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Use of Tax-Exempt Bonds for Facilities or Equipment Used in the Conduct of Embryonic Stem Cell Research

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I. Overview

On Aug. 9, 2001, President Bush announced a prohibition (the ''Bush directive'') on the use of federal funds for scientific research on human embryonic stem cell lines other than certain lines existing before that date (''non-approved ESC research''). Since that time, federal funding for stem cell research has been restricted to those stem cell lines that are identified in the stem cell registry created by the National Institutes of Health (''NIH'') as meeting President Bush's criteria (''approved ESC research''). While non-approved ESC research still may be conducted, the Bush directive is clear that such research may not be supported by federal funds in any way. For many researchers and institutions that are engaged in both non-approved ESC research and approved ESC research, this has resulted in more questions than answers as they attempt to determine how to keep these two areas of research separate in this new era.

NIH attempted to address many of the issues surrounding mixed funding of stem cell research in a series of ''Frequently Asked Questions'' posted on the NIH Web site (the ''NIH FAQs'').[1] NIH's guidance was the subject of a thorough and thoughtful analysis on the mixed funding situation which appeared in BNA's *Medical Research Law & Policy Report* in January 2005.[2] It has come to our attention, however, that there is no direct guidance, either governmental or academic, on the issue of whether the financing of a facility with tax-exempt bonds in and of itself restricts the types of research that can be conducted at that facility. Nowhere is this issue receiving more attention than in California, where in November 2004 voters approved Proposition 71, which will make as much as $3 billion over the next 10 years available to support human embryonic stem cell research conducted throughout the state. Up to 10 percent of this funding is to be allocated for grants to fund the construction of new facilities.

It is the purpose of this article to shed some light on the question of whether the use of tax-exempt bonds to finance construction of a new facility limits the type of research that can be conducted at that facility. For the reasons set forth below, we believe that the Bush directive does not restrict an institution from conducting non-approved ESC research in bond-financed facilities or from financing new facilities for such uses with proceeds of tax-exempt bonds. Moreover, non-approved ESC research and NIH-funded research (whether stem

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[1] National Institutes of Health, Stem Cell Information—Frequently asked Questions, *available at* http://stemcells.nih.gov/info/faqs.asp.

[2] Robert J. Kenney Jr., *How to Conduct Non-Federal Stem Cell Research Without Violating the Federal Stem Cell Funding Prohibition*, 4 BNA's MEDICAL RESEARCH LAW & POLICY REP. 39, 1/5/05.

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cell-related or not) properly may be conducted in the same facilities as long as NIH cost allocation principles are strictly followed in determining costs chargeable to NIH grants.

II. Non-approved ESC research will not jeopardize tax-exempt status of bonds

Under Section 103 and certain ancillary provisions of the Internal Revenue Code of 1986, as amended (the ''Code''),[3] interest paid on bonds issued for the benefit of an organization described in Section 501(c)(3) of the Code is exempt from federal income tax if certain requirements are satisfied. Tax-exempt treatment for such bonds thus is a product of statute, and an act of Congress signed by the President[4] would be required to withdraw the grant of tax exemption for interest on such bonds or to change the fundamental requirements thereof. Many of the requirements for tax-exempt treatment are contained in various Treasury regulations[5] promulgated pursuant to the Administrative Procedure Act (the ''APA'').[6] To modify these regulations, the procedures set forth by the APA must be followed, which require, among other things, publication of a notice of proposed rulemaking in the *Federal Register* and public hearings.[7]

The Bush directive, which was issued by the president in a nationally televised address on Aug. 9, 2001,[8] was neither a law enacted by Congress nor a ''rule''[9] adopted in accordance with the APA's procedural requirements.[10] Accordingly, the Bush directive alone cannot have altered the rules provided by the Code and Treasury regulations that, if satisfied, permit a bond issue to qualify for tax-exempt status.

It should be noted that the executive branch (through the Treasury Department and Internal Revenue Service) does possess some discretion in administering the nation's tax laws and regulations, including those relating to tax-exempt bonds.[11] However, the disallowance of tax-exempt treatment for bonds allocable to facilities used for non-approved ESC research (where such research is in furtherance of a tax-exempt organization's exempt purposes) would be a significant departure from current law and would be well outside the bounds of permitted administrative discretion.

