

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

TRANSFORMATIONAL LEARNING —
EFFECTIVE KNOWLEDGE EXCHANGE



GHC LIFE SCIENCES
Global Health Care, LLC

CO CHAIRS:



Matthew D'Ambrosio, MBA, JD, Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals Inc.



Gary Del Vecchio, Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb Company



Elizabeth Jobs, Esq., Head of Corporate Compliance and Legal Counsel, Spark Therapeutics

KEYNOTE SPEAKERS:



Thomas W. Abrams, RPh, MBA, Director, Office of Prescription Drug Promotion, Food and Drug Administration



Robert Barrington, PhD, Executive Director, Transparency International-UK



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



Benjamin C. Mizer, Esq., Principal Deputy Assistant Attorney General and Head of the Civil Division, US Department of Justice



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



Jeffrey S. Sallet, National Chief of Public Corruption and Civil Rights, Federal Bureau of Investigation

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& GRAY**

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CONTINUING EDUCATION CREDITS:

Accounting Professionals: Approved for up to 16 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, Pennsylvania and Texas MCLE Credit.

www.PharmaCongress.com

Onsite:

October 21 – 23, 2015

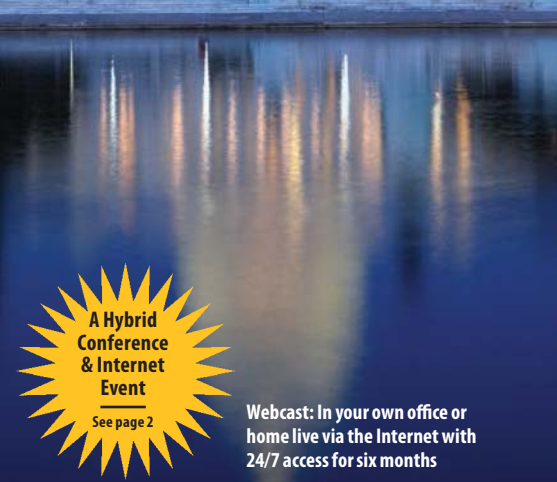
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**THE
PHARMACEUTICAL
COMPLIANCE
FORUM**

SPECIAL PCF REGISTRATION DISCOUNTS — See page 11.



**A Hybrid
Conference
& Internet
Event**

See page 2

Webcast: In your own office or
home live via the Internet with
24/7 access for six months

INVITATION TO ATTEND THE PCF PHARMA CONGRESS

As the new Vice President, Pharma and Medical Device Content, Global Health Care – Life Sciences, LLC, it is my pleasure to invite you to attend the 2015 Sixteenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum sponsored by the PCF. This year's Congress will feature presentations by leading government regulators, company compliance professionals, in-house counsel, prominent industry consultants and legal counsel. Please plan to join me and the Planning Committee for three stimulating days of continuing education, networking and best practice sharing.



Kelly B. Freeman, PhD, Vice President, Pharma and Medical Device Content, Global Health Care – Life Sciences, LLC; Former Senior Advisor, Ethics and Compliance, Eli Lilly and Company; Former Member, PCF Executive Committee, Indianapolis, IN

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 this three-day compliance congress each Fall. For membership information, contact Kelly Freeman via email at kellfreem@gmail.com. Please visit their website at www.PharmaComplianceForum.org.



THE PHARMACEUTICAL COMPLIANCE FORUM

AGENDA AT A GLANCE

Wednesday, October 21, 2015

7:30 am Congress Registration

8:00 am – 11:30 am **PRECONFERENCE SYMPOSIA** (Optional, Choose only one):

Precon I: Regulatory Concepts: Basic Principles	Precon II: Innovations in Risk Assessment, Auditing and Monitoring	Precon III: Advanced Issues in Domestic and Global Transparency ...	Precon IV: Advanced Global Compliances Issues
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OPENING PLENARY SESSION

1:00 pm Welcome and Introduction: PCF Co-Chairs

1:15 pm Keynote: OIG Update

2:00 pm AUSA Panel

2:45 pm FBI's New Focus on FCPA Investigations

3:15 pm Break

3:45 pm Keynote: FDA-OPDP Update

4:15 pm Chief Compliance Officer Roundtable

5:00 pm Panel: FCPA Anticorruption: Examining a Hypothetical Case from All Sides: DOJ, SEC, and CCO

