TAX EXEMPT AND
GOVERNMENT ENTITIES
DIVISION

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, D.C. 20224

Release Number: **201037037**
Release Date: 9/17/10
Date: June 23, 2010
UIL Code: 501.03-21

Contact Person:

Identification Number:

Contact Number:

Employer Identification Number:

Form Required To Be Filed:

Tax Years:

Dear

This is our final determination that you do not qualify for exemption from Federal income tax as an organization described in Internal Revenue Code section 501(c)(3). Recently, we sent you a letter in response to your application that proposed an adverse determination. The letter explained the facts, law and rationale, and gave you 30 days to file a protest. Since we did not receive a protest within the requisite 30 days, the proposed adverse determination is now final.

Since you do not qualify for exemption as an organization described in Code section 501(c)(3), donors may not deduct contributions to you under Code section 170. You must file Federal income tax returns on the form and for the years listed above within 30 days of this letter, unless you request an extension of time to file.

We will make this letter and our proposed adverse determination letter available for public inspection under Code section 6110, after deleting certain identifying information. Please read the enclosed Notice 437, *Notice of Intention to Disclose,* and review the two attached letters that show our proposed deletions. If you disagree with our proposed deletions, you should follow the instructions in Notice 437. If you agree with our deletions, you do not need to take any further action.

In accordance with Code section 6104(c), we will notify the appropriate State officials of our determination by sending them a copy of this final letter and the proposed adverse letter. You should contact your State officials if you have any questions about how this determination may affect your State responsibilities and requirements.

If you have any questions about this letter, please contact the person whose name and telephone number are shown in the heading of this letter. If you have any questions about your Federal income tax status and responsibilities, please contact IRS Customer Service at 1-800-829-1040 or the IRS Customer Service number for businesses, 1-800-829-4933. The IRS Customer Service number for people with hearing impairments is 1-800-829-4059.

Sincerely,

Rob Choi
Director, Exempt Organizations
Rulings & Agreements

Enclosure
Notice 437
Redacted Proposed Adverse Determination Letter
Redacted Final Adverse Determination Letter

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, D.C. 20224

TAX EXEMPT AND
GOVERNMENT ENTITIES
DIVISION

Date: April 23, 2010

Contact Person:

Identification Number:

Contact Number:

FAX Number:

Employer Identification Number:

B = State
D = Date
H = Hospital
U = Board Member
V = Board Member
W = Board Member
X = Board Member

UIL

501.03-21

Dear

We have considered your application for recognition of exemption from Federal income tax under Internal Revenue Code section 501(a). Based on the information provided, we have concluded that you do not qualify for exemption under Code section 501(c)(3). The basis for our conclusion is set forth below.

Issue

Do you qualify for exemption under section 501(c)(3) of the Code?

Facts

You were incorporated as a nonprofit corporation in B on date D. You do not have members.

You are governed by U, Director and President, V, Director, Vice President and Advisor, W, Director, and X, Director and Secretary. U and V are husband and wife, and X is the daughter of V. U is board certified in gastroenterology and internal medicine and is certified as a transplant hepatologist. V is a registered nurse with a master's degree in psychology. W is a

registered nurse, an employee of H, the chief office nurse of U's medical practice and H's liver center. At the present U, V, and W work approximately ten hours, one to two hours, and five hours per week, respectively. X is not involved in your day-to-day activities.

U has provided a copy of his professional services contract with H, where he also serves as medical director of H's liver disease center. U's services to H include medical services for the liver disease clinic.

Your statement of activities indicates that you were formed to participate in clinical research studies to benefit patients with hepatitis B and encephalopathy.

You conduct each study within formalized study protocols provided by the study sponsor; patient eligibility is based on an initial observed screening by U followed by physical and lab testing. Patients are monitored on a regular basis as required under study protocols. Patient exams and treatment conducted at the liver disease center at H by U and are coordinated by W and other employees of H.

Patients are informed of the research projects, and given protocols to review in order to determine if they wish to participate. As part of the clinical research studies, medical evaluations, laboratory tests, and medications are provided to patients afflicted with hepatitis B or encephalopathy at no charge. This is done in conjunction with U's medical practice at H.

You state that U is a renowned liver specialist in the United States, and is generally contacted by the pharmaceutical companies and/or the primary investigators. In your application, you state that from your inception through the present, U has participated as a secondary investigator in five clinical research studies.

1. To compare the safety and the effectiveness of one drug to another in subjects chronically infected with HBV. This study was completed.

