THE EIGHTH ANNUAL

Pharmaceutical Regulatory Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

CONTINUING EDUCATION CREDITS AVAILABLE: ACCME • ACMPE AHIMA • ANCC • CA BRN • CISSP/SSCP • HCCB • MCLE • NASBA

November 7–9, 2007

Omni Shoreham Hotel • Washington, DC

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Keynote Speakers:


Robert A. Ingram

Robert A. Ingram, Vice Chairman Pharmaceuticals, GlaxoSmithKline, Chairman, OSI Pharmaceuticals, Inc., Chairman, VALEANT Pharmaceuticals International, Research Triangle Park, NC


Mark W. Kline

Mark W. Kline, MD, Professor of Pediatrics, Chief, Retrovirology Clinic, Texas Children's Hospital, Director, Baylor International Pediatric AIDS Initiative, Assistant Program Director, General Clinical Research Center, Baylor College of Medicine, Houston, TX


Peter Lurie

Peter Lurie, MD, MPH, Deputy Director, Health Research Group, Public Citizen, Washington, DC


Lewis Morris

Lewis Morris, Esq., Chief Counsel, Office of Inspector General, Department of Health and Human Services, Washington, DC


James G. Sheehan

James G. Sheehan, Esq., Medicaid Inspector General, State of New York, Former Associate United States Attorney, US Attorney's Office, Eastern District of Pennsylvania, Albany, NY


David A. Shore

David A. Shore, PhD, Associate Dean, Founding Director, Trust Initiative, Harvard School of Public Health, Author, *The Trust Prescription for Healthcare: Building Your Reputation with Consumers*, Boston, MA


Malcolm Sparrow

Malcolm Sparrow, MPA, PhD, Professor of Practice of Public Management, Kennedy School of Government, Harvard University, Author, *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance*, Cambridge, MA

Co chairs:


Sujata T. Dayal

Sujata T. Dayal, Esq., Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories, Abbott Park, IL


Lori Queisser

Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ


Arjun Rajaratnam

Arjun Rajaratnam, Esq., Vice President & Compliance Officer, US Pharmaceuticals, GlaxoSmithKline, Research Triangle Park, NC


Bert Weinstein

Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma LP, Stamford, CT

Why This Conference Stands Out

"We have tried to make this conference different — interactive, creative and worthwhile."

—PCF Planning Committee

The leadership of the Pharmaceutical Compliance Forum (PCF), the sponsor of the Eighth Annual Pharmaceutical Regulatory and Compliance Congress, seeks to transform the event to reflect a new style of learning and knowledge exchange. To that end, the PCF special planning committee has created the following special aspects of the Pharma Congress agenda:

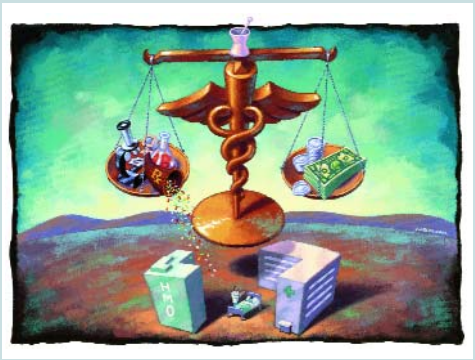
1. The Pharma Congress will feature a series of special sessions on these following crucial regulatory and compliance issues: relationships with healthcare professionals; managing risk with third parties and strategic partners; research, development and clinical trials; pharmacovigilance and drug safety; and state marketing, ethics and disclosure laws.

2. The Pharma Congress will feature a special, invitation-only track of interactive sessions with senior pharmaceutical compliance professionals to discuss best practices and initiatives for compliance.

3. The Pharma Congress will be interactive. In the plenary sessions each attendee will have a Meridia Audience response device with which he or she will be able to vote on questions put by the faculty. The attendee responses will be immediately projected on the session screens.

4. The Pharma Congress will feature two unique networking reception opportunities. The Wednesday evening networking reception will provide an opportunity to meet a number of key federal and state regulators and, Capitol Hill staff specializing in pharmaceutical policy. Thursday evening will feature a company Best Practices Compliance Policy and Procedure Poster Board and Exchange Reception throughout the Pharma Congress Exhibit Hall.

5. The Pharma Congress will feature an extraordinary series of keynote speakers.



Who Should Attend:

- Pharmaceutical and Health Care Executives and Board Members
- Compliance Executives
- Health Plan, Health System and Physician Organizations
- Medical Directors
- Physicians
- Pharmacists and Pharmacy Technicians
- Purchasers, including Private Employers and Public Purchasers
- Pharmaceutical Manufacturers
- Generic Pharmaceutical Manufacturers
- Site Management Organizations
- Clinical Research Organizations
- Pharmacy Benefit Management Companies
- Nurses
- Health Plans and Health Insurers
- Wholesale, Retail, Mail Order and Internet Pharmacies
- Health Care Attorneys and In-house Counsel
- Compliance Officers
- Privacy Officers
- Ethics Officers
- Food and Drug Law Attorneys
- Pharmaceutical Consultants
- Investment Bankers
- Venture Capitalists
- Health Care Regulators and Policy Makers
- Health Services Researchers and Academics
- Auditors

The Congress Goals and Objectives:

- List the role of the states in regulatory pharmaceutical enterprises.
- Explain in what ways big pharmaceutical companies should change in the future.
- Analyze and assess emerging regulatory and compliance issues.
- Describe ways to control risks, solve problems, and manage compliance within the regulatory guidelines.

