Twenty-Fifth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

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October 28 – 30, 2024

Grand Hyatt Washington • Washington, DC

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A Hybrid Event — Onsite or Virtual Online Event Live and Archived

All Times are EDT • Agenda Current as of September 10, 2024; Subject to Change and Regular Updates

FOR THE FIRST TIME ALL ONSITE ATTENDEES WILL ALSO HAVE ACCESS TO THE CONGRESS LIVE AND ARCHIVED VIRTUAL BROADCAST

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AGENDA AT A GLANCE

MONDAY, OCTOBER 28, 2024 DAY I CONGRESS MINI SUMMITS

MINI SUMMITS GROUP 1
9:00 – 9:50 am

Mini Summit 1: Interactions Between Sales and Medical Affairs

Mini Summit 2: Benchmarking and Brainstorming regarding Evolving Regulator Expectations relating to Off-Channel Communication

Mini Summit 3: OIG New General Compliance Program Guidance

Mini Summit 4: Update on Medical Device Regulatory and Enforcement Actions

Mini Summit 5: Compliance Governance and Board of Directors

Mini Summit 6: Health Equity Initiatives—Compliance Considerations

MINI SUMMITS GROUP 2
10:00 – 10:50 am

Mini Summit 7: Targeted, Tailored, True-to-Life: How DOJ Guidance Should Shape Your Compliance Training

Mini Summit 8: Responsible AI at the Cusp of Scale

Mini Summit 9: Hot Topics and Compliance Oversight in the Research and Development Area

Mini Summit 10: Recent Developments in Enforcement Actions

Mini Summit 11: Balancing Compliance and Legal Roles and Responsibilities

Mini Summit 12: Risk-Based Compliance Audits: Prioritizing What Matters Most

MINI SUMMITS GROUP 3
11:00 – 11:50 am

Mini Summit 13: Fair Market Value: Navigating the Ongoing Changes in HCP Compensation Compliance

Mini Summit 14: Compliance Training on the Digital Frontier

Mini Summit 15: Substance over Form: Practical Approaches to Enterprise Risk Management (ERM)

Mini Summit 16: Patient Support Programs and Patient Access Programs—A Look at the Evolution, Risks, and Enforcement Activity

Mini Summit 17: AI and Compliance Analytics: Real Case Studies for Managing HCP, HCO and Third-Party Risk

Mini Summit 18: Beyond Sales Representatives and MSLs: Considerations for Other Field-Based Roles

Mini Summit 19: ESG Overload – A CCO's Guide to a Balanced Program Implementation

MINI SUMMITS GROUP 4
12:00 – 12:50 pm

Mini Summit 20: Is Bigger Always Bad? Assessing Developing FTC Antitrust Enforcement Trends in Life Sciences

Mini Summit 21: Compliance Considerations for Rare Disease

Mini Summit 22: Enhancing Compliance and Overcoming Challenges under Corporate Integrity Agreements (CIA) through AI and Automation

Mini Summit 23: Fostering a Speak Up Culture

Mini Summit 24: Change Management for Compliance Program Transformation

Mini Summit 25: Presenting to Senior Executives Effectively

DAY I CONGRESS OPENING PLENARY SESSION **1:00 pm – 5:30 pm**

- Co-chair Welcome and Introduction
- Keynote Address
- Keynote Annual OIG Update
- Keynote Annual FDA Update
- Keynote Fireside Chat
- The Implications of AI for Lifesciences Operations and Business Models
- The Implications of AI for Lifesciences Ethics and Compliance Programs
- Chief Compliance Officer Fireside Chat

5:30 pm ADJOURNMENT AND NETWORKING RECEPTION

6:30 pm PHARMA-MEDICAL DEVICE CONGRESS ANNIVERSARY BANQUET

AGENDA AT A GLANCE

TUESDAY, OCTOBER 29, 2024

DAY II CHIEF COMPLIANCE OFFICER ROUNDTABLE 7:30 – 9:45 am

(PCF Sponsored Special Closed Morning Session, Invitation-only)

- CCO Roundtable Welcome and Introductions and Antitrust Admonition
- Behind the Scenes: Evaluating and Presenting Compliance Program Effectiveness to Judges, Juries and Regulators
- Measuring & Presenting Compliance Effectiveness to Company Leadership — Moderated Best Practice Session
- How Do you Optimize your Resources to Enhance your Compliance Program?

DAY II CONGRESS MINI SUMMITS

MINI SUMMITS GROUP 5
8:00 – 8:50 am

Mini Summit 26: Service Fees: Hidden Compliance Risks and Downstream Market Access and Government Price Reporting Implications

Mini Summit 27: Government Programs and Compliance Office Oversight

Mini Summit 28: Advancing Risk Management: A call to action for Integrated Risk Management (IRM) in Pharma

Mini Summit 29: Attention Please! Elevating E&C Learning & Engagement in the Age of Distraction

Mini Summit 30: Key Learnings from CMS Audits

Mini Summit 31: Exploring Risks and Enforcement Trends for Buy-and-Bill Drugs

MINI SUMMITS GROUP 6
9:00 – 9:50 am

Mini Summit 32: Global Compliance Considerations for Designing Patient Support Programs

Mini Summit 33: Qui Tam Declinations—Analysis and Trends When DOJ Declines to Intervene

Mini Summit 34: Privacy Top-Ten: Strategies and Tactics to Address Operational Impacts of the Evolving Privacy Landscape

Mini Summit 35: Hot Topics in State Law Compliance

Mini Summit 36: The Latest and Greatest in Enforcement and Guidelines for Social Media and Influencers

Mini Summit 37: Compliance Considerations for Genetic Testing

MINI SUMMITS GROUP 7
10:00 – 10:50 am

Mini Summit 38: The Role of Technology and Process Enhancements for Effective ABAC Third Party Vendor Diligence

Mini Summit 39: Intersecting Reforms Affecting Drug Pricing

Mini Summit 40: Best Practices in Investigations

Mini Summit 41: Detecting Bias in your AI Tools

Mini Summit 42: Evolving Risks in Medical Affairs

Mini Summit 43: Regulatory Landscape of Transparency US and OUS

MINI SUMMITS GROUP 8
11:00 – 11:50 am

Mini Summit 44: HCP Expense Auditing and Monitoring

Mini Summit 45: Lessons from Spend Transparency and Their Direct Application to Pricing Transparency

Mini Summit 46: State Law Updates—2024 Recap and 2025

Mini Summit 47: Addressing Nuances in Third-Party Risk Management for Medical Devices

Mini Summit 48: Market Access—Compliance Considerations When Resolving Disputes

Mini Summit 49: Analytics and Monitoring: Understanding the Risks and Underlying Complexity of Today's Copay Program Landscape

Mini Summit 50: Negotiating DOJ expectations and business challenges while creating a "Culture of Compliance"

DAY II CONGRESS CLOSING PLENARY SESSION 1:00 – 5:30 pm

- Welcome and Introduction: PCF Co-Chairs
- DOJ Keynote Fireside Chat
- Reflections on the 25-Year Congress Anniversary
- Updates from AdvaMed, BIO and PhRMA
- Investigations, Enforcement and Prosecutions Roundtable
- Perspectives from DOJ, HHS-OIG, and the Relators Bar on How Compliance Departments Can Effectively Prevent and Help Respond To Qui Tam Whistleblower Suits
- The Art of Storytelling—Effectively Conveying the Value of Compliance Beyond Activities and Data

WEDNESDAY, OCTOBER 30, 2024

DAY III PCF INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

8:00 – 12:00 pm

(Industry-only Session for Pharmaceutical and Medical Device Company Ethics and Compliance Professionals and In-house Counsel only. Hosted by PCF)

- Welcome and Introductions
- Antitrust Admonition
- Responsible AI in Action: Real Business Strategies and Mitigation Examples
- Benchmarking, Polling & Q&A Open Forum
- Compliance Breakdowns & Lessons Learned: Unpacking Boeing and Other Company Downfalls
- Hot Topic Table Discussions
- Final Open Forum and Wrap Up

AGENDA DAY I: MONDAY, OCTOBER 28, 2024

7:00 am **Registration Opens**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS: GROUP 1 9:00 – 9:50 am

Mini Summit 1: Interactions Between Sales and Medical Affairs

Join us for a panel session surrounding interactions between Sales and Medical Affairs personnel to maintain regulatory standards, foster integrity within a company, and ultimately ensure patient safety. We'll explore key topics like training and education, clear policies and procedures, and documentation and transparency, monitoring and auditing, firewalls and separation, and risk assessment and mitigation plans. This session aims to provide practical insights and strategies to improve collaboration and compliance within your organization while also promoting stakeholder access to important product information.

9:00 am **Introductions, Discussion and Q&A**

Paul S. Gadiock, JD, *Partner, McDermott Will & Emery; Former Associate Center Director for Policy, Center for Devices and Radiological Health and Associate Center Director for Policy, Center for Devices and Radiological Health, US Food and Drug Administration, San Franciso, CA*

Joseph E. Keeney, *Head of Ethics and Compliance, Galderma Laboratories, L.P.*

Terri L. Ledva, MS, *Director, Ethics & Compliance, Aurobindo Pharma LTD, East Windsor, NJ*

Mike Morgan, MBA, CCEP, *Ethics and Compliance Officer, North America Telix Pharmaceuticals; Former Ethics and Compliance Officer, North America, Corteva; Former Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN*

James (Jamie) Ravitz, JD, *Partner and Co-head, Life Sciences Industry Practice and Head, Food and Drug Administration (FDA) Practice, McDermott Will & Emery, Washington, DC (Moderator)*

Mini Summit 2: Benchmarking and Brainstorming regarding Evolving Regulator Expectations relating to Off-Channel Communication

Government and regulatory bodies have specific expectations for off-channel communications, and industry peers employ diverse compliance strategies.

Topics for discussion include:

- Do you permit off-channel communications for everyone or just for your medical representatives?
- Have you invested in dedicated on-channel communication platforms for interactions between representatives and healthcare professionals?
- How do practices differ in the US compared to international contexts, where apps like WhatsApp and WeChat are widely used?
- How are you balancing healthcare or government contract regulatory recordkeeping requirements (e.g., data privacy, healthcare, contractual, litigation) with the new DOJ expectations?

9:00 am **Introductions, Discussion and Q&A**

Jaime Guerrero, JD, *Vice President, Global Compliance, Edwards Lifesciences; Former Assistant United States Attorney, United States Attorneys' Office, Central District of California, Irvine, CA*

Anna Littman-Quinn, CPA, CFE, *Senior Manager, Forensic & Integrity Services, EY, Boston, MA*

Mike Stanek, JD, *Associate Vice President, Assistant General Counsel, Eli Lilly and Company, Indianapolis, IN*

Erin Brown Jones, MA, JD, *Deputy Office Managing Partner, Washington, DC, Latham & Watkins LLP, Washington, DC (Moderator)*

Mini Summit 3: OIG New General Compliance Program Guidance

A deeper dive into OIG's new guidance and its impact on your Compliance Adherence Practices. Learn how to best leverage the OIG Compliance Guide in light of the DOJ Evaluation of Corporate Compliance Programs.

9:00 am **Introductions, Discussion and Q&A**

Frank Adamo, MS, *Director Corporate Compliance and Ethics, Syneos Health; Former Senior Special Agent Office of the Inspector General, Department of JusticeFormer Special Agent, Drug Enforcement Administration, Somerset, NJ*

Alexis Shaw, *Deputy Chief Compliance Officer, Paratek Pharmaceuticals; Former Compliance Officer, Endo, King of Prussia, PA*

Eric Teasdale, JD, *Senior Director, US Business Ethics Global Business Ethics, Ipsen; Former Head of USBU Ethics & Compliance - Gastroenterology Business Unit, Patient Services & Market Access, Takeda, Cambridge, MA*

Amy Wilson, MBA, MSJ, *Vice President, Chief Compliance Officer, Esperion; Former Head of U.S. Compliance, MorphoSys, Boston, MA*

Robert Melillo, JD, *Co-founder and Managing Director, G&M Health; Former Vice President & Managing Director, Compliance Management and Commercial Services, PRS Franklin, an inVentiv Health Company, Frenchtown, NJ (Moderator)*

Mini Summit 4: Update on Medical Device Regulatory and Enforcement Actions

Join us for an enlightening and informative panel discussion that delves into the evolving landscape of medical device regulations and recent enforcement actions. This timely session will provide an update on the latest developments shaping the regulatory environment for medical devices, offering industry best practices and insights gleaned from recent cases that have influenced compliance strategies. Key discussion points will include:

- Enforcement Trends: Explore recent enforcement actions and their implications for medical device manufacturers, highlighting key lessons and areas of heightened regulatory scrutiny.
- Compliance Challenges: Discuss strategies to navigate and adhere to evolving regulatory requirements, ensuring robust compliance frameworks that meet industry standards.
- Global Harmonization Efforts: Assess progress towards global regulatory alignment and its impact on market access and the development of innovative medical devices.
- Future Outlook: Gain predictions on emerging regulatory trends and their potential implications for the medical device industry, shaping future compliance strategies and business decisions.

