SEVENTEENTH ANNUAL

Pharmaceutical and Medical Device Compliance Congress

TRANSFORMATIONAL LEARNING – EFFECTIVE KNOWLEDGE EXCHANGE

GHC LIFE SCIENCES
Global Health Care, LLC

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.*

James Gibney, *Senior Director of Compliance, Regeneron Pharmaceuticals*

Jeffrey Kawalek, MBA, *Associate Director, Compliance Risk, Novo Nordisk*

Glenna Shen, JD, MBT, *Executive Director, Worldwide Compliance and Business Ethics, Amgen 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*

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

Michael L. Shaw, JD, *Vice President and Compliance Officer, GlaxoSmithKline-NA Pharmaceuticals*

Caroline West, JD, *Global Chief Compliance Officer, Olympus Corporation*

CHIEF COMPLIANCE OFFICER MEETING

(Special Morning Session on October 19; Invitation-only)

KEYNOTE SPEAKERS:

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*

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.

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Onsite:

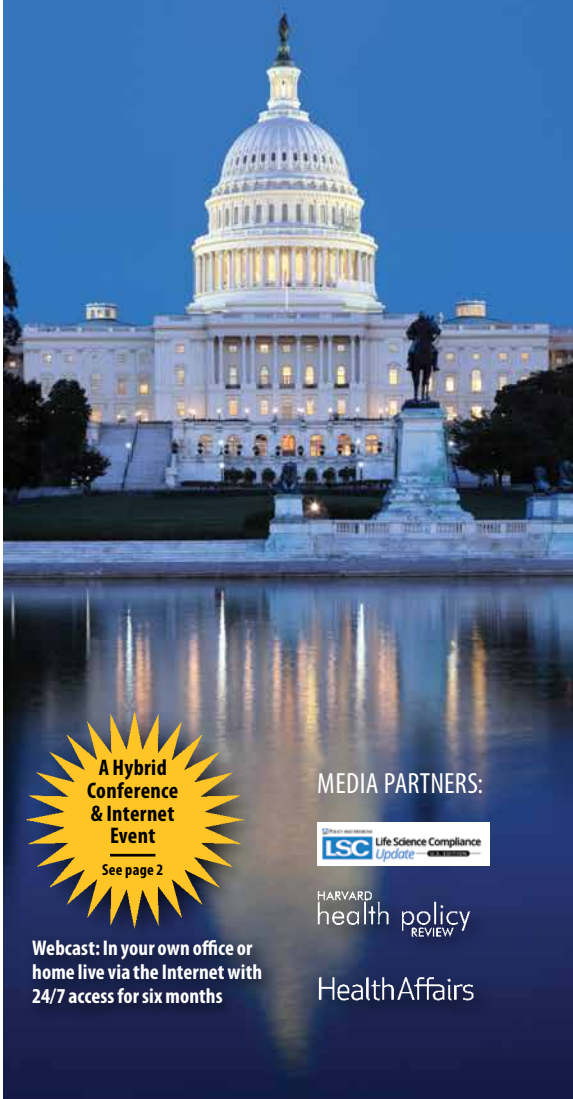
October 19 – 21, 2016

Washington, DC Mandarin Oriental

SPONSOR:

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

MEDIA PARTNERS:

LSC Life Science Compliance Update

HARVARD health policy REVIEW

HealthAffairs

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**.

THE PHARMACEUTICAL COMPLIANCE FORUM

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):*

I: Managed Markets 101 **II:** Being Prepared for External Investigations . . . **III:** Advanced Global Compliance Issues

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

MORNING PLENARY SESSION

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
MS IV: Organizational Design in an Expanding . . . Landscape
MS V: Enhancing Third Party Oversight & Due Diligence
MS VI: Leveraging Analytics for Monitoring

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

MS VII: Leveraging Publically Available Data . . .
MS VIII: Reimbursement Support, Patient Assistance . . .
MS IX: Medical Affairs
MS X: Compliance 2.0: Shared Ownership . . .
MS XI: What's New for Training Programs
MS XII: Advanced Issues in Third Party Relationships . . .

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
MS XVI: Advanced Compliance Issues for Medical Devices . . .
MS XVII: The New Marketplace . . .
MS XVIII: Evolution of Risk Assessment & Mgt. Programs

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

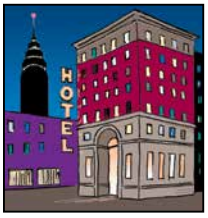
Friday, October 21, 2016: INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK, 8:30 am – Noon

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.



Onsite

LIVE AND ARCHIVED INTERNET ATTENDANCE

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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.

At your office . . .

