

Monday, December 8, 2008

Panorama A

5:00 p.m. WELCOME RECEPTION

6:30 p.m. DINNER

WELCOME

Stephen Ferguson, Chairman, Cook Group Incorporated

The Honorable David F. Durenberger, former U.S. Senator, Board of Directors, MTLF

7:15-8:30 KEYNOTE ADDRESS

FDA's Scientific Capacity

Gail H. Cassell, Ph.D., Vice President Scientific Affairs and Distinguished Lilly Research Scholar, Eli Lilly and Company; Member, FDA Science Advisory Board, "FDA Science and Mission at Risk"

Tuesday, December 9, 2008

Panorama Ballroom

7:30 am REGISTRATION AND CONTINENTAL BREAKFAST

8:00 am WELCOME

Dr. Ora Pescovitz, President and CEO, Riley Hospital for Children, Executive Associate Dean for Research, Indiana University School of Medicine, Interim V.P. for Research Affairs, Indiana University

David Johnson, President and CEO BioCrossroads; Board Member, MTLF

8:30-9:30 SESSION 1: FDA'S RESOURCES AND REGULATORY TOOLS: CAN FDA DO ITS JOB?

Philip J. Phillips, Medical Device Practice Director, Becker & Associates; former CDRH Deputy Director, Office of Device Evaluation

Discussants

Suzanne M. O'Shea, JD, LL.M., Counsel, Baker & Daniels; formerly 21 years at FDA with broad range of responsibilities including regulatory counsel

David S. Wilkes, MD, Director, Center for Immunobiology, IU School of Medicine; entrepreneur, ImmuneWorks, LLC

9:30-9:45 Break

**FDA in the 21st Century:
Issues and Their Impact on
Medical Technology**

9:45-11:00 SESSION II: ETHICS, CONFLICTS OF INTEREST

Eric M. Meslin, Ph.D., Director, Indiana University Center for Bioethics,
Associate Dean for Bioethics and Professor of Medicine and of Medical and
Molecular Genetics, Indiana University School of Medicine

Discussants:

Ora H. Pescovitz, MD President and CEO, Riley Hospital for Children,
Executive Associate Dean for Research, Indiana University School of Medicine,
Interim V.P. for Research Affairs, Indiana University

Neal Fearnot, Ph.D., President, Cook/MED Institute

11:00 INTRODUCTION OF MTLF TO INDIANA
Dan Peterson, Cook Group Incorporated

11:30 LUNCH

12:00 KEYNOTE ADDRESS
Challenges of Leadership at FDA

Jane Henney, M.D., Professor of Internal Medicine and Public Health Sciences,
University of Cincinnati; former Commissioner, Food and Drug Administration

1:00-1:45 KEYNOTE ADDRESS
FDA and the Political Process

The Honorable Evan Bayh, U.S. Senator (D/IN)

1:45- 3:00 FDA IN A GLOBALIZED ECONOMY; EXPANDING THE SCOPE OF THE
AGENCY

Susan Alpert, Ph.D., M.D., Senior Vice President, Chief Regulatory Officer,
Medtronic; former FDA official

Ralph Hall, JD, Distinguished Visiting Practitioner and Professor, University of
Minnesota Law School.

3:00 p.m. Next Steps and Concluding Remarks