A HYBRID CONFERENCE AND INTERNET EVENT

Join Us for Our Twentieth Year!

Twentieth Annual Pharmaceutical and Medical Device Compliance Congress

MANDARIN ORIENTAL • WASHINGTON, DC
NOVEMBER 6 – 8, 2019

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THE PHARMACEUTICAL COMPLIANCE FORUM

For Early Bird Registration Discount, Register by Friday, September 13!

Join us in celebrating the Twentieth Anniversary with PCF founding members as we reflect back, share lessons learned, identify new challenges, and shape the future of the compliance profession.

CO-CHAIRS:

Sujata T. Dayal, JD, *Vice President, Health Care Compliance and Privacy, Pharmaceuticals Group, Johnson & Johnson (PCF Secretary)*

Jeffrey M. Kawalek, MBA, *Deputy Chief Compliance Officer, Jazz Pharmaceuticals, Inc. (PCF Chair)*

Jennifer McGee, JD, *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc. (PCF Treasurer)*

Margaret Sparks, JD, *Associate Vice President, North America Ethics and Business Integrity, Sanofi US (PCF Co-Chair)*

Donna White, CCEP, *Vice President, Contracts and Compliance, Chiesi, USA (PCF Co-Chair)*

Joe Zimmerman, *Vice President and Chief Compliance Officer US, Ferring Pharmaceuticals (PCF Co-Chair)*

FEATURING A CHIEF COMPLIANCE OFFICER ROUNDTABLE WITH:

Jointly Sponsored by THE PHARMACEUTICAL COMPLIANCE FORUM and PhRMA

(Wednesday 11/6; Closed, Invitation-only)

Sally Molloy, JD, *Acting Chief, Strategy, Policy & Training Unit, Fraud Section, US DOJ*

CONTINUING EDUCATION CREDITS:

ACCOUNTING PROFESSIONALS: Approved for up to 19.0 NASBA CPE credits.

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

COMPLIANCE PROFESSIONALS: This education activity has been submitted to the Compliance Certification Board (CCB)® and is currently pending their review for approval of CCB CEUs.

KEYNOTE SPEAKERS:

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

Brian Allen Benczkowski, JD, *Assistant Attorney General, Criminal Division, DOJ*

Susan Dentzer, *Visiting Fellow, Duke-Margolis Center for Health Policy*

Robert I. Dodge, JD, *Assistant Director, FCPA Unit, SEC*

Alexandra Christina, Countess of Frederiksborg, *Member, Board of Directors & Chairperson Ethics and Compliance Board Committee, Ferring Pharmaceuticals*

David Last, JD, *Acting Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, DOJ*

Doug Lankler, JD, *Executive Vice President, General Counsel, Pfizer*

Daniel Ronald Levinson, JD, *Former Inspector General, US Department of Health and Human Services*

Lori Queisser, *Senior VP and Global Chief Compliance Officer, Teva*

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

Mary E. Riordan, JD, *Senior Counsel, Office of Counsel to the Inspector General, OIG, DHHS*

James Sheehan, JD, *Chief, Charities Bureau at New York State Department of Law*

AND FRIDAY INDUSTRY-ONLY BEST PRACTICES ROUNDTABLE WITH:

Jacob T. Elberg, JD, *Associate Professor of Law, Seton Hall Law School; Former Chief, Health Care and Government Fraud Unit and Assistant US Attorney, US Attorney's Office, District of New Jersey, US DOJ*

GOLD GRANTOR: Deloitte.

SILVER GRANTORS:

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Be a part of the premiere compliance event for pharmaceutical and medical device professionals at the 20th Anniversary PCF Compliance Congress. Join pharma and device compliance professionals, in-house counsel, regulators, prosecutors, attorneys and industry consultants to share ideas for ways to cultivate a culture of compliance with the highest integrity to enable access to better care and outcomes for patients. This forum is ideal for both compliance professionals and in-house counsel new to developing a compliance program and experienced professionals and counsel 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 pharma and 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, Lisbon, Vienna and Athens (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 2019 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.

AGENDA AT A GLANCE

WEDNESDAY, NOVEMBER 6

An Invitation-only CCO Roundtable *Hosted by the PCF and the PhRMA CCO Working Group*

PRECONFERENCE SESSIONS:
- Risk Assessment Recommendations Based on DOJ Updated Guidance
- Third Party Interactions, Including Distributors and Non-Distributor 3rd Party Vendor Compliance
- Investigations: Interconnectivity of Auditing, Monitoring, and Investigations, Including Privilege
- Emerging Role of Analytics, Big Data & AI Opportunities for Life Sciences . . .

OPENING PLENARY SESSION:
- Welcome and Introduction: PCF Co-Chairs
- 20th Anniversary Dialogue: Lessons Learned
- Keynote: OIG Update
- US DOJ Keynote
- FDA Keynote
- What Pharma/Medical Device Industries Can Learn from the Opioid Cases
- Annual Chief Compliance Officer Roundtable

THURSDAY, NOVEMBER 7

BREAKFAST WORKSHOPS:
- Compliance Considerations for Gene Therapy and Ultra Rare Disease Products
- HCP Contracting—Benchmarking and Lessons Learned . . .
- Navigating Drug Price Transparency Laws . . .

MORNING PLENARY SESSION:
- Co-chair Welcome and Introductions
- Keynote by Alexandra Christina, Countess of Frederiksborg
- US DOJ and US SEC Update on FCPA Enforcement
- AUSA Roundtable

MINI SUMMITS:
- Prosecuting Illegal Kickbacks: The Cost of Noncompliance
- Reduce Compliance Risk Using a "Portfolio" Approach to Training! (Microlearning Alone is Not the Answer)
- Setting Your Five-Year Strategic Compliance Plan
- Interactions with Patients Including Benchmarking on Patient Services Compliance
- Enhanced Compliance Monitoring
- Best Practices Calculating Profit Disgorgement in Preparation for Compliance Settlements
- Annual Medical Device Roundtable
- Lessons Learned from Enforcement Actions
- Compliance Program Operations: Building Effective and Right Sized Compliance Programs
- Value-Based Arrangements
- Framework for Determining Fair Market Value (FMV)
- Helping Patient Access to Products

