Day 1: May 27, 2015

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

Remarks by Acting Commissioner, Stephen M. Ostroff, M.D.

Session 1: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

1. Breakthroughs in Imprint Lithography and 3D Additive Fabrication
   by Joseph M. DeSimone, Ph.D.
2. Single Cell Methods in Cell Product Characterization
   by Malcolm Moos, MD, Ph.D.
3. Field Portable Devices – Taking the Laboratory to the Sample
   by Mark Witkowski, Ph.D.
4. The Intersection of Personalized Cardiac Therapies, Cell Based Diagnostics and Multivariate Physiological Monitoring
   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. E-Cigarette Use and Cigarette Smoking Behavior among U.S. Young Adults: A Mixed Methods Study
   by Blair N. Coleman, Ph.D., MPH  (Starts at 00:00)
2. Experimental Study of Patient Information Prototypes
   by LT. Oluwamurewa Oguntmein, 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. **Recent Findings from Nonhuman Primates on the Long-Term Adverse Behavioral Effects of General Anesthesia When Given During Early Brain Development**  
   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. **Enhancing Preparedness through Novel Partnerships for IT Innovation: USCIIT-PREP**  
   by J. Perren Cobb, M.D., F.C.C.M, F.A.C.S.

2. **Electrophysiological Biomarkers of Brain Injury**  
   by Cristin Welle, Ph.D.

3. **Pandemic Influenza Preparedness: Development of Novel Technologies for In-Depth Evaluation of Vaccine Efficacy and Long-Term Memory During H7 Clinical Trials**  
   by Surender Khurana, Ph.D.

4. **Filovirus Detection and Threat Mitigation**  
   by Steven Wood, Ph.D.

---

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

1. **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)

2. **GenomeTrakr: A Pathogen Databases to Build a Global Genomic Network for Pathogen Traceback and Outbreak Detection**  
   by Ruth E. Timme, Ph.D. (Starts at 00:28)

3. **The Nexus of Food Safety, Animal Health and Antimicrobial Resistance**  
   by Patrick McDermott, M.S., Ph.D. (Starts at 0:42)

4. **The Use of DNA Barcoding to Prevent Species-Specific Foodborne Illness and Detect Seafood Fraud**  
   by Jonathan Deeds, Ph.D. (Starts at 01:00)
5. **Non-Targeted Screening Methods for Identification of Chemical Hazards of Public Health Concern**  
   by Tim Croley, Ph.D. (Starts at 01:16)

---

**Day 2: May 28, 2015**

**Keynote**

*Cancer Genomes and the Wars against Cancer*  
by Bert Vogelstein, M.D.

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

1. **Screening for Counterfeit Pharmaceutical Products Using the CDx Device in Ultraviolet, Visible, and Infrared Modes for Field and Laboratory Use**  
   by Nicola Ranieri
2. **Methods for Detection of Allergens in Food and in the Processing Environment: Approaches and Challenges**  
   by Lauren Jackson, Ph.D.
3. **Advanced Analytics and Data Integration for Biomolecule Characterization**  
   by Sau Lee, Ph.D.
4. **Using NMR to Assess Structure and Comparability**  
   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)
2. **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. **Pharmacogenomics and Biomarker-Based Drug Development**  
   by Michael Pacanowski, Pharm.D., M.P.H. (Starts at 00:51)
Session 7: Modernize Toxicology to Enhance Product Safety

1. **Human Microlivers for Disease Modeling**  
   by Sangeeta Bhatia, M.D., Ph.D.

2. **Discovery and Analytical Validation of System Biology Translation Biomarkers of Toxicity**  
   by Richard D. Beger, Ph.D.

3. **Nonclinical Development of Neurotoxicity Biomarkers Using In Vivo MRI**  
   by Serguei Liachenko, M.D., Ph.D.

4. **Replacing the Clinical Thorough QT Study with a Panel of In Vitro Assays and Computational Integration**  
   by Norman Stockbridge, M.D., Ph.D.

5. **Humanized Hepatic Mice: In Vivo Model to Predict Human-Specific Immunotoxicity, Drug Metabolism and Hepatotoxicity**  
   by Kristina E. Howard, D.V.M., Ph.D.

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

1. **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. **Panel Discussion: Next Generation Sequencing Technology at FDA with Atul Butte MD, Ph.D., Carolyn Wilson, Ph.D., Hugh A. Rand, Ph.D., Zivana Tezek, Ph.D., and Weida Tong, Ph.D.**  
   Moderated by Eric Donaldson, Ph.D.  (Starts at 00:35)