-6.
7 Id. at 6-7.

Letter From The Chair

Melissa Markey, Esquire
Hall Render Killian Heath & Lyman PC
Troy, Michigan

Teaching Hospitals and Academic Medical Centers Practice Group is looking forward to a great Mid-Year Meeting, scheduled January 24 and 25 at the Ritz-Carlton in Washington, D.C. The Planning Committee has done another great job, and we eagerly anticipate the opportunity to see you in person!

As we approach this holiday season, I would like to convey my deep appreciation of those whose efforts are so critical to the Practice Group. We have four fantastic, energetic, and enthusiastic Vice Chairs, who devote many hours to providing our group with great teleconferences and other activities. We have an incredible staff at AHLA, who help us stay the course and accomplish our goals. And most of all, we have you—the members—who are our raison d’etre. We would love to hear from you regarding ideas or areas in which we can offer greater value. You are the most important part of AHLA and of our Practice Group, and we welcome your ideas and efforts!

As the election rhetoric heats up, I encourage you to become engaged in the debate regarding how we care for our sick and elderly. Healthcare in America is facing a crossroads, and our choices today will have long-lasting impact. Vaunted for years as providing the best healthcare on earth, America now finds itself outranked by not one, but several other systems. Once the land

8 Id. at 7-8.
9 Id. at 9.
10 51 Cal. 3d 120 and 264 F.Supp 2d 1064.
11 2007 WL 1738268, 9-11.
12 Id. at 10.
13 Id. at 12.
14 Id.
15 The court stated that it did not address that issue because it found clear intent of the research participants’ to make a gift of their materials to Washington University.
16 45 CFR 46.116. “No informed consent, whether oral or written, may include any exculpatory language through which the subject 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.”
17 “By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.”
18 The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 and the regulations promulgated thereunder.

Practice Groups

of unlimited opportunity, and a world-wide leader in innovation and discovery, we find ourselves cutting funds for research, and investing in compliance with ever more burdensome laws. And meanwhile, healthcare suffers. As counselors and advocates for our clients, we need to consider how we can best serve our clients and the patients they serve. How can we, as lawyers, help them serve the community, comply with diverse and wide-ranging regulation, and help staff and physicians preserve the spirit of healing which drove them to healthcare in the first place?

Healthcare has captured the attention of the public and politicians. It is shaping up to be a major issue in the upcoming elections. We owe it to our clients and patients to consider carefully long-term and short-term solutions to the current problems. We must consider other paradigms, other approaches, to supporting health and treating illness. We must critically assess how the system actually does work, in order to evaluate how the system should work. I encourage you to become engaged in the discourse. As lawyers, we have a duty to society. As healthcare attorneys, I believe we have a special duty—to the patients, to healthcare providers, and to the greater society—to contribute our knowledge, our understanding, and our experience to ensure that the information under consideration is complete, accurate, fair, and balanced.

Meanwhile, I wish each of you peace. Thank you for your special contribution to our group!
Obtaining Patient Consent: No Longer Just the Doctor’s Job

Sigrid C. Haines, Esquire
Lerch Early & Brewer
Bethesda, Maryland

I don’t know about you, but I stopped watching hospital dramas on television the night I saw a TV doctor yell to a nurse, “Consent the patient!” as he ran off to scrub for the emergency case. I know it is just television and that they are trying to make it more exciting, but it reminded me how much confusion remains about informed consent.

The concept of informed consent is simple: someone explains the risks, benefits, and alternatives to the patient, the patient has time to ask questions, and the patient decides whether he/she wishes to have the treatment. But the implementation is difficult: Did the patient have any real choice? Did the patient understand the discussion? Did the person seeking consent provide all the information necessary for the patient to make an informed decision?

For many years, the sole responsibility for obtaining informed consent rested with the physician who was to render the treatment. The physician was responsible for explaining the risks, benefits, and alternatives to the patient, and then the physician would write in the medical record something to the effect that he/she had obtained informed consent from the patient, whereupon he would render (or withhold) the treatment. Surely some physicians did a better job than others, but the hospital could legitimately rely on the physician’s representation. But, after a while, it began to seem like a good idea for the patient to sign a consent form at the hospital, so that the hospital would know that the patient had consented, and then the trouble started. With the introduction of the consent form, everyone began to confuse the consent form (which was to document consent) with the actual consent itself. More and more information began to be included in the consent form, and the form was generally presented to the patient by nurses or other hospital staff, rather than by the physician. And that got us to where we are today: with very specific requirements imposed on hospitals about the contents of consent forms and documentation of informed consent.