5:45 pm ADJOURNMENT AND NETWORKING RECEPTION

Thursday, October 22, 2015

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

MORNING PLENARY SESSION

8:00 am Welcome and Introductions

8:15 am US DOJ Civil Section Update

8:45 am Keynote: Transparency International's New Pharma Industry Initiative

9:15 am Qui Tam Panel

10:00 am Recent Developments in the Debate over Off-Label Communications and the First Amendment

10:30 am Networking Break

11:00 am – 12:00 pm MINI SUMMITS BLOCK A

MS I: Managing Speaker Program Compliance ...	MS II: R&D Compliance ...	MS III: Business Development Part 1 ...	MS IV: Evaluating Compliance Program Effectiveness ...	MS V: Payers and Providers Part 1 ...	MS VI: Patient Support Programs Part 1 ...
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12:00 pm NETWORKING LUNCHEON

1:15 pm – 2:15 pm MINI SUMMITS BLOCK B

MS VII: Predictive Analytics	MS VIII: Coordinating Risk Management ...	MS IX: Managing Multi-National HCP Meetings ...	MS X: Business Development Part 2 ...	MS XI: Impact of Public Disclosures ...	MS XII: Patient Support Programs Part 2 ...
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2:15 pm Transition Break

2:30 pm – 3:30 pm MINI SUMMITS BLOCK C

MS XIII: Innovation in Training and Communications	MS XIV: Compliance Considerations ...	MS XV: New Product Launches ...	MS XVI: Business Development Part 3 ...	MS XVII: Marketing and Medical Affairs ...	MS XVIII: Structuring Specialty Pharmacy Distribution ...	MS XIX: Payers and Providers Part 2 ...
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3:30 pm Networking Break

CLOSING PLENARY SESSION

4:00 pm Update from CMS on Open Payments

4:30 pm Consolidation, Vertical Integration and Cross-Border Business

5:15 pm Millennials and the Future of Ethics and Compliance Programs

6:30 pm Adjournment

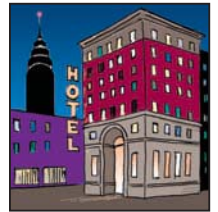
Friday, October 23, 2015: INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK, 8:30 am – Noon

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

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.



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... or home

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

7:30 am Congress Registration

PRECONFERENCE SYMPOSIA *(Optional, Choose only one)*

Preconference I: Regulatory Concepts: Basic Principles

8:00 am **Welcome and Overview**



James Gibney, Senior Director of Compliance, Regeneron Pharmaceuticals; Former Director, Worldwide Programs and US Investigations - Corporate Compliance, Pfizer, Tarrytown, NY (Moderator)

8:10 am **INDs, NDAs and Drug Development**



Natasha Leskovsek, RN, MPM, MBA, JD, Health Care and Life Sciences Regulatory Practice, Cooley, LLP, Washington DC

8:40 am **Scientific Exchange**



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

9:10 am **Patient Safety: Pharmacovigilance and REMS**



Dr. Seth B. Whitelaw, President and CEO, Whitelaw Compliance Group, LLC, West Chester, PA

9:30 am **Break**

9:50 am **Advertising and Promotion: HCPs and Consumers**



Janet L. "Lucy" Rose, MBA, President, Lucy Rose and Associates, LLC; Former Director, DDMAC, FDA, Washington, DC

10:50 am **Promotion to Payers and Government Price Reporting**



John Shakow, Esq., Partner, FDA and Life Sciences Practice, King & Spalding, Washington, DC

11:30 am **Preconference Adjournment**

Preconference II: Innovations in Risk Assessment, Auditing and Monitoring

8:00 am **Welcome and Overview**



Lori Alarimo, JD, Director, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant Consulting, Inc., Irvine, CA (Moderator)

8:10 am **Incorporating Effective Record Reviews In Your Auditing & Monitoring Plan**



