SEVENTEENTH ANNUAL Pharmaceutical and Medical Device Compliance Congress

TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

CO CHAIRS:
- Timothy Ayers, JD, MPH, Vice President, Chief Compliance Officer, Horizon Pharma plc
- Joseph Boyd, Director, Commercial Planning and Operations, Primus Pharmaceuticals, Inc.
- Matthew D'Ambrosio, JD, MBA, Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc.

CHIEF COMPLIANCE OFFICER ROUNDTABLE:
- Jill Fallows-Macaluso, JD, Vice President and Chief Compliance Officer, Novo Nordisk
- Jonathon Kellerman (Invited), Executive Vice President, Global Chief Compliance Officer, Allergan PLC
- Angela P. Main, Vice President, Global Chief Compliance Officer and Associate General Counsel, Zimmer Biomet

CHIEF COMPLIANCE OFFICER MEETING (Special Morning Session on October 19; Invitation-only)

KEYNOTE SPEAKERS:
- James Gibney, Senior Director of Compliance, Regeneron Pharmaceuticals
- Jeffrey Kawalek, MBA, Associate Director, Compliance Risk, Novo Nordisk
- Glenna Shen, JD, MBA, Executive Director, Worldwide Compliance and Business Ethics, Amgen Inc.

CONTINUING EDUCATION CREDITS:
- Accounting Professionals: Approved for up to 16.50 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 Pennsylvania MCLE Credit.

GOLD GRANTOR: Huron Life Sciences

SILVER GRANTORS: Deloitte, EY, Navigant, PwC

BRONZE GRANTORS: Cooley, AlixPartners, Arnold & Porter LLP, Hogan Lovells, Paul Hastings, Polaris LifeSciences, Ropes & Gray, Sidley Austin

CHIEF COMPLIANCE OFFICER SESSIONS:
- Transformative Learning — Effective Knowledge Exchange
  - Thomas W. Abrams, RPh, MBA, Director, Office of Prescription Drug Promotion, Food and Drug Administration
  - Joseph Beemsterboer, JD, Deputy Chief, Health Care Fraud Unit, Criminal Division, US Department of Justice, Washington, DC
  - Sophie Peresson, LLM, MA, Director, Pharmaceuticals & Healthcare Programme, Transparency International UK
  - Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, US Department of Health and Human Services

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 Vice President, Pharma and Medical Device Content, Global Health Care - Life Sciences, LLC, it is my pleasure to invite you to attend the 2016 Seventeenth Annual Pharmaceutical and Medical Device Compliance Congress 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, Sun City Center, FL

ABOUT THE CONGRESS SPONSOR

The Pharmaceutical Compliance Forum (PCF) is a coalition of senior compliance professionals and legal counsel from almost 60 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 several times a year, 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.

AGENDA AT A GLANCE

Wednesday, October 19, 2016
7:30 am  Congress Registration
8:00 am – 11:30 am  PRECONFERENCE SYMPOSIA (Optional, Choose only one):
8:30 am – 11:30 am  CHIEF COMPLIANCE OFFICER MEETING (Invitation Only)

OPENING PLENARY SESSION
1:00 pm  Welcome & Introduction
1:05 pm  Overview of the Pharmaceutical Marketplace & Politics in the United States
1:45 pm  Chief Compliance Officer Roundtable
2:45 pm  Break
3:05 pm  Keynote: Annual OIG Update
3:40 pm  FCPA Enforcement Panel
4:15 pm  Annual AUSA Roundtable
5:00 pm  Annual FDA-OPDP Update
5:30 pm  ADJOURNMENT & NETWORKING RECEPTION

Thursday, October 20, 2016
7:00 am  Registration Opens; Continental Breakfast in Exhibit Hall
8:00 am  Welcome to Day 2 Morning Plenary Session
8:10 am  Keynote: Transparency International
8:40 am  Behind the Bribe: Multiple Real-World Perspectives . . .
9:20 am  Truthful & Non-Misleading Communications & Recent First Amendment Cases
10:00 am  Break
10:30 am – 11:30 am  MINI SUMMITS BLOCK A

