

18th Annual Pharmaceutical and Medical Device Compliance Congress

MANDARIN ORIENTAL • WASHINGTON, DC
NOVEMBER 6 - 8, 2017



**For Early Bird Registration
Discount Register by
Friday, September 22!**

CO CHAIRS:



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



Sujata T. Dayal, JD, Vice President, Health Care Compliance and Privacy, Pharmaceuticals Group, Johnson & Johnson



Jeffrey Kawalek, MBA, Senior Director, Ethics & Compliance, North America, Ipsen Biopharmaceuticals, Inc.



Jennifer McGee, JD, Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc.



Margaret Sparks, JD, Associate Vice President, North America Ethics and Business Integrity, Sanofi, US

KEYNOTE SPEAKERS:



Thomas W. Abrams, RPh, MBA, Director, Office of Prescription Drug Promotion, FDA



Charles Cain, Esq., Deputy Chief, FCPA Unit, US SEC



Susan Dentzer, President and Chief Executive Officer, NEHI; Health Policy Analyst, The NewsHour



Jacob T. Elberg, JD, Chief, Health Care and Government Fraud Unit, United States Attorney's Office, District of New Jersey, US DOJ



Tarek Helou, Esq., Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US DOJ



Colin M. Huntley, JD, Assistant Director, Fraud Section, Civil Division, US DOJ



Jason Mehta, JD, Assistant US Attorney, United States Attorney's Office Middle District of Florida, US DOJ



Pablo Quiñones, JD, Chief, Strategy, Policy and Training Unit, Fraud Section, Criminal Division, US DOJ



Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, OIG, HHS



Gregg Shapiro, JD, Assistant US Attorney, US Attorney's Office, District of Massachusetts, US DOJ



James Sheehan, JD, Chief, Charities Bureau, Attorney General of New York



Jim Stansel, JD, Executive Vice President & General Counsel, PhRMA



Darryl Wegner, JD, Unit Chief, International Corruption Unit, FBI

FEATURING AN INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK
AND AN INVITATION-ONLY CHIEF COMPLIANCE OFFICER ROUNDTABLE

SPONSOR:



**THE
PHARMACEUTICAL
COMPLIANCE
FORUM**

CONTINUING EDUCATION CREDITS:

Accounting Professionals: Approved for up to 18.5 NASBA CPE credits.

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

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

PLATINUM GRANTOR:

Deloitte.

SILVER GRANTORS:



BRONZE GRANTORS:



MEDIA PARTNERS:



OVERVIEW

Be a part of the premiere compliance event for pharmaceutical and medical device professionals at the 18th Annual Compliance Congress. Join compliance professionals, regulators, lawyers and consultants to share ideas for ways to cultivate a culture of compliance with the highest integrity enabling better care and outcomes for patients. This forum is ideal for compliance professionals new to developing a compliance program or experienced professionals continuing to evolve their programs to best suit their organization's needs to address new challenges.

The Congress is the oldest and largest gathering of pharmaceutical and medical device compliance professionals and in-house counsel who come together annually to discuss best practices in legal and regulatory compliance. It is a part of a global pharma compliance congress series which has featured congresses in Berlin, Brussels, Budapest, Dubai, Istanbul, Paris, Rome, Warsaw and Lisbon (the International Pharma Compliance Congress) Singapore, Shanghai, Kuala Lumpur and Manila (the Asia Pacific Pharma Compliance Congress); Sao Paolo and Mexico City (the Latin American Pharma Compliance Congress); and Washington, DC (the PCF Pharma Compliance Congress).

We would like to thank the Congress sponsor, the Pharmaceutical Compliance Forum (PCF), the 2017 PCF co-chairs, planning committee, grantors and exhibitors and faculty for their direction and insight into timely updates to applicable statutes, regulations and program requirements impacting our industry.

This year's Pharma Congress host esteemed keynote speakers including representatives of Office of Inspector General (OIG), Department of Justice (DOJ), Securities and Exchange Commission (SEC), Federal Bureau of Investigation (FBI), Food & Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America, PhRMA, Qui Tam Attorneys, and numerous Global Chief Compliance Officers.

These stakeholders together with our expert panelists and you bring together the brightest minds to engage in meaningful discussion, address timely compliance issues, and provide a rich opportunity for networking.

AGENDA AT A GLANCE

MONDAY, NOVEMBER 6, 2017

Morning Invitation-only CCO RoundTable

Morning Pre-conferences:

Advanced Medical Affairs Compliance Issues
The Basics of Managed Markets
Medical Device Best Practice Compliance Updates
Government Programs for the Compliance Officer

Afternoon Opening Plenary Session:

OIG Compliance Update
DOJ Evaluation of Corporate Compliance Programs
DOJ, SEC and FBI FCPA Enforcement Update
AUSA Roundtable
Chief Compliance Officer Roundtable
Networking Reception

TUESDAY, NOVEMBER 7, 2017

Morning Plenary Session:

FDA Compliance Update
Qui Tam Roundtable
Demonstrating the Value of the Compliance Organization

Morning Mini Summit Block A:

Using Behavioral Economics to Improve Compliance Messaging Stickiness
HCP Engagement: The Road to Proactive Risk Management
Best Practices for Patient Assistance and Reimbursement Support
Managed Market Considerations for Hub and Specialty Pharmacy Arrangements
Compliance and Ethics Considerations in R&D
Using Data Analytics to Tell the Compliance Effectiveness Story
International Organization for Standardization (ISO) 37001

