



Medical Technology Leadership Forum

The Medical Technology Leadership Forum presents:

A University of Minnesota Summit

“Facilitating the Continuum from Experimental to Clinical Use: Designing Alternative Models”

Minneapolis, Minnesota
July 17th –18th, 2003

Innovation in medicine happens in an iterative, not linear, fashion. The purpose of this meeting is to think about alternatives to the current regulatory system of gates and hurdles as new technologies move from experimental to clinical. In many ways, every patient encounter provides an opportunity to learn more about how new technologies affect clinical outcomes; that information, in turn, can be fed back into the system to refine regulatory limitations and improve product design.

Thursday, July 17th

5:30 – 9:00 pm

Reception and Dinner

The Bakken Library and Museum
3537 Zenith Avenue South
Minneapolis

5:30 – 6:30 pm Cocktail Reception

6:30 – 7:30

Dinner

Greetings Dr. David Rhees, Executive Director, *The Bakken Library and Museum*

7:30 – 8:45

Welcome Hon. David Durenberger – *President, MTLF*

A Conversation with Dr. Mark McClellan,

Commissioner of the Food and Drug Administration (confirmed)
Hosted by Dr. Kenneth H. Keller-*University of Minnesota* and
Dr. Robert Nerem-*Georgia Tech*

8:45 – 9:30

Dessert & Cordials

First bus departs Bakken Museum for hotel at 9:00 pm
Second bus departs at 9:30 pm

Friday, July 18th

Walter Library
University of Minnesota
117 Pleasant Street, SE
Minneapolis

7:30 – 8:00 Registration and Continental Breakfast – Room 102 Walter Library

8:00 Opening Remarks – Room 101 Walter Library

Dr. Kenneth H. Keller
Hon. David Durenberger

8:15 Welcome

Dr. Robert Bruininks, *President, University of Minnesota*

8:30 Session 1:

Redesigning the Experimental Device Hurdles

The purpose of this panel is to identify the practical limitations associated with current pre-clinical regulatory methods; to discuss alternatives to randomized clinical trials; and to explore alternatives to and ways to expand upon conditional approvals.

Moderator: Dr. Robert Nerem - *Director, Petit Institute for Bioengineering and Bioscience, Georgia Institute of Technology*

Panelists:

Dr. David Feigal – *Director, Centers for Devices and Radiological Health, Food and Drug Administration*

Mr. Paul Citron – *Vice President, Technology Policy and Academic Relations, Medtronic, Inc.*

Dr. Michael Lysaght – *Professor of Medical Science, Brown University*

10:15 Break

10:30 Session II:

Finding Common Goals – Coordination between FDA and Payers

Questions to be explored by the panel include:

-How might the FDA and payers better share data?

-Are there opportunities to better coordinate conditional coverage?

-What lessons can be drawn from previous attempts at formal or informal coordination?

Moderator: Dr. Kenneth H. Keller

Panelists:

Dr. George Isham - *Medical Director, Chief Health Officer, Health Partners*

Dr. Sean Tunis – *Chief Medical Officer, Centers for Medicare and Medicaid Services*

12:00 pm Lunch Break
-An opportunity to visit with colleagues.

1:00 Session III
Post Market Issues: Engaging the Physicians and Patients in Continuous Data Collection and Analysis.
How can post-market data be gathered to feed back into the system? This panel discussion is intended to examine the policy issues related to continuous data collection, including clinical, privacy and ethical perspectives.

Moderator: Dr. Frank Cerra - *Sr. Vice President, Academic Health Center, University of Minnesota*

Panelists:

Dr. Jeffrey Kahn – *Director, Center for Bioethics – Professor of Medicine, University of Minnesota*

Dr. John Mayer – *Sr. Associate in Cardiac Surgery, Children’s Hospital, Harvard Medical School*

Dr. Fred Schoen – *Professor of Pathology, Harvard Medical School*

Dr. John Watson – *Director, Clinical and Molecular Medicine Program, National Heart, Lung & Blood Institute*

3:00 Wrap Up and Next Steps
Dr. Kenneth Keller

3:30 Adjourn

Program Committee:

Dr. Kenneth H. Keller

Professor Susan B. Foote

Dr. Robert Nerem