THE NINTH ANNUAL  Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum  PREPARING FOR THE NEXT WAVE OF CHANGE

October 27–29, 2008
Hyatt Regency On Capitol Hill • Washington, DC
www.PharmaCongress.com • 800-684-4549

Featured Faculty:
Diane E. Bieri, Esq., Vice President, General Counsel, Pharmaceutical Research and Manufacturers of America
John K. Iglehart, Founding Editor, Health Affairs, National Correspondent, New England Journal of Medicine
Michael K. Loucks, Esq., First Assistant U.S. Attorney, U.S. Attorney’s Office for the District of Massachusetts
Gerald F. Masoudi, Esq., Chief Counsel, Food and Drug Administration, Former Deputy Assistant Attorney General, International, Policy and Appellate Matters, Antitrust Division, U.S. Department of Justice
James G. Sheehan, Esq., New York State Medicaid Inspector General, Former Associate United States Attorney, U.S. Attorney’s Office, Eastern District of Pennsylvania
Theresa A. Toigo, MBA, R.Ph., Director, Office of Special Health Issues, Director, Office of Women’s Health, Food and Drug Administration

Co chairs:
Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation
Arjun Rajaratnam, Esq., Compliance Officer, Global Pharmaceuticals, GlaxoSmithKline
Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma LP

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TRAIN FOR PHARMA

Featured Tracks:
• Sales and Marketing Compliance Update
• Research, Development and Clinical Trials Compliance Update
• The “411” on Government Price Reporting
• Relationships with Healthcare Professionals Compliance Update
• Emerging Compliance Challenges
• Interactive International Case Studies
• Pharmacovigilance and Drug Safety Compliance Update
• Working with Third Parties, Vendors and Strategic Partners
• Creating an Environment for Productive Post-Settlement Interactions with the Government
• FCPA Compliance Update
• Interactive Domestic Case Studies

Sponsor:  THE PHARMACEUTICAL COMPLIANCE FORUM
Pharma Congress Overview

The leadership of the Pharmaceutical Compliance Forum (PCF), the sponsor of the Ninth 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:
   - Sales and Marketing Compliance Update,
   - Research, Development and Clinical Trials Compliance Update,
   - The “411” on Government Price Reporting: What Every Compliance Professional Needs to Know,
   - Relationships with Healthcare Professionals Compliance Update,
   - Emerging Compliance Challenges,
   - Pharmacovigilance and Drug Safety Compliance Update,
   - Working with Third Parties, Vendors and Strategic Partners,
   - Creating an Environment for Productive Post-Settlement Interactions with the Government: CIAs, DOJ Monitors and Disclosures, and
   - FCPA Compliance Update

2. The Pharma Congress will feature a special case study track on the following topics:
   - Interactive International Case Studies Covering a Range of Topics to Include: Distribution Channel Challenges; Third Party Oversight (Including Use of HCPs as Third Parties, and Anti-bribery and Anticorruption Considerations); Organization of International Congresses and Conferences for HCP Attendance; and Management of Allegations and Investigations, and
   - Interactive Domestic Case Studies Covering a Range of Topics to Include: Speaker Management Issues; In-Office Interactions; Conflicts of Interest Between Sales Reps and Customers; Firewall Issues Between Vendors who Provide Medical and Marketing Publication Services for the same Pharma Company; PhRMA Code Issues Prior to Implementation; and PhRMA Code issues that are not Crystal Clear

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 Monday 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. Tuesday 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

About the Pharmaceutical Compliance Forum:

The Pharmaceutical Compliance Forum (PCF), www.pharmacomplianceforum.org, is a coalition of compliance officials and legal counsel from more than 50 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 organization is open to other research based pharmaceutical manufacturers and has more than 370 individual members. 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. For membership information, contact Colleen Lacey at 215-599-6617 or via email at info@PharmaComplianceForum.org.
Preconference Symposia  
Monday, October 27, 2008

7:00 am Congress Registration  
8:00 am Preconferences Commence (Choose one)  

Preconference I: Pharmaceutical Regulatory and Compliance Basics  
8:00 am Welcome and Introduction  
Kelly B. Freeman, PhD, Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company, Indianapolis, IN (Co chair)  
Janet L. “Lucy” Rose, National Managing Director, Life Sciences Regulatory & Capital Markets Consulting, Deloitte & Touche LLP, Former Director, Division of Drug Marketing, Advertising, and Communications (DDMAC), Former Director, Office of Training and Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Washington, DC (Co chair)  

8:15 am Compliance Overview: Laws and Regulations, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the Federal Sentencing Guidelines, and Important Settlements with the Government  
Retta M. Riordan, Esq., Principal, Riordan Consulting LLC, Former Business Ethics and Compliance Officer, Organon USA Inc., Westfield, NJ  

