

THE TENTH  
ANNUAL

# Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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November 11 – 13, 2009

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## Co chairs:

- ◀ Colleen M. Craven, Vice President, Corporate Compliance & Business Practices, Endo Pharmaceuticals
- ◀ Margaret K. Feltz, Associate Director, Corporate Compliance, Purdue Pharma LP
- ◀ Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation



## Featured Faculty:

- ◀ Lanny A. Breuer, Esq., Head, Criminal Division, US Department of Justice



- ◀ Arthur Caplan, PhD, Professor of Bioethics, University of Pennsylvania



- ◀ Patrick L. Meehan, Esq., Former United States Attorney, Eastern District of Pennsylvania



- ◀ Lorin L. Reisner, Esq., Deputy Director of Enforcement, US Securities and Exchange Commission



- ◀ Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services

## Preconference Sessions:

- Compliance 101
- Recent Government Settlements
- Internet and Social Networking Communication

## Featured Plenary Sessions:


- Regulator Panel on Transparency and Disclosure
- Overview of Pfizer CIA: Lessons Learned
- OIG Update
- DOJ Civil Division Update
- DOJ Criminal Division Update
- SEC Enforcement Update
- Health Reform Update
- Ethics Update
- Making the Case for Compliance: A US Attorney's Perspective
- Effective and Compliant Promotion
- Medical Institution Perspectives on Restrictions with Pharmaceutical Companies
- PCF Pharmaceutical Compliance Professional and Legal Counsel Roundtable

## Featured Tracks:

- Compliance Program Elements: How to Implement and Enhance a Pharmaceutical Compliance Program to Meet Evolving Regulatory Standards
- An Integrated Approach to Compliance: Addressing Healthcare Fraud and Abuse Compliance Risks Throughout a Product's Lifecycle
- Transparency and Third Party Compliance Requirements
- Instituting a Truly Global Compliance Program

## Pharma Congress Overview

The leadership of the Pharmaceutical Compliance Forum (PCF), the sponsor of the Tenth 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:

- The Pharma Congress will feature the following preconference symposia:
  - Compliance 101
  - Recent Government Settlements
  - Internet and Social Networking Communication
- The Pharma Congress will feature a series of special sessions on these following crucial regulatory and compliance issues:
  - Regulator Panel on Transparency and Disclosure
  - Overview of Pfizer CIA: Lessons Learned
  - OIG Update
  - DOJ Civil Division Update
  - DOJ Criminal Division Update
  - SEC Enforcement Update
  - Health Reform Update
  - Ethics Update
  - Making the Case for Compliance: A US Attorney's Perspective
  - Effective and Compliant Promotion
  - Medical Institution Perspectives on Restrictions with Pharmaceutical Companies
  - PCF Pharmaceutical Compliance Professional and Legal Counsel Roundtable
- The Pharma Congress will feature tracks on the following topics:
  - Compliance Program Elements: How to Implement and Enhance a Pharmaceutical Compliance Program to Meet Evolving Regulatory Standards
  - An Integrated Approach to Compliance: Addressing Healthcare Fraud and Abuse Compliance Risks Throughout a Product's Lifecycle
  - Transparency and Third Party Compliance Requirements
  - Instituting a Truly Global Compliance Program
- 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.
 
- The Pharma Congress will feature an opening networking reception in the Pharma Congress Exhibit Hall.
- The Pharma Congress will feature an extraordinary series of keynote speakers.



### Who Should Attend:

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



### About the Pharmaceutical Compliance Forum:

The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance professionals and legal counsel from more than 50 of the largest research-based pharmaceutical manufacturers. The PCF was founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a three-day compliance congress each Fall. For membership information, contact Tim Bower at 215-599-6617 or via email at [info@PharmaComplianceForum.org](mailto:info@PharmaComplianceForum.org). Please visit their website at [www.pharmacomplianceforum.org](http://www.pharmacomplianceforum.org).

# Wednesday, November 11, 2009

## Preconference Symposia (Optional, choose one)

7:00 am Congress Registration

8:00 am Preconferences Commence (Choose one)

### PRECONFERENCE I: COMPLIANCE 101

This interactive pre-conference session, designed for new compliance professionals, or those new to the pharmaceutical industry. Compliance resources will be provided.

