2013 ICD² Schedule of Events

MONDAY, FEB 25

Lunch is provided in the Hill Country Dining Room. Please inform the staff you are with the ICD2 Conference.

Theme: At the Intersection of Global Policy, Regulation and Innovation

2:20-3:00 PM **Welcome/Opening Remarks**

Salomon Stavchansky, Ph.D.
ICD2 Conference Scientific Chair
Alcon Centennial Professor of Pharmaceutics
The University of Texas at Austin College of Pharmacy

M. Lynn Crismon, Pharm.D., FCCP, BCCP
Dean, James T. Doluisio Regents Chair & Behrens Inc. Centennial Professor of Health Outcomes & Pharmacy Practice
The University of Texas at Austin College of Pharmacy

Moderator: *Samuel D. Maldonado, M.D., MPH, FAAP*
Vice President & Head, Pediatric Drug Development Center for Excellence: Johnson & Johnson PRD

3:00-3:45 PM **FDA/CDER Update Challenges & Opportunities of FDASIA; Impact of User Fees BsUFA, MDUFA, GDUFA on Innovation and Access to Drugs; Impact of Globalization on ICH Implementation; Impact of FDASIA on Drug Product Quality**

Janet Woodcock, M.D.
Director CDER
DHHS/FDA/CDER/OD

Subtheme: Impact of FDA Proactive Approach to Transparency on Innovation and Drug Development - Risks and Benefits

Moderator: *John M. Engle, J.D.*
Engel & Novitt, LLP

3:45-4:15 PM **Benefits of Transparency - European Perspective**

Dr. Thomas Lönngren
Consultant / NDA Group

4:15-4:45 PM **Risks of Transparency - Intellectual Property and Liability Considerations - Industry and Legal Perspective**

James J. Kelley, J.D.
Senior Director - Associate General Patent Counsel
Eli Lilly and Company

Moderator: *Andrea Masciale, J.D.*
Vice President, Global Regulatory Policy & Intelligence, Janssen Pharmaceutical Companies of J&J

4:45-5:15 PM **Risks and Benefits of Transparency - FDA Perspective**

Steven Kozlowski
Director, Office of Biotechnology Products, FDA

5:15-5:45 PM **Point/Counterpoint Round Table Discussion**

6:00-7:15 PM **Welcome Reception & Dinner**
Canyons Dining Room

Theme: Patient Focused Drug Development

Moderator: *Kay Holcombe*
Senior Policy Advisor, Genzyme

7:15-8:00 PM **Impact of Patient's Perspective in Drug Development - Factoring Patient Benefit and Risk into FDA Decision-Making**

Charles A. Johnson, MB, ChB
Vice President
Global Medical Affairs
Vertex Pharmaceuticals

Robert J. Beall, Ph.D.
President & Chief Executive Officer
Cystic Fibrosis Foundation

TUESDAY, FEB 26

7:30 AM **Continental Breakfast Outside The Forum**

Theme: Point/Counterpoint Discussion: Globalization of R&D - Evolving Role of The United States in the Globalization of Research and Development

Subtheme: Clinical Perspectives

Moderator: *Joanne Waldstreicher, M.D.,* Chief Medical Officer
Johnson & Johnson

8:00-8:15 AM **Globalization of R&D - Evolving Role of The United States in the Globalization of Research and Development**

Joanne Waldstreicher, M.D.
Chief Medical Officer
Johnson & Johnson

8:15-8:50 AM **Globalization of Research and Development - Evolving Role of The United States - FDA Perspective**

Janet Woodcock, M.D.
Director CDER
DHHS/FDA/CDER/OD

8:50-9:20 AM **Globalization of Research and Development - Evolving Role of The United States - Industry Perspective**

Dr. Robert Kowalski
Senior Vice President
Global Head Regulatory Affairs
US Head of Development
Novartis Pharmaceuticals Corp.