Mini Summits *(Continued):*
- The Opioid Crisis: Compliance and Enforcement Trends
- Issues with Medical Device/Combination Products
- Charitable Contributions Compliance Considerations
- How do you Modernize your Compliance Program to Prepare for the Future of Health?
- Medical Affairs Proactive Communications, Engagement by Manufacturers
- Transparency and HCP Engagement
- Compliance – Board Communications: Effective Measurement and Reporting Strategies
- Best Practices when Transitioning from Healthcare Compliance Risk to Enterprise Risk Assessments
- Medical Device Asset Management Risk Considerations
- Responding to CCPA, GDPR and the Tumultuous World of Data Privacy
- Social Media Engagement by Manufacturers
- Conducting R&D Compliance Risk Assessments
- Ensuring a Smooth Transition of Compliance Programs During Mergers & Acquisitions
- Investigations: Properly Executing a Compliance Investigation Initiated by a Whistleblower
- Interactions with Specialty Pharmacy
- Practice Development Programs (e.g., Free or Discounted Marketing Services)

CLOSING PLENARY SESSION:
- Developments in Pharmaceutical and Medical Device Pricing and Cost Containment . . .
- The Changing Face of the Qui Tam

FRIDAY, NOVEMBER 8: Industry-only Best Practices Roundtable *Featuring Jacob T. Elberg, JD*

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

The Pharmaceutical Compliance Forum (PCF) is a not-for-profit membership coalition of compliance professionals and legal counsel from 75+ distinguished research-based pharmaceutical manufacturers and biotech companies.

Since 1999, PCF has been dedicated to the advancement of the pharmaceutical compliance profession. Our members meet several times a year to share knowledge, explore innovative solutions to complex compliance challenges and network with peers to build long lasting career relationships.

OUR VISION is to be the leading forum in the pharmaceutical industry for promoting excellence in the compliance profession and advancing effective compliance programs through solutions-oriented collaboration and innovative best practice sharing.

DEMONSTRATED VALUE & BENEFITS OF COMPANY PARTICIPATION IN PCF:

- New company members receive a $500 discount off first year's membership dues
- Full member benefits for all company employees
- Exclusive invitation to our members-only annual meeting priced well below the market rate of similar events;
- Complimentary Fall 1-Day Regional Meetings
- Discounted registration fees for each employee to the PCF Sponsored Pharma Congress in Washington D.C each year;
- Formalized benchmarking surveys with detailed analysis reports and searchable database to gauge efforts compared to peers.
- Access to our PCF Members Only website to view previous meeting presentations, materials and benchmarking surveys;
- Access to our member database to network with fellow members and companies;
- Co-Chair leadership opportunities for strategic planning and advancement of PCF
- Complimentary job postings on our PCF website for open positions. A superior recruiting tool. Non-participating companies pay $600 per posting;
- Special PCF Member discount on subscriptions to Life Science Compliance Update monthly newsletters;

For more information go to www.pharmacomplianceforum.org.

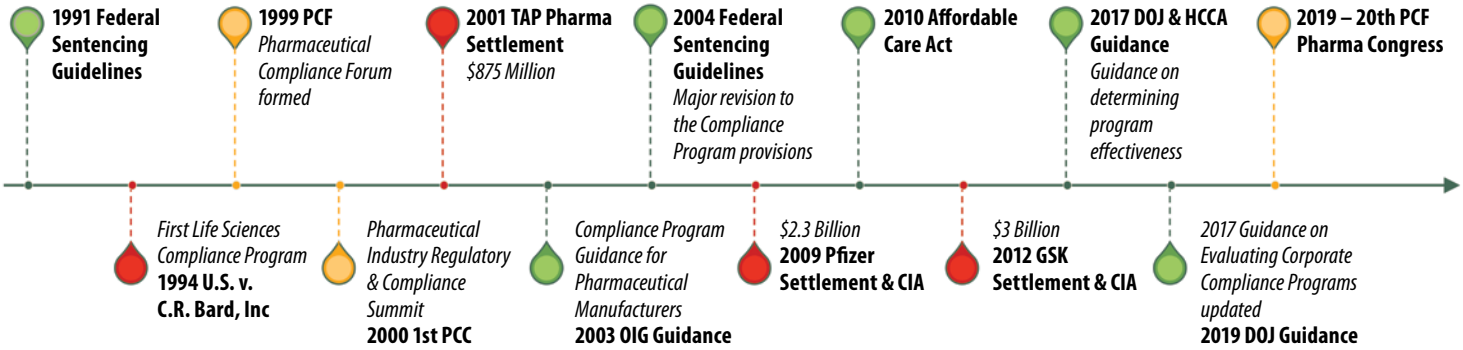
REMEMBER THE FIRST CONGRESS:

JOIN PCF

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

THE PHARMACEUTICAL COMPLIANCE FORUM

KEY EVENTS IN LIFE SCIENCE COMPLIANCE:



Prepared by Seth B. Whitelaw, JD, LLM, SJD. Read Life Science Compliance from the Beginning *on the Congress website.*

WEDNESDAY, NOVEMBER 6, 2019

7:00 am **Registration Opens and Networking Breakfast**

CHIEF COMPLIANCE OFFICER ROUNDTABLE

(Special Morning Session, Jointly Sponsored by PCF and PhRMA; Closed, Invitation-only)

THE PHARMACEUTICAL COMPLIANCE FORUM

PhRMA RESEARCH PROGRESS HOPE

7:45 am **Networking Buffet Breakfast** *Hosted by PhRMA and PCF*

8:15 am **Welcome & Introductions and 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*

8:30 am **DOJ's Evaluation of Corporate Compliance**

Sally Molloy, JD, *Acting Chief, Strategy, Policy and Training Unit, Fraud Section, US Department of Justice, Washington, DC*

9:15 am **Closed Door Discussions: How to Operationalize the DOJ Guidance?**

9:45 am **Break**

10:00 am **CCO Mentoring Program**

10:10 am **PhRMA Updates**

Julie Ritchie Wagner, JD, *Assistant General Counsel, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US DHHS, Washington, DC*

10:30 am **AdvaMed Updates**

Christopher L. White, JD, *Chief Operating Officer and General Counsel, Advanced Medical Technology Association (AdvaMed), Washington, DC*

10:50 am **Strategic Discussion with Board of Directors**

Thomas Costa, JD, *Member, US Board of Directors, Sanofi; Former Vice President, US Compliance and Ethics, Bristol-Myers Squibb, Washington, DC*