Margaret K. Feltz, *Associate Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)*

Wendy C. Goldstein, Esq., *Partner, Epstein Becker & Green P.C., New York, NY (Co chair)*

#### 8:00 am Introduction and Overview to the Seven Elements of an Effective Corporate Compliance Program

- Compliance Personnel and Infrastructure
- Written Standards
- Hotlines
- Training
- Auditing and Monitoring
- Investigations
- Screening and Discipline

10:15 am Break

#### 10:30 am Interactive Practice Session to Discuss Elements of an Effective Compliance Program

Noon Preconference Adjournment;  
Lunch on your Own

### PRECONFERENCE II: RECENT GOVERNMENT SETTLEMENTS AND LESSONS LEARNED

During this pre-conference session, the panels will present and discuss recent settlements in the pharmaceutical industry and the lessons that can be drawn for meeting the government's expectations for state of the art compliance programs.

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, US Department of Justice, Washington, DC (Co chair)*

Peter S. Spivack, Esq., *Partner, Hogan & Hartson, Washington, DC (Co chair)*

#### 8:00 am Introduction and Overview

#### 8:15 am State and Federal Enforcement of Off-label Promotion: What Compliance Lessons can be Drawn from Recent Cases

Jennifer Lynn Bragg, Esq., *Partner, Health Care and Life Sciences Group, Skadden Arps, LLP; Former Associate Chief Counsel for Enforcement, Food and Drug Administration, Washington, DC*

Meredith Manning, Esq., *Partner, Hogan & Hartson, LLC; Former Assistant US Attorney, Civil Division, US Attorney's Office; Former Associate Chief Counsel, Food and Drug Administration, Washington, DC*

Jeffrey Steger, Esq., *Trial Attorney, Office of Consumer Litigation, US Department of Justice, Washington, DC*

#### 9:15 am Anti-kickback Settlements

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, US Department of Justice, Washington, DC*

Jay Darden, Esq., *Assistant Chief, Fraud Section, US Department of Justice, Washington, DC*

10:00 am Break

#### 10:30 am FCPA

Sandy Merber, Esq., *Counsel, International Trade Regulation and Sourcing, General Electric Co., Washington, DC*

Hank Bond Walther, Esq., *Assistant Chief, Fraud Section, US Department of Justice, Criminal Division, Washington, DC*

Peter S. Spivack, Esq., *Partner, Hogan & Hartson, Washington, DC*

11:30 am Faculty Q&A

Noon Preconference Adjournment;  
Lunch on your Own

### PRECONFERENCE III: INTERNET AND SOCIAL NETWORKING COMMUNICATION

Pharmaceutical companies are increasingly seeking to connect with physicians and patients via the Internet, including both conventional forms of advertising and more involved interactions in chat rooms and social networking sites. This pre-conference workshop will explore industry views on Internet promotion and information exchange, as well as the approaches taken by the FDA and FTC to regulated Internet communications.

#### 8:00 am Introduction and Overview: Challenges for the Pharmaceutical Industry in Internet and Social Networking Marketing Activities

Daniel A. Kracov, Esq., *Partner and Chair, FDA and Healthcare Practice, Arnold & Porter LLC, Washington, DC (Co chair)*

Matthew M. Malloy, Esq., *Director and Associate General Counsel, The Procter & Gamble Company, Cincinnati, OH (Co chair)*

#### 8:45 am The Industry Perspective on the Regulation of the Internet and Social Networking Communications Marketing

Jeffrey K. Francer, Esq., *Assistant General Counsel, Pharmaceutical Research and Manufacturers Association, Washington, DC*

Robert Pineda, Esq., *Assistant Counsel, Regulatory, Merck & Co., Inc., North Wales, PA*

10:00 am Break

#### 10:15 am The Federal Trade Commission's Approach to Internet and Social Networking Marketing

Richard L. Cleland, *Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC*

#### 11:00 am Faculty Round Table Discussion Based on Hypotheticals: Marketing on the Internet and Social Networking Communications

Noon Preconference Adjournment;  
Lunch on your Own

# Wednesday, November 11, 2009

## Pharma Congress Day I •

### Recent Government Enforcement

- 1:00 pm**      **Welcome and Introduction**  
Colleen M. Craven, *Vice President, Corporate Compliance & Business Practices, Endo Pharmaceuticals, Chadds Ford, PA (Co chair)*
- 1:15 pm**      **Regulator Panel on Transparency and Disclosure**  
Melissa J. Lopes, Esq., *Deputy General Counsel, Massachusetts Department of Public Health, Boston, MA*  
George Till, MD, *State Legislator, Vermont, Jericho, VT*  
Cody Wiberg, PharmD, RPh, *Executive Director, Minnesota Board of Pharmacy, Minneapolis, MN*  
John Patrick Oroho, Esq., *Executive Vice President, Porzio Pharmaceutical Services; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ (Moderator)*