Networking Luncheon/Luncheon Mini Summits:

FDA Regulation and Cutting Edge Technology
Advancing Compliance: Pulling Critical Levers to Improve Effectiveness
The Evolution of Compliance Programs after Wells Fargo
Innovation and Compliance, They are not Mutually Exclusive

Afternoon Mini Summit Block B:

Third Party Risk Management/Due Diligence Update
Compliance in the Transactional Context
Managing an Internal Investigation under CIA, DPA and Data Analytics Failure
Recent FDA Guidance: Manufacturer Communications and Off-Label Memo
Small and Mid-Sized Pharma and Device Companies Compliance Considerations
Advanced Issues in Global Compliance
Effective and Balanced Monitoring Program Based on Risk

Afternoon Mini Summit Block C:

Advanced Compliance Issues When Contracting with Third Parties
The Next Generation of Agg Spend Solutions
Cyber Security for Pharma and Medical Device Companies
Pricing Considerations (Mylan Epipen, Marathon Pharmaceuticals, et al)
Optimizing Data Collection for Risk Assessments, Monitoring, and Auditing
Balancing Risks in Patient and Product Support

Afternoon Closing Plenary Session:

Role of Behavioral Economics in Ethics and Compliance
PhRMA Priorities and Policy Initiatives
Overview of the Policy and Politics of Pharma Pricing
Rewarding Results: Value-Based Contracting for Biopharmaceuticals

WEDNESDAY, NOVEMBER 8, 2017: Morning Industry-only Compliance Best Practices Think Tank
(Industry-only session for pharmaceutical company compliance professionals and in-house counsel only)

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.



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

ABOUT THE PHARMACEUTICAL COMPLIANCE FORUM

ABOUT THE PHARMACEUTICAL COMPLIANCE FORUM

The Pharmaceutical Compliance Forum (PCF) is a not-for-profit membership coalition of compliance professionals and legal counsel from 70 distinguished research-based pharmaceutical manufacturers and biotech companies.

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 sponsors a three-day Compliance Congress each Fall.

Generally, representatives from the companies who attend the meetings are compliance officers, compliance attorneys or other professionals with responsibility for oversight or other aspects of their respective corporate compliance programs.

MISSION STATEMENT

The purpose of the Pharmaceutical Compliance Forum is to discuss education and other industry practices regarding compliance with the ultimate aim of promoting effective pharmaceutical corporate compliance and ethics programs in accordance with the Federal Organization Sentencing Guidelines and the OIG Compliance Guidance for Pharmaceutical Manufacturers.

JOIN PCF



Non-member companies who are interested in joining PCF may contact **Debra Scanlon**, Administrator, Pharmaceutical Compliance Forum at info@pharmacomplianceforum.org.

BENEFITS OF BECOMING A PCF COMPANY MEMBER

- Save \$500 off your first year's membership dues when becoming a member
- Unlimited number of employees can join- No additional fees! All included in your annual corporate membership dues.
- All members have access to our exclusive Member Only website for networking with fellow members and viewing of past meeting materials, benchmarking surveys and other valuable resources!
- Exclusive invitation to the members only PCF Annual Spring and complimentary Fall Regional Meetings
- Monthly newsletter to stay informed on the latest news and meeting information.
- Save up to \$500 with discounted registration fees for each employee to PCF sponsored Pharma Congress in Washington DC each year
- Save up to \$500 with discounted registration fees for each employee to PCF sponsored International Pharmaceutical Regulatory and Compliance Congress and the Asia Pacific Pharmaceutical and Medical Device Compliance Congress
- Complimentary compliance & legal job postings on the PCF website. A superior recruiting tool! Non-members companies pay \$600 per posting.
- Special PCF Member discount on subscriptions to Life Science Compliance Update.

For more information go to www.pharmacomplianceforum.org.

2017 PCF PHARMA CONGRESS PLANNING COMMITTEE

CO CHAIRS

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

Sujata T. Dayal, JD, Vice President,
Health Care Compliance & Privacy,
Pharmaceuticals Group, Johnson & Johnson

Jeffrey Kawalek, MBA, Senior Director,
Ethics & Compliance, North America, Ipsen

Jennifer McGee, JD, Vice President
and Chief Compliance Officer, Otsuka

Margaret Sparks, JD, Associate Vice
President, North America Ethics and Business
Integrity, Sanofi

MEMBERS

Tony Alvizu, FTI Consulting

Eric Baim, JD, Vice President,
Head of Compliance US, Shire

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

Yogesh Bahl, CPA, MBA,
Managing Director, Alix Partners

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

Thomas Beimers, JD,
Partner, Hogan Lovells

Andy Bender, MS, MBA,
President and Founder, Polaris

Kathleen M. Boozang, JD, LLM,
Dean and Professor of Law, Seton Hall
University School of Law

Michael R. Clarke, JD, Vice President,
Corporate Compliance, Indivior

Kris Curry, MBA, Principal, EY

Michael B. Dussseau, Vice President,
Compliance Operations, Allergan PLC

Margaret K. Feltz, MA, JD, Vice President,
Ethics and Compliance, Purdue Pharma LP