THE PHARMACEUTICAL COMPLIANCE FORUM

About the Pharmaceutical Compliance Forum:

The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance officials and legal counsel from more than 50 of the largest pharmaceutical manufacturers. The PCF was founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The organization is open to others in the industry and has more than doubled in membership since its founding. The members meet twice a year, for one to two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field. For membership information, contact Colleen Lacey at 215-599-6617 or via email at info@PharmaComplianceForum.org.

Preconference Symposia

Wednesday, November 7, 2007

7:00 am **Congress Registration**

8:00 am **Preconferences Commence**

Preconference I: Compliance Program Basics: Monitoring, Auditing, Training
(Session will be interactive and participants will receive a toolkit at the end of this session with Compliance Program basics for training, monitoring and auditing.)

Colleen Craven, *Vice President, Ethics and Corporate Compliance, Endo Pharmaceuticals, Chadds Ford, PA (Co chair)*

Wendy C. Goldstein, Esq., *Member of the Firm, Epstein Becker & Green, New York, NY (Co chair)*

8:00 am **Overview:** Why Training, Monitoring and Auditing are the Critical Components of an Effective Compliance Program

8:45 am **Training:** OIG Compliance Program Guidance for Pharmaceutical Manufacturers; Establishing a Training Curriculum; Types of Training; and Keeping Training Relevant

9:30 am **Monitoring:** OIG Compliance Program Guidance for Pharmaceutical Manufacturers; Using Corporate Integrity Agreements and Other Sources to Establish a Monitoring Plan Based on Your Company's Risks; Considerations for Investigating Findings and How to Conduct such an Investigation; and Evaluation of Necessary Corrective Action (e.g., Training, Communication, Policy Enhancements)

10:15 am **Break**

10:45 am **Auditing:** OIG Compliance Program Guidance for Pharmaceutical Manufacturers; Using Corporate Integrity Agreements and Other Sources to Establish an Audit Plan Based on Your Company's Risks; Establishing an Audit Plan; and Conducting Audits and Discussion of Relevant Considerations (e.g., Communication Plans, Privilege Considerations, Reporting Findings, Investigating Findings, Corrective Action)

11:30 am **Comments, Questions and Answers**

Noon **Adjournment and Lunch on Your Own**

Preconference II: Payment/Reimbursement/ Reporting Update

8:00 am **Introductory Comments**
William A. Sarraille, Esq., *Partner, Sidley Austin LLP, Washington, DC (Co chair)*

Sue Seferian, Esq., *Senior Counsel, Johnson & Johnson, New Brunswick, NJ (Co chair)*

8:05 am **A Short History of Pricing Related Fraud and Abuse Issues**
Joseph W. Metro, Esq., *Partner, Reed Smith LLP, Washington, DC*

8:50 am **Recent Pricing Fraud and Abuse Litigation Developments -** Some Perspective on the Boston AWP Case and the FDB Settlement
Richard D. Raskin, Esq., *Partner, Sidley Austin LLP, Chicago, IL*

Jayson Slotnik, Esq., *Associate, Hogan & Hartson, Washington, DC*

9:40 am **Fraud and Abuse Issues in Part D Pricing and Contracting**
Marci Handler, Esq., *Member of the Firm, Epstein Becker & Green, Washington, DC*

10:10 am **Break**

10:25 am **Recent Pricing and Coverage Issues and Their Fraud and Abuse Implications -** The Final AMP and Best Price Rule; The OPPS Rule for 2008; The Physician Fee Schedule for 2008; Clinical Trial Coverage under the Medicare Program; and The Pending CHAMP Legislation, including Proposed Changes to Part D Coverage
Stephanie P. Gilson, Esq., *Johnson & Johnson, Washington, DC*

Ann Leopold Kaplan, Esq., *Assistant General Counsel, PhRMA, Washington, DC*

Jayson Slotnik, Esq., *Associate, Hogan & Hartson, Washington, DC*

William A. Sarraille, Esq., *Partner, Sidley Austin LLP, Washington, DC (Moderator)*

Noon **Adjournment and Lunch on Your Own**

Preconference III: Global Compliance Update
Ted Acosta, Esq., *Principal, Ernst & Young LLP, New York, NY (Co chair)*

Sujata T. Dayal, Esq., *Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories, Abbott Park, IL (Co chair)*

Andrew Hayward, Esq., *Senior Counsel, AstraZeneca, London, UK*

8:00 am **Organizing and Operating a Global Compliance Program -** Resources, Reporting, Scope, International Codes and Local Standards

8:45 am **Rolling Out Policies, Training and Compliance Guidance in the Global Setting**

9:30 am **Key Issues in Global Compliance -** Relationships with Physicians/Customers, CME, Donations, Post-Market, Third-Party Arrangements

10:15 am **Break**

10:45 am **Incorporating FCPA Compliance into Program Operations**

11:30 am **Comments, Questions and Answers**

Noon **Adjournment and Lunch on Your Own**

The leadership of the Pharmaceutical Compliance Forum (PCF), the sponsor of the Eighth Annual Pharmaceutical Regulatory and Compliance Congress, seeks to transform the event to reflect a new style of learning and knowledge exchange. To that end a PCF special planning committee has been charged with the transformation of the Pharma Congress.