Session continued next page

THE AGENDA OF THE FIRST PHARMA CONGRESS

9:00 am **Introductions, Discussion and Q&A**

Terra Buckley, JD, *Chief Compliance Officer, LivaNova; Former Executive Director, Head, Business Advisory Center of Excellence and US Healthcare Compliance, Celgene, Summit, NJ*

Jenny McVey, MS, PhD, *North America Compliance Officer, bioMérieux; Adjunct Professor, Fordham University School of Law, Salt Lake City, UT*

Kristen Dooley Perriello, JD, *Principal, Choate, Hall & Stewart, LLP; Former Special Assistant District Attorney, Suffolk County District Attorney's Office, Boston, MA*

Casey J. Horton, CFE, *Managing Director, Epsilon Life Sciences; Former Director, Compliance Operations, AbbVie, Chicago, IL (Moderator)*

Mini Summit 5: Compliance Governance and Board of Directors

Panelists will discuss how the Board's role and responsibility have evolved in response to recent legal and regulatory developments and the impact these changes have had on life sciences companies. The panel will offer practical tips for ensuring Board members are engaged, informed, and well-positioned to help the compliance officer and compliance function.

9:00 am **Introductions, Discussion and Q&A**

William L. Aprea, JD, *Senior Vice President, Legal and Interim Chief Compliance Officer, Phathom Pharmaceuticals, Florham Park, NJ*

Avia M. Dunn, JD, MBA, *Partner, Life Sciences and Health Care, Skadden, Arps, Slate, Meagher & Flom, Washington, DC*

Christine Gordon, JD, *Chief Compliance Officer & Head of GRC, Olympus Corporation of the Americas; Former Assistant US Attorney, US Attorney's Office, District of Philadelphia, Bethlehem, PA*

Eric M. Baim, *Partner, Dovetail Consulting Group LLC; Former Vice President, Head of Compliance, US, Shire; Former Executive Director, Global Integrity and Compliance, Novartis, Boston, MA (Moderator)*

Mini Summit 6: Health Equity Initiatives—Compliance Considerations

*Introduce and discuss compliance risks and considerations implicated by industry trends toward confronting unmet needs through initiatives addressing health equity and social determinants of health (SDOH).

*According to the World Health Organization (WHO), health and health equity are determined by the conditions in which people are born, grow, live, work, play and age, as well as biological determinants. Structural determinants (political, legal, and economic) along with social norms and institutional processes shape the picture that companies and compliance professionals face when assessing risk and navigating new territory.

*Notably, the HHS Office of Disease Prevention and Health Promotion (ODPHP)'s current iteration of its 10-year assessment and goal setting initiative for national health—called Healthy People 2030—has an increased focus on health equity/elimination of disparities, social determinants of health, and health literacy.

*Familiarize compliance professionals with 5 domains to SDOH identified in Healthy People 2030

Highlight recent health equity initiatives and challenges observed in industry.

Review of **OIG Advisory Opinion No. 22-19** as practical example of a manufacturer's Proposed Arrangement incorporating HE/SDOH factors and how HHS-OIG evaluated the relevant legal issues (AKS, CMP)

9:00 am **Introductions, Discussion and Q&A**

Yogesh Bahl, MBA, *Partner and Leader, Life Sciences and Healthcare Practice, Resolution Economics; Chief Financial Officer and Head of Investor Relations, IACTA Pharmaceuticals, New York, NY*

Nereyda Garcia, JD, *Head, Ethics & Compliance, US Business Unit, Takeda; Former Compliance Head, Rare Disease and Rare Blood Disorders, Sanofi, Boston, MA*

Danielle Pelot, JD, *Partner, Choate, Hall & Stewart, Boston, MA (Moderator)*

9:50 am **Transition Break**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS: GROUP 2 **10:00 – 10:50 am**

Mini Summit 7: Targeted, Tailored, True-to-Life: How DOJ Guidance Should Shape Your Compliance Training

- Let's Talk About the DOJ
- Target the Right Audiences
- Tailor Content for Your Organization
- Make Training True to Life
- Have Form Follow Function
- Measure Effectiveness

10:00 am **Introductions, Discussion and Q&A**

Jacob T. Elberg, JD, *Associate Professor & Faculty Director, Center for Health & Pharmaceutical Law, Seton Hall University School of Law; Former Chief, Health Care & Government Fraud Unit, Assistant US Attorney, US Attorney's Office, District of New Jersey, Newark, NJ*

David Falcone, *Vice President Global Compliance, Merz Aesthetics; Former Director of Privacy, Ethics and University Compliance Officer, Duke University, Raleigh, NC*

Catherine Kanzler, JD, *Vice President, Global Head of GRC Strategy & Planning, Olympus Corporation, Center Valley, PA*

Kirsten Liston, *Founder and Chief Executive Officer, Rethink Compliance; Co-author,* The Compliance Entrepreneur's Handbook: Tips, Tools, and Tactics to Find Your Killer Idea and Create Success on Your Own Terms, *Denver, CO (Moderator)*

Mini Summit 8: Responsible AI at the Cusp of Scale

GenAI use cases continue to advance rapidly as Proofs of Concept begin to scale across the healthcare value chain. Are Responsible AI approaches keeping pace? Come discuss the latest look at AI ethics, strategic risk frameworks, scaling governance, embedding tools to move towards "RAI by Design", the implications of new regulations, and observations on the key barriers and constraints challenging RAI implementation—crucial for any risk & compliance leader who aims to navigate the complexities of deploying AI responsibly.

10:00 am **Introductions, Discussion and Q&A**

Noah Broestl, MS, *Partner & Associate Director of Responsible AI, Boston Consulting Group (BCG); Former Safety Evaluations, Lead TPM, Bard, Google, Brooklyn, NY*

Dana Garbo, MS, JD, *Chief Privacy Officer, Medline Industries, LP, Advisory Council Member, Stillman School of Business, Seton Hall University; Former Privacy Lead, Embecta spin-off (Diabetes Care business unit, BD, Northfield, IL*

Christine A. Moundas, MPH, JD, *Partner, Ropes & Gray, LLP, New York, NY*

Tad Roselund, *Managing Director and Senior Partner, and Former Chief Risk Officer, The Boston Consulting Group, Montclair, NJ (Moderator)*

Mini Summit 9: Hot Topics and Compliance Oversight in the Research and Development Area

Many companies continue to struggle with how to define and resource a dedicated research and development-focused compliance function. While regulatory and quality risks are often well characterized and subject to oversight and control, this panel aims to identify areas of attention for compliance officers. Some areas for discussion will include review and needs assessment for use of clinical advisors, publication planning and development, clinical trial recruitment payments and initiatives, and due diligence on collaborative research partners outside the U.S.

10:00 am **Introductions, Discussion and Q&A**

Ryan Bonistalli, JD, *Senior Director, Compliance, Ultragenyx; Former Director, Corporate Compliance, Kaléo, San Francisco, CA*

Jill Dailey, JD, *Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer, New York, NY (PCF Board)*

Mahnu V. Davar, MA, JD, *Partner and Co-chair, Life Sciences & Healthcare Regulatory, Arnold & Porter; Adjunct Professor of Law, University of Pennsylvania Law School, Washington, DC, (Moderator)*

Mini Summit 10: Recent Developments in Enforcement Actions

This panel will explore recent enforcement actions impacting the pharma and device industries, including developments involving DOJ, the FTC, and FDA, and consider the compliance and legal implications of these matters as well as what they may foreshadow in the year to come.

10:00 am **Introductions, Discussion and Q&A**

Deidre Arnold, JD, *Vice President TR Strategy/US TTR Franchise, Commercial Legal, Alnylam Pharmaceuticals, Cambridge, MA*

Peter Jensen, JD, *Vice President, Global Chief Compliance Officer, Arthrex, Naples, FL*

Katherine C. Norris, MPA, *Senior Managing Director, Healthcare & Life Sciences Compliance, Disputes and Economics, Ankura, Honolulu, HI*

Maya P. Florence, JD, *Partner, Life Sciences and Health Care, Skadden, Arps, Slate, Meagher & Flom, Boston, MA (Moderator)*

Mini Summit 11: Balancing Compliance and Legal Roles and Responsibilities

This session will explore the respective roles of legal and compliance within a life sciences company. It will consider how prior enforcement matters, statements from the government, and considerations regarding attorney-client privilege may shape the contours of the two functions. It will also give suggestions for how to think about responsibilities within a particular organization and offer examples of best practices for working together.

10:00 am **Introductions, Discussion and Q&A**

Yvonne Clark, JD, *Vice President, Head of Corporate Compliance, Spark Therapeutics, Philadelphia, PA*

Terri Segura, JD, *Vice President, Compliance Officer, Americas, Zimmer Biomet, Chevy Chase, MD*

Natasha Trifun, JD, *Head of Ethics and Compliance for EUCAN/ International, R&D, and Operations for Alexion AstraZeneca Rare Disease; Former Corporate Counsel, Brazil Compliance Officer, Pfizer, Boston, MA*

Stefanie A. Doebler, JD, *Partner and Co-Chair, Health Care Practice Group, Covington & Burling, LLP, Washington, DC, (Co-Moderator)*

Sarah A. Franklin, JD, *Partner and Vice-Chair, Life Sciences Investigations Practice, Covington & Burling, LLP; Former Attorney, US Federal Trade Commission, Washington, DC (Co-Moderator)*

Mini Summit 12: Risk-Based Compliance Audits: Prioritizing What Matters Most

Join us for a dynamic panel discussion with compliance professionals, focusing on applying a risk-based approach to compliance auditing. Learn how to prioritize compliance efforts based on risk, ensuring strategic and impactful audits. Discover the importance of this approach, especially when budgets and resources are limited, to allocate efforts effectively. Gain insights into industry best practices and practical techniques for designing and implementing risk-based audits tailored to your organization's unique risk profile. Equip yourself with the knowledge to manage compliance risks efficiently and keep your organization resilient in a complex regulatory environment.

10:00 am **Introductions, Discussion and Q&A**

Sarah diFrancesca, JD, *Executive Director of Compliance, Dermatology, Incyte, Wilmington, DE*

Timothy P. Loper, JD, *Vice President, Head of US and Above Market Compliance and Ethics, Bristol Myers Squibb; Former AUSA, US Attorney's Offices, Washington, DC & Miami, FL, US Department of Justice, Princeton, NJ*

Russell Rose, JD, *Senior Manager, Deloitte, Dallas, TX*

Amanda Johnston, JD, RAC, *Partner, Gardner Law, PLLC; Adjunct Professor of Law, Mitchell Hamline School of Law, St. Paul, MN (Moderator)*

10:50 am **Transition Break**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS: GROUP 3 **11:00 – 11:50 am**

Mini Summit 13: Fair Market Value: Navigating the Ongoing Changes in HCP Compensation Compliance

Hear a panel of compliance veterans discuss the evolving landscape of HCP compensation within the life sciences industry. Gain a deeper understanding of how organizations around the globe are tackling critical topics such as inflation, HCP rate pushback, non-HCP tiering and the growing impact of social media influencers. Discover how to stay ahead of the curve and ensure compliance while leveraging new strategies to navigate the complexities of FMV in today's changing environment.

11:00 am **Introductions, Discussion and Q&A**

Kim Kwak, *Director, Global Corporate and Healthcare Compliance, Medline Industries, Cincinnati, OH*

Alexis Shaw, *Deputy Chief Compliance Officer, Paratek Pharmaceuticals; Former Compliance Officer, Endo, King of Prussia, PA*

Heather Young, JD, *Executive Director, Compliance Officer, Olympus Corporation of the Americas, Former Assistant US Attorney, US Attorney's Office, District of Philadelphia, Center Valley, PA*

Eric Bolesh, *Chief Operating Officer, Cutting Edge Information, Durham, NC (Moderator)*

Mini Summit 14: Compliance Training on the Digital Frontier

When we think about the "digital frontier" our thoughts immediately go to AI, and understandably so. It seems like there are new advances in AI every day, with the promise of making the lives of compliance professionals easier. However, when it comes to compliance training, we're constrained by the toolset for developing training and the technology platforms for delivering the training, which are lagging behind broader technological trends.

