## **2015 FDA Science Forum Webcasts**



Day 1: May 27, 2015

Welcome by Acting Chief Scientist Luciana Borio, M.D.

<u>Remarks</u> by Acting Commissioner, Stephen M. Ostroff, M.D.

#### Session 1: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

- 1. <u>Breakthroughs in Imprint Lithography and 3D Additive Fabrication</u> by Joseph M. DeSimone, Ph.D.
- 2. <u>Single Cell Methods in Cell Product Characterization</u> by Malcolm Moos, MD, Ph.D.
- 3. <u>Field Portable Devices Taking the Laboratory to the Sample</u> by Mark Witkowski, Ph.D.
- 4. <u>The Intersection of Personalized Cardiac Therapies, Cell Based Diagnostics and Multi-Variate Physiological Monitoring</u> by David G. Strauss, MD, Ph.D.

# Session 2: Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

- 1. <u>E-Cigarette Use and Cigarette Smoking Behavior among U.S. Young Adults: A Mixed</u> <u>Methods Study</u> by Blair N. Coleman, Ph.D., MPH (Starts at 00:00)
- Experimental Study of Patient Information Prototypes by LT. Oluwamurewa Oguntimein, M.H.S, CHES (Starts at 00:12)

- 3. Incorporating Patient Preferences into Regulatory Decision Making by Telba Irony, Ph.D. (Starts at 00:22)
- 4. <u>Recent Findings from Nonhuman Primates on the Long-Term Adverse Behavioral</u> <u>Effects of General Anesthesia When Given During Early Brain Development</u> by Merle G. Paule, Ph.D., A.T.S. (Starts at 00:38)

## Session 3: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

- 1. <u>Enhancing Preparedness through Novel Partnerships for IT Innovation: USCIIT-PREP</u> by J. Perren Cobb, M.D., F.C.C.M, F.A.C.S.
- 2. <u>Electrophysiological Biomarkers of Brain Injury</u> by Cristin Welle, Ph.D.
- 3. <u>Pandemic Influenza Preparedness: Development of Novel Technologies for In-Depth</u> <u>Evaluation of Vaccine Efficacy and Long-Term Memory During H7 Clinical Trials</u> by Surender Khurana, Ph.D.
- 4. <u>Filovirus Detection and Threat Mitigation</u> by Steven Wood, Ph.D.

## Session 4: Implement a New Prevention-Focused Food Safety System to Protect Public Health

- Food Safety Systems in the Americas: A perspective from the Pan-American Health Organization (PAHO) by Enrique Pérez-Gutiérrez, D.V.M., M.Sc., M.P.V.M., Ph.D. (Starts at 00:00)
- <u>GenomeTrakr: A Pathogen Databases to Build a Global Genomic Network for</u> <u>Pathogen Traceback and Outbreak Detection</u> by Ruth E. Timme, Ph.D. (Starts at 00:28)
- 3. <u>The Nexus of Food Safety, Animal Health and Antimicrobial Resistance</u> by Patrick McDermott, M.S., Ph.D. (Starts at 0:42)
- The Use of DNA Barcoding to Prevent Species-Specific Foodborne Illness and Detect Seafood Fraud by Jonathan Deeds, Ph.D. (Starts at 01:00)

 <u>Non-Targeted Screening Methods for Identification of Chemical Hazards of Public</u> <u>Health Concern</u> by Tim Croley, Ph.D. (Starts at 01:16)

### Day 2: May 28, 2015

#### Keynote

<u>Cancer Genomes and the Wars against Cancer</u> by Bert Vogelstein, M.D.

## Session 5: Support New Approaches to Improve Product Manufacturing and Quality

- 1. <u>Screening for Counterfeit Pharmaceutical Products Using the CDx Device in Ultraviolet,</u> <u>Visible, and Infrared Modes for Field and Laboratory Use</u> by Nicola Ranieri
- 2. <u>Methods for Detection of Allergens in Food and in the Processing Environment:</u> <u>Approaches and Challenges</u> by Lauren Jackson, Ph.D.
- 3. <u>Advanced Analytics and Data Integration for Biomolecule Characterization</u> by Sau Lee, Ph.D.
- 4. <u>Using NMR to Assess Structure and Comparability</u> by Daron Freedberg, Ph.D.

## Session 6: Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

- 1. Individualized Therapy as a Practical Aspect of Patient Care by Howard L. McLeod, Pharm.D. (Starts at 00:00)
- Not in Our Stars but in Ourselves: The Pharmacogenetic Determinants of Immunogenicity of Therapeutic Proteins by Zuben E. Sauna, Ph.D. (Starts at 00:31) )
- 3. <u>Pharmacogenomics and Biomarker-Based Drug Development</u> by Michael Pacanowski, Pharm.D., M.P.H. (Starts at 00:51)

4. <u>Statistical Evaluation of "Me-Too" Companion Diagnostic Tests for Selecting Therapies</u> by Gene Pennello, Ph.D. (Starts at 01:11)

#### Session 7: Modernize Toxicology to Enhance Product Safety

- 1. <u>Human Microlivers for Disease Modeling</u> by Sangeeta Bhatia, M.D., Ph.D.
- <u>Discovery and Analytical Validation of System Biology Translation Biomarkers of</u> <u>Toxicity</u> by Richard D. Beger, Ph.D.
- 3. <u>Nonclinical Development of Neurotoxicity Biomarkers Using In Vivo MRI</u> by Serguei Liachenko, M.D., Ph.D.
- 4. <u>Replacing the Clinical Thorough QT Study with a Panel of In Vitro Assays and</u> <u>Computational Integration</u> by Norman Stockbridge, M.D., Ph.D.
- 5. <u>Humanized Hepatic Mice: In Vivo Model to Predict Human-Specific Immunotoxicity,</u> <u>Drug Metabolism and Hepatotoxicity</u> by Kristina E. Howard, D.V.M., Ph.D.

## Session 8: Harness Diverse Data through Information Sciences to Improve Health Outcomes

- Transforming Trillions of Points of Data into Diagnostics, Therapeutics, and New Insights into Disease by Atul Butte, MD, Ph.D. (Starts at 00:00)
- 2. <u>Panel Discussion: Next Generation Sequencing Technology at FDA with Atul Butte MD,</u> <u>Ph.D., Carolyn Wilson, Ph.D., Hugh A. Rand, Ph.D., Zivana Tezek, Ph.D., and Weida</u> <u>Tong, Ph.D.</u>

Moderated by Eric Donaldson, Ph.D. (Starts at 00:35)