Shannon Kelley, JD, *Vice President, Head of North America Compliance, Sanofi; Former Assistant US Attorney and Deputy Chief of Litigation, Boston US Attorney's Office, Cambridge, MA*

Lesley C. Reynolds, JD, *Partner, Life Sciences Health Industry Group, Reed Smith, Washington, DC*

11:30 am **Open Discussions**

11:55 am **Adjournment**

PRECONFERENCE SYMPOSIA *(Optional, Choose only one)*

Preconference I: Risk Assessment Recommendations Based on DOJ Updated Guidance

8:00 am **Welcome and Overview**

Carla Brooks, MS, *Senior Director, Compliance Monitoring, Auditing and Investigations, United Therapeutics; Former US Compliance Director, Market Access and Government Affairs, AstraZeneca, Silver Spring, MD*

Jonathan Turner, MSc (Invited), *Vice President, Global Compliance Leader, Smith & Nephew; Adjunct Faculty, Florida State University and University of Memphis; Association of Certified Fraud Examiners, Memphis, TN*

Christine Handel, JD (Invited), *Vice President, Global Compliance Operations, Walgreens Boots Alliance, Deerfield, IL*

Jenny McVey, PhD, *Compliance Risk and Mitigation, Novo Nordisk, Inc.; Former Compliance Officer, Hands International, Princeton, NJ*

Jean McKiernan, MBA, *Managing Director, Dovetail Consulting Group, LLC, Chicago, IL (Moderator)*

10:00 am **Preconference I Adjournment**

Preconference II: Third Party Interactions, Including Distributors and Non-Distributor 3rd Party Vendor Compliance

10:00 am **Welcome and Overview**

Gregory Paw, JD, *Partner, Freeh, Sporkin & Sullivan; Former Director, New Jersey Division of Criminal Justice; Former Assistant US Attorney, US Attorney's Office, Eastern District of Pennsylvania, New York, NY*

Nancy S. Travis, MS, *Vice President, International Compliance and Governance, Advanced Medical Technology Association (AdvaMed), Washington, DC*

Angela Rodin, MBA, *Principal, KPMG; Former Vice President, Global Head of Investigations and Monitoring, GlaxoSmithKline Pharma GmbH, Washington, DC (Moderator)*

Preconference III: Investigations: Interconnectivity of Auditing, Monitoring, and Investigations, Including Privilege

8:00 am **Welcome and Overview**

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

Franziska Janorschke (Invited), *Global Head, Business Practices Office, Novartis International AG, Basel Area, Switzerland*

Christopher Novello, JD (Invited), *Head of Monitoring and Compliance Investigations, NA Ethics and Business Integrity, Sanofi; Former Senior Vice President, OvaScience, Boston, MA*

Casey J. Horton, CFE, *Director, Life Sciences, Governance, Risk and Compliance, Navigant, Chicago, IL (Moderator)*

Preconference IV: Emerging Role of Analytics, Big Data & AI Opportunities for Life Sciences: Implications for Ethics and Compliance

8:00 am **Welcome & Introductions**

8:15 am **Data and the Life Sciences: Overview of the Changes to Come**

Oscar Rodriguez, *Chief Architect, BlackThorn Therapeutics; Co-Chair, Technology and Standards Subcommittee, The Alliance for Artificial Intelligence in Healthcare (AAIH), New York, NY*

8:45 am **FDA Update: Regulation on the Digital Frontier**

M. Khair ElZarrad (Invited), *Deputy Director, Office for Medical Policy, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD*

9:15 am **The GDPR, State Privacy Laws and the Pharmaceutical Industry**

Patrice Ettinger, JD (Invited), *Chief Privacy Officer, Pfizer, New York, NY*

Pearl Hsieh, JD, *Senior Counsel, US Commercial, Group Counsel, Smith & Nephew, Columbia, MD*

Kimberly J. Gold, JD, *Partner, ReedSmith, New York, NY (Moderator)*

10:00 am **Regulation of AI in Life Sciences: Compliance and Ethics Implications**

Kelliann H. Payne, JD, *Partner, Hogan Lovells LLP; Former Assistant General Counsel, QVC, Inc., Philadelphia, PA*

10:30 am **Break**

10:45 am **Potential Data Privacy and AI Risks in the Product Life Cycle of a Medical Device**

Bernadette Broccolo, JD, *Partner, McDermott Will & Emery LLP, Chicago, IL*

11:15 am **Data and Compliance — Mitigating the Risk of Government Enforcement, Individual Liability, and Corporate Integrity Agreements through Analytics**

Sarah Venable, JD, MS, *North America Independent Business Monitoring Manager, GSK; Former Technical Consultant, Education Practice, SAS, Raleigh-Durham, NC*

Jared D. Crafton, *Principal, Assurance Services, Forensic & Integrity Services, EY, Boston, MA (Moderator)*

Noon **Preconference II, III and IV Adjournment/ Lunch on your Own**

WEDNESDAY, NOVEMBER 6, 2019

PHARMA CONGRESS AGENDA DAY I

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

Sujata T. Dayal, JD, *Vice President, Health Care Compliance and Privacy, Pharmaceuticals Group, Johnson & Johnson, Titusville, NJ (PCF Secretary)*

Jeffrey M. Kawalek, MBA, *Deputy Chief Compliance Officer, Jazz Pharmaceuticals, Inc., Philadelphia, PA (PCF Chair)*

Jennifer McGee, JD, *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Rockville, MD (PCF Treasurer)*

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

Donna White, CCEP, *Vice President, Contracts and Compliance, Chiesi, USA, Cary, NC (PCF Co-Chair)*

Joe Zimmerman, *Vice President and Chief Compliance Officer, US, Ferring Pharmaceuticals, Parsippany, NJ (PCF 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*

1:15 pm **20th Anniversary Dialogue: Lessons Learned from 20 Years of Pharma and Medical Device Investigations, Prosecutions, Ethics and Compliance**

Douglas M. Lankler, JD, *Executive Vice President, General Counsel, Pfizer; Former Assistant US Attorney, Southern District of New York, US Department of Justice, New York, NY*

Daniel Ronald Levinson, JD, *Former Inspector General, US Department of Health and Human Services; Former Inspector General, US General Services Administration; Former Chairman, US Merit Systems Protection Board; Former General Counsel, US Consumer Product Safety Commission, Washington, DC*

