THE TWELFTH ANNUAL Pharmacetical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING – EFFECTIVE KNOWLEDGE EXCHANGE

November 2–4, 2011
Mandarin Oriental • Washington, DC
www.PharmaCongress.com • 800-503-7419

Keynote Speakers:
- Ariel Kaminer, The Ethicist, New York Times Magazine
- John C. Lechleiter, PhD, Chairman, President and Chief Executive Officer, Eli Lilly and Company; Chairman-elect, PhRMA Board of Directors
- Richard M. Mullane (Colonel, USAF, Ret.), Former NASA Astronaut
- Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General
- Tony West, Esq., Head, Civil Division, US Department of Justice

Co chairs:
- Gary DelVecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company
- Margaret K. Feltz, Associate Director, Corporate Compliance, Purdue Pharma LP
- Kelly B. Freeman, PhD, Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company
- Michael L. Shaw, Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals

Featuring Preconferences:
- Compliance Basics
- Practical Approaches to Implementing an Aggregate Spend Program

Plenary Sessions:
- OIG Update
- DOJ Civil Division Update
- Coordinating Pharma Prosecutions
- FDA-DDMAC Update
- Pharma 2020
- Sunshine Act Regulations
- FCPA and UK Bribery Act Enforcement and Compliance Update
- Lessons of the Stevens Case
- Lessons of the Forrest and Purdue
- Best Practices to Avoid Individual Liability and Exclusion
- Compliance Professional Responsibilities in the Pharma, Biotech & Device Industries
- Board and Executive Responsibilities and Certifications

And the Following Tracks:
- Taking Your Compliance Program to a New Level
- Internal and External Investigations Update
- Fair Market Value Update
- FCPA and UK Bribery Act Compliance Update
- Compliance Lessons Learned from Medical Devices
- Advanced Issues in Auditing and Monitoring
- The Hottest Emerging Issues in Industry-HCP Relationships
- Government Payment and Price Reporting Update
- Research & Development and Clinical Trials
- Global Pharma and Device Compliance Issues
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. Please visit their website at www.pharmacomplianceforum.org.
**Wednesday, November 2, 2011**  
**Preconference Symposia** (Optional, choose one)

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am</td>
<td>Congress Registration</td>
</tr>
<tr>
<td>8:00 am</td>
<td>Preconferences Commence (Choose one)</td>
</tr>
</tbody>
</table>

**PRECONFERENCE I: COMPLIANCE BASICS**

8:00 am  Welcome and Introductions  
Kelly B. Freeman, PhD, Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN (Co chair)  
Sean P. Fahey, Esq., Partner, Pepper Hamilton LLP, Philadelphia, PA (Co chair)  

8:15 am  The Legal Framework: Laws and Regulations, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the Federal Sentencing Guidelines, and Important Settlements with the Government  
Sean P. Fahey, Esq., Partner, Pepper Hamilton LLP, Philadelphia, PA

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, Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN

**PRECONFERENCE II: PRACTICAL APPROACHES TO IMPLEMENTING AN AGGREGATE SPEND PROGRAM**

8:00 am Welcome and Introductions  
Eve M. Brunts, Esq., Partner, Ropes & Gray, Boston, MA (Co chair)  
Melanie Gross, JD, MPH, Corporate Counsel, Genentech, Inc., South San Francisco, CA (Co chair)  
Kelly N. "Nikki" Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC (Co chair)

8:30 am  PwC Benchmarking Survey on Aggregate Spend Programs  
David J. Wysocky, Director, Pharmaceutical and Life Sciences Practice, PricewaterhouseCoopers LLP, Florham Park, NJ

9:30 am Break

9:45 am  Roundtable on Getting Ready for Sunshine: Helping You Assess Readiness Across:  
- Business Policies and Procedures that Manage HCP Spend  
- Data Flow, Collection, Aggregation and Reporting  
- Information Systems to Support all Spend Activities  
- Anticipating and Managing External Reaction (e.g., HCPs, government, media, etc.) to Posted Data  
Melanie Gross, JD, MPH, Corporate Counsel, Genentech, Inc., South San Francisco, CA  
Timothy J. Nugent, CPA, CCEP, Managing Director, KPMG, LLP, Short Hills, NJ

