

Schaner & Lubitz, PLLC

Venture Philanthropy Legal Report Winter 2010 #2:

Everything You Ever Wanted To Know About Venture Philanthropy Transactions But Were Afraid To Ask

Since 1989, we have closed many transactions for disease foundation clients in the field that has come to be known as Venture Philanthropy. Though each charity and transaction have unique aspects, there are some issues that are either regularly raised by new entrants or continue to be the subject of discussion among experienced participants. In this article, we discuss many of these issues in a question and answer format.

We hope that this discussion helps you decide whether your organization should enter the field of Venture Philanthropy or, if you have already done so, we hope that this discussion informs your new transactions. Please feel free to contact us with any questions you may have about the unique aspects of your organization or deal.

1. CAN 501(c)(3) ORGANIZATIONS MAKE FINANCIAL INVESTMENTS IN FOR-PROFIT COMPANIES?

YES. The two basic limitations on 501(c)(3) investments in for-profit companies are (1) the purpose of the award must be consistent with the charitable or scientific purpose of the organization making the investment, and (2) the awardee must not be a “disqualified person” with respect to the awarding entity.

The tax regulations specifically identify scientific research for the purpose of discovering a cure for a disease as an appropriate tax-exempt purpose. Nevertheless, analysis of a particular transaction is appropriate to ensure that the investment is for the purpose of discovering a cure for a disease, and not for the purpose of ordinary commercial or industrial testing, which could disqualify the transaction from furthering the entity’s tax exempt purposes. Also, an entity engaging in venture philanthropy should take care that the purposes for which it is organized, which are defined in the entity’s organizing documents, contemplate engagement in the venture philanthropy field.

A disqualified person, defined in the tax code and regulations, is an individual or organization that is affiliated with the 501(c)(3) organization in a way that permits the disqualified person to exercise influence over decisions made by the 501(c)(3) organization. Transactions that involve such disqualified persons must be avoided.

2. SHOULD CHARITIES ESTABLISH AN AFFILIATE THROUGH WHICH TO CONDUCT ITS VENTURE PHILANTHROPY ACTIVITIES?

[A QUALIFIED] YES. Venture philanthropy as it relates to drug development and clinical trials increases liability risk. There are a variety of measures that investing organizations may take to mitigate that risk, such as obtaining insurance, ensuring appropriate informed consent and taking a mostly passive role in the project. However,

venture philanthropy investors, like all investors, want to maximize the chances for success, and they often seek to do so by lending their scientific expertise by assisting in the development of protocols and participating on project committees. Forming an affiliate controlled by a disease foundation is a means by which the foundation may perform these functions without risking the assets of the parent entity if such activities cause a claim or lawsuit.

One note of mild caution is in order: even though it is simple to do, forming an affiliate adds some operational complication. The affiliate must maintain a separate identity. Among other things, the affiliate must have a separate governing body, books and records, separate stationery and cards for employees, separate web sites and separate press releases. In short, the affiliate and the parent must be truly separate corporate entities. On balance, we believe that separate entity creation is prudent, and, with the proper guidance on an operational level as to how the parent and affiliate should maintain their separate identities, the affiliate can be maintained with a minimum of disruption to the other charitable activities of the parent organization.

3. WHAT CORPORATE FORM SHOULD AN AFFILIATE TAKE?

AN LLC. We usually recommend a limited liability company (LLC), because an LLC affords the limited liability protection sought by most disease foundations, and it also has the advantage of automatically deriving its federal tax status from its exempt parent without an additional request to the Internal Revenue Service (IRS) for tax exempt status. Such a wholly owned entity is referred to in IRS regulations as a “disregarded entity.” Though disregarded for tax purposes, such an entity is not disregarded for corporate purposes and can afford important liability protection. Donations made to the LLC are deductible in the same way that donations to the parent are deductible. An LLC must be 100% owned by its parent if it wants to derive its tax status from its parent. We recommend structuring the LLC so that it has separate director and officers, but a majority of such directors should also be members of the board of the parent organization.

4. SHOULD A CHARITY REQUIRE ROYALTIES OR ANOTHER EMOLUMENT FROM COMPANIES IN WHICH IT INVESTS?

[A QUALIFIED] YES. Although there is a difference of opinion among participants in the field, most charities have concluded that they should receive a return. Those who do not seek a return believe that such payments are speculative and detract from the real goal of a venture philanthropy project—the advancement of scientific research. Those who believe that no return should be required would rather exact other promises from the companies in which they invest, such as greater sharing of research materials among scientists.

In the end, the answer to this question mostly involves a business, not a legal judgment. On balance, we believe that a fair return is justified. Venture philanthropy helps to fill the gap in investment capital that occurs because commercial investors have decided that the science is not sufficiently developed, or the consumer pool is not sufficiently large, to

justify risking capital. Venture philanthropists and the biotechnology companies that seek such capital disagree. A venture philanthropist that chooses its investments wisely and that insists on a fair return can utilize any return to invest in additional cures and therapies, thus furthering its charitable purposes and the advancement of science. Especially, at a time when charitable fundraising is difficult, such returns also offer promise that charitable donations might some day be supplemented. Several of our clients have phase 2 and 3 drugs that could soon offer returns that could be used to stimulate the invention of new and better drugs.

