2006 FDA Science Forum

A Century of FDA Science: Pioneering the Future of Public Health

April 18-20, 2006
Washington Convention Center

Tuesday, April 18

Level 2 - L Street Bridge
7:30 am - 5:00 pm Registration

Level 2 - Hall D
7:30 am Poster Setup

Level 3 - Ballroom C
8:15 am - 8:45 am **Welcome**

Norris E. Alderson, Ph.D., Associate Commissioner for Science, FDA

Andrew von Eschenbach, M.D., Acting Commissioner of Food and Drugs

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
Remarks on the 100th Anniversary of the Pure Food and Drugs Act

8:45 am - 10:00 am **Plenary Session**
Historical Perspectives on FDA Science
This session will begin with a presentation of a brief history of the events leading up to the 1906 act by former FDA Chief Counsel Richard Cooper. Following this introduction, a panel of former FDA officials, will explore how major scientific accomplishments of FDA have impacted the development of the products, process and regulations of today.

Richard M. Cooper, Esq.
Gail Sherman
RADM John C. Villforth (retired)
J. Richard Crout, M.D.
John E, Vanderveen. Ph.D.
Richard E. Geyer, Esq.

Level 2 - Hall D
10:00 am - 10:30 am BREAK

Level 2 - Rms 201. 202A, 202B, 206, 207A, 207B
10:30 am - 12:30 pm Breakout Sessions 1-6

Session 1 – FDA Science at the Centennial: History and Perspective
Co-Chairs: Suzanne Junod, Ph.D., FDA History Office, Office of Regulatory Affairs, FDA
John Swan, FDA History Office, Office of Regulatory Affairs, FDA

10:30 am Introduction – Co-Chairs

10:35 am FDA: Past and Present Free Market Issues

Dan Carpenter, Ph.D., Professor of Government, Harvard University

11:00 am Regulating Teratogens: Fetal Alcohol Syndrome and Its Regulatory Implications
Janet Golden, Ph.D., Professor of History, Rutgers University

11:25 am Mid-Century Drug Regulation Case Study
Jeremy Greene, M.D., UCSF/Harvard

11:50 am Thalidomide as Seen from an International Perspective
Arthur Daemmrich, Chemical Heritage Foundation, Philadelphia

12:15 pm Questions and Discussion

Session 2 – Seafood Safety: From Algae to Aquaculture

Co-Chairs Marleen Wekell, Ph.D., Director, Office of Research, CVM, FDA
Robert Dickey, Ph.D., Research Biologist, Office of Seafood, CFSAN, FDA

10:30 Introduction – co chairs

10:35 am Monitoring drug residues and zoonotic disease in domestic and imported aquaculture products
Renate Reimschuessel, V.M.D., Ph.D., Research Biologist, Office of Research, CVM, FDA

11:00 am The Changing Seascape of Vibrio Ecology and Food Safety Management
Angelo DePaola Jr., Ph.D., Research Microbiologist, Office of Seafood, CFSAN, FDA

11:25 am Seafood toxins: New Challenges, New Solutions
Sherwood Hall, Ph.D., Supervisory Chemist, FDA, Office of Seafood, CFSAN, FDA

11:50 am Standards, facility certification, and food safety verification as means of assuring food safety of farmed shrimp
George Chamberlain, Ph.D., President, Global Aquaculture Alliance, St. Louis, MO

12:15 pm Questions and Discussion

Session 3 – Preparing for and Preventing a Modern Plague: Focus on Avian Flu

Co-Chairs Stephen Sundlof, D.V.M., Ph.D. Director, CVM, FDA
Richard Diamond, M.D., M.P.A., Office of the Director, CBER, FDA

10:30 am Introduction – co chairs

10:35 am Avian Influenza: Another "Mother of All Pandemics" or a "Swine Flu Debacle" – Applying Lessons from History Today
Jeffrey Taubenberger, M.D., Ph.D., Chief Department of Cell Pathology, Armed Forces Institute of Pathology