**Wednesday, November 2, 2011**  
**Pharma Congress Agenda Day I • Opening Plenary Session—Government Enforcement**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00 pm</td>
<td>Welcome and Introduction</td>
</tr>
<tr>
<td>1:15 pm</td>
<td>Keynote</td>
</tr>
<tr>
<td>1:45 pm</td>
<td>Keynote: OIG Update</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>Keynote: DOJ Civil Division Update</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Break</td>
</tr>
<tr>
<td>3:30 pm</td>
<td>Coordinating Pharma Prosecutions</td>
</tr>
<tr>
<td>4:15 pm</td>
<td>Keynote: FDA-DDMAC Update</td>
</tr>
</tbody>
</table>

John Poulin, Director, Life Sciences Practice, Huron Consulting Group, New York, NY  
Laura Scarrino, Esq., Chief Legal Officer, Tercica, Inc., A Subsidiary of the Ipsen Group, Brisbane, CA  
Jack T. Tanselle, Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Chicago, IL  

11:45 am  Wrap-up  
Eve M. Brunts, Esq., Partner, Ropes & Gray, Boston, MA (Co chair)  
Melanie Gross, JD, MPH, Corporate Counsel, Genentech, Inc., South San Francisco, CA (Co chair)  
Kelly N. "Nikki" Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC (Co chair)

Noon Preconference Adjournment and Lunch on your Own

**Wednesday, November 2, 2011**  
**Pharma Congress Agenda Day I • Opening Plenary Session—Government Enforcement**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00 pm</td>
<td>Welcome and Introduction</td>
</tr>
<tr>
<td>1:15 pm</td>
<td>Keynote</td>
</tr>
<tr>
<td>1:45 pm</td>
<td>Keynote: OIG Update</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>Keynote: DOJ Civil Division Update</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Break</td>
</tr>
<tr>
<td>3:30 pm</td>
<td>Coordinating Pharma Prosecutions</td>
</tr>
<tr>
<td>4:15 pm</td>
<td>Keynote: FDA-DDMAC Update</td>
</tr>
</tbody>
</table>

John Poulin, Director, Life Sciences Practice, Huron Consulting Group, New York, NY  
Laura Scarrino, Esq., Chief Legal Officer, Tercica, Inc., A Subsidiary of the Ipsen Group, Brisbane, CA  
Jack T. Tanselle, Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Chicago, IL  

11:45 am  Wrap-up  
Eve M. Brunts, Esq., Partner, Ropes & Gray, Boston, MA (Co chair)  
Melanie Gross, JD, MPH, Corporate Counsel, Genentech, Inc., South San Francisco, CA (Co chair)  
Kelly N. "Nikki" Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC (Co chair)

Noon Preconference Adjournment and Lunch on your Own
Thursday, November 3, 2011
Pharma Congress Agenda Day II •
Morning Plenary Session
7:00 am Registration Opens: Continental Breakfast in Exhibit Hall
8:00 am Welcome and Introduction to Day II Morning
Gary DelVecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ (Co chair)
8:15 am The New SEC Whistleblower Office
Sean McKessy, Esq. (Invited), Whistleblower Office, Division of Enforcement, Securities and Exchange Commission, Washington, DC
8:45 am FCPA and UK Bribery Act Enforcement and Compliance Update
Charles E. Cain, Esq. (Invited) Assistant Director, FCPA Unit, Director of the Division of Enforcement, Securities and Exchange Commission, Washington, DC
Nathaniel Edmonds, Esq., Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC
Vivian Robinson, Esq., Partner, McGuireWoods; Former General Counsel of the UK Serious Fraud Office; Former Head, QEB Hollis Whiteman Chambers, Recorder of the Crown Court and Treasurer of Inner Temple, London, UK
Ted Acosta, Esq., Principal, Ernst & Young LLP; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY and Paris, France (Moderator)
9:30 am Personal Accountability and Individual Liability of In-house Counsel and Chief Compliance Officers and Exclusions from Federal Health Programs
Lessons of the Stevens Case
Colleen A. Conry, Esq., Partner and Co-Chair, Government Enforcement Practice Group, Ropes & Gray; Former Senior Litigation Counsel, Criminal Division, Fraud Section, US Department of Justice, Washington, DC
Lessons of the Forrest and Purdue
Paul E. Kalb, JD, MD, Partner and Co-Head, Global Life Sciences Practice, Sidley Austin LLP, Washington, DC
10:00 am Break