Gary F. Giampetruzzi, JD, Partner and
Vice-Chair of Investigations, Paul Hastings

Wendy C. Goldstein, JD, Partner,
Health Care and Life Sciences Regulatory
Practice, Cooley, LLP

Steven Guymon, Senior Advisor, Global
Ethics and Compliance Capabilities, Eli Lilly

Laura G. Hoey, JD, Partner,
Ropes & Gray LLP

Erinn Hutchinson, Partner,
Advisory Services, PwC

Mike Joachim, JD, Compliance
Business Partner, Sanofi Genzyme

Jonathon L. Kellerman, Executive
Vice President, Global Chief Compliance
Officer, Allergan PLC

Shannon Kelley, Vice President,
Head of North America Compliance, Sanofi

Daniel A. Kracov, JD, Partner and
Head, FDA and Healthcare Practice,
Arnold & Porter Kaye Scholer, LLP

Terri Ledva, MS, Senior Manager,
Iroko Pharmaceuticals

Christine Longawa, MA, CPA, CFE,
Associate Director, Navigant Consulting

Maureen McGirr, JD, Vice President
Office of Ethics, Global Compliance
Organization, Merck

Ed Nowicki, JD, Vice President and
General Counsel, Pfizer, Inc.

Neil O'Flaherty, Partner, Baker McKenzie

John Patrick Oroho, JD, Executive Vice
President, and Chief Strategy Officer, Porzio
Life Sciences, LLC

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

Arjun Rajaratnam, JD, MS, Chief
Compliance Officer, Smith & Nephew

David Ralston, JD, MPH, Senior
Director, Associate General Counsel,
Business Conduct, Gilead Sciences

Kelly N. "Nikki" Reeves, MPA, JD,
Partner, King & Spalding

Michael Shaw, JD, Vice President and
Compliance Officer, US Pharmaceuticals,
GlaxoSmithKline

Paul Silver, Principal,
Deloitte & Touche LLP

Carlos Tessi, MD, PhD, Vice President,
Compliance, Shionogi

Donna Wachman, National Industry
Marketing Leader, Grant Thornton LLP

Julie Wagner, JD,
Assistant General Counsel, PhRMA

Seth B. Whitelaw, JD, LLM, SJD,
President and Chief Executive Officer,
Whitelaw Compliance Group, LLC



7:00 am Registration Opens

**SPECIAL MORNING SESSION, INVITATION-ONLY:
CHIEF COMPLIANCE OFFICER ROUNDTABLE**

**8:00 am Introductions, Moderated Discussion and Q&A
PCF Co-chairs
Antitrust Admonition**

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

PRECONFERENCE SYMPOSIA (Optional, Choose only one)

**PRECONFERENCE I: ADVANCED MEDICAL AFFAIRS
COMPLIANCE ISSUES**

8:00 am Welcome and Overview

- The Interfaces Between Medical Affairs and Commercial at the Strategic Level
- The Evolving Role of Medical Affairs in the Field
- Medical Affairs Personnel as Speakers — When is it Scientific Exchange and When is it Promotion?
- The Role of Medical Affairs with Payors: Health Economics Outcomes Research and Real World Evidence

Brian Conner, Vice President, Head of Corporate Compliance, Strongbridge BioPharma plc; Former Senior Director, Asst. Compliance Officer, Global Compliance, Shire; Former General Manager, Vice President, Regulatory and Quality Operations, Synageva; Former Compliance Officer of the Americas, Stiefel Laboratories, Feasterville Trevose, PA

Sarah diFrancesca, JD, Partner, Health Care and Life Sciences Regulatory Practice, Cooley, LLP, New York, NY

Monica Kwacinski, PharmD, Head of External Medical Affairs, Purdue Pharma LP, Stamford, CT

Mark Lange, JD, Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN

Pamela Lonzer, MJ, US Medical Advisor, Shire; Former Associate Director, Global Medical Affairs Compliance, Baxalta; Former Assistant Director, Research and Development-Global Compliance, Astellas Pharma, Chicago, IL

David Ralston, JD, MPH, Senior Director, Associate General Counsel, Business Conduct, Gilead Sciences, Former Section Head, Abbott Laboratories, Former Senior Legal Director, Schering Plough, Foster City, CA

Maureen Lloyd, Director, Pharmaceutical and Life Sciences, PwC; Former Executive Director, Medical - External Medical Communications, Pfizer Inc., New York, NY (Moderator)

Noon Preconference Adjournment/Lunch on your Own

PRECONFERENCE II: THE BASICS OF MANAGED MARKETS

8:00 am Welcome and Overview

- The Changing Landscape of Payor Communications
- View from the Marketplace: Rewarding Results: Moving Forward for Value-Based Contracting for Biopharmaceuticals
- Pre-Approval Information Exchange with Payors

Michelle Drozd, ScM (Invited), Deputy Vice President, Policy and Research, PhRMA, Washington, DC

David J. Farber, JD, Partner, Healthcare Lobbyist and Litigator, King & Spalding LLP, Washington, DC

Greg Sherman, JD, Commercial Counsel, Gilead Sciences, Foster City, CA

Ann E. Beasley, JD, Director, Navigant Consulting; Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA (Moderator)