Lori Queisser, *Senior Vice President and Global Chief Compliance Officer, Teva Pharmaceuticals; Former Senior Vice President, Global Compliance and Business Practices; Schering-Plough Corporation; Former Vice President, Chief Compliance Officer, Eli Lilly; Former Member, PCF Executive Committee, Horsham, PA*

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

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

Susan Winkler, JD, *Partner, Pierce Bainbridge; Former Assistant US Attorney and Head, Health Care Fraud Unit, US Attorney's Office for the District of Massachusetts, Boston, MA*

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

2:15 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*

3:00 pm **US DOJ Keynote**

Brian Allen Benczkowski, JD, *Assistant Attorney General, Criminal Division, US Department of Justice; Former Principal Deputy Assistant Attorney General for Legislative Affairs; Former Republican Staff Director, Committee on the Judiciary, US Senate; Former Staff, Senator Pete Domenici and Representative Jim Sensenbrenner, Washington, DC*

3:30 pm **Break**

4:00 pm **FDA Keynote**

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

4:30 pm **What Pharma/Medical Device Industries Can Learn from the Opioid Cases**

Rachael Honig, JD, *First Assistant US Attorney, US Attorney's Office, District of New Jersey, US Department of Justice; Former Corporate Counsel, Litigation, Celgene, New York, NY*

John C. Richter, JD, *Partner, King & Spalding; Former Acting Assistant Attorney General, Criminal Division , US Department of Justice; Former US Attorney, Western District of Oklahoma, Washington, DC*

5:00 pm **Annual Chief Compliance Officer Roundtable**

Charlene E. Davis, JD, *Associate Vice President and Head of Healthcare Compliance North America, Sun Pharmaceutical Industries, Inc.; Former Senior Compliance Counsel and Senior Director, Corporate Compliance and Compliance Operations, Otsuka Pharmaceutical, Princeton, NJ*

Adam Dubow, JD, *Global Chief Compliance and Ethics Officer, Bristol-Myers Squibb, Princeton, NJ*

Keith Korenchuk, MPH, JD, *Vice President and Chief Compliance Officer, Danaher Diagnostics and Beckman Coulter Diagnostics, DANAHER Corporation; Former Partner, Arnold & Porter Kaye Scholer, Chevy Chase, MD*

Dominique Laymand, Esq., *Executive Vice President, Chief Ethics and Compliance Officer, Ipsen Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Sunitha Ramamurthy, JD, *Head of Compliance, Loxo Oncology, wholly owned subsidiary of Eli Lilly; Former Executive Director, Office of Ethics and Compliance, Boehringer Ingelheim Pharmaceuticals, Stamford, CT*

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

6:00 pm **ADJOURNMENT AND NETWORKING RECEPTION AND 20TH ANNIVERSARY PARTY**

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 Twentieth Annual Pharmaceutical and Medical Device Compliance Congress. A special group rate of **$359.00 Deluxe Room per night** (plus applicable state and local 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. You may also make reservations by calling the Mandarin Oriental directly at (202) 787-6140 or Toll Free (888) 888-1778. Please ask for the "Pharmaceutical 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 **Sunday, October 13, 2019**. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

Mandarin Oriental • 1330 Maryland Avenue SW • Washington, DC 20024

THURSDAY, NOVEMBER 7, 2019

PHARMA CONGRESS: AGENDA DAY II

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

BREAKFAST WORKSHOPS (7:30 am – 8:15 am)

Breakfast Workshop I: Compliance Considerations for Gene Therapy and Ultra Rare Disease Products

Tiffany Cummings-Damiani, MBA, *Vice President, Corporate and Healthcare Compliance, Global Compliance, Insmed; Former Senior Director, Global Compliance, Teva, Philadelphia, PA*

Ali Lyons, *Senior Director, Ethics and Compliance, Aegerion Pharmaceuticals, a Novelion Therapeutics Company; Former Operations Lead, Ethics and Compliance, Eli Lilly and Company, Cambridge, MA*

Manny Tzavlakis, *Managing Partner, Helio Health, Morristown, NJ (Moderator)*

Breakfast Workshop II: HCP Contracting—Benchmarking and Lessons Learned from Thirty-Nine Peer Companies

Laura Skinner, MBA, *Senior Manager, Deloitte Advisory, Deloitte & Touche LLP, Austin, TX (Co-moderator)*

Mark Linver, MS, *Managing Director, Deloitte Advisory, Deloitte & Touche LLP, Stamford, CT (Co-moderator)*

Breakfast Workshop III: Navigating Drug Price Transparency Laws and the Role of Compliance

Josh Tomas O'Harra, MS, JD, *Assistant General Counsel, Eli Lilly and Company, Washington, DC*

Mark Scallon, MHA, *Senior Principal, IQVIA Global Compliance, Richmond, VA*

Donna White, CCEP, *Vice President, Contracts and Compliance, Chiesi, USA, Cary, NC (PCF Co-Chair)*

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

MORNING PLENARY SESSION

8:30 am **Co-chair Welcome and Introductions**

8:45 am **Keynote**

Alexandra Christina, Countess of Frederiksborg, *Member, Board of Directors and Chairperson, Ethics and Compliance Board Committee, Ferring Pharmaceuticals; Co-author,* The Sincerity Edge; *Former Poling Chair of Business and Government, Kelley School of Business, Indiana University, Copenhagen, Denmark*

9:15 am **US DOJ and US SEC Update on FCPA Enforcement**

Leslie Backschies, MA (Invited), *Supervisor, Special Agent and Unit Chief, International Corruption Unit, Federal Bureau of Investigation, Los Angeles, CA*

Robert I. Dodge, JD, *Assistant Director, FCPA Unit, US Securities and Exchange Commission; Former Assistant US Attorney, US Attorney's Office, Western District of Michigan; Former Assistant Section Chief, Environmental Defense Section, US Department of Justice, Washington, DC*

David Last, JD, *Acting Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC*

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

10:00 am **AUSA Roundtable**

John Claud, JD, *Assistant Director, Consumer Protection Branch, US Department of Justice, Washington, DC*

Rachael Honig, JD, *First Assistant US Attorney, US Attorney's Office, District of New Jersey, US Department of Justice; Former Corporate Counsel, Litigation, Celgene, New York, NY*

Amanda Masselam Strachan, JD, *Assistant US Attorney and Chief, Health Care Fraud Unit, 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)*