Aside from state laws (which are too specific for this article), the main sources of governance for most hospitals are The Joint Commission (JC) accreditation standards (for those hospitals who choose to be accredited) and the Medicare Conditions of Participation or CoPs (for those hospitals who choose to participate in the Medicare or Medicaid programs). Both have specific requirements regarding the documentation of consent and, in the reverse of the usual situation, the CoPs are more specific than the JC’s accreditation standards.

The JC’s 2008 Hospital Accreditation Standards provide that hospitals must have policies to describe the informed consent process, which procedures require informed consent, how informed consent is to be documented, and when treatment may be given without informed consent. The 2008 Standards also state that the informed consent process should include discussion of a number of specific elements, although it is unclear how the JC intends to enforce these obligations, which have traditionally been imposed on the members of the medical staff, rather than on the hospital itself. Most significantly for teaching hospitals, the Standards require that consent be obtained for recording or filming of patients other than for identification, diagnosis, or treatment of patients. When recording or filming is only for internal purposes (e.g., education), such consent may be part of a general consent, but if the recordings or films are to be used for external purposes (e.g., television), a specific, separate consent is required. Most notably for current purposes, the JC requires that patients receive “adequate” information about the persons responsible for providing care, including the name of their attending and consulting physician(s).

The CoPs are more specific. On April 17, 2007, the Centers for Medicare and Medicaid Services (CMS) issued new interpretive guidelines, to be effective immediately, regarding informed consent. One of the surprises in the new guidelines is that surveyors are to look for hospital policies and procedures that address, in detail, how the hospital will assure that patients receive information about their medical status, diagnosis, and prognosis.

Hospitals are also required to have policies to address how patient refusals of treatment will be addressed. In addition, hospitals are now required to have policies regarding how the hospital will address requests for treatment that are refused (e.g., treatments that are medically futile, experimental, or likely to be injurious). The CoPs also now state that the surgery informed consent policy must contain very specific elements, including...
who may obtain informed consent and how that consent is to be documented in the medical record before the treatment is provided (except in emergencies).

Most importantly for teaching hospitals, the CoPs require documentation of consent when physicians other than the operating practitioner (including residents and fellows) will be performing “important tasks related to the surgery.” Although the specific names of the assistants need no longer be in the consent form (a requirement that was particularly troublesome for teaching hospitals, when residents were often called upon with little notice to assist in surgery), the CoPs encourage the informed consent discussion to include the following:

1. That residents will perform portions of the surgery, based on their availability and competence in particular tasks;
2. That it will be decided at the time of surgery which residents will participate and the manner of their participation;
3. That residents performing surgery will be under supervision of the operating physician; and
4. That the operating physician may not be physically present in the same operating room for some or all surgical tasks performed by residents, based on the resident’s level of competence.\(^7\)

To ensure compliance with these standards, surveyors are directed to review the medical records of at least six non-emergency surgical patients. The new CoPs removed the requirement that the witness on the consent form be a professional.

Clearly, both the JC and the Medicare CoPs are trending toward the view that hospitals must exercise increased oversight over the processes of obtaining and documenting informed consent. Hospitals should work with their medical staffs and train their residents regarding the new requirements.

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Teaching Hospitals and Academic Medical Centers Practice Group Leadership

Melissa Markey  
Chair  
Hall Render Killian Heath & Lyman PC  
201 West Big Beaver Road  
Suite 315  
Troy, MI 48084  
(248) 457-7853 • mmarkey@hallrender.com

Andy Lemons  
Vice Chair – Membership  
Baker Donelson Bearman Caldwell & Berkowitz PC  
1600 Wachovia Tower  
420 20th Street North  
Birmingham, AL 35203-5200  
(205) 250-8327 • alemons@bakerdonelson.com

Veronica A. Marsich  
Vice Chair – Educational Programs  
Smith Haughey Rice & Roegge  
213 S Ashley St Ste 400  
Ann Arbor, MI 48104-1653  
(734) 213-8000 • vmarsich@shrr.com

Holley T. Lutz  
Vice Chair – Educational Programs & Research  
Sonnenschein Nath & Rosenthal LLP  
1301 K Street NW  
Suite 600 East Tower  
Washington, DC 20005  
(202) 408-6836 • hlutz@sonnenschein.com