MS I: Compliance Considerations for Managed Markets . . .
MS II: R&D Compliance
MS III: New Ethics-Based Approaches to Policies

11:30 am  NETWORKING LUNCHEON
12:30 pm – 1:30 pm  MINI SUMMITS BLOCK B

MS VII: Leveraging Publicly Available Data . . .
MS VIII: Reimbursement Support, Patient Assistance . . .
MS IX: Medical Affairs

1:30 pm  Transition Break
1:45 pm – 2:45 pm  MINI SUMMITS BLOCK C

MS XIII: Managed Markets Risk Assessment & Monitoring
MS XIV: Beyond Transparency
MS XV: Hubs & Specialty Pharmacy Arrangements

2:45 pm  Networking Break

CLOSING PLENARY SESSION
3:15 pm  Welcome to Closing Plenary Session
3:20 pm  Driving the Evolution of Compliance Programs into Systems Supporting Business Integrity
4:00 pm  Recent Developments in Executive Liability Cases: Vascular Solutions, Warner-Chilcott, & Acclarent
4:40 pm  Current Initiatives from the Trade Associations
5:30 pm  Adjournment

Friday, October 21, 2016: 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.

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 SYMPOSIA (Optional, Choose only one)

7:30 am Congress Registration

PRECONFERENCE I: Managed Markets 101: Overview of the US Payment Systems for Pharmaceuticals
8:00 am Welcome and Overview
Private and Employer-sponsored Payer System Basics
- Key Insurance Players
- Self-funded and fully-funded commercial plans
- Commercial insurance carriers
- Exchange plans
- Managed Federal health care program plans
- Other Key Players
- Wholesalers
- PBMs and GPOs
- Retail and Specialty Pharmacies
- Formularies, Contracts and Discounting Arrangements
Market Access Activities and Communications
- Patient Access Programs
- Drug assistance programs
- Co-pay and coupon cards
- Hub Services
- Current Options for Communicating Health Economic Information
- Data Purchasing
- Ancillary Services

Meenakshi Datta, JD, Partner, Sidley Austin LLP, Chicago, IL
Neil DeHenes, Senior Manager, Deloitte & Touche LLP, Tampa, FL

9:30 am Break

10:00 am Government Payer Systems
- Medicaid Best Price Reporting and Rebates
- Medicare Parts B and D
- VA and the Federal Supply Schedule
- 340B Program

Chris Cobourn, Managing Director, Huron Consulting Group, New York, NY
John Shakow, JD, Partner, FDA and Life Sciences Practice, King & Spalding, Washington, DC

11:30 am Preconference Adjournment

PRECONFERENCE II: Being Prepared for External Investigations, Subpoenas, and OIG Monitor Interactions

8:00 am Welcome and Overview
Sarah diFrancesca, JD, Associate, Cooley LLP, New York, NY (Moderator)

8:10 am Being Prepared for the Knock on the Door: Subpoenas and Domestic Investigations
Sarah diFrancesca, JD, Associate, Cooley LLP, New York, NY
Edward Glynn, MBA, Principal, EY, New York, NY

8:50 am Tactical Strategies in Negotiating with OIG in the Context of Investigations, CIAs, and Other Scenarios
Yogesh Bahl, CPA, MBA, Managing Director, Alix Partners, New York, NY
John Rah, JD, Partner, Morgan, Lewis & Bockius LLP, Washington, DC
Jon Smollen, JD, MA, Executive Vice President and Chief Compliance Officer, Endo International, Philadelphia, PA

9:30 am Break

10:00 am Considerations on the Use of Attorney Client Privilege
Kristin Graham Koehler, JD, Partner, Sidley Austin LLP, Washington, DC