10:45 am **Break**

MINI SUMMITS BLOCK A (11:15 am – 12:15 pm)

Mini Summit I: Prosecuting Illegal Kickbacks: The Cost of Noncompliance

Nereyda Garcia, JD, *Global Heath, Ethics and Compliance, Alnylam Pharmaceuticals; Former Sr. Director, Compliance, Biogen Idec, Cambridge, MA*

Nancy Grygiel, JD, *Vice President, Worldwide Compliance and Business Ethics, Amgen; Former Senior Director, Global Compliance, Mylan, Newbury Park, CA*

Carrie Sarhangi Love, JD, *Litigation Partner, Armstrong Teasdale; Former Assistant District Attorney, Office of the District Attorney, City of Philadelphia, Philadelphia, PA (Moderator)*

Mini Summit II: Reduce Compliance Risk Using a "Portfolio" Approach to Training! (Microlearning Alone is Not the Answer)

Erica Powers, *Director, Compliance Operations, Sage Therapeutics; Former Director Corporate Compliance, Vertex, Cambridge, MA*

Dan O'Connor, *Senior Vice President, PharmaCertify, a Division of NXLevel Solutions New York, NY (Moderator)*

Mini Summit III: Setting your Five-Year Strategic Compliance Plan

Amy Pawloski, *Compliance Officer, Operations, Endo Pharmaceuticals; Former Global Lead, Compliance Risk Mitigation and Monitoring Strategy, Bristol-Myers Squibb, Philadelphia, PA*

Susan Williamson, MBA, CPA, *Senior Vice President and Chief Compliance Officer, Endo Pharmaceuticals, Philadelphia, PA*

Mini Summit IV: Interactions with Patients Including Benchmarking on Patient Services Compliance

Chapman Richardson, *Global Head, Data Consumerization, Sanofi; Former Global Head Next Generation Digital, Novartis, Bridgewater, NJ*

Manny Tzavlakis, *Managing Partner, Helio Health, Morristown, NJ (Moderator)*

Mini Summit V: Enhanced Compliance Monitoring

Heather McCollum, JD, MHA, CCEP-I, *Director Compliance, Shionogi Inc, Florham Park, NJ*

Mark Zaleski, MBA, *Director Legal Compliance, Philips; Former Senior Finance Manager, Intel Corporation, Boston, MA*

Katie Schottmiller, MS, CPA, *Director, North America Independent Business Monitoring, GSK, Raleigh-Durham, NC*

Angela Rodin, MBA, *Principal, KPMG; Former Vice President, Global Head of Investigations and Monitoring, GlaxoSmithKline Pharma GmbH, Washington, DC (Moderator)*

Mini Summit VI: Best Practices Calculating Profit Disgorgement in Preparation for Compliance Settlements

Brad Mroski, CPA, CFE, *Managing Director, AlixPartners; Former Assistant Chief Accountant, Division of Enforcement, U.S. Securities & Exchange Committee Enforcement, Dallas, TX*

Patrick Phelan, JD, *Partner, Covington & Burling LLP, Washington, DC*

Yogesh Bahl, CPA, MBA, *Managing Director, AlixPartners, New York, NY (Moderator)*

Mini Summit VII: Annual Medical Device Roundtable

Maya P. Florence, JD, *Partner, Health Care and Life Sciences, Skadden Arps LLP, Boston, MA*

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

Christine Gordon, JD, *Deputy Chief Compliance Officer, Olympus Corporation of the Americas; Former Director, Board of Directors, ESSA Bancorp, Inc; Former Assistant District Attorney, Office of the District Attorney, City of Philadelphia, Bethlehem, PA*

Nancy S. Travis, MS, *Vice President, International Compliance and Governance, Advanced Medical Technology Association (AdvaMed), Washington, DC*

Eileen E. Erdos, *Principal, Forensic & Integrity Services, EY, Chicago, IL (Moderator)*

12:15 pm NETWORKING LUNCHEON

MINI SUMMITS BLOCK B (12:45 pm – 1:45 pm)

Mini Summit VIII: Lessons Learned from Enforcement Actions

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

Thomas M. Glavin, JD, *Chief Compliance Officer for the Americas, Olympus Corporation of the Americas; Former Vice President, US/Americas Compliance Officer, Shire, Center Valley, PA*

Nancy Grygiel, JD, *Vice President, Worldwide Compliance and Business Ethics, Amgen; Former Senior Director, Global Compliance, Mylan, Newbury Park, CA*

William Hrubes, MS, *Vice President and Chief Compliance Officer, ACell, Inc., Former Healthcare Compliance Officer, DePuy Orthopaedics, Columbia, MD*

Puja Leekha, JD, *Vice President, Chief Compliance Officer and Corporate Counsel, Corporate Compliance, Lundbeck Pharmaceuticals LLC; Former Division Legal Counsel and Compliance Officer, Stryker Corporation, Deerfield, IL*

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

Mini Summit IX: Compliance Program Operations: Building Effective and Right Sized Compliance Programs

Kimi Gorman, CCEP, CFE, *Senior Director, Ethics and Compliance, Novo Nordisk Inc.; Former Compliance Manager, B. Braun Medical, Princeton, NJ*

Cheryl Lee, MBA, *Executive Director, Worldwide Markets, Healthcare Compliance, Celgene; Former Senior Manager Compliance, Worldwide BioPharmaceutical Business, Pfizer Summit, NJ*

Anna L. Mack, *Senior Manager, Global Compliance, Danaher Diagnostics and Beckman Coulter Diagnostics, Orange County, CA*

Sunitha Ramamurthy, JD, *Head of Compliance, Loxo Oncology, wholly owned subsidiary of Eli Lilly; Former Executive Director, Office of Ethics and Compliance, Boehringer Ingelheim Pharmaceuticals, Stamford, CT*

Jonathan Wilkenfeld, MBA, *Partner, Potomac River Partners, Washington, DC (Moderator)*

Mini Summit X: Value-Based Arrangements

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

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*

Meenakshi Datta, JD, *Partner and Global Co-leader, Healthcare Practice, Sidley Austin LLP, Chicago, IL (Moderator)*

Mini Summit XI: Framework for Determining Fair Market Value (FMV)