Noon Preconference Adjournment/Lunch on your Own

PRECONFERENCE III: MEDICAL DEVICE COMPLIANCE BEST PRACTICE UPDATE

10:00 am Welcome and Overview

- The Importance of Corrective and Preventive Action (CAPA) for Medical Device Development
- Complaint Procedures (21 CFR 820.198)
- Medical Device Reporting Procedures (21 CFR 803.17.)
- Nonconforming Product Procedures

Jonathan Glazier, JD, MBA, Senior Legal Counsel, Legal Compliance, Philips Electronics North America; Former Senior Director of Corporate Compliance and Privacy Officer, Fresenius Medical Care North America, Andover, MA

Pamela W. Guthrie, JD, Senior Counsel, Professional Affairs and Compliance, MicroPort Orthopedics, Arlington, TN

William Hrubes, JD (Invited), Vice President, Chief Compliance Officer, ACell, Inc., Columbia, MD

Jessica R. Puathasnanon, JD (Invited), Senior Director and Global Chief Compliance Officer, Medtronic Diabetes Group, Medtronic PLC, Los Angeles, CA

Andrew R. Van Haute, JD, Associate, Sidley Austin LLP; Former Associate General Counsel, AdvaMed, Washington, DC

Matt Wetzel, JD, Vice President and Assistant General Counsel, Advanced Medical Technology Association (AdvaMed); Former Senior Counsel, Global Compliance and Ethics, Boston Scientific, Washington, DC

Becky Osowski, MJ, Senior Manager, Fraud Investigation and Dispute Services Practice, EY; Former US Healthcare Compliance Officer and Deputy Compliance Officer, Zimmer, Chicago, IL (Moderator)

Noon Preconference Adjournment/Lunch on your Own

PRECONFERENCE IV: GOVERNMENT PRICING COMPLIANCE AFTER AN ACQUISITION

10:00 am Welcome and Overview

Anisa Dhalla (Invited), Head, Ethics and Compliance, Americas, UCB, Atlanta, GA

John Knighton, JD, Vice President, Head of Global Compliance, Orexigen Therapeutic; Former Vice President, CCO, MicroPort Medical (Group) Co., Ltd., San Diego, CA

Cortnaye Swan, Senior Manager, Deloitte & Touche LLP, Kansas City, MO (Moderator)

Noon Preconference Adjournment/Lunch on your Own

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 Eighteenth 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 reservations at the group rate, go to **www.PharmaCongress.com** and click on the TRAVEL/HOTEL tab. Or, make reservations by calling The Mandarin Oriental directly at (202) 787 – 6140 or Toll Free (888) 888 – 1778 and request the Pharma Congress Group Rate. Reservations at the group rate will be accepted while rooms are available or until the cut-off date of **Monday, October 9, 2017**. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

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PHARMA CONGRESS: AGENDA DAY I OPENING PLenary SESSION

1:00 pm

DOJ Evaluation of Corporate Compliance Program and Other Updates



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



Sujata Dayal, JD, Vice President, Health Care Compliance and Privacy, Global Chief Compliance Officer, Pharmaceuticals, Johnson & Johnson, Titusville, NJ (Co-chair)



Jeffrey Kawalek, MBA, Senior Director, Ethics and Compliance, North America, Ipsen Biopharmaceuticals, Inc., New York, NY (Co-chair)



Jennifer McGee, JD, Chief Compliance Officer, Otsuka Pharmaceuticals, Inc., Princeton, NJ (Co-chair)



Margaret Sparks, JD, Associate Vice President, North America Ethics and Business Integrity, Sanofi, US, Bridgewater, NJ (Co-chair)

1:15 pm

Keynote: 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

2:00 pm

US DOJ Keynote: DOJ Evaluation of Corporate Compliance Program



Pablo Quiñones, JD, Chief, Strategy, Policy and Training Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC



Colin M. Huntley, JD, Senior Trial Counsel, Fraud Section, Commercial Litigation Branch, Civil Division, US Department of Justice, Washington, DC



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

2:45 pm

FCPA Enforcement Keynote: DOJ, SEC and FBI Update



Tarek Helou, JD, Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC



Charles Cain, Esq., Deputy Chief, FCPA Unit, US Securities and Exchange Commission, Washington, DC



Darryl Wegner, JD, Unit Chief, International Corruption Unit, FBI, 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, USA (Moderator)

3:30 pm Break

4:00 pm



AUSA Roundtable

Jacob T. Elberg, JD, Chief, Health Care and Government Fraud Unit, US Attorney's Office, District of New Jersey, US Department of Justice, Newark, NJ



Jason Mehta, JD, Assistant US Attorney, United States Attorney's Office Middle District of Florida, US Department of Justice, Jacksonville, FL



Gregg Shapiro, JD, Assistant US Attorney, US Attorney's Office, District of Massachusetts, US Department of Justice, 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)

4:45 pm



Announcements of Major Consulting Changes

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



Paul Silver, Principal, Regulatory & Compliance Life Sciences Leader, Deloitte & Touche LLP, Atlanta, Georgia

5:00 pm



Chief Compliance Officer Roundtable

Jill Dailey, MBA, JD, Vice President and Chief Compliance Officer, Incyte; Former Assistant General Counsel and Asia Pacific Compliance Lead, Pfizer; Former Head, US Ethics and Compliance, Novartis, New York, NY



Margaret K. Feltz, MA, JD, Vice President, Ethics & Compliance, Purdue Pharma LP; Former Member, PCF Executive Committee, Stamford, CT



