

THE IMPACT OF HEALTHCARE REFORM LEGISLATION

Georgia Bio
GTRI
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1. Therapeutic Discovery Tax Credit/Cash Grant

- A significant benefit for small and mid-sized (under 250 employees) biotech firms and their investors
- 50% tax credit for qualified biotech investments for tax years 2009 and 2010, or a grant for the same amount tax-free
- Available for pass-through entities, such as partnerships or S corporations, as well as traditional C corporations

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2. What Does the Credit Cover?

- The credit/grant covers research in tax years beginning in 2009 and 2010
- The taxpayer is provided 50% credit/grant for qualified investments in “qualifying therapeutic discovery projects”

3. What Expenses Count as Qualified Investments?

- The aggregate amount of costs paid or incurred in the taxable year for expenses necessary for and directly related to the conduct of a qualifying discovery project
- Cannot count the pay of employees covered by Section 162(m)(3) of the Tax Code – think CEOs
- Other excluded expenses include interest expenses, facility maintenance (e.g., mortgage or rent, insurance, and utilities), and certain indirect costs (G&A costs)

4. What is a Qualifying Therapeutic Discovery Project?

- A project designed to do one of three things
 - Treat or prevent diseases or conditions by conducting preclinical studies, clinical trials, or carrying out research protocols for the purpose of securing approval by the FDA
 - Diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions

4. What is a Qualifying Therapeutic Discovery Project? *(cont'd)*

- Finally, to qualify a venture may not have more than 250 employees in all business of the taxpayer -- a small biotech project at a big company will not qualify

5. What Biotech Companies Might Benefit?

- Those that are investing large resources in preclinical or clinical studies, which may take years to come to fruition and lead to FDA approval of a therapeutic product, can recoup a significant portion of these expenses
- Also, start-ups focusing on the development of diagnostic assays and applications to advance therapeutics and treatments
- Companies engaged in basic or applied research which may ultimately contribute to curing major diseases (e.g., companies studying transduction pathways, gene therapy and stem cell research)

6. What's the Catch?

- Unlike most tax credits, this new benefit is not available in unlimited amounts to all eligible taxpayers
- There is a set pot of money -- \$1 billion for the two tax years
- You will have to apply and compete

7. What Special Hurdles Are Involved?

- Must clear key requirements for accuracy, documentation, and justification of costs
- Treasury/IRS will assess projects (in consultation with Department of HHS) with emphasis on a number of different criteria

8. What Things Will Improve Your Application to Quality?

- Medical Benefit Criteria
 - Projects that will result in new therapies that will treat unmet medical needs or prevent, detect, or treat chronic or acute diseases and conditions
 - Projects that reduce long-term healthcare costs in the U.S.
 - Projects that may significantly advance the goal of curing cancer within the next 30 years

8. What Things Will Improve Your Application to Quality? *(cont'd)*

- Jobs and Economic Criteria
 - Applications that create and sustain high-quality, high paying jobs in the U.S.
 - Applications that advance U.S. competitiveness in the fields of life, biological sciences and medical science
 - No bar against research outside the U.S., but the strong sentiment is that the focus should be domestic jobs

9. How Soon Must You Apply?

- Program should be in place by May 21
- Applications approved within 30 days after that
- This may be ambitious, but Congress clearly intends for Treasury to move quickly
- Companies that qualify should not delay in assessing whether their activities qualify for the credit and whether their accounting documentation is such that they can tie expenditures to a specific therapeutic project

Other Provisions Affecting Drug and Device Research and Clinical Trials

- Cures Acceleration Network
 - Establishment of funding of the Cures Acceleration Network (CAN)
 - CAN will be administered by National Institutes of Health (NIH)
 - CAN will award grants and contracts to eligible entities to accelerate the development of high need cures

Other Provisions Affecting Drug and Device Research and Clinical Trials

(cont'd)

- “High need cure” is defined as a drug, device, or biologic that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition for which the incentives in the commercial market are unlikely to result in its adequate or timely development

Other Provisions Affecting Drug and Device Research and Clinical Trials

(cont'd)

- CAN can also provide resources to research institutions, biotech companies, pharmaceutical companies, disease advocacy organizations, patient advocacy organizations, medical centers, or academic research institutions to develop high need cures and facilitate FDA's review of the high need cures funded by CAN (awards cannot exceed \$15 million per project per fiscal year)

Other Provisions Affecting Drug and Device Research and Clinical Trials (cont'd)

- Health Insurance Coverage for Clinical Trial Costs
 - A group health plan or a health insurance insurer offering group or individual coverage may not deny a "qualifying individual" participation in an approved clinical trial
 - May not deny routine patient costs for items and services furnished as part of the trial
 - Health plan cannot discriminate against an individual for participating in a trial

Comparative Effectiveness Research (CER)

- Defined as “research evaluating and comparing health outcomes and the clinical effectiveness, risks and benefits of 2 or more medical treatments, services, and items”

Comparative Effectiveness Research (CER) *(cont'd)*

- Creates a private, nonprofit corporation (Patient Centered Outcomes Research Institute) to assist patients, clinicians, purchasers and policy-makers in making informed decisions by advancing the quality and relevance of evidence concerning the manner in which disease and health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that consider variations in patient subpopulations

Comparative Effectiveness Research (CER) *(cont'd)*

- Institute's charge is to identify national priorities, establish research agendas, and develop methodological research standards for CER
- The Institute shall have access to Centers for Medicare & Medicaid Services (CMS) data.
- Any research findings of the Institute must be broadly disseminated to the medical community and the general public

Comparative Effectiveness Research (CER) *(cont'd)*

- CMS can use the Institute's comparative effectiveness findings in making Medicare coverage decisions if such use is through a transparent process that includes public comment and considers the effect of subpopulations
- CMS, however, may not deny Medicare coverage based solely on CER