11:00 am Avian Influenza: Where Did It Come From, How Can It Spread, and How Can We Control It?
Daniel Perez, Ph.D., Assistant Professor, VA/MD Regional College of Veterinary Medicine, University of Maryland

11:25 am The "Nuts and Bolts" of Vaccine Development – What Are the Options for Maximizing Availability, Efficacy, and Safety?
Jerry Weir, Ph.D., Office of Vaccines Research and Review, CBER, FDA

11:50 am Tough Choices: Planning and Implementing the U.S. Strategy for Prevention and Control of Pandemic Influenza
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, DHHS

12:15 pm Questions and Discussion

Session 4 – Nanotechnology

Co-Chairs Steven Pollack, Ph.D., Office of Science and Engineering Laboratories (OSEL) CDRH, FDA
Nakissa Sadrieh, Ph.D., Associate Director for Research Policy and Implementation, CDER, FDA

10:30 am Introduction – co chairs

10:35 am Quantum dots: Emerging Applications in Biology, Imaging and Medicine
Igor L. Medintz, Ph.D., Center for Bio/Molecular Research, Naval Research Laboratory

11:00 am The Toxicology of Nanomaterials: Size, Number and Surface as Determinants of Toxicity
Günter Oberdörster, D.V.M., Ph.D., Department of Environmental Medicine, University of Rochester

11:25 am Preclinical Characterization of Nanomaterials Intended for Cancer Diagnostics and Therapeutics
Scott E. McNeil, Ph.D., Director, Nanotech Characterization Laboratory, NCI-Frederick, NIH

11:50 am From Microscopy Toward Nanoscopy and Nanobiosensing: How to Break the Diffraction Barrier in Subwavelength Nanoscale
Ilko K. Ilev, Ph.D., Division of Physics, OSEL, CDRH, FDA

12:15 pm Questions and Discussion

Session 5 – Clinical Trials and Statistics: A Glance at the Past and Present and a Look to the Future

Co-Chairs Robert O'Neill, Ph.D., Director, Office of Biostatistics, CDER, FDA
Greg Campbell, Ph.D., Office of Surveillance and Biometrics, CDRH, FDA

10:30 am Introduction – Co-Chairs

10:35 am A history of clinical trials from post Harris Kefauver, 1962, to present
Robert O'Neill, Ph.D., Director, Office of Biostatistics, CDER, FDA

11:00 am The future of clinical trials
David DeMets, Ph.D., Professor of Biostatistics and Medical Informatics, University of Wisconsin

11:25 am The future of clinical trials
John Feussner, M.D., M.P.H., FACP, Chairman, Department of Medicine, Medical University of South Carolina

11:50 am The Future of Clinical Trials - an Industry Perspective
Steve Snapinn, Ph.D., Amgen, Inc.

12:15 pm Questions and Discussion

Session 6 – Omics along the Critical Path to New Medical Products

Co-Chairs Yvonne Dragan, Ph.D., Director, Division of Systems Toxicology, NCTR

Felix Frueh, Ph.D., Associate Director for Genomics, Office of Clinical Pharmacology and Biopharmaceutics , CDER, FDA

10:30 am Introduction to Omics along the Critical Path to New Medical Products
Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA

10:55 am Impact of Omics on Various R&D Steps Leading Faster to Better Drugs
Jacky Vonderscher, Ph.D., V.P., Global Head of Biomarker Development,
Novartis Institutes for Biomedical Research, Inc.

11:20 am Combining Different -omics into a Coherent Approach for Modern Drug Development
Klaus Lindpaintner, M.D., Ph.D., VP and Director, Roche Genetics
F. Hoffmann-La Roche AG, Basel, CH

11:45 am Toward Systems Toxicology: An Integrated OMICs Platform
Yvonne Dragan, Ph.D., Director, Division of Systems Toxicology,
NCTR, FDA

12:00 pm The Impact of Pharmacogenomics at the FDA: A Glimpse at the Past and Future
Michael Orr, Ph.D., Staff Fellow, CDER, FDA

