27th Pharmaceutical and Medical Device Ethics and Compliance Congress

October 13 – 16, 2026

Washington Hilton • Washington, DC

Sponsored by the Pharmaceutical Compliance Forum (PCF)

GHC LIFE SCIENCES
Global Health Care, LLC

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

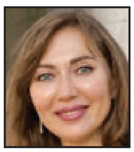
All Times are EDT • Agenda Current as of August 13, 2026 • Subject to Change and Regular Updates

GOVERNMENT KEYNOTE SPEAKERS:

Jacob Foster, JD, *Acting Chief, Health Care Fraud Unit, Criminal Division, Fraud Section, US Department of Justice*

Brenna Jenny, JD, MPH, *Deputy Assistant Attorney General, Commercial Litigation Branch, Civil Division, US Department of Justice*

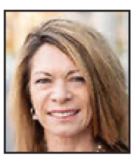
Mary E. Riordan, JD, *Senior Counsel to the Inspector General, HHS Inspector General*



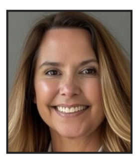
Veronika Peleshchuk Fradlin, MPP, *Director, Transparency & Data Group, Centers for Medicare & Medicaid Services, US Department of Health and Human Services*

Twyla Mosey, PharmD, RPh, *Director, Division of Advertising & Promotion Review, US Food and Drug Administration*

PCF BOARD:



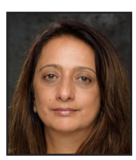
Donna White, CCEP, *Vice President and Compliance Officer, Chiesi Farmaceutici S.p.A., Americas Region (Board Chair)*



Jill Dailey, JD, *Vice President & Chief Compliance Officer, Oncology, Menarini Stemline*

Daryl Kreml, JD, *Vice President, Head of Ethics & Compliance, Global Oncology, Takeda*

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed*



Anisa Dhalla, *Vice President, Global Head, Ethics and Business Integrity, UCB*

Melissa T. Lozner, JD, *Senior Vice President, Chief Compliance Officer, Regeneron*

MEDICAL DEVICE EXECUTIVE STEERING COMMITTEE:

Sujata Dayal, LLM, JD, *Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International*

Mona Peterson Rosow, JD, MPH, *Former Vice President, Global Risk, Ethics & Compliance Officer, Mozarc Medical*

Daniel Spicehandler, JD, *Vice President Compliance, Commercial Divisions, Stryker*

JJ Kuhn, JD, *Chief Ethics & Compliance Officer, Danaher*

Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic*

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- Morning Concurrent Mini Summits
- Networking Luncheon
- Afternoon Opening Plenary Session
- Networking Reception

Day 3: Thursday, October 15, 2026

- Networking Breakfast
- Morning PCF CCO Roundtable (Invitation-only)
- Morning Concurrent Mini Summits
- Networking Luncheon
- Afternoon Closing Plenary Session

Day 4: Friday, October 16, 2026

- Networking Breakfast
- Morning PCF Industry-only Plenary Session
- Noon: Congress Adjournment

IMPORTANT THINGS TO REMEMBER AS YOU PREPARE TO ATTEND THE CONGRESS

- For the first time, the Congress is offering 5 half-day Focused Sessions on Hot Topics on Tuesday afternoon, October 13.
- Onsite attendees may register onsite as early as 10 am ET on Tuesday, October 13.
- All onsite attendees will have the ability to scan QR codes on badges to exchange contact information.
- For the first time, all Congress attendees (both onsite and online) will be able to text each other via the Congress App.
- All onsite attendees will also have access to the Congress. Virtual Video/Audio Archive for at least 9 months following the Congress. This will allow attendees to watch sessions that they missed at the Congress.

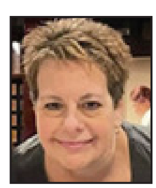
ABOUT THE CONGRESS SPONSOR, THE PHARMACEUTICAL COMPLIANCE FORUM

Since 1999, PCF has been dedicated to the advancement of the pharmaceutical compliance profession. 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.

The PCF's Vision is to be the leading forum in the pharmaceutical and biotech industry for promoting excellence in the compliance profession and advance effective and sustainable risk-based compliance programs through solutions-oriented collaboration and innovative best practice sharing.

PCF is proud of its Board, a team of six senior compliance executives who dedicate and volunteer their time to serve, each appointed by the membership for three-year terms. Our leadership team is responsible for setting the organization's strategic direction, overseeing business affairs, and ensuring we deliver meaningful value to our members.

For more information regarding the PCF, please contact PCF Administrator Debra Scanlon at deb_admin@pcf-org.com.



PCF Administrator Debra Scanlon (Deb)

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AGENDA AT A GLANCE

DAY 1: TUESDAY, OCTOBER 13, 2026

(Included in standard Congress registration)

11:00 am — **Registration Opens**

1:00 pm – 5:45 pm — **IN-DEPTH, HALF-DAY, AFTERNOON FOCUSED SESSIONS** *(Included in your Congress registration)*

Focused Session 1: **Whistleblower Complaints: From Hotline to Resolution: Managing Internal Investigations, Whistleblower Risk & Escalation Decisions**

1:00 pm	• Chair's Welcome and Introductions & DOJ/ FCA Enforcement Trends: Lessons from Whistleblower Cases
1:30 pm	• Qui Tam Counsel Roundtable
2:15 pm	• With Data and AI, Whistleblowers Set Off an FCA Tidal Wave
3:30 pm	• Hotline Isn't Enough: Building a Smart Investigations Ecosystem
4:15 pm	• Anatomy of an Internal Investigation
5:00 pm	• Managing Whistleblower Risk and Internal Escalation

