TAX EXEMPT AND
GOVERNMENT ENTITIES

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

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Contact Person:

ID Number:

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In reply refer to:
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E.I.N.

Dear :

You request rulings under sections 4942 and 4945 of the Internal Revenue Code involving the making of grants, contracts, or program-related investments with private industry for the purposes described in this ruling request ("Transactions").

Facts

You are exempt under section 501(c)(3) of Code and are classified as a private foundation.

One of your primary objectives is to reduce global health inequities by accelerating the discovery, development and adoption of health interventions that save lives and dramatically reduce the disease burden in developing countries. These health interventions take the form of disease specific tools (disease specific vaccines, drugs, diagnostics, etc.) built from health technology platforms appropriate for health care settings in the developing world. You accomplish these objectives by supporting the following activities: (i) discovery and invention essential for solving global health problems *("discovery")*; (ii) development (including testing) of specific medical tools and technologies ("Solutions") to establish proof of efficacy and effectiveness *("development")*; and (iii) testing and proving the value of appropriate Solution access strategies, including systems innovations to promote the adoption of improved health interventions in order to have a lasting health impact within developing countries *("adoption")*.

Specifically, the Transactions will be structured to stimulate private industry to create answers for health problems that disproportionately affect the developing world in order to further your charitable goals of (i) accelerating the prevention, elimination, or

eradication of diseases that disproportionately impact the developing world and (ii) increasing the availability of Solutions in low-resource settings.

You state discovery, development and adoption activities for innovations in health care Solutions follow a cycle (the "Innovation Cycle"). You have further determined to save lives and dramatically reduce the disease burden and inequities within developing countries, you must intervene in each of the three stages of this Innovation Cycle.

Stage One of the Innovation Cycle includes both basic research and applied research and development to the point of proof of principle at both the level of the platform health technology as well as the disease specific tool so as to determine the potential appropriateness of that tool for the target population.

Stage Two of the Innovation Cycle involves testing at various phases to support licensure by the U.S. Food and Drug Administration ("FDA") or other appropriate regulatory agency(ies), which is required before any tool may be delivered to the public, whether commercially or non-commercially.

Stage Three of the Innovation Cycle is the production and delivery of the new Solution.

You currently make grants to the government, nonprofit and academic sectors to further your charitable goals. While grants to these types of organizations produce important results, you determined that for charitable goals to be achieved, it is also essential to engage private industry directly. You state for many global health problems sustainable Solutions for use in the developing world are frequently held within private industry, but are largely undeveloped. To stimulate the participation of private industry in developing Solutions for the developing world, you determined you must directly engage commercial pharmaceutical and biotechnology companies to discover, develop and deploy Solutions addressing the diseases that disproportionately impact the developing world.

You will specifically target diseases that disproportionately afflict populations within developing countries. The target disease categories are as follows: Category I Diseases are those that are almost exclusively incident in developing countries. Category II Diseases are incident in both developed and developing countries, but the vast majority of cases occur in developing countries. Category III Diseases are also incident in both developed and developing countries, but with large numbers of vulnerable people in each.

You state you will only enter into a Transaction if the proposal (a) supports the discovery or development of Solutions essential to solving major global health problems and inequities, (b) facilitates the adoption of such Solutions in developing countries, or (c) enables the availability of such Solutions on an affordable basis to those people otherwise without access within developing countries.

You will select potential Transaction candidates for in-depth evaluation. Potential Transaction candidates will submit complete project proposals that include: a description of the project sufficient to confirm that it will further a charitable objective. Proposals are evaluated by your program staff and by independent external experts. You will evaluate each candidate and proposal in the context of your policy that addresses intellectual property and global access concerns (the "Global Access Policy"). The primary purpose of your Global Access Policy is to anticipate a strategy for making the intended Solutions readily available at affordable prices to those otherwise without access within the developing world and to increase the availability of Solutions in low-resource settings.

You will in order to accelerate the prevention, elimination, or eradication of diseases that disproportionately impact the developing word conduct appropriate due diligence to (i) evaluate the ownership and anticipated development associated with each Solution and the related intellectual property rights and (ii) confirm the grantee has developed a global access plan that outlines a reasonable strategy and principles for managing innovations for the purpose of facilitating the future availability and affordability in the developing world of the potential resulting Solutions. You will require the results of the early stage research for which a global access plan is unreasonable or impractical to be published in a treatise, thesis, trade publication, or in any other form that is available for the interested public.