12:30 - 1:30 Lunch on your own

Level 2 - Hall D
1:30 pm – 4:30 pm **POSTER SESSION**

Level 2 - Rm 202B
1:30 pm - 4:30 pm **PUBLIC SESSION**

Wednesday, April 19

Level 3 - Ballroom C
8:30 am – 9:30 am **PLENARY Lecture**
Creating the FDA for the 21st Century
Andrew von Eschenbach, M.D., Acting Commissioner of Food and Drugs

Level 2 - Hall D
9:30 am - 10:00 am BREAK

Level 2 - Rms 201. 202A, 202B, 206, 207A, 207B
10:00 am – 12:00 pm Breakout Sessions 7-12

Session 7 – Body Marking: Tattoos, Permanent Make-up and Laser Removal
Co-Chairs: Linda Katz, M.D., M.P.H. Director, Office of Cosmetics and Colors, CFSAN, FDA
Paul Howard, Ph.D., Photosciences Laboratory, NCTR, FDA

10:00 am Introduction – Paul Howard, Ph.D., Photosciences Laboratory, NCTR, FDA

10:05 am FDA Interest; Regulatory status, knowledge gap
Linda Katz, M.D., M.P.H. Director, Office of Cosmetics and Colors, CFSAN, FDA

10:30 am The Marketplace: Chemistry
Bhakti Petigara, Ph.D., Office of Cosmetics and Colors, CFSAN, FDA

10:55 am Adverse events: the Premier case study
Masja Straetemans, Ph.D., National Center for Environmental Health, CDC, Atlanta

11:20 am Dermatological implications: Tattoo removal
Rox Anderson, M.D., Professor in Dermatology, Harvard Medical School: Director, Wellman Center for Photomedicine, Massachusetts General Hospital, Boston

11:45 am Questions and Discussion

Session 8 – Partnering on the Critical Path to New Products

Co-chairs: Wendy Sanhai, Ph.D., Senior Scientific Advisor, Office of the Commissioner, FDA
Michelle Chenault, Ph.D., Deputy Director, Medical Device Fellowship Program, CDRH, FDA

10:00 am Introduction - Co-Chairs

10:05 am C-Path Partnerships – The Predictive Safety Test Consortium and others in development
Ray Woosley, M.D., Ph.D., President, C-Path Institute, Tucson, Arizona

10:30 am Imaging as a Biomarker - FDG PET in non-Hodgkin's Lymphoma
George Mills, M.D., Director, Division of Medical Imaging and Hematological Products, Office of New Drugs, CDER, FDA

10:55 am Numerical Models and Tools - "The Virtual Family"
Wolfgang Kainz, Ph.D., Visiting Scientist, OSEL, CDRH, FDA

11:20 am Using FDA's ECG Warehouse to monitor cardiac safety in medical product development
Mitchell W. Krucoff, M.D., FACC, Professor of Medicine and Director, Cardiovascular Devices Unit, Duke Clinical Research Unit, Duke University Medical Center

11:45 Questions and Discussion

Session 9 – Rapid Detection of Multiple Pathogens

Co-Chairs: Thomas Cebula, Ph.D., Director, Office of Applied Research and Safety Assessment,, CFSAN, FDA
Carl Sciacchitano, M.S., Director, Division of Field Science, ORA, FDA

10:00 am Introduction – Co-Chairs

10:05 am Can microbial Genomics Help Re-define a Species? Implication of the "pan-genome"
Jacques Ravel, Ph.D., Institute for Genomic Research, Rockville, MD

10:30 am Tiling Arrays and Optical Mapping: Their Use in Tracking Enteric Pathogens
Thomas Cebula, Ph.D., Director, OARSA, CFSAN, FDA s

10:55 am The TIGER Universal Pathogen Sensor
David Ecker, Ph.D., Chief Scientific Officer, Ibis Technologie

11:20 am Public Health Laboratory Current and Future Rapid Detection Systems/Technologies for Biothreat Agent Detection
Richard Meyer, Ph.D., CDC

11:45 am Wrap-up - Identifying Bottlenecks
Carl Sciacchitano, M.S., Division of Field Science, ORA, FDA

