THE FIFTEENTH ANNUAL

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Transformational Learning - Effective Knowledge Exchange

GHC LIFE SCIENCES
Global Health Care, LLC

CO CHAIRS:

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company*

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company*

Margaret K. Feltz, Esq., *Executive Director, Corporate Compliance, Purdue Pharma LP*

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc.*

KEYNOTE SPEAKERS:

Thomas W. Abrams, RPh, MBA, *Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration*

CMS.gov **Douglas Brown,** *Deputy Director, Data Sharing & Partnership Group, Center for Program Integrity, Centers for Medicare and Medicaid Services, US Department of Health and Human Services*

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

MEDIA PARTNER: Policy and Medicine — Supporting Innovation Through Collaboration

CONTINUING EDUCATION CREDITS:

Accountants: Approved for up to 17.5 NASBA CPE credits

Compliance Professionals: The Congress is currently pending approval to offer Compliance Certification Board CCB Credits.

Attorneys: The Congress is currently pending approval to offer California and Pennsylvania MCLE Credit.

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www.PharmaCongress.com

Onsite:

November 3 – 5, 2014

Washington, DC

Hyatt Regency on Capitol Hill

SPONSOR:

PCF THE PHARMACEUTICAL COMPLIANCE FORUM

SPECIAL PCF REGISTRATION DISCOUNTS — See page 11.

FEATURING THE FOLLOWING CLOSED SESSIONS ON DAY III:

INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

and

INDUSTRY CONSULTANT/ LEGAL COUNSEL COMPLIANCE BEST PRACTICES THINK TANK

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See page 2

ABOUT THE CONGRESS SPONSOR

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. PCF also sponsors a three-day compliance congress each Fall. For membership information, contact Kelly Freeman via email at **kbfreeman@lilly.com**. Please visit their website at **www.PharmaComplianceForum.org**.

2014 PHARMA CONGRESS PLANNING COMMITTEE

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb, Plainsboro, NJ (Co-chair)*

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

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN (Co-chair)*

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc., Philadelphia, PA (Co-chair)*

John T. Bentivoglio, Esq., *Partner, Skadden Arps LLP, Washington, DC*

Mary Bradley, Pharm.D, *Healthcare Compliance Officer, Johnson & Johnson, Philadelphia, PA*

Regina Gore Cavaliere, Esq., *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Princeton, NJ*

Gary F. Giampetruzzi, Esq., *Partner, Paul Hastings, New York, NY*

Alessandra Hawthorne, Esq., *Vice President, Chief Ethics and Compliance Officer, Boehringer-Ingelheim Pharmaceuticals, Ridgefield, CT*

Tanya Ivanov, Esq., *Compliance Officer, Corporate Counsel, XenoPort, Inc., Mountain View, CA*

Jeffrey S. Klimaski, MBA, CPA, *Vice President, Corporate Ethics, BTG International Inc., Philadelphia. PA*

Terri Ledva, *Chief Compliance Officer, Iroko Pharmaceuticals, Philadelphia, PA*

Seth H. Lundy, Esq. *Partner and Deputy Chair, FDA & Life Sciences Practice Group, King & Spalding, Washington, DC*

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

Maxine Nogard, *Senior Director, Global Corporate Compliance, Biogen Idec, Inc., Weston, MA*

John Patrick Oroho, Esq., *Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ*

Lori (Van Duyn) Queisser, *President, Queisser & Associates; Former Senior Vice President, Global Compliance and Business Practices, Schering-Plough; Former Vice President and Chief Compliance Officer, Eli Lilly and Company, Indianapolis, IN*

Jeffrey Rosenbaum, MBA, *Vice President, Chief Compliance Officer, Vertex Pharmaceuticals, Boston, MA*

Glenna Shen, Esq., *Head of Compliance, Onyx Pharmaceuticals, Los Angeles, CA*

Yuet-Ming Tham, Esq., *Partner, Sidley Austin LLP, Hong Kong*

AGENDA AT A GLANCE

DAY I: Monday, November 3, 2014:

MORNING - PRECONFERENCES:
- I: Advanced Issues in Domestic and Global Transparency
- II: Innovations in Auditing and Monitoring
- III: Advanced Issues and Best Practices in Investigations
- IV: Global Compliance Issues and Programs

AFTERNOON - OPENING PLENARY SESSION:
- OIG Update
- DOJ Update
- FDA-OPDP Update
- Compliance Officer Roundtable

NETWORKING RECEPTION

Day II: Tuesday, November 4, 2014:

MORNING - PLENARY SESSION:
- Compliance Department - C-suite Collaboration
- Qui Tam Panel
- Off-Label Communications and the Constitution

MORNING - MINI SUMMIT BLOCK A:
- I: Compliance Risk Assessments
- II: Advanced Issues in Monitoring
- III: Anti-corruption Update
- IV: Post-CIA Compliance
- V: Pharma Privacy and Security Update/ Compliance Education

NETWORKING LUNCHEON

AFTERNOON - MINI SUMMIT BLOCK B:
- VI: Compliance Considerations in Patient Support Programs
- VII: Compliance Issues Raised by M&A and Alliances
- VIII: Communications and Training
- IX: Compliance in Medical Affairs
- X: Government Pricing and Contracting

AFTERNOON - PLENARY SESSION: Transparency Update: Status of Sunshine Act Compliance

Day III: Wednesday, November 5, 2014:

MORNING CLOSED SESSIONS:
- Industry-Only Compliance Best Practices Think Tank
- Industry Consultant/Legal Counsel Best Practices Think Tank

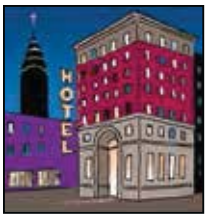
NOON: ADJOURNMENT

PARTICIPATION OPTIONS

TRADITIONAL ONSITE ATTENDANCE

Simply register, travel to the conference city and attend in person.