Chris Castro, CCEP, Associate Director, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant Consulting, Inc., Phoenix, AZ

8:50 am **Enhancing Sales Performance through Field Based Monitoring**



Kerry Clem, Senior Vice President, Sales, Acorda Therapeutics, Ardsley, NY



Wendy Heckelman, PhD, President and Founder, WLH Consulting, Inc., Fort Lauderdale, FL

9:30 am **Break**

9:45 am



Getting Ahead of the Game — Utilizing Data and Other Operational Indicators to Identify Potential Compliance Issues Early

Gary Keilty, Managing Director, FTI, Washington, DC



Daniel L. Dovdavyan, Esq., Assistant General Counsel North America Litigation & Investigations, Sanofi US, Bridgewater, NJ

10:30 am



Building a Compliance Data Analytics Capability

Amy Pawloski, CPA, CCEP, Head of US Compliance & Ethics Monitoring and Data Analytics, Bristol-Myers Squibb, Plainsboro, NJ

11:00 am



Effective Field Monitoring Essentials to Consider when Working with Sales, Marketing and Medical Teams

Scot Steinheiser, CHC, CCEP, Managing Partner and Founder, Commercial Compliance Consulting, SCS Compliance Group LLC, Mundelein, IL



Gary Mendelson, Assistant Director, Corporate Compliance for Oncology, Astellas, Greer, SC

11:30 am **Preconference Adjournment**

Preconference III: Advanced Issues in Domestic and Global Transparency and Analytics: Taking the Data to the Next Level

8:00 am **Welcome and Overview**



Edward Glynn, MBA, Principal, Ernst & Young LLP, New York, NY (Moderator)

8:10 am



Exploring the Analytics Maturity Model: Capitalizing on your Investment in Aggregate Spend

Corey Dunbar, CFE, Senior Manager, Fraud Investigations & Dispute Services, Ernst & Young LLP, New York, NY

8:50 am



Linking Aggregate Spend Data with Other Data Sources to Identify Compliance Trends, Learn about your Competitors and Provide Strategic Insights to the Business

Veronique Monjardet, PhD, Country Manager – France, Polaris, Paris, France

9:30 am

Break

9:50 am



Advanced Analytics: The Art of the Possible in Providing Value-Added Insights to the Business

Samir Hans, MS, Principal, Deloitte, Washington, DC

10:30 am



Using Company-specific and Open Payments Data to Ensure Accuracy and Gain Insights

Terrell Sweat, MBA, Compliance Director, Actelion Pharmaceuticals, South San Francisco, CA



Jonathan Wilkenfeld, MBA, President, Potomac River Partners, Vienna, VA

11:00 am



Growing and Integrating Global Transparency Analytics

Nadeem "Ned" Mumtaz, MBA, MIS, Practice Leader and Associate Partner, Streebo Inc., Princeton, NJ



Dr. Seth B. Whitelaw, President and CEO, Whitelaw Compliance Group, LLC, West Chester, PA

11:30 am **Preconference Adjournment**

Preconference IV: Advanced Global Compliances Issues

8:00 am Welcome and Overview



Nathaniel B. Edmonds, Esq., *Partner, Paul Hastings; Former Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC (Moderator)*

8:10 am Doing Business in China in 2016



David J. Ludlow, Esq., *Partner, Sidley Austin, Washington, DC*

8:40 am Is Brazil the Next Hot Spot?



Esther M. Flesch, Esq., *Partner, Trench, Rossi e Watanabe, A Baker McKenzie Affiliate, São Paulo, Brazil*

9:10 am Managing Compliance Risks Presented by Pharma Suppliers and Vendors: Beyond QRM and GMP



Traci Coughlan, Esq., *Principal, Advisory Services, The Red Flag Group, Berlin, MD*

9:40 am Break

10:00 am Applying Analytics to Compliance Programs Resulting in Informed Business Decisions



Joseph Coniker, GMP, *Principal, National Practice Leader, Business Analytics, Grant Thornton, Philadelphia, PA*

