ENGELBERG CENTER for Health Care Reform at BROOKINGS

FRIENDS of CANCER RESEARCH

# Conference on Clinical Cancer Research

Grand Hyatt Washington, Washington, DC
Thursday, November 10, 2011

**8:30 a.m.** **Welcome**
Mark McClellan, Director, Engelberg Center for Health Care Reform at Brookings

**8:35 a.m.** **Breakfast Keynote Address**
*Welcome:* Richard Schilsky, Deputy Director, University of Chicago Comprehensive Cancer Center; Chair, Government Relations Committee, American Society of Clinical Oncology
*Morning Keynote*: U.S. Senator Michael Bennet (D-CO)

**9:00 a.m.** **Panel 1 – Alternative Trial Designs Based on Tumor Genetics/Pathway Characteristics Instead of Histology**
*Moderator:* George Demetri, Director, Ludwig Center at Dana-Farber Cancer Institute

- Robert Becker, Medical Officer, U.S. Food and Drug Administration
- Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration.
- James Doroshow, Director, Division of Cancer, National Cancer Institute
- Perry Nisen, Senior Vice President, Cancer Research, GlaxoSmithKline
- Joshua Sommer, Executive Director, The Chordoma Foundation

**10:20 a.m.** **Break**

**10:35 a.m.** **Panel 2 – Evidence for Use of Maintenance Therapy**
*Moderator:* Richard Schilsky, Deputy Director, University of Chicago Comprehensive Cancer Center

- Anthony Murgo, Associate Director for Regulatory Science, U.S. Food and Drug Administration
- Margaret Mooney, Chief, Clinical Investigations Branch, National Cancer Institute
- Tal Zaks, Vice President, Oncology, Sanofi-Aventis
- Patty Spears, Patient Advocate, Susan G. Komen for the Cure

**12:00 p.m.** **Break**

**12:15 p.m.** **Lunch and Keynote Address**
*Welcome*: Ellen Sigal, Chair and Founder, Friends of Cancer Research
*Lunch Keynote*: Margaret Hamburg, Commissioner, U.S. Food and Drug Administration

**1:35 p.m.** **Panel 3 – Symptom Measurement in Clinical Trials**
*Moderator:* Ethan Basch, Associate Attending Physician, Memorial Sloan-Kettering Cancer Center

- Laurie Burke, Associate Director for Study Endpoints and Labeling, U.S. Food and Drug Administration
- Gini Kwitkowski, Lead Clinical Analyst, U.S. Food and Drug Administration
- Lori Minasian, Chief, Community Oncology and Prevention Trials Research Group, National Cancer Institute
- Brian Seal, Director, Health Economics and Outcomes Research, Bayer HealthCare
- Richard Levy, Executive Vice President, Chief Drug Development and Medical Officer, Incyte
- Mark Gorman, Director of Survivorship Policy, National Coalition for Cancer Survivorship

**3:00 p.m.** **Break**

**3:10 p.m.** **Panel 4 – Development Paths for New Drugs with Large Effects Seen Early**
*Co-Moderators:* Tom Fleming, Professor, Biostatistics, University of Washington, and Mikkael Sekeres, Associate Professor of Medicine, Cleveland Clinic

- Raji Sridhara, Director, Division of Biostatistics V, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Ed Korn, Biometric Research Branch, National Cancer Institute
- Wyndham Wilson, Senior Investigator, Chief, Lymphoma Therapeutics Section, National Cancer Institute
- Gracie Lieberman, Director, Biostatistics, Genentech
- Jane Perlmutter, President and Founder, Gemini Group

**4:30 p.m.** **Summary and Closing Remarks**
Mark McClellan, Director, Engelberg Center for Health Care Reform at Brookings