But there is a broader challenge at play. Coupled with the need to train "digital natives," employees who have grown up on the so-called digital frontier, these limiting platforms present compliance leaders with a conundrum: how to use what we've got to effectively train digital natives as well as the "digital immigrants" within our organizations. This session aims to provide practical ideas for addressing this conundrum while leveraging the power of new technologies and embracing new ways to use tried and true approaches.

Session continued next page

THE AGENDA OF THE FIRST PHARMA CONGRESS

THE FIRST ANNUAL PHARMACEUTICAL INDUSTRY

The Issue

Over the past few years, the pharmaceutical industry has come under increased scrutiny from the federal government. The US Government and the FDA have begun to more rigorously enforce the rules and regulations that apply to the pharmaceutical industry. Until recently, the majority of the government's enforcement efforts have focused on health care providers. Now pharmaceutical companies are finding themselves under the gun. Pharmaceutical companies are being forced to update their knowledge of existing laws and incorporate them into their business plans as well as create future business plans that comply with the often ambiguous and confusing federal regulations. Critical issues such as drug pricing, sales and marketing practice, conducting clinical trials and a proposed Medicare prescription drug benefit are many topics that will be discussed at this important summit.

The Summit

The First Annual Pharmaceutical Industry Regulatory and Compliance Summit has been established as a direct result of the heightened need for corporate compliance programs, increased government scrutiny and new regulations being imposed upon the pharmaceutical industry. It will bring together the nation's leaders in the pharmaceutical industry. This one-day conference, sponsored by the Health Care Compliance Association in association with the Food and Drug Law Institute will be held October 18, 2000, at the Grand Hyatt Hotel, Washington, DC.

Pharmaceutical professionals looking for a comprehensive understanding of the current and future compliance laws and regulations and enforcement initiatives affecting the pharmaceutical industry should plan to attend.

Sponsoring Organizations

The First Annual Pharmaceutical Industry Regulatory & Compliance Summit is sponsored by:
The Health Care Compliance Association (HCCA), the 501 (c) (6) association representing approximately 2000 of the nation's healthcare chief compliance officers. HCCA offers a number of programs. For more information on HCCA, call 1-800-580-8373 or go to the HCCA website at www.hcca-info.org.

In Association with the:
Food and Drug Law Institute (FDLI) is a non-profit institute dedicated to advancing the public health by providing a neutral forum for critical examinations of the laws, regulations, and policies related to drugs, medical devices, other healthcare technologies, and food. For more information call (800) 956-6293 or visit www.fdli.org.

Extensive Written Materials

The Faculty of the Summit will prepare written materials to accompany their presentations, including copies of presentation overheads, slides and related materials that will be included with the summit materials.

Who Should Attend:

Health Care Executives and Board Members
Health Plan, Health System and Physician Organization Medical Directors
Physicians
Pharmacists
Registered Nurses
Purchasers, including Private Employers and Public Purchasers
Pharmaceutical Manufacturers
Generic Pharmaceutical Manufacturers
Site Management Organizations
Clinical Research Organizations
Pharmacy Benefit Management Companies
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
Pharmaceutical Consultants
Investment Bankers
Venture Capitalists
Health Care Regulators and Policy Makers
Health Services Researchers and Academics

Summit Goals and Objectives

At the conclusion of the Summit, attendees should be able to:
- Discuss the regulators' enforcement initiatives pertaining to the pharmaceutical industry.
- Explain how clinical trials should be conducted and build controls to mitigate potential risk.
- Relate to case studies that demonstrate how multinational corporations expanded their compliance programs to international operations.
- Take appropriate steps if a government investigation is initiated.
- Discuss the legal and ethical issues raised by advances in Genomics.
- Apply practical tips about implementing compliance programs in Pharmaceutical Companies.
- Understand the FDA labeling and advertising requirements and build compliance programs around those requirements.
- Appreciate the field of BioEthics and its relation to the pharmaceutical industry.
- Understand legal obstacles associated with promoting drugs on the internet and develop strategies to deal with them.
- Learn drug sample regulations and develop strategies for dealing with them.
- Gain appreciation for applicability of HIPAA statute to the pharmaceutical industry and learn compliance strategies.
- Learn the do's and don'ts of government pricing and develop necessary controls to bill medicaid.

Prerequisites: None

SAVE THE DATE: NOVEMBER 15 – 17, 2000

The National Congress on the Future of Genomics, Biotechnology & Pharmaceuticals in Medical Care
Hyatt Regency Hotel, Crystal City, VA
www.PharmaCongress.com • 888-294-3504

11:00 am **Introductions, Discussion and Q&A**

Traci Maldonado, *Senior Manager, Ethics & Compliance Training, Policy & Communications, Novo Nordisk, Princeton, NJ*

Erica Powers, *Head, US Commercial Compliance and Compliance Operations, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals, Boston, MA*

Daniel O'Connor, *Senior Vice President, NXLevel Compliance; Former Vice President, Learning & Development, Morgan Stanley, New York, NY (Moderator)*

Mini Summit 15: Substance over Form: Practical Approaches to Enterprise Risk Management (ERM)

Substance over Form: Practical Approaches to Enterprise Risk Management (ERM)
The approach to ERM has become over-engineered, resulting in focus on process vs. targeting the risks that count. Join us for an interactive discussion on the key considerations for practical ERM:

- Creating a sustainable process to consistently identify, prioritize and measure risks being raised
- Integrating ERM with the overall business strategy and culture
- Prioritizing risks and resources based on likelihood and impact
- Leveraging both qualitative and quantitative data to derive the full value of risk insights
- Breaking siloes to effectively enable cross-functional triangulation of risk

11:00 am **Introductions, Discussion and Q&A**

Susan Barsky, MS, *Vice President, Corporate Compliance, Biocryst; Former Head, North America Compliance, United Therapeutics, Raleigh, NC*

William Benvenuto, JD, *Senior Vice President, Chief Legal Affairs, Compliance & Privacy Officer, Travere; Former Assistant General Counsel & Chief Compliance Officer, Millennium Health, San Diego, CA*

Ed Sleeper, MS, *Vice President, Chief Ethics and Compliance Officer, Veloxis Pharmaceuticals; Former Global Chief Ethics and Compliance Officer, HUTCHMED, Cary, NC*

Michael L. Shaw, JD, *Global Head of Compliance, Privacy and Risk, ZS; Former Vice President and Compliance Officer, GlaxoSmithKline; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, Princeton, NJ (Moderator)*

Mini Summit 16: Patient Support Programs and Patient Access Programs—A Look at the Evolution, Risks, and Enforcement Activity

Patient Support (PSPs) and Patient Assistance Programs (PAPs) have been an integral part of the healthcare system, bridging patient access to essential healthcare. However, in reviewing the evolving legal landscape and increasing scope and application of the AKS on these activities, compliance professionals are facing ongoing challenges in providing advice to mitigate the risks often associated with these programs. In particular, the areas of sponsored genetic and diagnostic testing programs, nursing support, Independent Charity Patient Assistance Programs and co-pay assistance continue to pose enforcement risk, and companies are prone to face challenges in navigating these risks while assisting patients.

This panel will explore the laws that PSPs and PAPs implicate and recent enforcement activity in this space. The discussion will also cover the general areas of risks to avoid with respect to the Anti-Kickback Statute (AKS), HIPAA/Data Privacy and FDCA/Off-Label prescribing, and offer up some key learnings to ensure compliance.

11:00 am **Introductions, Discussion and Q&A**

Andrew Clark, MBA, *Partner/Principal, Forensic & Integrity Services, EY, Washington, DC*

Michael G. Hercz, JD, *Senior Vice President & General Counsel, Sentynl; Former Executive Director, Enterprise Risk Management, Amgen, Los Angeles, CA*

Samantha Barrett Badlam, JD, *Partner, Litigation & Enforcement Group, Ropes & Gray, Washington, DC (Moderator)*

Mini Summit 17: AI and Compliance Analytics: Real Case Studies for Managing HCP, HCO and Third-Party Risk

Ensuring that your compliance program is effective at mitigating risks related to HCPs, HCOs, and third parties requires you to measure and monitor those risks. Detecting those risks in near real-time using AI and compliance analytics has emerged as the leading way to achieve that goal and can mean that issues are corrected before non-compliance becomes systemic. Learn how 4 companies have leveraged such technology for real-time data-driven monitoring. During this session, we will discuss:

- How to monitor enterprise financial data practically for risks related to HCPs, HCOs and third parties
- How to configure your data analytics and leverage AI to target your compliance resources to the highest risks
- How to use insights across the compliance organization and beyond
- Best practices for rolling out and staffing such an analytics program

11:00 am **Introductions, Discussion and Q&A**

Melissa Kaschak, CPA, CFE, CISA, *Compliance Operations and ERM, Olympus Corporation of the Americas, Allentown, PA*

Angelique Lee, JD, *Vice President, Chief Compliance & Ethics Officer, Jazz Pharmaceuticals; Former VP, Global Chief Compliance Officer; R&D Legal Lead, Greenwich Biosciences & GW Pharmaceuticals, Orange County, CA*

Natasha Trifun, JD, *Head of Ethics and Compliance for EUCAN/ International, R&D, and Operations for Alexion AstraZeneca Rare Disease; Former Corporate Counsel, Brazil Compliance Officer, Pfizer, Boston, MA*

Parth Chanda, MPA, JD, *Founder and Chief Executive Officer, Lextegrity; Former Chief Compliance Counsel - Global Oncology, Pfizer, New York, NY (Moderator)*

Mini Summit 18: Beyond Sales Representatives and MSLs: Considerations for Other Field-Based Roles

TLLs, CNEs, NAMs, KAMs, FRMs, oh my! This panel, comprised of a diverse set of senior life science compliance leaders, will explore the proliferation of field-based roles across our industry and the emerging compliance concerns.

Called by various names at different companies, we will dive into the alphabet soup of field team members interacting with HCPs, HCOs, payors, patients, and other customers to discuss:

- An overview of "non-traditional" field roles such as thought leaders, regional marketing, reimbursement, GPO and account sales, nurse educators, outcomes liaisons, and more
- The risks associated with each group's activities
- Discussion of appropriate cross-functional interactions
- Approaches to ensuring these roles understand the expectations for ethical and compliant behavior

11:00 am **Introductions, Discussion and Q&A**

Gus Papandrikos, MBA, *Global Head of Compliance Assurance, Daiichi Sankyo; Former Senior Head, Compliance Operations, Global Compliance & Risk Management, Shire, New York, NY*

Timothy Roberts, MA, *Global Chief Compliance Officer, Legend Biotech; Former Senior Director Compliance & Privacy U.S, Ferring; Former Head, Ethics, Risk & Compliance, Integrated Marketing, Novartis, Mendham, NJ*

Adam Oakley, *Senior Director, Potomac River Partners, Washington, DC, (Moderator)*

Mini Summit 19: ESG Overload — A CCO's Guide to a Balanced Program Implementation

In this session you will receive some practical tips on implementing and developing an Environmental, Social and Governance (ESG) program. There is significant overlap in life science companies' Compliance Programs and ESG Programs. You will hear case studies from two Industry experts – one in Healthcare Compliance and one in ESG. They will share some of their learnings on how to work together to leverage existing Compliance Program efforts to support ESG program design, take advantage of a CCOs internal business knowledge and network in developing standard ways of information gathering and reporting, and ideas on how to calibrate decisions on where to expend resources for the ongoing ESG journey.

Ann Beasley, JD, *Managing Director, Life Sciences Consulting Group, Paul Hastings; Former Senior Vice President and Chief Compliance Officer, Zai Lab, Boston, MA*

Session continued next page

Jim Massey, MS, *Advisor/Consultant to Executives, Founders, C-suite, Board Directors, ROUTE 2 INC; Board Member One Tree Planted; Former Chief Sustainability Officer, Zai Lab, Washington DC*

11:50 am **Networking Luncheon**

11:50 am **EXHIBIT HALL OPENS & NETWORKING LUNCHEON**

11:50 pm **Networking Luncheon with Desert and Coffee in the Exhibit Hall**

PHARMA-MED DEVICE CONGRESS LUNCHEON

You may pick up your box lunch and bring it to networking tables in the exhibit hall and foyer or to your Mini Summit.