10:30 am Monitoring and Auditing of Third Parties



Jeff Antoon, *Director Internal Audit, Johnson & Johnson, New Brunswick, NJ*

11:00 am Application of Attorney-Client Privilege in the Context of Internal Cross-Border Bribery Investigations



Vivian Robinson, Esq., *Queen's Counsel, Partner, McGuireWoods; Former General Counsel of the UK Serious Fraud Office; Former Head QEB Hollis Whiteman Chambers, Recorder of the Crown Court and Former Treasurer of Inner Temple, London, UK*

11:30 am Preconference Adjournment

**PHARMA CONGRESS: AGENDA DAY I
OPENING PLENARY SESSION**

1:00 pm Welcome and Introduction: PCF Co-Chairs



Matthew D'Ambrosio, JD, MBA, *Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc., Marlborough, MA (Co-chair)*



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



Elizabeth V. Jobs, Esq., *Head of Corporate Compliance and Legal Counsel, Spark Therapeutics, Philadelphia, PA (Co-chair)*

1:15 pm Keynote: 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*



Introduction by Matthew D'Ambrosio, JD, MBA, *Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc., Marlborough, MA (Co-chair)*

2:00 pm AUSA Panel



M. Beth Leahy, Esq. (Invited), *Assistant US Attorney, United States Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA*

Richard Robinson, Esq. (Invited), *Section Chief-Major Frauds, Criminal Division, United States Attorney's Office, Central District of California, Los Angeles, CA*



K. Nathaniel Yeager, Esq., *Chief, Health Care Fraud Unit, United States Attorney's Office, District of Massachusetts, Boston, MA*



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

HOTEL INFORMATION/RESERVATIONS

The Mandarin Oriental is the official hotel for the **SIXTEENTH PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS**. A special group rate of \$300.00 Deluxe Room 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 can also make reservations by calling the Mandarin Oriental directly at **(202) 787-6140** or Toll Free **(888) 888-1778**. Please ask for the Pharma Congress Group Rate when you call.

Reservations at the group rate will be accepted while rooms are available or until the cut-off date of **Tuesday, September 29, 2015**. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

The Pharmaceutical Compliance Congress does not contract with any third party organization to make hotel reservations for attendees of the Congress. All attendees should make their hotel reservations directly with the hotel and not with a third party vendor.

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2:45 pm



FBI's New Focus on FCPA Investigations

Jeffrey S. Sallet, *National Chief of Public Corruption and Civil Rights, Federal Bureau of Investigation, Washington, DC*



Introduction by Kris Curry, MBA, *Principal, Fraud Investigation & Dispute Services, Ernst & Young LLP; Former Vice President, Health Care Compliance, Pharmaceuticals Group, Johnson & Johnson, Philadelphia, PA*

3:15 pm

Break

3:45 pm

Keynote: FDA-OPDP Update



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



Introduction by Janet L. "Lucy" Rose, MBA, *President, Lucy Rose and Associates, LLC; Former Director, DDMAC, FDA, Washington, DC*

4:15 pm

Chief Compliance Officer Roundtable: Now that the CIA is Completed, How is the Ethics and Compliance Program Evolving?



Melissa S. Barnes, Esq., *Chief Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN*



Tricia Glover, *Vice President, US Chief Compliance Officer, Teva Pharmaceuticals, Kansas City, MO*



Jonathon Kellerman, *Executive Vice President, Global Chief Compliance Officer, Allergan PLC, Parsippany, NJ*



Lawrence P. Platkin, *Vice President and Head, U.S. Compliance Center of Excellence, Bayer Corporation, Whippany, NJ*



Trudy Tan, CPA, *Vice President Compliance International, AstraZeneca, Wilmington, DE*



Erinn Hutchinson, *Partner, Advisory Services, PwC, Philadelphia, PA (Moderator)*

5:00 pm

Panel: FCPA Anticorruption: Examining a Hypothetical Case from All Sides: DOJ, SEC, and CCO



Jeffrey H. Knox, Esq., *Partner, Simpson Thacher; Former Chief, Fraud Section, Criminal Division, US Department of Justice, Washington, DC*



Cheryl J. Scarboro, Esq., *Partner, Simpson Thacher; Former Chief, FCPA Unit, US Securities and Exchange Commission, Washington, DC*