Masha Chestukhin, MSJ, *Associate Director, Sanofi Genzyme, Jamaica Plain, MA*

Sujata T. Dayal, JD, *Vice President, Health Care Compliance & Privacy, Pharmaceuticals Group, Johnson & Johnson, Titusville, NJ (PCF Secretary)*

Jennifer McGee, JD, *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Rockville, MD (PCF Treasurer)*

Julie DeLong, CFA, *Senior Managing Director, Ankura Consulting Group, LLC, Atlanta, GA (Co-moderator)*

CJ DeKreek, CFA, *Senior Director, Ankura Consulting Group, LLC, Atlanta, GA (Co-moderator)*

Mini Summit XII: Helping Patient Access to Products

Timothy Ayers, JD, MPH, *Life Science Compliance Consulting, LLC; Former VP, Chief Compliance Officer, Horizon Pharma plc., Oklahoma City, OK*

Michael R. Clarke, CCEP, JD, *Vice President, Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior, Inc., Bridgewater, NJ*

Elizabeth Weiss, JD, *Assistant General Counsel; Chief Compliance Counsel, Pfizer, Peapack, NJ*

Amy Greenstein, JD/MSFS, *Associate Principal, IQVIA, Boston, MA (Co-moderator)*

Darren R. Jones, CIA, *Senior Principal, Commercial Compliance, Global Consulting Practice Leader, IQVIA, New York, NY (Co-moderator)*

Mini Summit XIII: The Opioid Crisis: Compliance and Enforcement Trends

Danielle Davis (Invited), *Former Compliance Director, Insys Therapeutics, Chandler, AZ*

Michael G. Hercz, JD, *Senior Vice President and General Counsel, Sentynl Therapeutics, Inc., Solana Beach, CA*

Mini Summit XIV: Issues with Medical Device/Combination Products

Deeona Gaskin, MPH, JD, *Associate, Sidley Austin, LLP; Former Associate Chief Council, US Food and Drug Administration, Washington, DC (Co-Moderator)*

William A. McConagha, JD, *Partner, Sidley Austin, LLP; Former Health Policy Advisor, Health, Education, Labor and Pensions Committee, US Senate; Former Assistant Commissioner, US Food and Drug Administration, Washington, DC (Co-Moderator)*

MINI SUMMITS BLOCK C (2:00 pm – 3:00 pm)

Mini Summit XV: Charitable Contributions Compliance Considerations

Christine Fiore, MBA, *Executive Director, Ethics and Commercial Compliance, Boehringer Ingelheim; Former Group Director Ethics and Compliance, Smith & Nephew, Ridgefield, CT*

Keith Korenchuk, MPH, JD, *Vice President and Chief Compliance Officer, Danaher Diagnostics and Beckman Coulter Diagnostics, DANAHER Corporation; Former Partner, Arnold & Porter Kaye Scholer, Chevy Chase, MD*

Elaina Filauro, *Senior Manager, Deloitte Advisory, Deloitte & Touche LLP, New York, NY*

BJ D'Avella, MBA, *Senior Manager, Deloitte Advisory, Deloitte & Touche LLP, New York, NY (Moderator)*

Mini Summit XVI: How do you Modernize your Compliance Program to Prepare for the Future of Health?

Brian Conner, *Chief Compliance Officer, Strongbridge Biopharma plc; Former Assistant Compliance Officer of the Americas, Shire, Feasterville Trevose, PA*

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

Joshua M. Marks, JD, *Vice President and Chief Ethics & Compliance Officer, Boehringer Ingelheim USA Corporation, Ridgefield, CT*

Ashley Riley, JD, *Senior Manager, Deloitte Advisory, Deloitte & Touche LLP, Charlotte, NC*

Jack Tanselle, MBA, *Managing Director, Deloitte Advisory, Deloitte & Touche LLP, Indianapolis, IN (Moderator)*

Mini Summit XVII: Medical Affairs Proactive Communications, Engagement by Manufacturers

Gary Del Vecchio, *Health Care Compliance Officer, Cardiovascular and Metabolism, The Janssen Pharmaceutical Companies of Johnson & Johnson; Former Executive Director, US Pharmaceutical Compliance and Ethics, Bristol-Myers Squibb, Pennington, NJ*

Casper Partovi, MA, JD, *Vice President, Law, Amgen, Los Angeles, CA*

Ann-Marie Tejcek, MA, *Senior Director North American Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN*

Alison Fethke, JD, *Counsel, Ropes & Gray LLP; Former Division Counsel, Legal, Regulatory and Compliance, AbbVie, Chicago, IL (Moderator)*

Mini Summit XVIII: Transparency and HCP Engagement

Heather McCollum, JD, MHA, CCEP-I, *Director Compliance, Shionogi Inc, Florham Park, NJ*

Mark Zaleski, MBA, *Director Legal Compliance, Philips; Former Senior Finance Manager, Intel Corporation, Boston, MA*

Michael O'Connor, *Vice President of Compliance Technology, Porzio Life Sciences, LLC; Former Global Head Compliance and Ethics Operations, Alexion; Former Executive Director, Global Head, IS Business Consulting, Boehringer Ingelheim, New York, NY (Moderator)*

Mini Summit XIX: Compliance – Board Communications: Effective Measurement and Reporting Strategies

Ela Bochenek, JD, *Vice President and Chief Compliance Officer, Nabriva Therapeutics plc; Former Assistant Dean Graduate & Professional Education, Seton Hall University School of Law, King of Prussia, PA*

Thomas Costa, JD, *Member, US Board of Directors, Sanofi; Former Vice President, US Compliance and Ethics, Bristol-Myers Squibb, Washington, DC*

Kristin Graham Koehler, JD, *Partner, Sidley Austin LLP, Washington DC*

Katherine Norris, MPA, *Director, Corporate Compliance & Risk Management, Berkeley Research Group LLC, Washington, DC*

Mini Summit XX: Best Practices when Transitioning from Healthcare Compliance Risk to Enterprise Risk Assessments

Christie Camelio, *Vice President and US Healthcare Compliance Officer, Celgene; Former Head of Risk Management, Novartis, Summit, NJ*

Christian A. Dingler, *Associate Director, Navigant Life Sciences, Richmond, VA*

Anna L. Mack, *Senior Manager, Global Compliance, Danaher Diagnostics and Beckman, Coulter Diagnostics, Orange County, CA*

Jenny McVey, PhD, *Compliance Risk and Mitigation, Novo Nordisk, Inc. Former Compliance Officer, Hands International, Princeton, NJ*