Arjun Rajaratnam, JD, MS, Chief Compliance Officer, Smith & Nephew; Former Compliance Officer, US Pharmaceuticals, GlaxoSmithKline; Former Member, PCF Executive Committee, Raleigh, NC



David Ralston, JD, MPH, Senior Director, Associate General Counsel, Business Conduct, Gilead Sciences; Former Section Head, Abbott Laboratories; Former Senior Legal Director, Schering Plough, Foster City, CA



Paul Silver, Principal, Regulatory & Compliance Life Sciences Leader, Deloitte & Touche LLP, Atlanta, Georgia (Moderator)

6:00 pm

ADJOURNMENT AND NETWORKING RECEPTION

PHARMA CONGRESS: AGENDA DAY II

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

MORNING PLENARY SESSION

8:00 am **Co-chair Welcome and Introductions**

8:15 am **FDA Keynote**



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

8:45 am **Qui Tam Roundtable**



Michael A. Morse, JD, Partner, Pietragallo, Gordon, Alfano, Bosick & Raspanti; Former Assistant District Attorney, Philadelphia District Attorney's Office, Philadelphia PA



Neil V. Getnick, JD, Managing Partner, Getnick & Getnick LLP; Former Assistant District Attorney, Manhattan District Attorney's Office, New York, NY



Robert Patten, JD, President and Chief Executive Officer, Taxpayers Against Fraud and TAF Education Fund; Former Assistant Attorney General and Managing Attorney, Medicaid Fraud Division, The Commonwealth of Massachusetts, Holliston, MA



Virginia "Ginny" A. Gibson, JD, Partner, Hogan Lovells; Former Executive Assistant US Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA (Co-Moderator)



Kathleen Meriwether, Partner/Principal, EY; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA (Co-Moderator)

9:30 am **Demonstrating the Value of the Compliance Organization**



Kathleen M. Boozang, JD, LLM, Dean and Professor of Law, Seton Hall University School of Law, Newark, NJ



Jonathon L. Kellerman, Executive Vice President, Global Chief Compliance Officer, Allergan PLC, New York, NY



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



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

10:15 am **Break**

MINI SUMMITS BLOCK A 10:45 am – 11:45 am

Mini Summit I: Compliance Messaging: Using Behavioral Economics to Improve Messaging Stickiness

Brian Miller, PhD (Invited), Director of Compliance and Ethics Training, Otsuka Pharmaceutical Companies, Senior Manager of Learning Technologies, AstraZeneca; Former Associate Director Learning Design & Technology, Merck, Philadelphia, PA

Jon Smollen, MA, JD, Director, Center for Compliance and Ethics, Temple Law School; Former Executive Vice President and Chief Compliance Officer, Endo; Former Vice President and Chief Compliance Officer, Siemens Healthcare USA; Former Vice President, Commercial Excellence and Compliance, Wyeth, Philadelphia, PA

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

Mini Summit II: HCP Engagement: The Road to Proactive Risk Management

Tom Glavin, JD, Chief Compliance Officer, Olympus; Former Vice President, US/Americas Compliance Officer, Shire; Former US Corporate Compliance Officer, Sanofi-Aventis, Center Valley, PA

Daniel A. Kracov, JD, Partner and Head, FDA and Healthcare Practice, Arnold & Porter Kaye Scholer LLP, Washington, DC

Laura Skinner, Senior Manager, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, Austin, TX (Moderator)

Mini Summit III: Enforcement Trends, Risk Assessments and Best Practices for Patient Assistance and Reimbursement Support

Jennifer Chillas, JD, Senior Corporate Counsel, Bristol-Myers Squibb, Princeton Pike, NJ

Nereyda Garcia, JD, Global Head, Ethics and Compliance, Alnylam Pharmaceuticals; Former Senior Director, Compliance, Biogen Idec, Boston, MA

Laura G. Hoey, JD, Partner, Ropes & Gray LLP; Former Assistant US Attorney, US Attorney's Office, Eastern District of Arkansas, US Department of Justice, Chicago, IL

Casey J. Horton, CFE, Director, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant Consulting, Chicago, IL (Moderator)

Mini Summit IV: Managed Market Considerations for Hub and Specialty Pharmacy Arrangements

Terra Buckley, JD, Head of US Compliance, Helsinn; Former Director, Ethics and Compliance, North America, Ipsen; Former Associate Director, Compliance, Aptalis Pharma, Iselin, NJ

Greg Sherman, JD, Counsel III, Gilead Sciences, Foster City, CA

Lisa Walkush, Principal, Advisory Services: National Life Sciences Sector Leader, Grant Thornton LLP, Philadelphia, PA

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

Mini Summit V: Compliance and Ethics Considerations in R&D

David Cromley, Head, R&D Compliance, Merck, Philadelphia, PA

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

Sue Seferian, Health Care Compliance Officer, Johnson & Johnson, Titusville, NJ

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

Anup Kharode, MBA, Principal, Pharmaceutical & Life Sciences R&D Advisory Services, PwC, Philadelphia, PA (Moderator)

Mini Summit VI: Compliance Program Effectiveness: Using Data Analytics to Tell the Story

Anthony Brennan, MBA, Senior Manager, Fraud Investigation & Dispute Services, EY; Former Senior Director, Governance, Metrics and Reporting, Health Care Compliance, Johnson & Johnson, Iselin, NJ