PCF Special Planning Committee:

Sujata T. Dayal, Esq., Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories (Co chair)

Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation (Co chair)

Arjun Rajaratnam, Vice President & Compliance Officer, US Pharmaceuticals, GlaxoSmithKline (Co chair)

Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma LP (Co chair)

Ted Acosta, Esq., Principal, Ernst & Young LLP

Scott Bass, Esq., Partner, Sidley Austin LLP

John T. Bentivoglio, Esq., Partner, King & Spalding LLP

Kathleen Boozang, Esq., Associate Dean for Academic Affairs, Cofounder, Health Law & Policy Program, and Health Law, Science and Technology Graduate Programs, Seton Hall Law School

Robert P. Brady, Esq., Partner, Hogan & Hartson LLP

David B. Chandler, PhD, DABT, Director of Outcomes and Analysis, Corporate Compliance, Amgen

Colleen Craven, Vice President, Ethics and Corporate Compliance, Endo Pharmaceuticals

David Davidovic, Senior Director, Business Practices, Genentech, Inc.

William T. Fitzgerald, Vice President, Global Compliance, Alcon Laboratories

Wendy C. Goldstein, Esq., Partner, Epstein Becker & Green

Peter N. Grant, JD, PhD, President, Health Care Conference Administrators, LLC

Stephen Kanovsky, US Corporate Compliance Officer, Sanofi-Aventis US, Inc.

Keith M. Korenchuk, JD, MPH, Of Counsel, Covington & Burling LLP

Daniel A. Kracov, Esq., Partner, Arnold & Porter

Steve Mohr, Esq., Global Compliance Officer, AstraZeneca

Brian Riewerts, Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP

Sue Seferian, Esq., Senior Counsel, Johnson & Johnson

Paul J. Silver, Managing Director, National Life Sciences Practice, Huron Consulting Group

Jonathan K. Sprole, Vice President, Deputy General Counsel and Chief Compliance Officer, Bristol-Myers Squibb Company

Caroline West, Esq., Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc.

Pharma Congress Agenda:

Day I: Perspectives on the Pharmaceutical Sector in Changing Times
Wednesday, November 7, 2007

1:00 pm — **Welcome and Annual State of the Pharmaceutical Compliance Enterprise Address**

Lori Queisser, *Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ (Co chair)*

1:30 pm — **The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance**

Malcolm Sparrow, MPA, PhD, *Professor of Practice of Public Management and Faculty Chair, Executive Program on Strategic Management of Regulatory and Enforcement Agencies, Kennedy School of Government, Harvard University, Author,* The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance *and* License to Steal: How Fraud Bleeds America's Health Care System, *Cambridge, MA*

2:15 pm — **How Big Pharma Should Change**

Peter Lurie, MD, MPH, *Deputy Director, Health Research Group, Public Citizen, Washington, DC*

3:00 pm — **Conflicts of Interest**

Steven E. Nissen, MD, FACC, *Chairman, Department of Cardiovascular Medicine, Cleveland Clinic Foundation, Immediate Past-President, American College of Cardiology, Cleveland, OH*

3:45 pm — **Break**

4:00 pm — **OIG Update**

Lewis Morris, Esq., *Chief Counsel, Office of Inspector General, Department of Health and Human Services, Washington, DC*

4:45 pm — **The Role of States in Regulating the Pharmaceutical Enterprise**

James G. Sheehan, Esq., *Medicaid Inspector General, State of New York, Former Associate United States Attorney, U.S. Attorney's Office, Eastern District of Pennsylvania, Albany, NY*

5:15 pm — **State Attorney General Roundtable**

Jim Donahue, Esq., *Pennsylvania Chief Deputy Attorney General, Antitrust, Pennsylvania Office of the Attorney General, Harrisburg, PA*

John Guthrie, Esq., *Director, Medicaid Fraud Control Unit, Ohio Office of Attorney General, Columbus, OH*

David Hart, Esq., *Assistant Attorney General, Consumer Protection, Oregon Office of the Attorney General, Salem, OR*

John Krayniak, Esq., *Assistant Attorney General and Senior Counsel, Medicaid Fraud Control Unit, New Jersey Office of the Attorney General, Trenton, NJ*

Pat Lupinetti, Esq. (Invited), *Assistant Attorney General, Medicaid Fraud Control Unit, New York Office of Attorney General, Albany, NY*

Patrick J. O'Connell, Esq., *Section Chief, Civil Medicaid Fraud, Texas Office of the Attorney General, Austin, TX*

Kathleen M. Boozang, Esq., *Associate Dean and Professor of Law, Cofounder, Health Law & Policy Program, and Health Law, Science and Technology Graduate Programs Seton Hall University School of Law, Newark, NJ (Moderator)*

6:15 pm **Adjournment and Meet the Regulators Networking Reception**

The Pharma Congress Wednesday networking reception will offer an opportunity to meet a number of key federal and state regulators and Capitol Hill staff specializing in pharmaceutical policy.