PROS: subject matter immersion; professional networking opportunities; faculty interaction.



Onsite

LIVE AND ARCHIVED INTERNET ATTENDANCE

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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

MONDAY, NOVEMBER 3, 2014

PRECONFERENCE SYMPOSIA

(Optional; Requires separate registration; Choose only one)

7:30 am **Congress Registration Opens**

Preconference I: Advanced Issues in Domestic and Global Transparency: Aggregate Spend, Disclosure, Sunshine Act, and R&D and Medical Affairs Transparency

8:30 am **Welcome and Overview**

John Patrick Oroho, Esq., *Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ (Moderator)*

Kelly N. "Nikki" Reeves, MPA, JD, *Partner, King & Spalding LLP; Legal Counsel, Ad Hoc Sunshine and State Law Compliance Group, Washington, DC (Moderator)*

9:15 am **Domestic Commercial Transparency: Disclosure, Aggregate Spend and Sunshine**

Kate Farrington, *Associate Director, Aggregate Spend, Forest Laboratories, New York, NY*

Christine Mikail, Esq., *Senior Vice President and General Counsel, NPS Pharmaceutical; Former Executive Vice President and Chief Compliance Officer, Dendreon, New York, NY*

9:45 am **Global Transparency**

Anthony Brennan, *Senior Director, HCC Governance, Metrics and Reporting, Johnson & Johnson, New York, NY*

Katrina Cahill, *Global Transparency Lead, Biogen Idec, Cambridge, MA*

David Wysocky, MBA, *Partner, PwC, New York, NY*

10:30 am **Break**

10:45 am **Global Transparency** *(Continued)*

11:30 am **R&D and Medical Affairs Transparency**

Karen D. Green, *R&D Health Care Compliance Officer, Pharmaceuticals Group, Johnson & Johnson, Titusville NJ*

Seth Whitelaw, JD, LLM, SJD, *Director, Life Sciences Regulatory Compliance Practice, Deloitte & Touche LLP; Former R&D Compliance Officer, GlaxoSmithKline; Former Legal Compliance Officer, SmithKline Beecham, Philadelphia, PA*

Mary Bradley, PharmD, *Healthcare Compliance Officer, Johnson & Johnson, Philadelphia, PA (Moderator)*

Noon **Preconference Adjournment; Lunch on your Own**

Preconference II: Innovations in Auditing and Monitoring

- **The Use of Risk Assessments to Guide Audit Planning and Ensuring Alignment with the Business**
- **Compliance Auditing Best Practice**
  - Drivers for Continued Focus on Compliance Auditing — Data Collection, Analysis and Reporting, etc.
  - Compliance Audit Focus Areas — Where are We Seeing the Highest Risks?
  - Strategies for Conducting Effective Risk-Based Control Audits
  - Legal Considerations — When Should an Audit be Privileged, if Ever?
- **Compliance Monitoring Best Practices**
  - Drivers for Continued Focus on Compliance Monitoring — CIA's, Commercial, R&D, etc.
  - Types of Monitoring — Physical, Electronic, Risk-Based Targeting and Scoring Process
  - Strategies for Identifying Trends in Monitoring Results
- **Maintaining Appropriate Stakeholder Awareness of Compliance Risk through Effective Reporting**
- **Panel/Audience Discussion on Different Approaches, Perspectives and Practices**
- **A Look to the Future: What's Needed, What's Wanted, and What Do We Need to Get There in the Next 2-5 Years?**

8:30 am **Welcome and Introduction**

BJ D'Avella, MBA, *Director, Huron Consulting Group, New York, NY*

Eve Costopoulos, *Vice President, Chief Ethics and Compliance Officer, Eisai Inc., Woodcliff Lake, NJ*

Erik Eglite, MBA, JD, DPM, *Vice President, Chief Compliance Officer and Corporate Counsel, Lundbeck Pharmaceuticals, Chicago, IL*

Dan Dalton, MBA, JD, *Senior Vice President, Chief Compliance Officer, Salix Pharmaceuticals, Raleigh, NC*

Darren R. Jones, *Director, Polaris, New York, NY*

Jeffrey Klimaski, *Vice President, Corporate Ethics and Compliance Officer, BTG International Inc., Philadelphia, PA*

Paul J. Silver, *Practice Leader and Managing Director, Huron Consulting Group, Atlanta, GA*

L. Stephan Vincze, LD, LLM, MBA, *Partner, Polaris; Former Senior Vice President, Chief Compliance Officer, Warner Chilcott; Former Vice President, Ethics and Compliance Officer/Privacy Officer, TAP Pharmaceutical Products Inc., Boston, MA (Moderator)*

Noon **Preconference Adjournment; Lunch on your Own**

Preconferences Continued on page 4

HOTEL INFORMATION/RESERVATIONS

The Hyatt Regency Washington on Capitol Hill is the official hotel for the **FIFTEENTH PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS.** A special group rate of $269.00 single/double per night (plus tax) has been arranged for Congress Attendees.