Neil F. O’Flaherty  
Vice Chair – Publications  
Olsson Frank & Weeda PC  
1400 16th St NW, Ste. 400  
Washington, DC 20036-2216  
(202) 518-6368 • noflaherty@ofwlaw.com

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Practice Groups Staff

Trinita Robinson  
Vice President of Practice Groups  
(202) 833-6943  
trobinson@healthlawyers.org

Emilee Hughes  
Practice Groups Manager  
(202) 833-0776  
ehughes@healthlawyers.org

Magdalena Wencel  
Practice Groups Administrator  
(202) 833-0769  
mwencel@healthlawyers.org

Kristina Hilton  
Practice Groups Assistant  
(202) 833-0765  
khilton@healthlawyers.org
A Challenge for Issuers of Tax-Exempt Bonds: IRS Revenue Procedure 2007-47

Adam P. Rifkind, Esquire
Office of Research Services
University of Pennsylvania
Philadelphia, Pennsylvania

After a decade, the Internal Revenue Service (IRS) has updated a revenue procedure that is especially significant for those state, local, and 501(c)(3) organizations with outstanding tax-exempt bonds subject to 26 U.S.C. §§ 141 or 145, respectively, that conduct research for industry. Revenue Procedure 97-14 has been modified and superseded by Rev. Proc. 2007-47 for “any [industry-sponsored] research agreements entered into, materially modified, or extended on or after June 26, 2007.” For community hospitals, teaching hospitals, and academic medical centers that issue or are conduits for such tax-exempt bonds to finance property; Rev. Proc. 2007-47 is the latest announcement from the IRS for determining whether a research agreement results in private business use for the purposes of 26 USC §§ 141(b) and 154(a)(2)(b), respectively. In conjunction with other factors, a determination that the proceeds of a tax-exempt bond are being used for a private business use may result in the IRS determining that the interest earned from that bond is taxable. This article will explain parts of Rev. Proc. 2007-47, with regard to industry-sponsored research agreements. Some state, local, and 501(c)(3) universities and hospitals conduct research sponsored by industry, so understanding how the IRS views the agreements controlling that research is prudent. Rev. Proc. 2007-47 discusses federally-sponsored research as well, but that will not be discussed in this article. Bond issuers or conduits are encouraged to consult with bond counsel about the implications and ramifications of Rev. Proc. 2007-47.

I. Background

Under 26 U.S.C. § 103(a), income from state and local bonds is not taxable at the federal level. Tax-exempt status is extended to certain private activity bonds by 26 U.S.C. § 103(b). Private activity bonds that meet certain tests are called “qualified bonds” and are tax exempt. Section 141 of Title 26 provides that a state or local bond is tax exempt under 26 U.S.C. § 103 and describes the circumstances under which the bond will lose tax-exempt status. Section 145 of Title 26 provides that a bond issued by a 501(c)(3) organization is tax exempt, referring to 26 U.S.C. § 141 for criteria, with some qualifications, under which the bond will lose tax-exempt status. State, local, or qualified 501(c)(3) bonds will lose their tax-exempt status if the issuer enters into certain arrangements. Such bonds will lose their tax-exemption if they meet one of two sets of conditions. The first set of conditions regards meeting both (i) the private business use test and (ii) the private security or payment test.

(b) Private business tests

(1) Private business use test

Except as otherwise provided in this subsection, an issue meets the test of this paragraph if more than 10 percent of the proceeds of the issue are to be used for any private business use.

(2) Private security or payment test

Except as otherwise provided in this subsection, an issue meets the test of this paragraph if the payment of the principal of, or the interest on, more than 10 percent of the proceeds of such issue is (under the terms of such issue or any underlying arrangement) directly or indirectly—

(A) secured by any interest in—

(i) property used or to be used for a private business use, or

(ii) payments in respect of such property, or

(B) to be derived from payments (whether or not to the issuer) in respect of property, or borrowed money, used or to be used for a private business use.

For bonds issued by 501(c)(3) organizations, the thresholds for the private business tests is five percent of net proceeds, where 26 U.S.C. § 141(b) provides for ten percent of proceeds thresholds for state and local governments. Dollar amounts of use are aggregated in the determination of percentage of use; no one research agreement may reach a threshold, but several research agreements may reach the threshold in the aggregate. The IRS will find private business use in connection with the use of the proceeds of a bond if certain terms are present in a research agreement entered into by a state or local issuer or a 501(c)(3) issuer:

(6) Research agreements—

(i) Facts and circumstances test. Except as provided in paragraph (d) of this section, an agreement by a non-governmental person to sponsor research performed by a governmental person may result in private business use of the property used for the research, based on all of the facts and circumstances.