Pharma Congress Agenda:

Day II, Thursday, November 8, 2007

8:00 am **Welcome and Introduction to Day Two**

Bert Weinstein, Esq., *Vice President, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)*

8:15 am **Our Customers' Perspectives Panel**

Matthew N. Tuchow, Esq. (Invited), *Senior Counsel, McKesson Corporation, San Francisco, CA*

Daniel C. Walden, *Senior Vice President and Chief Compliance Officer, Medco Health Solutions, New Rochelle, NY*

Dan Walsh, *Chief Compliance Officer, Cardinal, Dublin, OH*

Jane Whitney (Invited), *Chief Compliance Officer, Mount Sinai Medical School, New York, NY*

Ted Acosta, Esq., *Principal, Ernst & Young LLP, New York, NY (Moderator)*

9:30 am **Transition Break**

9:45 am **Track I: Pharma Congress Concurrent Sessions**

1.01 Relationships with Healthcare Professionals Track: US Healthcare Professionals Abroad - Issues and Practical Solutions, Covering Participation in International Congresses, Consulting or Speaking Engagements, Poster Presentations, Medical Education and Other Issues

Valli F. Baldassano, Esq., *Partner, Fox Rothschild LLP, Former Vice President of Global Compliance, Schering-Plough, Former Assistant US Attorney, Criminal Division, United States Attorney's Office, Eastern District of Pennsylvania, Warrington, PA*

1.02 Managing Risk with Third Parties and Strategic Partners Track: How to Conduct a Risk Assessment - Assessing Your Vendor Relationships and Creating a Risk Ranking for Auditing and Monitoring of Tour Specific Vendors and a Compliance Case Study of Patient Assistance Programs

Walter Campbell, *Director, Corporate Audit and Risk Management, Merck & Co., White House Station, NJ*

Debjit Ghosh, *Director, National Life Sciences Practice, Huron Consulting Group, New York, NY*

1.03 Research, Development and Clinical Trials Track: Key Compliance Risks Regarding Clinical Trials

Julie Kane, *Chief Compliance Officer, Novartis, East Hanover, NJ*

Meredith Manning, Esq., *Partner, Hogan & Hartson, Former assistant US Attorney, Civil Division, US Attorney's Office, Washington, DC*

Kathleen Meriwether, Esq., *Principal, Fraud Investigation & Dispute Services, Ernst & Young, Former Assistant United States Attorney, Eastern District of Pennsylvania, Department of Justice, Philadelphia, PA*

1.04 Pharmacovigilance and Drug Safety Track: The Top 10 Pharmacovigilance Issues Compliance and Legal Should Know

John D. Balian, MD, *Senior Vice President, Global Pharmacovigilance and Epidemiology, Bristol Myers Squibb, New York, NY*

Chris Holmes, *Principal, WCI Consulting Ltd, Denmead, UK*

1.05 State Marketing, Ethics and Disclosure Laws Track: Overview of State Marketing Laws and Regulations

Linda Pissott Reig, Esq., *Principal, Porzio, Bromberg & Newman, PC, Morristown, NJ*

Retta M. Riordan, Esq., *Business Ethics & Compliance Officer, Organon USA Inc., Roseland, NJ*

1.06 Advanced Best Practices Roundtable Track (Invitation-only): Challenges of Creating and Maintaining a Compliance Culture - Building an ethical culture: art or science, evolution or revolution; Tone at the top: how to make it effective; Creating a non-retaliatory environment; Maintaining the momentum - keeping your program fresh

Jacqueline Brevard, Esq., *Chief Ethics and Compliance Officer, Merck & Co., Whitehouse Station, NJ*

Keith M. Korenchuk, JD, MPH, *Of Counsel, Covington & Burling LLP, Washington, DC*

Steve Mohr, Esq., *Global Compliance Officer, AstraZeneca, London, UK*

Lori Queisser, *Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ*

Arjun Rajaratnam, Esq., *Vice President & Compliance Officer - US Pharmaceuticals, GlaxoSmithKline, Research Triangle Park, NC*

Jonathan K. Sprole, *Vice President, Deputy General Counsel and Chief Compliance Officer, Bristol-Myers Squibb Company, New York, NY*

11:00 am **Transition Break**

11:15 am **Track II: Pharma Congress Concurrent Sessions**

2.01 Relationships with Healthcare Professionals Track: FCPA and the Practical Implications to Interactions with HCPs

Gary Giampetruzzi, Esq., *Assistant General Counsel and Deputy Compliance Officer, Pfizer, New York, NY*

Michael Horowitz, Esq., *Partner, Cadwalader, Wickersham & Taft LLP, Commissioner, United States Sentencing Commission, Former Chief of Staff, Criminal Division, United States Department of Justice, Washington, DC*

William Jacobson, Esq., *Assistant Chief, Fraud Section, Criminal Division, United States Department of Justice, Washington, DC*

Adam Turteltaub, *Corporate Relations Executive, LRN, Los Angeles, CA*

2.02 Managing Risk with Third Parties and Strategic Partners Track: The Changing Business Environment: Regulatory Impact on Vendor Relationships, Commercial Contracting and Government Price Reporting - Mitigating Risks Related to Fraud and Abuse; Regulatory Changes and Their Impact on Commercial Contracting; and Understanding Vendor Services and Assessing Fair Market Value

Timothy Nugent, *Managing Director, National Life Sciences Practice, Huron Consulting Group, New York, NY*