10:30 am Personal Accountability and Individual Liability of In-house Counsel and Chief Compliance Officers and Exclusions from Federal Health Programs
Best Practices to Avoid Individual Liability and Exclusion
Colleen A. Conry, Esq., Partner and Co-Chair, Government Enforcement Practice Group, Ropes & Gray; Former Senior Litigation Counsel, Criminal Division, Fraud Section, US Department of Justice, Washington, DC
Gary F. Giampetruzzi, Esq., Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY
Paul E. Kalb, JD, MD, Partner and Co-Head, Global Life Sciences Practice, Sidley Austin LLP, Washington, DC
Arjun Rajaratnam, Esq., Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC
Thomas M. Gallagher, Esq., Partner and Chair, White Collar and Corporate Investigations Practice Group, Pepper Hamilton LLP; Former Prosecutor, Criminal Division, US Attorney’s Office, Eastern District of Pennsylvania, Philadelphia, PA (Moderator)
11:15 am Compliance Professional Responsibilities in the Pharmaceutical, Biotech & Medical Device Industries
Christopher D. Zalesky, JD, CCEP, RAC, Vice President Global Policy and Guidance, Johnson & Johnson Health Care Compliance and Privacy, New Brunswick, NJ
11:45 am Board and Executive Responsibilities and Certifications
12:15 pm Networking Lunch

DAY II AFTERNOON TRACK SESSIONS I

TRACK I: Taking Your Compliance Program to a New Level: Building a Culture of Compliance; Compliance Program Branding; Making Policies and Procedures Relevant to Internal Constituencies; Envisioning the Compliance Professional of the Future; Recruitment and Retention
Timothy Ayers, Esq., Associate General Counsel, Executive Director of Compliance, Seattle Genetics, Bothell, WA (Co chair)
Elizabeth V. Jobes, Esq., Vice President and Chief Compliance Officer, Adolor; Former Assistant District Attorney, Philadelphia, PA, Exton, PA (Co chair)
1:15 pm PwC Annual Compliance Organization and Administration Survey
1:45 pm Responding to Health Reform: How Pharma and Device Manufacturers can Participate in Delivery System and Payment Reform—Strategic, Legal and Compliance Implications
Constance A. Wilkinson, Esq., Member, Epstein Becker & Green, PC, Washington, DC
2:15 pm Taking your Compliance Program to the Next Level: Building a Culture of Compliance; Compliance Program Branding: Making Policies and Procedures Relevant to Internal Constituencies; Envisioning the Compliance Professional of the Future; Recruitment and Retention
Lori Alarimo, Esq. (Invited), Vice President, Deputy Compliance Officer, Allergan; Former Assistant General Counsel, Pfizer, Irvine, CA
David Gaffin, Esq. (Invited), Deputy General Counsel and Senior Director Government Affairs, Alkermes, Boston, MA
Heather Reilly Powell, Esq., Director, Compliance Training and Reporting, Datich Sankyo, Inc.; Former Associate Director, Global Compliance, Cephalon, Inc., Parsippany, NJ
Christopher D. Zalesky, JD, CCEP, RAC, Vice President Global Policy and Guidance, Johnson & Johnson Health Care Compliance and Privacy, New Brunswick, NJ
Timothy Ayers, Esq., Associate General Counsel, Executive Director of Compliance, Seattle Genetics, Bothell, WA (Co chair)
Elizabeth V. Jobes, Esq., Vice President and Chief Compliance Officer, Adolor; Former Assistant District Attorney, Philadelphia, PA, Exton, PA (Co chair)

2:55 pm Ethical Challenges of Internal Investigations and the Representation of Individuals in Light of the Government’s New Focus on Individuals
Jonathan L. Diesenhaus, Esq., Partner, Hogan Lovells US LLP; Former Senior Trial Counsel, Civil Division of the US Department of Justice, Washington, DC

3:15 pm Break

TRACK II: Internal and External Investigations Update
Jonathan L. Diesenhaus, Esq., Partner, Hogan Lovells US LLP; Former Senior Trial Counsel, Civil Division of the US Department of Justice, Washington, DC (Co chair)
Constance A. Wilkinson, Esq., Partner, Epstein Becker & Green, Washington, DC (Co chair)

1:15 pm Defending Government Pharmaceutical/Device Investigations and Qui Tam Litigation
Mark A. Jensen, Esq., Partner, King & Spalding LLP, Washington, DC

1:40 pm Responding to State Attorneys General Investigations
Barry H. Boise, Esq., Partner, Pepper Hamilton LLP, Philadelphia, PA