10:30 am International and Multi-National Investigations
Michael K. Loucks, JD, Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, United States Department of Justice, Washington, DC

11:00 am Considerations for Self-Reporting
Nathaniel B. Edmonds, JD (Invited), Partner, Paul Hastings; Former Assistant Chief, Foreign Corrupt Practices Act Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC

11:30 am Preconference Adjournment

PRECONFERENCE III: Advanced Global Compliance Issues

8:00 am Welcome and Overview

8:10 am European Transparency and Compliance Monitoring Evolution
George Fife, Executive Director, Fraud Investigation and Dispute Services, EY; Former Executive Director, Compliance & Ethics, Bristol-Myers Squibb, Paris, France

8:50 am Standardizing an FMV Process for HCP Payments Globally
Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY

9:30 am Break

9:50 am EFPIA Data Demonstrates the Challenges Confronting Companies
Jeffrey Campbell, JD, President, Porzio Life Sciences, LLC, Morristown, NJ
Brian Sharkey, JD, Vice President, Porzio Life Sciences, LLC, Morristown, NJ

10:30 am Emerging Trends in Latin America
Colleen A. Conry, JD, Partner, Ropes and Gray; Former Senior Litigation Counsel, Fraud Section, Criminal Division, United States Department of Justice, Washington, DC

11:00 am Recent Developments in Asia and China
David J. Ludlow, JD, Partner, Sidley Austin LLP, Washington, DC

11:30 am Preconference Adjournment
### WEDNESDAY, OCTOBER 19, 2016

**CHIEF COMPLIANCE OFFICER MEETING**
*(Special Morning Session; Invitation-only)*

- **8:30 am** Breakfast
- **9:00 am** Welcome and Antitrust Admonition
  - Matthew D’Ambrosio, JD, MBA, Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc., Marlborough, MA
  - Jennifer McGee, JD, Chief Compliance Officer, Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD
  - Lori Queisser, JD, Senior Vice President and Global Chief Compliance Officer, Teva Pharmaceuticals; Former Member, PCF Executive Committee; Former Senior Vice President, Global Compliance and Business Practices, Schering-Plough; Former Vice President, Chief Compliance Officer, Eli Lilly, Horsham, PA
  - Michael L. Shaw, JD, Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals; Former Member, PCF Executive Committee; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, Philadelphia, PA
- **11:30 am** CCO Meeting Adjournment

**HOTEL INFORMATION/RESERVATIONS**

- The Mandarin Oriental, Washington DC is the official hotel for the 17th Annual Pharmaceutical and Medical Device Compliance Congress. A special group rate of $315.00 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 September 20, 2016. After this date, reservations will be accepted on a space-available basis at the prevailing rate.
- The Mandarin Oriental, 1330 Maryland Avenue SW, Washington, DC 20024

**WEDNESDAY, OCTOBER 19, 2016**

**PHARMA CONGRESS: AGENDA DAY I**

1:00 pm Welcome and Introduction
- Matthew D’Ambrosio, JD, MBA, Senior Vice President, Chief Compliance and Ethics Officer, Sunovion Pharmaceuticals, Inc., Marlborough, MA (Co-chair)
- Glenna Shen, JD, MBT, Executive Director, Worldwide Compliance and Business Ethics, Amgen Inc., Thousand Oaks, CA (Co-chair)

1:05 pm Overview of the Pharmaceutical Marketplace and Politics in the United States
- Scott Gottlieb, MD *(Invited)*, Resident Fellow, American Enterprise Institute; Columnist and Blogger, Forbes Magazine; Former Deputy Commissioner for Medical and Scientific Affairs, Food and Drug Administration, Washington, DC
- John Rother, JD, President and Chief Executive Officer, National Coalition on Health Care; Former Executive Vice President for Policy, Strategy, and International Affairs, American Association of Retired Persons (AARP); Former Chief Counsel, United States Senate Special Committee on Aging, Washington, DC

