

JUNE 30, 2010

## Reminder: Applications under the \$1 Billion Qualifying Therapeutic Discovery Project Program Due July 21, 2010

BY JONATHAN T. CAIN AND TRAVIS L. BLAIS

The IRS recently announced that firms may begin applying for certification for tax credits or grants available under the Qualifying Therapeutic Discovery Project Program. In recent advisories, we reported that the Patient Protection and Affordable Care Act (aka the health care reform bill) includes \$1 billion in tax credits and grants to defray the costs of therapeutic research for small and mid-size life sciences companies, including drug, therapeutic, and diagnostic companies. The new, temporary program offers a choice between an income tax credit and a cash grant (not to exceed \$5 million per company) for up to 50% of a company's costs paid or incurred in 2009 and 2010 and directly related to a "qualifying therapeutic discovery project" (QTDP).

### Timeline for Application, Review, and Certification

[Form 8942](#), Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program, and its [instructions](#) are now available. The Project Information Memorandum, the form for which is found at <http://grants.nih.gov/grants/> is used to describe scientific details of the project. There is only a *one-month* application window; applications must be postmarked no later than July 21, 2010. The IRS will conduct a preliminary review of all timely filed applications by September 30, 2010 to eliminate applications that are incomplete or from unqualified taxpayers. The IRS will issue certification notices to recipients by October 29, 2010.

### Application Process

Companies must submit a separate application for each QTDP for which they seek a credit or grant (multiple applications are permitted). A complete application will consist of three components:

- an IRS Form 8942,
- a Project Information Memorandum, and
- a consent to disclose certain information to permit publication of

*For further information regarding this or any issue related to Health Care Reform, please contact one of the professionals listed below or the Mintz Levin attorney who ordinarily handles your legal affairs.*

#### Life Sciences

William T. Whelan  
*Co-Chair, Life Sciences Practice*  
(617) 348-1869  
WWhelan@mintz.com

Jeffrey M. Wiesen  
*Chair, Biotechnology Practice*  
(617) 348-1759  
JWiesen@mintz.com

Joel I. Papernik  
*Co-Chair, Mergers and Acquisitions Practice*  
(212) 692-6774  
JIPapernik@mintz.com

Lewis J. Geffen  
*Member*  
(617) 348-1834  
LJGeffen@mintz.com

Stanford N. ("Ford") Goldman, Jr.  
*Member*  
(617) 348-1708  
FNGoldman@mintz.com

Ivor R. Elrifi, Ph.D.  
*Co-Chair, Intellectual Property Practice*  
(617) 348-1747  
IRElrifi@mintz.com

Brady Berg  
*Member*  
(650) 251-7758  
BBerg@mintz.com

Lance S. Kurata  
*Member*  
(858) 314-1525  
LKurata@mintz.com

information concerning program awards.

The Form 8942 requires information about the company's ownership, number of employees working on the QTDP, basic information about the status of the QTDP, and information concerning the company's qualified investments for 2009 and 2010, including salary costs, lab costs, contractor costs, and other qualified investments.

The IRS will review the Form 8942 to determine which projects (1) have the greatest potential to create and sustain high-quality, high-paying jobs in the U.S., (2) have the greatest potential to advance U.S. competitiveness in the life, biological, and medical sciences, and (3) have the greatest potential to produce a new or significantly improved technology as compared to existing commercial technologies, and will lead to the construction or use of a production facility in the U.S. within the next five years.

The Department of Health and Human Services (HHS) will review the Project Information Memorandum to determine whether a project meets the definition of a QTDP and shows a reasonable potential to meet one or more of the goals specified in the statute. As we previously reported, a QTDP is a project designed to achieve any of the following objectives:

- To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, or clinical studies, or carrying out research protocols. To satisfy this objective, the project must be for the purpose of obtaining approval of a project under one of two statutory provisions: Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (a new drug application) or Section 351(a) of the Public Health Service Act (PHSA) (a biologic license application). For example, a medical countermeasure against a known threat or emerging infectious disease that is developed for the purpose of securing approval under one these provisions would satisfy this objective. However, generic drugs, which are approved under Section 505(j) of the FFDCA, and biosimilar projects, which are approved under Section 351(k) of the PHSA, would be excluded. Dietary supplements and most cosmetics would also be excluded because they are generally not the subject of a new drug or biologic license application.
- To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions. The IRS guidance explains that this might include, for example, a test that would determine which patients with a particular disease or condition would be likely to respond best to a particular drug or device. But any project that diagnoses a disease or condition would meet this criterion, whether or not it determines molecular factors or is a molecular diagnostic. Thus, relevant products would include point of care diagnostics for infectious agents.
- To develop a product, process, or technology to further the delivery or administration of therapeutics. The IRS guidance notes that the term "therapeutics" is narrower than the term "therapy," and means drugs or medical devices, as those terms are defined in Section 201(g) and (h) of the FFDCA. Thus, a drug-eluting stent or infusion pump would be an example of a product that furthers the delivery or administration of therapeutics. However, products that deliver other therapies which are not therapeutics, such as speech, physical, and cognitive therapies, would be excluded.