For these reasons, therefore, the Bush directive could not have adversely affected the tax-exempt status of bonds issued to finance facilities in which non-approved ESC research is conducted. One caveat applies: the usual tax law restrictions on research conducted in bond-financed facilities—most significantly, the private business use rules[12]—still would apply in the case of non-approved ESC research. Among other things, if a private party is sponsoring the research, the arrangement generally should be structured to comply with the ''sponsored research'' rules of IRS Revenue Procedure 97-14.[13]

III. Non-approved ESC research in bond-financed facilities is not a per se violation of the Bush directive

We also have considered whether the Bush directive is itself violated by non-approved ESC research in bond-financed facilities. The president's address on Aug. 9, 2001, did not specifically indicate whether non-approved ESC research could be conducted in facilities financed with the proceeds of tax-exempt bonds, nor is the issue specifically addressed by the limited federal guidance on the Bush directive.[14]

It is very likely, however, that the directive was *not* intended to restrict non-approved ESC research from being conducted in such facilities. Both the president's address and NIH FAQs, as the most pertinent federal guidance on the directive, refer only to the use of ''*federal funds*'' for non-approved ESC research. Had the Bush directive been intended to cover tax-exempt bond financing, either a broader term such as ''*federal benefits*'' or ''*federal subsidy*'' undoubtedly would have been used—or the issue would have been specifically addressed. Furthermore, although the NIH FAQs state that federal funds may not be used directly ''or indirectly'' to support non-approved ESC research, there is no suggestion in the NIH FAQs or any other published authority that the benefit of tax-exempt financing represents a form of ''indirect'' support provided by federal funds. Rather, the NIH FAQs give as an example of such ''indirect'' support the use of federal funding to

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[3] Section 103 of the Internal Revenue Code provides that, subject to certain exceptions, gross income does not include interest on any ''State or local bond.'' Sections 141-150 of the Code and the Treasury Department regulations thereunder provide detailed rules for determining whether a given bond qualifies for the Section 103 exclusion. In particular, Section 145 of the Code sets forth certain requirements (among others) for bonds issued on behalf of a Section 501(c)(3) organization to be eligible for the Section 103 exclusion.

[4] *See* U.S. Const. art. I, § 7, cl. 2.

[5] *See, e.g.*, Treas. Reg. §§ 1.141-1 to 1.141-16; §§ 1.145-1 to 1.145-2; §§ 1.148-1 to 1.148-11A.

[6] *See* 5 U.S.C. §§ 500-596.

[7] *See* 5 U.S.C. § 553.

[8] *Remarks by the President on Stem Cell Research* (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/20010809_2.html.

[9] *See* 5 U.S.C. § 551(5).

[10] *See* 5 U.S.C. §§ 500-596.

[11] For example, the IRS publishes revenue rulings to set forth its official position on the application of federal tax law to specific sets of facts. Many courts afford some deference to revenue rulings, unless they are unreasonable or inconsistent with prevailing law. *See*, *e.g.*, *Estate of McLendon v. Comm'r*, 135 F.3d 1017, 1023-24 (5th Cir. 1998); *Salomon Inc. v. United States*, 976 F.2d 837, 841 (2nd Cir. 1992).

[12] Very generally, in the case of bonds issued on behalf of a Section 501(c)(3) organization, the private business use test measures whether more than a de minimis portion of the proceeds of the bonds is ''used'' directly or indirectly in a trade or business carried on by any private user (or by the exempt organization in an unrelated trade or business). In a typical case, the test serves to limit the amount of space in a bond-financed facility that may be ''used'' by private users (or by the exempt organization in an unrelated trade or business) to 3 percent of the total square footage of the facility. *See* Code §§ 141, 145; Treas. Reg. § 1.141-3(g), § 1.145-2(c)(2).

[13] Revenue Procedure 97-14 provides in general that a sponsored research agreement does not give rise to private business use if any license or other use of the resulting technology by the sponsor is permitted only on the same terms as the exempt organization would permit that use by any unrelated, non-sponsoring party, with the price paid for that use determined at the time the license or other resulting technology is available for use.

[14] *See* NIH, Stem Cell Information—Frequently asked Questions, *available at* http://stemcells.nih.gov/info/faqs.asp.

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pay ''facilities and administrative costs''[15] and that the means of avoiding such direct or indirect support is strict compliance with the federal grant cost allocation principles of NIH (*see below for further discussion*).

Our view that the Bush directive was intended merely to restrict the use of NIH funding, not the use of facilities financed with state or federal tax-exempt bonds, is supported by consideration of the context in which the Bush directive was issued. For a number of years prior to 2001, and as is still the case now, the annual appropriations bill for the Department of Health and Human Services (''HHS'') (which includes NIH) provided that, in general, no NIH grants could be used in research in which a human embryo is created or destroyed.[16] In 1999, the HHS Office of General Counsel stated in a legal opinion that it interpreted this language *not* to preclude NIH funding for research utilizing human embryonic stem cells on the ground that embryonic stem cells are not themselves embryos according to the statutory definition of that term.[17] While the statutory definition of ''human embryos'' was limited to ''organisms'' derived from human gametes, the Office of General Counsel argued that pluripotent stem cells are not organisms in and of themselves, as they ''do not have the capacity to develop into an organism that could perform all the life functions of a human being.''[18] This interpretation by the Office of General Counsel was criticized in some quarters.[19] Although the Bush directive did not specifically refer to this position taken by the HHS Office of General Counsel, it is reasonable to presume that the directive was intended to reverse this position with respect to NIH funding of research utilizing newly created lines of human embryonic stem cells. There is no suggestion in this context that the directive was intended to restrict the use of facilities financed with tax-exempt bonds.[20]

