FDA Critical Path Initiative (CPI) on the Move

Complexities and Challenges

September 15-16, 2008 | Marriott Bethesda Pooks Hill, Bethesda, MD, USA

PROGRAM CHAIR

RACHEL E. BEHRMAN, MD, MPH
Director, Office of Critical Path Programs, OC, FDA

LEONARD SACKS, MD
Deputy Director, Office of Critical Path Programs, OC, FDA

PROGRAM COMMITTEE

SOUSAN S. ALTAIE, PhD
Scientific Policy Advisor, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH, FDA

RICHARD BEGER, PhD
Branch Chief, Center for Metabolomics, Division of Systems Toxicology, NCTR, FDA

DIANNE L. BENJAMIN, MS, RD, LDN, CP-FS
Policy Analyst, Executive Operations Staff, Office of the Center Director, CFSAN, FDA

ASHLEY BOAM, MSBE
Chief, Interventional Cardiology Devices Branch, Divison of Cardiovascular Devices, CDRH, FDA

SHAAVHREE BUCKMAN, MD, PhD, FAAP
Acting Director, Office of Translational Sciences, CDER, FDA

DEVOTA DEMARCO
Special Assistant, Office of Critical Path Programs, OC, FDA

CAROL FEDORCHAK
Policy Analyst, CFSAN, FDA

KAREN E. R. LAMPE, PhD
Microbiologist
Division of Human Food Safety, Microbial Food Safety Team, CVM, FDA

BAITANG NING, PhD
Research Scientist, NCTR, FDA

NANCY STANISIC
Health Science Administrator, Office of Critical Path Programs, OC, FDA

ANN STATEN, RD
Senior Policy Analyst, Office of Critical Path Programs, OC, FDA

VINCENT VILKER, PhD
Director, Office of Testing and Research
Office of Pharmaceutical Science, CDER, FDA

CAROLYN WILSON, PhD
Associate Director for Research, CBER, FDA

CONTACT INFORMATION

Program Manager, Kathleen Donner
Phone +1-215-293-5810
email Kathleen.Donner@diahome.org

Critical Path Initiative: A Key FDA Science-based Effort to Modernize the Science and Tools Used in the Development, Evaluation, Manufacture, and Use of all FDA-regulated products.

This workshop will explore what has been accomplished, current projects and their status, and future opportunities.

BREAKOUT SESSIONS BY FDA CENTER

Interact directly with FDA Center Leaders! Each breakout will feature presentations followed by audience Q&A, interaction, and discussion.

- National Center for Toxicological Research (NCTR)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Veterinary Medicine (CVM)
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)

ROUNDTABLE SESSION WITH FDA CENTER DIRECTORS

The last session of the day will bring together all of the FDA Center Directors for a dynamic roundtable discussion!

FEATURED SESSION TOPICS

- Why We Need Biomarkers
- Why CPI, What We've Done, What We Want to Do
- Innovation: An Economic Perspective
- Predictive Biomarkers
- Patients and Consumers on the Critical Path
- Partnerships (Lessons Learned and Intellectual Property Issues)
- Transforming Clinical Trials

TARGET AUDIENCE

Government, academia, and industry professionals involved in:

- **Public health**
- **Consumer advocacy**
- **Medical product development**
- **Health economics and outcomes research**
- **Research & development**
- **Regulatory affairs**
- **Food allergen thresholds**
- **Food additive safety databases**
- **Molecular epidemiology and microbial forensics**
- **Biomarkers for chronic disease risk**

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DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

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To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives: At the conclusion of this conference, participants should be able to:

- Explain the purpose of the Critical Path program;
- Identify future challenges of the CPI;
- Define how to initiate Critical Path projects; and
- Discuss current Critical Path projects.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice.
Recording of information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.