- 2:15 pm**      **Overview: Pfizer CIA Promotional Monitoring Requirements**  
Lori Alarimo, Esq., *Senior Corporate Counsel, Promotional Quality Assurance, Pfizer Inc., New York, NY*  
Edward Nowicki, Esq., *Deputy Compliance Officer-Global Programs, Senior Corporate Counsel, Corporate Compliance, Pfizer Inc., New York, NY*

- 2:45 pm**      **Transition Break**

### DAY I AFTERNOON TRACK SESSIONS

- 3:00 pm**      **AFTERNOON TRACK I: Compliance Program Elements: How to Implement and Enhance a Pharmaceutical Compliance Program to Meet Evolving Regulatory Standards**
- This track will teach attendees the “how” of compliance program operations, not just focus on the “what”.
  - This track will be particularly useful for attendees who are new to compliance and/or new to the pharmaceutical industry

- 3:00 pm**      **How to Structure your Compliance Department**  
Doreen F. Shulman, *Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb, Princeton, NJ (Co chair)*

- Peter S. Spivack, Esq., *Partner, Hogan & Hartson, Washington, DC (Co chair)*

- Jack T. Tanselle, *Director, Navigant Consulting, Inc., Chicago, IL (Co chair)*

- 3:30 pm**      **How to Create and Maintain Procedural Documents**  
Frances T. Germann, *Director, Procedural Document Governance, Bristol-Myers Squibb, Princeton, NJ*

- 4:00 pm**      **How to Deliver Innovative and Effective Compliance Training**  
Jack T. Tanselle, *Director, Navigant Consulting, Inc., Chicago, IL*  
Mark Williamson, *Director, Compliance and Ethics Education and Communication, Bristol-Myers Squibb, Princeton, NJ*

- 4:45 pm**      **How Program Management can Keep you on Track**  
Leila A. Daiuto, *Director, Life Sciences & Healthcare, Axentis, Inc., Cleveland, OH*  
Edward H. Leskauskas, *Director, Compliance and Ethics Operations and Program Management, Bristol-Myers Squibb, Princeton, NJ*

- 5:30 pm**      **Adjournment and Networking Reception**

- 3:00 pm**      **AFTERNOON TRACK II: An Integrated Approach to Compliance: Addressing Healthcare Fraud and Abuse Compliance Risks Throughout a Product's Lifecycle**

- This track will focus on healthcare fraud and abuse compliance risks in the areas of clinical research and development and sales and marketing, including government price reporting, pharmacovigilance and medical information.
- This track will be particularly useful for seasoned pharmaceutical compliance professionals

- 3:00 pm**      **Introduction and Overview**  
John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, Department of Justice, Washington, DC (Co chair)*

- Elizabeth V. Jobes, Esq., *Vice President and Chief Compliance Officer, Adolor Corporation; Former Senior Director, Global Compliance Officer, Cephalon; Former Assistant District Attorney, Philadelphia District Attorney's Office, Exton, PA (Co chair)*

- Brian Riewerts, *Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP, Baltimore, MD (Co chair)*

- 3:15 pm**      **Advanced Issues in Clinical Compliance**  
Colleen Gorman, *Senior Director, Technical Operations Lead, Pfizer, Inc., New York, NY*  
Anup Kharode, *Senior Manager, US Pharmaceutical and Life Sciences Advisory, PricewaterhouseCoopers LLP, Formerly Principal Scientist, Clinical Development, GlaxoSmithKline, Philadelphia, PA*  
Kelly N. “Nikki” Reeves, MPA, JD, *Partner, King & Spalding LLP, Washington, DC*

- 4:00 pm**      **Advanced Issues in Commercial (Sales & Marketing) Compliance**  
Karen Lowney, *Senior Director of Global Compliance, Cephalon, Former Director of International Compliance, Schering-Plough, Frazer, PA*

- Kathy Tench, *Manager, Huron Consulting Group, New York, NY*

- Manny Tzavlakis, *Director, Life Sciences Advisory Services, Huron Consulting Group, New York, NY*