## Government Contracts & Grants

Jonathan T. Cain  
*Member*  
(202) 585-3508  
JTCain@mintz.com

## Health Law

Karen S. Lovitch  
*Practice Leader,  
Health Law Practice*  
(202) 434-7324  
KSLovitch@mintz.com

Stephen C. Curley  
*Co-Chair, Healthcare Deal  
Lawyers Group*  
(212) 692-6217  
SCCurley@mintz.com

## Tax

Michael L. Lieberman  
*Chair, Tax Practice*  
(617) 348-1682  
MLieberman@mintz.com

Travis L. Blais  
*Associate*  
(617) 348-1684  
TLLBlais@mintz.com

[WWW.MINTZ.COM](http://WWW.MINTZ.COM)

A project must also show a reasonable potential to meet one or more of the following goals:

- To develop new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions. The therapy must be novel and cannot be the same as, or difficult to meaningfully distinguish from, a therapy currently on the market. According to the IRS guidance, unmet medical needs would include novel influenza vaccine technologies, broad spectrum anti-viral medications, novel antibiotic, and platform vaccine technologies.
- To reduce long-term health care costs in the United States.
- To significantly advance the goal of curing cancer within the next 30 years.

If HHS determines that the project meets the therapeutic goals of the statute, and the IRS determines that, compared to the submissions of other taxpayers, it is more likely to advance the employment and U.S. competitiveness goals of the statute, then a certification will be awarded.

*There is no right to appeal a denial of or the amount of a credit or grant.* Applicants must meet all qualifying requirements and demonstrate the merits of their QTDP in their initial submissions. The program is competitive. Your application will be evaluated with all others received, and only those that demonstrate both therapeutic and economic benefits for the U.S. are likely to be approved. Therefore, in addition to compiling accounting information concerning your company's investment in therapeutic technologies, it will be essential that your application for certification also demonstrates sound technical merit and a business case.

## Additional Details on Applying for a Grant

Applicants may elect to apply for a grant in lieu of a tax credit when filing the Form 8942. If a taxpayer applies for and receives certification for a credit, it may file an amended Form 8942 later if it wishes to receive a grant instead of a tax credit. If the applicant requests a grant in its initial Form 8942 and receives certification for 2009, it will receive payment of the grant by October 29, 2010. Payment of the 2010 portion of the grant will be made after close of the taxpayer's 2010 tax year. Applicants seeking grants instead of a tax credit also must obtain a DUNS number before filing their application. These are administrative steps that should be completed before filing the Form 8942. More information, including [questions and answers](#) on this program, can be found at [IRS.gov](http://IRS.gov).

Mintz Levin's health law, tax, and government grants and contracts attorneys are prepared to help you submit the most effective application for this competitive program.

\* \* \*

For up-to-date information regarding health care reform, please visit our [Health Care Reform: Analysis & Perspectives](#) page.

Please [click here](#) to learn more about our health care reform practice.

Mintz Levin Advisory

[www.mintz.com](http://www.mintz.com)

Copyright © 2010 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

This communication may be considered attorney advertising under the rules of some states. The information and materials contained herein have been provided as a service by the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.; however, the information and materials do not, and are not intended to, constitute legal advice. Neither transmission nor receipt of such information and materials will create an attorney-client relationship between the sender and receiver. The hiring of an attorney is an important decision that should not be based solely upon advertisements or solicitations. Users are advised not to take, or refrain from taking, any action based upon the information and materials contained herein without consulting legal counsel engaged for a particular matter. Furthermore, prior results do not guarantee a similar outcome.

The distribution list is maintained at Mintz Levin's main office, located at One Financial Center, Boston, Massachusetts 02111. If you no longer wish to receive electronic mailings from the firm, please visit <http://www.mintz.com/unsubscribe.cfm> to unsubscribe.

0496-0510-BOS-HCR