John Shakow, Esq., *Counsel, King & Spalding LLP, Washington, DC*

2.03 Research, Development and Clinical Trials Track: How to Conduct a Clinical Research Compliance Assessment

Elizabeth Jobes, *Deputy Compliance Counsel, Cephalon, Inc., Former Assistant District Attorney, Frazer, PA*

Kelly N. (Nikki) Reeves, Esq., *Partner, King & Spalding LLP, Washington, DC*

2.04 Pharmacovigilance and Drug Safety Track: Pharmacovigilance Reporting and Analysis: Product Liability Concerns

Jeffrey M. Senger, Esq., *Deputy Chief Counsel, Food and Drug Administration, Washington, DC*

Diane P. Sullivan, *Esq., Partner, Dechert LLP, Princeton, NJ*

2.05 State Marketing, Ethics and Disclosure Laws: State Lobbying and Ethics Laws and Regulations

John T. Bentivoglio, Esq., *Partner, King & Spalding LLP, Washington, DC*

Steven C. Benz, Esq., *General Counsel, Eli Lilly & Co., Indianapolis, IN*

Tara Ryan (Invited), *Senior Director, State Policy, PhRMA, Washington, DC*

2.06 Advanced Best Practices Roundtable Track (Invitation-only): The Compliance Process: Executing The Program - Conducting the risk assessment: how do you do it and how do you embed it?; Securing adequate resources for compliance: how much do you need and how do you get it?; Compliance education globally - what works and how do you demonstrate it? Compliance performance scorecards - methodology (monitoring, auditing, surveys), metrics, and mysteries!; Upward reporting and escalation - how to structure the report? When do you escalate an issue?; Investigation and correction - effective and timely investigations, root cause analysis and continuous improvement

12:30 pm **Networking Luncheon in the Exhibit Hall**

Special Box Lunch Report: Off-Label Investigations and Their Public Health Implications

Paul E. Kalb, JD, MD, *Partner, Sidley Austin LLP, Washington, DC*

1:30 pm **Plenary Session: Plaintiffs Attorney Qui Tam Panel**

Peter Chatfield, Esq., *Partner, Phillips & Cohen LLP, Washington, DC*

Thomas M. Greene, Esq. (Invited), *Partner, Greene and Hoffman, Boston, MA*

Mark Allen Kleiman, Esq., *Partner, Law Offices of Mark Allen Kleiman, Los Angeles, CA*

Stephen Meagher, Esq., *Partner, Law Offices of Stephen Meagher, San Francisco, CA*

Lesley Ann Skillen, Esq., *Partner, Getnick & Getnick, New York, NY*

Dara A. Corrigan, Esq., *Partner, Arnold & Porter, Former Acting Inspector General, Department of Health and Human Services, Washington, DC (Moderator)*

2:30 pm **Transition Break**

2:45 pm **Track III: Pharma Congress Concurrent Sessions**

3.01 Relationships with Healthcare Professionals Track: 2010 and Beyond - Interactions with Healthcare Professionals in a Changing Sales Environment: Life After Donuts

Stephen Kanovsky, *US Corporate Compliance Officer, Sanofi-Aventis US, Inc., Bridgewater NJ*

Ann Lewis, Esq., *Vice President and Senior Counsel, Bristol-Myers Squibb Co., New York, NY*

3.02 Managing Risk with Third Parties and Strategic Partners Track: State Law Compliance – Managing Reporting Risks Related to Third Party Vendors - Defining potential risks and providing recommendations on creating structured processes and documentation protocols to mitigate those risks.

William Buzzeo, *Vice President & General Manager, Cegedim Dendrite, Richmond, VA*

William T. Fitzgerald, *Vice President, Global Compliance, Alcon Laboratories, Fort Worth, TX*

Paul J. Silver, *Managing Director, National Life Sciences Practice, Huron Consulting Group, Atlanta, GA*

3.03 Research, Development and Clinical Trials Track: Compliance in Clinical Research - Recent Lessons and Best Practices, Covering Compliance and Cultural Challenges in Global Clinical Trials; Issues in Outsourcing of Trials to Clinical

Research Organizations; Best Practices in Auditing and Monitoring; Adapting Good Clinical Practice Problems to New Research Settings and Designs; Issues in Human Subject Protections; and Addressing Scientific Misconduct in Clinical Trials
Kristina Borror, PhD, *Director, Division of Compliance Oversight, Office for Human Research Protections, Department of Health and Human Services, Rockville, MD*

Justin P. McCarthy, Esq., *General Counsel, Global Research & Development, Pfizer Inc., New London, CT*

Joseph P. Salewski (Invited), *Deputy Director, Division of Scientific Investigations, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD*

Michael A. Swit, Esq., *Vice President, Life Sciences, The Weinberg Group, Encinitas, CA*

Daniel A. Kracov, Esq., *Partner, Arnold & Porter, Washington, DC (Moderator)*

3.04 Pharmacovigilance and Drug Safety Track: Safety Issues in Fraud and Abuse Investigations
Kathleen Meriwether, Esq., *Principal, Fraud Investigation & Dispute Services, Ernst & Young, Former Assistant United States Attorney, Eastern District of Pennsylvania, Department of Justice, Philadelphia, PA*