IV. In a mixed-use facility, allocation rules must be observed

Although there appears to be no *per se* prohibition on conducting non-approved ESC research in bond-financed space, scientists and institutions must ensure that the direct and indirect costs of non-approved ESC research are allocated to other sources of funding and not NIH grants when conducted in a facility (bond-financed or not) containing both non-approved ESC research and research supported by NIH grants (stem cell-related or not). The NIH FAQs indicate that, so long as a scientist or institution strictly follows the federal cost principles and administrative requirements under Office of Management and Budget (''OMB'') Circulars A-110 and A-21, the scientist or institution will have established that no costs allocable to non-approved ESC research have been supported by federal funds.[21] Accordingly, if those principles are strictly observed, institutions are not required to prohibit non-approved ESC research in facilities in which approved ESC research also is being conducted. Of course, failure to follow these cost allocation principles will not only jeopardize any NIH grants funding approved ESC research, but also will directly violate the Bush directive. Thus, it is imperative that the cost allocation principles set forth in the regulations be strictly observed in facilities (regardless of bond financing) in which both approved and non-approved ESC research are being conducted.

V. Evolving area of law

The fact that the science and law in this area are so new, together with the political sensitivities over the issue of ESC research and the prospect of future scientific advances, may well lead to significant developments in the law that will need to be followed. Indeed, on May 24, 2005, legislation passed the House (H.R. 810, the proposed ''Stem Cell Research Enhancement Act of 2005'') that expressly would permit the federal funding of certain stem cell lines created on or after Aug. 9, 2001, essentially overturning a key portion of the Bush directive. Under the proposed Stem Cell Research Enhancement Act of 2005, human embryonic stem cells would be eligible for use in federally supported research, regardless of the date on which the stem cells were derived from a human embryo, provided that: (1) the stem cells were derived from human embryos originally created for fertility treatment and in excess of need; (2) prior to donation, it was determined that the embryos would have been discarded as opposed to implanted in a woman; and (3) written informed consent was obtained from the donors of the embryos without any financial or other inducements. Essentially, the legislation incorporates many of the ethical requirements from the Bush directive, but eliminates the requirement that only research on stem cell lines derived before Aug. 9, 2001, are eligible for federal support. Following passage in the House in May 2005, H.R. 810 was placed on the Senate legislative calendar and, at present, awaits action in the Senate. Although the bill reportedly has bipartisan support, it is too early to predict whether it will be approved by the Senate or survive a likely presidential veto.

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[15] Facilities and administrative costs (''F&A costs'') ''means costs that are incurred for common or joint objectives and, therefore, cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity. F&A costs are synonymous with 'indirect' costs.'' 2 C.F.R. pt. 220, Appendix A, § B.4 (2005).

[16] *E.g.*, H.R. 3424, 106th Cong., § 510 (enacted as Pub. L. 106-113, Nov. 29, 1999); H.R. 5656, 106th Cong., § 510 (enacted as Pub. L. 106-554, Dec. 21, 2000).

[17] This interpretation by the Office of General Counsel was largely adopted by NIH guidelines issued in August 2000. *See* 65 Fed. Reg. 51975 (Aug. 25, 2000).

[18] Memorandum from Harriet S. Rabb, General Counsel of the U.S. Dept. of Health and Human Services, to Harold Varmus, Director of the National Institutes of Health, rendering legal opinion regarding federal funding for research involving human pluripotent stem cells (Jan. 15, 1999) (on file with the author).

[19] *See, e.g.,* Nicholas Wade, *Ruling in Favor of Stem Cell Research Draws Fire of 70 Lawmakers*, N.Y. TIMES, Feb. 17, 1999, at A12.

[20] A recent article in BNA's *Medical Research Law & Policy Report* sparked some discussion as to whether the Bush directive was indeed intended to prohibit non-approved ESC research in bond-financed facilities. *See* W. Randy Kubetin, *Outlook 2005*, 4 BNA'S MEDICAL RESEARCH LAW & POLICY REP. 5, 1/5/05.

[21] OMB Circulars A-110 and A-21, now codified at 2 C.F.R. parts 215 and 220, respectively, set forth basic principles for allocating direct and indirect (i.e., F&A) costs of research to federal grants, including those by the NIH for approved ESC research, as well as basic principles for the charging of F&A cost rates.