PHARMA-MED DEVICE CONGRESS MINI SUMMITS: GROUP 4 12:00 – 12:50 pm

Mini Summit 20: Is Bigger Always Bad? Assessing Developing FTC Antitrust Enforcement Trends in Life Sciences

12:00 pm **Introductions, Discussion and Q&A**

Scott S. Liebman, JD, *Partner, Chair of FDA Regulatory & Compliance, Co-Chair of Life Sciences Practice, Sheppard Mullin Richter & Hampton LLP, New York, NY*

Jared P. Nagley, JD, *Partner, Sheppard Mullin Richter & Hampton LLP; Former Attorney, Federal Trade Commission, New York, NY*

Mini Summit 21: Compliance Considerations for Rare Disease

Companies that launch rare disease treatments successfully excel in three main areas—disease state awareness among healthcare professionals, commitment to the patient community and innovative patient access. They demonstrate great commitment to the rare disease community, both patients and patient advocates, caregivers and families. They have pioneering methods for patient identification, including widespread use of diagnostic testing, especially genetic testing. They provide assistance to help patients and their caregivers navigate healthcare systems globally. This session will talk through challenges companies face, tactics to overcome these challenges, and pathways to compliant patient support.

12:00 pm **Introductions, Discussion and Q&A**

Michael G. Hercz, JD, *Senior Vice President & General Counsel, Sentynl; Former Executive Director, Enterprise Risk Management, Amgen, Los Angeles, CA*

Gregory S. Moss, LLB, *Chief Business and Legal Officer; Corporate Secretary and Chief Compliance Officer, Evommune, Inc., Member Board Of Directors, Vitls; Former Executive Vice President, General Counsel and Corporate Secretary, Chief Compliance Officer, Kadmon Holdings, Inc., New York, NY*

Keren Tenenbaum, JD, *US General Counsel and Chief Compliance Officer, Ascendis; Former General Counsel, Vice President, Legal & Compliance, US, Vifor Pharma, New York, NY*

Ronald L. Wisor, Jr, JD, *Partner, Lifesciences and Healthcare, Hogan Lovells, Washington, DC*

S. Joy Dowdle, JD, *Partner, Paul Hastings, Houston, TX (Moderator)*

Mini Summit 22: Enhancing Compliance and Overcoming Challenges under Corporate Integrity Agreements (CIA) through AI and Automation

The panel aims to provide attendees with practical insights into how AI and technology can transform the landscape of compliance management, making it more proactive and less burdensome to discuss opportunities and challenges.

Overview of Corporate Integrity Agreements (CIAs): CIAs are formal agreements between healthcare organizations and the Office of Inspector General (OIG) designed to ensure compliance with federal healthcare program requirements and FDA regulations over a five- to ten-year period. These agreements mandate rigorous internal controls, compliance frameworks, and regular oversight, which are crucial in upholding organizational integrity.

12:00 pm **Introductions, Discussion and Q&A**

Saul B. Helman, MD, *President, Epsilon Life Sciences, Chicago, IL*

Laura E. Heyduk, *Head, US Compliance, Biogen; Former Compliance Director, Healthcare Compliance, Insulet, Cambridge, MA*

Scott A. Memmott, JD, *Partner, Morgan, Lewis & Bockius LLP, Former Special Assistant US Attorney, Eastern District of Virginia, Washington, DC*

Erin Vales, *Principal Consultant, Cresen Solutions, Richmond, VA (Moderator)*

Mini Summit 23: Fostering a Speak Up Culture

- Strategies to remove roadblocks and encourage employees to speak up
- Effective, targeted, creative messaging to foster and improve speak-up culture
- Data to show your reporting system is working

12:00 pm **Introductions, Discussion and Q&A**

Cindy Cetani, LPEC, NACD.DC®, *Chief Integrity and Compliance Officer, Indivior; Former Group Integrity and Compliance, Head, Compliance Operations, Novartis, Glen Allen, VA (PCF Board)*

Margaret K. Feltz, MA, JD, *Vice President, Ethics & Compliance, Chief Compliance Office, Purdue Pharma LP; Former Co-chair, PCF, Stamford, CT*

Kassie Harrold, JD, *Executive Vice President, Chief Compliance Officer, Integrity & Compliance, Mallinckrodt; Former Global Compliance Counsel, Solutia, Hampton, NJ*

Andrea Falcione, JD, CCEP, *Chief Ethics and Compliance Officer and Head of Advisory Services, Rethink Compliance, Boston, MA (Moderator)*

Mini Summit 24: Change Management for Compliance Program Transformation

This session will provide insights and strategies for effectively managing change during the transformation of compliance programs. With regulatory requirements continuously evolving, organizations need to adapt their compliance programs to stay ahead. This session will explore best practices and practical approaches to navigate the complexities of change management, ensuring a smooth and successful transformation while maintaining compliance. Attendees will gain valuable knowledge and tools to effectively lead change initiatives, engage stakeholders, overcome resistance, and foster a culture of continuous compliance improvement.

Session continued next page

THE AGENDA OF THE FIRST PHARMA CONGRESS

REGULATORY & COMPLIANCE SUMMIT

Wednesday, October 18th

8:00 am	**Welcome**
8:00 – 8:30 am	**The OIG's Enforcement Initiatives in the Pharmaceutical Industry** Lewis Morris, *Assistant Inspector General for Legal Affairs, Office of the Inspector General in the US Department of Health and Human Services*
8:30 – 9:00 am	**State Enforcement Initiatives in the Pharmaceutical Industry** Carolyn J. McElroy, *Director, Maryland Medicaid Fraud Control Unit*
9:00 – 9:30 am	**A Federal Prosecutor's Perspective on the Pharmaceutical Industry** James Sheehan, Esq., *Assistant US Attorney and Chief of the Civil Division, US Attorney's Office for the Eastern District of Pennsylvania*
9:30 – 10:00 am	**Insights into the Department of Justice's Enforcement Initiatives** John Bentivoglio, Esq., *Partner, Arnold & Porter and Former Associate Deputy Attorney General and Special Counsel for Health Care Fraud, Department of Justice*
10:00 – 10:30 am	**FDA Enforcement Initiatives** Arvin P. Schroff, Ph.D., *Arvin Schroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration*
10:30 – 11:00 am	**Regulator Q & A** Questions and answers with the morning presenters.
11:00 – 11:30 am	**Break**
11:30 am – 12:30 pm CONCURRENT SESSIONS I	**A. The Practical Implications of the Anti-Kickback Laws to Pharmaceutical Sales and Marketing** Joseph Metro, Esq., *Partner, Reed Smith Shaw & McClay* Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company* **B. Clinical Trials: Compliance Implications and Solutions** Larry McDade, Esq., *Office of Consumer Litigation, Department of Justice* Loretta Stipa, *Resident Agent-in-Charge, FDA's Office of Criminal Investigations* Claudia Baldassano, MD, *University of Pennsylvania* **C. Compliance on a Global Scale: How to Shape a Compliance Program for a Multinational Pharmaceutical Company** Bert Weinstein, Esq., *Vice President and Assistant General Counsel, Merck & Co., Inc.* Caroline West, Esq., *Vice President, Global Litigation and Compliance, Aventis Pharmaceuticals* **D. "Houston We Have a Problem" What to Do When the Feds Come Knocking** Mike Kendall, Esq. (Moderator), *Partner, McDermott, Will & Emery* Rick Robinson, Esq., *Partner, Fulbright & Jaworski* Patricia Meador, Esq., *Partner, Womble, Carlyle Sandridge & Rice*
12:30 – 2:30 pm	**Luncheon and Presentations**
1:00 – 1:30 pm	**The Legal and Ethical Issues Raised by Advances in Genomics** Barbara P. Fuller, JD, RHIA, *Senior Policy Advisor, National Human Genome Research Institute, National Institutes of Health*
1:30 – 2:30 pm	**Compliance Roundtable** Eric Siegel, Esq., *Counsel, SmithKline Beecham* Valli Baldassano, Esq., *Director, Global Compliance, Pharmacia Corporation* Janice Forsyth, Esq., *Chief Compliance Officer, Express Scripts, Inc.* Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company* Brent L. Saunders, JD, MBA (Moderator), *Director, PricewaterhouseCoopers*
2:30 – 2:45 pm	**Break**
2:45 – 3:45 pm CONCURRENT SESSIONS II	**A. Compliance with FDA Labeling and Advertising Requirements** Louis Morris, Ph.D., *Senior Vice President, SCP Communications* Robert B. Nicholas, Esq., *Partner, McDermott, Will & Emery*

12:00 pm **Introductions, Discussion and Q&A**

Kevin L. Espinoza, MBA, *Vice President, Deputy Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo and BTG, Richmond, VA*

Jeffrey Kawalek, MBA, *Chief Compliance Officer, Zambon US; Former Deputy Chief Compliance Officer US, Jazz Pharmaceuticals, New York, NY*

Baris Goc, *Partner, Life Sciences Risk Consulting Team, PwC, New York, NY (Moderator)*

Mini Summit 25: Presenting to Senior Executives Effectively

Increase your chances of getting buy-in from senior leadership. Join this interactive discussion to share key strategies and techniques for presentation content/style to manage and address the priorities of senior leaders, such as distilling complex information and how to use storytelling, visuals, and data effectively to engage senior leaders and convey key points persuasively.

12:00 pm **Introductions, Discussion and Q&A**

Nereyda Garcia, JD, *Head, Ethics & Compliance, US Business Unit, Takeda; Former Compliance Head, Rare Disease and Rare Blood Disorders, Sanofi, Boston, MA*

John S. Rah, JD, *Counsel, Potter & Murdock, Potomac, MD*

Omar Richardson, *Senior Director, Compliance, Shinogi; Former Compliance Officer, Grünenthal Group, New York, NY*

David Amendola, *Director, Resolution Economics; Former, Global Compliance Risk Evaluation and Management, ConvaTec, New York, NY, (Moderator)*

12:50 pm **Transition Break**

PHARMA-MED DEVICE CONGRESS OPENING PLENARY SESSION

1:00 pm **Co-chair Welcome and Introduction**

Donna White, CCEP, *Vice President and Compliance Officer, Chiesi, Cary, NC (PCF Board)*

Antitrust Admonition

Seth H. Lundy, JD, *Partner, FDA and Life Sciences, King & Spalding, Washington, DC*

1:15 pm **Keynote Address**

Brent Saunders, MBA, JD, *Chairman & Chief Executive Officer, Bausch + Lomb; Former Chair, President & CEO, Allergan; President & CEO, Actavis plc; President & CEO, Forest Laboratories; President, Global Consumer Healthcare; Schering-Plough; Co-founder, International Association of Privacy Professionals and Pharmaceutical Compliance Forum, Miami Beach, FL*

1:45 pm **Keynote Annual OIG Update**

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

2:30 pm **Keynote Annual FDA Update**

Catherine (Katie) Gray, PharmD, *Acting Director, Office of Prescription Drug Promotion, US Food and Drug Administration, Baltimore, MD*

3:00 pm **Keynote Fireside Chat**

Myrtle Potter, *Board, Liberty Mutual, Guardant Health, Opentrons & University of Chicago; Former President and CEO, Sumitomo Pharma America & Chair, Sumitomo Pharma UK; Former CEO, Sumitovant Biopharma; Former Vant Operating Chair, Roivant; Former President, Commercial Operations, Genentech; Former President, Cardiovascular/ Metabolics, BMS, Cambridge, MA*

Interviewed by: Susan Dentzer, *President and Chief Executive Officer, America's Physician Groups; Wrote and Hosted PBS documentary, Reinventing American Healthcare; Former Editor in Chief,* Health Affairs; *Former Health Correspondent, PBS NewsHour, Washington, DC*

3:30 pm **Break**

4:00 pm **The Implications of AI for Lifesciences Operations and Business Models**

Regina Barzilay, PhD, *School of Engineering Distinguished Professor for AI and Health, MIT Center for Machine Learning in Health; AI Faculty Lead, Jameel Clinic, MIT Computer Science & Artificial Intelligence Lab; Recipient, MacArthur Genius Fellowship, NSF Career Award, and AAAI Squirrel AI Award for Artificial Intelligence for the Benefit of Humanity, Cambridge, MA*

4:20 pm **The Implications of AI for Lifesciences Ethics and Compliance Programs**

This panel will focus on sharing real-world case studies of how AI is being utilized in Compliance, as well as discuss what Compliance teams should be monitoring in other areas of the organization (Commercial, Clinical, Market Access, etc).