Focused Session 2: **Pharmaceutical and Medical Device Advanced Privacy and Security/Cybersecurity Updates**

1:00 pm	• Chair Welcome, Overview and Introductions
1:15 pm	• The Basics of Healthcare Privacy for Compliance Professionals and an Overview of Privacy Issues Unique to Pharmaceutical and Medical Device Enterprises
1:45 pm	• The International Association of Privacy Professionals Present: Overview of Key Privacy Compliance Issues for Pharma and Medical Device
2:30 pm	• The International Pharmaceutical and Medical Device Privacy Consortium Presents Advanced Strategies for Addressing Privacy and Cybersecurity Issues for Life Sciences Companies
3:15 pm	• Companies from the Cybersecurity Working Group, Health Sector Coordinating Council
4:15 pm	• Cybersecurity Best Practices for Pharma and Device
5:00 pm	• Session Faculty Q&A

Focused Session 3: **Managing Medical — Commercial Interactions: Strategic Collaboration, Evolving Roles & Risk-Based Governance**

1:00 pm	• Co-Chair's Introductions & Session Overview
1:15 pm	• Strategic Planning Together, Tactical Execution Separately: Practical Case Studies in Medical–Commercial Collaboration
2:00 pm	• Beyond Sales Representatives and MSLs: Understanding Emerging Field-Based Roles and Governance Challenge
3:15 pm	• Protecting Medical Independence While Enabling Strategic Cross-Functional Collaboration
4:00 pm	• Medical–Commercial Boundaries: Congresses, Sponsorships & Promotional Risk
4:45 pm	• Have We Become Too Restrictive? Rethinking Medical–Commercial Governance for the Next Era

Focused Session 4: **AI in Action: Real-World Compliance Case Studies from the Front Lines of AI Use in Life Science Compliance Departments**

1:00 pm	• AI Basics, Life Science Industry Ethics and Compliance Applications
1:30 pm	• A Brief Overview of the Epsilon and qordata Annual AI Use Compliance Survey
2:00 pm	• Facilitated Case Study Discussion: From Transcript to Insights: How Compliance Teams Are Using AI to Transform Investigations
2:30 pm	• Facilitated Case Study Discussion: AI Governing AI: Leveraging Artificial Intelligence to Develop Effective Governance Policies
3:15 pm	• Facilitated Case Study Discussion: AI-Assisted Monitoring and Detection of Potential Policy Violations
3:45 pm	• Facilitated Case Study Discussion: Agentic AI Use for Continuous Risk Assessment (vs Annual)
4:15 pm	• The Unspoken Risk of AI: Moral Outsourcing — and Why "Add Human Judgment" Isn't Enough
5:00 pm	• The Health Care Compliance Association Presents: Advanced Strategies in Using AI to Monitor and Improve Compliance: Lessons from Other Healthcare Sectors

Focused Session 5: **GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers & The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know**

1:00 pm	• Chair's Introductions & Session Overview
1:15 pm	• GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers
4:00 pm	• The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know

DAY 2: WEDNESDAY, OCTOBER 14, 2026

7:00 am — **Registration Opens & Networking Breakfast in Exhibit Hall**

8:00 am – 8:50 am — **MORNING MINI SUMMITS: GROUP 1**

MS1: Compliance Independence in the Real World: Governance Models That Work	MS2: The Agentic Compliance Function of the Future	MS3: Evolution of Patient Finding Activities	MS4: First Product Launch: Policy Development Strategies and Techniques	MS5: Speaker Programs in 2026: Practical Legal and Compliance Considerations for Executing from Beginning to End Amid Ongoing Scrutiny

9:00 am – 9:50 am — **MORNING MINI SUMMITS: GROUP 2**

MS6: From Pronouncements to Practice: Understanding DOJ Enforcement Priorities	MS7: Boring is Risky! Want Stronger Ethics and Compliance Engagement? Train & Communicate Colorfully	MS8: Best Practices for Data Analytics	MS9: On the Front Lines: Navigating Field Force & Sales Compliance Risk	MS10: Global Compliance Updates	MS11: Designing HCP Engagement with Transparency Built In

9:50 am – 10:10 am — **NETWORKING BREAK (in the Exhibit Hall)**

10:10 am – 11:00 am — **MORNING MINI SUMMITS: GROUP 3**

MS12: Compliance and M&A: Why Early Engagement Matters	MS13: The State of Medical Device Compliance: Annual Industry Roundtable	MS14: The State We're In: Legal Trends Reshaping Pharmaceutical Compliance	MS15: External Funding Risks and Mitigation: Latest Trends in Exhibit & Display and Sponsorship Requests	MS16: Beyond the Questionnaire: Building a Risk-Based Third-Party Management Program That Actually Works	MS17: Navigating Today's Enforcement Landscape with Culture, Data, and Ethics

11:10 am – 12:00 pm — **MORNING MINI SUMMITS: GROUP 4**

MS18: Risk Advantage: How Resilient Organizations are Capturing Opportunity through Uncertainty	MS 19: View from the Top: Practical Advice for Accelerating Your Compliance Career	MS 20: Direct-to-Consumer (DTC) Models: Emerging Compliance Risks and Governance Considerations	MS 21: Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks	MS 22: Navigating the Evolving US Privacy Landscape	MS 23: Agentic Risk Management: Transforming Compliance Across Key Business Processes

12:00 pm – 1:00 pm — **NETWORKING LUNCHEON**

OPTIONAL SMALL AND MID-SIZED LIFE SCIENCE COMPANIES LUNCHEON

Grab your box lunch and join a luncheon discussion designed for emerging and smaller life sciences companies that have limited to no existing compliance program elements. The focus is on helping compliance leaders determine where to begin and how to build a program in a practical, risk-based way.