To make your hotel reservations online please go to www.PharmaCongress.com and click on the Travel/Hotel tab.

You may also make a reservation by calling Central Reservations toll free at **1-888-421-1442**. Please refer to **Pharma Congress** in order to obtain the group rate.

Reservations at the group rate will be accepted until the cut-off date of **Friday, October 10, 2014**. After this, reservations will be accepted on a space-available basis at the prevailing rate.

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MONDAY, NOVEMBER 3, 2014 *Preconferences, Continued from page 3*

Preconference III: Advanced Issues and Best Practices in Investigations

- **Internal Investigations**
  - Best Practices in Conducting Internal Investigations
  - Issues Related to Voluntary Disclosure
  - Attorney-Client Privilege
  - How to Conduct Internal Investigation Cross Examinations
  - Coordination with HR, Legal and Business
- **Responding to Government Investigations**
  - Best Practices in Responding to Government Investigations
  - Search Warrant
  - Grand Jury Subpoena

8:30 am **Welcome and Introduction**

Sarah K. diFrancesca, Esq., *Associate, Health Care and Life Sciences Regulatory Group, Cooley, LLP, New York, NY*

Diane DeLoria, CCEP, CFA, *Director, Health Care Compliance Investigations, Pharmaceuticals Group, Johnson & Johnson, Titusville NJ*

Gary F. Giampetruzzi, Esq., *Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY*

Elizabeth J. Gorman, Esq., *Vice President, Legal Commercial, Acorda Therapeutics, Inc., Ardsley, NY*

Liz Lewis, Esq., *Chief Counsel and Chief Compliance Officer and Head, Patient Advocacy, Takeda Pharmaceuticals International Co/Millennium: The Takeda Oncology Company, Boston, MA*

Michael K. Loucks, Esq., *Partner, Skadden Arps LLP; Former Acting United States Attorney, US Attorney's Office for the District of Massachusetts, Washington, DC (Moderator)*

Noon **Preconference Adjournment; Lunch on your Own**

Preconference IV: Global Compliance Issues and Programs

- **Implementing a Global Compliance Program: Practical Operational Challenges and Issues**
- **Sponsorship of HCPs: Understanding the New Landscape**
- **Negotiating, Managing, Auditing and Monitoring Third Party Relationships**
- **Global HCP/KOL Engagement Management**
- **Developing Effective Strategies for Working with the Business**
- **Medical/Commercial Boundaries in the Global Context**

8:30 am **Welcome and Introduction**

Yogesh Bahl, CPA, MBA, *Managing Director, AlixPartners, New York, NY*

Rachel Batykefer, CCEP, *Associate Director, Compliance, Teva Pharmaceuticals; Former Manager, Compliance Education, Tyco International, Philadelphia, PA*

Michael D. Bell, Esq., *President, R-Squared, Princeton, NJ*

Paul Curtin, Esq., *Compliance Officer - Global Research and Development, Actavis; Former Head of Compliance - Ex-US, Forest Laboratories, New York, NY*

David Hodgson, CPA, *Partner, Deloitte & Touche LLP, New York, NY*

Kirt Kraeuter, MGA, *Head of Compliance, European Markets, Australia/New Zealand, and Canada, Bristol-Myers Squibb, Philadelphia, PA*

Keith M. Korenchuk, JD, MPH, *Partner, Arnold & Porter LLP, Washington, DC (Moderator)*

Noon **Preconference Adjournment; Lunch on your Own**

MONDAY, NOVEMBER 3, 2014

PHARMA CONGRESS: AGENDA DAY I













Compliance Officer Roundtable and Government Enforcement

1:00 pm **Welcome and Introduction**

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ (Co-chair)*

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

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN (Co-chair)*

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc., Philadelphia, PA (Co-chair)*

1:30 pm **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*

2:15 pm **US DOJ Update**

Faculty to be announced

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-moderator)*

Michael K. Loucks, Esq., *Partner, Skadden Arps LLP; Former Acting United States Attorney, US Attorney's Office for the District of Massachusetts, Washington, DC (Co-moderator)*

3:00 pm **FDA/OPDP Update**

Thomas W. Abrams, RPh, MBA, *Director, Division of Drug Marketing, Advertising, and Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Silver Spring, MD*

3:30 pm **Break**

4:00 pm **Compliance Officer Roundtable**

Regina Gore Cavaliere, Esq., *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Princeton, NJ*

Sujata Dayal, *Vice President Health Care Compliance and Privacy, Pharmaceuticals, Johnson & Johnson; Former Global Chief Compliance Officer and Corporate Vice President, Biomet, Inc.; Former Member, PCF Executive Committee, Chicago, IL*

Laurie D'Alessio, *Vice President, Global Compliance Organization, Merck & Co., Inc., Whitehouse Station, NJ*

Michael L. Shaw, Esq., *Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services; Former Member, PCF Executive Committee, Philadelphia, PA*

