Tax Provisions Affecting Life Sciences Companies in New Health Care Reform

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The Patient Protection and Affordable Care Act (the "PPACA") was signed into law by the President on March 23, 2010, and its companion law, the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act") was signed into law by the President on March 30, 2010. The new laws provide a comprehensive reform to the health care system, including provisions creating a substantial new tax credit for therapeutic discovery projects, as well as taxes that affect companies in the life sciences area.

These new tax provisions include:

- a 50% investment tax credit or grant for expenditures related to therapeutic discovery projects for 2009 and 2010;
- an annual fee (based on market share) on branded prescription drug and biologics manufacturers and importers beginning in 2011; and
- a 2.3% excise tax on medical device manufacturers beginning in 2013 (replacing the annual fee that was going to be imposed under the PPACA).

50% Investment Tax Credit / Grant for Therapeutic Discovery Projects for 2009 and 2010

The new laws provide that by May 22, 2010 the Secretary of the Treasury must establish a program that provides for a 50% investment tax credit with respect to qualified expenditures made for qualifying therapeutic discovery projects. Significantly, the credit can be taken as a grant at the election of the company so that life sciences companies that are not yet tax-paying can still take advantage of this important program. The program is limited to expenditures made in taxable years

beginning in 2009 and in 2010, and the total combined amount available for credits or grants is $1 billion. The credit is only available to companies that employ not more than 250 employees.

Application. Companies must apply to the Secretary of the Treasury for the tax credit (or grant).

The Secretary will consider only those qualifying projects that show reasonable potential:

- to result in new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions;
- to reduce long-term U.S. health care costs; or
- to significantly advance the goal of curing cancer within the next 30 years.

The Secretary shall also take into consideration those projects with the greatest potential:

- to create and sustain high quality, high paying jobs in the United States; and
- to advance U.S. competitiveness in the fields of life, biological, and medical sciences.

The Secretary shall approve or deny an application within 30 days of submission.

Qualifying Projects and Qualified Expenditures. Qualifying projects are those that are designed:

- to develop a product to treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, clinical studies, and research protocols;
- to diagnose diseases or conditions or to determine related molecular factors by developing molecular diagnostics to guide therapeutic decisions; or
- to develop a product, process or technology to further the delivery or administration of therapeutics.

Qualified expenditures for such projects that are eligible for the credit include costs paid or incurred for expenses necessary for and directly related to the conduct of such projects but excluding the following items:

- compensation for the CEO and the four highest-paid officers;
- interest expenses;
- facility maintenance expenses (such as mortgage or rent payments, insurance, utility or maintenance costs);
- indirect costs (such as general and administrative costs) related to administrative, service or support departments (such as personnel, accounting, data processing, security, legal,

etc.); and

- other expenses identified by the Secretary of the Treasury.

Denial of Double Tax Benefit. Taxpayers will not receive research credits, orphan drug credits, or bonus depreciation for these qualified expenditures, and qualified expenditures are not deductible. Additionally, the basis of qualified expenditures that are subject to depreciation must be reduced by the amount of the investment tax credit for that expenditure.

Special Rules for Grants. Grants are not available for any Federal, State or local government (or any political subdivision, agency, or instrumentality), tax-exempt organization under Code Section 501(c), clean renewable energy bond lender, cooperative electric company, or any pass-through entity involving any of these.

Once the Secretary establishes the program, we will provide additional guidance regarding the application requirements and procedures.

Annual Fee on Branded Prescription Drug and Biologics Manufacturers and Importers

Beginning in the 2011 calendar year, an annual fee must be paid by a manufacturer or importer of branded prescription drugs and biologics for sale to certain specified government programs (Medicare Part D, Medicare Part B, Medicaid, prescription drug programs for the Department of Veteran Affairs and Department of Defense, and TRICARE retail pharmacy program), to directly fund the Medicare Part B trust fund.

There is a set aggregate annual fee imposed on all covered manufacturers and importers (starting at $2.5 billion for 2011 and growing to $4.1 billion for 2018 before it decreases to $2.8 billion for years after 2018) and this amount will be allocated to individual manufacturers and importers based on each one's relative market share. A manufacturer or importer's market share is determined based on the sales of branded prescription drugs or biologics of the manufacturer or importer compared to the sales of all covered manufacturers and importers (0% of sales not more than $5 million are counted, then 10% of sales over $5 million but not more than $125 million, growing to 100% of sales over $400 million). The fee will be treated as an excise tax and is not deductible for U.S. income tax purposes.

The annual fee covers any manufacturer or importer with gross receipts from branded prescription drug or biologic sales. Members of a controlled group (including foreign corporations) are treated as a single covered entity, with joint and several liability imposed on all members.

The branded prescription drugs and biologics covered include:

- any drug which is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act and for which an application was submitted under section 505(b) of the Federal Food,

Drug, and Cosmetic Act; and

- any biological product for which an application was submitted under section 351(a) of the Public Health Service Act,

but generally do not include sales of any drug or biological product with respect to which an orphan drug tax credit was allowed.

Excise Tax on Medical Device Manufacturers

Beginning in the 2013 calendar year, an excise tax equal to 2.3% of the sales price must be paid on the sale of any taxable medical device by the manufacturer, producer, or importer of the device. This excise tax replaces the allocable aggregate annual fee of $2 billion (similar to the annual fee imposed on branded prescription drug and biologics manufacturers and importers) that was going to be imposed under the PPACA before it was repealed by the Reconciliation Act and replaced with this excise tax.

The taxable medical devices covered are any device, as defined under section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans, but do not include eyeglasses, contact lenses, hearing aids, and other medical devices designated by the Secretary of the Treasury as generally purchased at retail by the general public for individual use.

The excise tax does not apply to sales if the device is used for further manufacture or export by the initial purchaser or a second purchaser, but, unlike many other excise taxes, this excise tax does apply to sales for use as supplies for vessels or aircraft, or sales to State or local governments, nonprofit educational organizations, or qualified blood collector organizations.

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