The Eighth Annual Pharmaceutical Regulatory Compliance Congress and Best Practices Forum

Continuing Education Credits Available: ACCME • ACMPE • AHIMA • ANCC • CA BRN • CISSP/SSCP • HCCB • MCLE • NASBA

November 7–9, 2007
Omni Shoreham Hotel • Washington, DC

Diamond Grantor: Price Waterhouse Coopers
Gold Grantor: Ernst & Young
Silver Grantors: Arnold & Porter LLP, Huron Consulting Group, Covington & Burling, B. King & Spalding
Bronze Grantors: Davis Wright Tremaine LLP, Hogan & Hartson, Sidley

Keynote Speakers:
- Robert A. Ingram, Vice Chairman, Pharmaceuticals, GlaxoSmithKline, Chairman, OSI Pharmaceuticals, Inc., Chairman, Valeant Pharmaceuticals International, Research Triangle Park, NC
- 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, MD, MPH, Deputy Director, Health Research Group, Public Citizen, Washington, DC
- Lewis Morris, Esq., Chief Counsel, Office of Inspector General, Department of Health and Human Services, Washington, DC
- 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, 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, Esq., Ethics and Compliance Officer, Pharmaceutical Products Group, Abbott Laboratories, Abbott Park, IL
- 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
- 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 | Nurses |
| Compliance Executives | Health Plans and Health Insurers |
| Health Plan, Health System and Physician Organizations | Wholesale, Retail, Mail Order and Internet Pharmacies |
| Medical Directors | Health Care Attorneys and In-house Counsel |
| Physicians | Compliance Officers |
| Pharmacists and Pharmacy Technicians | Privacy Officers |
| Purchasers, including Private Employers and Public Purchasers | Ethics Officers |
| Pharmaceutical Manufacturers | Food and Drug Law Attorneys |
| Generic Pharmaceutical Manufacturers | Pharmaceutical Consultants |
| Site Management Organizations | Investment Bankers |
| Clinical Research Organizations | Venture Capitalists |
| Pharmacy Benefit Management Companies | Health Care Regulators and Policy Makers |
| Compliance Officers | Health Services Researchers and Academics |
| Privacy Officers | 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.

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; 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

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 Kraynak, Esq., Assistant Attorney General and Senior Counsel, Medicaid Fraud Control Unit, New Jersey Office of the Attorney General, Trenton, NJ
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 Your Specific Vendors and a Compliance Case Study of Patient Assistance Programs

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.

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 Turleltaub, 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  

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
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 DeWygnaert, 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  

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  

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

Transition Break  

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  

4:00 pm  

4:15 pm  

Track IV: Pharma Congress Concurrent Sessions  

Transition Break  

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?  

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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  

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Tim Schmidt, Executive Director, Institutional Sales, Boehringer Ingelheim, Ridgefield, CT
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

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

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
Save the Date:

THIRD ANNUAL MEDICAL DEVICE REGULATORY, REIMBURSEMENT AND COMPLIANCE CONGRESS AT HARVARD
Sponsored by AdvaMed, Harvard Health Policy Review and Health Affairs
March 26 - 28, 2008
Harvard University
Cambridge, MA
www.DeviceCongress.com

SECOND INTERNATIONAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS
Sponsored by the Pharmaceutical Compliance Forum
May 28 - 29, 2008
Paris, France
www.InternationalPharmaCongress.com

FOURTH FDA REGULATORY AND COMPLIANCE SYMPOSIUM AT HARVARD
Sponsored by FDAnews, Harvard Health Policy Review and Health Affairs
August 19 - 22, 2008
Harvard University
Cambridge, MA
www.FDASymposium.com

NINTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS
Sponsored by Pharmaceutical Compliance Forum
October 27 - 29, 2008
Washington, DC
www.PharmaCongress.com

Continuing Education Credits
Total credit hours include pre-conferences

This course jointly sponsored by Medical Education Collaborative and Healthcare Conference Administrators

ACCMCE - 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.

Medical Education Collaborative designates this educational activity for a maximum of 21.25 category 1 credits towards the AMA Physician’s Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

ACMPE - This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

AHIMA - This program is pending prior approval for 21.5 CE Credits for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA).

ANCC - Medical Education Collaborative (MEC) is the accredited provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. RNs, LPNs, LVNs and NPs can receive up to 21.5 contact hours for participation in this program. This program is cosponsored with Medical Education Collaborative, Inc. (MEC) and Healthcare Conference Administrators, LLC.

