

**"A new era of personalized medicine is coming."**

➤ Sen. Edward Kennedy (D-Mass.)



# Personalized Medicine: Promises and Challenges

A National Conference Sponsored by the  
**American Association for the Advancement of Science (AAAS)**  
and the **Food and Drug Law Institute (FDLI)**



ADVANCING SCIENCE, SERVING SOCIETY



**June 20, 2008 | AAAS Headquarters | Washington, D.C.**

**Participating Organizations:** American Society of Human Genetics, Genetic Alliance,  
Hastings Center, International Pharmaceutical Privacy Consortium,  
Kennedy Institute of Ethics and Personalized Medicine Coalition  
*More organizations to be announced.*

A two-part, national conference offering a high-level roundtable discussion in the morning and a seminar on legal, regulatory and policy issues on personalized medicine in the afternoon. You can attend either session or the entire conference. But space is limited, so register now.

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**Morning Session 9:00 am - 12 Noon**

## Anticipating Personalized Medicine: A Roundtable Discussion

Register at [www.aaas.org/spp/sfrrl/PMRoundtable](http://www.aaas.org/spp/sfrrl/PMRoundtable)

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**Afternoon Session 1:00 pm - 5:00 pm**

## Implementing Personalized Medicine: A Legal, Regulatory and Policy Seminar

Register at [www.fdpi.org](http://www.fdpi.org)

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**Attend Both Sessions! 9:00 am - 5:00 pm**

Register at [www.fdpi.org](http://www.fdpi.org)

*Session Details on reverse ➤*



The Food and Drug Law Institute  
1155 15th Street NW, Suite 800  
Washington, DC 20005  
[www.fdpi.org](http://www.fdpi.org)

**"This is a time of excitement and change. We need to strive to envision and seek opportunities, not fight them."**

➤ Jesse Goodman, CBER Director, FDA, speaking about personalized medicine at FDLI's Annual Conference



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#### Morning Session **Anticipating Personalized Medicine: A Roundtable Discussion**

Although doctors have long incorporated personal information like family history into treatment plans, personalized medicine holds the promise of revolutionizing medical care by using knowledge of molecular biology and genetics that will allow more precise diagnoses, better diagnostic tests, greater predictability of disease course, more successful therapies by targeting the right treatments to the right patients, and improved patient safety by selecting drugs and their proper dosage to reduce adverse side effects.

The stakeholders participating in the morning Roundtable — including scientists, physicians, the pharmaceutical and insurance industries, government, patient groups, and others — will discuss a case study, which will be used as a springboard to confront issues from the highly technical to the economic, ethical and regulatory that will need to be addressed if personalized medicine is to be incorporated into mainstream health care.

#### Moderator

**Susan Dentzer**

Health policy journalist and on-air correspondent for the PBS NewsHour  
Editor-in-Chief, *Health Affairs* (effective May, 1, 2008)

#### Morning Speakers

**M.F. Finley Austin, Ph.D.**, Head, US External Research & Innovation Environment, Hoffmann-La Roche, Inc.

**Greg Downing, D.O., Ph.D.**, Program Director, Personalized Health Care, Immediate Office of the Secretary, Department of Health and Human Services

**Carolina Hinestrosa, M.A., M.P.H.**, Executive Vice President of Programs and Planning, National Breast Cancer Coalition

**Howard P. Levy, M.D., Ph.D.**, Clinician and Professor, Johns Hopkins University

**Kavita Patel, M.D., M.S.H.S.**, Deputy Staff Director, Health Subcommittee of Senator Edward M. Kennedy

**Joan A. Scott, M.S., C.G.C.**, Deputy Director, Genetics and Public Policy Center, Johns Hopkins University

**Grail Sipes, J.D.**, Partner, Covington & Burling

*More panelists to be announced*

#### Afternoon Session **Implementing Personalized Medicine: A Legal, Regulatory and Policy Seminar**

This afternoon Seminar focuses on the legal, regulatory and policy implications of developing drugs, biologicals and diagnostics for the rapidly emerging field known as personalized medicine.

Expert panelists from government, private industry, science and medicine will provide invaluable information on the legal and regulatory challenges faced by professionals practicing in areas affected by personalized medicine, including labeling issues, laboratory developed tests, IVD approval and reimbursement, and PGx-tailored drugs and companion diagnostics.

#### Moderators

**Jeffery N. Gibbs**, Principal, Hyman, Phelps & McNamara, P.C.

**Gail H. Javitt, J.D., M.P.H.**, Law & Policy Director, The Genetics and Public Policy Center, The Johns Hopkins University

#### Keynote Speaker

**Mark B. McClellan, M.D., Ph.D.**, Senior Fellow and Director, Engelberg Center for Health Care Reform, The Brookings Institution and former FDA Commissioner & CMS Administrator

#### Afternoon Speakers

**Kevin T. Conroy**, President and CEO, Third Wave Technologies, Inc.

**Steven I. Gutman, Ph.D.**, Director, Office of In Vitro Diagnostic Device Evaluation & Safety, CDRH, FDA

**Shiew-Mei Huang, Ph.D.**, Deputy Director for Science, Office of Clinical Pharmacology, CDER, FDA

**Steve McPhail**, President and Chief Executive Officer, Expression Analysis, Inc.

**Bruce Quinn, M.D., Ph.D.**, Senior Health Policy Specialist, Foley Hoag LLP

**Allen D. Roses, M.D.**, Jefferson-Pilot Professor of Neurobiology and Genetics, Professor of Medicine, and Director, Deane Drug Discovery Institute,

Duke University Medical Center; Senior Scholar, Fuqua School of Business; Member, Duke Institute of

Genome Sciences and Policy

*More speakers to be announced*

**To learn more about this program, please visit [www.fdpi.org](http://www.fdpi.org) or call (800) 956-6293 | (202) 371-1420**