You will conduct a pre-grant inquiry, consistent with section 53.4945-5(b)(2) of the Income Tax Regulations, to give a reasonable person assurance that the grantee will use the grant funds solely for the intended purposes. Each Transaction will be governed by an agreement that establishes its terms and conditions. You will exercise expenditure responsibility as provided in section 4945(h) of the Code with respect to Transactions structured as grants or program-related investments, and will require each company to hold funds in a separate fund as provided in section 53.4945-6(c)(2)(i) of the regulations. The Transaction agreements will establish reporting procedures to permit you to monitor use of Transaction funds and the progress made toward the purposes of the project.

RULINGS REQUESTED

You request the following rulings:

1. The Transactions will constitute qualifying distributions for purposes of section 4942(g) of the Code.

2. The Transactions will not constitute taxable expenditures for purposes of section 4945(d)(5) of the Code.

LAW

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, scientific, educational, or testing for public safety purposes no part of the net earnings of which inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(d)(2) of the regulations provides the term "charitable" as used in section 501(c)(3) of the Code includes relief of the poor and distressed or of the underprivileged, advancement of science, combating community deterioration or lessening the burdens of government.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations provides an organization organized and operated for scientific purposes can qualify under section 501(c)(3) of the Code only if it serves a public rather than a private interest. See section 1.501(c)(3)-1(d)(5)(iii) and (iv).

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

Section 1.501(c)(3)-1(d)(5)(iii) of the regulations provides scientific research will be regarded as carried on in the public interest if –

(a) The research results "including any patents, copyrights, processes or formulae . . . are made available to the public on a nondiscriminatory basis;"

(b) The research is carried out for the United States, or any of its agencies or instrumentalities, or for a state or a political subdivision thereof; or

(c) The research "is directed toward benefiting the public." The regulations provide the following four examples of research that benefits the public, to include research that is:

(1) intended to aid in the scientific education of college or university students;

(2) published in a form that is "available to the interested public;"

(3) carried on for the purpose of discovering a cure for a disease; *or*

(4) carried on for the purpose of aiding a geographical area by attracting, developing, or retaining industry in the area.

Section 1.501(c)(3)-1(d)(5)(iv) of the regulations provides an organization will not be regarded as organized and operated for the purpose of carrying on scientific research in the public interest if either (or both) of the following two conditions is true:

- *Condition 1:* The organization conducts research only for persons who are directly or indirectly its creators, if such persons are not section 501(c)(3) organizations.
- *Condition 2:* The organization (1) directly or indirectly retains "ownership or control of more than an insubstantial portion of the patents, copyrights, processes, or formulae" that result from its research activities, *and* (2) "does not make such patents, copyrights, processes, or formulae available to the public" on a nondiscriminatory basis. However, the organization may satisfy the public availability requirement through an exclusive license of its intellectual property if an exclusive license "is the only practicable manner" to ensure that the intellectual property will be used to benefit the public.

Section 170(c)(2)(B) of the Code describes a corporation, trust, or community chest,

fund, or foundation organized and operated exclusively for religious, charitable, scientific, literary, or educational purposes, or to foster national or international amateur sports competition, or for the prevention of cruelty to children or animals.

Section 4942(a) of the Code imposes an excise tax on the undistributed income of a private foundation. "Undistributed income" is defined, in part, as the amount by which a private foundation's qualifying distributions are less than the foundation's minimum investment return.

Section 4942(g)(1)(A) of the Code defines a "qualifying distribution" to mean any amount (including that portion of reasonable and necessary administrative expenses) paid by a private foundation to accomplish one or more purposes described in section 170(c)(2)(B) of the Code (other than contributions to organizations controlled by the foundation or to non-operating foundations unless certain requirements are met).

Section 53.4942(a)-3(a)(2) of the regulations defines the term "qualifying distribution" as any amount (including program related-investments, as defined in section 4944(c), and reasonable and necessary administrative expenses) paid to accomplish one or more purposes described in section 170(c)(1) or 170(c)(2)(B) of the Code.

Section 4945 of the Code imposes an excise tax on each taxable expenditure made by a private foundation.

Section 4945(d)(4) of the Code defines a taxable expenditure to include any amount paid or incurred by a private foundation as a grant to an organization unless such organization is described in paragraph (1), (2) or (3) of section 509(a) or is an exempt operating foundation (as defined in section 4940(d)(2)), or unless the private foundation exercises expenditure responsibility with respect to such grant in accordance with section 4945(h) of the Code.

Section 4945(d)(5) of the Code defines a taxable expenditure to include any amount paid or incurred by a private foundation for any purpose other than one specified in section 170(c)(2)(B) of the Code.

Section 53.4945-6(b)(1)(v) of the regulations confirms that a payment is not treated as a taxable expenditure if it constitutes a qualifying distribution under section 4942(g) of the Code.