Rachel Batykefer, *Vice President, CIA and Compliance Operations, Mallinckrodt Pharmaceuticals; Former Senior Director, Global Compliance & Ethics Training, Policy & Operations, Teva Pharmaceuticals, Bridgewater, NJ*

Laura E. Heyduk, *Head, US Compliance, Biogen; Former Compliance Director, Healthcare Compliance, Insulet, Cambridge, MA*

Kelly J. Tope, JD, MBA, *Head of USBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Former Global Director, Compliance-Transparency, Monitoring, Systems, Data Analytics & Process Improvement, Zimmer Biomet, Boston, MA*

Manny Tzavlakis, *Managing Partner, HELIO, Morristown, NJ (Moderator)*

4:45 pm **Chief Compliance Officer Fireside Chat**

Peter Brensilver, MPH, JD, *Senior Vice President, Chief Global Commercial Compliance & Risk Counsel, Pfizer, New York, NY*

Jessica Colón, JD, MPH, CHC, *Vice President, Associate General Counsel, Chief Compliance & Privacy Officer, West Business Compliance & Integrity, West Pharmaceutical Services, Inc., Exton, PA*

Isabel Duffy, JD, *Senior Vice President, Chief Ethics and Compliance Officer, Merck, Wayne, PA*

Tara R. Shewchuk, JD, LLM, *Global Chief Ethics & Compliance Officer, Medtronic, Minneapolis, MN*

Paul Silver, *Corporate Intelligence Services Practice Leader, Life Sciences Regulatory, Legal, and Compliance Leader, Deloitte Advisory, Atlanta, GA (Moderator)*

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

6:30 pm **PHARMA-MEDICAL DEVICE CONGRESS 25TH ANNIVERSARY BANQUET**

(Attendance at the Banquet is limited and requires a separate registration.)

25TH ANNIVERSARY GALA BANQUET MONDAY, OCTOBER 28, 6:30 PM

Celebrate this special milestone of the Congress and PCF's contributions to the industry over the last 25 years with an evening of fine dining, festivities, and fun! Previous PCF contributors will be recognized, and entertainment will be hosted by L&E: Comedians Who Know Compliance featuring pianist and comedian T. J. Shanoff and L&E's CEO, Founder Ronnie Feldman.

AGENDA DAY II: TUESDAY, OCTOBER 29, 2024

PHARMA-MED DEVICE CONGRESS DAY II

7:30 am **Registration Opens: Continental Breakfast**

CHIEF COMPLIANCE OFFICER ROUNDTABLE

(PCF Sponsored Special Closed Morning Session, Invitation-only)

7:30 am **Invitation-only Breakfast**

8:00 am **CCO Roundtable Welcome and Introductions and Antitrust Admonition**

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed; Florham Park, NJ (PCF Board)*

Anisa Dhalla, *Vice President and Chief Ethics and Compliance Officer, UCB, Acworth, GA (PCF Board)*

Antitrust Admonition:

Kristin Graham Koehler, JD, *Office Managing Partner, Washington DC Office, Management Committee, and Executive Committee Member, Sidley Austin LLP, Washington, DC*

8:15 am **Behind the Scenes: Evaluating and Presenting Compliance Program Effectiveness to Judges, Juries and Regulators**

This session delves into the intricacies of evaluating and presenting the effectiveness of compliance programs to external parties. Hear first-hand accounts of approaches and considerations for demonstrating a robust and dynamic compliance framework that can withstand scrutiny, as well as pitfalls to avoid when appearing before the most discerning stakeholders.

Michael R. Clarke, JD, CCEP, NACD.DC®, *Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec, Bridgewater, NJ (Medical Device Executive Committee)*

Jeff Hessekiel, JD (Invited), *Executive Vice President, General Counsel & Secretary, Exelixis, Alameda, CA*

Allan J. Medina, JD, *Partner, Goodwin Procter LLP; Former Senior Deputy Chief, Criminal Division, US Department of Justice, Washington, DC*

Katherine C. Norris, MPA, *Senior Managing Director, Healthcare & Life Sciences Compliance, Disputes and Economics, Ankura; Honolulu, HI (Moderator)*

9:00 am **Measuring & Presenting Compliance Effectiveness to Company Leadership — Moderated Best Practice Session**

Open discussion on strategies employed to effectively measure and tailor compliance metrics for impact when presenting the success of the compliance program to senior leadership.

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed; Florham Park, NJ (PCF Board)*

Anisa Dhalla, *Vice President and Chief Ethics and Compliance Officer, UCB, Acworth, GA (PCF Board)*

9:45 am **Break**

10:00 am **How Do you Optimize your Resources to Enhance your Compliance Program?**

Discussions will center on the various strategies and best practices employed to maximize compliance impact while efficiently allocating resources based on risks. Key focus areas to include:

- Shifting resources effectively to mitigate risks
- Tools utilized and what guides decisions
- Leveraging technology, shared services, and outsourcing
- Determining skills needed for your team in planning for future
- Considerations in building a diverse compliance talent pipeline

Session continued next page

THE AGENDA OF THE FIRST PHARMA CONGRESS

CONCURRENT SESSIONS II Continued

B. **BioEthics and the Pharmaceutical Industry**
Art Kaplan, Ph.D., *Center for Bio-Ethics, University of Pennsylvania*

C. **Internet Drug Promotions: Legal and Compliance Issues**
Douglas Snyder, Esq., *Senior Counsel, SmithKline Beecham*
William McConagha, Esq., *Associate Chief Counsel, US Food and Drug Administration, Office of the Chief Counsel*
Stephen J. Haynes, Esq., *Vice President, Integrity Resource Group, Inc.*

D. **PDMA Compliance & Drug Samples**
Raymond A. Bonner, Esq., *Partner, Sidley & Austin*
Donald O. Beers, Esq., *Partner, Arnold & Porter; Former Associate Chief Counsel, FDA*

3:45 – 4:00 pm **Break**

4:00 – 5:00 pm CONCURRENT SESSIONS III

A. **Applicability of HIPAA to the Pharmaceutical Enterprise and Potential Compliance Strategies**
Aidan Collins, *Partner, Deloitte & Touche LLP*
Paul T. Smith, Esq., *Partner, Davis Wright Tremaine*
Elizabeth E. Friberg RN, MSN, PAHM, *PricewaterhouseCoopers*

B. **Using Technology to Build a Cooperative Relationship with FDA**
Janice McFarland, *Executive Vice President, EduNeering, Inc.*

C. **Hot Topics: Recent Investigations and Probes**
Paul Kalb, MD, JD (Moderator), *Partner, Sidley & Austin*
Paul Silver, *Ernst & Young*
Joseph F. Savage, Jr., Esq., *Testa, Hurwitz & Thibeault*
W. McKay Henderson, *Partner, PricewaterhouseCoopers LLP*

D. **Medicaid Pricing Compliance**
Donna Boswell, Esq., *Partner, Hogan & Hartson*
Lynn Shapiro Snyder, Esq., *Partner, Epstein Becker & Green*
Anthony L. Farino, *Partner, PricewaterhouseCoopers*
Laurie Radler, *Partner, Deloitte & Touche LLP*

Continuing Education Credits

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Collaborative and Health Care Conference Administrators, LLC. Medical Education Collaborative (MEC), a non-profit education organization, is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of this CME activity.

Medical Education Collaborative designates this educational activity for a maximum of 7.5 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Medical Education Collaborative, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Medical Education Collaborative, Inc. has assigned 7.5 contact hours/.75 CEUs of continuing pharmaceutical education credit. ACPE provider number: 815-999-00-067-L04

Participants will be required to sign in daily and complete an evaluation form for credit. Registration fee includes certificate, which will be mailed within six weeks after the meeting.

CNA (Nursing Credit) - This educational activity for 9 contact hours is provided by Medical Education Collaborative. Medical Education Collaborative is approved as a provider of continuing education in nursing by the Colorado Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

California BRN Provider Number: CEP-12990
Florida BN Provider Number: FBN-2773

ACHE - Medical Education Collaborative is authorized to award 7.5 hours of pre-approved Category II (non-ACHE) continuing education credit for this program toward advancement or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward Category II credit should list their attendance when applying for advancement or re-certification in ACHE.

ABA MCLE - Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 7.5 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of $1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at (303) 278-1900 ext. 151 starting two to three weeks prior to the program date.

NASBA - Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN, 37219-2417. Telephone: 615-880-4200.

A maximum of 9 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

ACMPE – This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

HCCB - This program has been approved for 9 HCCB continuing education credits for compliance certification.

Peter Brensilver, MPH, JD, *Senior Vice President, Chief Global Commercial Compliance & Risk Counsel, Pfizer, New York, NY*

Tara R. Shewchuk, JD, LLM, *Global Chief Ethics and Compliance Officer, Medtronic, Minneapolis, MN*

Dana Silber McMahon, JD, *Vice President, Global Chief Compliance Officer, Head of Privacy & Enterprise Risk, Stryker*

Ed Sleeper, MS, *Vice President, Chief Ethics and Compliance Officer, Veloxis, Bridgewater, NJ*

Anisa Dhalla, *Vice President and Chief Ethics and Compliance Officer, UCB, Acworth, GA (PCF Board)*

10:45 am **Career Development Discussion: Looking Beyond the CCO Role**

Hear from peers who have successfully navigated the transition beyond executive compliance roles. Their experience and practical advice can illuminate a potential new career path or professional growth opportunity for you.

Thomas E. Costa, JD, *Member, US Board of Directors, Sanofi; Former Vice President, US Compliance & Ethics, Bristol Myers Squibb, Morrisville, PA*

Sujata Dayal, JD, *Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International; Former Vice President & Global Chief Compliance Officer, Medline Industries, Inc.; Former Vice President Health Care Compliance & Privacy, Johnson & Johnson, Gaithersburg, MD (Medical Device Executive Committee)*

Ted Acosta, MS, JD, *Leader, Office of Strategic Relationships, EY; Former Global Life Sciences Leader for Fraud Investigation & Dispute Services, EY; Former Senior Counsel, Office of The Inspector General, US Department of Health and Human Services, New York, NY (Moderator)*

11:30 am **CCO Exchange Open Forum & Benchmarking**

Opportunity to ask questions and benchmark against peers for valuable insights-Come prepared with questions!

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed; Florham Park, NJ (PCF Board)*

Anisa Dhalla, *ice President and Chief Ethics and Compliance Officer, UCB, Acworth, GA (PCF Board)*

11:55 am **Wrap Up**

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed; Florham Park, NJ (PCF Board)*

Noon **Adjournment**

MORNING MINI SUMMITS
PHARMA-MED DEVICE CONGRESS MINI SUMMITS
GROUP 5 8:00 – 8:50 am

Mini Summit 26: Service Fees: Hidden Compliance Risks and Downstream Market Access and Government Price Reporting Implications

Pharmaceutical and Med-device companies frequently contract with third-party entities such as distributors, wholesalers, pharmacies, pharmacy benefit managers, group purchasing organizations, etc., as part of their market access and penetration strategy. However, market access and pricing teams often are not aware of the long-term commercial impacts and potential compliance risks inherent in these arrangements. "Service fees" paid to third-party entities can present both Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") risks if the services are not bona fide, e.g., not itemized in a written contract and the compensation value is not within the Fair Market Value ("FMV") range. In addition to ensuring that the compensation is not viewed as an inducement for referrals, companies must also be extra careful while negotiating the fees paid to third party entities since the service fee has a direct impact on government pricing calculations and hence, the amount reimbursed by the government for federal programs such as Medicare and Medicaid.

In this session, we will discuss:

1. Regulatory implications related to FMV of services;
2. Market access and price reporting considerations;
3. Examples of relevant enforcement actions; and,
4. Service fee FMV valuation principles and practical application of these principles.

8:00 am **Introductions, Discussion and Q&A**

Micah Ackerman, JD, *Associate Director, Ethics and Compliance, Eisai Inc; Former Senior Compliance Manager, Pfizer, New York, NY*

Shannon Moesaa, JD, *VP Commercial and Healthcare Compliance Counsel, Karuna; Former Assistant General Counsel, Arena Pharmaceuticals, Inc.; Former Senior Corporate Counsel, EMD Serono, Inc., Boston, MA*

Matthew E. Wetzel, JD, *Partner, Goodwin Procter LLP, Washington, DC*

Laura A. Skinner, MBA, *Managing Director, Life Sciences Consulting Group, Paul Hastings, New York, NY (Moderator)*

Mini Summit 27: Government Programs and Compliance Office Oversight

Government Programs (GP) compliance, meaning a manufacturer's compliance with the operational requirements of Medicaid, Medicare, the VA and 340B, is an increasingly significant focus area for life science companies. Between the False Claims Act and the Anti-Kickback Statute, compliance risks are significant. However, although compliance functions are essential in guiding their organizations, many professionals struggle to appreciate GP complexities and how best to monitor and provide the appropriate oversight within this area. The OIG has clearly demonstrated that GP compliance is on their radar, and compliance professionals need to be appropriately informed. In this session, our panel will discuss the requirements and complexities of GP compliance and oversight. Our panelists represent both small and large life sciences companies, the compliance organization, as well as internal and external counsel. You will hear about perspectives on risk across the organization, which will help you understand how to approach the challenging and critical area of GP compliance within your company.