9:00 am FDA Regulatory Overview: Trends Affecting the Regulation of Advertising and Promotion, the FDA Review Process and Requirements for Claim Support, Fair Balance, and DTC Promotion  
Janet L. “Lucy” Rose, National Managing Director, Life Sciences Regulatory & Capital Markets Consulting, Deloitte & Touche LLP, Former Director, Division of Drug Marketing, Advertising, and Communications (DDMAC), Former Director, Office of Training and Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Washington, DC  

10:00 am Break  
10:15 am Implementing the Seven Elements of a Compliance Program: Practical Advice and Best Practices for Policy Development, Training, Communications, Monitoring, Auditing, and Corrective Actions  
Kelly B. Freeman, PhD, Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company, Indianapolis, IN  

11:15 am Questions and Comments  
Noon Preconference Adjournment; Lunch on your Own  

Preconference II: State Marketing, Ethics and Disclosure Laws and Federal Preemption  
8:00 am Welcome and Introduction  
Janice G. Cunningham, Esq., Healthcare Compliance Officer and Corporate Counsel, Barrier Therapeutics Inc., Princeton, NJ (Co chair)  
Jeffrey L. Handwerker, Esq., Partner, Arnold & Porter, Washington, DC (Co chair)  

Janice G. Cunningham, Esq., Healthcare Compliance Officer and Corporate Counsel, Barrier Therapeutics Inc., Princeton, NJ  
Jeffrey L. Handwerker, Esq., Partner, Arnold & Porter, Washington, DC  

9:00 am What’s on the Horizon? Licensure Concerns for Pharma Companies  
David W. Ogden, Esq., Partner and Co chair, Government and Regulatory Litigation Practice Group, Wilmer Hale, Former Assistant Attorney General, Civil Division, US Department of Justice, Washington, DC  

10:30 am The Federal Sunshine Act  
Ann Leopold Kaplan, Esq., Assistant General Counsel, PhRMA, Washington, DC  

11:00 am Panel Discussion: Revised PhRMA Code: What’s Changed and What’s the Impact on State Laws? State AG Perspective: Where is the Focus for the Coming Year? What are Advocacy Groups Doing?  
John T. Bentivoglio, Esq., Partner, King & Spalding LLP, Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, Department of Justice, Washington, DC  
Julie Brill, Esq., Assistant Attorney General, State of Vermont, Montpelier, VT  
Sean Flynn, Esq., Associate Director, American University Washington College of Law, Washington, DC  

11:30 am Questions and Answers  
Noon Preconference Adjournment; Lunch on your Own  

Preconference III: Auditing, Monitoring and Effective Internal Investigations  
8:00 am Welcome and Introduction  
Wendy C. Goldstein, Esq., Partner and Chair, Pharmaceutical Industry Health, Regulatory Practice Group, Epstein Becker & Green, New York, NY (Co chair)  
Tracy Mastro, Director, Life Sciences Advisory Services, Huron Consulting Group, Washington, DC (Co chair)  
Jonathan Williams, Esq., Director, Health Care Compliance, Genentech, Inc. San Francisco, CA (Co chair)  

Janice G. Cunningham, Esq., Healthcare Compliance Officer and Corporate Counsel, Barrier Therapeutics Inc., Princeton, NJ  
Jeffrey L. Handwerker, Esq., Partner, Arnold & Porter, Washington, DC  

9:00 am What’s on the Horizon? Licensure Concerns for Pharma Companies  
David W. Ogden, Esq., Partner and Co chair, Government and Regulatory Litigation Practice Group, Wilmer Hale, Former Assistant Attorney General, Civil Division, US Department of Justice, Washington, DC  

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John T. Bentivoglio, Esq., Partner, King & Spalding LLP, Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, Department of Justice, Washington, DC  
Julie Brill, Esq., Assistant Attorney General, State of Vermont, Montpelier, VT  
Sean Flynn, Esq., Associate Director, American University Washington College of Law, Washington, DC  

11:30 am Questions and Answers  
Noon Preconference Adjournment; Lunch on your Own  