The discussion will address questions such as:

- Which risks should be prioritized first?
- When should key compliance program elements and controls be implemented?
- How do you build a roadmap that aligns with the company's stage of growth?
- How do you maximize limited resources while establishing an effective compliance program?

1:00 pm – 5:45 pm — **PHARMA/DEVICE CONGRESS OPENING PLENARY SESSION**

1:00 pm	Welcome and Introduction: PCF Board
1:15 pm	C-Suite Keynote Welcome Fireside Chat
1:45 pm	Keynote Annual OIG Update
2:30 pm	Keynote US DOJ Criminal Division Update Fireside Chat
3:00 pm	Tech & Human-in-the-Loop Compliance (Why Human Judgment Matters More Than Ever)
3:30 pm	Networking Break in the Exhibit Hall
4:00 pm	The Next Generation of Compliance: Leveraging Data to Stay Ahead of Risk
4:30 pm	Integrated Risk Transformation in Pharma/Medical Device: From Compliance Burden to Strategic Advantage
5:00 pm	Annual Chief Compliance Officers Fireside Chat
5:45 pm	Opening Plenary Session Adjournment

5:45 pm – 6:45 pm — **NETWORKING RECEPTION**

DAY 3: THURSDAY, OCTOBER 15, 2026

7:00 am — **Registration Opens: Breakfast Buffet in Exhibit Hall**

PCF CHIEF COMPLIANCE OFFICER ROUNDTABLE *(PCF-Sponsored, Exclusive Invitation-Only, Closed-Door Session)*

8:00 am	CCO Roundtable Welcome and Introductions
8:15 am	Future of the Compliance Profession in an AI Driven Environment
9:00 am	Executive Breakout by Company Size — Part 1
9:40 am	Networking Break in Exhibit Hall
10:00 am	Executive Breakout by Company Size — Part 2
10:40 am	Board Oversight of Compliance: What Audit Firms Observe and What Regulators Require
11:30 am	Open Forum: Opportunities for Benchmarking and Peer-driven Q&A. Bring your questions!
11:55 am	Wrap-up
12:00 pm	Adjournment

8:00 am – 8:50 am — **MORNING MINI SUMMITS: GROUP 5**

- MS24: Identifying and Managing Risk Associated with AI
- MS25: A Look Under the Hood: Exploring PBM and Payer Arrangement Risks and Emerging Reporting Requirements
- MS26: From Speak-Up to Proof: Turning DOJ and OIG Expectations into Defensible, AI-Enabled Compliance Operations
- MS27: Manufacturer–Specialty Pharmacy Relationships: Managing Compliance Risk in Specialty and Rare-Disease Commercial Models
- MS28: The Future of Compliance Monitoring: AI Agents, Risk Intelligence and Practical Adoption

9:00 am – 9:50 am — **MORNING MINI SUMMITS: GROUP 6**

- MS29: Building the Compliance Operating Model for What's Next
- MS30: Leveraging AI for More Efficient and Effective Investigations
- MS31: Compliance Considerations, Enforcements and Guidelines on Social Media Activities
- MS32: Building a Compliance Roadmap: Practical Strategies for Scaling Compliance Programs
- MS33: Fair Market Value in Flux: Navigating Complex Fee Arrangements, HCP & Patient Engagement, and Influencer Compensation Risks
- MS34: Future-Proofing the Compliance Function: Operating Models for an AI-Enabled World

9:50 am – 10:10 am — **NETWORKING BREAK (in the Exhibit Hall)**

10:10 am – 11:00 am — **MORNING MINI SUMMITS GROUP 7**

- MS35: Unstructured Data and Advanced Monitoring Strategies
- MS36: Leading Practices for Managing Investigations Panel
- MS37: Navigating Regulatory Uncertainties in Life Sciences
- MS38: Compliance Considerations for Rare Disease Products
- MS39: From Oversight to Partnership: Strengthening Collaboration Between Compliance and the Business
- MS40: Digital Ecosystem Considerations for Pharmaceutical Companies

11:10 am – 12:00 pm — **MORNING MINI SUMMITS GROUP 8**

- MS41: Holistic, Ongoing Monitoring Case Studies in Compliance
- MS42: Emerging Commercial & Market Access Risk in Life Sciences: Navigating Innovation, Compliance, and Evolving Access Models
- MS43: Effectively Leveraging Post-Investigation Mitigation to Create a Narrative of Continuous Improvement
- MS44: Transparency Reporting; Update on the Centers for Medicare and Medicaid Services Open Payments Program
- MS45: Can Learning Data Reduce Risk? Using Measurement to Drive Defensible, Risk-Based Compliance Training
- MS46: AI in Clinical Practice: Compliance, Governance & FDA Oversight

12:00 pm – 1:10 pm — **NETWORKING LUNCHEON with Dessert and Coffee in the Exhibit Hall**

12:10 pm – 1:00 pm — **LUNCHEON MINI SUMMITS GROUP 9**

- MS47: Direct-to-Consumer (DTC) Models in the Pharmaceutical Space
- MS48: ROI of AI: Separating Value from Hype
- MS49: Lean, Credible, Defensible: Compliance Programs That Work Without Big Budgets
- MS50: Data Analytics & Compliance Monitoring in an AI-Powered World
- MS51: Collaborating to Create Lasting Solutions During and After Monitoring or Investigations
- MS52: Annual FDA Office of Prescription Drug Promotion Update