(ii) Research agreements that are properly treated as other types of private business use. A research agreement with respect to financed property results in private business use of that property if the sponsor is treated as the lessee or owner of financed property for federal income tax purposes, unless an exception
under paragraph (d) of this section applies to the arrangement.\textsuperscript{10}

The second set of conditions that may lead to the IRS considering the income from a bond to be taxable are referred to as the private loan financing test.\textsuperscript{21}

(c) Private loan financing test

(1) In general

An issue meets the test of this subsection if the amount of the proceeds of the issue which are to be used (directly or indirectly) to make or finance loans (other than loans described in paragraph (2)) to persons other than governmental units exceeds the lesser of –

(A) 5 percent of such proceeds, or

(B) $5,000,000.\textsuperscript{12}

Rev. Proc. 2007-47 deals with the private business use test, not the private security or financing test or the private loan financing test. As will be discussed later, the Revenue Procedure does indirectly address the private security or financing test. The other tests will have to be evaluated to determine whether a bond would lose its tax-exempt status, in the event an issuer found that its research agreements met the private business use test and that the amount of private business use was greater than the threshold amounts.

II. Rev. Proc. 2007-47 and the Private Business Use Test

With regard to industry-sponsored research agreements, Rev. Proc. 2007-47 discusses which terms will lead to the IRS considering the research conducted to be a private business use of the proceeds of any tax-exempt bond used to finance a property.\textsuperscript{13}

The IRS defines three terms in Rev. Proc. 2007-47: “basic research,” “qualified user,” and “sponsor.”\textsuperscript{14} Basic research “means any original investigation for the advancement of scientific knowledge not having a specific commercial objective.”\textsuperscript{15} Rev. Proc. 2007-47 gives an example of what is not basic research: “product testing supporting the trade or business of a specific nongovernmental person.”\textsuperscript{16} A qualified user is a state or local government unit or 501(c)(3) organization.\textsuperscript{17} A sponsor is any person or entity, other than a qualified user, that supports research under an agreement.\textsuperscript{18}

A research agreement with an industry sponsor will not result in private business use if one of two conditions are met.\textsuperscript{19} Both sets of conditions require that the agreement be for basic research.\textsuperscript{20} One condition is that “any license or other use of resulting technology by the sponsor is permitted only on the same terms as the [bond issuer] would permit that use by any unrelated, non-sponsoring party (that is, the sponsor must pay a competitive price for its use), and the price paid for that use must be determined at the time the license or other resulting technology is available for use.”\textsuperscript{21} The other condition has several prongs:

(1) A single sponsor agrees, or multiple sponsors agree, to fund governmentally performed research;

(2) The qualified user determines the research to be performed and the manner in which it is to be performed (for example, selection of the personnel to perform the research);

(3) Title to any patent or other product incidentally resulting from the basic research lies exclusively with the qualified user; and

(4) The sponsor or sponsors are entitled to no more than a nonexclusive, royalty-free license to use the product of any of that research.\textsuperscript{22}

For those universities and hospitals conducting industry-sponsored clinical research, the definition of basic research arguably causes all product-related, safety, and efficacy studies to be considered private business use. “Basic research” is also defined in Rev. Proc. 97-14, in nearly identical terms (the Rev. Proc. 2007-47 definition omits “1986” as a descriptor of the Code).\textsuperscript{23} Basic research is defined in the Code in a section regarding credit for increasing research activities; the first sentence of that definition is substantially the same to those used in the definitions in Rev. Proc. 2007-47 and Rev. Proc. 97-14.\textsuperscript{24} This is to say that the IRS is being consistent with statutory definitions when it defined the term “basic research” in both Revenue Procedures. Basic research is similarly defined with regard to education sciences reform as: “research . . . to gain fundamental knowledge or understanding of phenomena and observable facts, without specific application toward processes or products . . . .”\textsuperscript{25} This consistency in definition supports the argument that basic research, as used in Rev. Proc. 2007-47, specifically excludes product testing. It is arguably the case that any research agreements regarding product testing, including clinical trials, animal studies, and in vitro testing of specific sponsor investigational drugs or devices, would result in remuneration considered private business use.