- 4:30 pm**      **Advanced Issues in Medical Affairs Compliance**  
Elizabeth V. Jobes, Esq., *Vice President and Chief Compliance Officer, Adolor Corporation, Exton, PA*  
Harvey C. Kaish, *Vice President and Senior Counsel, Bristol-Myers Squibb, Plainsboro, NJ*  
Ann E. Lewis, Esq., *Counsel, Ropes and Gray, former Vice-President and Senior Counsel, U.S. Healthcare Law Compliance, Bristol-Myers, Squibb, New York, NY*

- 5:30 pm**      **Adjournment and Networking Reception**

3:00 pm

### **AFTERNOON TRACK III: Transparency and Third Party Compliance Requirements**

- This track will focus on state and federal marketing disclosure laws, clinical trial disclosure laws and vendor access requirements

#### **3:00 pm Introduction and Overview**

Eve Costopoulos, *Vice President, Global Compliance, Schering-Plough Corporation, Kenilworth, NJ (Co chair)*

Kris Curry, *Senior Director, Health Care Compliance Operations, Johnson & Johnson Pharmaceutical Research & Development, Titusville, NJ (Co chair)*

Gregory H. Levine, Esq., *Partner, Ropes & Gray, Washington, DC (Co chair)*

Paul J. Silver, *Managing Director, Practice Leader, Life Sciences Advisory Services, Huron Consulting Group, Atlanta, GA (Co chair)*

#### **3:15 pm Sunshine Act: Latest Developments and Industry Impact**

Albert F. Cacoza, Jr., Esq., *Partner, Ropes & Gray LLP; Former Counsel, Subcommittee on Labor, Committee on Labor and Human Resources, United States Senate, Washington, DC*

Marina Pearlman, *Senior Corporate Counsel, Pfizer, New York, NY*

#### **3:45 pm Disclosure of Clinical Trial Results: Obligations and Best Practices**

Mark A. DeWyngaert, MBA, PhD, *Managing Director, Huron Consulting Group, New York, NY*

Craig A. Metz, PhD, *Vice President Regulatory Affairs, GlaxoSmithKline, Research Triangle Park, NC*

#### **4:15 pm Disclosure of Third-Party Data: Compliance and Beyond**

Anthony Brennan, *Director, Policy and Audit Interface, Johnson & Johnson, Titusville, NJ*

Howard L. Dorfman, Esq., *Counsel, Ropes & Gray LLP; Former Chief Legal Officer, Pharmaceutical Division, Bayer Healthcare LLC; Former Counsel, US Medicines Group, Bristol-Myers Squibb, New York, NY*

Katie B. Topolewski, *Senior Counsel, Commercial Business, Corporate Compliance, Endo Pharmaceuticals, Chadds Ford, PA*

Dave Wysocky, *Director, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopersLLP, Lebanon, NJ*

Patricia Molino, *Vice President Public Affairs, Johnson & Johnson Corporate Communications, New Brunswick, NJ*

Kris Curry, *Senior Director, Health Care Compliance Operations, Johnson & Johnson Pharmaceuticals Groups, Titusville, NJ (Moderator)*

#### **5:00 pm Third Party Data: How to Collect and Use It Effectively**

Eve Costopoulos, *Vice President, Global Compliance, Schering-Plough Corporation, Kenilworth, NJ*

Debjit A. Ghosh, MS, MPH, *Managing Director, Huron Consulting Group, New York, NY*

#### **5:30 pm Adjournment and Networking Reception**

3:00 pm

### **AFTERNOON TRACK IV: Instituting a Truly Global Compliance Program**

- This track will focus on a number of areas that companies operating globally need to make sure they have considered as their compliance organizations mature. This track is for legal counsel and seasoned compliance professionals in global organizations.