1:45 pm Chief Compliance Officer Roundtable
- Jill Fallows-Macaluso, JD, Vice President and Chief Compliance Officer, Novo Nordisk Inc., Princeton, NJ
- Jonathon Kellerman *(Invited)*, Executive Vice President, Global Chief Compliance Officer, Allergan PLC, Parsippany, NJ
- Angela P. Main, MA, Vice President, Global Chief Compliance Officer and Associate General Counsel, Zimmer Biomet; Former Senior Legal Counsel Covidien Pte Ltd, Washington, DC

### PHARMACEUTICAL AND MEDICAL DEVICE COMPLIANCE CONGRESS DATES & LOCATION

**September 20-21, 2016**

The Pharmaceutical and Medical Device 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.

**For more information, please visit:**

www.PharmaCongress.com
THURSDAY, OCTOBER 20, 2016

PHARMA CONGRESS: AGENDA DAY II

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

MORNING PLENARY SESSION

8:00 am Welcome to Day 2 Morning Plenary Session

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

8:10 am Keynote: Transparency International

Sophie Peresson, LL.M., MA, Director, Pharmaceuticals & Healthcare Programme, Transparency International UK, London, UK

8:40 am Behind the Bribe: Multiple Real-World Perspectives on How Foreign Bribery Occurs, Is Investigated, and Could Be Prevented

Richard Bistrong, Chief Executive Officer, Front-Line Anti-Bribery LLC, Contributing Editor, The FCPA Blog, New York, NY

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

9:20 am Truthful and Non-Misleading Communications and Recent First Amendment Cases

Floyd Abrams, JD, Partner, Cahill Gordon & Reindel LLP, Represented Amarin Corporation in Amarin Pharma, Inc. et al. v. FDA et al. No. 15-3588 (S.D.N.Y. May 7, 2015), New York, NY

Kellie B. Combs, JD, Counsel, Ropes & Gray; Co-counsel to Medical Information Working Group, Represented Pacira Pharmaceuticals in Pacira Pharmaceuticals, Inc. v. FDA, 15-cf-07055 (SDNY Sept. 8, 2015), Washington, DC

Lisa Dwyer, JD, Partner, King & Spalding; Former Senior Policy Advisor, Office of Policy; Former Deputy Chief of Staff to the Commissioner, US Food and Drug Administration, Washington, DC

Joshua M. Sharfstein, MD, Associate Dean for Public Health Practice and Training, Johns Hopkins Bloomberg School of Public Health; Former Principal Deputy Commissioner; US Food and Drug Administration; Former Health Policy Advisor for Congressman Henry A. Waxman, Baltimore, MD

Colleen Klazmeier, JD, Partner, Sidley Austin LLP, Co-Counsel for Medical Information Working Group, Washington, DC (Moderator)

10:00 am Break

MINI SUMMITS BLOCK A 10:30 am – 11:30 am

Mini Summit I: Compliance Considerations for the Managed Markets Business

Blake Bolinger, JD (Invited), Director, US Pharmaceuticals, Compliance and Ethics, Bristol-Myers Squibb, Plainsboro, NJ

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

Jennifer McGee, JD, Chief Compliance Officer, Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD

Seth Lundy, JD, Partner, King and Spalding, Washington, DC (Moderator)

Mini Summit II: R&D Compliance

David Cromley, JD, Associate Vice President, Global Compliance Organization, Merck, North Wales, PA

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

Sue Seferian, JD, Global R&D Health Care Compliance Officer, Johnson & Johnson, New Brunswick, NJ

Michelle Shwery, MBA, Senior Advisor, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN

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

Mini Summit III: New Ethics-Based Approaches to Policies

Michael Ace, MS, Advisor, Ethics and Compliance, Global Policies and Standards, Eli Lilly and Company, Indianapolis, IN

James Massey, MS, Vice President, Global Compliance, Enablement and Assurance, AstraZeneca, Gaithersburg, MD