Even if the IRS does not consider such testing to fall outside of the definition of basic research, the research agreement would have to contain terms that would not assign inventions to sponsors, because such an assignment would value the invention prior to it being made. Such an assignment provision assesses zero value to the invention, since the sponsor would pay no more than the compensation for the conduct of the research that it is already obligated to pay under the agreement. The assessment is made when the research agreement is executed, rather than when the invention is made; therefore, an assignment provision falls outside of the safe harbor. The research agreement would also have to contain an invention provision that does not treat the sponsor any differently than “any unrelated, non-sponsoring party” with respect to inventions arising from the research. Often, in the author’s experience, sponsors are granted a first option to negotiate a license. Sometimes the option is described as “exclusive,” though it is usually time-limited. Once more clarification becomes available through IRS enforcement of 26 C.F.R. § 1.141-
3(b)(6), the contours of basic research and acceptable inventions provisions will be easier to understand.

The second set of characteristics is more restrictive than the first set. As discussed in endnote nineteen, § 6.03(1) may restrict the applicability of § 6.03 to research performed by a government entity, rather than by either government or 501(c)(3) entities. According to § 6.03(2), the research may be sponsored, but it cannot be directed. The qualified user determines the research to be performed. Section 6.03(2) also provides, by way of an example, that the qualified user determines who will conduct the research. In the author’s experience, an agreement for industry-sponsored research always names a principal investigator, though sub-investigators and others working on the study are rarely named. Section 6.03(3) provides for inventions to belong to the qualified user, not the sponsor. Finally, qualified users are prohibited by § 6.03(4) from granting, in the research agreement, any right to inventions greater than a nonexclusive, royalty-free license.

III. Rev. Proc. 2007-47 and the Private Security or Payment Test

While the purpose of Rev. Proc. 2007-47 is to describe the conditions under which a research agreement does not result in private business use, it also indirectly addresses the private security or payment test. The private security or payment test accounts for the source of funds that pay the debt service of the tax-exempt bonds. If payments made by an industry sponsor are under a research agreement that the IRS considers to be private business use, then the payments may also be considered to be private payment of the debt service. Therefore, it is possible for research agreements to satisfy both the private business use test and the private payment leg of the private security or payment test. Meeting both tests would lead the IRS to consider the interest earned from the bonds financing the property to be taxable to the bond holder.

IV. Conclusion

With regard to industry-sponsored research agreements, Rev. Proc. 2007-47 changes little from its predecessor Rev. Proc. 97-14. The definition of basic research still arguably excludes all product testing on behalf of industry sponsors, therefore, regardless of the terms of research agreements covering such testing, the remuneration for the conduct of the research would be considered private business use of a tax-exempt bond financed property. Further, the remuneration would be factored into the private payment prong of the private use tests. For industry-sponsored basic research, it is possible that industry will not accept the terms required to characterize the research agreements as not providing a private business use to the sponsor. The Code and IRS regulations are complex and difficult to apply, and Rev. Proc. 2007-47 is ambiguous on some matters. However, in the past decade, a headline search and review of several tax-focused websites, including the IRS website, reveals little attention being paid by the IRS to the contents of research agreements and the characteristics of the research they cover. The focus of the IRS and Congress may change in the future; witness the recent attention paid to community benefit of tax-exempt hospitals, executive compensation at exempt organizations, and use of endowment proceeds by universities.


2 26 C.F.R. § 1.141-1(b) provides that “[f]inanced means constructed, reconstructed, or acquired with proceeds of an issue.”


6 26 U.S.C. § 141(a). See 26 C.F.R. § 1.141-3(g) for how to determine the measurement of private business use, as calculated over time and by use of bond proceeds.

7 26 U.S.C. § 141(b).


9 26 C.F.R. §§ 1.141-3(a)(3) and 1.141-4(a)(2).

10 26 C.F.R. §§ 1.141-3(b)(6) and 1.145-2(a).


12 26 U.S.C. § 141(c). In 26 C.F.R. § 1.141-5, this section is interpreted to refer to bond proceeds loaned to persons other than governmental persons. Governmental persons include state and local governmental units, according to 26 C.F.R. § 1.141-10(h), and, according to 26 U.S.C. § 145(a)(2)(B), 501(c)(3) organizations are considered governmental persons, with some qualification.