CA BRN - Provider approved by the California Board of Registered Nursing, Provider Number CEP 12990, for 25.8 contact hour(s).

CISSP/SSCP - This program may qualify for security professions (CISSP) or security practitioner (SSCP) continuing education credit. CISSPs and SSCPs may apply for CPE credit for participating in the conference online at www.isc2.org.

HCCB - This program is pending prior approval for 21.5 HCCB continuing education credits for compliance certification.

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.

NASBA - Medical Education Collaborative is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN 37219-2417. Web site: <file://www.nasba.org>www.nasba.org. A maximum of 25.8 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am</td>
<td>Congress Registration</td>
</tr>
<tr>
<td>8:00 am</td>
<td><img src="image1" alt="Preconference I: Compliance Program Basics: Monitoring, Auditing, Training" /></td>
</tr>
<tr>
<td></td>
<td><img src="image2" alt="Preconference II: Payment/Reimbursement/Reporting Update" /></td>
</tr>
<tr>
<td></td>
<td><img src="image3" alt="Preconference III: Global Compliance Update" /></td>
</tr>
<tr>
<td>Noon</td>
<td>Adjournment and Lunch on Your Own</td>
</tr>
</tbody>
</table>

### Pharma Congress Day I • Perspectives on the Pharmaceutical Sector in Changing Times

**Wednesday, November 7, 2007**

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

### Pharma Congress Day II • Thursday, November 8, 2007

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 am</td>
<td>Welcome and Introduction to Day Two</td>
</tr>
<tr>
<td>8:15 am</td>
<td>Our Customers’ Perspectives Panel</td>
</tr>
<tr>
<td>9:30 am</td>
<td>Transition Break</td>
</tr>
<tr>
<td>9:45 am</td>
<td><img src="image4" alt="Track I Concurrents" /> [1.01] Relationships with Healthcare Professionals Track: US Healthcare Professionals Abroad</td>
</tr>
<tr>
<td></td>
<td>[1.02] Managing Risk with Third Parties and Strategic Partners Track: How to Conduct a Risk Assessment</td>
</tr>
<tr>
<td></td>
<td>[1.03] Research, Development and Clinical Trials Track: Key Compliance Risks Regarding Clinical Trials</td>
</tr>
<tr>
<td></td>
<td>[1.04] Pharmacovigilance/Drug Safety Track: Top 10 Pharmacovigilance Issues Compliance and Legal Should Know</td>
</tr>
<tr>
<td></td>
<td>[1.05] State Marketing, Ethics and Disclosure Laws Track: Overview of State Marketing Laws and Regulations</td>
</tr>
<tr>
<td></td>
<td>[1.06] Advanced Best Practices Roundtable Track: Creating and Maintaining a Compliance Culture*</td>
</tr>
<tr>
<td>11:00 am</td>
<td>Transition Break</td>
</tr>
<tr>
<td>11:15 am</td>
<td><img src="image5" alt="Track II Concurrents" /> [2.01] Relationships with Healthcare Professionals Track: FCPA and Practical Implications to Interactions with HCPs</td>
</tr>
<tr>
<td></td>
<td>[2.03] Research, Development and Clinical Trials Track: How to Conduct a Clinical Research Compliance Assessment</td>
</tr>
<tr>
<td></td>
<td>[2.05] State Marketing, Ethics and Disclosure Laws Track: State Lobbying and Ethics Laws and Regulations</td>
</tr>
<tr>
<td>12:30 pm</td>
<td>Networking Luncheon/Special Box Lunch Report: Off-Label Investigations and Their Public Health Implications</td>
</tr>
<tr>
<td>1:30 pm</td>
<td>Plenary Session: Plaintiffs Attorney Qui Tam Panel</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>Transition Break</td>
</tr>
<tr>
<td>2:45 pm</td>
<td><img src="image6" alt="Track III Concurrents" /> [3.01] Relationships with Healthcare Professionals Track: 2010 and Beyond</td>
</tr>
<tr>
<td></td>
<td>[3.02] Managing Risk with Third Parties and Strategic Partners Track: Managing Reporting Risks Related to Third Party Vendors</td>
</tr>
<tr>
<td></td>
<td>[3.03] Research, Development and Clinical Trials Track: Compliance in Clinical Research</td>
</tr>
<tr>
<td></td>
<td>[3.05] State Marketing, Ethics and Disclosure Laws: Regulators’ Panel</td>
</tr>
<tr>
<td>4:00 pm</td>
<td>Transition Break</td>
</tr>
<tr>
<td>4:15 pm</td>
<td><img src="image7" alt="Track IV Concurrents" /> [4.01] Relationships with Healthcare Professionals Track: A Message From the Dark Side</td>
</tr>
<tr>
<td></td>
<td>[4.02] Managing Risk with Third Parties and Strategic Partners Track: Why you Should Care about Activities Related to Clinical Trials</td>
</tr>
<tr>
<td></td>
<td>[4.03] Research, Development and Clinical Trials Track: A Perfect Storm Case Study</td>
</tr>
<tr>
<td></td>
<td>[4.05] State Marketing, Ethics and Disclosure Laws: Tracking, Aggregating and Reporting Challenges, Solutions and Business Process Implications</td>
</tr>
<tr>
<td>5:30 pm</td>
<td>Transition Break</td>
</tr>
<tr>
<td>5:45 pm</td>
<td>Introduction to Afternoon Plenary Session; Overview of PCF Best Pharmaceutical Compliance Practices Poster Boards</td>
</tr>
<tr>
<td>6:15 pm</td>
<td>Adjournment and Company Best Practice Policy and Procedure Poster Board and Exchange Reception</td>
</tr>
</tbody>
</table>