Preconference Adjournment; Lunch on your Own
The leadership of the Pharmaceutical Compliance Forum (PCF), the sponsor of the Ninth 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:
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 M. Boozang, Esq., Associate Dean and Professor of Law, Co founder, Health Law & Policy Program, and Health Law, Science and Technology Graduate Programs, Seton Hall University School of Law
David B. Chandler, Ph.D., DABT, Director of Outcomes and Analysis Corporate Compliance, Amgen
Timothy Cleary, Esq., Vice President, Legal Affairs and Chief Compliance Officer, Sanofi Pasteur Inc.
Janice G. Cunningham, Esq., Healthcare Compliance Officer and Corporate Counsel, Barrier Therapeutics Inc.
David Davidovic, Senior Director, Business Practices, Genentech
Kelly B. Freeman, Ph.D., Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company
Abhiroop Gandhi, Commercial Compliance, Actelion Pharmaceuticals US, Inc.
Wendy C. Goldstein, Esq., Partner, Epstein Becker & Green
Peter N. Grant, JD, Ph.D., President, Health Care Conference Administrators, LLC
Keith M. Korenchuk, JD, MPH, Of Counsel, Covington & Burling LLP
Daniel A. Kracov, Esq., Partner, Arnold & Porter
Greg Levine, Esq., Partner, Ropes & Gray
Meredith Manning, Esq., Partner, Hogan & Hartson
Edward Miller, Esq., Vice President, Associate General Counsel and Chief Compliance Officer, Boehringer Ingelheim Pharmaceuticals, Inc.
Steve Mohr, Esq., Global Compliance Officer, AstraZeneca
Lawrence P. Platkin, Esq., Vice President and Compliance Officer, Bayer HealthCare LLC
Brian Riewerts, Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP
Sue Seferian, Esq., Senior Counsel, Johnson & Johnson
Doreen F. Shulman, Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb
Paul J. Silver, Managing Director, Huron Consulting Group
Scot Steinheiser, Assistant Director, Corporate Compliance Astellas US LLC
Jack T. Tanselle, Director, Navigant Consulting, Inc.

8:00 am Preconference IV: Dangerous Documents: Finding Land Mines In Your FDA Records and Emails
Guidant, Merck, Bayer, Eli Lilly, and American Home Products were sued. During discovery, they were forced to produce their employees’ emails and other documents that they thought were confidential. These documents contained inflammatory statements that embarrassed the companies. They had to enter into expensive settlements. If your employees haven’t been trained on how to write complete, accurate emails and documents that show the depth of your corporate culture of compliance, your firm could be subject to a similar costly result. This preconference provides actual examples and practical advice about how to avoid problems before they occur, and correct mistakes before they happen. Using actual case studies the preconference session explains:

- How to write informative documents that don’t make you a target
- How to avoid land mines in wording and presentation
- How documents tell the story of the corporate culture
- The dangers in not monitoring employees’ emails
- The risks of leaving blanks and using white-out in required records
- How to distinguish between fact and opinion
- Why it is crucial to follow a document retention program

8:15 am Case Study: Implementing a Compliance Monitoring Program — How do you get Started? How do you Know if it’s Really Effective? What are Some Useful Tools?
Tracy Mastro, Director, Life Sciences Advisory Services, Huron Consulting Group, Washington, DC
Chris Santarcangelo, Assistant Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT
Jonathan Williams, Esq., Director, Health Care Compliance, Genentech, Inc., San Francisco, CA

9:30 am Break

9:45 am Identifying and Responding to Potential Violations: An Interactive Discussion of the Stages of an Internal Investigation and Better Practices for Conducting Effective Reviews
David Anderson, Healthcare Compliance Office Internal Investigator, Genentech, South San Francisco, CA
Dan Dovdavany, Esq., Senior Corporate Counsel, US Litigation and Investigations, Sanofi-Aventis, Bridgewater, NJ
Wendy C. Goldstein, Esq., Partner and Chair, Pharmaceutical Industry Health, Regulatory Practice Group, Epstein Becker & Green, New York, NY
Liz Lewis, Esq., Vice President, Deputy General Counsel, Millennium Pharmaceuticals, The Takeda Oncology Company, Cambridge, MA

11:00 am Break
11:15 am Implementation of a Corrective Action Plan
Janis Crum, Esq., Associate Director, Healthcare Compliance Office, Genentech, Inc., South San Francisco, CA

11:45 am Questions and Answers
Noon Pre-conference Adjournment; Lunch on your own

11:45 am Break
Pharma Congress Agenda
Monday, October 27, 2008 • Day I
Perspectives on the Pharmaceutical Sector in Changing Times

1:00 pm  Welcome and Introduction
Lori Queisser, Senior Vice President, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ (Co chair)

1:15 pm  Pharmaceutical Compliance: How Far We’ve Come and Where we Need to Go
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

2:00 pm  OIG Update
Lewis Morris, Esq. (Invited), Chief Counsel, Office of Inspector General, Department of Health and Human Services, Washington, DC

3:00 pm  Break

3:30 pm  DOJ Update
Michael K. Loucks, Esq., First Assistant U.S. Attorney, U.S. Attorney’s Office for the District of Massachusetts, Boston, MA

4:00 pm  Department of Justice Update
Daniel R. Anderson, Esq. (Invited), Assistant Director, Commercial Litigation, Civil Division, United States Department of Justice, Former Assistant Attorney General and Director, Medicaid Fraud Control Unit, State of Maryland, Washington, DC

4:30 pm  The Newly Revised PhRMA Code
Diane E. Bieri, Esq., Vice President, General Counsel, Pharmaceutical Research and Manufacturers of America, Washington, DC