Susan Winkler, Esq. (Invited), *Assistant United States Attorney, Deputy Health Care Fraud Chief, United States Attorney's Office, District of Massachusetts, Boston, MA*

3.05 State Marketing, Ethics and Disclosure Laws: Regulators' Panel
Thomas Bradley, Esq. (Invited), *Office of the Maine Attorney General, Augusta, ME*

Shana Phares (Invited), *Acting Pharmaceutical Advocate, Governor's Pharmaceutical Advocate Office, Charleston, WV*

Marjorie Powell, Esq. (Invited), *Senior Assistant General Counsel, PhRMA, Washington, DC*

Marcia B. Wooden, RPh, CPM (Invited), *Executive Director, Board of Pharmacy and Pharmaceutical Control, District of Columbia Department of Health, Washington, DC*

3.06 Advanced Best Practices Roundtable Track (Invitation-only): Hot Topics: Critical Compliance Substantive Issues - Anti-bribery/anti-corruption; Off-label promotion; Research and development issues

4:00 pm **Transition Break**

4:15 pm **Track IV: Pharma Congress Concurrent Sessions**

4.01 Relationships with Healthcare Professionals Track: A Message from the Dark Side - How Compliance Professionals can help the Business in Interactions with Healthcare Providers
Tim Schmidt, *Executive Director, Institutional Sales, Boehringer Ingelheim, Ridgefield, CT*

4.02 Managing Risk with Third Parties and Strategic Partners Track: Why you Should Care about Activities Related to Clinical Trials - Current Trends and Government Interest, covering: When is an Activity a Perceived Off-Label Communication or a Potential Kick-Back Issue?; Do you Hold your third Party Vendors to the same standards as you do for Internal Activities?; Changing Landscape: the "Off-Shoring" of Clinical Research-Implications to Data Integrity and Reporting Activity; and What is the Role of Compliance in this Process?

Mark DeWyngaert, PhD, *Managing Director, National Life Sciences Practice, Huron Consulting Group, New York, NY*

Ned Kelly, MD, *Vice President, Global Pharmacovigilance, Strategic Research and Safety, Quintiles, Durham, NC*

Dr. Craig Metz, PhD, *Vice President of US Regulatory Affairs, GlaxoSmithKline, Research Triangle Park, NC*

4.03 Research, Development and Clinical Trials Track: Clinical Trial Fraud - A Perfect Storm Case Study - Allegations of fraud and regulatory non-compliance in the context of clinical trials can result in a myriad of potential enforcement actions involving sponsors, monitors and clinical investigators, including False Claims Act, FDA actions (civil and criminal) including the possibility of disgorgement; NIH sanctions; State enforcement; HHS/OIG; and OHRP
Stephen Immelt, Esq., *Partner, Hogan & Hartson LLP, Baltimore, MD*

4.04 Pharmacovigilance and Drug Safety Track: The Future of Pharmacovigilance: Hot Issues on the Horizon
Brian D. Edwards, MD, MRCP, *Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Limited, Surrey, UK*

Maurits J.F. Lugard, MA, JD, LLM, *Partner, Sidley Austin LLP, Former Principal Legal Adviser on Trade and Environment and Health and Safety, European Commission's Legal Service, Brussels, Belgium*

4.05 State Marketing, Ethics and Disclosure Laws: Tracking, Aggregating and Reporting Challenges, Solutions and Business Process Implications
Ann Beasley Bacon, Esq., *Senior Corporate Counsel, Sepracor Inc., Marlborough, MA*

Andy Bender, MSc, MBA, *Partner, Polaris Management Partners, New York, NY*

Cindy Cetani, *Director of Ethics and Compliance, Novartis, East Hanover, NJ*

Justin A. Dillon, *Associate Director, Business Practices & Compliance, Merck & Co, Inc., North Wales, PA*

Michael Dusseau, *Senior Director, Compliance USA, Schering-Plough, Kenilworth, NJ*

David Davidovic, *Senior Director, Business Practices, Genentech, San Francisco, CA (Moderator)*

5:30 pm **Transition Break**

5:45 pm **Introduction to Afternoon Plenary Session; Overview of PCF Best Pharmaceutical Compliance Practices Poster Boards**

Sujata T. Dayal, Esq., *Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories, Abbott Park, IL (Co chair)*

6:15 pm **Adjournment and Company Best Practice Policy and Procedure Poster Board and Exchange Reception**

The Pharma Congress Thursday networking reception will feature the exchange and presentation of company best practice policy and procedures at poster boards throughout the Pharma Congress Exhibit Hall.

Pharma Congress Agenda:

Day III, Friday, November 9, 2007

8:00 am **Introduction to Day Three; Presentation of PCF Pharmaceutical Compliance Professional of the Year Award**

Arjun Rajaratnam, Esq., *Vice President & Compliance Officer, US Pharmaceuticals, GlaxoSmithKline, Research Triangle Park, NC (Co chair)*

8:15 am **Keynote Address: The Value of Medicine**

Robert A. Ingram, *Vice Chairman Pharmaceuticals, GlaxoSmithKline, Chairman, OSI Pharmaceuticals, Inc., Chairman, VALEANT Pharmaceuticals International, Vice Chairman, American Cancer Society Foundation, Founder, CEO Roundtable on Cancer, Chairman, American Foundation for Pharmaceutical Education, Research Triangle Park, NC*