1:10 pm – 5:15 pm — **CLOSING PLENARY SESSION**

1:10 pm	Welcome and Introduction: PCF Board
1:15 pm	Keynote Annual DOJ Civil Division Update Fireside Chat
1:45 pm	Investigations, Enforcement and Prosecutions Roundtable
2:15 pm	Updates from AdvaMed, BIO and PhRMA
2:45 pm	Market Access in 2026 and Beyond: A Shifting Compliance Landscape
3:15 pm	Networking Break in Exhibit Hall
3:45 pm	Burgeoning Compliance Risks
4:15 pm	AI and the Evolving Compliance Function
4:45 pm	Managing Risk in Unsettled Times
5:15 pm	**CLOSING PLENARY SESSION ADJOURNMENT**

DAY 4: FRIDAY, OCTOBER 16, 2026

8:00 am – 12:00 pm — **PCF INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK**

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

DETAILED AGENDA

TUESDAY, OCTOBER 13, 2026

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 1 (Included in standard Congress registration.)

11:00 am Registration Opens /Lunch on Your Own

FEATURING FIVE CONCURRENT SPECIAL FOCUSED SESSIONS

Focused Session 1: Whistleblower Complaints: From Hotline to Resolution: Managing Internal Investigations, Whistleblower Risk & Escalation Decisions

1:00 pm **Chair's Welcome and Introductions & DOJ/FCA Enforcement Trends: Lessons from Whistleblower Cases**

John Kelly, JD, *Partner and Chair, Healthcare Industry Practice, Barnes & Thornburg; Former Assistant Chief for Health Care Fraud, Criminal Division, Fraud Section, US Department of Justice; Washington, DC (Chair)*

1:30 pm **Qui Tam Counsel Roundtable**

Mary A. Inman, JD, *Partner, Whistleblower Partners; Founding Member & Board Chair, Psst.org; Member of Advisory Board, Whistleblowing Canada Research Society; San Francisco, CA*

Linda Severin, JD, *Managing Member, Whistleblower Law Collaborative; Former Assistant US Attorney, Southern District of New York, US Department of Justice; Boston, MA*

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

Sarah M. Hall, JD, *Partner, Member of the Firm, Epstein Becker Green; Former Trial Attorney, Fraud Section, Criminal Division, US Department of Justice; Washington, DC (Moderator)*

2:15 pm **With Data and AI, Whistleblowers Set Off an FCA Tidal Wave**

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

Stewart Kameen, JD, *Partner, Davis Wright Tremaine; Former Senior Counsel, Industry Guidance Branch, Office of Counsel to the Inspector General, US Department of Health and Human Services, Washington, DC*

3:00 pm **Networking Break**

3:30 pm **Hotline Isn't Enough: Building a Smart Investigations Ecosystem**

Michael Clarke, JD, CCEP, NACD.DC®, *Principal, Jaeger-Plymouth Advisors; Retired Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior; Bridgewater, NJ (Former Medical Device Executive Committee)*

Saraswatha Lalitha Putcha, MA, *Director, Product & Client Delivery, Cresen Solutions; Philadelphia, PA (Moderator)*

4:15 pm **Anatomy of an Internal Investigation**

Naveen Ganesh, MA, JD. *Vice President, Global Head of Investigations, Ethics & Compliance, Takeda; Former Head of Investigations & Monitoring, North America & Global Specialty Care, Sanofi; Former Compliance Assurance & Investigations, Lead, Verily; Boston, MA*

Sarah L. Whipple, JD, *Principal, WhipEdge Solutions, Member, Rare Disease Compliance Consortium (RDCC); Former Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Needham, MA*

Amanda P. Masselam Strachan, JD, *Partner, WilmerHale; Former Chief, Criminal Division, US Attorney's Office for the District of Massachusetts; Former Assistant US Attorney, US Attorneys' Offices, US Department of Justice; Boston, MA (Moderator)*

5:00 pm **Managing Whistleblower Risk and Internal Escalation**

John S. Rah, JD, *Counsel and Head, Life Sciences Compliance Practice, Potter & Murdock; Potomac, MD*

Olga Zinavenka, CPA, MBA, *Head of Compliance Operations, Keenova; Former Executive Director, Head of Compliance Operations, Endo; Former Compliance Officer – Europe, Middle East and Africa; Paoli, PA*

Warren T. Allen II, MPP, JD, *Principal, Miles & Stockbridge; Professorial Lecturer in Law (White Collar Crime), The George Washington University Law School; Washington, DC (Co-Moderator)*

David Amendola, *Director, Life Sciences, Resolution Economics; Former Global Compliance Risk, Evaluation & Management, ConvaTec; New York, NY (Co-Moderator)*

5:30 pm **Adjournment**

Focused Session 2: Pharmaceutical and Medical Device Advanced Privacy and Security/ Cybersecurity Updates

1:00 pm **Chair Welcome, Overview and Introductions**

Mary Devlin Capizzi, JD, MBA, *Partner, Faegre Drinker; General Counsel, International Pharmaceutical and Medical Device Privacy Consortium; Washington, DC (Chair)*

1:15 pm **The Basics of Healthcare Privacy for Compliance Professionals and an Overview of Privacy Issues Unique to Pharmaceutical and Medical Device Enterprises**

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

1:45 pm **The International Association of Privacy Professionals (IAPP) Presents: The Future of Responsible Data Practices for Pharma and Medical Devices**