#### **3:00 pm Introduction and Overview Panel: What is a Global Compliance Organization in Practice?**

Scott Bass, Esq., *Partner, Sidley Austin LLP, Washington, DC (Co chair)*

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

Caroline West, Esq., *Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc., Wayne, PA (Co chair)*

#### **3:45 pm Panel: Building Promotional and Event Review Processes in an International Environment**

Keith M. Korenchuk, JD, MPH, *Partner, Arnold & Porter, Washington, DC*

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

Sheila Stranks, *Senior Director and Deputy Compliance Officer, International, Shire Pharmaceuticals Group PLC; Magistrate, Basingstoke Law Courts, Basingstoke, Hampshire, UK*

Sharon J. White, *Director, International Compliance Office, Wyeth Pharmaceuticals, Collegeville, PA*

#### **4:30 pm Safety and Pharmacovigilance Issues Globally**

Joseph C. Famulare, *Deputy Director, Office of Compliance, Food and Drug Administration, Silver Spring MD*

Michael Giffin, *Director of Life Sciences, World Class International, New York, NY*

#### **5:15 pm Reference Pricing: Staying Ahead of Evolving Regulatory Landscape**

James C. Stansel, Esq., *Partner, Sidley Austin LLP; Former Acting General Counsel, US Department of Health & Human Services, Washington, DC*

#### **6:00 pm Adjournment and Networking Reception**

# Thursday, November 12, 2009

## Pharma Congress Day II

7:00 am **Registration Opens:  
Continental Breakfast in Exhibit Hall**

### MORNING PLENARY SESSION

8:00 am **Welcome and Introduction to  
Day II Morning Plenary Session**  
Margaret K. Feltz, *Associate Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)*

8:15 am **OIG Update**  
Mary E. Riordan, Esq., *Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, Washington, DC*

9:15 am **DOJ Civil Division Update**  
Tony West, Esq., *Head, Civil Division, US Department of Justice; Former California Special Assistant Attorney General; Former Assistant US Attorney, Northern California, Washington, DC*

9:45 am **DOJ Criminal Division Update**  
Lanny A. Breuer, Esq., *Head, Criminal Division, US Department of Justice; Former Special White House Counsel; Former Assistant District Attorney, New York City, Washington, DC*

10:15 am **Break**

10:45 am **Making the Case for Compliance:  
A US Attorney's Perspective**  
Patrick L. Meehan, Esq., *Partner, Conrad O'Brien Gellman & Rohm, Former United States Attorney, Eastern District of Pennsylvania, Philadelphia, PA*

11:15 am **SEC Enforcement Update**  
Lorin L. Reisner, Esq., *Deputy Director of Enforcement, US Securities and Exchange Commission; Former Assistant United States Attorney, Southern District of New York, Washington, DC*

NOON **Networking Luncheon**

### DAY II AFTERNOON TRACK SESSIONS

1:00 pm **AFTERNOON TRACK I: Compliance Program Elements: How to Implement and Enhance a Pharmaceutical Compliance Program to Meet Evolving Regulatory Standards (Continued)**

1:00 pm **How to Receive Allegations of Compliance Violations and Conduct Investigations**  
Mary Ann Northrup, *Associate Director, Navigant, Inc., Chicago, IL*

Chuck Rosenberg, Esq., *Partner, Hogan & Hartson LLP; Former US Attorney, Eastern District of Virginia; Former US Attorney, Southern District of Texas, Washington, DC*

1:45 pm **How to Design and Conduct an Effective Compliance Auditing and Monitoring Program**  
A. Monica Jonhart, *Senior Director, Healthcare Auditing & Monitoring, Otsuka America Pharmaceutical, Inc., Princeton, NJ*

Chris Santarcangelo, *Assistant Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT*

2:30 pm **How to Communicate and Collaborate with Colleagues in Related Functions and Departments**

Joseph J. Skupen, *Senior Director, US Corporate Compliance, sanofi-aventis, Bridgewater, NJ*

Robert M. Trotta, II, *Senior Director, Compliance and Ethics, Bristol-Myers Squibb, Princeton, NJ*

3:15 pm **How to Communicate with the Board of Directors About your Compliance Program**  
Saul B. Helman, MD, *Managing Director, Navigant Consulting, Inc., Chicago, IL*

Doreen F. Shulman, *Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb, Princeton, NJ*

3:45 pm **Break**

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1:00 pm **AFTERNOON TRACK II: An Integrated Approach to Compliance: Addressing Healthcare Fraud and Abuse Compliance Risks Throughout a Product's Lifecycle (Continued)**

1:00 pm **Advanced Issues in Managed Care and Reimbursement**  
John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP, Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, US Department of Justice, Washington, DC (Co chair)*

Eric Siegel, *Chief Compliance Officer, EMD Serono, Inc., Rockland, MA (Co chair)*

