INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(k) CLEARANCE PROCESS: WORKSHOP #1

Hotel Monaco
Paris Ballroom
700 F St., NW
Washington DC 20004

Draft Agenda

Monday, June 14, 2010

8:30 AM **Welcome and Opening Remarks**
David Challoner, Chair, IOM Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process

8:50 **Legislative History of the Medical Device Amendments of 1976**
Peter Barton Hutt, Covington & Burling, LLP

9:30 **Premarket Notification: A Key Element of US Medical Device Regulation**
Philip J. Phillips, PCG, LLC
Larry Kessler, University of Washington, School of Public Health (coauthor)

10:10 **Break**

10:30 **FDA's Compliance Infrastructure**
Timothy A. Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health, FDA

11:10 **Structure of the Medical Device Industry Innovation Ecosystem**
Josh Makower, Consulting Associate Professor of Medicine, Stanford University Biodesign Program, and Founder & CEO, ExploraMed Development, LLC

12:00 PM **Lunch**

1:30 **Impact of the Regulatory Framework on Medical Device Development and Innovation**
David W Feigal, Jr., Vice President, Global Regulatory, Amgen, and Associate Faculty, Arizona State University School of Law

2:10 **Balancing Patient Safety and Innovation**
Panel Discussion
Moderated by William Vodra, Committee Member
Panelists:

- Workshop speakers: David W Feigal, Jr., Peter Barton Hutt, Josh

Makower, Philip Phillips, and Tim Ulatowski
- Amy Allina, Program and Policy Director, National Women's Health Network
- D. Bruce Burlington, Independent Consultant
- William Vaughan, Consultant, Consumer's Union

3:00 **Break**

3:15 **Public comment – Registered Speakers**
(5 minutes per speaker)

5:00 **Recess**

Tuesday, June 15, 2010

8:30 AM **Welcome**
David Challoner, Chair, IOM Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process

8:40 **Comparative Overview of Medical Device Regulatory Systems**
David Jefferys, Senior Vice President, Global Regulatory, Healthcare Policy Department, Eisai Europe Ltd

9:20 **Past, Present and Future of Global Harmonization**
Janet Trunzo, Executive Vice President, Technology & Regulatory Affairs, Advanced Medical Technology Association (AdvaMed)

10:00 **Update on PWC's Medical Innovation Technology Score Card**
Doug Mowen, Managing Director, Medical Device Industry Practice, PricewaterhouseCoopers

10:40 **Break**

10:50 **The Global Regulatory Environment**
Panel Discussion
Moderated by Kathryn Zoon, Committee Member
Panelists:
- David Jefferys, Janet Trunzo and Doug Mowen

11:30 **Public comment – Registered Speakers**
(5 minutes per speaker)

12:00 PM **Adjourn**