2. To compare the safety and tolerability of two drugs in subjects with chronic hepatitis B and decompensate liver disease. This study was completed.

3. To determine the safety, effectiveness and subjects' ability to take a drug twice daily to prevent hepatic encephalopathy. This study was completed.

4. To evaluate the effect of a drug in combination with endoscopic treatment, to address acute variceal bleeding. This study was completed.

5. To evaluate the long-term safety and tolerability of a drug in subjects with a history of hepatic encephalopathy. This study is ongoing.

You subsequently provide an updated list that U has participated as a secondary investigator in seven clinical research studies focusing on chronic liver disease. The two additional clinical research studies include a contract with another research company to identify patients for its site and an observational trial study of a drug on the market to evaluate the long-term safety and

tolerability of a drug in subjects with a history of hepatic encephalopathy. Both of the two additional studies are on going and involved different sponsors. You state that U hopes to participate in one to three studies each year. You state that the research projects are developed by the pharmaceutical companies, and that all past, current and planned research studies are on and assumed to be on a contract basis.

The clinical research flow chart shows that the sponsor (pharmaceutical company) provides protocols and payments for the research; the monitoring company (third party) monitors protocols and payments; U is the investigator (researcher); U submits the study results to the monitor company, which submits the finished results to the sponsor; and the sponsor then submits comprehensive pharmaceutical evaluations to the FDA. Similar steps of the process are also discussed in your correspondence that the results of the research are furnished to the monitoring companies and the ownership of the study results is retained by the pharmaceutical companies per contractual agreements.

U selects the research projects that U will undertake based on appropriateness for U's area of interest and expertise focusing on chronic liver disease, physical capabilities and limits, and patient availability based on protocols.

All original documents from each study remain on-site with you until notification is received from the sponsor to destroy the documents. You state that there are no preferences given as to results or time of release other than what is contractually required under each study contract. However, U assigns all intellectual property rights to the sponsoring pharmaceutical companies and is prohibited from publishing the results of his research under the study contractual agreements.

At the present, it is your intent to obtain funding on a level that would only allow research participation within the scope of the research projects proposed by your sponsors. You state that your fundraising consists of research study sponsorship by drug companies. Your revenues for the first two years were solely from two pharmaceutical companies.

Law

Section 501(c)(3) of the Code provides for the exemption from federal income tax of corporations organized and operated exclusively for charitable or educational purposes, provided that no part of the net earnings inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(c)(1) of the regulations provides that an organization operates exclusively for exempt purposes only if it engages primarily in activities that accomplish exempt purposes specified in section 501(c)(3) of the Code. An organization must not engage in substantial activities that fail to further an exempt purpose.

Section 1.501(c)(3)-1(d)(1)(ii) of the regulations provides that an organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a private interest. To meet this requirement, it is necessary for an organization to establish that it is not organized

or operated for the benefit of private interests.

Section 1.501(c)(3)–1(d)(5)(iii) of the Regulations provides that scientific research will be regarded as in the public interest:

> a. If the results of such research (including any patents, copyrights, processes, or formulae resulting from such research) are made available to the public on a nondiscriminatory basis;
>
> b. If such research is performed for the United States, or any of its agencies or instrumentalities, or for a State or political subdivision thereof;
>
> c. If such research is directed toward benefiting the public.

Rev. Rul. 69–632, 1969–2 C.B. 120, held that an association composed of the members of a particular industry was not exempt under IRC 501(c)(3) because the association sponsored research projects to develop new and improved uses for the industry's products. Although patents and trademarks resulting from the research were licensed royalty free, the primary beneficiaries of the association's research program were the members of the industry.

Rev. Rul. 65–1, 1965–1 C.B. 226, held that an organization which promoted and fostered the development and design of machinery in connection with a commercial operation, and in connection therewith had the power to sell, assign and grant licenses with respect to its copyrights, trademarks, trade names, or patent rights, did not qualify for exemption.

Rev. Rul. 68-373, 1968-2 C.B. 206 held that a nonprofit organization primarily engaged in testing drugs for commercial pharmaceutical companies did not qualify for exemption.

