# MEETING AGENDA

**MARCH 12-13, 2012**

Keck Center  
500 Fifth Street NW  
Washington, DC 20001

## DAY ONE: MONDAY, MARCH 12, 2012  
The Keck Center, Room 100

### SESSION 1 - CLOSED  
IOM COMMITTEE PROCESS AND CHARGE TO COMMITTEE  
ROOM 204

### SESSION 2 - OPEN  
QUESTIONS ON STATEMENT OF TASK  
ROOM 204

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| 11:10 – 11:30 | Project Timeline and Statement of Task  
Sponsor Representative Introductions  
**Larry Gostin**, Committee Chair |
| 11:30-11:45 | The Charge to the Committee  
**Jennifer Devine**, Deputy Director, Global Regulatory Operations & Policy, FDA  
**Kate Bond**, Associate Director for Technical Cooperation and Capacity Building, FDA |
| 11:45-12:15 | Questions |
| 12:15-1:15 | Lunch |

### SESSION 3 - OPEN  
TECHNOLOGIES FOR DETECTING UNSAFE DRUGS  
ROOM 100

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| 1:15-1:25 | Welcome and Introductions  
Committee Chair |
| 1:25- 1:45 | The Strengths and Weaknesses of the Detection Technologies Currently Available  
**Mark Witkowski**, Supervisory Chemist, Trace Examination Section Forensic Chemistry Center, FDA |
1:50- 2:10  Importance of Reliable Detection Technologies in the Field  
*Ashifi Gogo,* Chief Executive, Sproxil

2:15- 2:30  Break

2:30-2:50  Using Analytic Detection Technologies in Singapore  
*Lim Chin Chin,* Forensic Laboratory Director and Forensic Scientist, Singapore Health Science Authority

2:55-3:15  Using Analytic Detection Technologies in Peru  
*Percy Alberto Ocampo Rujel,* former Executive Director, Directorate of Control and Health Surveillance, Peru

3:20-3:40  Case Study on Merck’s Use of Detection Technologies  
*Anthony Zook,* Director of Anti-Counterfeiting, Merck

3:45-4:30  Panel Discussion, The Future of Reliable Detection Technologies in the Field  
*Patrick Lukulay,* Moderator

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<td>COMMITTEE PLANNING</td>
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DAY TWO: TUESDAY, MARCH 13, 2012
The Keck Center, Room 100

8:00 Breakfast Available

SESSION 5 – OPEN
FRAMING AND DEFINING THE PROBLEM

8:15-8:30 Opening Remarks
Mary Lou Valdez, Associate Commissioner, Office of International Programs, FDA

8:45-9:45 Varying Interpretations of the Terms Counterfeit, Falsified, and Substandard
Howard Zucker, Senior Advisor, Massachusetts General Hospital
Rohit Malpani, Senior Advisor for Campaigns, Oxfam America
Roger Bate, Legatum Fellow in Global Prosperity, American Enterprise Institute
David R. Gaugh, Vice-President for Regulatory Science, Generic Pharmaceutical Association

9:45-10:15 Panel Discussion on Terminology and the Problem of Fake Drugs
Bryan Liang, Moderator

10:15-10:30 Break

10:30-11:45 Economic and Trade Interests in Counterfeit, Falsified, and Substandard Drugs
Nicholas Cappuccino, Chief Executive, Pharmaceutical Intellectual Resource Services, LLC
John Clark, Chief Security Officer and Vice President of Global Security, Pfizer
Jamie Love, Director, Knowledge Economy International
P.V. Appaji, Executive Director, Pharmaceuticals Export Promotion Council of India

11:45-12:15 Panel Discussion on Health, Economic, and Trade Dimensions of the Problem
Prashant Yadav, Moderator

12:15-1:15 Lunch

SESSION 6 – OPEN
NATIONAL AND INTERNATIONAL COLLABORATION

1:15-2:15 Enforcement in Pharmaceutical Fraud
Susanne Keitel, Director, European Directorate for Quality of Medicines and Healthcare, Council of Europe
Aline Plancon, Manager, Interpol Medical Products Counterfeiting and Pharmaceutical Crime Unit (by video conference)
Sebastian Mollo, Intelligence Director, Pharmaceutical Security Institute
Invited, Federation Indian Chambers of Commerce and Industry
Daniel Carpenter, Moderator
U.S. Government Work against Pharmaceutical Fraud

**Catherine Hill-Herndon**, Director, Office of International Health and Biodefense, US Department of State

**Linda Marks**, Attorney, US Department of Justice

**Jeffery Gren**, Director, Office of Health and Consumer Goods, U. S. Department of Commerce

**Ilisa Bernstein**, Director, Office of Compliance, Center for Drug Evaluation Research, FDA

**Margareth Ndomondo-Sigonda**, Moderator

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**3:30:3:45 Break**

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**SESSION 7 – OPEN**

**SCOPE OF WORK ON THE PROBLEM**

**3:45-4:30** Investigating Trends and Analyzing Policy in Pharmaceutical Fraud

**Laurie Garrett**, Senior Fellow for Global Health, Council on Foreign Relations

**Alan Coukell**, Director Medical Programs, Pew Health Group

**Judit Rius**, US Manager of the Campaign for Access to Essential Medicines, Doctors Without Borders

**Ann Marie Kimball**, Moderator

**4:30-5:00** Closing Remarks

**Larry Gostin**, Committee Chair

**5:00 Adjourn**