SUNDAY • SEPTEMBER 14

6:00-8:00 PM REGISTRATION

MONDAY • SEPTEMBER 15

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS
Frank Torti, MD
Principal Duty Commissioner and Chief Scientist, Office of the Commissioner, FDA
Rachel Behrman, MD
Director, Office of Critical Path Programs, FDA

8:30-9:30 AM SESSION I

Introduction

Why We Need Biomarkers
Mark Harrington
Treatment Action Group

Why CPI, What We've Done, What We Want to Do
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Innovation: An Economic Perspective
Mark B. McClellan, MD, PhD
Director, Engelberg Center for Health Care Reform at the Brookings Institution and Leonard D. Schaeffer Chair in Health Policy Studies, Brookings Institution

9:30-9:45 AM REFRESHMENT BREAK

9:45-11:30 AM SESSION 2

Predictive Biomarkers
Panel Leads
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA
Raymond L. Woosley, MD, PhD
President and CEO, The Critical Path Institute

Panelists

Qualify Improved Translational Safety Biomarkers for Early Drug Development
Frank D. Sistare, PhD
Executive Director, Safety Assessment, Merck and Co., Inc.

The Alzheimer's Disease-Neuroimaging Initiative (ADNI)
Richard J. Hodes, MD
Director, National Institute on Aging, National Institutes of Health
Timothy Wright, MD
Head of Translational Sciences, Novartis

Role of Prospective Clinical Trials to Qualify Biomarkers Predictive of Drug Response
Gary Kelloff, MD
Special Advisor to NCI's Cancer Imaging Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute

Harmonization of Immune Response Assays
Axel Hoos, MD, PhD
Group Director, Ipilimumab, Bristol-Myers Squibb

11:30 AM-12:15 PM LUNCHEON

12:15-1:15 PM SESSION 3

Patients and Consumers on the Critical Path

Panel Leads

Theresa A. Toigo, RPh, MBA
Director, Office of Special Health Issues, FDA

Nancy Roach
President, C3: Colorectal Cancer Coalition

Introduction
Theresa A. Toigo, RPh, MBA
Director, Office of Special Health Issues, FDA

Incorporating Patient and Consumer Input into Regulatory Decisions at FDA
Richard Klein
Public Health Specialist, Office of Special Health Issues, FDA

Path of a Patient Advocate at FDA
Nancy Roach
President, C3: Colorectal Cancer Coalition

Engagement of Patients, Consumers, and Health Care Professionals in the Sentinel Initiative
Janet Marchibroda
CEO, eHealth Initiative and Foundation

Concluding Remarks
Nancy Roach
President, C3: Colorectal Cancer Coalition

1:15-2:45 PM SESSION 4

Partnerships (Lessons Learned and Future Challenges)

Panel Leads

Jeff Cossman, MD
Chief Science Officer, Critical Path Institute

Leonard Sacks, MD
Deputy Director, Office of Critical Path Programs, FDA

Panelists

Industry-induced Private Partnerships
Arthur L. Holden, MD
Chairman and CEO, Pharmaceutical Biomedical Research Consortium, Ltd.

Partnering with the Government from the NIH Perspective
Barbara B. Mittleman, MD
Director, Public-Private Partnership Program, Office of Science Policy, Office of the Director, National Institutes of Health

Overview of Legal Considerations in Public Private Partnerships
Annette Levey, JD
Office of General Counsel, National Institutes of Health

Experience in Setting Up a Couple of Consortia
Jacky Vonderscher, PhD
Senior Vice President, Global Head of Molecular Medicine Labs Group Research, Hoffmann-La Roche, Switzerland

David Wholley, MD
Foundation for the National Institutes of Health

Industry-induced Private Partnerships
Rebecca D. Kush, PhD
President and CEO, CDISC
Ed Nuzum, DVM, PhD
Chief, Biodefense Vaccines and Other Biological Products Development Section, Office of Biodefense Research Affairs (OBRA), DMID/NIAID/National Institutes of Health

2:45-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 5

Transforming Clinical Trials

Panel Leads

Rachel Behrman, MD
Director, Office of Critical Path Programs, FDA

Robert Califf, MD
Vice Chancellor for Clinical Research, Duke University Medical Center; Director, Duke Translational Medicine Institute

Panelists

Glenn J. Gormley, MD
President and CEO, Gemin X Pharmaceuticals

Mark Behm
Senior Director, Compliance Advice and Assurance, AstraZeneca LP

Clinical Trials Transformation Initiative (CTTI)
Judith M. Kramer, MD, MS
Executive Director, Clinical Trials Transformation Initiative (CTTI), Duke Translational Medicine Institute