Ashley Watson, Esq., *Senior Vice President, Chief Ethics & Compliance Officer, Merck & Co, Inc.; Former Counsel, Chief Ethics and Compliance Officer, Hewlett-Packard, Philadelphia, PA*



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

5:45 pm

ADJOURNMENT AND NETWORKING RECEPTION

THURSDAY, OCTOBER 22, 2015

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. Jobs, Esq., *Head of Corporate Compliance and Legal Counsel, Spark Therapeutics, Philadelphia, PA (Co-chair)*

8:15 am

US DOJ Civil Section Update



Benjamin Mizer, Esq., *Principal Deputy Assistant Attorney General and Head of the Civil Division, US Department of Justice; Former Counselor to Attorney General Eric H. Holder, Jr., Washington, DC*



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

8:45 am

Keynote: Transparency International's New Pharma Industry Initiative



Robert Barrington, PhD, *Executive Director, Transparency International-UK, London, UK*



Introduction by Jack Tanselle, MBA, *Managing Director, Navigant Consulting, Inc., Indianapolis, IN*

9:15 am

Qui Tam Panel



Jillian Estes, Esq., *Partner, James Hoyer Newcomer & Smiljanich, PA; Former Attorney, International Division, National Center for Missing and Exploited Children, Tampa, FL*



Loren Jacobson, Esq., *Partner, Waters & Kraus LLP, Dallas, TX*



Joseph Trautwein, Esq., *Joseph Trautwein & Associates LLC; Former Assistant US Attorney, Eastern District of Pennsylvania, Philadelphia, PA*



Jonathan Diesenhaus, Esq., *Partner, Hogan Lovells LLP; Former Senior Trial Counsel, Fraud Section, Civil Division, US Department of Justice, Washington, DC (Moderator)*

10:00 am

Recent Developments in the Debate over Off-Label Communications and the First Amendment



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



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

10:30 am

Networking Break

MINI SUMMITS BLOCK A 11:00 am – 12:00 pm

Mini Summit I: Managing Speaker Program Compliance: Benchmarking and Best Practices

Gregory Beeman, Lilly USA Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN

Ronni E. Fuchs, Esq., Partner, Pepper Hamilton LLP, Princeton, NJ

Raymond S. Wymierski, MBA, MJP, Associate Director, Compliance, Avanir Pharmaceuticals, Inc., Aliso Viejo, CA

Katherine Buckley, MBA, Principal, Pharmaceutical and Life Sciences Advisory Practice, PwC, Philadelphia, PA (Moderator)

Mini Summit II: R&D Compliance: Prepare Now for Future Enforcement

Dennis K. Barnes, JD, MBA, CPA, Vice President, Chief Compliance Officer, PAREXEL International, Waltham, MA

Paul Curtin, JD, CFE, Executive Director, R&D Compliance, Allergan; Former Head of Compliance - Ex-US, Forest Laboratories, Jersey City, NJ

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

George K. Ng, Esq., Executive Vice President & Chief Legal Officer, Sorrento Therapeutics, Inc., San Diego, CA

Yogesh Bahl, CPA, MBA, Managing Director, Alix Partners, New York, NY (Moderator)

Mini Summit III: Business Development Part 1: Mergers and Acquisitions — Preparing to be Acquired and Pre-Deal Due Diligence

Timothy Ayers, JD, MPH, Vice President, Chief Compliance Officer, Horizon Pharma plc; Former Vice President, Chief Compliance Officer, Dendreon, Chicago, IL

Justin Dillon, Senior Director - Compliance, Auditing & Monitoring, Incyte, Wilmington, DE

Michael B. Dusseau, Vice President, Compliance Operations, Allergan plc; Former Vice President, Compliance, Bayer, Parsippany, NJ

William I. Intner, Esq., Partner, Hogan Lovells LLP, Baltimore, MD

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

Mini Summit IV: Evaluating Compliance Program Effectiveness — Board Responsibilities, Board Advisors, and Compliance Experts