### Pharma Congress Day III • Friday, November 9, 2007

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

* Invitation Only
**REGISTRATION FORM**

**HOW TO REGISTER**

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

**ONLINE:** Secure online registration at www.PharmaCongress.com.

**FAX:** 760-418-8084 (include credit card information with registration)

**MAIL:** Conference Office, 3291 West Wilson Road, Pahrump, NV 89048

**FOR REGISTRATION QUESTIONS:**

**PHONE:** 800-684-4549 Monday-Friday, 9 AM - 5 PM Pacific Time

**E-MAIL:** registration@hcconferences.com

(Registration is not available by phone or e-mail.)

**COMPLETE THE FOLLOWING. PLEASE PRINT:**

---

**NAME**

**SIGNATURE OF REGISTRANT - REQUIRED**

**TITLE**

**ORGANIZATION**

**DEPARTMENT**

**ADDRESS**

**CITY/STATE/ZIP**

**TELEPHONE**

**FAX - Please include fax number if you wish to receive a confirmation letter.**

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○ Special needs (dietary or physical):

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**THREE COST-EFFECTIVE LEARNING OPTIONS**

1. Complete Preconference and Congress Passport:
   - Through 9/29/07 $2,190*
   - After 9/29/07 $2,390
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2. Congress Sessions:
   - Through 9/29/07 $1,795*
   - After 9/29/07 $1,995
   For 3 or more registrants from the same institution, the registration fee is $1,595 (registration forms must be submitted simultaneously).

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

   - 9:45 am Concurrent Sessions I
     - 1.01
   - 11:15 am Concurrent Sessions II
     - 2.01
   - 2:45 pm Concurrent Sessions III
     - 3.01
   - 4:15 pm Concurrent Sessions IV
     - 4.01

3. Preconference Workshop:
   - $495

   **Wednesday, November 7, 2007, 8:00 am — Choose one only:**

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

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

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**METHOD OF PAYMENT FOR TUITION**

Make payment by check (to Health Care Conference Administrators LLC), MasterCard, Visa or American Express. A $20 fee will be charged on any returned checks. Groups: Have registration and credit card information for each person. List all group members on FAX cover sheet.

**TAX DEDUCTIBILITY**

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○ Check/money order enclosed
   (checks payable to Health Care Conference Administrators LLC)

○ Payment by credit card:
   ○ American Express ○ Visa ○ Mastercard

If paying by check, a credit card number must be given to hold registration and duly noted on the registration form to hold and not process. If payment by check is not received by seven days prior to the conference, credit card payment will be processed.

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**TOTAL:** $________

**ACCOUNT #:**

**EXPIRATION DATE:**

**NAME OF CARDHOLDER:**

**SIGNATURE OF CARDHOLDER:**

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When purchased with full Congress Registration:

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- **Video iPod:** $375

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**TOTAL:** $________
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