Kris Curry, *Principal, Fraud Investigation and Dispute Services, Ernst & Young LLP; Former Vice President, Health Care Compliance, Pharmaceuticals Group, Johnson & Johnson, Philadelphia, PA (Moderator)*

5:00 pm **ADJOURNMENT AND NETWORKING RECEPTION**

TUESDAY, NOVEMBER 4, 2014

PHARMA CONGRESS: AGENDA DAY II

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

MORNING PLENARY SESSION

8:00 am **Welcome and Introductions**

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc., Philadelphia, PA (Co-chair)*

8:15 am **Best Practices in Compliance Department – C-suite Collaboration**

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN*

Judy Lynch, *Senior Vice President, Employee Services, GlaxoSmithKline, Drexel Hill, PA*

Paula Taylor Whitfield, Esq., *Senior Director, Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN*

Other faculty to be announced.

Brian Riewerts, *Principal, Global Governance, Risk and Compliance Leader, Pharmaceutical and Life Sciences Advisory, PwC, Baltimore, MD (Moderator)*

9:15 am **Qui Tam Panel**

Jamie M. Bennett, Esq., *Partner, Ashcraft & Gerel, LLP; Former Assistant United States Attorney, District of Maryland, Landover, MD*

Suzanne E. Durell, Esq., *Partner, Durell Law Office; Former Deputy Associate Attorney General, United States Justice Department, Boston, MA*

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

Virginia "Ginny" A. Gibson, Esq., *Partner, Hogan Lovells LLP; Former Executive Assistant U.S. Attorney, Eastern District of Pennsylvania, Philadelphia, PA (Moderator)*

10:00 am **Off-Label Communications and the Constitution: Will FDA Finally Change its Policies?**

Paul E. Kalb, JD, MD, *Partner and Global Coordinator, Life Sciences Practice, Sidley Austin LLP, Washington, DC*

10:30 am **Break**

11:00 am **PHARMA CONGRESS MINI SUMMITS**

MINI SUMMITS BLOCK A

Mini Summit I: Compliance Risk Assessments

- **Compliance Gap or Risk Assessments have become a key component of the Corporate Governance Programs.**
- **Such assessments can be broad [encompass many areas of operation] or narrow [focused upon specific areas where issues have been identified or are anticipated].**
- **Assessment is to identify Compliance programming "gaps" relative to 7 elements of an effective compliance program as described by OIG, as well as the 15 PhRMA Code sections.**
- **Documentation is reviewed and anonymous interview sessions are conducted with Compliance and Legal, as well as key persons from other functions, especially commercial activities.**
- **The objective is to identify compliance-related areas/activities where additional emphasis or resources might be needed. Key components of the assessment include:**
  - Identification of significant "perceived" Compliance-related risks that the Company either presently confronts and/or that it may confront in the next twelve months.
  - Infrastructure: Adequacy of the methods by which the Company develops, maintains, and monitors internal Policies and Procedures.
  - Programming: A "gap" assessment relative to current policies and procedures, identification of additional policies and procedures that might be considered to strengthen the current Commercial Compliance program.

11:00 am **Introduction, Panel Discussion and Q&A**

Thomas Cornely, *Health Care Compliance Officer, Pharmaceuticals Group, Johnson & Johnson, Horsham PA*

Kenneth R. Pina, RPH, JD, *Founding Principal, Core Risks, Ltd., LLC; Former Vice President, General Counsel and Secretary, Rhone-Poulenc Rorer Pharmaceuticals Inc., Ardmore, PA*

Kelly N. "Nikki" Reeves, MPA, JD, *Partner, King & Spalding LLP; Legal Counsel, Ad Hoc Sunshine and State Law Compliance Group, Washington, DC*

Eric H. Siegel, JD, MBA, *Chief Compliance Officer, Incyte; Former Chief Compliance Officer, EMD Serono, Wilmington, DE*

Jack T. Tanselle, *Managing Director, Healthcare Dispute Compliance and Investigation Practice, Navigant Consulting, Inc., Indianapolis, IN*

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc., Philadelphia, PA (Moderator)*

12:30 pm **Networking Luncheon**

Mini Summit II: Advanced Issues in Monitoring

- **Ensuring a Risk-Based Approach to Data Analysis**
- **Maximizing Business Accountability for Monitoring Results**
- **Engaging the Leadership on Behavioral Trends**
- **Discuss Tools to Extract and Assess Aggregate Data**
- **Explore Techniques to Evaluate Outliers and Trending Data Informing Risk**
- **Share Business Engagement Tactics and Best Practices to Enhance Accountability**
- **Discuss Approaches to Measurement and Reporting**

11:00 am **Introduction, Panel Discussion and Q&A**

Anthony Brennan, *Senior Director Healthcare Compliance, Johnson & Johnson, New York, NY*

Michael Driscoll, CPA, *Senior Manager, Health Care Compliance, Johnson & Johnson, New York, NY*

Kevin L. Espinoza, MBA, *Vice President, Ethics & Compliance, BTG International, Raleigh, NC*

Terri Ledva, *Senior Manager Compliance, Iroko Pharmaceuticals, Philadelphia, PA*