5:00 pm  Adjournment and Meet the Regulator Networking Reception
The Pharma Congress Monday network reception will feature an opportunity to meet a number of key Federal and state regulators and Capitol Hill staff specializing in pharmaceutical policy.
Thomas E. Costa, Vice President, U.S. Pharmaceuticals Compliance & Ethics, Bristol-Myers Squibb, Princeton, NJ (Co chair)

Pharma Congress Agenda
Tuesday, October 28, 2008 • Day II

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

MORNING PLENARY SESSION

8:00 am  Welcome and Introduction to Day II
Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)

8:15 am  PCF Pharmaceutical Compliance Professional and Legal Counsel Roundtable: Preparing for the Next Wave of Change
Gerald F. Masoudi, Esq., Chief Counsel, Food and Drug Administration, Former Deputy Assistant Attorney General, International, Policy and Appellate Matters, Antitrust Division, US Department of Justice, Rockville, MD
Lewis Morris, Esq. (Invited), Chief Counsel, Office of Inspector General, Department of Health and Human Services, Washington, DC
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
Doreen F. Shulman, Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb
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/Co chair)

9:15 am  Transition Break

PHARMA CONGRESS MORNING TRACK SESSIONS

Morning Track I: Sales and Marketing Compliance Update

TRACK
CO CHAIRS
Gregory H. Levine, Esq., Partner, Ropes & Gray, Washington, DC (Co chair)
Edward Miller, Esq., Vice President, Associate General Counsel and Chief Compliance Officer, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT (Co chair)
Lawrence P. Palkin, Esq., Vice President and Compliance Officer, Bayer HealthCare LLC, Wayne, NJ (Co chair)
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Session Details</th>
<th>Speakers</th>
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| 9:30 am | Sales & Marketing Compliance Lessons from Recent Developments: Recent settlements, CIAs; Compliance Challenges in Implementing the Revised PhRMA Code; FDA Draft Guidance on Off-Label Dissemination; AAAMC Report on Industry Funding of Medical Education; Access Issues and Industry Responses; and Sunshine Act and State Transparency Laws | Gregory H. Levine, Esq., Partner, Ropes & Gray, Washington, DC  
Edward Miller, Esq., Vice President, Associate General Counsel and Chief Compliance Officer, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT  
Lawrence P. Platkin, Esq., Vice President and Compliance Officer, Bayer HealthCare LLC, Wayne, NJ |                                                                                                                                                                                                               |
| 10:30 am | State Laws: Assessing Challenges, What’s Ahead: State Reporting Implementation Challenges — Dealing with Incomplete Data; Specific Challenges Requiring Legal Interpretation; Tracking Total Spend; Effectiveness of State Reporting Requirements in Changing Company Practices; and Future Areas of State Focus | Regina Cavaliere, Esq., Vice President and Senior Counsel, Health Care Law Compliance, Pharmaceuticals, Alpharma Pharmaceuticals LLC, Bridgewater, NJ  
Ann Lewis, Esq., Counsel, Ropes & Gray LLP, New York, NY  
Una Nash, Associate Director, Compliance-Marketing and Sales, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT |                                                                                                                                                                                                               |
| Noon    | Panel Discussion/Q&A                                                                                                     |                                                                                                                                                                                                               |                                                                                                                                          |
| 10:30 am | GAP Analysis: How we Get to Where we Want to be — Managing GCP Inspections Pre-Approval                                      | Robert F. Church, Esq., Partner, Hogan & Hartson, LLP, Former Associate Chief Counsel for Drugs, Food and Drug Administration, Los Angeles, CA                                                                 |                                                                                                                                          |
| 11:00 am | The Intersection of the False Claims Act and FDA’s Authority over Clinical Trials                                         | Robert P. Brady, Esq., Partner and Co director, Pharmaceutical and Biotechnology Practice Group, Hogan & Hartson, LLP, Former Executive Assistant to the Commissioner, Food and Drug Administration, Washington, DC |                                                                                                                                          |
| 11:30 am | FDA and Duke University’s Clinical Trials Initiative                                                                     | TBD                                                                                                                                                                                                           |                                                                                                                                          |
| Noon    | Proceed to Networking Luncheon                                                                                           |                                                                                                                                                                                                               |                                                                                                                                          |
| 9:30 am | Current Compliance Challenges — Developing a Robust Compliance Framework for Price Reporting Using the OIG’s Seven Elements | Tim Nugent, Managing Director, Huron Consulting Group, New York, NY (Co chair)  
Alice Valder Curran, Hogan & Hartson, Partner, Washington, DC (Co chair) |                                                                                                                                                                                                               |
| 10:00 am | Assessing Future Regulatory and Compliance Developments — An Assessment of the Current Landscape and Future Legislative Changes Medicaid, Medicare, and VA Price Reporting Obligations | Alice Valder Curran, Partner, Hogan & Hartson, Washington, DC |                                                                                                                                                                                                               |
| 10:30 am | GAP Analysis: How we Get to Where we Want to be in Government Price Reporting Compliance                                  | Allison Pugsley, Esq., Attorney-at-Law, Hogan & Hartson LLP, Washington, DC |                                                                                                                                                                                                               |
| 11:00 am | A Primer on Service Fee Payments and Fair Market Value for Price Reporting                                                | Debjit Ghosh, Director, Huron Consulting Group, New York, NY |                                                                                                                                                                                                               |
| 11:30 am | Practical Case Study: A Compliance Professional’s Playbook on Conducting a Pricing Assessment                            | Jessica A. Gottlieb, Esq., Director & Associate Counsel, Marketing Compliance, Barr Laboratories, Inc., Former Associate Counsel at Roche Pharmaceuticals, Montvale, NJ  
Tim Nugent, Managing Director, Huron Consulting Group, New York, NY |                                                                                                                                                                                                               |
| Noon    | Proceed to Networking Luncheon                                                                                           |                                                                                                                                                                                                               |                                                                                                                                          |
**Morning Track IV: Relationships with Healthcare Professionals Compliance Update**