Kristin Rand, JD, MA, *Vice President and Compliance Officer, Seattle Genetics; Former Compliance Director, Policy, Ethics, Training & Communication, Genentech, New York, NY*

Ann E. Beasley, JD, *Director, Life Sciences, Governance, Risk and Compliance, Navigant Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA (Moderator)*

Mini Summit XXI: Medical Device Asset Management Risk Considerations

Heather Young, JD, *Senior Manager, Compliance Business Partner, Olympus Corporation of the Americas; Former Assistant District Attorney, Office of the District Attorney, City of Philadelphia, Philadelphia, PA*

Kamleh J. Nicola, LLB, *Partner, Baker & McKenzie LLP, Toronto, Ontario (Moderator)*

3:00 pm Transition Break

MINI SUMMITS BLOCK D **(3:30 pm – 4:30 pm)**

Mini Summit XXII: Responding to CCPA, GDPR and the Tumultuous World of Data Privacy

Jennifer Chillas, JD, *Senior Corporate Counsel, Bristol-Myers Squibb, New York, NY*

Catherine Williams, JD, *Director, Privacy Office, Novo Nordisk; Former Assistant General Counsel, Privacy & K-12, Corrections & Leisure, Aramark, Plainsboro, NJ*

Adam Greene, JD, MPH, *Partner and Co-chair, Health Information & HIPAA Practice, Davis Wright Tremaine LLP; Former Senior Health Information Technology and Privacy Specialist, Office for Civil Rights, HHS, Washington, DC (Co-moderator)*

Rena Verma, MBA, *Senior Managing Director, Information Governance, Privacy and Security Practice, FTI Consulting, New York, NY (Co-moderator)*

Mini Summit XXIII: Social Media Engagement by Manufacturers

Joanne Kwan, JD, PhD, *Corporate Counsel, Commercial, Exelixis, San Francisco, CA*

Jessica C. Sergi, JD, *Senior Legal Counsel, Neurology & Immunology, EMD Serono, Rockland, MA*

Seth B. Whitelaw, JD, LLM, SJD, *President and Chief Executive Officer, Whitelaw Compliance Group, LLC; Editor,* Life Science Compliance Update; *Senior Fellow and Adjunct Professor, Life Sciences Compliance at Mitchell Hamline School of Law, West Chester, PA*

Beth Weinman, JD, *Counsel, Ropes & Gray LLP; Former Associate Chief Counsel, US Food and Drug Administration, Washington, DC (Moderator)*

Mini Summit XXIV: Conducting R&D Compliance Risk Assessments

Jeffrey (Jeff) Fleming, JD, *Assistant General Counsel, Pharma R&D, GlaxoSmithKline, Philadelphia, PA*

Gregory S. Moss, JD, *Senior Vice President, Deputy General Counsel, Kadmon Holdings, Inc., New York, NY*

Kelly N. "Nikki" Reeves, MPA, JD, *Partner and Co-chair, Life Sciences and Healthcare Industry Group, King & Spalding LLP, Washington, DC (Moderator)*

Mini Summit XXV: Ensuring a Smooth Transition of Compliance Programs During Mergers & Acquisitions

Karen Johnson, MBA, *Executive Director Compliance and Ethics, Corporate Ombudsman, Bristol-Myers Squibb, Princeton Pike, NJ*

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

Sunitha Ramamurthy, JD, *Head of Compliance, Loxo Oncology, wholly owned subsidiary of Eli Lilly; Former Executive Director, Office of Ethics and Compliance, Boehringer Ingelheim Pharmaceuticals, Stamford, CT*

Gildas Durand, *Principal, Forensic and Integrity Services, EY, Miami, FL (Moderator)*

Mini Summit XXVI: Investigations: Properly Executing a Compliance Investigation Initiated by a Whistleblower

Heather McCollum, JD, MHA, CCEP-I (Invited), *Director Compliance, Shionogi Inc, Florham Park, NJ*

Richard H. Walker, JD, *Partner, King & Spalding; Former Director of Enforcement, US Securities and Exchange Commission, New York, NY*

Susan Markel, *Managing Director, AlixPartners; Former Chief Accountant, Division of Enforcement, US Securities and Exchange Commission, Washington DC (Moderator)*

Mini Summit XXVII: Interactions with Specialty Pharmacy

Timothy Ayers, JD, MPH, *Life Science Compliance Consulting, LLC; Former VP, Chief Compliance Officer, Horizon Pharma plc., Oklahoma City, OK*

Mark A. DeWyngaert, PhD, *Managing Director, Deloitte Advisory, Deloitte & Touche LLP, Stamford, CT*

Richard Liner, JD, MPH, *Senior Counsel, Compliance and Investigations, Bayer Healthcare, Whippany, NJ*

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

Mini Summit XXVIII: Practice Development Programs (e.g., Free or Discounted Marketing Services)

Noel Demetria Denice, JD, *Legal Counsel, Philips, Boston, MA*

Keith Korenchuk, MPH, JD, *Vice President and Chief Compliance Officer, Danaher Diagnostics and Beckman Coulter Diagnostics, DANAHER Corporation; Former Partner, Arnold & Porter Kaye Scholer, Chevy Chase, MD*

Thomas Beimers, JD, *Partner, Hogan Lovells; Former Senior Counsel, Office of Counsel to the Inspector General; Former Special Assistant United States Attorney, US Attorney's Office, Eastern District of Michigan, Minneapolis, MN and Washington, DC (Moderator)*

4:30 pm Transition Break

CLOSING PLENARY SESSION

4:45 pm **Developments in Pharmaceutical and Medical Device Pricing and Cost Containment: Implication for Ethics and Compliance Professionals**

Susan Dentzer, *Visiting Fellow, Robert J. Margolis Center for Health Policy, Duke University; Analyst on Health Policy,* The NewsHour; *Former President and CEO, NEHI, (The Network for Excellence in Health Innovation); Former Editor,* Health Affairs, *Washington, DC*

5:15 pm **The Changing Face of the Qui Tam**

Meredith S. Auten, JD, *Partner, Morgan Lewis; Co-chair, White Collar Committee, Qui Tam Subcommittee, ABA Criminal Justice Section, Philadelphia, PA*