Rev. Rul. 76–296, 1976–2 C.B. 141, distinguishes two situations involving scientific research undertaken pursuant to contracts with private industry. Commercially sponsored research that otherwise qualifies as scientific research under IRC 501(c)(3) constitutes scientific research carried on in the public interest if the results, including all relevant information, are timely published in a form available to the interested public, even though it is performed pursuant to a contract under which the sponsor has the right to obtain ownership of the patent. Research is not in the public interest, and constitutes unrelated trade or business within the meaning of IRC 513, if publication is withheld or delayed significantly beyond the time reasonably necessary to establish ownership rights. The organization will agree, on request, to forego or significantly delay publication of results of a particular project to protect the sponsor's processes, technical data, or patent rights.

Better Business Bureau of Washington D.C., Inc. v. United States, 326 U.S. 279 (1945), held that the presence of a single nonexempt purpose, if substantial in nature, will preclude tax exemption under section 501(c)(3) of the Code.

In Schoger Foundation v. Commissioner, 76 T.C. 380 (1981) it was held that if an activity serves

a substantial nonexempt purpose, the organization does not qualify for exemption even if the activity also furthers an exempt purpose.

In IIT Research Institute v. United States, 9 Cl. Ct. 13 (Cl. Ct. 1985), a U.S. Claims Court reviewed the activities of an organization exempt under section 501(c)(3) of the Code. The organization contracted with a variety of industry members to perform research for them. The court defined the term "scientific" to include "the process by which knowledge is systematized or classified through the use of observation, experimentation, or reasoning." The court found that the organization was not involved in the commercialization of the products or process developed as a result of its research. IIT Research Institute only developed a project to the point where the research principles were established. At this point, the sponsors would make the principles available to different customers, usually in the form of newly developed products or equipment. The court found significance in the fact that IIT Research Institute did not engage in any consumer or market research or ordinary testing of the type which is carried on incident to commercial operations. The court therefore found that the organization's activities were research and not ordinary testing carried on as an incident to commercial or industrial operations.

In American Campaign Academy v. Commissioner, 92 TC 1053 (1989), the organization conducted an educational program for professional political campaign workers. It furnished classrooms, materials, and qualified instructors. Admission was through a competitive application process. The Service argued that the Academy substantially benefited the private interests of Republican party entities and candidates, thereby advancing a nonexempt private purpose. The relationship between the Academy and "Republican party entities and candidates" was not one of control, although the Academy was an outgrowth of a training program operated by National Republican Congressional Committee. The Academy argued that the prohibition against private benefit is limited to situations in which an organization's insiders are benefited. The Tax Court, however, disagreed with this view, and stated that an organization's conferral of benefits on disinterested persons may cause it to serve a private interest within the meaning of section 1.501(c)(3)- 1(d)(1)(ii). Private benefit was defined as "nonincidental benefits conferred on disinterested persons that serve private interests."

Application of Law

You are not described in section 501(c)(3) because you are not organized and operated exclusively for charitable, educational, scientific or religious purposes.

You are not described in section 1.501(c)(3)-1(c)(1) of the regulations because more than an insubstantial part of your activities is devoted to non-exempt purposes. Your activities are conducted to accomplish the commercial purposes for the benefits of the pharmaceutical companies.

You are not described in section 1.501(c)(3)-1(d)(1)(ii) of the regulations because you are operated for the benefits of private interests of U, a researcher, and the sponsoring pharmaceutical companies.

You are not described in section 1.501(c)(3)–1(d)(5)(iii) of the regulations because your research is not regarded as in the public interest and serves U, your only investigator and researcher, and the pharmaceutical companies, sponsors of your research studies.

You are similar to the organization described in Rev. Rul. 69-632, supra, because you mainly conduct clinical trials for the sponsors. Of your seven studies thus far, six are involved in testing and comparing the safety and effectiveness of certain drugs for your sponsoring pharmaceutical companies and one is to find patients for a research company.

You are similar to the research organization described in Rev. Rul. 65-1, supra, because the ownership of your research results is controlled and retained by the sponsoring pharmaceutical companies.

You are similar to the organization described in Rev. Rul. 68-373, supra, because you conduct clinical trial research by comparing and evaluating certain drugs for the pharmaceutical companies, as evidenced in your description of studies, revenues and contractual agreements.

Unlike situation 1 discussed in Rev. Rul. 76–296, supra, your research does not serve the public interest because U, your only investigator and researcher, assigns all intellectual property rights to the sponsoring pharmaceutical companies and is prohibited from publishing the research results per study contractual agreements. You are similar to situation 2 described in Rev. Rul. 76-296, supra, because your research is in the control of the sponsors; the sponsors own the intellectual property rights; the original research documents are destroyed upon notification from the sponsors; and U, your researcher, is prohibited from publishing the research results to accommodate the sponsor's business interest per contractual agreements. Thus, your research is not scientific research within the meaning of section 501(c)(3).