Questions and Discussion

Session 10 – Bioinformatics

Co-Chairs: Fred Farmer, Ph.D., Chief Information Officer, FDA
Josep Prous, Ph.D., M.A., Executive Vice-President, Prous Science

10:00 am Introduction – Co-Chairs

10:05 am A Brief History of Scientific Computing in the Center for Food Safety & Applied Nutrition at FDA
Larry Dusold, M.S., CFSAN, FDA

10:30 am What the IUPAC Chemical Identifier (INChi) Means to You
Stephen Heller, Ph.D., National Institute of Standards and Technology

10:55 am Bioinformatics at Johnson & Johnson: the Future of FDA-Regulated Products
Lance Riggio., Ph.D. Director of Informatics, Johnson and Johnson

11:20 am HealthGrid: Grid Technologies for Biomedicine
Mary E. Kratz, MT (ASCP), University of Michigan Medical School, Information Services.

11:45 am Questions and Discussion

Session 11 – Risk-Based Inspections and Monitoring

Co-Chairs: David Horowitz, Esq., Office of Regulatory Affairs, FDA
Malcolm Bertoni, M.S., Office of Policy and Planning, OC, FDA

10:00 am Introduction – Co-Chairs

10:05 am Overview of Risk-based Prioritization for Inspection at FDA
Kara Morgan, Ph.D., Office of Policy and Planning, FDA

10:15 am CDER Risk-based Prioritization Model for Inspection
John Gardner, M.D., DrPH., Office of Compliance, CDRH, FDA

10:35 am CDRH Risk-Based Inspection Process
Karen L. Moss, Director, Division of Risk Management Operations, CDRH, FDA

10:55 am NRC's Risk-Informed Apporach for the Materials Program
Thomas Young, Senior Project Manager/Health Physicist,
Office of Nuclear Material and Safeguards, U.S. Nuclear Regulatory Commission

11:20 am The Consequence Management System
Andrew Jaine, Ph.D., BT Safety, LLC.

11:45 am Questions and Discussion

Session 12 – Personalized Medicine

Co-Chairs: Sue-Jane Wang, Ph.D., Associate Director, Office of Biostatistics, Office of Pharmacoepidemiology and Statistical Science (OPSS), CDER, FDA
William Slikker, Ph.D., Acting Director, NCTR, FDA

10:00 am Introduction – Co-Chairs

10:05 am The importance of personalized medicine: what it is and why it is critical
Catherine Wheeler, M.D., Global Product Director, Oncology, AstraZeneca

10:30 am Regulatory pathways to personalized medicine
Douglas Throckmorton, M.D., Deputy Director, CDER, FDA

10:55 am Molecular epidemiological tool kit for personalized medicine
Luke Ratnasinghe, Ph.D., Director, Center for Structural Genomics, NCTR, FDA

11:20 am Statistical classification methods for getting from concept to reality: using high-dimensional genomic and other biomarkers to assign patients to therapies
Hojin Moon, Ph.D., Mathematical Statistician, NCTR, FDA

11:45 am Questions and Discussion

12:00 pm – 1:30 pm Lunch on your own
Awards luncheon for awardees and Center Directors only

Level 3 - Ballroom C

1:30 pm – 2:15 pm PLENARY Lecture
FDA's International Role in the World of the 21st Century
Murray M. Lumpkin, M.D.
Deputy Commissioner for International and Special Programs

Level 2 - Rms 201. 202A, 202B, 206, 207A, 207B

2:30 pm – 4:30 pm Breakout Sessions 13-18

Session 13 – Obesity

Co-Chairs: Robert Brackett, Ph.D., Director, CFSAN, FDA
Van Hubbard, M.D., Ph.D., Senior Advisor to the Secretary on Obesity and Associate Director for Nutritional Sciences, NIH

2:30 pm Introduction - Co-Chairs

2:35 pm From Challenges to Funding Opportunities in Obesity: NIH Perspective on Initiative Development
Philip F. Smith, Ph.D., Co-Director, Office of Obesity Research, NIH