Seth B. Whitelaw, JD, PhD, President and Chief Executive Officer, Whitelaw Compliance Group, LLC; Editor, Life Science Compliance Update, West Chester, PA

Mini Summit IV: Organizational Design in an Expanding Global Transparency Landscape

Stacy Hornaday, Senior Manager, Deloitte & Touche LLP, Chicago, IL

Additional Panelists TBD

Clarissa Crain, Senior Manager, Life Sciences and Health Care, Deloitte & Touche LLP, Philadelphia, PA (Moderator)

Mini Summit V: Enhancing Third Party Oversight and Due Diligence

Anthony Alvizu, CPA, EnCE, CFE, Managing Director, Global Risk and Investigations Practice, FTI Consulting, Chicago, IL

Thomas E. Costa, JD, Compliance Consultant; Former Vice President U.S. Compliance and Ethics, Bristol-Myers Squibb, Princeton, NJ

Paul J. Peterson, CPA, CFE, CIA, CFF, Senior Manager, Forensic, Investigative and Dispute Services Practice, Grant Thornton LLP, McLean, VA (Moderator)

Mini Summit VI: Leveraging Analytics for Monitoring

Michaeline Daboul, President and Chief Executive Officer, MMIS, Inc., Medispend, Portsmouth, NH

Regina Gore Cavaliere, JD, Principal, Regulatory Enforcement and Compliance, Life Sciences Sector, KPMG LLP; Former Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical Inc., Short Hills, NJ

Amy Pawloski, CPE, CCE, Head of US Compliance and Ethics Monitoring and Data Analytics, Bristol-Myers Squibb, Plainsboro, NJ

Heather McCollum, JD, MHA, Director, Compliance, Shionogi, Inc., Florham Park, NJ (Moderator)

11:30 am NETWORKING LUNCHEON
MINI SUMMITS BLOCK B 12:30 pm – 1:30 pm

Mini Summit VII: Leveraging Publicly Available Data: Taking Open Payment Data a Step Further
Ellen Carman, Manager, Business Advisory Services, Life Sciences Sector, Grant Thornton LLP, Philadelphia, PA
Additional Panelists TBD

Mini Summit VIII: Reimbursement Support, Patient Assistance Programs, Coupons, and Charitable Foundations
Jeffrey Fleming, JD, Vice President and Chief Compliance Officer, Vertex Pharmaceuticals; Former Vice President Compliance North America and US Compliance Officer, AstaZeneca Pharmaceuticals LP, Boston, MA
Dana Kuhn, PhD, President, Patient Services Inc., Richmond, VA
Ann Beasley, JD, Director, Navigant; Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA (Moderator)

Mini Summit IX: Medical Affairs
Brian J. Conner, Director, Huron Consulting Group; Former Senior Director, Assistant Compliance Officer, Global Compliance, Shire Pharmaceuticals, Atlanta, GA
Kevin Ryan, JD, MS, Senior Director, Compliance: New Products, Novo Nordisk, Princeton, NJ
Kelly N. “Nikki” Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC (Moderator)

Mini Summit XI: What’s New for Training Programs
Jonathan Glazier, JD, MBA, Senior Legal Counsel, Legal Compliance, Philips Electronics North America, Andover, MA
Jill Mason, JD, Chief Compliance Officer, OrthoFix; Former Senior Global Compliance Director, St. Jude Medical, Dallas, TX
Steven Sitek, MEd, Ethics and Compliance Learning and Education, Novartis Pharmaceuticals Corporation, East Hanover, NJ
Gary Keilty, Managing Director, FTI Consulting, Health Solutions Practice, Washington, DC (Moderator)

Ela Bochenek, JD, Vice President, Global Compliance, Insmid Incorporated, Bridgewater, NJ
John DeMarrais, MBA, Managing Director, Deloitte & Touche LLP, Parsippany, NJ
Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC
Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY (Moderator)