**TRACK CO CHAIRS**

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

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

**9:30 am**

Emerging (Regulatory and Prosecutorial) Focus on Physicians

Sharon Joyce, Esq., Assistant Attorney General, State of New Jersey, Newark, NJ

Kevin O’Dowd, Esq., Assistant United States Attorney, United States Department of Justice, District of New Jersey, Newark, NJ

**10:15 am**

Orthopedics Panel: Learning from the Implementation to Comply with Settlement Requirements

Austin A. Byrd, Vice President, Ethics, Compliance and Professional Affairs Orthopedic Reconstruction Global Business Unit, Smith & Nephew, Memphis, TN

John P. Inglesino, Esq., Member, Stern & Kilcullen, LLC, Roseland, NJ

Jeff Klimaski, Vice President and Global Corporate Compliance Officer, Stryker Laboratories, Inc., Duluth, GA

Mary Ann McDonald (Invited), Stryker Corporation, Kalamazoo, MI

Laura C. O’Donnell, Chief Compliance Officer, Zimmer Holdings, Inc., Warsaw, IN

Noon

Proceed to Networking Luncheon

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**Morning Track V: Emerging Compliance Challenges**

**TRACK CO CHAIRS**

Indrani Franchini, Deputy Compliance Officer, US, Pfizer, New York, NY (Co chair)

Peter Claude, Partner, PricewaterhouseCoopers LLP, Florham Park, NJ (Co chair)

Daniel A. Kracov, Esq., Partner, Arnold & Porter, Washington, DC (Co chair)

**9:30 am**

Executive Liability: Beyond the Park Doctrine

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

Vernessa Thomas Pollard, Esq., Counsel, Arnold & Porter LLP, Former Associate Chief Counsel, Food and Drug Administration, Washington, DC

**10:10 am**

Relationships between Pharmaceutical Companies and Research Publications

Indrani Franchini, Deputy Compliance Officer, US, Pfizer, New York, NY

**10:45 am**

Maintaining Compliance in a Changing World

Peter Claude, Partner, PricewaterhouseCoopers LLP, Florham Park, NJ

**11:15 am**

The Implementation of Fair Market Value: What Can We Learn From Recent Enforcement Actions?

Abhiroop Gandhi, Commercial Compliance, Actelion Pharmaceuticals US, Inc., South San Francisco, CA

Debjit A. Ghosh, Life Sciences Advisory Services, Huron Consulting Group, LLC, New York, NY

Vickie McCormick, Vice President, Health Care Compliance, DePuy Orthopaedics, Warsaw, IN

Noon

Proceed to Networking Luncheon

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**Morning Track VI: Interactive International Case Studies Covering a Range of Topics to Include: Distribution Channel Challenges; Third Party Oversight (Including Use of HCPs as Third Parties, and Anti-bribery and Anti-corruption Considerations); Organization of International Congresses and Conferences for HCP Attendance; and Management of Allegations and Investigations**

**TRACK CO CHAIRS**

Sue Egan, Vice President Compliance, AstraZeneca PLC, London, UK (Co chair)

Keith M. Korenchuk, JD, MPH, Of Counsel, Covington & Burling LLP, Washington, DC (Co chair)

Michael Shaw, Global Head, Ethics and Compliance, Novartis Oncology, Former Senior Counsel, Office of Inspector General, Department of Health and Human Services, Florham Park, NJ (Co chair)

Doreen F. Shulman, Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb, Princeton, NJ (Co chair)

Noon

Proceed to Networking Luncheon

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Special Box Lunch Report: New Theories of Prosecution Under False Claims Act

Paul E. Kalb, JD, MD, Partner, Sidley Austin LLP, Washington, DC
PHARMA CONGRESS AFTERNOON TRACK SESSIONS