. . . 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

WEDNESDAY, OCTOBER 19, 2016

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, *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**

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 Reitred 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*

Lori Queisser, *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*

Caroline West, JD, *Global Chief Compliance Officer, Olympus Corporation; Former Senior Vice President, Chief Compliance and Risk Officer, Shire, Philadelphia, PA*

Paul Silver, *Practice Leader and Managing Director, Huron Life Sciences, Atlanta, GA (Moderator)*

2:45 pm **Break**

3:05 pm **Keynote: Annual OIG Update**

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

3:40 pm **FCPA Enforcement Panel**

Joseph Beemsterboer, JD, *Deputy Chief, Health Care Fraud Unit, Criminal Division, US Department of Justice, Washington, DC*

Kara Brockmeyer, JD (Invited), *Chief, FCPA Unit, US Securities & Exchange Commission, Washington, DC*

Gejaa Gobena, JD, *Partner, Hogan Lovells; Former Deputy Chief, Criminal Division, Fraud Section, US Department of Justice, Washington, DC (Moderator)*

4:15 pm **Annual AUSA Roundtable**

Kenneth M. Abell, JD, *Assistant US Attorney, Chief, Civil Health Fraud, Eastern District of New York, US Department of Justice, New York, NY*

Jacob Elberg, JD, *Chief, Health Care and Government Fraud Unit, US Attorney's Office, District of New Jersey, US Department of Justice, Newark, NJ*

Gregg Shapiro, JD, *Assistant US Attorney, US Attorney's Office, District of Massachusetts, US Department of Justice, Boston, MA*

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

5:00 pm **Annual FDA-OPDP Update**

Thomas W. Abrams, RPh, MBA, *Director, Office of Prescription Drug Promotion, US Food and Drug Administration, Silver Spring, MD*

5:30 pm **ADJOURNMENT AND NETWORKING RECEPTION**

HOTEL INFORMATION/RESERVATIONS

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.

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 **Tuesday, September 20, 2016**. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

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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, LLM, 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*

George "Ren" McEachern, CFE, CAMS, *Supervisory Special Agent, US Federal Bureau of Investigation, Washington, DC*

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*

Coleen Klasmeier, 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, CPA, CCEP, *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 Publically 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

Lee Taurman, *Principal, National Life Sciences Advisory Leader, Grant Thornton LLP, Iselin, NJ (Moderator)*

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, AstraZeneca Pharmaceuticals LP, Boston, MA*

Dana Kuhn, PhD, *President, Patient Services Inc., Richmond, VA*

Ronald Wisor, JD, *Partner, Hogan Lovells, Washington, DC*

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 X: Compliance 2.0: Shared Ownership of Effective Compliance Across Business Functions

Additional Panelists TBD

Jack Tanselle, MBA, *Managing Director, Huron Life Sciences, Indianapolis, IN (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)*

Mini Summit XII: Advanced Issues in Third Party Relationships: Risk Assessments, Fair Market Value, Monitoring and Auditing of On-Going Relationships

Ela Bochenek, JD, *Vice President, Global Compliance, Insmed 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

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1. Go to http://guidebook.com/g/pharmacongress2016
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*

Thomas A. Gregory, CPA, CFA, *Partner, Fraud Investigation and Dispute Services, EY, Atlanta, GA*

John Linehan, JD, *Healthcare Attorney, Epstein Becker Green, Washington, DC*

Thomas W. Beimers, JD, *Partner, Hogan Lovells; Former Senior Counsel for Administrative and Civil Remedies, Office of the Inspector General, US Department of Health and Human Services, Minneapolis, MN (Moderator)*

Mini Summit XVI: Advanced Compliance Issues for Medical Devices: Working through Distributors

Jose M. Ayala, MBA, *Program Director, Global Channel Compliance, Medtronic, Minneapolis, MN*

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*

Victoria Browning, CCEP, *Compliance Officer, KARL STORZ North America, El Segundo, CA (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*

Susan Lee, JD (Invited), *Partner, Hogan Lovells LLP, Washington, DC*

Mark DeWyngaert, MBA, PhD, *Managing Director, Huron Life Sciences, New York, NY (Moderator)*

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

3:15 pm **Welcome to Closing Plenary Session**

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

3:20 pm **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)*

4:00 pm **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*

Reid H. Weingarten, JD, *Partner, Steptoe & Johnson LLP; Defense Counsel for William Facteau, Former CEO, Acclarent, Inc., Washington, DC*