Once a charity decides that it wants to take a return from a company in which it invests, legal skill must be activated to ensure that the return is properly classified as a royalty or similar return and thus exempt from taxation. In addition, other business judgments, such as what is a fair return and how should the return be triggered, also become relevant.

5. IF ROYALTIES ARE REQUESTED, WHAT FORM SHOULD THEY TAKE?

Royalties can be paid in a lump sum, periodically, or as a percentage of Net Sales (a term that may be defined by the parties to the transaction, but which has a customary definition). When we request royalties on behalf of a client, we know from long experience that royalties are one of three or four issues that take the longest to negotiate.

Since scientific development is the principal purpose of these transactions, usually there is a need to get the scientists working as quickly as possible. With this in mind, on smaller awards, we generally recommend that the return be fashioned as a multiple of the award. The specific multiple depends on when in the scientific development process the award is made—the earlier the award, the greater the risk that the investing charity will receive no scientific or monetary return; thus, a higher multiple is warranted. In our experience, the range generally accepted by small awardees has been between three and six times the amount of the award, with a bonus multiple for particularly successful sales.

For larger awards, a percentage of Net Sales is often appropriate. For such larger awards, the percentage range varies depending on the size of the award, its timing, and the type of therapy being sought and the size of the potential market. Compounds demand a considerably higher percentage than devices.

Awardees frequently will sublicense an invention or product before it is commercialized. Accordingly, we invariably request a percentage of any license payment received by an awardee for any license payments received by the awardee. For the same reasons that we recommend a return in the first place, it is entirely appropriate that a charity also should share in these early rewards. Indeed, the risk that a product at this stage never will be commercialized is often still high so that a royalty from Net Sales may never be realized, making a payment triggered by license the only return that a charity may see in connection with its investment.

6. WHAT PROTECTION SHOULD YOU DEMAND AGAINST THE AWARDEE CEASING ITS DEVELOPMENT SOLELY FOR BUSINESS REASONS?

AN INTERRUPTION LICENSE. Investing charities should anticipate exposure to substantial scientific risk, but such risk should not be sustained for any awardee that decides to abandon the project for a more attractive one. Accordingly, we usually recommend that charities seek an Interruption License to guard against a continued cessation of the research project.

Since this is another area in which the corresponding negotiation takes time, skill and effort, we sometimes are asked whether an Interruption License is worth the effort. In addition to the risk associated with not obtaining such a license that we have described above, we offer the following responses. First, we have successfully negotiated Interruption Licenses in the overwhelming majority of the venture philanthropy transactions on which we have worked—therefore, they are attainable. Second, we have had two instances in the past twelve months in which promising research has been interrupted for economic reasons, which is not surprising in this economy. In both instances our client has been able to activate its Interruption License and save the promise of the potential therapy involved. In short, the effort is worth it.

7. WHAT OTHER LEGAL PROTECTIONS SHOULD A CHARITY REQUIRE IN VENTURE PHILANTHROPY TRANSACTIONS?

An investing charity should ensure that it receives indemnification from awardees against claims or lawsuits arising from the work performed by them, and the charity should require evidence of its awardees' subscription to an appropriate amount and type of insurance such that the investor will receive comfort that the awardee can defend and pay for any liability it incurs in connection with its work.

Even though there are not many incidents in which charities have been sued for damages associated with the results of a drug research project, a claim or lawsuit can happen, and the associated liability could be significant or even crippling, Indemnification is appropriate and necessary to ensure the survival of the entity engaging in the investment. Entities that engage in venture philanthropy are, as already discussed, generally passive participants, but when they engage in activities related to the development of a protocol or participate in a project advisory committee liability risks increase. Indemnification backed by insurance should be a prerequisite before engaging in a transaction.

8. ARE THERE OTHER FACTORS THAT SHOULD BE CONSIDERED WHEN ENGAGING IN VENTURE PHILANTHROPY TRANSACTIONS?

YES. As we said at the beginning, each charity and venture philanthropy transaction is unique. It is impossible to predetermine all of the factors that may arise. We have done many of these transactions, and in each one there has been one or more (sometimes many more) issues that have arisen which are somewhat unique. We recommend that you

examine each transaction anew, with the above-imparted information in mind. If you think that your unique issues can benefit from our advice and representation, we would be happy to consult with you.

About the authors

Ken Schaner has practiced law for more than 40 years. He began his legal career at the Internal Revenue Service, where he was part of the team that drafted the 1969 amendments to the tax code pertaining to exempt organizations. He was a founding partner of Swidler & Berlin, where he also served as managing partner and head of the corporate practice, and then a partner at Bingham McCutchen before founding Schaner & Lubitz, PLLC.

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