9:20-9:35 AM **Break**

Moderator: *Joanne Palmisano, M.D., FACP*
Vice President Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals

9:35-10:10 AM **New Initiatives of The Office of Generic Drugs - Challenges and Opportunities offered by GDUFA**

Greg Geba, M.D., MPH
Director of the Office of Generic Drugs, FDA

10:10-10:40 AM **Challenges and Opportunities by GDUFA - GPhA Perspective**

David Gaugh
Senior Vice President for Sciences and Regulatory, GPhA

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Moderator: *Volker Fischer, Ph.D.*
Abbott Laboratories

10:40-11:10 AM **Globalization of Research and Development - Academic Clinical Perspective**
David E. Gerber, M.D.
Assistant Professor, Division of Hematology-Oncology
Harold C. Simmons Cancer Center
University of Texas Southwestern Medical Center

11:10-11:40 AM **Globalization of Research and Development - Evolving Role of The United States - CRO Clinical Perspective**
Kenneth A. Somberg, M.D., M.B.A.
Chief Medical Officer
Covance, Inc.

Moderator: *Kenneth I Kaitin, Ph.D.*
Professor and Director
Tufts Center for the Study of Drug Development
Tufts University School of Medicine

11:40-12:10 PM **Point/Counterpoint Round Table Discussion**

12:10-1:30 PM **Lunch**
Hill Country Dining Room

Theme: Globalization of Research and Development - Evolving Role of The United States and Quality of Pharmaceuticals

SubTheme: Chemistry, Manufacturing and Controls (CMC)

Moderator: *Charles P. Hoiberg, Ph.D.*
Executive Director
Pfizer Pharmaceuticals

1:30-2:15 PM **Confidence in Quality: Global Challenges and Opportunity - Current and Future State**
Christine M.V. Moore, Ph.D.
Acting Director
ONDQA/CDER/FDA

2:15-2:45 PM **Confidence in Quality: Global Challenges & Opportunities - Registering a Product in Many Markets**
Roger Nosal
Vice President, Global CMC
Pfizer Inc.

2:45-3:00 PM **Break**

Moderator: *Terrance W. Ocheltree, Ph.D., R.Ph.*
Director, Division of New Drug Quality Assessment II
ONDQA/OPS/CDER

3:00-3:30 PM **Confidence in Quality: Global Challenges and Opportunity - Future State**
Christopher Sinko, Ph.D.
Senior Vice President
Bristol-Myers Squibb

3:30-4:00 PM **Point/Counterpoint Round Table Discussion**

4:00-4:15 PM **Break**

Theme: Impact of Health Technical Assessments and Drug Reimbursement Models on Drug Development

Moderator: *Dr. Susan Longman*
North America Head, Drug Regulatory Affairs
Novartis Pharmaceuticals

4:15-4:45 PM **Introductory Remarks and European Model for Drug Reimbursement Lessons Learned**
Thomas Lönngren, M.D.
Consultant / NDA Group

4:45-5:15 PM **Drug Pricing and Reimbursement in the US, UK and Germany**
Joshua P. Cohen, Ph.D.
Senior Research Fellow
Tufts Center for the Study of Drug Development

5:15-5:45 PM **Cost-effectiveness Analysis of Differential Pricing of Drugs for Access**
Adrian Thomas, M.D., FRACP
Vice President, Global Market Access & Commercial Strategy Operations
Janssen Global Services, LLC

5:45-6:15 PM **Point/Counterpoint Round Table Discussion**

6:15-6:40 PM **Break**

6:40-8:45 PM **Dinner**
The Pavilion

Subtheme: Pathway to Global Product Quality and Safety

Moderator: *Mehul Mehta, Ph.D.*
Director, Division of Clinical Pharmacology I, OTS/CDER/FDA

6:40-7:40 PM **Update on the Pathway to Global Product Safety and Quality**
Deborah M. Autor, Esq.
Deputy Commissioner for Global Regulatory Operations and Policy
FDA

Moderator: *Gerald J. Yakatan, Ph.D.*
Founder, IriSys Inc.

7:40-9:00 PM **FDA Panel Discussion**
Janet Woodcock, M.D.
Director CDER

Deborah M. Autor, Esq.
Deputy Commissioner for Global Regulatory Operations and Policy

Greg Geba, M.D., MPH
Director of the Office of Generic Drugs

Steven Kozlowski
Director, Office of Biotechnology Products

Mehul Mehta, Ph.D.
Director, Division of Clinical Pharmacology I
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Christine M.V. Moore, Ph.D.
Acting Director
ONDQA/CDER

Terrance W. Ocheltree, Ph.D., R.Ph.
Director, Division of New Drug Quality Assessment II
ONDQA/OPS/CDER

WEDNESDAY, FEB 27

Registrants Depart

Continental Breakfast available outside the Houston Room