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

4:40 pm **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*

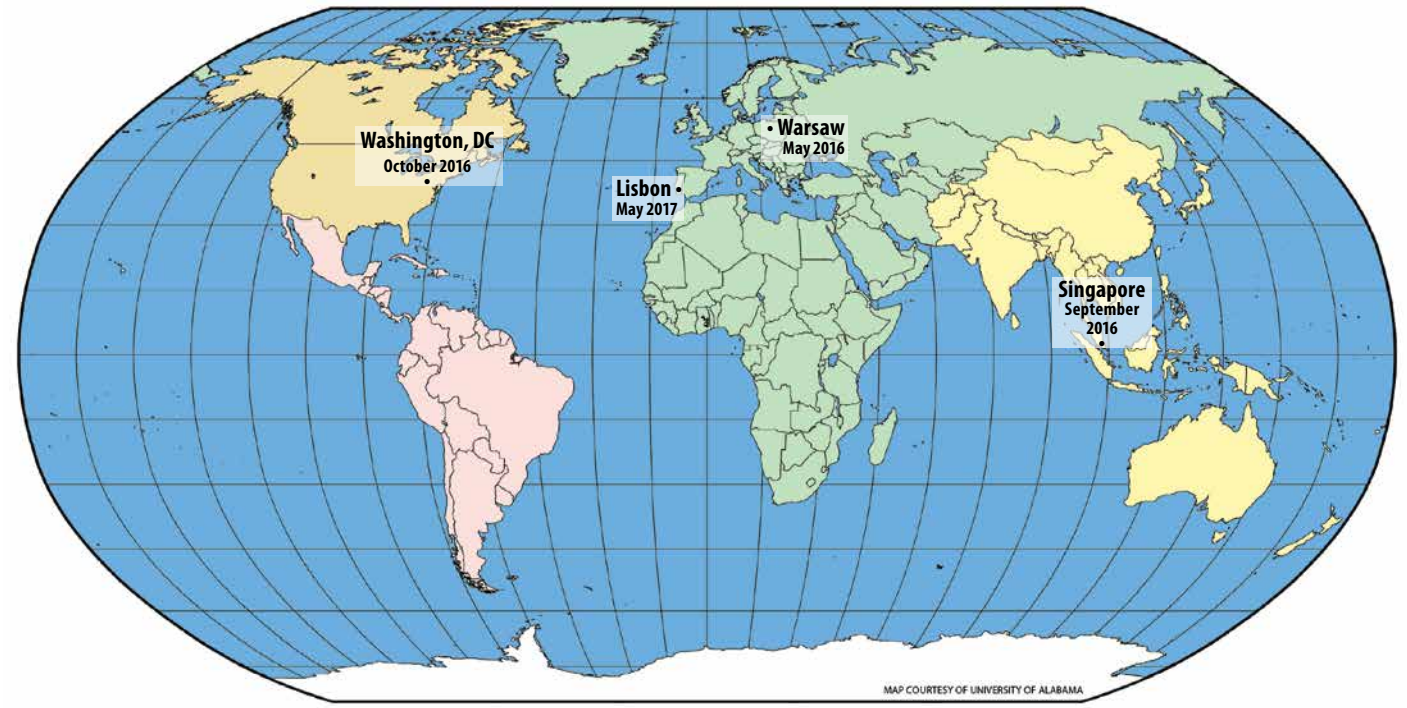
James Stansel, JD, *Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA); Former Partner, Sidley Austin LLP; Former Acting General Counsel, US Department of Health and Human Services, Washington, DC*

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)*

5:30 pm **Adjournment**

2016/2017 GLOBAL PHARMA COMPLIANCE CONGRESSES



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 Admonition**

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**

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Carlos Tessi, MD, PhD, *Vice President, Compliance, Shionogi, Inc., Florham Park, NJ*

Donna Wachman, *National Industry Marketing Leader, Grant Thornton LLP, Charlotte, NC*

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

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SELECT YOUR MINI-SUMMITS – Thursday, October 20 (One from each group):

BLOCK A – 10:30 am

❑ **I:** Compliance Considerations for Managed Markets . . .

❑ **II:** R&D Compliance

❑ **III:** New Ethics-Based Approaches to Policies

❑ **IV:** Organizational Design in an Expanding . . . Landscape

❑ **V:** Enhancing Third Party Oversight and Due Diligence

❑ **VI:** Leveraging Analytics for Monitoring

BLOCK B – 12:30 pm

❑ **VII:** Leveraging Publically Available Data . . .

❑ **VIII:** Reimbursement Support, Patient Assistance Programs, Coupons, and Charitable Foundations

❑ **IX:** Medical Affairs

❑ **X:** Compliance 2.0 . . .

❑ **XI:** What's New for Training Programs

❑ **XII:** Advanced Issues in Third Party Relationships . . .

BLOCK C – 1:45 pm

❑ **XIII:** Managed Markets Risk Assessment and Monitoring

❑ **XIV:** Beyond Transparency

❑ **XV:** Hubs and Specialty Pharmacy Arrangements

❑ **XVI:** Advanced Compliance Issues for Medical Devices . . .

❑ **XVII:** The New Marketplace . . .

❑ **XVIII:** Evolution of Risk Assessment and Management Programs

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