8:00 am **Introductions, Discussion and Q&A**

Matthew Berkle, JD, LLM, *Member, Berkle Consulting LLC; Former Vice President, General Counsel, Head of Ethics and Compliance, Breckenridge Pharmaceutical, Inc.; Former Head of North America Legal and Compliance, ALK-Abelló, Inc., Roseland, NJ*

Manya Deehr, JD, *Founder and Principal, Deehr Law; Compliance Officer, Orexo and Zealand; Former partner Morgan Lewis and Cooley; Former Compliance Officer Recordati Rare Diseases, Compass, Vernalis, Velcera, Eurand, Dymedso, and Pediva, Newtown, PA*

John Shakow, JD, *Partner, King & Spalding LLP, Washington, DC*

Chris Cobourn, MS, *Managing Director GP Practice Lead, HELIO, Placida, FL (Moderator)*

Mini Summit 28: Advancing Risk Management: A call to action for Integrated Risk Management (IRM) in Pharma

The pharmaceutical sector has historically identified, monitored and mitigated risks in silos across disparate risk functions (e.g., E&C, Privacy, Quality, Cyber, Internal Audit, Internal Controls, etc.) supported by distinct people, process and technology capabilities. As the regulatory environment evolves, risks such as AI emerge more quickly, and risk management technologies advance, a new more integrated way to manage risk is needed.

Join us for a discussion to:

• Demystify Integrated Risk Management (IRM) and its applicable across healthcare compliance, privacy, cyber, third parties, info governance, AI, Quality and more.

• Understand lessons learned from other highly regulated industries, such as financial services, and forward-thinking technology companies.

• Explore the benefits and challenges of implementing an integrated approach to risk management.

• Learn about leading practices and real-life case studies that highlight how to get the necessary support and where to start.

• Discuss emerging trends and technologies shaping the future of integrated risk management in the pharmaceutical industry.

8:00 am **Introductions, Discussion and Q&A**

Brian Long, MBA, *Partner, Health Industries Risk & Regulatory, PwC, Chicago, IL*

Michael Reyes, *Senior Manager—Health Industries Risk & Regulatory Consulting, PwC; Former Analyst, Compliance Analytics, Edwards Lifesciences, Dallas, TX*

Mini Summit 29: Attention Please! Elevating E&C Learning & Engagement in the Age of Distraction

In this presentation we will share the business case for blending entertainment with learning to improve engagement, awareness and stickiness of learning. We'll discuss the behavioral science, we'll share strategies and we'll do some show and tell.

• Discuss the value of maintaining a regular cadence of short, positive, snackable communications and burst learning.

• Learn techniques to get attention and stand out in a noisy environment without message fatigue.

• Review positive, playful examples that impact speak up culture, compliance culture and improve the reputation of the E&C brand.

8:00 am **Introductions, Discussion and Q&A**

Ronnie Feldman, *Founder, Chief Executive Officer and Creative Director, L&E: Comedians Who Know Compliance; Former Headed, Second City's Comedic, Ethics, and Compliance Video Series, RealBiz Shorts, Chicago, IL*

Laura Hamm, *Director, Ethics and Compliance, Esperion; Former Senior Director, Corporate Compliance, Aimmune Therapeutics, San Jose, CA*

Mini Summit 30: Key Learnings from CMS Audits

Join us for an insightful session tailored for compliance professionals in the life sciences sector, where we will delve into the critical takeaways from recent CMS audits. This session will provide a comprehensive overview of the most common audit findings and offer practical strategies to enhance your organization's compliance framework. Attendees will gain valuable insights into best practices for preparing for audits, addressing compliance gaps, and implementing effective corrective actions. Equip yourself with the knowledge to navigate the complexities of CMS audits and ensure your organization remains compliant and audit ready.

8:00 am **Introductions, Discussion and Q&A**

James Perkins, JD, MBA/MS, *Compliance Officer, Diabetes, Medtronic, Nashville, TN*

Juan Diego Alonso Succar, MBA, JD, *Director, Ethics & Compliance, Purdue Pharma LP, Stamford, CT*

Audrey DeGuarde, MSJ, *Vice President, Customer Success & Compliance Operations, RLDatix Life Sciences, Morristown, NJ (Moderator)*

Mini Summit 31: Exploring Risks and Enforcement Trends for Buy-and-Bill Drugs

The panel will discuss the supply, distribution, promotion, and reimbursement of buy-and-bill drugs, including key risk areas such as pharmacy/medical benefit switches, coverage of service and administration fees, and reimbursement support for providers, including under the Anti-Kickback Statute and government price reporting laws.

8:00 am **Introductions, Discussion and Q&A**

Eve M. Brunts, JD, LLM, *Partner, Ropes & Gray, Boston, MA*

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

Margaux Hall, JD, *Partner, Ropes & Gray, Washington, DC*

8:50 am **Transition Break**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS GROUP 6 **9:00 – 9:50 am**

Mini Summit 32: Global Compliance Considerations for Designing Patient Support Programs

Global Compliance Considerations for Patient Support Programs will be shared in an interactive discussion with the panel.

9:00 am **Introductions, Discussion and Q&A**

Peter Agnoletto, CPA, *Compliance Officer, General Medicines and Consumer Health Care, Sanofi; Former Chief Compliance Officer & Chief Audit Executive & ERM Leader, Par Pharma, Bridgewater, NJ*

Howard Holloway, *Global Governance Lead, Global Medical Affairs, Medical Excellence Operations & Governance, Patient Oriented Programs, Novartis; Former Project Manager, Emerging Markets, Medical & Development, Pfizer, Zurich, Switzerland*

Julia Heller, *Principal, Global Commercial Compliance Consulting, US Leader, IQVIA Principal, Philadelphia, PA (Moderator)*

Mini Summit 33: Qui Tam Declinations—Analysis and Trends When DOJ Declines to Intervene

*Overview of recent declinations through analyzing allegations, jurisdictions, profile of relators, and type of claims asserted.

*Recent outcomes (including settlements) after the government declines to intervene and relators pursue cases.

9:00 am **Introductions, Discussion and Q&A**

Sara K. Frank, JD, *Principal, Choate, Hall & Stewart, Boston, MA*

Gregg Shapiro, JD, *Founder, Gregg Shapiro Law, LLC; Former Assistant US Attorney and Chief, Affirmative Civil Enforcement Unit, US Attorney's Office, District of Massachusetts, US Department of Justice, Boston, MA*

Mini Summit 34: Privacy Top-Ten: Strategies and Tactics to Address Operational Impacts of the Evolving Privacy Landscape

• Discuss strategies to enable and leverage cross-functional teams and drive operational changes necessary to comply with new requirements

• Identify prioritized tactics and key steps aimed at capturing resource efficiencies and supporting broad organizational impact

• Share good and better privacy management practices, lessons learned, and success stories

9:00 am **Introductions, Discussion and Q&A**

Jill Atstupenas, JD, *Director, Compliance Syndax Pharmaceuticals, Inc., Boston, MA*

Tom Hiney, JD, CIPP/US, CIPM, *Senior Director, Blueprint Medicines, Boston, MA*

Patrick Santiago, MBA, CIPM, *Director, Global Data Privacy, Genmab; Former Associate Director, U.S. Data Privacy Operations, Boehringer Ingelheim; Former Senior Privacy Program Manager, Ethics Compliance & Privacy, Genmab, Plainsboro, NJ*

Kris Hall, JD, CIPP/CIPM, *Managing Director, Dovetail; Former VP, Chief Privacy Officer, Celgene; Former VP, Head of Privacy, Shire; Former Senior Director of Privacy, Philips Healthcare, Bridgton, ME (Moderator)*

Mini Summit 35: Hot Topics in State Law Compliance

This session will provide an overview of the evolving state law landscape specifically in the data privacy and drug price transparency space, including state laws and regulations that directly impact drug and device companies. Our discussion will include the fast-moving legal landscape of current state privacy laws with an emphasis on the treatment of sensitive data and data subject rights, as well as the ever-growing prescription drug price transparency reporting laws and prescription drug affordability boards, and how companies can safeguard sensitive corporate information as reporting requirements become more onerous.

9:00 am **Introductions, Discussion and Q&A**

Alfred R. Brunetti, JD, *Principal, Porzio, Bromberg & Newman, Former Assistant Prosecutor, Union County Prosecutor's Office, Morristown, NJ*

Sara R. Simon, JD, *Counsel, Porzio, Bromberg & Newman; Former Director, US Health Care Compliance Certification Program, Seton Hall University School of Law, Morristown, NJ*

Mini Summit 36: The Latest and Greatest in Enforcement and Guidelines for Social Media and Influencers

With the advent of social media and other digital platforms, the FDA faces the challenge of regulating an ever-expanding digital landscape and companies have to navigate the potential pitfalls. The rise in the use of social media influencers has introduced even more complexity. FDA has issued social media guidance in the past, but we rely also on more recent FDA Untitled Letters and Warning Letters to read the tea leaves on FDA's current advertising and promotion policy. Social media platforms like "Facebook," "YouTube," "Twitter," "LinkedIn," and "Instagram" are the most cited in FDA enforcement letters. In addition to FDA, companies must be aware of the risk of FTC enforcement action, particularly in the area of influencer marketing. Companies also have to determine with how to compliantly compensate influencers who may be HCPs or patients. Learn the current social media enforcement landscape and hear how companies grapple with these challenges.

9:00 am **Introductions, Discussion and Q&A**

David J. Bloch, JD, *Principal Legal Counsel, Medtronic, Washington, DC*

Saad Khan, *Head of Compliance, US Respiratory, Immunology, Vaccines & Immune Therapies, AstraZeneca; Former Commercial Controls Lead; Strategy, Planning & Operations (US Commercial) and Operational Compliance Lead; Business Risk & Compliance (Finance), GSK, Philadelphia, PA*

Rosemary McKenna, JD, *Director, Regulatory Legal, Organon; Former Director, Regulatory Legal, Merck Philadelphia, PA*

Nikki Reeves, JD, *Partner and Co-chair, Life Sciences and Healthcare Industry Group, King & Spalding, Washington, DC (Co-Moderator)*

Paul Silver, *Principal and Corporate Intelligence Services, Practice Leader, Deloitte Advisory, Atlanta, GA (Co-Moderator)*

Mini Summit 37: Compliance Considerations for Genetic Testing

This session analyzes the role of sponsored genetic testing programs in patient access to care, the legal landscape relating to such programs, including recent guidance from HHS-OIG, and the compliance considerations that pharmaceutical companies should consider in developing and executing such programs.

9:00 am **Introductions, Discussion and Q&A**

Lindsay Breedlove, JD, *Senior Director, Head of Litigation & Investigations and N. American Regulatory Counsel, Ultragenyx Pharmaceutical, San Francisco, CA*

Allison DeLaurentis, JD, *Senior Counsel, Litigation and Government Investigations, Bristol Myers Squibb, Philadelphia, PA*

Abraham George, JD, *Chief of the Civil Division, US Attorney's Office, Massachusetts, US Department of Justice, Boston, MA*

Miranda Hooker, JD, *Partner, Goodwin Procter LLP; Former Assistant United States Attorney, United States Attorney's Office, District of Massachusetts, US Department of Justice, Boston, MA (Moderator)*

9:50 am **Transition Break**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS GROUP 7 **10:00 – 10:50 am**

Mini Summit 38: The Role of Technology and Process Enhancements for Effective ABAC Third Party Vendor Diligence

The Role of Technology and Process Enhancements for Effective ABAC Third Party Vendor Diligence

- Setting the Stage: The legal, regulatory & business implications of Third Party Due Diligence programs and how far companies are expected to go with respect to sub-contractors.
- Program Benchmarking: How does my Company's Third Party Due Diligence Program compare to my peers?
- Balancing Risk & Return: Embracing the tech-enablement of your current and future Third Party Due Diligence program and how to manage the risks of integrating Artificial Intelligence into your compliance operations.
- Operational Effectiveness: Aligning your program with Agency expectations and enhancing your and your program's "defensible narrative"

10:00 am **Introductions, Discussion and Q&A**

Aurélie Ercoli, LLM, PhD, *Partner, White-Collar, Investigations and Government Enforcement Practice Group, DLA Piper, Washington, DC*

Alishia G. Farr, MJ, *Senior Manager, Global Compliance Risk Evaluation and Mitigation, Convatec, Atlanta, GA*

Mark Pearson, MBA, *Principal, Deloitte, Chicago, IL*

Shuba Balasubramanian, MBA, *Principal, Deloitte, Dallas, TX (Moderator)*

Mini Summit 39: Intersecting Reforms Affecting Drug Pricing

Drug pricing matters can often be overlooked by the Ethics & Compliance function, but recent trends in drug pricing reforms and oversight warrant heightened attention. Between changes driven by the Inflation Reduction Act, regulatory developments from CMS, and continued interest from DOJ/OIG on pricing, contracting, and service fee arrangements, this session will highlight key drug pricing pressures that Ethics & Compliance leaders should address from involvement in pricing committees to performing their broader oversight role to foster a cross-functional culture of compliance.