Melissa Bianchi, JD, *Partner and Leader, Firm's Digital Health Initiative, Hogan Lovells Cadwalader; Washington, DC*

Patrice Ettinger, JD, CIPP/US, *Vice President, Chief Privacy Officer, Regeneron; Former Chief Privacy Officer, Pfizer; Former Chief Privacy Officer, Avon; Past Chair, International Association of Privacy Professionals; New York, NY*

Gabe Maldoff, JD, *Partner, Data, Privacy, and Cybersecurity practice, Goodwin Procter; Adjunct Professor, Maine Law School, Washington, DC*

Cobun Zweifel-Keegan, JD, CIPP/US, CIPM, *Managing Director, International Association of Privacy Professionals; Former Deputy Director, Privacy Initiatives, Better Business Bureau; Washington DC (Moderator)*

2:30 pm **The International Pharmaceutical and Medical Device Privacy Consortium Presents Advanced Strategies for Addressing Privacy and Cybersecurity Issues for Life Sciences Companies**

Kimberly J. Gold, JD, *Chief Privacy Officer, Senior Associate General Counsel and Executive Director, Privacy Law, Genentech; Former Privacy Secondee, Pfizer; San Francisco, CA*

Tahvia Jenkins, JD, CIPP/US, *US Privacy Officer & Counsel, Sanofi; Former Assistant Counsel, Health Affairs, Privacy, and Data Protection, University of California, Cambridge, MA*

Danielle Manner, JD, *Chief Privacy Officer and Senior Associate General Counsel, Gilead; Former Senior Privacy Counsel, Pfizer; Chicago, IL*

Nick Merker, JD, *Vice President, Assistant General Counsel, Chief Privacy Officer & Head of Digital Legal Office, Eli Lilly, Indianapolis, IN*

Mary Devlin Capizzi, JD, MBA, *Partner, Faegre Drinker; General Counsel, International Pharmaceutical and Medical Device Privacy Consortium; Washington, DC (Moderator)*

3:15 pm **Companies from the Cybersecurity Working Group, Health Sector Coordinating Council**

Gregory T. Garcia, *Executive Director, Cybersecurity Working Group, Health Sector Coordinating Council; Former Assistant Secretary for Cybersecurity, US Department of Homeland Security; Washington, DC*

3:45 pm **Networking Break**

4:15 pm **Cybersecurity Best Practices for Pharma and Device**

David J. Scott, MS, *Managing Director, Forensic & Integrity Services, EY; Former Assistant Director, Counterterrorism, and Head, Operations Branch, Cyber Division, Director, National Cyber Investigative Joint Task Force, Federal Bureau of Investigation; Leesburg, VA*

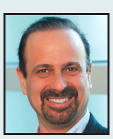
5:00 pm **Session Faculty Q&A**

Jamie E. Darch, JD, *Partner, HIPAA and State Data Privacy & Cybersecurity Law, Ropes & Gray; Chicago, IL (Moderator)*

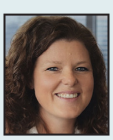
5:45 pm **Adjournment**

Focused Session 3: Managing Medical-Commercial Interactions: Strategic Collaboration, Evolving Roles & Risk-Based Governance

1:00 pm **Co-Chair's Introductions & Session Overview**



Peter Agnoletto, CPA, *Compliance Officer, General Medicines and Consumer Health Care, Sanofi; Former Senior Director, Chief Compliance Officer & Chief Audit Executive & ERM Leader, Par Pharmaceutical Companies; Bridgewater, NJ (Co-Chair)*



Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR; Chicago, IL (Co-Chair)*

1:15 pm **Strategic Planning Together, Tactical Execution Separately: Practical Case Studies in Medical–Commercial Collaboration**

Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR; Chicago, IL*

Samantha Brabant Philis, MS, *Director, E&C Policy, Training, and Business Operations, Jazz Pharmaceuticals; Former North America Compliance Manager, Cushman & Wakefield; Chicago, IL*

Samantha Sutherland, *Director, Life Sciences Consulting Practice, Baker Tilly; Jersey City, NJ (Moderator)*

2:00 pm **Beyond Sales Representatives and MSLs: Understanding Emerging Field-Based Roles and Governance Challenges**

Sri Burra, MBA, *Director, US Ethics and Compliance, Organon; Former Ethics & Compliance Lead, North America, Haleon; Former Transformation Lead, Ethics & Compliance Workstream GSK, Malvern, PA*

Matt Chandler, JD, *Director, Epsilon Life Sciences; Richmond, VA (Moderator)*

2:45 pm **Networking Break**

Session continued next page

Focused Session 3 *continued*

3:15 pm **Protecting Medical Independence While Enabling Strategic Cross-Functional Collaboration**

Peter Lee, JD, LLM, *Chief Compliance Officer, Kura Oncology; Former Chief Compliance Officer, Mirati Therapeutics; Former Chief Compliance Officer, Heron Therapeutics; San Diego, CA*

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

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

4:00 pm **Medical–Commercial Boundaries: Congresses, Sponsorships & Promotional Risk**

Akosua Tuffour-Brown, JD, *Corporate Counsel, US General Medicines, Sanofi; Morristown, NJ/Washington, DC*

Maureen Cawley, JD, *Senior Director, Corporate Counsel, Incyte; Former Global Agreements Attorney, Merck; Philadelphia, PA*

Achsah Warren, MSJ, *Vice President, Head of Compliance, Sumitomo Pharma America; Former Vice President Compliance, Urovant Sciences; Former Senior Compliance Manager, Allergan, Irvine, CA*