Amy Patterson, MD
Director, Office of Biotechnology Activities, National Institutes of Health

Joanne R. Less, PhD
Director, Good Clinical Practice Program, Office of Scientific Health and Communications, FDA

Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

TUESDAY • SEPTEMBER 16

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 AM-12:00 PM SESSION 6

Looking Forward: Breakout Sessions by Center

Breakout sessions will be held simultaneously and will include in-depth discussion with Center leaders and Directors and time for Q&A. *The refreshment break will be held from 10:00-10:30 AM.*

National Center for Toxicological Research (NCTR)

Critical Path Research and Development at the NCTR

Breakout Leader
William Slikker, Jr., PhD
Director, National Center for Toxicological Research, FDA

Overview: Critical Path Research at the NCTR
William Slikker, Jr., PhD
Director, National Center for Toxicological Research, FDA

Lessons Learned from MAQC I and MAQC II
Leming Shi, PhD
Computational Chemist, National Center for Toxicological Research, FDA

Concepts and Challenges for Developing Personalized Nutritional Medicine for the FDA and World Populations
James A. Kaput, PhD
Director, Division of Personalized Nutrition and Medicine, National Center for Toxicological Research, FDA

A Systems Biology Approach to Idiosyncratic Liver Toxicity
James C. Fuscoe, PhD
Director, Center for Functional Genomics, National Center for Toxicological Research, FDA

Critical Path Research in Microbiology at the NCTR
John B. Sutherland, PhD
National Center for Toxicological Research, FDA

Development of a PIG-A Gene Mutation Assay for Use in Pharmaceutical Safety Testing during Clinical Trials
Vasily Dobrovolsky, PhD
National Center for Toxicological Research, FDA

FDA Electronic Data Submission Pilots for Standardized Study Data
Weida Tong, PhD
Director, Center for Toxicoinformatics, National Center for Toxicological Research, FDA

Incorporating Bio-Imaging Tools into Toxicological Research
Merle Paule, PhD
Director, Division of Neurotoxicology, National Center for Toxicological Research, FDA

PANEL DISCUSSION

All Speakers Above and

James A. Popp, DVM, PhD
Stratoxon, LLC

Center for Food Safety and Applied Nutrition (CFSAN)

BREAKOUT LEADER
Donald L. Zink, PhD
Acting Senior Science Advisor, Senior Scientist, FDA

Food Allergen Thresholds: Applications and Data Gaps

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires the labeling of foods that contain ingredients that are, or that contain, any one of eight major food allergens. FALCPA also contains provisions that allow for labeling exemptions obtained through either a notification or petition process. The criteria used to evaluate these notifications ("does not contain allergenic protein") and petitions ("does not cause an allergic response that poses a risk to human health") require an understanding of how to determine the levels and distributions of allergen response thresholds within sensitive populations.

Steven Gendel, PhD
Center for Food Safety and Applied Nutrition, FDA

Quantitative Structure Activity Relationship Analysis and Chemoinformatics Meet Human Health Effects and Food Additives

Aggressive statutory timelines for the premarket review of food ingredients has created a need to provide computational toxicology support for more timely and systematic safety decisions. In addition, the need for risk analysis in short time frames to support emergency response to food and food ingredient contamination requires that preclinical and clinical data relevant to safety as well as tools for analyzing that data be immediately available at the FDA reviewer's desktop.

Over the past several years, OFAS has implemented the use of QSAR in its evaluation of food ingredients and made significant strides in capturing and making available in electronic format preclinical safety data to our review scientists.