Thomas E. Costa, Esq., Compliance Consultant; Former Vice President, US Pharmaceuticals Compliance, Bristol-Myers Squibb, Yardley, PA

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

Lawrence P. Platkin, Vice President and Head, U.S. Compliance Center of Excellence, Bayer Corporation, Whippany, NJ

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

Mini Summit V: Payers and Providers Part 1: Evolving Healthcare Systems and Promotional Interactions

Chris Cobourn, Managing Director, Huron Consulting Group, New York, NY

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

Jeffrey Rosenbaum, MBA, Senior Vice President, Chief Compliance and Risk Officer, Shire; Former Chief Compliance Officer, Vertex Pharmaceuticals, Lexington, MA

Brian Riewerts, MPA, Partner, Global Pharmaceuticals and Life Sciences, PwC, Philadelphia, PA (Moderator)

Mini Summit VI: Patient Support Programs Part 1: Getting Closer to the Patient

Thomas M. Glavin, Esq., Vice President, Deputy Compliance Officer, Shire, Philadelphia, PA

Stephen M. Lawniczak, Esq., Senior Counsel, AbbVie, Chicago, IL

Alison Fethke, Esq., Counsel, Health Care Group, Ropes & Gray, Chicago, IL (Moderator)

12:00 pm NETWORKING LUNCHEON

MINI SUMMITS BLOCK B 1:15 pm – 2:15 pm

Mini Summit VII: Predictive Analytics

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

Mark Linver, MS, Managing Director, Huron Consulting Group, New York, NY (Moderator)

Mini Summit VIII: Coordinating Risk Management across the Control Functions: Audit, Compliance, Finance, Legal, Regulatory and Quality — An Opportunity to Leverage Technology

John Conrad, Principal, Deloitte, Philadelphia, PA

Mini Summit IX: Managing Multi-National HCP Meetings: Complying with the Codes and Transparency Requirements

Jodie Gillon, MPH (Invited), Head, External Interface Office, AstraZeneca, New York, NY

Tali Guy, Esq., Senior Director, Global R&D Compliance Officer, Teva Pharmaceutical Industries Ltd., Petah Tikva, Israel

Marc Eigner, MBA, MS, Senior Partner and Co-Founder, Polaris, New York, NY (Moderator)

Mini Summit X: Business Development Part 2: Mergers and Acquisitions — Post-Deal Due Diligence and Integration Challenges

Corey R. Amundson, Esq., First Assistant United States Attorney and Chief, Criminal Division, United States Attorney's Office, Middle District of Louisiana, Baton Rouge, LA

Jeffrey L. Handwerker, Esq., Partner, Arnold & Porter LLP, Washington, DC

Mark A. Jensen, Esq., Partner, Special Matters and Government Investigations Team, King & Spalding, Washington, DC

Joanne Lahner, Esq., Vice President, GHH Compliance, Merck & Co., Inc., North Wales, PA

Maureen McGirr, Esq., Vice President, Office of Ethics, Global Compliance Organization, Merck & Co., Inc., Kenilworth, NJ (Moderator)

Mini Summit XI: The Impact of Public Disclosures on Operations and Processes within Life Science Organizations

Michael O'Connor, MS, Senior Director, Compliance and Ethics, Alexion Pharmaceuticals, Inc., Cheshire, CT

Gus Papandrikos, MBA, Senior Director, Compliance, Daiichi Sankyo, Parsippany, NJ

William Buzzeo, MS, General Manager, US Compliance, IMS Health, Plymouth Meeting, PA (Moderator)

Mini Summit XII: Patient Support Programs Part 2: Patient Services: Privacy and Pharmacovigilance Considerations

William Greenrose, MA, MBA, Director, Advisory - Governance Regulatory and Risk Strategies Practice, Deloitte & Touche, LLC, Boston, MA

Megan Mikkelsen, CIPP/US, CHPS, Director, US Chief Privacy Officer, Teva Pharmaceuticals, Kansas City, MO

Terra L. Reynolds, Esq., Of Counsel, Litigation Department, Paul Hastings LLP; Former Assistant U.S. Attorney, Northern District of Illinois, Chicago, IL