Marc Stephen Raspanti, JD, *Partner, Pietragallo Gordon Alfano Bosick & Raspanti, LLP; Co-chair, White Collar Committee Qui Tam Subcommittee, ABA Criminal Justice Section, Philadelphia, PA*

Virginia "Ginny" A. Gibson, JD, *Partner, Hogan Lovells LLP; Former First Assistant U.S. Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA (Moderator)*

6:00 pm **ADJOURNMENT**

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FRIDAY, NOVEMBER 8, 2019

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**

Sujata T. Dayal, JD, *Vice President, Health Care Compliance and Privacy, Pharmaceuticals Group, Johnson & Johnson, Titusville, NJ (PCF Secretary)*

Jeffrey M. Kawalek, MBA, *Deputy Chief Compliance Officer, Jazz Pharmaceuticals, Inc., Philadelphia, PA (PCF Chair)*

Jennifer McGee, JD, *Vice President and Chief Compliance Officer, Otsuka America Pharmaceutical, Inc., Rockville, MD (PCF Treasurer)*

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

Donna White, CCEP, *Vice President, Contracts and Compliance, Chiesi, USA, Cary, NC (PCF Co-Chair)*

Joe Zimmerman, *Vice President and Chief Compliance Officer, US, Ferring Pharmaceuticals, Parsippany, NJ (PCF Co-Chair)*

PhRMA Update

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*

AdvaMed Update

Nancy S. Travis, MS, *Vice President, International Compliance and Governance, Advanced Medical Technology Association (AdvaMed), Washington, DC*

Thoughts as a Former Government Prosecutor Specifically Focused on Data Analytics, Monitoring and Measuring Compliance Effectiveness

Jacob T. Elberg, JD, *Associate Professor of Law, Seton Hall Law School, U.S. Attorney's Office, District of New Jersey; Former Chief, Health Care & Government Fraud Unit and Assistant U.S. Attorney, US Attorney's Office, District of New Jersey, US Department of Justice, Newark, NJ*

Lessons Learned from the Recent Co-pay Assistance Settlements and How these Learnings May Apply to Patient Interactions/ and Oother Assistance Programs

Stefanie A. Doebler, JD, *Of Counsel, Covington & Burling LLP, Washington, DC*

Sarah A. Franklin, JD, *Partner, and Vice-chair, Life Sciences Litigation and Investigations Practice Group, Covington & Burling LLP; Former Attorney, Bureau of Consumer Protection, Division of Marketing Practices, Federal Trade Commission, Washington, DC*

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❑ Pharmaceutical Compliance Forum Group Rate/Conference Only – each of 10 registrations: $1,495

SELECT YOUR MINI-SUMMITS – THURSDAY, NOVEMBER 8 (One from each group):

BLOCK A – 11:15 am
❑ **I:** Prosecuting Illegal Kickbacks: The Cost of Noncompliance
❑ **II:** Reduce Compliance Risk Using a "Portfolio" Approach . . .
❑ **III:** Setting your Five-Year Strategic Compliance Plan
❑ **IV:** Interactions with Patients Including Benchmarking . . .
❑ **V:** Enhanced Compliance Monitoring
❑ **VI:** Best Practices Calculating Profit Disgorgement . . .
❑ **VII:** Annual Medical Device Roundtable

BLOCK B – 12:45 pm
❑ **VIII:** Lesson Learned from Enforcement Actions
❑ **IX:** Compliance Program Operations . . .
❑ **X:** Value-Based Arrangements
❑ **XI:** Framework for Determining . . . FMV
❑ **XII:** Helping Patient Access to Products
❑ **XIII:** The Opioid Crisis: Compliance and Enforcement Trends
❑ **XIV:** Issues with Med Device/Combination Products

BLOCK C – 2:00 pm
❑ **XV:** Charitable Contributions Compliance Considerations
❑ **XVI:** How do you Modernize your Compliance Program . . .
❑ **XVII:** Medical Affairs Proactive Communications . . .
❑ **XVIII:** Transparency and HCP Engagement
❑ **XIX:** Compliance – Board Communications . . .
❑ **XX:** Best Practices when Transitioning . . .
❑ **XXI:** Medical Device Asset Management Risk . . .

BLOCK D – 3:30 pm
❑ **XXII:** Responding to CCPA, GDPR and . . . Data Privacy
❑ **XXIII:** Social Media Engagement by Manufacturers
❑ **XXIV:** Conducting R&D Compliance Risk Assessments
❑ **XXV:** Ensuring a Smooth Transition . . .
❑ **XXVII:** Interactions with Specialty Pharmacy
❑ **XXVIII:** Practice Development Programs . . .

CONFERENCE ELECTRONIC MEDIA:
Onsite Attendees — Following the Congress, the audio/video and Powerpoint presentations are made available in the following formats. To take advantage of the discounted prices below, you must reserve media WITH your Congress registration:

❑ Flash Drive ($129 + $15 shipping) $ 144 ❑ 6 months' access on Web $ 129

WEBCAST CONFERENCE ATTENDANCE

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

STANDARD RATES:

INDIVIDUAL REGISTRATION (Includes Preconference and Conference):

❑ Through Friday, September 13, 2019* $ 795
❑ Through Friday, October 4, 2019** $ 995
❑ After Friday, October 4, 2019 $1,195

THE PHARMACEUTICAL COMPLIANCE FORUM

SPECIAL PHARMACEUTICAL COMPLIANCE FORUM PCF RATES***:

(Includes Preconference and Conference):

❑ PCF Rate $ 695

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Group registration offers the substantial volume discounts set forth below. **All webcast group registrants are enrolled in the preconference and conference.** Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track employee conference participation. Rates are per person.

Conference Access:
❑ 5 or more $595 each ❑ 20 or more $395 each
❑ 10 or more $495 each ❑ 40 or more $295 each

See INTELLECTUAL PROPERTY POLICY, page 10.

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* This price reflects a discount for registration and payment received through Friday, Sept. 13, 2019.

** This price reflects a discount for registration and payment received through Friday, Oct. 4, 2019.

*** To qualify for the PCF member rate an individual must be a employee of a member company of the Pharmaceutical Compliance Forum (PCF), www.PharmaComplianceForum.org.

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You may also register online at www.PharmaCongress.com.

❑ Check/money order enclosed (payable to Health Care Conference Administrators LLC)

❑ Payment by credit card: ❑ American Express ❑ Visa ❑ Mastercard

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