Kirk B. Arvidson, PhD
Center for Food Safety and Applied Nutrition, FDA

Mitchell A. Cheeseman, PhD
Center for Food Safety and Applied Nutrition, FDA

Positioning US FDA in the International Regulatory Initiatives via the Computational Toxicology Program in CFSAN

US FDA CFSAN and CDER have embarked on a program to incorporate reliable QSAR computational toxicology methods into the workflow of the risk assessment process. Through a Cooperative Research and Development Agreement, this program provides: 1) structure-searchable toxicity databases, 2) QSAR computational toxicology prediction software, 3) a tool to streamline the review and database processes by integrating these activities, and 4) the ability to assess chemical fate via read-across or predictions. This program will have an important impact on international initiatives. The DSL program in Canada, and REACH, and the 7th Amendment for Cosmetics in the EU are legislative initiatives that have invigorated the demand for robust QSAR computational toxicology techniques and highly sophisticated databases. EU and OECD have made numerous publicly free tools and databases available on their regulatory agencies' websites. US EPA initiated a ToxCast program for OECD countries to be part of this effort, possibly redefining EPS's risk assessment methodology. This talk emphasizes how US FDA CFSAN plays an important role in the international community through its computational toxicology program.

Chihae Yang, PhD
Chief Scientific Officer, Leadscope, Inc.

Kirk B. Arvidson, PhD
Center for Food Safety and Applied Nutrition, FDA

Mitchell A. Cheeseman, PhD
Center for Food Safety and Applied Nutrition, FDA

Where Molecular Epidemiology and Microbial Forensics Meet for Food Safety

This summer's investigation of the outbreak of *Salmonella* Saintpaul initially linked to tomatoes has required major efforts by FDA and was referred to by Commissioner von Eschenbach as "the most prolonged, difficult, and complex foodborne outbreak in FDA's history. Owing to part of the difficulty was the lengthy timeframe for identification of *Salmonella* in food samples and subsequent assay of positive samples for identification of the Saintpaul sub-species. Several of the the technologies developed in partnership with the National Bioforensics Analysis Center (NBFAC) of the Department of Homeland Security for forensics identification and tracking of strains of *E. coli, Shigella, Salmonella*, and other foodborne pathogens that might be used as agents of bioterrorism might be applied to epidemiological investigation of natural outbreaks. The projects serve the Critical Path mission for translation of FDA research into applications that serve public health and safety.

Joseph E. LeClerc, PhD
Center for Food Safety and Applied Nutrition, FDA

Developing a Framework for Biomarker Qualification for Chronic Disease Risk

Surrogate endpoints of chronic disease risk are risk biomarkers that serve as a substitute for clinical endpoints (e.g., coronary heart disease). Surrogate endpoints predict clinical benefit and can be modified by various factors such as diet, drugs and lifestyle. The lack of surrogate endpoints requires that the actual clinical endpoint be measured in response to an intervention, such as diet change. Validated modifiable risk biomarkers for chronic disease risk are very limited. The specific goal is to develop a framework for validating modifiable risk factors (biomarkers) for chronic diseases such as cancer, heart disease, diabetes and others that can be the subject of a health claim or qualified health claim.

Kathleen Ellwood, PhD
Center for Food Safety and Applied Nutrition, FDA

Center for Veterinary Medicine (CVM)

Delivering the Technology to Meet the Therapeutic and Production Needs for Animals in the 21st Century

Breakout Leaders

Kevin Greenlees, PhD
Center for Veterinary Medicine, FDA

Animal Health Industry Embraces Underlying Principles of CPI

Stephen F. Sutherland, DVM
Senior Director, Regulatory Affairs
Pfizer Animal Health

Speakers and Panelists

Interrogating the Genomic Diversity of Enteric Pathogens Using a Novel 85 Genome Salmonella enterica, Escherichia coli, Shigella *and* Vibrio cholerae *Multi-Species Microarray*
Isha Patel
Center for Food Safety and Applied Nutrition, FDA

Pharmacogenomics of the MDR-1 Gene Mutation and the Effect on P-Glycoprotein Substrates in Dogs
Haile Yancy, PhD
Center for Veterinary Medicine, FDA

Development of Immediate Release Oral Formulations Using the Concept of Quality by Design (QbD) and Predicting in vivo *and* in vitro *Performance for Low Solubility Drugs in Humans and Veterinary Species*
Marilyn Martinez, PhD
Center for Veterinary Medicine, FDA
Raafat Fahmy, PhD
Center for Veterinary Medicine, FDA