3:00 pm Obesity Research at the Agency for Healthcare Research and Quality
Iris R. Mabry, M.D., M.P.H., Senior Advisor on Obesity Issues, Center for Primary Care, Prevention and Clinical Partnerships, Agency for Healthcare Research and Quality, Department of Health and Human Services

3:25 pm Obesity Prevention and Control: from Surveillance to Public Health Impact
Dixie E. Snider, M.D., M.P.H., Chief Science Officer, Office of the Director, CDC

3:50 pm Nutrition Information and Obesity: CFSAN's Qualitative and Quantitative Findings
Steven Bradbard, Ph.D., Consumer Studies Specialist, CFSAN, FDA

4:15 pm Questions and Discussion

Session 14 – Bringing home biomarkers: science, regulation, and common sense

Co-Chairs: Kathryn M. Carbone, M.D., Associate Director for Research, CBER, FDA
Sousan Altaie, Ph.D., Scientific Policy Advisor, Office of In Vitro Diagnostics, CDRH, FDA

2:30 pm Introduction - Co-Chairs

2:35 pm CDER and Biomarkers: Clinical endpoints
Shirley Murphy, M.D., Deputy Director, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA

3:00 pm CDRH and Biomarkers: Strategies for the development of in vitro diagnostics
Francis Kalush, Ph.D., Office of In Vitro Diagnostics, CDRH, FDA

3:25 pm CBER and Biomarkers of Product Quality
Kathryn M. Carbone, M.D., Associate Director for Research, CBER, FDA

3:50 pm Novel Biomarkers of Early Kidney Damage in Drug Development
Martin Shaw, Senior Scientific Officer, Biomarkers, Biotrin International

4:15 pm Questions and Discussion

Session 15 – Current Challenges in the Treatment of Parasitic Diseases in Humans and Animals

Co-Chairs: Donald Prater, D.V.M., Office of New Animal Drug Evaluation, CVM, FDA
Leonard Sachs, M.D., Office of New Drugs, CDER, FDA

2:30 pm Introduction - Co-Chairs

2:35 pm Parasite Control in the Face of Widespread Drug Resistance: Changing Roles and Responsibilities for Advisors and Regulatory Officials?
Ray Kaplan, D.V.M., Ph.D., University of Georgia, Athens, Georgia

3:00 pm Anthelmintic Resistant Parasites in Ruminants (Cattle)
Louis Gasbarre, Ph.D., USDA, Maryland

3:25 pm Anthelmintic Resistant Parasites in Ruminants: Producer Point of View
Larry Smith, D.V.M., L. L. Smith Research and Development, Wisconsin

3:50 pm Resistant Parasites in Humans
Leonard Sacks, M.D., Office of New Drugs, CDER, FDA

4:15 pm Questions and Discussion

Session 16 – Combination Products

Co-Chairs: Heather Rosecrans, Head of Premarket Notification section CDRH, FDA
Mark D. Kramer, Director of Office of Combination Products, OC, FDA

2:30 pm Introduction - Co-Chairs

2:35 pm Case study: Cordis Cypher Sirolimus-Eluting Stent
Ron Dadino, Vice President, Pharmaceutical and Package Development, Cordis, a Johnson & Johnson Company

3:00 pm Case Study: Boston Scientific Taxus Paclitaxel-Eluting Stent
Kathleen M. Miller, Ph.D., Corporate Research Fellow, Boston Scientific

3:25 pm Regulatory challenges
Ashley Boam, M.S., Chief, Interventional Cardiology Devices Branch, ODE, CDRH, FDA

3:50 pm Drug-eluting stents: pharmaceutical challenges
Kasturi Srinivasachar, Ph.D., Office of New Drug Quality Assureance, CDER, FDA

4:10 pm Beyond drug-eluting stents: the next frontier in drug delivery
Bozena Michniak-Kohn, Ph.D., M.R.Pharm.S., Associate Professor of Pharmaceutics, Ernest Mario School of Pharmacy, Rutgers University