Marc Scallon, MHA, *Principal, KPMG LLP, San Francisco, CA*

Jeffrey S. Klimaski, MBA, CPA, *Vice President, Corporate Ethics & Compliance Officer, BTG International Inc., Philadelphia. PA (Moderator)*

12:30 pm **Networking Luncheon**

Mini Summit III: Anti-corruption Update: FCPA, UK Bribery Act and Beyond

- Government Anti-corruption Enforcement in the US, UK, China and Elsewhere
- More Recent Enactment of Anti-corruption Regimes in Latin America and Other Regions
- Dodd-Frank, the Plaintiffs' Bar and a New Wave of Potential Whistleblowers Worldwide
- Review Lessons Learned from Recent Cases and Enforcement Actions
- Best Practices for Anti-corruption Compliance in BRIC and Other High Risk Markets
- Leading Edge Strategies and Controls, including Enhanced Monitoring, to Mitigate Risk

11:00 am Introduction, Panel Discussion and Q&A

Saul Helman, MD, *Managing Director and Life Sciences Practice Leader, Navigant Consulting, Inc., Indianapolis, IN*

Susan Goetz Markel, CPA, *Managing Director, Financial Advisory Services Group, AlixPartners; Former Chief Accountant, Division of Enforcement, US Security and Exchange Commission, New York, NY*

Karen Patruno Sheehy, Esq. (Invited), *Vice President, Head of North America Compliance, Sanofi, New York, NY*

Jon Smollen, MA, JD (Invited), *Executive Vice President and Chief Compliance Officer, Endo; Former Vice President and Chief Compliance Officer, Siemens Healthcare USA, Philadelphia, PA*

Gary F. Giampetruzzi, Esq., *Partner, Paul Hastings; Former Vice President, Assistant General Counsel and Head of Government Investigations, Pfizer Inc., New York, NY (Moderator)*

12:30 pm Networking Luncheon

Mini Summit IV: Post-CIA Compliance: Maintaining the Momentum

- Completion of a CIA is part of an evolutionary process that is the life cycle of a mature, compliant organization.
- Lessons learned from the CIA that should be carried over into the future.
- Which policies, procedures and operations are currently working well?
- Additional policies, not part of the original CIA, may need to be streamlined or eliminated.
- What change may be necessary to a company's monitoring and auditing plans post CIA requirements?
- What existing resources within the compliance department will still be needed going forward?
- Should certain positions be reassigned to other areas of the organization (e.g., business, quality assurance, internal audit)?
- Current data should be leveraged to proactively manage compliance requirements going forward.
- How can the compliance department partner with commercial operations to provide the best value to the organization?

11:00 am Introduction, Panel Discussion and Q&A

Christopher Fletchall, MBA, *Senior Advisor Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN*

Wendy C. Goldstein, Esq., *Partner, Health Care and Life Sciences Regulatory Practice, Cooley, LLP, New York, NY*

Gary Keilty, Esq., *Managing Director, Huron Consulting Group; Chair, Litigation and Risk Management Interest Group, ABA Health Law Section, Washington, DC*

Barbara McCullough, *Director for Corporate Integrity Agreement Operations, AstraZeneca Pharmaceuticals LP, Philadelphia, PA*

Lawrence P. Platkin, *Vice President and Compliance Officer, Bayer Healthcare LLC, New York, NY*

Rosemary Ernst Weghorst, MHA, *Director, Huron Consulting Group, Cincinnati, OH (Moderator)*

12:30 pm Networking Luncheon

Mini Summit V: Hot Compliance Issues Updates

11:00 am Pharma Privacy Update: 10 Things You Need to Know about Privacy

- Update on Key Global Privacy Trends and New Laws
- Advice from Industry Leaders on Trending Privacy Issues that Impact the Business' Global Expansion, Use of New Technologies and New Business Models
- Practical Tips and Best Practices on How Leading Pharma and Life Sciences Companies have Addressed Compliance and Other Risks
- Key Program Areas (e.g., Clinical Research, CRM Databases, Sales and Marketing Activities, FCPA Due Diligence)

Debra Bromson, Esq., *Senior Corporate Counsel and Chief Privacy Officer, Jazz Pharmaceuticals; Former Senior Counsel Commercial and Privacy, AstraZeneca Pharmaceuticals LP, Philadelphia, PA*

Agatha O'Malley, MStPH, JD, *Chief Privacy Officer, Shire Pharmaceuticals, Philadelphia, PA*

James Koenig, Esq., *Global Leader, Commercial Privacy and Health Cybersecurity and Incident Response, Booz Allen Hamilton, Philadelphia, PA (Moderator)*

11:45 am Best Practices for a Compliance Education Program

- Critical Role of Education in a World Class Compliance Program
- Steps to Design and Implement an Effective Program
- Best Practices for Evaluating and Sustaining a Compliance Education Program

Rachel Batykefer, CCEP, *Associate Director of Global Compliance, Teva Pharmaceuticals, Philadelphia, PA*

Matthew Ruble, *Director, Business Advisory Services, Grant Thornton LLP, Philadelphia, PA*

Lisa Walkush, *Principal and Life Sciences Advisory Practice Leader, Grant Thornton LLP, Philadelphia, PA (Moderator)*