Characterization and Functional Analysis of Bronchial Antimicrobial Peptides Using an Animal Pneumonia Model
Jeffrey Ward, PhD
Center for Veterinary Medicine, FDA

Pharmacogenetics in Veterinary Medicine: Past, Present and Future
Katrina L. Mealey, DVM, PhD
Associate Professor, College of Veterinary Medicine, Washington State University

Resistance to 3rd Generation Cephalosporins in Salmonella from NARMS Retail Meats Studies
Shaohua Zhao
Research Microbiologist, Center for Veterinary Medicine, FDA

Center for Biologics Evaluation and Research (CBER)

Predictive Markers of Safety, Toxicity, and Efficacy

Breakout Leaders

Carolyn A. Wilson, PhD
Associate Director for Research, Center for Biologics Evaluation and Research, FDA

CBER Research: On the Critical Path
Carolyn A. Wilson, PhD
Associate Director for Research, Center for Biologics Evaluation and Research, FDA

Critical Path Genomics Research Addressing Regulatory Challenges
Raj K. Puri, MD, PhD
Director, Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research, FDA

Gene and Micro RNA Expression Profiling to Improve Potency and Stability Testing of Cellular Therapies
David Stroncek, MD
Chief, Cell Processing Section, Department of Transfusion Medicine Clinical Center, National Institutes of Health

Statistical Issues Concerning Cancer Vaccines, Biomarkers and Clinical Trials
Richard Simon, DSc
National Cancer Institute
Boguang Zhen, PhD
Mathematical Statistician, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, FDA

Biomarkers for Predicting the Safety and Efficacy of Vaccines
Konstantin Chumakov, PhD
Associate Director for Research (Acting), Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA

Hemoglobin-based Oxygen Carriers
Felice D'Agnillo
Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA

FDA Panelists

Ashok Batra, MD
Director, Division of Clinical Evaluation and Pharmacology/Toxicology, Office of Cellular, Tissues, and Gene Therapies, Center for Biologics Evaluation and Research, FDA

Basil Golding, MD
Director, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA

Center for Devices and Radiological Health (CDRH)

A New Paradigm in Medical Device Design and Evaluation

Moderators

Larry Kessler, ScD
Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA
Sousan S. Altaie, PhD
Scientific Policy Advisor, OIVD, Center for Devices and Radiological Health, FDA

Speakers

Leveraging Medical Imaging and Computer Models in Cardiovascular Device Design and Evaluation
Charles A. Taylor, PhD
Associate Professor of Bioengineering, Stanford University

Accelerating the Availability of an Artificial Pancreas: Progress to Date and Remaining Challenges
Cynthia Rice
Director, New Technology Access
Juvenile Diabetes Research Foundation (JDRF)
Arleen Pinkos
Scientific Reviewer, Office of In Vitro Diagnostic Device Evaluation and Safety; Chair, Interagency Artificial Pancreas Working Group, Center for Devices and Radiological Health, FDA

Translational Biomarkers for Early Detection of Kidney Toxicity
Vishal S. Vaidya, PhD
Head, Laboratory of Kidney Toxicology and Regeneration, Instructor in Medicine, Harvard Medical School Associate Biologist, Brigham and Women's Hospital

NCI Initiatives for Quantitative Imaging as a Biomarker
Larry Clarke, PhD
Cancer Imaging Program, National Cancer Institute, National Institutes of Health

Validation of Computational Fluid Dynamic Techniques Used to Evaluate Medical Devices
Sandy Stewart, PhD
Office of Science and Engineering Laboratories, Division of Solid and Fluid Mechanics, Center for Devices and Radiological Health, FDA

PANELISTS

All Speakers Above and

Donna R. Lochner
Office of Device Evaluation, Division of Cardiovascular Devices, Center for Devices and Radiological Health, FDA

Ronald Brown, PhD
Office of Science and Engineering Laboratories, DB, Center for Devices and Radiological Health, FDA

Kyle J. Myers, PhD
Division of Imaging and Applied Mathematics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

Nick Petrick, PhD
Division of Imaging and Applied Mathematics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

Center for Drug Evaluation and Research (CDER)

