Jump-Starting Biomedical Research and Development: Health Care Reform Provides Tax Credits

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The Patient Protection and Affordable Care Act (Pub. L. No. 111-148), will do much to expand health insurance coverage to the majority of Americans and improve access to high quality health care services. In addition to expanding coverage and improving quality, the Qualifying Therapeutic Discovery Project Tax Credit included in the law will be a valuable tool for industry to incentivize the development of cutting edge drugs, diagnostics, biologics, and medical devices.

Qualifying Therapeutic Discovery Project Tax Credit

PPACA amends the Internal Revenue Code to create a new, temporary, qualifying therapeutic discovery project tax credit for tax years 2009 and 2010, available to companies with 250 or fewer employees. The tax credit is equal to 50% of the qualified investment for the taxable year for any qualifying therapeutic discovery project, but the total volume of tax credits to be awarded to all applicants may not exceed $1 billion for 2009 and 2010 in the aggregate.

A qualified investment means the aggregate amount of costs and expenses paid or incurred during tax years beginning in or coinciding with the 2009 and 2010 calendar years "necessary for and directly related to" the conduct of the qualifying therapeutic discovery project. It does not include certain expenses such as: salaries paid to a CEO and certain highly paid executives of public companies, interest, certain facility maintenance and overhead expenses, service costs, or any other expense determined by the Treasury Department to be excluded. The Treasury Department must establish a program to certify eligible expenses within 60 days of enactment of PPACA. Once the program is established, the Treasury Department must approve or deny an application for the tax credit within 30 days of receipt and must publicly disclose the amount of the credit awarded to each applicant and the identity of the applicant awarded the credit.

A qualifying therapeutic discovery project is a project which is designed to:

- Treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols for the purpose of obtaining FDA approval of the product; or
- Diagnose diseases or conditions to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or
- Develop a product, process, or technology to further the delivery or administration of therapeutics.

In addition to the above criteria, the Treasury Department, when certifying the expenses eligible for the tax credit, must consider whether the qualifying therapeutic discovery project: (1) has reasonable potential to result in new therapies to treat areas of unmet medical need; to prevent, detect, or treat chronic or acute diseases; to reduce the long-term health care costs in the U.S.; or to significantly advance the goal of curing cancer within 30 years; and (2) has potential to create and sustain high quality, high paying jobs in the U.S. and to advance the U.S. global competitiveness in life, biological, and medical sciences. These two criteria are intended to bridge innovative research with economic stimulus, and build off of significant efforts in the American Recovery and Reinvestment Act of 2009 to utilize the life sciences industry to revitalize the economy.

The PPACA provision also includes special rules for calculating the credit relative to other tax credits (such as the research tax credit and the so-called orphan drug tax credit), and prohibits double benefits (qualified expenses counting toward both the qualifying therapeutic discovery tax credit and deductions for business expenses or depreciation).

To help companies that are not profitable take advantage of the research and development incentive, in lieu of the tax credit, the Treasury Department may award a grant in the amount of 50% of the qualified investment for the qualified therapeutic discovery project, provided the qualified investment is certified as described above. Under forthcoming Treasury Department regulations, an application for the tax credit program above may be converted to an application for the grant program, although tax-exempt 501(c) organizations and governmental entities are not eligible for the grant. Otherwise, virtually all other rules and definitions that apply to the qualifying therapeutic discovery project tax credit apply similarly to the grant program.

Future Outlook

The tax credit is intended to stimulate research and development of cutting edge medical products. Moreover, the tax credit clearly recognizes biopharmaceutical and medical device companies as a critical element in continuing to revitalize the economy. Because the credit is capped at $1 billion in the aggregate, it will be important for companies to monitor the Treasury Department's establishment of the certification program, and to submit applications for certification as quickly as possible.