2:00 pm **Impact of REMs Program Requirements to Pharma**  
Karla Stricker Anderson, *Managing Director, PricewaterhouseCoopers LLP, McLean, VA*  
Jim Tizzard, *Chief Executive Officer, WCI Consulting Limited, Denmead, Hampshire, UK*

3:00 pm **Wrap-up Faculty Panel Discussion**

3:45 pm **Break**

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1:00 pm **AFTERNOON TRACK III: Transparency and Third Party Compliance Requirements (Continued)**

1:00 pm **Overview of Day Two**

1:10 pm **Developing a Global Approach for Third-Party Due Diligence Programs**  
William R. Baker, III, Esq., *Partner, Latham & Watkins, Washington, DC*

Colleen A. Conry, Esq., *Partner, Ropes and Gray LLP, Washington, DC*

2:00 pm **Aggregate Spend & State Reporting — Do You Know Where Your Third Parties Are?**  
Michael Bell, *President, R-Squared, Princeton Junction, NJ*

Marci Juneau, *Huron Consulting Group, New York, NY*

Eric Siegel, *US Chief Compliance Officer, EMD Serono, Inc., Rockland, MA*

**2:45 pm Harmonization of FMV Policies & Procedures Internally and With Your Third Party Vendors**

Jeffrey J. Brady, *President, Advanced Health Media, LLC, Bridgewater, NJ*

Brian A. Dahl, Esq., *Director of Compliance, Teva North America, Kansas City, MO*

Meghan Davis, *Manager, Life Sciences Advisory Services, Huron Consulting Group, New York, NY*

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

**3:45 pm Break**

# Friday, November 13, 2009

## Pharma Congress Day III • Policy and Ethics

**8:00 am**

### Introduction to Day Three

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

**8:15 am**

### Keynote: Health Reform Update

Representative Mike Ross (D-AR) (Invited), *Leader, Blue Dog Coalition; Member, House Committee on Energy and Commerce and Energy and Health Subcommittees, United States House of Representatives, Washington, DC*

**8:45 am**

### Effective and Compliant Promotion: Best Practice Training and Monitoring Techniques, A Personal Account on the Effects of a Misbranding Charge

Mary Holloway, *President - Sales and Marketing, DMH BioPharm Advisors, LLC; Former Sales Director, Astellas; Former Northeast Regional Sales Manager, Pfizer, Bridgewater, NJ*

Dee Mahoney, *President - Operations, DMH BioPharm Advisors, LLC; Former Senior Vice President, General Manager, US Specialty Markets Business Unit, Pfizer, New York, NY*

**9:15 am**

### Medical Institution Perspectives on Restrictions with Pharmaceutical Companies: Insights on Use of HCPs as Speakers/Consultants, Access for Pharmaceutical Sales Reps and MSLS, and Transparency

Ivy Baer, Esq., *Director and Regulatory Counsel, Association of American Medical Colleges, Washington, DC*

Pamela J. Grimm, Esq., *Senior Associate Counsel and Vice President Legal and Regulatory Affairs, University of Pittsburgh Medical Center, Pittsburgh, PA*

Jessica L. Quinn, JD, *Vice President and Chief Compliance Officer, The University of Texas M.D. Anderson Cancer Center, Houston, TX*

Michael Shaw, Esq., *Vice President & Compliance Officer, GlaxoSmithKline - NA Pharmaceuticals, GlaxoSmithKline Pharmaceutical, Philadelphia, PA (Moderator)*

**10:15 am**

**Break**

**10:30 am**

### The Ethics of Utilizing Unlicensed Drugs and Vaccines to Combat H1N1 Flu and Other Public Health Challenges in the U.S. and Other Nations

Arthur Caplan, PhD, *Emanuel and Robert Hart Professor of Bioethics, Chair, Department of Medical Ethics; Director, Center for Bioethics, University of Pennsylvania, Philadelphia, PA*

**11:00 am**

### PCF Pharmaceutical Compliance Professional and Legal Counsel Roundtable

Ann Beasley Bacon, *Vice President, Global Integrity and Compliance and Compliance Officer-Vaccines, Americas, Novartis Vaccines and Diagnostics, Cambridge, MA*

**1:00 pm**

### AFTERNOON TRACK IV: Instituting a Truly Global Compliance Program (Continued)

**1:00 pm Recap and Review of Day 1 by Co chairs**

**1:15 pm DOJ's New FCPA Initiative on Pharma and Device Manufacturers**

Steve Kim, Esq., *Trial Attorney, Fraud Section, US Department of Justice, Former Assistant United States Attorney, Eastern District of New York, Washington, DC*