13 See 26 C.F.R. § 1.141-1(b).


16 Id.


18 Id.

19 Id., Subsection 6.01 provides that a research agreement described in either § 6.02 or 6.03 does not result in private business use. The title of § 6.02 is “Corporate-sponsored research,” while the title of § 6.03 is “Industry or federally-sponsored research agreements.” However, § 6.03 refers to industry or federally-sponsored research. Rev. Proc. 2007-47 makes no distinction between “corporate” and “industry.” It is possible that a research agreement with a for-profit entity, to avoid using either term, will not result in private business use if it meets either the conditions of § 6.02 or § 6.03. Section 6.03 seems directed towards governmental issuers subject to § 141, rather than 501(c)(3) issuers subject to § 145, because § 6.03(1) refers specifically to “governmentally performed basic research.” If the IRS meant to include 501(c)(3) issuers in Section 6.03, then it would have referred to “qualified user performed basic research.” Qualified users include 501(c)(3) issuers. However, the next two criteria of § 6.03 refer to qualified users. It is difficult to say with certainty whether § 6.03 refers only to governments or to both governments and 501(c)(3) issuers.

20 Id.

21 Id., § 6.02.

22 Id., § 6.03.


28 26 C.F.R. § 1.141-4(c)(2)(i).


30 Id.

31 Id., § 6.02.

32 Id., § 6.03.
Upcoming Teleconferences

Three-Part Series
Delivering the Medicare Part D Benefit: Contracting Issues for Part D Plan Sponsors, PBMs, Pharmacies, and Providers

Part I: Contracting Requirements: Part D Plan Sponsors and Their Contractors

Tuesday, January 8, 2008
This teleconference will review common contracting requirements and issues for Part D Plan Sponsors and their downstream contractors, including PBMs, pharmacies, and other providers. The speakers will address contracting requirements for each party; monitoring, auditing, and oversight responsibilities of the Part D Plan Sponsors and their contractors; and practical guidance regarding common compliance and drafting issues. This teleconference will have a three-speaker panel representing the perspectives of Part D Plan Sponsors, CMS, and pharmacies and other providers.

 Disclosure of Unanticipated Outcomes: Merging Patient Safety, Ethics, and Litigation Strategy (Fundamental)

Wednesday, January 9, 2008
This teleconference will discuss how to communicate with families of children who have suffered unanticipated outcomes in the hospital. It will address the following:
• How to identify and discuss disclosure issues unique in pediatric settings.
• How to distinguish disclosure from apology.
• How to outline the ethical dimensions of disclosure and its transcription into the reconciliation model-disclosure as an essential piece of an effective litigation strategy.
• How to examine a particular legal issue that is related to disclosure, e.g., statutory trends, insurance complications for hospitals and non-employed physicians.

Health Plan Tiering Arrangements: A New Paradigm

Thursday, January 10, 2008
This teleconference will discuss a range of legal issues surrounding the development and implementation of tiered provider networks based upon an evaluation of physician quality and efficiency. Such tiered arrangements, while designed to improve health care quality and efficiency, have been the subject of litigation and critical regulatory inquiry. In November 2007, the New York State Attorney General announced settlement agreements with the four largest national health insurers; the settlement agreements create a model physician ranking program based on certain measurements and processes. The teleconference will have a three-speaker panel representing the perspectives of Part D Plan Sponsors, CMS, and pharmacies and other providers.

Where the Healthcare Research and U.S. Export Regulations Meet: Do You Know What is Coming Into and Out of Your Labs?

Tuesday, January 15, 2008
Government agencies are focusing on areas of scientific misconduct and are increasingly targeting academic medical centers. The teleconference will cover the following:
• An overview on how U.S. export controls apply to healthcare;
• Biohazards and the licensing and documentation issues;
• Foreign Nationals and the research and employment considerations;
• Software and technology exports and where to draw the line in e-mail and elsewhere;
• Penalties and risks associated with noncompliance; and
• Practical guidelines for an effective compliance program.

Three-Part Series
Delivering the Medicare Part D Benefit: Contracting Issues for Part D Plan Sponsors, PBMs, Pharmacies, and Providers

Part II: Contracting Issues: Part D Plan Sponsors and PBMs

Wednesday, January 30, 2008
This teleconference will focus specifically on the Plan-PBM relationship with the panel including representatives presenting both perspectives.

Physician Group Practice: What Does the Future Hold?