2:05 pm Analyzing Data in Off Label and Other Cases—From Production to Damages
Thomas A. Gregory, CFA, MBA, Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP, Atlanta, GA
Kathleen Meriwether, Esq., Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA

2:30 pm Working with the Board of Directors in Responding to an Investigation
Constance A. Wilkinson, Esq., Partner, Epstein Becker & Green, Washington, DC

TRACK III: Fair Market Value Update
Eric Siegel, JD, MBA, Chief Compliance Officer, Incyte Corporation, Philadelphia, PA (Co chair)
Paul J. Silver, Managing Director and Practice Leader, Life Sciences Practice, Huron Consulting Group, Atlanta, GA (Co chair)

1:15 pm International FMV: Growing Trends
Mark A. DeWyngaert, PhD, Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY
Jeff Rosenbaum, Global Head, Ethics & Compliance, Novartis Oncology, Florham Park, NJ

1:45 pm Developing a Global FMV Methodology
Bridget Bourgeois, Partner, Ernst & Young LLC, Atlanta, GA

2:15 pm Fair Market Value and the Emerging Company
Eric Siegel, Esq., Chief Compliance Officer, Incyte Corporation, Philadelphia, PA

2:45 pm Operationalizing Fair Market Value
Dieter Peise, Associate Director Ethics & Compliance, Novartis, New York, NY

3:15 pm Break

TRACK IV: FCPA and UK Bribery Act Compliance Update
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)
Gary F. Giampetruzzi, Esq., Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY (Co chair)

1:15 pm Focus on China: Assessing Your FCPA Risk Exposure in R&D and Manufacturing Operations, and Bracing for a New Era of Local Enforcement
Hui Chen, Esq., Senior Corporate Counsel, Asia-Pacific Regional Lead, International Compliance Investigations, Pfizer Inc., New York, NY
Peter S. Spivack, Esq., Partner, and Co-Leader, Investigations, White Collar and Fraud Practice Area, Hogan Lovells US LLP, Washington, DC

2:00 pm Maintaining Research Integrity While Minimizing Bribery Risks in Foreign Clinical Trials: Effective Due Diligence and Oversight Strategies for your Doctors, CROs, and HCPs
2:45 pm  UK Bribery Act Update
Vivian Robinson, Esq., Partner, McGuireWoods; Former General Counsel of the UK Serious Fraud Office; Former Head, QEB Hollis Whiteman Chambers; Recorder of the Crown Court and Treasurer of Inner Temple, London, UK

3:15 pm  Break

TRACK V: Compliance Lessons Learned from Medical Devices
Sujata T. Dayal, Esq., Corporate Vice President and Chief Compliance Officer, Biomet; Former Counsel, Domestic Legal Operations, Abbott Laboratories; Former Member, PCF Executive Committee, Warsaw, IN (Co chair)
Arjun Rajaratnam, Esq., Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC (Co chair)

1:15 pm  Compliance Lessons Learned from Medical Devices:
• Building Global Compliance Organizations
• Operating Under Deferred Prosecution Agreements (DPAs)
• Collaborating with HCPs—Physician Inventors
• Managing Distributors and Sales Agents
• Sales Reps in the Operating Room
• Emerging GMP/QSR Issues
• Global Monitoring Programs
Scott Bass, Esq., Partner and Co-Head, Global Life Sciences Practice, Sidley Austin LLP, Washington, DC
Sujata T. Dayal, Esq., Corporate Vice President and Chief Compliance Officer, Biomet; Former Counsel, Domestic Legal Operations, Abbott Laboratories; Former Member, PCF Executive Committee, Warsaw, IN
Stephen J. Immelt, Esq., Partner, Hogan Lovells; Former Assistant U.S. Attorney, District of Maryland, US Department of Justice, Baltimore, MD
Gregory H. Levine, Esq., Partner and Co chair, Life Sciences Practice Group, Ropes & Gray, Washington, DC
David E. Matyas, Esq., Member, Epstein Becker & Green, Washington, DC
Arjun Rajaratnam, Esq., Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Durham, NC
Tom Schumacher, Esq., Vice President, Chief Ethics and Compliance Officer, Medtronic, Minneapolis, MN