Kirk Ogrosky, Esq., *Deputy Chief, Fraud Section, US Department of Justice, Washington, DC*

**2:15 pm Anti-Bribery Concerns: FCPA and Beyond**

Ed Buthusiem, Esq., *Senior Vice President, Special Counsel to the General Counsel, GlaxoSmithKline, King of Prussia, PA*

Greg Crouse, CPA, *Partner, Pharmaceutical Compliance Investigative & Dispute Services, Ernst & Young, Washington, DC*

R. Scott Meece, Esq., *General Counsel and Senior Vice President, Bayer Healthcare LLC, Tarrytown, NY*

**3:00 pm Panel Discussion: Lessons from the Trenches — Brazil and China**

José Alexandre Buaiz Neto, Esq., *Partner, Pinheiro Neto Advogados, Brazil*

Damon Burrows, Esq., *Vice President and Assistant General Counsel - Regulatory, Allergan, Inc., Irvine, CA*

Jack C. Silhavy, Esq., *Assistant General Counsel, Astellas US LLC, Deerfield, IL*

**3:45 pm**

**Break**

### AFTERNOON PLENARY SESSION

**4:15 pm**

**Afternoon Plenary Session: Updates and Best Practices Reports from the Track Co chairs**

**5:15 pm**

**Adjournment**

*Session Continued Next Page*

*Session Continued from Page 7*

Regina Gore Cavaliere, Esq., *Chief Compliance Officer/Vice President Ethics, Quality & Compliance, Otsuka America Pharmaceutical, Inc.; Former Vice President and Senior Counsel, Alpharma Pharmaceuticals; Former Senior Counsel, Bristol-Myers Squibb Company, Princeton, NJ*

Douglas M. Lankler, Esq., *Deputy General Counsel, and Chief Compliance Officer, Associate General Counsel, and Chief Compliance Officer, Pfizer; Former Assistant US Attorney, Southern District of New York, United States Department of Justice, New York, NY*

Edward Miller, Esq., *Vice President, Associate General Counsel and Chief Compliance Officer, Boehringer Ingelheim USA, Inc.; Former Senior Trial Attorney, US Department of Justice, Ridgefield, CT*

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

12:30 pm

**Adjournment**

## 2009 PCF Pharma Congress Planning Committee:

Colleen M. Craven, Vice President, Corporate Compliance & Business Practices, Endo Pharmaceuticals (Co chair)

Margaret K. Feltz, Associate Director, Corporate Compliance, Purdue Pharma LP (Co chair)

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

Scott Bass, Esq., Partner, Sidley Austin LLP

John T. Bentivoglio, Esq., Partner, Skadden Arps LLP

Eve Costopoulos, Vice President, Global Compliance, Schering-Plough Corporation

Kris Curry, Senior Director, Health Care Compliance Operations, Johnson & Johnson Pharmaceuticals Groups

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

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Kathleen Meriwether, Esq., Principal, Fraud Investigation & Dispute Services, Ernst & Young

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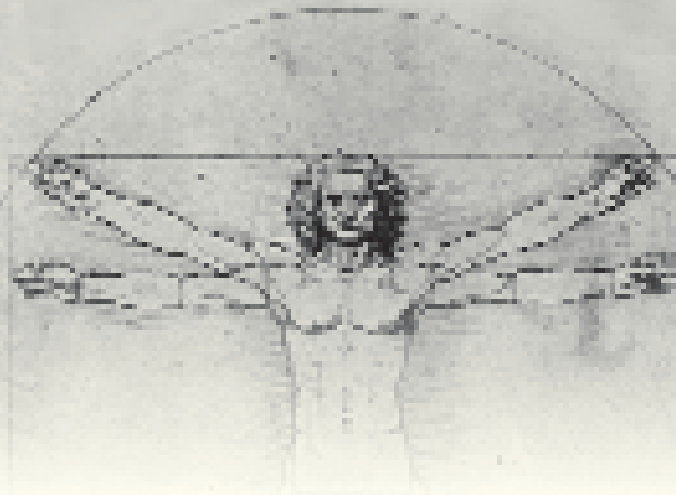
Paul J. Silver, Managing Director, Practice Leader, Life Sciences Advisory Services, Huron Consulting Group

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