You are similar to the organizations ruled in Better Business Bureau, supra, and Schoger Foundation v. Commissioner, supra, because your activities serve substantial nonexempt purposes and because you have failed to establish that you are organized or operated exclusively for the benefit of public interests rather than those of your sponsors. Six of your seven studies are involved in drug testing and evaluations for the sponsoring pharmaceutical companies. Even the one that is not involved in a clinical study does not even further the exempt purposes because you are contracted to identify patients for a research company and you list a pharmaceutical company as the sponsor.

Unlike IIT Research Institute v. United States, supra, you conduct clinical research mainly to study the safety and effectiveness of different drugs for commercial purposes on behalf of the pharmaceutical companies.

Your benefits to U and the commercial sponsors outweigh any public benefits that you may provide. Although participants in your research studies on hepatitis B and encephalopathy may be deemed beneficial by not having to pay for their medications during the clinical trials, the results of your studies serve private interests other than incidentally. Thus, you are not entitled to exemption. See American Campaign Academy v. Commissioner, supra.

Applicant's Position

You have indicated that you qualify for exemption because you believe that U and the sponsors do not directly benefit from your activities.

Service Response to Applicant's Position

In the contrary, the primary beneficiaries of your research program are U and the pharmaceutical companies. U directly benefits from your activities because you are formed to obtain funding for his research. The pharmaceutical companies directly benefit from your activities because they develop and pay you for the studies and retain ownership of the results. Any public benefits that may be derived from your research results now or later give no comfort to the facts that you privately serve your researcher U and sponsoring pharmaceutical companies that own the intellectual property rights to your research. Such private interest goes beyond the description of section 501(c)(3). Thus, your research is not considered scientific research as described in section 501(c)(3) as stated in the regulations.

Conclusion

Based on the facts and information submitted, you are not operated exclusively for exempt purposes. Your operations further a substantial nonexempt business purpose and the private interests of private parties. Therefore, you are not described in section 501(c)(3) of the Code.

You have the right to file a protest if you believe this determination is incorrect. To protest, you must submit a statement of your views and fully explain your reasoning. You must submit the statement, signed by one of your officers, within 30 days from the date of this letter. We will consider your statement and decide if the information affects our determination. If your statement does not provide a basis to reconsider our determination, we will forward your case to our Appeals Office. You can find more information about the role of the Appeals Office in Publication 892, Exempt Organization Appeal Procedures for Unagreed Issues.

An attorney, certified public accountant, or an individual enrolled to practice before the Internal Revenue Service may represent you during the appeal process. If you want representation during the appeal process, you must file a proper power of attorney, Form 2848, Power of Attorney and Declaration of Representative, if you have not already done so. You can find more information about representation in Publication 947, Practice Before the IRS and Power of Attorney. All forms and publications mentioned in this letter can be found at www.irs.gov, Forms and Publications.

If you do not file a protest within 30 days, you will not be able to file a suit for declaratory judgment in court because the Internal Revenue Service (IRS) will consider the failure to appeal as a failure to exhaust available administrative remedies. Code section 7428(b)(2) provides, in part, that a declaratory judgment or decree shall not be issued in any proceeding unless the Tax Court, the United States Court of Federal Claims, or the District Court of the United States for

the District of Columbia determines that the organization involved has exhausted all of the administrative remedies available to it within the IRS.

If you do not intend to protest this determination, you do not need to take any further action. If we do not hear from you within 30 days, we will issue a final adverse determination letter. That letter will provide information about filing tax returns and other matters.

Please send your protest statement, Form 2848, and any supporting documents to the applicable address:

Mail to:

Internal Revenue Service
EO Determinations Quality Assurance
Room 7-008
P.O. Box 2508
Cincinnati, OH 45201

Deliver to:

Internal Revenue Service
EO Determinations Quality Assurance
550 Main Street, Room 7-008
Cincinnati, OH 45202

You may fax your statement using the fax number shown in the heading of this letter. If you fax your statement, please call the person identified in the heading of this letter to confirm that he or she received your fax.

If you have any questions, please contact the person whose name and telephone number are shown in the heading of this letter.

Sincerely,

Rob Choi
Director, Exempt Organizations
Rulings & Agreements

Enclosure, Publication 892