Afternoon Track I: Pharmacovigilance and Drug Safety Compliance Update

 TRACK
CO CHAIRS
David B. Chandler, Ph.D., DABT, Director of Outcomes and Analysis Corporate Compliance, Amgen, Thousand Oaks, CA (Co chair)
Meredith Manning, Esq., Partner, Hogan & Hartson, Washington, DC (Co chair)

1:15 pm Current Compliance Challenges
Robert F. Church, Esq., Partner, Hogan & Hartson, Former Executive Director, Global Research and Development Compliance Department, Amgen, Former Associate Chief Counsel for Drugs, Food and Drug Administration, Los Angeles, CA

1:45 pm Assessing Future Regulatory and Compliance Developments
Beverly H. Lorell, MD, Senior Medical and Policy Advisor, FDA/Healthcare Practice Group, King & Spalding, Former Vice President and Global Chief Medical, and Technology Officer, Guidant Corporation, Washington, DC

2:15 pm GAP Analysis: How we Get to Where we Want to Be
John P. Ford, Esq., Counsel, Sidley Austin LLP, Former Senior Democratic Counsel, Energy and Commerce Committee, United States House of Representatives, Washington, DC

2:45 pm REMS
Suzanne Barone, PhD, Consumer Safety Officer, Food and Drug Administration, Silver Spring, MD

3:15 pm Sentinel Program
Steen Ottosen, MD, Executive Director, Global Safety, Amgen, Thousand Oaks, CA

3:45 pm Break

Afternoon Track II: Working with Third Parties, Vendors and Strategic Partners

 TRACK
CO CHAIRS
David Davidovic, Senior Director, Business Practices, Genentech, San Francisco, CA (Co chair)
Paul J. Silver, Managing Director, Huron Consulting Group, Atlanta, GA (Co chair)

1:15 pm Current Compliance Challenges Involved in Working With Third Parties — What Things Should We Worry About?
David Davidovic, Senior Director, Business Practices, Genentech, San Francisco, CA
Paul J. Silver, Managing Director, Huron Consulting Group, Atlanta, GA

1:45 pm Due Diligence Monitoring and Auditing of Third Party Vendors
Diana Borges, Compliance Manager, Teva North America, North Wales, PA
Brian Dahl, Director of Compliance, Teva Pharmaceuticals, Kansas City, MO

2:45 pm Robust Agreements and Vendor Training: When, Where and How
Janis Crum, Esq., Associate Director of Auditing, Genentech, South San Francisco, CA
Mark DeWyngaert, PhD, Managing Director, Huron Consulting Group, New York, NY
Ned Kelly, MD, Vice President, Pharmacovigilance, Quintiles, Research Triangle Park, NC

3:45 pm Break

Afternoon Track III: Creating an Environment for Productive Post-Settlement Interactions with the Government: CIAs, DOJ Monitors and Disclosures

 TRACK
CO CHAIRS
Thomas A. Gregory, CPA, CFA, Principal, Ernst & Young LLP, Atlanta, GA (Co chair)
Michael Dusseau, Executive Director, Compliance Services, Global Compliance and Business Practices, Schering-Plough Corporation, Kenilworth, NJ (Co chair)

1:15 pm The Government Perspective
Thomas A. Gregory, CFA, MBA, Principal, Ernst & Young LLP, Atlanta, GA
Daniel R. Miller, Esq., Deputy Attorney General and Director, Medicaid Fraud Control Unit, Delaware Department of Justice, Vice President, National Association of Medicaid Fraud Control Units (NAMFCU), Wilmington, DE
Jeffrey M. Senger, Esq., Deputy Chief Counsel, Food and Drug Administration, Former Senior Counsel to the Associate Attorney General, US Department of Justice, Rockville, MD

1:45 pm The Industry Perspective
Thomas E. Costa, Esq., Vice President, US Pharmaceuticals Compliance & Ethics, Bristol-Myers Squibb, Princeton, NJ
Kathy DiGiorno, Vice President and Chief Ethics and Compliance Officer, Medtronic, Inc, Minneapolis, MN
Thomas A. Gregory, CFA, MBA, Principal, Ernst & Young LLP, Atlanta, GA

2:30 pm The Industry Perspective
Jacqueline K. Huber (Invited), Corporate Vice President and Chief Compliance Officer, Biomet, Inc, Warsaw, IN

2:45 pm Robust Agreements and Vendor Training: When, Where and How
Janis Crum, Esq., Associate Director of Auditing, Genentech, South San Francisco, CA
Mark DeWyngaert, PhD, Managing Director, Huron Consulting Group, New York, NY
Ned Kelly, MD, Vice President, Pharmacovigilance, Quintiles, Research Triangle Park, NC

3:45 pm Break
Afternoon Track IV: FCPA Compliance Update

1:15 pm Overview of the FCPA: Scope, Key Definitions, Exceptions and Affirmative Defenses, Books and Record Keeping Requirements, and Interaction with Anti-bribery Laws in Other Countries
Joseph B. Tompkins, Jr., Esq., Partner, Sidley Austin LLP, Former Deputy Chief, Fraud Section, Department of Justice, Washington, DC (Co chair)