8:45 am **Compliance Professionals' Roundtable**

Sujata T. Dayal, Esq., *Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories, Abbott Park, IL*

Anne Nobles, Esq., *Vice President for Compliance and Enterprise Risk Management, Eli Lilly and Company, Indianapolis, IN*

Lori Queisser, *Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ*

Arjun Rajaratnam, Esq., *Vice President & Compliance Officer, US Pharmaceuticals, GlaxoSmithKline, Research Triangle Park, NC*

Kathy Schroeher, Esq. (Invited), *Associate General Counsel, Johnson & Johnson, New Brunswick, NJ*

Jonathan K. Sprole, *Vice President, Deputy General Counsel and Chief Compliance Officer, Bristol-Myers Squibb Company, New York, NY*

Bert Weinstein, Esq., *Vice President, Corporate Compliance, Purdue Pharma LP, Stamford, CT*

Brian Riewerts, *Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP, Washington, DC (Moderator)*

9:45 am **Branding and Trust**

David A. Shore, PhD, *Associate Dean, Founding Director, Trust Initiative, and Director, Forces of Change Program; Harvard School of Public Health, Author,* The Trust Prescription for Healthcare: Building Your Reputation with Consumers *and* The Trust Crisis in Healthcare: Causes, Consequences, Cures, *Boston, MA*

10:45 am **Break**

11:00 am **Roundtable on Good Things that Pharma Companies Do and Lessons Learned**

Company Presentations

Mark W. Kline, MD, *Professor of Pediatrics, Chief, Retrovirology Clinic, Texas Children's Hospital, Director, Baylor International Pediatric AIDS Initiative, Assistant Program Director, General Clinical Research Center, Baylor College of Medicine, Houston, TX*

Jonathan K. Sprole, *Vice President, Deputy General Counsel and Chief Compliance Officer, Bristol-Myers Squibb Company, New York, NY (Moderator)*

12:15 pm **Adjournment**

THE PHARMACEUTICAL COMPLIANCE FORUM

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ACCME - This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Collaborative, Inc. (MEC) and Healthcare Conference Administrators, LLC. MEC is accredited by the ACCME to provide continuing medical education for physicians. Medical Education Collaborative designates this educational activity for a maximum of 21.5 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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MCLE - Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 25.8 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of $1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules and regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at 303-420-3252, ext 37 starting two to three weeks prior to the program date. MEC is a State Bar of California approved MCLE provider. Lawyers wanting credit in Virginia and Kansas must apply individually to their respective bars for approval of this course – courses submitted by the sponsor are no longer approved for MCLE credit in those states.

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No prerequisites or advance requirements exist for this activity. This is a group-live activity. For more information regarding administrative policies such as complaint or refund, call MEC at (866) 420-3252 x37

Participants must attend at least one program session and complete an evaluation plus an application for credit in order to receive a certificate. Certificates will be mailed within 6-8 weeks.

Schedule at a Glance

Preconference Symposia • Wednesday, November 7, 2007

7:00 am Congress Registration

8:00 am

- Preconference I: Compliance Program Basics: Monitoring, Auditing, Training
- Preconference II: Payment/ Reimbursement/Reporting Update
- Preconference III: Global Compliance Update

Noon Adjournment and Lunch on Your Own

Pharma Congress Day I • Perspectives on the Pharmaceutical Sector in Changing Times Wednesday, November 7, 2007

1:00 pm Welcome and Annual State of the Pharmaceutical Compliance Enterprise Address
1:30 pm The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance
2:15 pm How Big Pharma Should Change
3:00 pm Conflicts of Interest
3:45 pm Break
4:00 pm OIG Update
4:45 pm The Role of States in Regulating the Pharmaceutical Enterprise
5:15 pm State Attorney General Roundtable
6:15 pm Adjournment and Meet the Regulators Networking Reception

Pharma Congress Day II • Thursday, November 8, 2007

8:00 am Welcome and Introduction to Day Two
8:15 am Our Customers' Perspectives Panel
9:30 am Transition Break

9:45 am Track I Concurrents

- 1.01 Relationships with Healthcare Professionals Track: US Healthcare Professionals Abroad
- 1.02 Managing Risk with Third Parties and Strategic Partners Track: How to Conduct a Risk Assessment
- 1.03 Research, Development and Clinical Trials Track: Key Compliance Risks Regarding Clinical Trials
- 1.04 Pharmacovigilance/Drug Safety Track: Top 10 Pharma-covigilance Issues Compliance and Legal Should Know
- 1.05 State Marketing, Ethics and Disclosure Laws Track: Overview of State Marketing Laws and Regulations
- 1.06 Advanced Best Practices Roundtable Track: Challenges of Creating and Maintaining a Compliance Culture*

11:00 am Transition Break

11:15 am Track II Concurrents

- 2.01 Relationships with Healthcare Professionals Track: FCPA and Practical Implications to Interactions with HCPs
- 2.02 Managing Risk with Third Parties and Strategic Partners Track: The Changing Business Environment
- 2.03 Research, Development and Clinical Trials Track: How to Conduct a Clinical Research Compliance Assessment
- 2.04 Pharmacovigilance/Drug Safety Track: Pharmacovigilance Reporting and Analysis: Product Liability Concerns
- 2.05 State Marketing, Ethics and Disclosure Laws Track: State Lobbying and Ethics Laws and Regulations
- 2.06 Advanced Best Practices Roundtable Track: The Compliance Process: Executing The Program*