1:30 pm Transition Break

ID 6

GET THE CONFERENCE APP ON YOUR MOBILE DEVICE!
2. Tap the “Download” button to download the free Guidebook app (mobile users can be texted a link)
3. Open Guidebook and get our “Pharma Congress” guide

MINI SUMMITS BLOCK C 1:45 pm – 2:45 pm

Mini Summit XIII: Managed Markets Risk Assessment and Monitoring
Additional Panelists TBD
Katherine Buckley, MBA, Principal, PwC Risk Consulting, Philadelphia, PA (Moderator)

Mini Summit XIV: Beyond Transparency: HCP Interaction Risk Management
Michael B. Dusseau, Vice President, Compliance Operations, Allergan plc, Parsippany, NJ
Erik Eglite, DPM, JD, MBA (Invited), Vice President, Chief Compliance Officer and Corporate Counsel, Marathon Pharmaceuticals; Former Vice President, Chief Compliance Officer and Corporate Counsel, Lundbeck, Chicago, IL
Kelly N. “Nikki” Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC
John Patrick Oroho, JD, Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ (Moderator)

Mini Summit XV: Hubs and Specialty Pharmacy Arrangements: Structuring Service Agreements
Sarah Anne Franklin, JD, Partner, Covington & Burling LLP, Washington, DC
Traci Coughlan, JD, Principal, Advisory Services, The Red Flag Group, Berlin, MD
Traci Coughlan, JD (Invited), Vice President, Compliance, Advanced Surgical Division and Latin America, Smith & Nephew, Andover, MA
Victoria Browning, CCEP, Compliance Officer, KARL STORZ North America, El Segundo, CA (Moderator)

Mini Summit XVI: The New Marketplace: Value-Based Contracting and Other New Developments
Jeffrey L. Handwerker, JD, Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC
Susan Lee, JD, Partner, Hogan Lovells LLP, Washington, DC
Mark DeWyngaert, MBA, PhD, Managing Director, Huron Life Sciences, New York, NY (Moderator)

Mini Summit XVII: The New Marketplace: Value-Based Contracting and Other New Developments
Jeffrey L. Handwerker, JD, Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC
Traci Coughlan, JD, Principal, Advisory Services, The Red Flag Group, Berlin, MD
Lori Reber, JD (Invited), Vice President, Compliance, Advanced Surgical Division and Latin America, Smith & Nephew, Andover, MA

Mini Summit XVIII: Evolution of Risk Assessment and Management Programs
Kara Bonitatibus, JD, Assistant General Counsel, Compliance Lead for Compliance Policy and Strategic Operations, Pfizer, Inc., New York, NY
Anthony Brennan, CPA, CFE (Invited), Senior Director, Governance, Metrics and Reporting, Health Care Compliance, Johnson & Johnson, Titusville, NJ
Kevin L. Espinoza, MBA, Global Vice President, Ethics and Compliance, BTG International; Former R&D Compliance Officer, Forest Laboratories (now Allergan), Durham, NC
Chris Morris, MBA, CPA, CFE, Managing Consultant, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant, Phoenix, AZ (Moderator)

2:45 pm Networking Break
CLOSING PLENARY SESSION

Welcome to Closing Plenary Session
Jeffrey Kawalek, MBA, Associate Director, Compliance Risk, Novo Nordisk, New York, NY (Co-chair)

Driving the Evolution of Compliance Programs into Systems Supporting Business Integrity
Eric Baim, JD, MA, Vice President, Head of Compliance US, Shire, Boston, MA
Maureen McGirr, JD, Vice President, Office of Ethics, Global Compliance Organization, Merck & Co., Inc., Kenilworth, NJ
Doug Worthington, JD, Vice President, Compliance & Ethics, US, Bristol-Myers Squibb, Princeton, NJ
Kris Curry, MBA, Principal, Fraud Investigation and Dispute Services, EY; Former Vice President, Health Care Compliance, Pharmaceuticals Group, Johnson & Johnson, Philadelphia, PA (Moderator)

