

Internal Revenue Service

Department of the Treasury

District
Director

1100 Commerce St., Dallas, Texas 75242

Date: NOV 24 1995

Employer ID Number:
[REDACTED]

Person to Contact:
[REDACTED]

Telephone Number:
[REDACTED]

Refer Reply To:
[REDACTED]

Dear Sir or Madam:

We have considered your application for recognition of exemption from Federal income tax under section 501(c)(3) of the Internal Revenue Code.

You were incorporated as a nonprofit corporation in the State of [REDACTED] on [REDACTED]. According to your Articles of Incorporation you were formed exclusively for educational purposes within the meaning of section 501(c)(3) of the Internal Revenue Code. Your application for exemption indicates you were formed as an entity to do research by the physicians of [REDACTED] and that the research will involve treatment modalities for various diseases of the musculoskeletal system. All of the members of your Board of Directors are physicians with [REDACTED]

The information submitted with your application describes [REDACTED] drug studies or research projects which you are conducting or soon will be. Two of the studies compare the effectiveness of [REDACTED], brand name [REDACTED], to [REDACTED] and [REDACTED] for pain associated with arthritis of the hip or knee. Those two studies are sponsored by [REDACTED], the pharmaceutical company which makes [REDACTED]. Another drug study, also sponsored by [REDACTED], is to compare the effectiveness of a drug called [REDACTED] to [REDACTED] for postoperative orthopedic pain. An additional drug study, sponsored by [REDACTED], formerly [REDACTED] evaluates the effect of a new drug called [REDACTED] on the transfusion requirements and blood loss in patients undergoing hip replacement surgery. These drug studies are initiated by the drug companies and the drug companies establish and dictate the protocol. If the patients are paid for their participation in the studies, they are paid by the drug companies. The data generated by the studies is the property of the drug companies. However, investigators are allowed to publish the results in medical journals. A fifth study, called a patient satisfaction survey, is being conducted to determine patient satisfaction with the services provided by [REDACTED]. Questionnaires are distributed to patients and the data will be used to identify and improve areas which receive satisfaction ratings. Another study involved determining the effectiveness of braces in the treatment of osteoarthritis of the knee. The study is sponsored by [REDACTED], a brace manufacturer, and [REDACTED] braces are used in the study. Two other studies involve the use of cell saver blood and predonation of blood for elective hip and knee arthroplasty to determine which is more effective, and a carpal tunnel

[REDACTED]

syndrome study the results of which will be used in patient education and rehabilitation. A study called the [REDACTED] Study, sponsored by [REDACTED], is being done to measure the patient outcomes of patients treated by [REDACTED] to evaluate and improve the patient care provided by them. The final study described by you is one sponsored by [REDACTED] for the purpose of determining whether individual or group therapy after total hip arthroplasty is more cost effective or produces the best outcome.

Until you are able to afford your own facility, either the [REDACTED] or [REDACTED] may provide space. Some [REDACTED] personnel may be provided at no cost. You indicate that, while most of your initial funding will come from companies sponsoring pharmaceutical research, you anticipate that grants and donations will be obtained from other nonprofit entities and from individuals.

Section 501(c)(3) of the Code provides for the exemption from federal income tax of organizations that are organized and operated exclusively for charitable and scientific purposes.

Section 1.501(c)(3)-1(d)(1)(ii) of the Income Tax Regulations provides that an organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a private purpose. 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)(i) of the regulations in defining the term "scientific" provides that since an organization may meet the requirements of section 501(c)(3) only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations further provides that scientific research does not include activities of a type ordinarily carried on as incidental to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products.

Revenue Ruling 68-373, 1968-2 C.B. 208, illustrates the above. In that ruling, it was held that an organization which primarily engaged in testing drugs for commercial pharmaceutical companies did not qualify for exemption under section 501(c)(3) of the Code. The organization's principal activity was the clinical testing of drugs for pharmaceutical companies. The testing was required to comply with FDA requirements that drugs be tested for safety and efficacy before they can be marketed. The pharmaceutical companies selected the drugs to be tested and the results were freely available for publication. All of the organization's income was derived from the pharmaceutical companies in payment for testing services. The ruling held that the clinical testing of drugs is an activity ordinarily carried on as incidental to a pharmaceutical company's commercial operations. It further held that the clinical testing of a drug for safety and efficacy in order to meet FDA requirements for marketing principally serves the private interest of the manufacturer rather than the public interest. Accordingly, because the organization served a private interest rather than a public interest, the organization failed to qualify for 501(c)(3) exemption.

In your case, we believe the clinical drug-testing you engage in serves the

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[REDACTED]

commercial interests of the sponsoring pharmaceutical companies. The purpose of the first three studies described above is to compare the effectiveness of the sponsor's drug with others. The fourth study, the [REDACTED] study, is conducted to determine the effectiveness of the drug when used in connection with certain surgery. This drug testing is done to enable the pharmaceutical company to more effectively market their products. If it can be shown that their product performs better than other brands, they can market their product on that basis. Further, if drug studies can demonstrate a broader effectiveness or use for the drug, the greater its marketability. Although the drugs you are testing already have FDA approval, we believe your drug testing is conducted in the same manner and for the same purpose as the organization described in Revenue Ruling 68-373, supra. You are providing a service for the pharmaceutical companies which is incidental to their commercial operations and to the marketing of their products. Clinical testing to determine the efficacy of the drugs serves the private interests of the pharmaceutical companies rather than an exclusively public purpose and is not scientific research within the meaning of section 1.501(c)(3)-1(d)(5)(ii) of the regulations.

Additionally, we also believe your Patient Satisfaction Survey clearly serves the private interest of [REDACTED]. The purpose of the study is to improve their operating efficiency in all areas. The study was to measure customer satisfaction with physicians, office personnel, the business office, and the timeliness of services. The data would be used to identify and improve areas which receive low ratings. It should be noted that [REDACTED] is comprised of [REDACTED] collaborative orthopedic group practices, totaling [REDACTED] physicians in all. Likewise, we believe the Study benefits [REDACTED] in that it serves to improve their operating efficiency in particular rather than to improve medical care in general.

Accordingly, because we have determined that your activities serve substantial private interests, tax-exemption under section 501(c)(3) of the Code is denied. You should file federal income tax returns.

If you do not agree with these conclusions, you may, within 30 days from the date of this letter, file in duplicate a brief of the facts, law, and argument that clearly sets forth your position. If you desire an oral discussion of the issue, please indicate this in your protest. The enclosed Publication 390 gives instructions for filing a protest.

If you do not file a protest with this office within 30 days of the date of this report or letter, this proposed determination will become final.

If you do not protest this proposed determination in a timely manner, it will be considered by the Internal Revenue Code as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Internal Revenue Code provides in part that, "A declaratory judgment or decree under this section shall not be issued in any proceeding unless the Tax Court, the Court of Claims, or the district court of the United States for the District of Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service."

If this determination letter becomes a final determination, we will notify the appropriate State Officials, as required by section 6104(c) of the Code, that

[REDACTED]

based on the information we have, we are unable to recognize you as an organization of the type described in Code section 501(c)(3).

If you agree with these conclusions or do not wish to file a written protest, please sign and return Form 6018 in the enclosed self-addressed envelope as soon as possible.

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

Sincerely,

[REDACTED]

[REDACTED]

District Director

Enclosures:
Publication 892
Form 6018