# Income From Properly Structured Trials Can Be Exempt From Taxation, Attorneys Say

(*BNA Health Law Reporter*, Dec. 9, 2010) Academic medical centers (AMCs) that conduct clinical drug trials have strong arguments for designating income derived from these activities as "related to" recognized exempt purposes—scientific research, medical student education, and patient care—and thereby justifying that it not be treated as unrelated business taxable income (UBTI) by the Internal Revenue Service, according to attorneys who advise nonprofit medical and research organizations.

Although certain clinical trials, especially those that are designed to help a drug company gain Food and Drug Administration approval for a new drug, may be harder to characterize as sufficiently "related to" an exempt purpose of a Section 501(c)(3) organization to avoid having its clinical trial revenues treated as UBTI, most clinical trials can, with proper structuring of contracts and sufficient documentation, be shown to serve recognized exempt purposes, the attorneys said.

Clinical drug studies undertaken before trials; clinical trials relating to proposed new uses of existing drugs; and those trials involving an AMC's students, faculty, and patients are the initiatives least likely to generate revenues that can be characterized as UBTI by IRS. Even pre-approval clinical trials can be structured, and exempt treatment of revenues defended, where faculty and students are extensively involved, where results will be disseminated as broadly as possible, and where the scientific purposes to be furthered by the trial and potential contributions to medical science are detailed before hand, they added.

"If hospitals can negotiate the contract language to include the right to participate in designing the research protocol and the right to publish the results, even after a reasonable delay to allow the sponsor to protect any intellectual property rights, then the arrangement probably would not be challenged by the IRS in the first place," they said. The attorneys, Douglas K. Anning, of Polsinelli Shughart PC, Kansas City, Mo., and John C. Sawyer, of Alston & Bird LLP, Atlanta, provided their comments in an interview with BNA and in conjunction with a recent presentation on "Tax Aspect of Clinical Research and Studies" at the American Health Lawyers Association's conference on Tax Issues for Healthcare Organizations, held in Washington.

**Tax or Exemption Issue?**

Most academic medical centers also will be at a low risk of having their federal tax exemption threatened by clinical drug trials because the income, even if determined to be UBTI, will not be a sufficiently large percentage of overall revenues, they continued. Only if the amount of UBTI is large enough that it reflects that the activity is or has become the organization's "primary purpose" will exemption be at risk, the attorneys said.

They noted that this dynamic might change if the clinical drug trials are conducted by an exempt subsidiary. In that case, the subsidiary's exemption could, depending on the specific facts and circumstances, be at risk, they added.

If there is UBTI, how much is too much? Anning asked. “If the exempt organization is primarily engaged in exempt activities, the IRS may tolerate a high percentage of UBTI, but if it is primarily engaged in unrelated activities, the IRS will not tolerate much UBTI.”

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According to Anning, under Treasury Regulation 1.513(a)/Regulation 1.513-1(d)(1), income from a trade or business that is regularly carried on and that is not substantially related to exempt purposes may be treated as UBTI. Exceptions include research conducted by colleges, universities, and hospitals (Section 512(b)(8)) and research conducted by an organization primarily organized for purposes of carrying on fundamental research the results of which are freely available to the public (Section 512(b)(9)).

The regulations state that research does not include activities “incident to commercial or industrial operations” or “ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc.,” Anning said, citing 1.501(c)(3)-1(d)(5)(ii) and 1.512(b)-1(f)(4).

Sawyer said that the IRS will resolve the UBTI consequences of a given research activity by employing a three-part test that asks whether the questioned activity is scientific, whether it is research, and whether it is in the public interest. “If the answer to any of the three questions is no, then the IRS will likely conclude the income is taxable,” Sawyer said.

In assessing the three components, Sawyer continued, the IRS will analyze the first two using a three-part test it “discovered” from Midwest Research Inst. v. United States, 554 F. Supp. 1379 (W.D. Mo. 1983), aff'd 744 F.2d 635 (8th Cir. 1984) and memorialized in IRS General Counsel Memorandum 29883. That test requires project supervision and design by professionals, a project designed to solve a problem through a search for demonstrable truth using the scientific method, and a research goal that furthers a scientific purpose.

**Concerns About ‘Incident To.'**

As far as the IRS is concerned, Anning said, an organization organized solely for the purpose of performing clinical drug trials for pharmaceutical companies to obtain FDA approval will not qualify for the research exception.
“This is not the issue facing most academic medical centers, for which testing is an ancillary activity, not a sole activity,” Anning said. “Many activities won't qualify for the

stand-alone exemption but can still be related to other exempt purposes such as lab testing or the sale of drugs, DME, or hearing aids."