Mahnu V. Davar, MA, JD, *Partner and Co-chair, Life Sciences & Healthcare Regulatory, Arnold & Porter; Washington, DC (Moderator)*

4:45 pm **Have We Become Too Restrictive? Rethinking Medical–Commercial Governance for the Next Era**

Giulia Del Cane, MBA; *Ethics & Business Integrity Strategic Advisor, Global and US Specialty Care, Sanofi; Boston, MA*

Peter Agnoletto, CPA, *Compliance Officer, General Medicines and Consumer Health Care, Sanofi; Former Senior Director, Chief Compliance Officer & Chief Audit Executive & ERM Leader, Par Pharmaceutical Companies, Bridgewater, NJ (Co-Chair)*

Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR; Chicago, IL (Co-Chair)*

5:30 pm **Adjournment**

Focused Session 4: AI in Action: Real-World Compliance Case Studies from the Front Lines of AI Use in Life Science Compliance Departments

1:00 pm **AI Basics, Life Science Industry Ethics and Compliance Applications**

John Poulin, *Chief Technology Officer and Partner, HELIO; Boston, MA (Chair)*

1:30 pm **A Brief Overview of the Epsilon and qordata Annual AI Use Compliance Survey**

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

Michael T. O'Connor, *Chief Executive Officer, qordata; Angel Investor, Angel Investor Forum; New York, NY*

2:00 pm **Facilitated Case Study Discussion: From Transcript to Insights: How Compliance Teams Are Using AI to Transform Investigations**

Briana Cabrera, MS, CFE, *Senior Director, Global Privacy & Compliance, Investigations, Medtronic, Miami, FL*

Alexis Shaw, ACFE, *Deputy Chief Compliance Officer, Paratek Pharmaceuticals; Former Compliance Officer, Endo Pharmaceuticals; Former Global Compliance Investigations Manager, Boston Scientific; King of Prussia, PA*

Minna Bak, MBA, *Director, HELIO; Boston, MA (Moderator)*

2:30 pm **Facilitated Case Study Discussion: AI Governing AI: Leveraging Artificial Intelligence to Develop Effective Governance Policies**

Marla Izbicky, JD, *Senior Director, Senior Corporate Counsel, Harmony Biosciences; Chicago, IL*

Neeraj Gupta, MBA, *President, Chief Technology Officer, Cresen Solutions; Chester Springs, PA (Moderator)*

3:00 pm **Networking Break**

3:15 pm **Facilitated Case Study Discussion: AI-Assisted Monitoring and Detection of Potential Policy Violations**

Ron Strauss, *Vice President Compliance, MiMedx; Former Sales Leader, Eli Lilly Specialty; Marietta, GA*

John Poulin, *Chief Technology Officer and Partner, HELIO; Boston, MA (Moderator)*

3:45 pm **Facilitated Case Study Discussion: Agentic AI Use for Continuous Risk Assessment (vs Annual)**

Matthew Stasiunas, PMP, CCEP, LPEC, *RAMP & Project Management Lead, Indivior; Former Senior Specialist, Integrity and Compliance, Kaléo; Richmond, VA*

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)*

4:15 pm **The Unspoken Risk of AI: Moral Outsourcing — and Why "Add Human Judgment" Isn't Enough**

Benjamin Correa, JD, *Partner, Food, Drug & Medical Device, Sidley Austin; Washington, DC*

Stacy E. Yeung, JD, *Vice President, General Counsel and Corporate Secretary, SELLAS Life Sciences Group; Former Assistant General Counsel, Arena Pharmaceuticals; Former Deputy General Counsel, DBV Technologies; New York, NY*

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

Session continued next page

Focused Session 4 *continued*

5:00 pm **The Health Care Compliance Association Presents: Advanced Strategies in Using AI to Monitor and Improve Compliance: Lessons from Other Healthcare Sectors**

Joan Podleski, CCEP, CHPC, CHRC, CHC, *Vice President & Chief Privacy Officer, Children's Health System of Texas; Former Director, Institutional Ethics & Compliance Program, Duke University; Dallas, TX*

R. Brett Short, CHC, CHPC, CHRC, *Chief Compliance Officer and Chief Privacy Officer, University of Kentucky; Board & Immediate Past Chair, Health Care Compliance Association; Lexington, KY*

Betsy Wade, MPH, CHC, CHPC, CAN, *Chief Compliance & Ethics Officer, Signature Healthcare; Board & Treasurer, Health Care Compliance Association; Louisville, KY*

Kelly Willenberg, MBA, DBA, CHC, CHRC, *Chief Executive Officer, Kelly Willenberg & Associates; Board & Second Vice Chair, Health Care Compliance Association, Greenville, SC*

5:45 pm **Adjournment**

Focused Session 5: GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers & The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know

1:00 pm **Chair's Introductions & Session Overview**

Chris Cobourn, MS, *Managing Director Government Programs Practice Lead, HELIO; Placida, FL (Chair)*

1:15 pm **GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers**

Tracy Mumpower, *Director Managed Services, Life Science Revenue Management, Government Pricing & Commercial Contacting, HELIO; Former Manager, Commercial Contract Administration, King Pharmaceuticals; Bristol, VA*

John Shakow, JD, *Pharmaceutical Government Price Reporting Expert; Partner, FDA & Life Sciences Practice, King & Spalding; Washington, DC*

Chris Cobourn, MS, *Managing Director Government Programs Practice Lead, HELIO; Placida, FL (Moderator)*