3:15 pm  Break

DAY II AFTERNOON TRACK SESSIONS II

TRACK VI: Advanced Issues in Auditing and Monitoring
Joseph J. Skupen, CPA, Senior Director, US Corporate Compliance, sanofi-aventis US, Bridgewater, NJ (Co chair)
Jack T. Tanselle, Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Chicago, IL (Co chair)

3:45 pm  Monitoring Medical Affairs (MSLs, IIS, Medical Information)
Eileen Erdos, Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP, Chicago, IL
Kathleen Meriwether, Esq., Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA

4:15 pm  Using Data and Analysis to Advance Your Monitoring Efforts
Manny Tzavalakis, Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY
Suj Patel, Director, Life Sciences Practice, Huron Consulting Group, New York, NY

4:45 pm  Field Force Monitoring
Dennis K. Barnes, JD, CPA, Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Chicago, IL

5:15 pm  Use of Outside Vendors in Monitoring Compliance Programs
Fred Eaton, MBA, Partner and Chair, Market Value Practice, Polaris Management Partners, New York, NY

5:45 pm  Adjournment

TRACK VII: Healthcare Professionals Compliance Update—the Hottest Emerging Issues in Industry/HCP Relationships
Maureen Doyle-Scharff, MBA, FACME, Senior Director, Team Lead, Medical Education Group, Pfizer, Columbus, OH (Co chair)
Seth H. Lundy, Esq., Partner, King & Spalding LLP, Washington, DC (Co chair)

3:45 pm  Challenges Implementing Recent CIA Requirements — Lessons Learned
Seth H. Lundy, Esq., Partner, King & Spalding LLP, Washington, DC
Daniel Moynihan, Esq., Chief Compliance Officer and Former Associate General Counsel, EMD Serono, Rockland, MA
Scott A. Memott, Esq., Partner, Morgan Lewis; Former Trial Attorney, Civil Division, US Department of Justice; Former Special Assistant US Attorney in Norfolk, Virginia, Washington, DC
Tracy Mastro, MBA, Director, Life Sciences Practice, Huron Consulting Group, Washington, DC

4:45 pm  Risk Stratification and Monitoring of Industry-funded Third Party Educational Activities, Grants and Charitable Contributions
Maureen Doyle-Scharff, MBA, FACME, Senior Director, Team Lead, Medical Education Group, Pfizer, Columbus, OH
Edmund Greenidge, Esq., Director, Grants and Charitable Contributions, Janssen Biotech, Inc., Philadelphia, PA
Hilary J. Schmidt, PhD, Vice President Independent Grants and Learning, sanofi-aventis US, Bridgewater, NJ

5:45 pm  Adjournment
TRACK VIII: Government Payment and Price Reporting Update
William A. Sarraille, Esq., Partner, Sidley Austin LLP, Washington, DC (Co chair)
Jerry Wolf, Director, Healthcare Dispute, Compliance and Investigation Practice, Navigant Consulting, Inc., Philadelphia, PA (Co chair)
3:45 pm Government Price Reporting Update
Jeffrey L. Handwerker, Esq., Partner, Arnold & Porter, Washington, DC
4:15 pm Quick Diagnostics for the Compliance Officer: Process and System
Susan Dunne, Director, Life Sciences Practice, Huron Consulting Group, Washington, DC
Mark Linver, Managing Director, Life Sciences Practice, Huron Consulting Group, New York, NY
5:00 pm 340B Expansion and Diversion issues
Commander Krista Pedley, PharmD, MS, Director, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), Washington, DC
William A. Sarraille, Esq., Partner, Sidley Austin LLP, Washington, DC
5:45 pm Adjournment

TRACK IX: Research & Development and Clinical Trials
Kelly B. Freeman, PhD, Ethics and Compliance Officer, Eli Lilly and Company; Executive Committee Member, Pharmaceutical Compliance Forum, Indianapolis, IN (Co chair)
Daniel A. Krakov, Esq., Partner and Chair, FDA and Healthcare Practice, Arnold & Porter LLC, Washington, DC (Co chair)
3:45 pm Updating the Common Rule Governing Human Subjects Research Protections
Jerry A. Menikoff, MD, JD, Director, Office for Human Research Protections, Office of Public Health and Science, US Department of Health and Human Services; Former Director, Office of Human Subjects Research, National Institutes of Health, Rockville, MD
4:15 pm Risk Management in Clinical Development
Jeffrey S. Kasher, PhD, Vice President Global Clinical Development, Eli Lilly and Company, Indianapolis, IN
Andy Lee, Senior Vice President, Head Global Clinical Operations, Genzyme, Boston, MA
Winifred (Ann) Meeker-O’Connell, MS, Acting Associate Director of Risk Science, Intelligence and Prioritization, Office of Scientific Investigation (OSI), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Silver Spring, MD
Briggs Morrison, MD, Senior Vice President, Pfizer, New York, NY
5:15 pm Mini Summit Faculty Discussion
Panel: Maintaining Compliance and Quality with Increasing Outsourcing to Contract Research Organizations
5:45 pm Adjournment