In *ITT Research Institute v. U.S.*, 9 Cl. Ct. 13 (1985), the court found research is scientific when it (i) involves observations or experimentation to formulate or verify facts or natural laws; (ii) adds to knowledge within the medical field; or (iii) can only be performed by individuals with advanced scientific or technical expertise.

Revenue Ruling 68-373, 1968-2 C.B. 206, the Service ruled that an organization whose primary activity was clinically testing drugs for commercial pharmaceutical companies to comply with the Food and Drug Administration's requirements that drugs be tested for safety and efficacy before they can be marketed was not engaged in scientific research.

Rev. Rul. 76-296, 1976-2 C.B. 142, states commercially sponsored research otherwise

qualifying as scientific research under section 501(c)(3) of the Code, the results of which, including all relevant information, are timely published in such form as to be available to the interested public, constitutes scientific research carried on in the public interest. However, research, the publication of which is withheld or delayed significantly beyond the time reasonably necessary to establish ownership rights, however, is not in the public interest and constitutes the conduct of unrelated trade or business within the meaning of section 513.

ANALYSIS

You will enter into Transactions to promote or accelerate scientific research and development of Solutions to prevent, eliminate, or eradicate diseases disproportionately impacting the developing world and to increase the availability of Solutions in low-resource settings. As a result, the Transactions will further your charitable and scientific purposes within the meaning of sections 170(c)(2)(B) and 501(c)(3) of the Code.

The term "scientific" includes "scientific research" carried on in the public interest. See section 1.501(c)(3)-1(d)(5)(i) of the regulations. An activity is scientific research in the public interest if (1) it is scientific; (2) it is research; and (3) it is in the public interest. Section 1.501(c)(3)-1(d)(5)(i) states the determination of whether research is "scientific" for purposes of section 501(c)(3) does not depend on whether such research is classified as "fundamental" or "basic" as contrasted with "applied" or "practical". The research you will fund will be scientific because: it will involve observations or experimentation to formulate or verify facts or natural laws; it will add to knowledge within the medical field; and can only be performed by individuals with advanced scientific or technical expertise. See *ITT Research Institute*, supra.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations state scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products. The information you submitted indicates the research you will fund will not be carried on pursuant to commercial or industrial operations. Further, the facts submitted indicate the Stage Two Innovation Cycle research you will fund involving FDA requirements will not be your primary activity. See Rev. Rul. 68-373, supra.

The scientific research funded by your Transactions will be carried on in the public interest because it will be directed toward benefiting the public. First, as part of each Transaction for early stage research, the researcher will be required to adequately and timely publish its research results, disclosing substantially all information concerning the research results that would be useful and beneficial to the interested public. See section 1.501(c)(3)-1(d)(5)(iii) of the regulations. The researchers will be required to comply with the timing guidance set out in Rev. Rul. 76-296, supra, with respect to when research results must be made available. Second, scientific research funded by your Transactions will be directed toward discovering the cure for, curing, or eliminating a disease. See 1.501(c)(3)-1(d)(5)(iii)(c)(3) of the regulations. Thus, Transactions will be in the public interest.

Because the Transactions for research will be scientific, research and in the public interest, the Transactions will be "scientific" within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations. Accordingly, such grants further a scientific purpose within the meaning of section 501(c)(3) of the Code. Thus, the Transactions will constitute qualifying distributions for

purposes of section 4942(g) because the Transactions will accomplish one or more purposes described in section 170(c)(2)(B). Similarly, the Transactions will not constitute taxable expenditures for purposes of section 4945(d)(5) of the Code because the Transactions will be for section 170(c)(2)(B) purposes.

CONCLUSION

A. The Transactions will constitute qualifying distributions for purposes of section 4942(g) of the Code.

B. The Transactions will not constitute taxable expenditures for purposes of section 4945(d)(5) of the Code.

Pursuant to a Power of Attorney on file in this office, a copy of this letter is being sent to your authorized representative. This ruling letter does not address the applicability of any section of the Code or regulations to the facts submitted other than with respect to the sections described.

This ruling letter is directed only to the organizations that requested them. This ruling letter supersedes our ruling letter dated October 3, 2005. Section 6110(k)(3) of the Code provides that they may not be used or cited as precedent.

This ruling will be made available for public inspection under section 6110 of the Code after deletions of identifying information are made. For details, see enclosed Notice 437, Notice of Intention to Disclose. A copy of this ruling with deletions that we intend to make available for public inspection is attached to Notice 437. If you disagree with our proposed deletions, you should follow the instructions in Notice 437.

Please keep a copy of this ruling letter in your permanent records.

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

Sincerely yours,

Lawrence M. Brauer
Acting Manager,
EO Technical
Technical Group 1

Enclosure: Notice 437