Stephanie Wisdo, Esq., Corporate Attorney, Otsuka America Pharmaceutical, Inc., Princeton, NJ

Regina Gore Cavaliere, Esq., Principal, Advisory, KPMG; Former Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Short Hills, NJ (Moderator)

2:15 pm Transition 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 SUMMITS BLOCK C 2:30 pm – 3:30 pm

Mini Summit XIII: Innovation in Training and Communications

Jayson Dukes, Senior Managing Director, FTI, New York, NY

Margaret K. Feltz, MA, JD, Executive Director, Corporate Compliance, Purdue Pharma LP; Former Member, PCF Executive Committee, Stamford, CT

Matthew Ruble, MS, Senior Manager, Grant Thornton, Philadelphia, PA (Moderator)

Mini Summit XIV: Compliance Considerations when Evaluating Non-Traditional HCP Compensation Arrangements: Royalties, Stock Options, and Licensing Agreements

Stuart A. Neiberg, MAcc, CPA, CFA, Director, HealthCare Appraisers, Delray Beach, FL

Lee H. Rosebush, JD, PharmD, MS, MBA, Pharmacy Team Leader and FDA Partner, Baker & Hostetler LLP, Washington DC

Ann S. Brandt, PhD, Partner, HealthCare Appraisers, Inc., Delray Beach, FL (Moderator)

Mini Summit XV: New Product Launches and the Pre-Launch Period — Strengthening the Partnership with the Business

Terri Ledva, MS, Senior Manager Compliance, Iroko Pharmaceuticals LLC, Philadelphia, PA

Kari Loeser, Esq., Senior Counsel, Jazz Pharmaceuticals, Palo Alto, CA

Fernando Villegas, MS, Director, Oncology Marketing, Jazz Pharmaceuticals, Palo Alto, CA

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

Mini Summit XVI: Business Development Part 3: Joint Ventures and Co-Promotion Arrangements

Kathleen Hamill, Esq., Assistant General Counsel, Johnson & Johnson, Philadelphia, PA

Kellie Combs, Esq., Counsel, Ropes & Gray, Washington, DC (Moderator)

Mini Summit XVII: Marketing and Medical Affairs: Where is the Line in the Sand?

Mark A. DeWyngaert, MBA, PhD, Managing Director, Huron Consulting Group, New York, NY (Moderator)

Mini Summit XVIII: Structuring Specialty Pharmacy Distribution Arrangements in a Turbulent Regulatory Environment

Thomas Beimers, Esq., Healthcare, Compliance, and Government Investigations Attorney at Faegre Baker Daniels LLP, Minneapolis, MN

John “Jack” S. Linehan, Esq., Healthcare Attorney, Epstein Becker & Green, Washington, DC (Moderator)

Mini Summit XIX: Payers and Providers Part 2: Value Propositions in Contractual Relationships — Real World Evidence, Outcomes Research, and Comparative Effectiveness

Kathleen Peterson, Esq., Special Counsel, Cooley LLP, Washington, DC

BJ D’Avella, MBA, Senior Director, Huron Consulting Group, New York, NY (Moderator)

3:30 pm Networking Break

CLOSING PLENARY SESSION

4:00 pm Update from CMS on Open Payments



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, Baltimore, MD



Introduction by Paul Silver, Practice Leader and Managing Director, Huron Consulting Group, Atlanta, GA

4:30 pm



Consolidation, Vertical Integration and Cross-Border Business: Confronting “Next Generation” Compliance Priorities

Barbara Rowland, Esq., Principal, Internal Investigations and White Collar Defense Group, Post & Schell, PC, Washington, DC



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

5:15 pm



Millennials and the Future of Ethics and Compliance Programs: New Technologies and Eternal Issues

Professor Ann E. Tenbrunsel, Author of Blind Spots: Why We Fail to Do What’s Right, and What We Can Do about It (with Max Bazerman); David E. Gallo Professor of Business Ethics, University of Notre Dame; Rex and Alice A. Martin Research Director of the Institute for Ethical Business Worldwide, Notre Dame, IN



