THE FIFTEENTH ANNUAL
Pharmaceutical Regulatory and Compliance Congress and
Best Practices Forum

TRANSFORMATIONAL LEARNING - EFFECTIVE KNOWLEDGE EXCHANGE

Onsite:
November 3 – 5, 2014
Washington, DC

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
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:

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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Deloitte. Huron Life Sciences

BRONZE GRANTORS:
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ARNOLD & PORTER LLP
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Internet with 24/7 access for six months

A Hybrid Conference & Internet Event
See page 2
ABOUT THE CONGRESS SPONSOR

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 DeVvecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb, Plainsboro, NJ (Co-chair)
Margaret K. Felz, 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, XenonPort, Inc., Mountain View, CA
Jeffrey S. Klimaski, MBA, CPA, Vice President, Corporate Ethics, RTG 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:
OG Update
DOJ Update
FDA-OPPP 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.

LIVE AND ARCHIVED INTERNET ATTENDANCE

Watch the conference in live streaming video over the Internet and at your convenience at any time 24/7 for six months following the event.
The archived conference includes speaker videos and coordinated PowerPoint presentations.
PROS: live digital feed and 24/7 Internet access for the next six months; accessible in the office, at home or anywhere worldwide with Internet access; avoid travel expense and hassle; no time away from the office.

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
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)

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)

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, JD, 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

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 PharmaCongress 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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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

MONDAY, NOVEMBER 3, 2014

8:30 am  Welcome and Introduction

Sarah K. dirfrancesca, 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

MONDAY, NOVEMBER 3, 2014

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
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 (Co-chair)

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 Comely, Health Care Compliance Officer, Pharmaceuticals Group, Johnson & Johnson, Horsham, PA
Kenneth R. Pina, RPH, JD, Founding Principal, Care 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., Former Vice President and Chief Compliance Officer, Siemens Healthcare USA, Philadelphia, PA

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, CCEP, 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

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 206-673-4815 or email exhibits@hconferences.com.
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 Perioso, CPA, Partner, Deloitte Financial Advisory Services LLP, Boston, MA
L. Stephan Vincke, 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
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 D. 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. Kacoy, Esq., Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC (Moderator)
3:00 pm  Break

Mini Summit X: Government Pricing and Contracting
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
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.

2014 Global Pharma Compliance Congresses

Washington, DC
- February 2014
- November 2014

Mexico City
- July 2014

Shanghai
- September 2014

Dubai
- May 2014

MAP COURTESY OF UNIVERSITY OF ALABAMA
SAVE THE DATE!  NINTH INTERNATIONAL PHARMACEUTICAL COMPLIANCE CONGRESS

A Hybrid Conference & Internet Event
See website

May 11 – 13, 2015
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2. Each registrant will receive a user name and password for access. Registrants will be able to change their user names and passwords and manage their accounts.
3. Internet registrants will enjoy six (6) months access from date of issuance of user name and password.
4. Only one user (per user name and password) may view or access archived content. It is not permissible to share user names and password with third parties. Should Internet registrants choose to access post conference content via Flash Drive, this individual use limitation applies. It is not permissible to share alternative media with third parties.
5. User name and password use will be monitored to assure compliance.
6. Each Internet registration is subject to a "bandwidth" or capacity use cap of 5 gb per user per month. When this capacity use cap is hit, the registration lapses. Said registration will be again made available at the start of the next month so long as the registration period has not lapsed and is subject to the same capacity cap.
7. For webcast registrants there will be no refunds for cancellations. Please call the Conference Office at 800-503-7419 or 206-452-5662 for further information.

REGARDING ONSITE REGISTRATION, CANCELLATIONS AND SUBSTITUTIONS
1. For onsite group registrations, full registration and credit card information is required for each registrant. List all members of groups registering concurrently on fax or scanned cover sheet.
2. For onsite registrants there will be no refunds for "no-shows" or for cancellations. You may send a substitute or switch to the webcast option. Please call the Conference Office at 800-503-7419 or 206-452-5662 for further information.

METHOD OF PAYMENT FOR TUITION
Make payment to Health Care Conference Administrators LLC by check, MasterCard, Visa or American Express. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC. Checks or money orders should be made payable to Health Care Conference Administrators LLC. A $30 fee will be charged on any returned checks.

REGISTRATION OPTIONS
Registration may be made online or via mail, fax or scan.
You may register through either of the following:
• 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.

The following credit cards are accepted: American Express, Visa or MasterCard. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC. For registrants awaiting company check or money order, a credit card number should be given to hold registration. If payment is not received by seven days prior to the Congress, credit card payment will be processed.

TAX DEDUCTIBILITY
Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor. Federal Tax ID: 91-1892021.

CANCELLATIONS/SUBSTITUTIONS
No refunds will be given for "no-shows" or for cancellations of either webcast or onsite registrations. You may send a substitute or transfer your onsite registration to an webcast registration. For more information, please call the Conference Office at 800-503-7419 or 206-452-5662.

INTELLECTUAL PROPERTY POLICY
Unauthorized sharing of Congress content via Internet access through the sharing of user names and passwords or via alternative media (Flash Drive) through the sharing of said media is restricted by law and may subject the copyright infringer to substantial civil damages. The Congress aggressively pursues copyright infringers. If a registrant needs the ability to share Congress content within his or her organization, multiple Congress registrations are available at discounted rates.

The Congress will pay a reward for information regarding unauthorized sharing of Congress content. The reward will be one quarter (25%) of any recovery resulting from a copyright infringement (less legal fees and other expenses related to the recovery) up to a maximum reward payment of $25,000. The payment will be made to the individual or individuals who in the opinion of our legal counsel first provided the factual information, which was necessary for the recovery. If you have knowledge regarding the unauthorized Congress content sharing, contact the Congress registration office.