Mini Summit VII: International Organization for Standardization (ISO) 37001: A New Era of Anti-bribery/ Anti-corruption (ABAC) Compliance

Michael K. Loucks, JD, Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, US Department of Justice, Washington, DC

Louis Ramos, JD, Partner, DLA Piper; Former Assistant General Counsel, Compliance Division, Pfizer; Former Assistant US Attorney, US Attorney's Office, District of Columbia, Washington, DC

Paul J. Peterson, CPA, CIA, CFE, CFF, Senior Manager, Forensic Advisory Services, Grant Thornton, Alexandria, VA (Moderator)

11:45 am **NETWORKING LUNCHEON**

OPTIONAL LUNCHEON MINI SUMMITS 11:55 am – 12:55 pm

Luncheon Mini Summit VIII: FDA Regulation and Cutting Edge Technology - What Pharmaceutical and Medical Device Companies Should Know

- Digital Health Product Regulation by FDA
- FDA's Regulatory Approach for Regenerative Medicine
- FDA Regulation of 3-D Printing in the Pharmaceutical and Medical Device Industries

Chia-Feng Lu, JD, Associate, Baker McKenzie, Washington, DC

Neil O'Flaherty, JD, Partner, Baker McKenzie, Washington, DC

Luncheon Mini Summit IX: Advancing Compliance: Pulling Critical Levers to Improve Effectiveness

Jill Fallows-Macaluso, JD, Chief Compliance Officer and Vice President, Novo-Nordisk, Princeton, NJ

Lindsay Havern, JD, Vice President and Assistant General Counsel, Pfizer, New York, NY

Bryan Timer, Associate Director, Data Analytics & Transparency, Merck, Allentown, PA

Clarissa Crain, Senior Manager, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, Philadelphia, PA (Co-Moderator)

Jack Tanselle, MBA, Managing Director, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, Indianapolis, IN (Co-Moderator)

Luncheon Mini Summit X: The Evolution of Compliance Programs and Lessons Learned from Recent Rulings

Raymond A. Bonner, JD, Partner and Chair, Food, Drug and Medical Device Compliance and Enforcement Practice, Sidley Austin LLP; Former Assistant US Attorney, US Attorney's Office, District of Maryland, Washington, DC

Jonathan Glazier, JD, MBA, Senior Legal Counsel, Legal Compliance, Philips Electronics North America; Former Senior Director of Corporate Compliance and Privacy Officer, Fresenius Medical Care North America, Andover, MA

Mike Joachim, JD (Invited), Compliance Business Partner, Sanofi Genzyme; Former Head of Global Corporate Compliance; Former Associate Vice President, North America Compliance, Genzyme/Sanofi, Cambridge, MA

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

Gary Keilty, Managing Director, FTI Consulting, Tampa, FL (Moderator)

Luncheon Mini Summit XI: Innovation and Compliance, They are not Mutually Exclusive

Tom Costa, JD, Pharmaceutical Consultant, Sanofi Board of Directors; Former Vice President, US Compliance & Ethics, Bristol-Myers Squibb, Washington, DC

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

Joseph Coniker, Principal, Enterprise Performance Management (EPM) Analytics, Grant Thornton LLP, Raleigh, NC (Moderator)

MINI SUMMITS BLOCK B 1:00 pm – 2:00 pm

Mini Summit XII: Third Party Risk Management/ Due Diligence Update

Kenneth Borgerding, JD, Vice President, Chief Compliance Officer & Corporate Counsel, Lundbeck; Former Senior Counsel, Takeda, Chicago, IL

Anthony L. Alvizu, Managing Director, Global Risk & Investigations Practice, FTI Consulting, Indianapolis, IN (Moderator)

Mini Summit XIII: Compliance in the Transactional Context: Agreements, Due Diligence, Integration and Post-Transaction Step

Alison Fethke, JD, Counsel, Ropes & Gray LLP; Former Counsel, Legal, Regulatory and Compliance, AbbVie, Chicago, IL

Tracy Strong, JD, Vice President, International Compliance Officer, Laboratory Corporation of America, Burlington, NC

Daniel A. Kracov, JD, Partner and Head, FDA and Healthcare Practice, Arnold & Porter Kaye Scholer LLP, Washington, DC

Gildas Durand, Partner/Principal, Fraud Investigation and Internal Audit, EY, Miami, FL (Moderator)

Mini Summit XIV: Hands on Learning: Managing an Internal Investigation under a CIA, DPA and a Data Analytics Failure

John Seungjoo Rah, JD, Partner, DLA Piper, Washington, DC

Jane H. Yoon, JD, Of Counsel, Litigation Department, Paul Hastings; Former Assistant United States Attorney, Health Care and Government Fraud Unit, US Attorney's Office for the District of New Jersey, US Department of Justice, New York, NY

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

Mini Summit XV: Recent FDA Guidance Document Manufacturer Communications and the Memo on Off-Label

Kathryn Pryze, CCEP, Compliance Director, US Medical Affairs and US Corporate Affairs, AstraZeneca, Wilmington, DE

Donna White, CCEP, Vice President, Contracts & Compliance, Chiesi USA, Inc.; Former Senior Director, Contracts and Compliance, Cornerstone Therapeutics, Cary, NC

