

# Program

Thursday, October 20<sup>th</sup>

Campus Club, University of Minnesota

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**5:30 Reception**

**6:30 Dinner**

**7:00 Evening Speaker**

*Dr. William Brody, President, Johns Hopkins University*

***“I’ll Have My Scapegoat Medium Rare: The Changing Role of Post-Market Surveillance”***

**Conversation and Discussion**

Friday, October 21<sup>st</sup>

A.I. Johnson Great Room, McNamara Alumni Center (Gateway Center), University of Minnesota

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**7:30 – 8:00 am Registration and Continental Breakfast**

**8:00 am Welcome**

**Dr. Kenneth H. Keller**, Charles M. Denny, Jr. Professor of Science, Technology and Public Policy; Professor of Chemical Engineering and Materials Science, University of Minnesota; Co-Director, Medical Technology Leadership Forum

**Susan B. Foote, JD**, Associate Professor, University of Minnesota School of Public Health; Co-Director, Medical Technology Leadership Forum

**8:15 am - 9:45 am Session I**

***Changing Role of Evidence Requirement in Post-Market World of the FDA***

*Presenter*

**Dr. Dan Shultz**, Director, Center for Devices and Radiological Health, Food and Drug Administration

*Moderator*

**Dr. Kenneth H. Keller**, Charles M. Denny, Jr. Professor of Science, Technology and Public Policy; Professor of Chemical Engineering and Materials Science, University of Minnesota; Co-Director, Medical Technology Leadership Forum

*Commentary*

**Dr. Mark D. Carlson**, Professor of Medicine, Assoc. VP for Government Relations, Case Western Reserve U.

**Mr. David Nexon**, Executive Vice President, AdvaMed

**10:00 am – 11:30 am Session II**

***Changing Role of Evidence in Post-Approval World: Role of CMS***

*Presenter*

**Dr. Barry M. Straube**, MD, Acting Chief Medical Officer, CMS; Acting Director, Office of Clinical Standards and Quality

*Moderator*

**Dr. Kenneth H. Keller**, Charles M. Denny, Jr. Professor of Science, Technology and Public Policy; Professor of Chemical Engineering and Materials Science, University of Minnesota; Co-Director, Medical Technology Leadership Forum

*Commentary*

**Dr. Daniel Schaber**, VP Cardiac Rhythm Management Clinical Research, Medtronic

**Mr. Steve Northrup**, Health Policy Advisor for Senate Health, Education, Labor and Pensions Committee

**Dr. Joseph Smith**, Senior Vice President and Chief Medical Officer, Guidant Cardiac Rhythm Management

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## **11:30 – 12:00 Noon                      Session III**

### *Policy Options and Opportunities*

*An open dialogue among all participants asking broad questions about the goals of FDA and CMS efforts, what are they designed to serve, what are the constraints of law and policy to rational approaches to these issues.*

#### *Moderator*

**Dr. Kenneth H. Keller**, Charles M. Denny, Jr. Professor of Science, Technology and Public Policy; Professor of Chemical Engineering and Materials Science, University of Minnesota; Co-Director, Medical Technology Leadership Forum

## **Noon – 1:00 pm**

## **Lunch**

## **1:00 pm – 2:15 pm**

## **Session IV**

### *Health Plan Perspective*

*Large health plans are developing significant capacity to manage information about technology outcomes, adverse events and other post-market issues. What is the private sector capacity and what are the limitations?*

#### *Moderator*

**Hon. David Durenberger**, Chairman, Advisory Board, Medical Technology Leadership Forum

#### *Presenters*

**Dr. Richard Justman**, Medical Director, United Health Group

**Dr. Jed Weissberg**, Associate Executive Director for Quality and Performance Improvement, The Permanente Federation

**Dr. Richard Gilfillan**, CEO, Geisinger Health Plan

## **2:30 pm – 3:00 pm**

## **Session V**

### *What role do physicians play in this new world of post-market evidence gathering?*

*Increasingly, physicians are being asked to play a greater role in gathering evidence, managing utilization, and improving quality. What are physician options and perspectives? Role of Practitioners in Post-Approval Evidence*

#### *Moderator*

**Hon. David Durenberger**, Chairman, Advisory Board, Medical Technology Leadership Forum

#### *Commentary*

**Dr. Robert Hauser**, President and CEO, Minneapolis Heart Institute

**Dr. Richard Coutts**, American Association of Orthopedic Surgeons

## **3:30 pm**

## **Next Steps and Adjourn**