1:45 pm Current Trends in Enforcement/Recent Cases: Industry Sweeps, Including Pharma and Medical Device Industries, Increased Extraterritorial Reach, Increased Collaboration Between DOJ and SEC, Imposition of Independent Monitors, Increased Focus on Fines, etc. for Individuals, not Just Companies, Discussion of Recent Enforcement Actions — Pleas, Sanctions Imposed, etc.
Stephen L. Braga, Esq., Partner, Ropes & Gray, Adjunct Professor, Georgetown University Law Center, Washington, DC

2:15 pm Implementing an Effective Anti-Corruption Compliance Program — Lessons Learned
Michael Bridwell, Global Manager, Compliance and Ethics Program Development, Eli Lilly and Company, Indianapolis, IN
John Kuckelman, Esq., Global Anti-Corruption and International Trade, Regulations Counsel, International Legal, Eli Lilly and Company, Indianapolis, IN

2:45 pm Issues in Conducting FCPA Investigations Outside the US and How to Deal with Them: Data Protection/Privacy Laws in Non-US Jurisdictions; Privilege Issues in Multi-national Investigations, Collecting, Reviewing and Retrieving Electronic and Hard-copy Documents; Issues in Interviewing Witnesses Outside the US, and Dealing with the DOJ and SEC while Conducting an Investigation
Sandee I. Priser, JD, CPA, Partner, Ernst & Young LLP, Chicago, IL
Leslie A. Shubert, Esq., Partner, Sidley Austin LLP, Washington, DC

3:15 pm The Importance of FCPA Due Diligence in International Mergers, Acquisitions and Joint Venture
Leslie A. Shubert, Esq., Partner, Sidley Austin LLP, Washington, DC
Joseph B. Tompkins, Jr., Esq., Partner, Sidley Austin LLP, Former Deputy Chief, Fraud Section, Department of Justice, Washington, DC

3:45 pm Break

Afternoon Track V: Interactive Domestic Case Studies Covering a Range of Sales & Marketing “Hot” Topics such as: Speaker Management Issues; In-Office Interactions; Conflicts of Interest with Customers; Firewall Issues Related to Marketing/Medical Vendors; and PhRMA Code Issues Pre- and Post- Implementation.

3:45 pm Break

AFTERNOON PLENARY SESSION

4:15 pm Introduction to Afternoon Plenary Session
Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)

4:30 pm How Government Uses Data in Analyzing Illegal Activities

5:00 pm Adjournment and Company Best Practice Policy and Procedure Poster Board and Exchange Reception
The Pharma Congress Wednesday Networking Reception will feature the exchange and presentation of company best practice policy and procedures at poster boards throughout the Pharma Congress Exhibit.
Margaret Feltz, Associate Director, Corporate Compliance, Purdue Pharma LP, Stamford, CT (Co chair)
Pharma Congress Agenda
Wednesday, October 29, 2008 • Day III

7:00 am  Registration Opens
Continental Breakfast in Exhibit Hall

8:00 am  Introduction to Day Three
Arjun Rajaratnam, Esq., Vice President &
Compliance Officer - US Pharmaceuticals,
GlaxoSmithKline, Research Triangle Park, NC
(Chair)

8:15 am  The Future of the Pharmaceutical
Sector in American Healthcare
Mark McClellan, MD, PhD (Invited), Director,
Engelberg Center for Health Care Reform,
Brookings Institution, Former CMS Administrator
and FDA Commissioner, Washington, DC

8:45 am  Blog Roundtable
Patrick Clinton, Editor-in-Chief, Pharmaceutical
Executive, Advanstar Communications,
New York, NY (Moderator)

9:30 am  PCF CIA Survey
John T. Bentivoglio, Esq., Partner, King & Spalding LLP;
Former Special Counsel for Healthcare Fraud and Chief
Privacy Officer, Department of Justice, Washington, DC

10:00 am  Break

10:30 am  A Dialogue on the Health Reform Visions
of the Presidential Candidates with
Particular Focus on Medical Innovation
and Pharmaceutical Research
Judith M. Feder, PhD (Invited), Advisor to the
Barack Obama Campaign, Former Staff Director,
US Bipartisan Commission on Comprehensive Health
Care, Former Principal Deputy Assistant Secretary,
Department of Health and Human Services,
Washington, DC
Jay Khosla, JD, MHA, Health Policy Advisor,
John McCain 2008, Former Health Counsel, Budget
Committee, United States Senate, Washington, DC
John K. Iglehart, Founding Editor, Health Affairs,
National Correspondent, New England Journal of
Medicine, Washington, DC