3:30 pm **Networking Break**

4:00 pm **The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know**

Kristie Champlin Gurley, JD, *Partner, Covington & Burling; Former Counsel, Office of the General Counsel, CMS Division, US Department of Health and Human Services; Washington, DC*

Tracy Mumpower, *Director Managed Services, Life Science Revenue Management, Government Pricing & Commercial Contacting, HELIO; Former Manager, Commercial Contract Administration, King Pharmaceuticals; Bristol, VA*

Kristin M. Hicks, JD, *Partner, Life Sciences & Healthcare Regulatory, Arnold & Porter; Washington, DC*

Stephanie Trunk, JD, *Partner, Life Science Practice Group, Arent Fox; Former Legal Counsel, Catalyst Health Solutions; Washington, DC*

Chris Cobourn, MS, *Managing Director Government Programs Practice Lead, HELIO; Placida, FL (Moderator)*

5:30 pm **Adjournment**

WEDNESDAY, OCTOBER 14, 2026

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 2

7:00 am **Registration Opens & Networking Breakfast in Exhibit Hall**

MORNING MINI SUMMITS: GROUP 1 (8:00 am - 8:50 am)

Mini Summit 1: Compliance Independence in The Real World: Governance Models That Work

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

Kathy Johnson, JD, *Vice President, Commercial and Development Legal, Vertex Pharmaceuticals; Former US Legal Counsel Consultant, Takeda; Former Senior Director, Legal Counsel, Shire; Boston, MA*

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

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

Mini Summit 2: The Agentic Compliance Function of the Future

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

Emily (Jaffe) Singh, *Partner, Global Spend Transparency Practice Leader, PwC; Chicago, IL (Moderator)*

Mini Summit 3: Evolution of Patient Finding Activities

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

Betania Glorio, *Senior Vice President, Chief Compliance Officer, Avidity Biosciences; Former Chief Compliance Officer and Head of Group Compliance and Data Privacy, EMD Serono; Former Global Head of Compliance, Healthcare, Merck KGaA Boston, MA*

Jesse Siegel, JD, *Head of Business Ethics, Americas, Ipsen; Former Senior Counsel, Neurology & Immunology, EMD Serono; Cambridge, MA*

Sara K. Frank, JD, *Principal, Choate Hall & Stewart; Boston, MA (Moderator)*

Mini Summit 4: First Product Launch: Policy Development Strategies and Techniques

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

Michael Morgan, MBA, CCEP, *Global Compliance Officer, Telix Pharmaceuticals (US); Member, Business Ethics Indiana; Former Ethics and Compliance Officer-North America, Corteva; Indianapolis, IN*

Sandra Park, JD, *Senior Vice President, Legal & Chief Compliance Officer, Vera Therapeutics; Former General Counsel & Chief Compliance Officer, IDEOlogy Health; Former Vice President, Commercial Legal, Kite, a Gilead Company; Brisbane, CA*

Hannah Putnam, MHA, CHC, CHRC, *Head of Ethics & Compliance Operations, Oncology, Takeda; Former Senior Director, Ethics & Compliance, Veloxis; Former Senior Corporate Ethics & Compliance Officer, Fresenius; Cambridge, MA*

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

Mini Summit 5: Speaker Programs in 2026: Practical Legal and Compliance Considerations for Executing from Beginning to End Amid Ongoing Scrutiny

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

Sharon R. Delshad, JD, *Senior Director, Legal-Compliance Counsel, Travere Therapeutics; San Diego, CA*

Tracey Hannon, JD, *Director, Compliance Business Partner, Alexion Pharmaceuticals; Former Compliance Counsel, Ionis Pharmaceuticals; Boston, MA*

Lauren Ann Pond, JD, *Assistant General Counsel, BridgeBio; Former Commercial Counsel, Biogen; Former Counsel, Takeda; Palo Alto, CA*

Noah C. Goldstein, JD, *Counsel, Pharma, Biotech & Medical Device Legal, Regulatory, & Compliance, Porzio Bromberg & Newman; Westborough, MA (Moderator)*

8:50 am **Transition Break**

MORNING MINI SUMMITS: GROUP 2 (9:00 am - 9:50 am)

Mini Summit 6: From Pronouncements to Practice: Understanding DOJ Enforcement Priorities

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

Christina O. Hud, JD, *Senior Counsel, Global Investigations, Pfizer; Former Health Care Fraud Acting Unit Chief and Senior Trial Counsel at US Department of Justice, US Attorney's Office for the District of New Jersey; New York, NY*

Michelle Dineen Jerrett, JD, *Regional Head of Investigations & Monitoring, North America, Sanofi; Former Legal Director, Endoscopy, Boston Scientific; Former Assistant United States Attorney, US Attorney's Office, District of Massachusetts; Cambridge, MA*

Emily Treanor, JD, *Head of Global Investigations & Enterprise Risk Management, Alnylam Pharmaceuticals; Washington, DC*

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

Mini Summit 7: Boring is Risky! Want Stronger Ethics and Compliance Engagement? Train & Communicate Colorfully

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

Regina Gore Cavaliere, JD, *Chief Ethics and Compliance Officer, Vice President Regulatory and Compliance, Henry Schein; Melville, NY*

Ronnie H. Feldman, *Founder, Chief Executive Officer and Creative Director, Learnings & Entertainment: Comedians Who Improve Compliance; Chicago, IL*

Mini Summit 8: Best Practices for Data Analytics

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

Colleen Doyle, ACFE, *Senior Director, Risk Insights and Management, Novo Nordisk; Former Senior Director, Compliance & Risk Insights, Sage Therapeutics; Plainsboro, NJ*

