

FOR IMMEDIATE RELEASE
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Media Advisory

From: Food and Drug Law Institute (FDLI)
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FDLI, AAAS Host June 20 Conference on Personalized Medicine

Mark McClellan to Give Keynote Speech

Better knowledge of the body's genetic and molecular machinery is pointing toward new drugs and treatments that are custom-designed for each individual. But this emerging era of health care, called personalized medicine, also brings concerns about genetic privacy, adequacy of insurance coverage and industry marketing strategies.

To help the food and drug industry and healthcare stakeholders to meet those challenges, the Food and Drug Law Institute (FDLI) and the American Association for the Advancement of Science (AAAS) are sponsoring a two-part national conference on personalized medicine June 20 at the AAAS Headquarters in Washington, D.C. from 9:00 a.m. to 5:00 p.m.

A morning roundtable session will explore personalized medicine through a hypothetical case study about a new biomarker for breast cancer recurrence. The panelists include scientists, government officials and a patient advocate.

The afternoon session on "Implementing Personalized Medicine" will feature a keynote speech by Mark B. McClellan, M.D., director of the Engelberg Center for Health Care Reform at the Brookings Institution and former head of the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid (CMS). The participants include industry and FDA officials who must grapple with new regulatory and policy issues arising from advances in personalized medicine.

The morning roundtable on "Anticipating Personalized Medicine" is free and open to the public. RSVP at <http://www.aaas.org/spp/sfrl/PMRoundtable/>. There is a fee required for the afternoon session. To register for that session or to learn more about the program, go to: <http://www.fdpi.org/conf/435/>.

NOTE: Reporters planning to attend the event are asked to RSVP to Michael Levin-Epstein of FDLI, 202-222-0897, mdl@fdli.org.

The morning roundtable will be moderated by Susan Dentzer, editor-in-chief of the journal *Health Affairs*. The panelists are:

- Finley Austin, Head, U.S. External Research & Innovation Environment, Hoffmann-La Roche, Inc.
- Carol Isaacson Barash, Principal, Genetics, Ethics & Policy Consulting
- Greg Downing, Program Director for Personalized Health Care, Office of the Secretary, Department of Health and Human Services
- Carolina Hiestrosa, Executive Vice President of programs and planning, National Breast Cancer Coalition
- Dr. Howard P. Levy, Assistant Professor, McKusick-Nathan Institute of Genetic Medicine, Johns Hopkins University

Continued

- Dr. Kavita Patel, Deputy Staff Director, Senate Health, Education, Labor and Pensions Committee
- Charles Rotimi, Director, National Institutes of Health Intramural Center for Genomics and Health Disparities
- Grail Sipes, Partner, Covington & Burling

The afternoon session will be moderated by Jeffery N. Gibbs, Principal, Hyman, Phelps & McNamara, P.C. and Gail H. Javitt, Law & Policy Director for The Genetics and Public Policy Center, The Johns Hopkins University. The speakers are:

- Kevin T. Conroy, President and Chief Executive Officer, Third Wave Technologies, Inc.
- Maryellen de Mars, Director for Clinical Biomarkers, Critical Path Institute
- Steven I. Gutman, Director, Office of In Vitro Diagnostic Device Evaluation & Safety, FDA Center for Devices and Radiological Health
- Shiew-Mei Huang, Deputy Director for Science, Office of Clinical Pharmacology, FDA Center for Drug Evaluation and Research
- David J. Hunter, Professor of Cancer Prevention and Nutrition, Harvard School of Public Health
- Steve McPhail, President and Chief Executive Officer, Expression Analysis, Inc.
- Bruce Quinn, Senior Health Policy Specialist, Foley Hoag LLP
- Dr. Allen D. Roses, Director, Deane Drug Discovery Institute, Duke University Medical Center; and Senior Scholar at the Fuqua School of Business.

In addition to AAAS and FDLI, the following groups are participating in the conference:

American Society of Human Genetics
Association for Molecular Pathology
Genetic Alliance
The Hastings Center
International Pharmaceutical Privacy Consortium
Kennedy Institute of Ethics
Personalized Medicine Coalition

Founded in 1949, FDLI publishes the award-winning, peer-reviewed *Food and Drug Law Journal*; the bimonthly magazine *Update; FDA Directory*; and dozens of books and publications for attorneys, regulatory affairs practitioners, scientists, health care professionals, government employees and marketers in the food and drug field. For more information, visit www.fdpi.org