Webinar

Thursday, January 31, 2008
Over the next several years, physician group practices will experience a drastic transformation both in the way they are organized and in the way they deliver healthcare to their patients. This webinar, presented from a non-legal perspective, explores the five critical elements that will affect the group practice model; these include technology, reimbursement, increased demand for healthcare services, physician supply, and malpractice insurance.

Presenters will give statistics and examples that will better prepare attendees to help their clients solve the problems that will result from this inevitable reorganization.

Three-Part Series
Delivering the Medicare Part D Benefit: Contracting Issues for Part D Plan Sponsors, PBMs, Pharmacies, and Providers

Part III: Final Rules Affecting Medicare Parts C and D

Thursday, February 7, 2008
Part III in the teleconference series will address the final rules affecting Medicare Parts C and D.

Unless otherwise noted, all teleconferences are held 1:00-2:30 pm Eastern.

For a complete listing, more information, and to register, visit the online teleconference calendar: www.healthlawyers.org/teleconferences
Following are some of the highlights from April through October of this year:

**April 30 – May 4, 2007, issue:**

**Medicare Changes Plans for Coverage of Carotid Stents Used to Prevent Strokes**

The *New York Times* reported that CMS has abandoned its previously announced plans to expand Medicare coverage for the use of stents in carotid neck arteries, which are used to prevent strokes. Instead, Medicare will continue its policy that restricts payment for such stents to fewer than ten percent of the 150,000 to 200,000 Americans who annually undergo surgery to clear blockages that restrict blood flow to the brain.

**May 7 – 11, 2007, issue:**

**HPV Vaccine Effective After Three Years**

According to two industry-sponsored studies reported in the *New England Journal of Medicine*, the HPV vaccine (Gardasil) was nearly one hundred percent effective in preventing disease from two major cancer-causing strains in participants in a three-year Gardasil Study. Investigators concluded that the vaccine is highly effective in women who have never been infected with the four vaccine strains, but less so in a more exposed population. However, questions about overall vaccine effectiveness, the duration of protection, and possible long-term adverse effects remain.

**May 14 – 18, 2007, issue:**

**IRS Directive on EHR Software and Tax Exemption**

Under an IRS directive issued May 11, tax-exempt hospitals that enter into certain arrangements with physicians to help facilitate adoption of electronic health record (EHR) technologies will not violate federal tax laws. As reported by *BNA Health Law Reporter*, the directive said that the subsidization by exempt hospitals will not, if properly structured, be treated as a private benefit or inurement.

**June 4 – 8, 2007, issue:**

**Scientists Create Stem Cells From Skin**

The *Washington Post* reported that on June 6, three teams of scientists said they had coaxed ordinary mouse skin cells to become what are effectively embryonic stem cells without creating or destroying embryos in the process. If the process works for human cells, it would mean that a person’s own skin cells could be converted directly into stem cells without having to collect healthy human eggs or destroy human embryos—steps that until now have been required to obtain embryonic stem cells.

**June 18 – 22, 2007, issue:**

**Shortage of Cardiothoracic Surgeons**

*Kaiser Daily Health Policy Report* reported a projected shortage in cardiothoracic surgeons in the near future. Some speculate that because the government has reduced reimbursement rates for coronary artery bypass surgery by nearly fifty percent since 1987, young doctors are choosing other fields that offer shorter training and greater rewards.

**July 2 – 6, 2007, issue:**

**Massachusetts Begins Universal Healthcare**

The *Washington Post* reported that on July 1, Massachusetts became the first State in the nation to require its residents to have health insurance or face financial penalties. Making insurance mandatory—and more affordable—for Massachusetts’ 6.5 million residents is the centerpiece of the law. However, costs may still be high for some, and state officials expect to exempt 60,000 residents from the new law because they cannot afford the insurance, even though they earn too much to qualify for subsidies.

**July 16 – 20, 2007, issue:**

**VA Secretary Resigns**

As reported by the *Kaiser Daily Health Policy Report* on July 17, 2007, Department of Veterans Affairs Secretary Jim Nicholson resigned after months of struggling to respond to allegations of inadequate healthcare for veterans injured in the Iraq war.