Recent Developments in Executive Liability Cases: Vascular Solutions, Warner-Chilcott, and Acclarent
John W. Lundquist, JD, Shareholder, Fredrikson and Byron, P.A.; Defense Counsel for Howard Root, CEO, Vascular Solutions, Inc., Minneapolis, MN
Joseph F. Savage, Jr., JD, Partner, Goodwin Procter LLP; Defense Counsel for W. Carl Reichel, Former President, Warner Chilcott, Boston, MA

Current Initiatives from the Trade Associations
Chrisoula Nikidis, Executive Director, Ethics and Compliance, Innovative Medicines Canada; Industry Co-Chair Designate, APEC Biopharmaceutical Working Group on Ethics, Ottawa, Canada
Deborah M. Shelton, JD, Deputy General Counsel, Biotechnology Innovation Organization (BIO); Former Senior Counsel, Amgen, Washington, DC
James Stansel, JD, Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA); Former Partner, Sidley Austin LLP; Former Acting General Counsel, US Department of Health and Human Services, Washington, DC
Christopher L. White, JD, Senior Executive Vice President and General Counsel, Advanced Medical Technology Association (AdvaMed), Washington, DC
Alexis Wong, Director, PwC Risk Consulting, Denver, CO (Moderator)

Adjournment

2016/2017 GLOBAL PHARMA COMPLIANCE CONGRESSES

Washington, DC
October 2016
Lisbon
May 2016
Warsaw
May 2016
Singapore
September 2016

Map courtesy of University of Alabama
FRIDAY, OCTOBER 21, 2016

PHARMA CONGRESS:
AGENDA DAY III

INDUSTRY-ONLY COMPLIANCE 
BEST PRACTICES THINK TANK

(Industry-only Session for Pharmaceutical Company Ethics and Compliance Professionals and In-house Counsel Only)

8:30 am 
Introductions and Antitrust Admition

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

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

Jeffrey Kawalek, MBA, Associate Director, Compliance Risk, Novo Nordisk, New York, NY (Co-chair)

Glenna Shen, JD, MBT, Executive Director, Worldwide Compliance and Business Ethics, Amgen Inc., Thousand Oaks, CA (Co-chair)

8:45 am 
Updates from BIO and PhRMA

John Murphy, JD, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, DC

Deborah M. Shelton, JD (Invited), Deputy General Counsel, Biotechnology Innovation Organization (BIO); Former Senior Counsel, Amgen, Washington, DC

10:00 am 
Break

10:30am 
Facilitated Small Group 
Best Practice Sharing on Key Topics

Noon 
CONGRESS ADJOURNMENT

2016 PCF PHARMA CONGRESS PLANNING COMMITTEE

Timothy Ayers, JD, MPH, Vice President, Chief Compliance Officer, Horizon Pharma plc; Former Vice President, Chief Compliance Officer, Dundrean, Chicago, IL (Co-chair)

Joseph Boyd, Director, Commercial Planning & Operations, Primas Pharmaceuticals, Inc.; Former Director, Operations, Ethics & Compliance Department, Astellas US LLC, Scottsdale, AZ (Co-chair)

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

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

Jeffrey Kawalek, MBA, Associate Director, Compliance Risk, Novo Nordisk, New York, NY (Co-chair)

Glenna Shen, JD, MBT, Executive Director, Worldwide Compliance and Business Ethics, Amgen Inc., Thousand Oaks, CA (Co-chair)

Eric Baim, Vice President, Head of Compliance US, Shire, Boston, MA

Scott Bass, JD, Partner and Head, Global Life Sciences Team, Sidley Austin LLP, Washington, DC

John T. Bentivoglio, JD, Partner, Skadden Arps LLP, Washington, DC

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

Ann Beasley, JD, Director, Navigant; Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA

Thomas Beimers, JD, Partner, Hogan Lovells, Minneapolis, MN

Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY

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