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.

GENERAL TERMS AND CONDITIONS
Program subject to cancellation or change. If the program is cancelled the only liability of the Congress will be to refund the registration fee paid. The Congress shall have no liability regarding travel or other costs. Registration form submitted via fax, mail, email or online constitutes binding agreement between the parties.

FOR FURTHER INFORMATION
Call 800-503-7419 (Continental US, Alaska and Hawaii only) or 206-452-5662, send e-mail to registration@hcconferences.com, or visit our website at www.PharmaCongress.com.

HOW TO REGISTER: Fully complete the form on page 11 (one form per registrant, photocopies acceptable). Payment must accompany each registration (U.S. funds, payable to Health Care Conference Administrators, LLC).

FAX: 206-319-5303 (include credit card information with registration)
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
E-MAIL: registration@hcconferences.com

PHARMA CONGRESS CONTINUING EDUCATION CREDITS

NASBA CPE CREDIT
Health Care Conference Administrators, LLC is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: www.learningmarket.org.
A recommended maximum of 17.5 credits based on a 50-minute hour will be granted for the entire learning activity. This program addresses topics that are of a current concern in the compliance environment. This is an update, group-live activity. For more information regarding administrative policies such as complaints or refunds, call 206-757-8053 or petergrant@dwt.com.

COMPLIANCE CERTIFICATION BOARD CONTINUING EDUCATION UNITS (CCB CEUs)
The Congress is currently pending approval to offer Compliance Certification Board CCB Credits.

PENDING CONTINUING EDUCATION CREDITS
The Congress is currently pending approval to offer California and Pennsylvania MCLE Credit.

CERTIFICATE OF ATTENDANCE
Onsite attendees can request a Certificate of Attendance which they can file with appropriate entities for credit, and webcast attendees can request an Online Certificate of Attendance on which they can certify the number of hours they watched and can file with appropriate entities for credit.
ATTENDANCE OF CLOSED SESSIONS LIMITED
As noted on page 8, 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.

ONSITE CONFERENCE ATTENDANCE

STANDARD RATES:

PRECONFERENCES (Choose one):
- I: Advanced Issues in Domestic and Global Transparency … $ 959
- II: Innovations in Auditing and Monitoring $ 959
- III: Advanced Issues and Best Practices in Investigations $ 959
- IV: Global Compliance Issues and Programs $ 959

CONFERENCE (Does not include Preconference or Postconference):
- Through Friday, September 19, 2014* $ 1,995
- Through Friday, October 10, 2014** $ 2,195
- After Friday, October 10, 2014 $ 2,395

GROUP REGISTRATION DISCOUNT (Does not include Preconference):
Three or more registrations submitted from the same organization at the same time receive the following discounted rates for conference registration only. To qualify, all registrations must be submitted simultaneously:
- Through Friday, September 19, 2014* each $1,795
- Through Friday, October 10, 2014** each $1,995
- After Friday, October 10, 2014 each $2,195

WEBCAST CONFERENCE ATTENDANCE

All webcast registrants are automatically registered for the preconference and conference. Webcast conference registration includes the live Internet feed from the Congress, plus six months of continued archived Internet access, available 24/7. Preconference sessions are audio only. Mini Summit sessions will be audio streamed. The closed sessions on Day III of the Congress will not be included in Congress live and archived Internet broadcast.

STANDARD RATES:

INDIVIDUAL REGISTRATION:
- Through Friday, September 19, 2014* $ 795
- Through Friday, October 10, 2014** $ 995
- After Friday, October 10, 2014 $ 1,195

GROUP REGISTRATION:
Group registration offers the substantial volume discounts set forth below. All group registrants are enrolled in the preconference and conference. Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track employee conference participation.
Conference Access:
- 5 or more $395 each
- 10 or more $495 each
- 40 or more $295 each

See INTELLECTUAL PROPERTY POLICY, page 10.

CONFERENCE ELECTRONIC MEDIA:
Webcast attendees — Following the Congress, the video and presentations are made available on a flash drive. To take advantage of the discounted price below, you must reserve media with your Congress registration:
Flash Drive ($129 + $15 shipping) $ 144
(All webcast attendees automatically receive 6 months access on web.)

PAYMENT

TOTAL FOR ALL OPTIONS, ONSITE OR WEBCAST:
Please enclose payment with your registration and return it to the Registrar at Pharma Congress, 22529 39th Ave SE, Bothell, WA 98021, or fax your credit card payment to 206-319-5303. You may also register online at www.PharmaCongress.com.
- Check/money order enclosed (payable to Health Care Conference Administrators LLC)
- Payment by credit card: American Express, Visa, Mastercard
If a credit card number is being given to hold registration only until such time as a check is received it must be so noted. If payment is not received by seven days prior to the Congress, the credit card payment will be processed. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC.

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. For webcast and onsite registrants there will be no refunds for “no-shows” or cancellations.

ACCOUNT #
EXPIRATION DATE
SECURITY CODE
NAME OF CARDHOLDER
SIGNATURE OF CARDHOLDER

COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:

NAME
SIGNATURE OF REGISTRANT - REQUIRED
JOB TITLE
ORGANIZATION
ADDRESS
CITY/STATE/ZIP
TELEPHONE
E-MAIL
☐ Special Needs (Dietary or Physical)
THE FIFTEENTH ANNUAL
Pharmaceutical Regulatory
and Compliance Congress

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Washington, DC
Hilton Regency on Capitol Hill

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