When an exempt organization contracts with a commercial enterprise to perform services, such as a clinical trial, any analysis of whether the trial will generate UBTI should include consideration of the "incident to commercial operations test," derived from Section 1.501(c)(3), Anning said.

Anning then proposed what he described as a "kinder, gentler" IRS approach that asks:

- Is regulation or exempt status germane to the UBTI determination? Many activities don't qualify for exemption, such as lab testing or the sale of durable medical equipment, drugs, or hearing aids, yet also do not cause UBTI.
- Even if the regulation applies, are there other means under the regulation of satisfying the public interest requirement, such as the education of medical students or the search for a disease cure?
- Does Section 512(b)(8), which has no publication requirement, or Section 512(b)(9), which states only that results must be freely available to the public, apply?

Anning concluded that publication rights should be part of the contract and that researchers should know that publication is sufficient, but not necessary, to avoid UBTI.
Anning then outlined a methodology for analyzing UBTI issues. "First you have to ask, do you fit squarely into one of the fact patterns of the favorable PLR/TAM: PLR 7936006 and TAM 8230002. If not, to determine if there is UBTI you have to ask, is the clinical trial substantially related to the exempt purposes of research, education, and treatment, and, if not, is the testing 'research' for the purposes of the 512(b)(8) or (b)(9) exceptions?"

**Relevant Revenue Rulings**

Rev. Rul. 68-373 takes the hard line position, Sawyer said, that clinical trials designed solely to get FDA approval of a new drug are ordinary testing and not research.
Sawyer also described several relevant IRS private letter rulings. PLR 7936006 involved a medical school that conducted clinical studies for pharmaceutical companies. The studies focused on the effects of various drugs as they related to the diagnosis of or the development of new treatment methods for human diseases. The researchers designed and managed the research, including data collection and analysis.
The results of the study were published and utilized in the instruction of students, some of whom were involved in the research activities. The IRS concluded that the studies were not mere quality control programs or ordinary testing for certification purposes, as a final procedural step before marketing, but instead research within the meaning of Section 512(b)(8). Consequently, the IRS decided the income derived from the studies was not UBTI.

Another PLR (8016010) involved a hospital that entered into an agreement with a drug company to conduct clinical tests on an experimental asthma drug. In this case, the drug company designed the protocol and the results of the trials were intended to be used in FDA submissions.

The IRS concluded that the clinical tests were not scientific research because the hospital did not design the tests and failed to demonstrate a connection between the clinical tests and patient care. Since the tests were incidental to the drug company's commercial operations and were not shown to be related to the hospital's exempt purposes, income derived from the test was considered to be UBTI.

In PLR 200852036, according to Sawyer, an exempt organization proposed to fund clinical trials for the treatment and cure of an “orphan” disease using new drugs and drug combinations to be conducted by a variety of sites using patients suffering from the disease. The IRS concluded that the tests primarily aided those suffering from the disease and added to the body of knowledge used to cure it. Consequently, the IRS characterized the proposed activities as scientific research, notwithstanding the potential benefit commercial drug manufacturers might derive from the effort.

Anning discussed another relevant ruling, PLR 8230002 , and an example involving a hospital that conducts Phase I-III testing for pharmaceutical companies to obtain FDA approval for new drugs. Some of the testing uses patients who might benefit from the drug (“for benefit” testing), while some uses nonpatient volunteers or patients with unrelated disorders to test metabolic levels and toxicity levels (“not-for-benefit” testing). The for-benefit testing does not result in UBTI, while the not-for-benefit testing does result in UBTI, Anning said.

Anning affirmed that, according to PLR 7936006, clinical trials conducted by a medical school for pharmaceutical companies for the purpose of searching for new applications of existing drugs do not generate UBTI. Such work is seen as “substantially-related” when the studies are designed by faculty and conducted by faculty and students, or when the results are published or the studies are used in the instruction of students. Even if the trials are not “substantially related,” they still might qualify for the 512(b)(8) exception, he said.

**Publish or Perish?**

Reg. §1.501(c)(3)-1(d)(5)(iii) states that scientific research will be regarded as carried on in the public interest if the results of the research, including any patents, copyrights, processes, or formula resulting from such research, are made available to the public on a nondiscriminatory basis, which means commercial sponsors cannot be promised exclusive or preferential licensing rights; the research is performed for the United States or any of its agencies or instrumentalities or for a state or political subdivision thereof; or the research is directed toward benefiting the public.

Anning concluded by addressing the IRS position of the importance of publication of a clinical trial's results on the determination of whether or not there was UBTI since publication could satisfy the public interest requirement. He said PLR 793605 and TAM 8230002 indicate that publication is a fact, but not the sole fact, the IRS relies on for this determination.

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