Session 17 – Advances and Frontiers in Using Records Databases for Surveillance of Medical Products

Co-Chairs: RADM Steven Galson, M.D., M.P.H., Director, CDER, FDA
Gerald Dal Pan, M.D., M.H.S., Director, Office of Drug Safety, CDER, FDA

2:30 pm Introduction - Co-Chairs

2:35 pm Drug safety in the Department of Veterans Affairs
Francesca Cunningham, Pharm.D., Department of Veterans Affairs

3:00 pm Frontiers in surveillance of medical devices
Rosalie A. Bright, Sc.D., Office of Surveillance and Biometrics, CDRH, FDA

3:25 pm Prompt, active identification of ADR signals using population-based data
Richard Platt, M.D., M.S., Professor and Chair, Dept. of Ambulatory Care and Prevention, Harvard Medical School

3:50 pm Medications - adverse events, unanticipated benefits and what to do about them - the Indiana experience
J. Marc Overhage, M.D., Regenstrief Institute for Health Care, Indiana University School of Medicine

4:15 pm Questions and Discussion

Session 18 – The Impact of the Pediatric Experience on the FDA: Where We Have Been and Where We Are Going

Co-Chairs: Rosemary Roberts, M.D., Director, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA
William Slikker, Ph.D., Acting Director, NCTR, FDA

2:30 pm Introduction - Co-Chairs

2:35 pm Adult/Pediatric Differences in PK/PD: What we have learned and the Future
Rosemary Roberts, M.D., Director, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA

3:00 pm Differences between Adults and Children – Issues in the Development and Evaluation of Medical Devices.
Aron Yustein, M.D., Deputy Director, Office of Device Evaluation, CDRH, FDA

3:25 pm Use of preclinical juvenile animal models in Designing studies for Children
William Slikker, Ph.D., Acting Director, NCTR, FDA

3:50 pm Current Ethical Concerns in Pediatric Research
Sara Goldkind, M.D., M.A., Office of Pediatric Therapeutics, FDA

4:15 pm Questions and Discussion

4:30 pm Remove posters and exhibits

Thursday, April 20

Level 3 - Ballroom C

8:30 am - 10:00 am PLENARY SESSION
Public Health Preparedness
Margaret O'K. Glavin, Moderator
Associate Commissioner for Regulatory Affairs, FDA

ADM John Agwunobi
Assistant Secretary for Health, US Department of Health and Human Services

Emerging and Re-emerging Infectious Diseases:
The Perpetual Challenge to Global Health
Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases, NIH

Accelerating the development and availability of new vaccines for a pandemic or other emerging threats - present and future
Jesse Goodman, M.D., M.P.H.
Director, Center for Biologics Evaluation and Research, FDA

Level 2 - Hall D
10:00 am - 10:30 am BREAK

Level 2 - Rms 201. 202A, 202B, 206, 207A, 207B
10:30 – 12:30 Breakout Sessions 19-23

Session 19 – Blood and Tissue Safety
Co-Chairs: Jonathan Goldsmith, M.D., Deputy Director, Office of Blood Research and Review (OBRR), CBER, FDA
Tomislav Modric, D.V.M., Ph.D., Office of New Animal Drug Evaluation (ONADE), CVM, FDA

10:30 am Introduction – History of blood and tissue product regulation
Jonathan Goldsmith, M.D., OBRR, CBER, FDA

10:35 am Blood substitutes: a Moving Target
Abdu Alayash, Ph.D., OBRR, CBER, FDA

11:00 am Transmissible Spongiform Encephalopathies (TSEs)
Robert Rowher, Ph.D., Head, Neurovirology Laboratory, VA Maryland Healthcare System

11:25 am Xenotransplantation technology
David Cooper, M.D., Ph.D., Professor of Surgery, Thomas E. Starzl Transplantation Institute, University of Pittsburgh Medical Center

11:50 am Xenotransplantaion and viral safety
Carolyn Wilson, Ph.D., Office of Cellular, Tissue and Gene Therapy (OCTG), CBER, FDA