12:30 pm NETWORKING LUNCHEON

1:30 pm PHARMA CONGRESS MINI SUMMITS

MINI SUMMITS BLOCK B

Mini Summit VI: Compliance Considerations in Patient Support Programs

- Patient Education and Support
- Discounts and Rebates
- Copay and Deductible Support

1:30 pm Introduction, Panel Discussion and Q&A

Alison Fethke, Esq., *Counsel, Ropes & Gray; Former Division Counsel, Legal Regulatory and Compliance, Abbvie, Inc., Chicago, IL*

Bradford Patrick, Esq., *Division Counsel, AbbVie Inc., Chicago, IL*

Ronald L. Wisor, Jr., Esq., *Partner, Hogan Lovells US LLP, Washington, DC (Moderator)*

3:00 pm Break

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Mini Summit VII: Compliance Issues Raised by Mergers, Acquisitions and Alliances

1:30 pm **Pre-Merger, Acquisition and Alliance Due Diligence**

Erik Eglite, MBA, JD, DPM, *Vice President, Chief Compliance Officer and Corporate Counsel, Lundbeck Pharmaceuticals, Chicago, IL*

Jeremy Perisho, CPA, *Partner, Deloitte Financial Advisory Services LLP, Boston, MA*

L. Stephan Vincze, LD, LLM, MBA, *Partner, Polaris; Former Senior Vice President, Chief Compliance Officer, Warner Chilcott; Former Vice President, Ethics and Compliance Officer/ Privacy Officer, TAP Pharmaceutical Products Inc., Boston, MA (Moderator)*

2:15 pm **Post-Merger, Acquisition and Alliance: Considerations in Melding Compliance Programs**

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ*

Ed Leskauskas (Invited), *Vice President, Ethics and Compliance, Ipsen Biopharmaceuticals; Former Director, US Pharmaceuticals Compliance and Ethics, Bristol-Myers Squibb, Basking Ridge, NJ*

Bert Weinstein, Esq., *Vice President, Corporate Compliance, Purdue Pharmaceuticals; Former Vice President and Assistant General Counsel, Merck, Stamford, CT*

Jean McKiernan, MBA, *Director, Advisory Pharmaceutical and Life Sciences, PwC, Chicago, IL (Moderator)*

3:00 pm **Break**

Mini Summit VIII: Communications and Training

1:30 pm **Lessons in "Stickiness"**

Matthew Yesko, CPLP, *Senior Consultant, Aquinas Leadership Group; Former Associate Director, Commercial Training, Inspire Pharmaceuticals, Raleigh, NC*

2:15 pm **How Do You Eat an Elephant? Ensuring the Abundance of Policy Information is Digestible and Understood!**

Eric Baim, MA, JD, *Executive Director, Policy and Risk Management, Novartis, East Hanover, NJ*

Steve Sitek, MEd, *Head of Learning, Novartis; Adjunct Professor, Rutgers Business School, East Hanover, NJ*

3:00 pm **Break**

Mini Summit IX: Compliance in Medical Affairs: Medical Liaisons, Publications and Clinical Trials

- Interactions with Patient Advocacy Organizations
- Participation in Scientific and Medical Meetings Prior to Product Approval
- Compliance Considerations in Press Releases Regarding Clinical Trial Results
- Updates to EU Requirements for Clinical Trials
- Clinical Data Integrity Controls
- Clinical Data Transparency Practices

1:30 pm **Introduction, Panel Discussion and Q&A**

Paul Curtin, Esq., *Compliance Officer - Global Research and Development, Actavis; Former Head of Compliance - Ex-US, Forest Laboratories, New York, NY*

Howard L. Dorfman, Esq., *Vice President General Counsel, Ferring Pharmaceuticals Inc.; Former Vice President, Assistant General Counsel, Bayer, Parsippany , NJ*

Stephanie Macholtz, Esq. (Invited), *Director Corporate Compliance, Biogen Idec, Boston, MA*

Cliff Saffron, JD, *Principal, KPMG LLP, New York, NY*

Paul Subacius, *Health Care Compliance Officer, Pharmaceuticals Group, Johnson & Johnson, Titusville NJ*

Daniel A. Kracov, Esq., *Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC (Moderator)*

3:00 pm **Break**

Mini Summit X: Government Pricing and Contracting

- Medicaid Drug Rebate Program Average Manufacturer Price, Best Price, and Unit Rebate Amount
- Medicare Part B Average Sales Price
- Public Health Service 340B Drug Pricing Program
- Federal Government Contracts and Pricing: FSS, VA, DoD, and TRICARE
- State Drug Price Reporting Regimes
- Recent Government Pricing Regulatory Developments
- Keys to an Effective Government Pricing Compliance Program
- Government Pricing Enforcement Landscape

1:30 pm **Introduction, Panel Discussion and Q&A**

Katherine Buckley, MBA, *Director, Pharmaceutical and Life Sciences Risk & Compliance, PwC, Philadelphia, PA*

Avril McKean Dieser, MA, JD, *Senior Counsel, AbbVie, Inc., Chicago, IL*

Marcy Imada, *Principal, Deloitte & Touche LLP, Los Angeles, CA*

Miree Lee, MS, MBA, *Government Pricing & Commercial Contracts Consultant, Miree Lee Consulting, LLC; Former Director, Contracts & Pricing, Daiichi Pharmaceutical Corporation, Phoenix, AZ*