12:30 pm Networking Luncheon/Special Box Lunch Report: Off-Label Investigations and Their Public Health Implications
1:30 pm Plenary Session: Plaintiffs Attorney Qui Tam Panel

2:30 pm Transition Break

2:45 pm Track III Concurrents

- 3.01 Relationships with Healthcare Professionals Track: 2010 and Beyond
- 3.02 Managing Risk with Third Parties and Strategic Partners Track: State Law Compliance - Managing Reporting Risks Related to Third Party Vendors
- 3.03 Research, Development and Clinical Trials Track: Compliance in Clinical Research
- 3.04 Pharmacovigilance/Drug Safety Track: Safety Issues in Fraud and Abuse Investigations
- 3.05 State Marketing, Ethics and Disclosure Laws: Regulators' Panel
- 3.06 Advanced Best Practices Roundtable Track: Hot Topics: Critical Compliance Substantive Issues*

4:00 pm Transition Break

4:15 pm Track IV Concurrents

- 4.01 Relationships with Healthcare Professionals Track: A Message from the Dark Side
- 4.02 Managing Risk with Third Parties and Strategic Partners Track: Why you Should Care about Activities Related to Clinical Trials
- 4.03 Research, Development and Clinical Trials Track: Clinical Trial Fraud - A Perfect Storm Case Study
- 4.04 Pharmacovigilance/Drug Safety Track: The Future of Pharmacovigilance: Hot Issues on the Horizon
- 4.05 State Marketing, Ethics and Disclosure Laws: Tracking, Aggregating and Reporting Challenges, Solutions and Business Process Implications

5:30 pm Transition Break
5:45 pm Introduction to Afternoon Plenary Session; Overview of PCF Best Pharmaceutical Compliance Practices Poster Boards
6:15 pm Adjournment and Company Best Practice Policy and Procedure Poster Board and Exchange Reception

Pharma Congress Day III • Friday, November 9, 2007

8:00 am Introduction to Day Three; Presentation of PCF Pharmaceutical Compliance Professional of the Year Award
8:15 am Keynote Address: The Value of Medicine
8:45 am Compliance Professionals' Roundtable
9:45 am Branding and Trust
10:45 am Break
11:00 am Roundtable on Good Things that Pharma Companies Do and Lessons Learned/Company Presentations
12:15 pm Adjournment

* Invitation Only

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HOW TO REGISTER

Fully complete the following (one form per registrant, photocopies acceptable). Payment must accompany each registration.

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Thursday, November 8, 2007 — Select One Session per Time Slot:

9:45 am Concurrent Sessions I
o 1.01 o 1.02 o 1.03 o 1.04 o 1.05

11:15 am Concurrent Sessions II
o 2.01 o 2.02 o 2.03 o 2.04 o 2.05

2:45 pm Concurrent Sessions III
o 3.01 o 3.02 o 3.03 o 3.04 o 3.05

4:15 pm Concurrent Sessions IV
o 4.01 o 4.02 o 4.03 o 4.04 o 4.05

3. Preconference Workshop: o $495
Wednesday, November 7, 2007, 8:00 am — Choose one only:
- o **Preconference I:** Compliance Program Basics: Monitoring, Auditing, Training
- o **Preconference II:** Payment/Reimbursement Reporting Update
- o **Preconference III:** Global Compliance Update

*This price reflects a discount for registration & payment received by 9/29/07.

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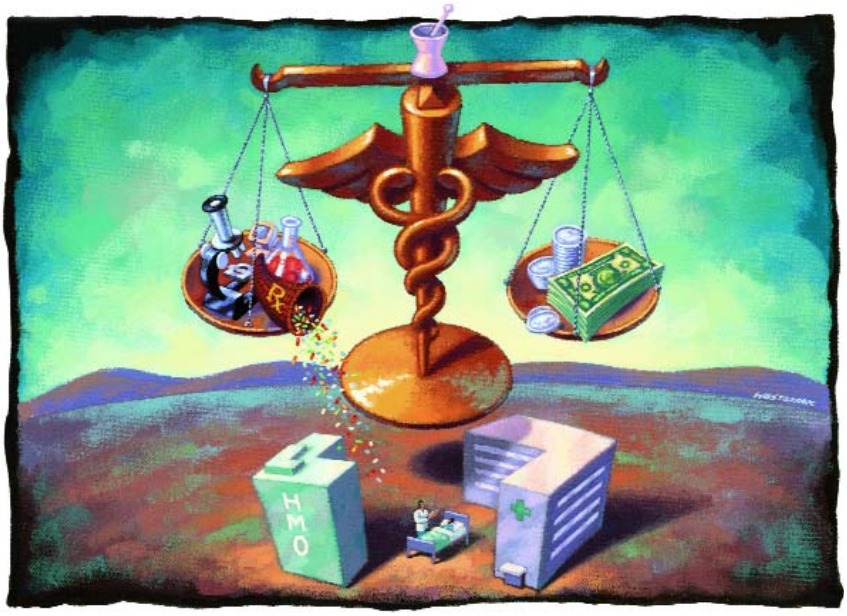

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