Noon  Congress Adjournment

Schedule at a Glance • Monday, October 27, 2008

8:00 am  PRECONFERENCE SYMPOSSIA
Preconference I: Pharmaceutical
Regulatory and Compliance Basics
Preconference II: State Marketing, Ethics and
Disclosure Laws and Federal Preemption
Preconference III: Auditing, Monitoring
and Effective Internal Investigations
Preconference IV: Dangerous Documents:
Finding Land Mines In Your FDA Records and Emails

Pharma Congress Agenda Day I • Perspectives on the Pharmaceutical Sector in Changing Times
1:00 pm  Welcome and Introduction
1:15 pm  Pharmaceutical Compliance: How Far We've Come and Where we Need to Go
2:00 pm  OIG Update
3:00 pm  Break
3:30 pm  DOJ Update
4:00 pm  Department of Justice Update
4:30 pm  The Newly Revised PhRMA Code
5:00 pm  Adjournment and Meet the Regulator Networking Reception

Pharma Congress Agenda Day II • Tuesday, October 28, 2008

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

MORNING PLENARY SESSION
8:00 am  Welcome and Introduction to Day II
8:15 am  PCF Pharmaceutical Compliance Professional and Legal Counsel Roundtable: Preparing for the Next Wave of Change
9:15 am  Transition Break
9:30 am  PHARMA CONGRESS MORNING TRACK SESSIONS

Morning Track I: Sales and Marketing Compliance Update
Morning Track II: Research, Development and Clinical Trials Compliance Update
Morning Track III: The “411” on Government Price Reporting . . .
Morning Track IV: Relationships with Healthcare Professionals Compliance Update
Morning Track V: Emerging Compliance Challenges
Morning Track VI: Interactive International Case Studies Covering a Range of Topics . . .

Noon  Proceed to Networking Luncheon • Special Box Lunch Report: New Theories of Prosecution Under False Claims Act
1:15 pm  PHARMA CONGRESS AFTERNOON TRACK SESSIONS

Afternoon Track I: Pharmacovigilance and Drug Safety Compliance Update
Afternoon Track II: Working with Third Parties, Vendors and Strategic Partners
Afternoon Track III: Creating an Environment for Productive Post-Settlement Interactions with the Government . . .
Afternoon Track IV: FCPA Compliance Update
Afternoon Track V: Interactive Domestic Case Studies Covering a Range of Sales & Marketing “Hot” Topics . . .

AFTERNOON PLENARY SESSION
4:15 pm  Introduction to Afternoon Plenary Session
4:30 pm  How Government Uses Data in Analyzing Illegal Activities
5:00 pm  Adjournment and Company Best Practice Policy and Procedure Poster Board and Exchange Reception

Pharma Congress Agenda Day III • Wednesday, October 29, 2008

7:00 am  Registration Opens; Continental Breakfast in Exhibit Hall
8:00 am  Introduction to Day Three
8:15 am  The Future of the Pharmaceutical Sector in American Healthcare
8:45 am  Blog Roundtable
9:30 am  PCF CIA Survey
10:00 am  Break
10:30 am  A Dialogue on the Health Reform Visions of the Presidential Candidates with Particular Focus on Medical Innovation and Pharmaceutical Research

Noon  Congress Adjournment
REGISTRATION FORM

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

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
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Preconference Symposia:
☐ $ 495
Monday, October 27, 2008, 8:00 am — Choose one only:
☐ Preconference I: Pharmaceutical Regulatory and Compliance Basics
☐ Preconference II: State Marketing, Ethics and Disclosure Laws and Federal Preemption
☐ Preconference III: Auditing, Monitoring and Effective Internal Investigations
☐ Preconference IV: Dangerous Documents: Finding Land Mines In Your FDA Records and Emails

Congress Sessions:
☐ Through Friday, September 19, 2008 $1,795*
☐ After Friday, September 19, 2008 $1,995

Group Rate:
For 3 or more registrants from the same institution, the registration fee is $1,595 (registration forms must be submitted simultaneously).
☐ Group rate, per person $1,595

Select Your Tracks:
Tuesday, October 28, 2008 — Select One Track per Time Slot:
9:30 am • Morning Tracks
☐ AM Track I ☐ AM Track II ☐ AM Track III ☐ AM Track IV ☐ AM Track V ☐ AM Track VI

1:15 pm • Afternoon Tracks
☐ PM Track I ☐ PM Track II ☐ PM Track III ☐ PM Track IV ☐ PM Track V

*This price reflects a discount for registration & payment received by Friday, Sept. 19, 2008.

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HOTEL INFORMATION/RESERVATIONS
Special group rates of $284.00/single and $309.00/double per night (plus tax) have been arranged for the dates of Sunday, October 26 – Wednesday, October 29, 2008. Please make reservations directly with the Hyatt Regency Washington On Capitol Hill and mention “Pharmaceutical Compliance Congress” to receive the group rate. Reservations will be accepted until Monday, September 29, 2008. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

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