Friday, November 4, 2011
Pharma Congress: Agenda Day III
Closing Plenary Session—Policy and Ethics
8:00 am Introduction to Day Three
Michael L. Shaw, Esq., Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, Office of Inspector General, Philadelphia, PA (Co chair)
8:15 am Panel: OIG Monitors of CIAs and Independent Review Organizations (IROs) for CIAs and FCPA Settlements
Office of Inspector General (Invited), US Department of Health and Human Services, Washington, DC
Jayson Dukes, CPA, Senior Managing Director, FTI Consulting, New York, NY
Thomas A. Gregory, CFA, MBA, Principal, Ernst & Young LLP, Atlanta, GA (Moderator)
9:00 am Panel: Interfacing between Third Party Vendors and Client Companies — Compliance Best Practices
Emma Boyev, Director Regulatory Compliance, Commercial Enterprise Office, Quintiles, Parsippany, NJ
William E. Buzzeo, MS, Vice President and General Manager, Compliance Solutions Division, Cegedim Relationship Management, Richmond, VA
2011 PCF Pharma Congress Planning Committee:
Ted Acosta, Esq., Principal, Ernst & Young LLP
Timothy Ayers, Esq., Associate General Counsel, Executive Director of Compliance, Seattle Genetics
Scott Bass, Esq., Partner, Sidley Austin LLP
John T. Bentivoglio, Esq., Partner, Skadden Arps LLP
Colleen Conry, Esq., Partner, Ropes & Gray
Sujiata T. Dayal, Corporate Vice President and Chief Compliance Officer, Global Operations, Biomet, Inc.
Thomas M. Gallagher, Esq., Partner and Chair, White Collar and Corporate Investigations Practice Group, Pepper Hamilton LLP
Gary F. Giampetruzzi, Esq., Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc.
Wendy C. Goldstein, Esq., Partner, Epstein Becker & Green
Alessandra N. Hawthorne, Vice President, Chief Ethics and Compliance Officer, Boehringer Ingelheim USA, Inc.
Elizabeth V. Jobes, Esq., Vice President and Chief Compliance Officer, Adolor
Daniel Kracov, Esq., Partner, Arnold & Porter
Jonathan Kellerman, Partner, Global Pharmaceutical Advisory Services Group, PricewaterhouseCoopers LLP
Marie L. Martino, US Compliance Officer, AstraZeneca Pharmaceuticals LP
Maxine Nogard, Senior Director, Global Corporate Compliance, Biogen Idec, Inc.
Lawrence P. Platkin, Vice President and Compliance Officer, Bayer Healthcare LLC
Arjun Rajaratnam, Chief Compliance Officer, Smith & Nephew
Kelly N. “Nikki” Reeves, MPA, JD, Partner, King & Spalding LLP
Susan Romanus, Vice President, Chief Ethics & Compliance Officer, Daiichi Sankyo
Jeffrey Rosenbaum, Global Head, Ethics & Compliance, Novartis Oncology
Karen Patruno Sheehy, Esq., Vice President, US Corporate Compliance Officer, sanofi-aventis
Eric Siegel, Esq., Chief Compliance Officer, Incyte Corporation
Paul J. Silver, Managing Director and Practice Leader, Huron Consulting Group
Jack T. Tanselle, Director, Navigant Consulting, Inc.
Caroline West, Esq., Senior Vice President, Chief Compliance and Risk Officer, Shire Pharmaceuticals, Inc.
Ronald L. Wisor, Jr., Esq., Partner, Hogan Lovells US LLP
Christopher D. Zalesky, Executive Director World Wide Office of Health Care Compliance & Privacy, Johnson & Johnson
Richard L. Zimmerman, Partner, Forensic Advisory Services, KPMG LLP