12:15 pm Questions and Discussion

Session 20 – Public Health During Natural Disasters: The FDA Katrina-Rita Experience
Co-Chairs: RADM Richard Barror., Chief Engineer, USPHS
CAPT Darcy Hanes, Ph.D., Office of Applied Research and Safety Assessment, CFSAN, FDA

10:35 am Coordinating the FDA Response to Katrina and Rita
Ellen Morrison, Director, Office of Crisis Management, FDA

11:00 am Medical care, support, supplies and pharmaceuticals in the field setting
CDR Sarah Linde-Feucht, M.D., Office of Orphan Product Development, FDA

11:25 am Implementing a Continuity of Operations (COOP) Plan
Tyler Thornburg, Director, New Orleans Office, Office of Regulatory Affairs, FDA

11:50 am Food Safety and Inspectional Issues
Chester Morris, Director of State Programs, SE Region, ORA Atlanta

12:15 pm Concluding Remarks

Session 21 – Minimally Invasive Devices

Co-Chairs: Joshua Pfefer, CDRH
Gerry Harris, CDRH

10:30 am Introduction
Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA

10:40 am Optical Coherence Tomography for Detection of Atherosclerotic Plaque
Guillermo J. Tearney, M.D., Ph.D., Associate Professor of Pathology, Wellman Center for Photomedicine, Harvard Medical School

11:05 Some Recent Advances in Therapeutic Ultrasound
Lawrence Crum, Ph.D., Director, Center for Industrial and Medical Ultrasound, Applied Physics Laboratory, University of Washington, Seattle, WA

11:30 Recent Advances in Medical Imaging
Kyle Myers, Ph.D., Laboratory Leader, Medical Imaging and Diagnostics, Division of Imaging and Applied Mathematics, OSEL, CDRH, FDA

11:55 Image-guided Surgery and Drug Therapy
Bradford Wood, M.D., Interventional Radiologist, Diagnostic Radiology Department, Clinical Center, NIH

12:20 pm Questions and Discussion

Session 22 – Managing Uncertainty in Risk Assessment: Probabilistic Approaches

Co-Chairs: Robert Buchanan, Ph.D., Director, Office of Science, CFSAN, FDA
Gregg Claycamp, Ph.D., Director, Scientific Support Staff, ONADE, CVM, FDA

10:30 am Introduction – co chairs

10:35 am Probabilistic Approaches to Characterization of Toxicity
Lorenz Rhomberg, Ph.D., Principal, Gradient Corporation

11:00 Hierarchical Probabilistic Models for Managing Uncertainty
Ralph Kodell, Ph.D, Director, Division of Biometry and Risk Assessment, NCTR, FDA

11:25 Statistics, Public Health, and Probability
Clark Carrington, Ph.D., Office of Plant and Dairy Foods, CFSAN, FDA

11:50 Misuse and Non-Use of Uncertainty Analysis in Health Risk Assessment

Adam Finkel, D.Sc, Professor, UMDNJ School of Public Health and Visiting Professor, Princeton University

12:15 pm Questions and Discussion

Session 23 – Novel Approaches to Cancer Therapy and Monitoring

Co-Chairs: Robert Justice, M.D., CDER, FDA
Raj Puri, M.D., Ph.D., CBER, FDA

10:30 am Introduction - co chairs

10:35 am Development and Evaluation of Targeted Cancer Therapies
Amna Ibrahim, M.D., Acting Medical Team Leader, CDER, FDA

11:00 am Challenges in the Development of Therapeutic Cancer Vaccines
Ke Liu, M.D., Ph.D. Medical Officer, CBER, FDA

11:35 am Novel issues in Cancer Therapy: Autoimmunity and Therapeutic Response
Jim Yang, M.D., National Cancer Institute

11:50 am The Emerging Role and Challenges for Imaging in Drug Development
Lawrence Schwartz M.D., Director, Magnetic Resonance Imaging, Memorial Sloan – Kettering Cancer Institute

12:15 pm Questions and Discussion

12:30 pm **Science Forum Ends**