**July 30 – August 2, 2007, issue:**

**Brigham to Offer Partial-Face Transplants**

The *Associated Press* reported that Brigham & Women’s Hospital in Boston has given a surgical team permission to perform partial-face transplants for certain disfigured patients. Brigham & Women’s is the second U.S. hospital to make public its plans to offer the controversial and rare medical procedure; the first was the Cleveland Clinic. To date, only three partial-face transplants have been announced worldwide. Two were performed in France and one in China.
August 6 – 10, 2007, issue:

U.S. Court of Appeals Rules Patients Have No Constitutional Right to Experimental Drugs

As reported by BNAs Health Law Reporter, the U.S. Court of Appeals for the D.C. Circuit held that patients have no constitutionally protected right to experimental medicine used in FDA clinical trials, even though it may save their lives. Plaintiffs, groups seeking a right of access to potentially life-saving medications used in FDA clinical trials, intend to petition the U.S. Supreme Court for writ of certiorari.

August 20 – 24, 2007, issue:

Medicare Will Not Pay for “Preventable” Errors

As reported by the Kaiser Daily Health Policy Report, beginning October 2007, Medicare will no longer reimburse hospitals for the treatment of preventable errors, injuries, and infections that occur in their facilities. Conditions for which Medicare will no longer reimburse include: falls; mediastinitis (an infection that can develop after heart surgery); pressure ulcers; urinary tract and vascular infections that result from improper use of catheters; an object left in the body during surgery; air embolisms; and blood incompatibility.

August 27 – 31, 2007, issue:

Stem Cells May Repair Heart Muscles

The Seattle Times reported that scientists from the University of Washington and a private biotechnology company found that human embryonic stem cells have been used to re-grow the heart muscles of rats that survived lab-induced heart attacks. Unlike many tissues in the body, heart muscle cells do not regenerate, thus these findings offer encouragement that treatments based on embryonic stem cells someday might be used to help people who suffer heart attacks, a leading cause of death in the U.S.

September 3 – 7, 2007, issue:

FDA Panel Backs New AIDS Drug

The L.A. Times reported that on September 5, a federal advisory panel unanimously recommended accelerated approval for a new AIDS drug designed to treat patients with drug-resistant strains of the virus. Isentress, developed by Merck & Co., prevents HIV from merging into the DNA of human cells. Full approval is expected within months.

September 10 – 14, 2007, issue:

Medical Research Conducted on Space Station

Modern Healthcare’s Daily Dose reported that NASA and the NIH signed an agreement allowing NIH scientists to use NASA’s International Space Station to conduct medical research. The researchers expect to benefit from the near gravity-free environment while conducting experiments and long-term studies of gravity’s effect on bone and muscle deterioration, balance disorders, disease development, and other conditions.

October 1 – 5, 2007, issue:

FDA Experts Urge Ban on Children’s Cold Medicines

The New York Times reported that safety experts for the FDA urged the agency to consider an outright ban on over-the-counter, multi-symptom cough and cold medicines for children under six years old. The experts’ safety review suggests the removal of those drugs from the market, along with the standardization of droppers, cups, and syringes included with products for children, will reduce the risks of confusion and overdose.

October 15 – 21, 2007, issue:

House Fails to Override Bush’s SCHIP Veto

As reported by the Kaiser Daily Health Public Policy Report, the House of Representatives, by a 273-156 vote, failed to override President Bush’s veto of a bill to reauthorize and expand the State Children’s Health Insurance Program (SCHIP). Earlier this month, Bush vetoed the legislation that would have provided an additional $35 billion in SCHIP funding over the next five years and increased SCHIP’s total spending to $60 billion.

October 15 – 21, 2007, issue:

Drug-Resistant Staph Infections Are Spreading

The New York Times reported that a recent CDC study shows the increasing prevalence of the virulent drug-resistant bacteria, methicillin-resistant Staphylococcus aureus (MRSA). MRSA can be brought unknowingly into hospitals and nursing homes by patients who show no symptoms and can be transmitted through contact as casual as the brush of a physician’s lab coat.

* Teaching Hospital Updates were compiled by Reesa Benkoff, Esquire, of Hall Render Killian Heath & Lyman PLLC, Troy, MI.
Teleconference CD Recordings – A Great Addition to Your Resource Library!

Practice Group sponsored teleconferences are held throughout the year on hot topics and analyses of healthcare law related issues and cases. If you are unable to participate in any given teleconference, you may purchase a CD recording (includes materials) by calling our Member Service Center at (202) 833-0766, or online at www.healthlawyers.org/teleconferences/CDs.

To view a listing of available CDs, please visit: www.healthlawyers.org/teleconferences/CDs

For more information about future teleconferences, see page 9.