Alexis Stroud, MBA, CQA, Director, Quality and Compliance, QPharma, Inc., New York, NY
David Young, Senior Director, Commercial Compliance, Enterprise Compliance Office, Quintiles, Atlanta, GA
Marc L. Miller, CPA, CFF, Partner, Forensic Practice, KPMG, New York, NY (Moderator)

9:45 am Keynote: Ethics and Contemporary Society

10:15 am Break

10:30 am Reflections on My Transition from Government Service to Private Practice
Michael K. Loucks, Esq., Partner, Skadden Arps LLP; Former First Assistant US Attorney, U.S. Attorney’s Office for the District of Massachusetts, Washington, DC

11:00 am Creating a Culture of Compliance and Transparency: Lessons from the Challenger Disaster
Richard M. Mullane (Colonel, USAF, Ret.), Former NASA Astronaut; Recipient, Air Force Distinguished Flying Cross, Legion of Merit and the NASA Space Flight Medal, Albuquerque, NM

11:30 am Facilitating Disclosure and Prohibiting Retaliation
Michael L. Koon, Esq., Partner, Shook Hardy, Washington, DC
Shelley R. Slade, Esq., Whistleblower Attorney, Partner, Vogel, Slade & Goldstein; Former Senior Counsel, Health Care Fraud, Civil Division, US Department of Justice, Washington, DC
Michael L. Shaw, Esq., Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, Office of Inspector General, Philadelphia, PA (Moderator)

12:15 pm Adjournment

EXHIBIT AND SPONSORSHIP OPPORTUNITIES
Take advantage of this unique opportunity to expand your reach! The Congress is attended by highly influential and experienced professionals. Sponsorship offers you strategic positioning as an industry leader. For more information call Justin Sorensen at 206-452-0609.

CONTINUING EDUCATION UNITS (CEUs)
The Congress does not offer pre-approved Continuing Education Credits (CEUs) directly. However, attendees can request a Certificate of Attendance which they can file with appropriate entities for credit.
THE TWELFTH ANNUAL PHARMACEUTICAL CONGRESS
REGISTRATION FORM

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

FAX: 206-319-5303 (include credit card information with registration)
MAIL: Conference Office, 22529 39th Ave SE, Bothell, WA 98021

FOR REGISTRATION QUESTIONS:
PHONE: Toll free 800-503-7419 (Continental U.S., Alaska, Hawaii and Canada only) or 206-452-5528
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
ADDRESS
CITY/STATE/ZIP
TELEPHONE
FAX
E-MAIL

— Choose one only:
○ Special needs
(dietary or physical):

PRECONFERENCE SYMPOSIA:
Preconference Symposia: $495

Wednesday, November 2, 2011 — Choose one only:
○ Preconference I: Compliance Basics
○ Preconference II: Practical Approaches to Implementing an Aggregate Spend Program

STANDARD RATE FOR CONFERENCE ONLY:
○ Through Friday, September 9, 2011* $1,595
○ Through Friday, October 7, 2011** $1,795
○ After Friday, October 7, 2011 $1,995

PCF RATE FOR CONFERENCE ONLY:
○ PCF Member Rate*** $1,495

GROUP RATE:
For 3 or more registrants from the same institution, the registration fee is $1,495 (registration forms must be submitted simultaneously).

Select Your Track — Choose one only:

DAY II AFTERNOON TRACK SESSIONS I
○ Track I: Taking Your Compliance Program to a New Level
○ Track II: Internal and External Investigations Update
○ Track III: Fair Market Value Update
○ Track IV: FCWA and UK Bribery Act Compliance Update
○ Track V: Compliance Lessons Learned from Medical Devices

DAY II AFTERNOON TRACK SESSIONS II
○ Track VI: Advanced Issues in Auditing and Monitoring
○ Track VII: The Hottest Emerging Issues in Industry/HCP Relationships
○ Track VIII: Government Payment and Price Reporting Update
○ Track IX: Research & Development and Clinical Trials
○ Track X: Global Pharma and Device Compliance Issues

PHARMA CONGRESS MULTIMEDA****
To get this discounted price you must purchase MEDIA WITH your registration. Conference Audio/Video and PowerPoint on Flash Drive ($99 + $15 shipping) $ 114

REGISTRATION BINDING AGREEMENT
Registration (whether online or by this form) constitutes a contract and all of these terms and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit/debit card dispute. There will be no refunds for “no-shows” or cancellations.

TOTAL FOR ALL OPTIONS: $_______