



Coverage Policy in an Era of Personalized Medicine: Evaluating and Paying for Genetic Testing Services

**October 12, 2006
Washington D.C.**

8.15: Registration and Continental Breakfast

8.45: Welcome Stuart Altman, Professor, Brandeis University

9.00: The market for genetic testing services
Mara Aspinall, President, Genetics, Genzyme Inc.

How is genetic testing being used to inform decisions about drug therapies? Who are the major suppliers and consumers of these tests? What are emerging business models for test developers and suppliers? How do suppliers develop evidence to show the effectiveness of new tests? What are the major public policy issues affecting the development and use of genetic testing to personalize medical treatment?

10.00: Coverage and payment policies for genetic testing
JoAnne Armstrong, Senior Medical Director, Aetna Inc.
Steve Phurrough, Director, Coverage and Analysis Group, CMS

Under what circumstances will third-party payers cover genetic testing services? How can payers verify the accuracy of genetic tests or the quality of laboratories? Can genetic testing be used by payers as grounds for identifying therapies that are ineffective and should not be covered for specific sub-populations? Are payers willing to pay higher prices for targeted drugs based on expectation of enhanced effectiveness?

11.30: How will pharmacogenetics affect current pharmaceutical business models?
John Orloff, Vice President, Development, Novartis Pharmaceuticals

How actively are drug firms pursuing targeted therapies based on genetic variations? How will advances in pharmacogenetics affect the cost of drug development? Are more targeted therapies likely to result in premium drug pricing? What public policy and regulatory changes could accelerate development of targeted therapies?

12.30: Luncheon address:

Regulatory issues for genetic testing and targeted drug development
Janet Woodcock, Deputy Commissioner, FDA

What are potential future FDA activities related to evaluating genetic testing? How will genetic information be incorporated into the FDA's review process for new drugs? What are promising areas of the Critical Path initiative for accelerating product development?