Elizabeth F. Lindquist, Esq., *Associate, FDA & Life Sciences Practice Group, King & Spalding, Washington, DC*

John D. Shakow, Esq., *Partner, FDA & Life Sciences Practice, King & Spalding, Washington, DC (Moderator)*

3:00 pm **Break**

CLOSING PLENARY SESSION

3:30 pm **Welcome and Introductions**

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ (Co-chair)*

3:45 pm **CMS Sunshine Act Implementation Update**

Douglas Brown, *Deputy Director, Data Sharing & Partnership Group, Center for Program Integrity, Centers for Medicare and Medicaid Services, US Department of Health and Human Services, Washington, DC*

4:15 pm **Transparency Update: Status of Sunshine Act Compliance**

Maya A. Babu, MD, MBA, *Member, Board of Trustees, American Medical Association; Neurosurgery Resident, Mayo Clinic, Rochester, MN*

Margaret K. Feltz, Esq., *Executive Director, Corporate Compliance, Purdue Pharma LP; Member, PCF Executive Committee, Stamford, CT*

John Murphy, Esq., *Assistant General Counsel, PhRMA; Former Senior Director, State Government Relations, Health Policy, Biotechnology Industry Organization, Washington, DC*

Charles Ornstein, *Senior Reporter, ProPublica; Vice President, Association of Health Care Journalists; Awardee, Pulitzer Prize for Public Service, New York, NY*

John Patrick Oroho, Esq., *Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ (Co-moderator)*

Kelly N. "Nikki" Reeves, MPA, JD, *Partner, King & Spalding LLP; Legal Counsel, Ad Hoc Sunshine and State Law Compliance Group, Washington, DC (Co-moderator)*

5:30 pm **Adjournment**

WEDNESDAY, NOVEMBER 5, 2014

PHARMA CONGRESS: AGENDA DAY III *(Concurrent Sessions)*

CLOSED SESSION I: INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

(Industry-only session for pharmaceutical company compliance professionals and in-house counsel only; not included in Congress live and archived Internet broadcast. Session will be attended by antitrust counsel.)

8:30 am **Introduction, Discussion of Select Issues and Q&A**

Gary DelVecchio, *Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company, Plainsboro, NJ (Co-chair)*

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

Kelly B. Freeman, PhD, *Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN (Co-chair)*

Elizabeth V. Jobes, Esq., *Senior Vice President, Chief Compliance Officer, Auxilium Pharmaceuticals Inc., Philadelphia, PA (Co-chair)*

Noon **CONGRESS ADJOURNMENT**

ATTENDANCE OF CLOSED SESSIONS LIMITED

As noted above, attendance of closed sessions is limited to company compliance professionals and in-house counsel only with regard to Closed Session I; and consultants and legal counsel to the pharmaceutical industry only with regard to Closed Session II. The purpose of the closed sessions is to permit the respective groups to engage in a more focused exchange of views regarding issue priority and best compliance practices. Upon registration, the attendee will be asked to complete a brief form to request attendance of a closed session. If there is a question raised regarding qualification to attend a closed session, a subcommittee of the Congress planning committee will make the final determination. Attendees who are not qualified to attend either session will receive a complimentary Congress Flash Drive.

CLOSED SESSION II: INDUSTRY CONSULTANT/LEGAL COUNSEL COMPLIANCE BEST PRACTICES THINK TANK

(Session for consultants and legal counsel to the pharmaceutical industry only; not included in Congress live and archived Internet broadcast. Session will be attended by antitrust counsel.)

8:30 am **Introduction, Discussion of Select Issues and Q&A**

Organizing Committee:

Gary F. Giampetruzzi, Esq., *Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY*

Virginia "Ginny" A. Gibson, Esq., *Partner, Hogan Lovells LLP; Former Executive Assistant U.S. Attorney, Eastern District of Pennsylvania, Philadelphia, PA*

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

John Patrick Oroho, Esq., *Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ*

Kelly N. "Nikki" Reeves, MPA, JD, *Partner, King & Spalding LLP; Legal Counsel, Ad Hoc Sunshine and State Law Compliance Group, Washington, DC*

Brian Riewerts, *Principal, Global Governance, Risk and Compliance Leader, Pharmaceutical and Life Sciences Advisory, PwC, Baltimore, MD*

Paul J. Silver, *Practice Leader and Managing Director, Huron Consulting Group, Atlanta, GA*

Jack T. Tanselle, *Managing Director, Healthcare Dispute Compliance and Investigation Practice, Navigant Consulting, Inc., Indianapolis, IN*