10:00 am **Introductions, Discussion and Q&A**

David Cromley, JD, *Principal, Cromley Consulting, LLC, Adjunct Professor, Villanova University Charles Widger School of Law; Former Associate Vice President, Global Compliance Organization, Merck, Glenside, PA*

Constance A. Wilkinson, JD, *Board of Directors, Member of the Firm, Epstein Becker & Green, P.C., Washington, DC*

Garrett Pape, JD, *Principal, EY, Chicago, IL (Moderator)*

Mini Summit 40: Best Practices in Investigations

We will discuss key areas related to investigations, including:

- Aligning with business and responsible management teams on decisions regarding disciplinary actions, based on the severity of policy violations.
- Collaborating with the organization on corrective and preventive actions following investigations, including developing management action plans focused on mitigation strategies.
- Utilizing investigation findings to inform risk assessments, policies, processes, monitoring, and training within the overall compliance program.
- Managing the investigation team to oversee investigation strategy, metrics, and process improvement.
- Best practices on how to interview those have potentially engaged in misconduct in a way that respects everyone's rights and produces favorable outcomes.
- How to mitigate an 'open secret' mindset and culture so that those who might witness misconduct feel comfortable approaching investigators.
- How to 'spark' positive and proactive relationships between investigators and the wider workforce which might preempt larger challenges ahead.

Session continued next page

10:00 am **Introductions, Discussion and Q&A**

Richard Bistrong, MA, *Chief Executive Officer, Front-Line Anti-Bribery LLC; Market Development Consultant, LRN; Contributor, HBR & Fast Company, Former Confidential Human Source & Cooperating Witness, FBI and US DOJ; Former Cooperating Witness, City of London Police, HMRC & CPS, UK, New York, NY*

Gary Del Vecchio, *Health Care Compliance Officer Global Medical Affairs, Data Sciences, Cardiopulmonary & Business Development, Johnson & Johnson; Former Executive Director, US Pharmaceutical Compliance and Ethics, Bristol Myers Squibb, Titusville, NJ*

Mara Senn, JD, *Executive Global Compliance Lead, Investigations, Monitoring & Transparency (IMT), GE HealthCare; Former Co-Chair, Global Anti-Corruption Committee of the Criminal Justice Section, American Bar Association; Former Director & Senior Counsel, Global Compliance Investigations, Zimmer Biomet, Washington, DC*

Meredith S. Auten, JD, *Partner, Morgan, Lewis & Bockius LLP; National co-chair of the ABA's Criminal Justice Section White Collar Committee Qui Tam Subcommittee; Former member of the Criminal Justice Appointment Panel, US District Court, Eastern District of Pennsylvania; Former Hearing Committee Member of the Disciplinary Board of the Supreme Court of Pennsylvania, Philadelphia, PA (Moderator)*

Mini Summit 41: Detecting Bias in your AI Tools

Do you know if your AI tools are biased? Deploying AI without evaluating whether there is inherent bias within the algorithms creates significant risks. This panel of AI experts will discuss the types of AI bias that can exist, how to evaluate those biases, and how to resolve those biases. The panel will discuss the developing regulations involving AI bias and will consider AI applications in research and development, healthcare claims, human resources, and other areas.

10:00 am **Introductions, Discussion and Q&A**

Christopher Corallo, *Deputy Chief Compliance Officer, Convatec, Bridgewater, NJ*

Mahnu V. Davar, MA, JD, *Partner and Co-chair, Life Sciences & Healthcare Regulatory, Arnold & Porter; Adjunct Professor of Law, University of Pennsylvania Law School, Washington, DC*

Paul H. Luehr, JD, *Partner, Privacy and Data Security, Manatt, Washington, DC*

Victoria (Vicki) A. Lipnic, JD, *Partner, Head of Human Capital Strategy Group, Resolution Economics; Former Commissioner & Acting Chair, US Equal Employment Opportunity Commission, Washington, DC (Moderator)*

Mini Summit 42: Evolving Risks in Medical Affairs

- The History Behind the Traditionally Separated Relationship Between the Medical and Commercial Functions
- Medical & Commercial Interactions: Scientific Exchange and Payor Communications
  - Key Factors Driving Change
  - Pre-launch and Post-launch Considerations
  - Recent FDA Guidance and What it Means
- Case Studies

10:00 am **Introductions, Discussion and Q&A**

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

Gerard Leeman, *Senior Director, Compliance, Ono Pharma; Former Global Head of Compliance, Life Science and Performance Materials, Merck KGaA, Cambridge, MA*

Tyler Wiseman, MBA, JD, *Chief Legal Officer, Elevar Therapeutics; Former Corporate Counsel, Praxis Precision Medicines, Boston, MA*

L. Stephan Vincze, JD, LLM, MBA, *President and Chief Executive Officer, TRESTLE Compliance; Former Sr. Vice President and Chief Compliance Officer, Warner Chilcot; Former Vice President, Ethics and Compliance Officer, TAP Pharmaceutical, Boston, MA (Moderator)*

Mini Summit 43: Regulatory Landscape of Transparency US and OUS

This session will provide an update and discussion of trends and developments in US and OUS transparency reporting requirements, including the US Sunshine Act (including audits), US sales rep-based reporting laws, and global transparency requirements, including newly enacted requirements in Italy.

10:00 am **Introductions, Discussion and Q&A**

Brian A. Bohnenkamp, MHA, JD, *Partner, FDA & Life Sciences Practice, King & Spalding, Washington, DC (Co-Moderator)*

Elan Schefflein, JD, *Senior Compliance Advisor, MedPro Systems, New York, NY (Co-Moderator)*

10:50 am **Transition Break**

PHARMA-MED DEVICE CONGRESS MINI SUMMITS GROUP 8 **11:00 – 11:50 am**

Mini Summit 44: HCP Expense Auditing and Monitoring

We will examine some common cases where compliance teams are challenged with expense auditing and monitoring; and how to leverage AI to improve coverage of expense reports and reduce errors.

Here are the topics that we will be discussing during the session:

- Importance of Conducting Expense Report Audits
- Challenges in Conducting Expense Audits with examples
- Best Practices to Overcome Challenges
- Traditional methods vs. Modern methods
- Specific AI Techniques to Address Challenges

11:00 am **Introductions, Discussions and Q&**

Sri Burra, MBA, *Former Ethics & Compliance Lead, North America, Haleon, Former Transformation Lead, Ethics & Compliance Workstream, GSK, Malvern, PA*

Audriana "Audi" Grant, *Senior Manager, Monitoring & Auditing, Ethics, Compliance & Privacy, Novo Nordisk, Plainsboro, NJ*

Salman Kasbati, *Chief Operating Officer, Qordata*

James M. Dawson, *Vice President, Compliance Solutions, qordata; Former Vice President and Chief Compliance Officer, United Therapeutics; Former Vice President, Global Compliance Officer, Consumer Healthcare, GSK, Carrboro, NC (Moderator)*

Mini Summit 45: Lessons from Spend Transparency and Their Direct Application to Pricing Transparency

In an era where data-driven decision-making is paramount, understanding the nuances of transparency in both spend and pricing can significantly impact organizational success. Our speakers will delve into key topics, including the importance of data accuracy, the role of technology in facilitating transparency, and best practices for implementing effective transparency strategies. Discover how lessons from spend transparency can be directly applied to pricing transparency, providing you with actionable insights to drive your organization's success.

11:00 am **Introductions, Discussion and Q&A**

John Oroho, JD, *Senior Advisor, Global Life Sciences—RLDatix Life Sciences, Of Counsel, Porzio, Bromberg and Newman PC, Morristown, NJ*

Meghan Zalasky, *Associate Manager, Regulatory Account Lead, Global Transparency, RLDatix Life Sciences, Hackettstown, NJ*

Mini Summit 46: State Law Updates—2024 Recap and 2025

Keep up with the constant changes in the state laws. This session will provide a year in review of the 2024 passed legislations as well as introduced proposed legislations. What should you expect in 2025?

11:00 am **Introductions, Discussion and Q&A**

Steven Cohen, MBA, *Vice President—Chief Ethics and Compliance Officer, North America and Canada, Eli Lilly and Company, Indianapolis, IN*

Olivia Krzeminski, JD, *Associate Director Compliance, G&M Health, New York, NY*

Mini Summit 47: Addressing Nuances in Third-Party Risk Management for Medical Devices

• How are you embedding or merging the different types of third-party due diligence (human rights, sustainability, anti-corruption, sanctions, financial, etc.)?
• Does your company address these due diligence requirements through a consolidated third-party risk management program or in silos?
• What are some best practices around the involvement of the business units, Procurement, and other departments in conduct of the due diligence, evaluation of risks, design of risk mitigation plans, implementation of those plans, and management of the resulting residual risk?
• What best practices can you share around franchisee or JV compliance programs, et al.?
• What do you do when there's a negative third-party review?
• What does third-party due diligence monitoring of sponsorships and donations look like for you?
• What are some past practices for managing high-risk and ultra-high-risk third parties in high-risk countries?

11:00 am **Introductions, Discussion and Q&A**

Abhiroop Gandhi, MBA, MS, *Vice President, Compliance, Rigel Pharmaceuticals, Former Trust & Compliance Officer and Head of Strategic Risk Management, Verily (Google Life Sciences) San Francisco, CA*

Patricia Petit, MBA, *Executive Director, Compliance Officer, Olympus Corporation of the Americas, Miami, FL*

Blair Shaw, JD, CIPP/US, *Vice President, Corporate Compliance, Fortrea; Former Global Program Senior Director, Vendor/Third Party Compliance Global Program, Otsuka America Pharmaceutical, Inc., Jenkintown, PA*

Seth Whitelaw, JD, *President & CEO, Whitelaw Compliance Group, Adjunct Professor, Saint Joseph's University; Senior Fellow and Adjunct Professor, Life Sciences Compliance, Mitchell Hamline School of Law, Philadelphia, PA*

David Fisher, MS, *President and Chief Operating Officer, TD International, Washington, DC (Moderator)*

Mini Summit 48: Market Access—Compliance Considerations When Resolving Disputes

Dispute Resolution Compliance Considerations. Pharmaceutical manufacturers are increasingly using cross-functional governance processes to handle both informal and formal disputes with customers such as PBMs, wholesalers, GPOs, and others. Come to this session to learn about best practices in managing disputes arising from differing contract language interpretations, audit findings, and shifts in the industry environment with various regulatory changes such as 340B and Medicare Part D redesign. This session will focus on governance and risk management in light of the Anti-Kickback Statute and government pricing laws.

11:00 am **Introductions, Discussion and Q&A**

David Ralston, JD, *Managed Care Attorney Consultant; Market Access Legal Specialist, Biogen, and Rocket Pharmaceuticals, Boston, MA*

Sulin Shah, JD, *Law Offices of Sulin Shah; Legal Consultant, Soleno Therapeutics; Former VP, US General Counsel, PharmaEssentia & Orphazyme A/S, Chicago, IL*

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

Mini Summit 49: Analytics and Monitoring: Understanding the Risks and Underlying Complexity of Today's Copay Program Landscape

PBMs, pharmacies, and other organizations are making it more and more challenging and complex for manufacturers to effectively support patients and assist with their ability to pay for critically important drugs. As these organizations develop new and innovative ways to impact manufacturer copay and affordability programs, access teams are thinking through new ways to address these challenges and continue to appropriately support their patients. Now more than ever, manufacturers should invest in, and develop their monitoring and data analytic capabilities to ensure the integrity of their programs and prevent fraud, waste, and abuse. During this session we will discuss the rapidly evolving landscape of copay programs, how manufacturers are addressing the complexity and changes, and the associated risks that compliance officers should be thinking about.

11:00 am **Introductions, Discussion and Q&A**

Evan Bartell, *Partner, Risk Consulting, KPMG, New York, NY (Moderator)*

Mini Summit 50: Negotiating DOJ expectations and business challenges while creating a "Culture of Compliance"

Compliance professionals can face many challenges motivating change within corporate cultures. Whether it be creating a new compliance program or revitalizing an established compliance program, compliance often must overcome inertia, resistance and other obstacles to engage the business, change engrained practices, and overcome industry norms in achieving this goal. This panel will explore how some companies have tackled these issues. This will include candid discussions of some of the sticky situations they've faced in trying to establish a culture of compliance as well as the practical, effective strategies they have implemented to secure buy-in from the organization.