Sujata Dayal, Esq., 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



Amy O’Connor, MPP (Invited), Senior Director, Digital and Social Media Communications, Eli Lilly and Company, Indianapolis, IN



Jeremy Perisho, Partner and US FAS Leader, Life Sciences & Health Care, Deloitte Financial Advisory Services LLP, Boston, MA (Moderator)

6:30 pm

Adjournment

FRIDAY, OCTOBER 23, 2015

PHARMA CONGRESS: AGENDA DAY III

INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK (Industry-only session for pharmaceutical company compliance professionals and in-house counsel only)

8:30 am

Introduction to Day Three



Matthew D’Ambrosio, JD, MBA, Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc., Marlborough, MA (Co-chair)



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



Elizabeth V. Jobes, Esq., Head of Corporate Counsel and Legal Counsel, Spark Therapeutics, Philadelphia, PA (Co-chair)

Including an Update from PhRMA



Jeff Francer, Esq., Vice President and Senior Counsel, PhRMA; Former Associate Chief Counsel, Food and Drug Administration, Washington, DC



Lauren K. Roth, Esq., Assistant General Counsel, PhRMA, Washington, DC

Noon CONGRESS ADJOURNMENT

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Margaret Jackson, MS, National Industry Marketing Director, Grant Thornton LLP, Raleigh, NC

Michael Joachim, Esq., Head of Global Corporate Compliance, Genzyme, a Sanofi Company, Cambridge, MA

Jeffrey S. Klimaski, MBA, CPA, Vice President, Global Ethics and Compliance Officer, BTG International Inc., Philadelphia, PA

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

Jeremy Perisho, Partner and US FAS Leader, Life Sciences & Health Care, Deloitte Financial Advisory Services LLP, Boston, MA

Lori Queisser, Senior Vice President and Global Chief Compliance Officer, Teva Pharmaceuticals, Horsham, PA

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Jeffrey Rosenbaum, MBA, Senior Vice President, Chief Compliance and Risk Officer, Shire; Former Chief Compliance Officer, Vertex Pharmaceuticals, Lexington, MA

Michael Shaw, Esq., Vice President and Compliance Officer, North America Pharmaceuticals & Global Franchises, GlaxoSmithKline, Philadelphia, PA

Glenna Shen, Esq., Head of Compliance, Onyx Pharmaceuticals, South San Francisco, CA

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David Vance, Esq., Senior Director Business Conduct, Noven Pharmaceuticals, Inc., Miami, FL

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SELECT YOUR MINI-SUMMITS – Thursday, October 22 (One from each group):

- | | | |
|---|--|---|
| <p>BLOCK A – 11:00 am</p> <ul style="list-style-type: none"> <input type="checkbox"/> I: Managing Speaker Program Compliance ... <input type="checkbox"/> II: R&D Compliance ... <input type="checkbox"/> III: Business Development Part 1 ... <input type="checkbox"/> IV: Evaluating Compliance Program Effectiveness ... <input type="checkbox"/> V: Payers & Providers Part 1: Evolving Healthcare Systems ... <input type="checkbox"/> VI: Patient Support Part 1 ... | <p>BLOCK B – 1:15 pm</p> <ul style="list-style-type: none"> <input type="checkbox"/> VII: Predictive Analytics <input type="checkbox"/> VIII: Coordinating Risk Management ... <input type="checkbox"/> IX: Managing Multi-National HCP Meetings ... <input type="checkbox"/> X: Business Development Part 2 ... <input type="checkbox"/> XI: Impact of Public Disclosures ... <input type="checkbox"/> XII: Patient Support Part 2 ... | <p>BLOCK C – 2:30 pm</p> <ul style="list-style-type: none"> <input type="checkbox"/> XIII: Innovation in Training ... <input type="checkbox"/> XIV: Compliance Considerations ... <input type="checkbox"/> XV: New Product Launches ... <input type="checkbox"/> XVI: Business Development Part 3 ... <input type="checkbox"/> XVII: Marketing & Medical ... <input type="checkbox"/> XVIII: Structuring Specialty Pharmacy Distribution ... <input type="checkbox"/> XIX: Payers & Providers Part 2: Value Propositions ... |
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