Noon **CONGRESS ADJOURNMENT**

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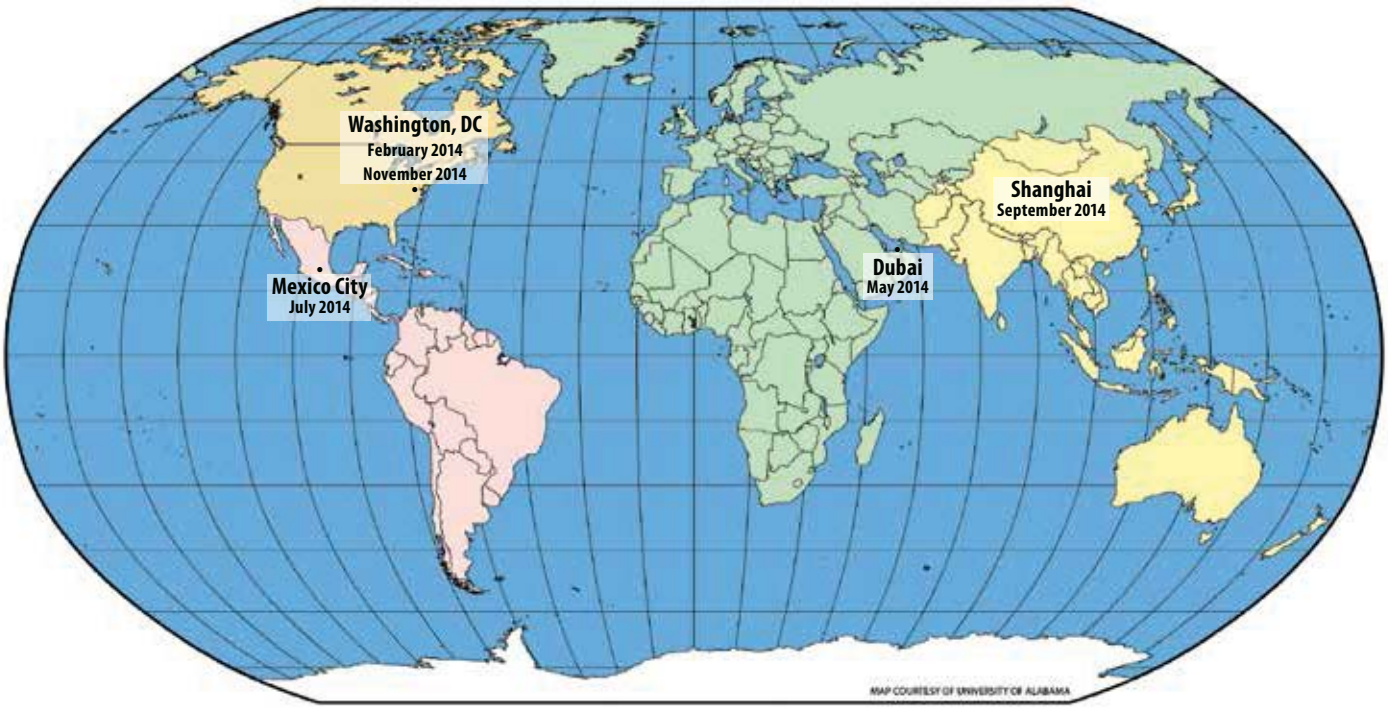

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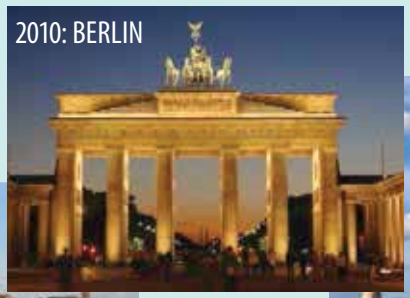

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• Online at www.PharmaCongress.com.

• Fax/Mail/Email using this printed registration form. Mail the completed form with payment to the Conference registrar at 22529 39th Ave. SE, Bothell, WA 98021, or fax the completed form to 206-319-5303, or scan and email the completed form to registration@hcconferences.com. Checks or money orders should be made payable to Health Care Conference Administrators LLC.

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MAIL: Conference Office, 22529 39th Ave SE, Bothell, WA 98021

FOR REGISTRATION QUESTIONS:
PHONE: 800-503-7419 (Continental US, Alaska and Hawaii only) or 206-452-5662, Monday-Friday, 7 AM - 5 PM PST

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The Congress is currently pending approval to offer Compliance Certification Board CCB Credits.

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❑ Pharmaceutical Compliance Forum Group Rate/Conference Only $1,595

SELECT YOUR MINI-SUMMITS – Tuesday, November 4 (One from each group):

BLOCK A – 11:00 am

- ❑ **MS I:** Compliance Risk Assessments
- ❑ **MS II:** Advanced Issues in Monitoring
- ❑ **MS III:** Anti-corruption Update: FCPA, UK Bribery Act and Beyond
- ❑ **MS IV:** Post-CIA Compliance: Maintaining the Momentum
- ❑ **MS V:** Hot Compliance Issues Updates

BLOCK B – 1:30 pm

- ❑ **MS VI:** Compliance Considerations in Patient Support Programs
- ❑ **MS VII:** Compliance Issues Raised by Mergers, Acquisitions and Alliances
- ❑ **MS VIII:** Communications and Training
- ❑ **MS IX:** Compliance in Medical Affairs: Medical Liaisons, Publications and Clinical Trials
- ❑ **MS X:** Government Pricing and Contracting

SELECT YOUR CONCURRENT SESSION –Wednesday, November 5:

❑ Closed Session I: Industry-Only Compliance Best Practices Think Tank

❑ Closed Session II: Industry Consultant/Legal Counsel Compliance Best Practices Think Tank

(Attendance is limited and requires application and qualification. See ATTENDANCE OF CLOSED SESSIONS LIMITED above for more information.)

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* This price reflects a discount for registration and payment received through Friday, Sept. 19, 2014.

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