Leveraging Prior Knowledge to Inform Decision Making

BREAKOUT LEADERS

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Gail H. Cassell, MD
Vice President, Scientific Affairs, Eli Lilly and Company

FDA SPEAKERS

ECG Warehouse
Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products Office of Drug Evaluation I, Center for Drug Evaluation and Research, FDA

Analgesic Clinical Trials Project and SAFEKIDS Project
Robert A. Rappaport, MD
Director, Division of Anesthesia, Analgesia and Rheumatology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA

A Critical Path Project: Leveraging Prior Quantitative Knowledge Using Disease Models
Dr. Jogarao V. Gobburu
Pharmacometrics, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, FDA

QSAR Computational Toxicology
R. Daniel Benz, PhD
Informatics and Computational Safety Analysis Staff
Center for Drug Evaluation and Research, FDA

Quality by Design-Critical Path and Other Leveraging Activities
Helen N. Winkle
Director, Office of Pharmaceutical Science
Center for Drug Evaluation and Research, FDA

Molecular Clinical Safety Program: Integrating Chemistry, Pre-Clinical and Clinical Knowledge to Maximize Patient Safety
June S. Almenoff, MD, PhD, FACP
Vice President, Safety Evaluation and Risk Management
Global Clinical Safety and Pharmacovigilance
GlaxoSmithKline

PANELISTS

Donald R. Stanski, MD
Global Head, Modeling and Simulation, Novartis

Raymond L. Woosley, MD, PhD
President and CEO, The Critical Path Institute

Jonca Bull, MD
Vice President, FDA Liaison, US Medical and Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Steven Kozlowski, MD
Director, Office of Biotechnology Products
Office of Pharmaceutical Science
Center for Drug Evaluation and Research, FDA

12:00-1:00 PM LUNCHEON

1:00-3:00 PM SESSION 7

LOOKING FORWARD: ROUNDTABLE SESSION WITH THE FDA CENTER DIRECTORS

PANEL LEADS

Rachel Behrman, MD
Director, Office of Critical Path Programs, FDA

Raymond L. Woosley, MD, PhD
President and CEO, The Critical Path Institute

Mark B. McClellan, MD, PhD
Director, Engelberg Center for Health Care Reform at the Brookings Institution and Leonard D. Schaeffer Chair in Health Policy Studies, Brookings Institution

PANELISTS (TO SUMMARIZE 3 TOP PRIORITY AREAS IN THEIR SECTOR)

Daniel G. Schultz, MD
Director, Center for Devices and Radiological Health, FDA

William Slikker, PhD
Director, National Center for Toxicological Research, FDA

Stephen F. Sundlof, DVM, PhD
Director, Center for Food Safety and Applied Nutrition, FDA

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Jesse Goodman, MD, MPH
Director, Center for Biologics Evaluation and Research, FDA

Tracey Forfa, DVM
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA

3:00-3:15 PM CLOSING REMARKS

3:15 PM CONFERENCE ADJOURNED

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Complexities and Challenges

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Co-sponsored by FDA and DIA Drug Information Association

Register online or fax this page to +1-215-442-6199

EVENT CONTACT INFORMATION

Contact Kathleen Donner at the DIA office by telephone at +1-215-293-5810, fax +1-215-442-6199 or email Kathleen.Donner@diahome.org.

Registration Fees

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CANCELLATION POLICY: On or before SEPTEMBER 9, 2008

Administrative fee that will be withheld from refund amount:

Industry = $200

Government or Academia or Nonprofit = $100

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

❑ **I cannot attend but please keep me informed of DIA's future events.**
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TRAVEL AND HOTEL

The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Marriott Bethesda Pooks Hill is holding a block of rooms at the reduced rate below until August 25, 2008, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $196 **Double $196**

Please contact the Marriott Bethesda Pooks Hill by telephone at +1-800-228-9290 or +1-301-897-9400 and mention the DIA event. The hotel is located at 5151 Pooks Hill Road, Bethesda, MD 20814, USA.

Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

REGISTRATION FORM

PLEASE CONSIDER THIS FORM AN INVOICE 08039

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❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.