



## **Federal Strategies for Promoting Affordable Biologics: Enhancing Market Competition**

**June 11, 2009**

**8:30 Continental Breakfast**

**9:00 Introduction:** Stuart Altman Ph.D, Professor, Brandeis University

**9:10 Promoting Access to Affordable Biologic Therapies in Medicare**

Biologic therapies advance the standard of care for many serious medical conditions; however, their high costs pose a major concern for patients and purchasers. Although Medicare is the largest purchaser of biologic therapies, its ability to manage spending for Part B drugs is limited. This session will focus on strategies Medicare must consider in balancing the goals of access, affordability and incentives for innovation as it considers purchasing policies for biologics.

Presenter: Peter Bach, M.D., M.A.P.P., Associate Attending Physician, Memorial Sloan-Kettering Cancer Center

**9:45 Biosimilars and the FDA Approval Process**

This session will examine issues that the FDA must address in order to establish an abbreviated approval pathway for biosimilars. Key issues include establishing adequate patient safety protections and developing methods for determining "interchangeability" with the referenced biologic.

Presenter: William Egan, Ph.D., Vice President, PharmaNet Consulting  
Responder: Jonca Bull, M.D., V.P., Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

**10:45 Break**

**11:00 Potential Impacts of Biosimilars in the US Market**

This session will explore the potential impact of introducing biosimilars into the US market including competition, cost, and innovation by examining the experience of other countries.

Speaker: Paul Heldman, Senior Health Policy Analyst, Potomac Research Group  
Discussants: Steven Miller M.D., Senior Vice President & Chief Medical Officer, Express Scripts, Inc.

**12:00 Lunch Speaker & Panel: Enhancing Competition in the US**

The Federal Trade Commission (FTC) has studied the market for biologics and has identified key issues for enhancing competition. This session will focus on the FTC recommendations to the legislature and will be followed by a panel that will address a range of issues including the data exclusivity period for brand products.

Presenter: Pamela Jones Harbour, Commissioner, Federal Trade Commission  
Panelists: Alex Brill, Research Fellow, American Enterprise Institute for Public Policy Research  
Henry G. Grabowski, Ph.D., Professor, Duke University  
Cole Pinnow, Vice President, Global Specialty Pharmaceuticals, Hospira Inc.

**2:30 Adjourn**