Kellie B. Combs, JD, Partner, Ropes & Gray, Washington, DC

Liisa Eisenlohr, PhD, MBA, Associate Director, Navigant; Former Senior Director, Global Medical Information, Clovis Oncology; Former Clinical Scientist, Genentech, San Francisco, CA (Moderator)

Mini Summit XVI: Compliance Considerations for Small and Mid-Sized Pharma and Medical Device Companies

Sergio Alegre, JD, Vice President, Global Compliance, Osmotica Pharmaceutical Corp.; Former Executive Director Compliance, Pacira Pharmaceuticals, Inc., New York, NY

Holly Kramen, JD, Vice President, Global Compliance Officer, Circassia, Morrisville, NC

Jennifer Sanfilippo, JD, Vice President, Commercial Integrity Counsel, The Medicines Company, New York, NY

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 XVII: Advanced Issues in Global Compliance: Best Practices for Globalizing Core Compliance Functions (Staffing, Risk Assessments, Auditing/Monitoring and Investigations) or Developing a Tailored Auditing and Monitoring Program Globally

Nereyda Garcia, JD, Global Head, Ethics and Compliance, Alnylam Pharmaceuticals; Former Senior Director, Compliance, Biogen Idec, Boston, MA

Jonathan Levy, JD, Corporate Compliance Lead, Spark Therapeutics; Former Associate Director of Compliance and Ethics, US Pharmaceuticals, Bristol-Myers Squibb, Philadelphia, PA

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

Meghan Naas, MA, Senior Finance Manager, Compliance, TESARO, Inc., Waltham, MA

Brian Sharkey, JD, Principal, Porzio, Bromberg & Newman, PC, Morristown, NJ (Moderator)

Mini Summit XVIII: Effective and Balanced Monitoring Program based on Risk

Terri Ledva, MS, Senior Manager, Iroko Pharmaceuticals; Former Associate Director, Ethics and Compliance, Bristol-Myers Squibb, Philadelphia, PA

Brian Van Hoy, Vice President, G & M Health LLC; Former Director, Ethics and Compliance, Eli Lilly, Bridgewater, NJ (Moderator)

2:00 pm Transition Break

MINI SUMMITS BLOCK C 2:15 pm – 3:15 pm

Mini Summit XIX: Advanced Compliance Issues When Contracting with Third Parties

Robert F. Church, JD, Partner, Hogan Lovells US LLP; Former, Associate General Counsel/ Executive Director, Amgen, Los Angeles, CA

Mark A. DeWyngaert, MBA, PhD, Managing Director, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, New York, NY (Co-Moderator)

Oliver Steck, Principal, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, New York, NY (Co-Moderator)

Mini Summit XX: Agg Spend 2.0: The Next Generation of Agg Spend Solutions, including Data Collection and Adjudication Challenges, Integration with Compliance Controls and Monitoring and Global Challenges

Michael Connor, MS, Senior Director, Global Head Compliance and Ethics Operations, Alexion Pharmaceuticals, Inc., New Haven CT

Kelly N. "Nikki" Reeves, MPA, JD, Partner, King & Spalding LLP, Washington, DC

Darren R. Jones, CIA, Managing Partner, Polaris Management Partners, New York, NY (Moderator)

Mini Summit XXI: Cyber Security for Pharma and Medical Device Companies

Justin Herring, JD (Invited), Assistant United States Attorney, United States Attorney's Office, District of New Jersey, Newark, NJ

Jamil N. Jaffer, JD, Vice President for Strategy and Business Development, IronNet Cybersecurity; Adjunct Professor and Founder, National Security Law & Policy Program, Antonin Scalia Law School, George Mason University, Washington, DC

William J. Hughes, Jr., JD, LL.M., Principal, Porzio, Bromberg & Newman, PC; Assistant US Attorney and Trial Attorney, US Department of Justice, Morristown, NJ (Moderator)

Mini Summit XXII: Pricing Considerations (Mylan Epipen, Marathon Pharmaceuticals, et al)

John D. Shakow, JD, Partner, King & Spalding LLP, Washington, DC

Kris Curry, MBA, Principal, Fraud Investigation and Dispute Services, EY; Former Vice President, Global Chief Compliance Officer, Pharma Sector, Johnson & Johnson, Philadelphia, PA (Moderator)

Mini Summit XXIII: Optimizing Data Collection for Use in Risk Assessments, Monitoring, and Auditing

Amy Pawloski, Global Lead, Compliance Risk Mitigation and Monitoring Strategy, Bristol-Myers Squibb, Philadelphia, PA

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

Mini Summit XXIV: The Winding Path to the Patient: Balancing Risks in Patient and Product Support

Meenakshi Datta, JD, Partner, Sidley Austin LLP, Chicago, IL

BJ D'Avella, Senior Manager, Life Sciences Regulatory and Operational Risk, Deloitte & Touche LLP, Atlanta, GA

3:15 pm Networking Break

CLOSING PLENARY SESSION

3:45 pm

Keynote: The Role of Behavioral Economics in Ethics and Compliance



Jim Sheehan, JD, Chief, Charities Bureau at Attorney General of New York; Chief Integrity Officer, Executive Deputy Commissioner, City of New York Human Resources Administration; Medicaid Inspector General, New York Office of the Medicaid Inspector General; Former Associate United States Attorney, US Attorney's Office for the Eastern District of Pennsylvania, New York, NY