11:00 am **Introductions, Discussion and Q&A**

Kate Godfrey, JD, CCEP, *Senior Vice President, Global Chief Compliance Officer, Chief Compliance Officer, Karl Storz, US; Former Vice President, Chief Compliance and Privacy Officer, Veracyte, Inc., Seattle, WA*

Zach Hornsby, JD, *Chief Ethics & Compliance Officer B. Braun of America, B. Braun Medical Inc.; Former Chief Business Integrity & Responsibility Officer, Technology Enabled Services, Change Healthcare; Former Chief Compliance Officer, Americas, Elekta, Atlanta, GA*

Jonathan Turner, MSc, *Chief Compliance & Privacy Officer, ZOLL Medical Corporation; Former Vice President, Ethics & Compliance, Americas Region and Global Ortho, Sports & Wound Franchises, Smith & Nephew, Pittsburgh, PA*

Amy Bentsen, JD, *McDermott Will & Emery, Atlanta, GA (Moderator)*

NETWORKING LUNCHEON

11:50 am **Networking Luncheon with Desert and Coffee in the Exhibit Hall**

CLOSING PLENARY SESSION

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

1:15 pm **DOJ Keynote Fireside Chat**

Charlene Fullmer, JD, *Assistant U.S. Attorney, Deputy Chief Civil Division, US Attorney's Office, Eastern District of Pennsylvania, US Department of Justice; Former Attorney Advisor, Federal Bureau of Investigation and US Department of Transportation, Philadelphia, PA*

Ellen Bowden McIntyre, JD, *Assistant US Attorney and Deputy Chief, Affirmative Civil Enforcement, US Attorney's Office, Middle District of Tennessee, US Department of Justice; Recipient, Executive Office for US Attorney's Directors Award, Nashville, TN*

Amanda Strachan, JD, *Assistant US Attorney and Chief, Criminal Division, US Attorney's Office for the District of Massachusetts, US Department of Justice; Recipient, 2 Attorney General's Awards for Distinguished Service; Recognized as 2023 Most Outstanding AUSA, Boston, MA*

Interviewed by: Gary F. Giampetruzzi, JD, *Partner & Global Chair Life Sciences Department, Paul Hastings; Former Vice President, Assistant General Counsel, Pfizer, New York, NY*

2:00 pm **Reflections on the 25-Year Congress Anniversary**

Join us for a memorable session as we celebrate the remarkable journey of the Pharmaceutical Compliance Forum over the past 25 years. During this session, we will reflect on the significant milestones achieved, the challenges overcome, and the transformative impact our collective efforts have had on the industry. Using Chat PwC (our GenAI capability) we will look back into the engaging presentations and insightful discussions of the past 25 years, we will then look ahead to the evolution of compliance standards, the advancements in technology, and the changing regulatory landscape that will shape our industry.

We will honor the contributions of key industry leaders who have championed compliance, acknowledging their dedication and

Session continued next page

expertise. By sharing their stories, we will gain valuable insights and inspiration to continue driving progress in the years to come.

Join us as we celebrate this momentous occasion as we look ahead to a future of continued growth, innovation, and unwavering commitment to compliance. This session promises to be a thought-provoking and inspiring gathering of industry professionals, united in our common goal of ensuring integrity and trust in the pharmaceutical industry.

Nancy Grygiel, LLM, *Senior Vice President and Chief Compliance Officer, Amgen; Former VP Compliance, Corporate and International, Allergan; Former Senior Director Global Compliance, Mylan, Newbury Park, CA*

Jonathon L. Kellerman, *Global Chief Ethics, Compliance and Privacy Officer & Global Head of Business Transformation, Bausch + Lomb; Former Executive Vice President & Global Chief Compliance Officer, Allergan, Bridgewater, NJ*

Lori Queisser, *President, Queisser and Associates; Fromer SVP & Global CCO, Teva; Former Sr. VP Global Compliance & Business Practices; Schering-Plough; Former VP & CCO, Eli Lilly; Former Member, PCF Executive Committee, Syracuse, IN*

Brian Riewerts, *Principal, Pharmaceutical and Life Sciences, Cyber Risk and Regulatory Leader, PwC, Washington, DC (Moderator)*

2:45 pm

Updates from AdvaMed, BIO and PhRMA

John Delacourt, JD, *Deputy General Counsel, Biotechnology Innovation Organization; Former Chief Antitrust Counsel, Office of Policy Planning, Federal Trade Commission, Washington, DC*

Ida Nassar, JD, *Vice President, Assistant General Counsel, Ethics & Compliance, AdvaMed; Former Senior Attorney, Office of Chief Counsel, Drug Enforcement Administration, Washington, DC*

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

3:15 pm

Networking Break in Exhibit Hall

3:45 pm

Investigations, Enforcement and Prosecutions Roundtable

Jennifer Bragg, JD, *Partner, Latham and Watkins; Former Associate Chief Counsel for Enforcement, Office of Chief Counsel, US Food and Drug Administration, Washington, DC*

Greg Demske, JD, *Partner, Goodwin Procter; Former Chief Counsel, Office of Inspector General, US Department of Health and Human Services, Washington, DC*

Sarah A. Franklin, JD, *Partner and Vice-Chair, Life Sciences Investigations Practice, Covington & Burling, LLP; Former Attorney, US Federal Trade Commission, Washington, DC*

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

Kip Ebel, MBA, *Principal, Forensic & Integrity Services, EY, New York, NY (Moderator)*

4:30 pm

Perspectives from DOJ, HHS-OIG, and the Relators Bar on How Compliance Departments Can Effectively Prevent and Help Respond To Qui Tam Whistleblower Suits

Qui tam suits filed by whistleblowers (also known as relators) trigger a significant percentage of DOJ's False Claims Act (FCA) investigations each year. A company caught in the crosshairs of such an investigation is forced to divert financial and employee resources to the task, can face liability up to treble damages plus penalties, and may be drawn into protracted litigation with the whistleblower even if the government declines to intervene. This panel will explore the practical steps a compliance department can take to reduce the risk of a qui tam filing in the first place, as well as the role of self-disclosure, cooperation, and remediation in the context of FCA enforcement. The panel also will discuss compliance measures that can help a company demonstrate to the government that its compliance program is effective.

Colin M. Huntley, JD, *Deputy Director, Fraud Section, Civil Division, US Department of Justice, Washington, DC*

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*

Linda Severin, JD, *Managing Member, Whistleblower Law Collaborative LLC; Former Assistant US Attorney in the Southern District of New York and Chief, New York/New Jersey Organized Crime Drug Enforcement Task Force, US Department of Justice, Boston, MA*

Amy D. Kossak, JD, *Partner, Ropes & Gray; Former Senior Trial Counsel, US Department of Justice, Washington, DC (Moderator)*

5:00 pm

The Art of Storytelling—Effectively Conveying the Value of Compliance Beyond Activities and Data

Data is lovely . . . sometimes. Are metrics and data needed to tell your story during a meeting with executive leaders, such as the C-Suite, Board, or Executive Team? Sometimes. But you need to know the story you want to tell first and how to deliver it in a compelling way, which requires stepping away from the data. This Ted-Talk style session will share some of the techniques needed to not only tell an effective story, but how to get your audience to re-tell your story – a true "measure" of success.

Michael R. Clarke, JD, CCEP, NACD.DC®, *Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec: Bridgewater, NJ (Medical Device Executive Committee)*

Sujata Dayal, JD, *Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International; Former Vice President & Global Chief Compliance Officer, Medline Industries, Inc.; Former Vice President Health Care Compliance & Privacy, Johnson & Johnson, Gaithersburg, MD (Medical Device Executive Committee)*

Brooke Nelson, JD, *Vice President, Ethics & Business Integrity, North America & Global Specialty Care, Sanofi, Boston, MA*

Yogesh Bahl, MBA, *Partner and Leader, Life Sciences and Healthcare Practice, Resolution Economics; Chief Financial Officer and Head of Investor Relations, IACTA Pharmaceuticals, New York, NY (Moderator)*

5:30 pm

ADJOURNMENT

AGENDA DAY III: WEDNESDAY, OCTOBER 30, 2024

PCF INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

(Industry-only Session for Pharmaceutical and Medical Device Company Ethics and Compliance Professionals and In-house Counsel only. Hosted by PCF)

7:30 am **Registration Opens; Continental Breakfast**

8:00 am **Industry-Only Welcome and Introductions and Antitrust Admonition**

Jill Dailey, JD, *Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer, New York, NY (PCF Board)*

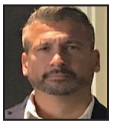
Daryl Kreml, JD, *Senior Vice President, Chief Enterprise Risk and Compliance Officer, Sage Therapeutics, Boston, MA (PCF Board)*

Antitrust Admonition:
Brian A. Bohnenkamp, MHA, JD, *Partner, FDA & Life Sciences Practice, King & Spalding, Washington, DC*

8:15 am **Responsible AI in Action: Real Business Strategies and Mitigation Examples**

In this ever-evolving landscape, AI can be both a powerful ally and a formidable challenge to the Business and the Compliance function. Business leaders seek innovation, efficiency, and competitive advantage, while compliance professionals safeguard ethical practices, legal adherence, and risk mitigation. Balancing these objectives is essential for successful AI deployment.

In this session, we will discuss real life examples of how various sized companies are leveraging AI across the Business and Compliance. We'll explore the challenges, opportunities, and best practices for harnessing AI's potential while ensuring overall governance, accountability, transparency, and fairness.



Christopher Corallo, *Deputy Chief Compliance Officer, Convatec, Bridgewater, NJ*

Don DiLanno, MBA, *Director of Global Healthcare Compliance, Insmed; Former Senior Manager, Compliance, Mallinckrodt, Lebanon, NJ*

Nevada Heft, JD, *Global Privacy Director, Merck, Upper Gwynedd, PA*

Michael L. Shaw, JD, *Global Head of Compliance, Privacy and Risk, ZS; Former Vice President and Compliance Officer, GlaxoSmithKline; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, Princeton, NJ (Moderator)*

9:00 am **Benchmarking, Polling and Q&A Open Forum**

Opportunity to ask questions and benchmark against peers for valuable insights — Come prepared with questions!

Cindy Cetani, LPEC, NACD.DC®, *Chief Integrity and Compliance Officer, Indivior; Former Group Integrity and Compliance, Head, Compliance Operations, Novartis, Glen Allen, VA (PCF Board)*

Jill Dailey, JD, *Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer, New York, NY (PCF Board)*

Daryl Kreml, JD, *Senior Vice President, Chief Enterprise Risk and Compliance Officer, Sage Therapeutics, Boston, MA (PCF Board)*

9:45 am **Break**

10:00 am **Compliance Breakdowns & Lessons Learned: Unpacking Boeing and Other Company Downfalls**

Our expert speaker will discuss compliance failures using real-world examples with a spotlight on Boeing and other companies recently in the news. We will unpack the root causes and warning signs overlooked. What led to these breakdowns? Was it organizational culture, process gaps, or external pressures? Walk away with tangible key learnings from this thought-provoking session of compliance missteps and what could have been done to prevent it.

11:00 am **Hot Topic Table Discussions**

Cindy Cetani, LPEC, NACD.DC®, *Chief Integrity and Compliance Officer, Indivior; Former Group Integrity and Compliance, Head, Compliance Operations, Novartis, Glen Allen, VA (PCF Board)*

11:30 am **Final Open Forum**

Last opportunity for questions and benchmarking

Jill Dailey, JD, *Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer, New York, NY (PCF Board)*

Daryl Kreml, JD, *Senior Vice President, Chief Enterprise Risk and Compliance Officer, Sage Therapeutics, Boston, MA (PCF Board)*

11:55 am **WRAP UP/CONGRESS ADJOURNMENT**

Daryl Kreml, JD, *Senior Vice President, Chief Enterprise Risk and Compliance Officer, Sage Therapeutics, Boston, MA (PCF Board)*

Congress Sponsor: Pharmaceutical Compliance Forum

Who We Are

For over 25+ years, PCF has been exclusively dedicated to the advancement of the pharmaceutical and biotech compliance community through networking, education, and best practice sharing.

Our Meetings provide a forum for members 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 and biotech industry for promoting excellence in the compliance profession and advancing effective risk-based compliance programs through solutions-oriented collaboration and innovative best practice sharing.

Deb Scanlon, PCF Administrator