4:15 pm

Interview regrading PhRMA Priorities and Policy Initiatives



Jim Stansel, JD, General Counsel, PhRMA, Washington, DC



Ann E. Beasley, JD, Director, Navigant Consulting; Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA (Moderator)

4:45 pm

Brief Overview of the Policy and Politics of Pharma Pricing



Susan Dentzer, President and Chief Executive Officer, The Network for Excellence in Health Innovation (NEHI); Analyst on Health Policy, The News Hour; Former Editor, Health Affairs, Washington, DC

5:00 pm

View from the Marketplace: Rewarding Results: Moving Forward for Value-Based Contracting for Biopharmaceuticals



Jim Clement, MHA (Invited), Executive Director, Cost of Care and Supply Chain Strategy, Aetna; Former National Account Manager, PBMs and Specialty Pharmacy, Genentech, Inc.; Former Director, Pharmaceutical Contracting, Express Scripts, Inc., Hartford, CT



David Hartenbaum, MD, MBA, Executive Director, Account Management, Merck, Philadelphia, PA



Dorothy Hoffman, MPP (Invited), Director, Healthcare Transformation and Policy Partnerships, Eli Lilly and Company, Indianapolis, IN



Julie Ritchie Wagner, JD, Assistant General Counsel, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US Department of Health and Human Services, Washington, DC



Susan Dentzer, President and Chief Executive Officer, The Network for Excellence in Health Innovation (NEHI); Analyst on Health Policy, The News Hour; Former Editor, Health Affairs, Washington, DC (Moderator)

6:00 pm

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WEDNESDAY, NOVEMBER 8, 2017

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)



Sujata Dayal, JD, Vice President, Health Care Compliance and Privacy,
Global Chief Compliance Officer, Pharmaceuticals, Johnson & Johnson,
Titusville, NJ (Co-chair)



Jeffrey Kawalek, MBA, Senior Director, Ethics & Compliance,
North America, Ipsen Biopharmaceuticals, Inc., New York, NY (Co-chair)



Jennifer McGee, JD, Chief Compliance Officer, Otsuka Pharmaceuticals,
Inc., Princeton, NJ (Co-chair)



Margaret Sparks, JD, Associate Vice President, North America Ethics
and Business Integrity, Sanofi, US, Bridgewater, NJ (Co-chair)



Antitrust Admonition

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

**Considerations for Operationalizing the DOJ
Evaluation of Corporate Compliance Programs
Guidance and HCCA Measuring Compliance
Program Effectiveness Guide.**

Deep dive/working session on the two recent
guidance documents:

- DOJ Evaluation of Corporate Compliance Programs
- HCCA Measuring Compliance Program
Effectiveness Guide

Noon

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- Fax/Mail/Email using this printed registration form. Mail the completed form with payment to the Conference registrar at 12330 N.E. 8th Street, Suite 101, Bellevue, WA 98005-3187, or fax the completed form to 206-319-5303, or scan and email the completed form to registration@hcconferences.com. Checks or money orders should be made payable to Health Care Conference Administrators LLC.

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PENDING CONTINUING EDUCATION CREDITS

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- | | |
|--|--------|
| <input type="checkbox"/> I: Medical Affairs (4 hours) | \$ 595 |
| <input type="checkbox"/> II: Managed Markets (4 hours) | \$ 595 |
| <input type="checkbox"/> III: Medical Device (2 hours) | \$ 345 |
| <input type="checkbox"/> IV: Government Programs (2 hours) | \$ 345 |

CONFERENCE – STANDARD INDIVIDUAL REGISTRATION

(Does not include Preconference):

- | | |
|--|---------|
| <input type="checkbox"/> Through Friday, September 22, 2017* | \$1,995 |
| <input type="checkbox"/> Through Friday, October 13, 2017** | \$2,195 |
| <input type="checkbox"/> After Friday, October 13, 2017 | \$2,395 |

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- | | |
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- | | |
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| <input type="checkbox"/> II: Managed Markets (4 hours) | \$ 495 |
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| <input type="checkbox"/> IV: Government Programs (2 hours) | \$ 245 |

CONFERENCE – SPECIAL PCF INDIVIDUAL RATES***

(Does not include Preconference):

- | | |
|--|---------|
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|--|---------|
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- | | |
|---|---------|
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|---|---------|

SELECT YOUR MINI-SUMMITS – TUESDAY, NOVEMBER 7 (One from each group):

- | | |
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| BLOCK A – 10:45 am | BLOCK B – 1:00 pm |
| <input type="checkbox"/> I: Compliance Messaging ... | <input type="checkbox"/> XII: Third Party Risk Management/Due Diligence ... |
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| LUNCH MINI SUMMITS – 11:55 am | BLOCK C – 2:15 pm |
| <input type="checkbox"/> VIII: FDA Regulation and Cutting Edge Technology ... | <input type="checkbox"/> XIX: Advanced Compliance Issues When Contracting ... |
| <input type="checkbox"/> IX: Advancing Compliance ... | <input type="checkbox"/> XX: Agg Spend 2.0 ... |
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- | | |
|-----------------------------------|--------|
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| | <input type="checkbox"/> 10 or more \$495 each | <input type="checkbox"/> 40 or more \$295 each |

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