Christian Malias, MBA, *Associate Director, Compliance Program Development, Insmed; Former Associate Director Compliance Business Partner, Sage Therapeutics; Former Global Corporate Compliance Manager, Adaptimmune; Pittsburgh, PA*

Erica Powers, CHC, *Founder & Chief Executive Officer, Ethical Paths; Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals; Boston, MA (Moderator)*

Mini Summit 9: On the Front Lines: Navigating Field Force and Sales Compliance Risk

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

Ron Strauss, *Vice President Compliance, MiMedx; Former Sales Leader, Eli Lilly Specialty; Marietta, GA*

Sarah L. Whipple, JD, *Principal, WhipEdge Solutions; Member, Rare Disease Compliance Consortium (RDCC); Former Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Needham, MA*

Brian Van Hoy, RPh, *Vice President of Compliance, G&M Health; Former Director, Compliance & Ethics, Eli Lilly; Somerset, NJ (Moderator)*

Mini Summit 10: Global Compliance Updates

10:10 am **Introductions, Discussions and Q&A**

Andrew Blasi, MBA, *Founder & Chief Executive Officer, Ethicist International; Founding Member, Anti-Corruption Leaders Hub, OECD; Faculty, International Anti-Corruption Academy; Washington, DC (Moderator)*

Mini Summit 11: Designing HCP Engagement with Transparency Built In

Kaoutar Afif, Manager, *Ethics & Compliance, Cardinal Health; Dublin, OH*

Peggy Kruk, HMCC, *Compliance Manager, MiMedX; Former Director, Compliance, Program Services, Vaniam Group; Dallas, GA*

Jacob Wolf, MBA, *Chief Commercial Officer, Cresen Solutions; Orlando, FL (Moderator)*

9:50 am **Networking Break in Exhibit Hall**

MORNING MINI SUMMITS: GROUP 3 (10:10 am – 11:00 am)

Mini Summit 12: Compliance and M&A: Why Early Engagement Matters

10:10 am **Introductions, Discussions and Q&A**

Eliza L. Andonova, JD, *Partner, Global Regulatory, Hogan Lovells Cadwalader; Washington, DC*

Megan Roberts, CPA, MS, *Head of Integrity & Compliance, Par Health; Former Senior Director, Integrity & Compliance; St. Louis, MO*

Heather Young, JD, *Senior Director, Compliance Officer, Global Business Partner, Olympus Corporation of the Americas; Former Assistant District Attorney, Philadelphia District Attorney's Office, Philadelphia, PA; Center Valley, PA*

Russell Rose, JD, *Managing Director, Life Sciences, Deloitte Consulting; Dallas, TX (Moderator)*

Mini Summit 13: The State of Medical Device Compliance: Annual Industry Roundtable

10:10 am **Introductions, Discussions and Q&A**

Kate Godfrey, JD, CCEP, *Senior Vice President, Global Chief Compliance Officer, Chief Compliance Officer KSNA, Karl Storz North America; El Segundo, CA*

JJ Kuhn, JD, *Chief Ethics & Compliance Officer, Danaher; Former Senior Vice President and Chief Ethics & Compliance Officer, Solventum; Former Vice President Chief Counsel, Global Investigations, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

Diane Seol, JD, *Of Counsel, Choate Hall & Stewart; Former Assistant United States Attorney, Affirmative Civil Enforcement Unit, US Attorney's Office, District of Massachusetts; Boston, MA*

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

Mini Summit 14: The State We're In: Legal & Enforcement Trends Reshaping Pharmaceutical Compliance

10:10 am **Introductions, Discussions and Q&A**

Olivia Krzeminski, JD, *Director of Compliance & Legal Research, G&M Health; Somerset, NJ (Moderator)*

Mini Summit 15: External Funding Risks and Mitigation: Latest Trends in Exhibit & Display and Sponsorship Requests

10:10 am **Introductions, Discussions and Q&A**

Asha Green, JD, MPA, CCEP, CHC, *Director, US Compliance, Ferring; Former Global Head, I&C Risk Assessment and Mitigation Planning and Senior Business Advisor, Indivior; Parsippany, NJ*

Alison J. Page, JD, *Assistant General Counsel, Oncology and US Market Access & Patient Services Compliance Lead, Pfizer; New York, NY*

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

Mini Summit 16: Beyond the Questionnaire: Building a Risk-Based Third-Party Management Program That Actually Works

10:10 am **Introductions, Discussions and Q&A**

Ariadna Quesada, MSJ (Invited), *Vice President of Compliance - Global Compliance & Privacy lead, Zoll Medical; Former Compliance Director Europe & MEATI, Hillrom; Former Ethics and Compliance Officer, The Netherlands, AbbVie; Madrid, Spain*

Suki Wiltman, *Vice President, Global Ethics & Compliance, Ipsen; Former Business Partner, Governance, Ethics & Compliance, GSK; Former Senior Corporate Compliance Manager, Allergan Canada; Toronto, Canada*

David Fisher, MS, *President, TDI Solutions; Former Vice President & General Manager, Cyber Innovations, Battelle; Washington, DC (Moderator)*

Mini Summit 17: Navigating Today's Enforcement Landscape with Culture, Data, and Ethics

10:10 am **Introductions, Discussions and Q&A**

Hui Chen, JD, *Co-Founder, Culture. Data. Ethics; Former Chief Integrity Adviser, Hawaii Attorney General; Former Compliance Counsel Expert (Consultant), US Department of Justice; Former Assistant General Counsel, Pfizer; Honolulu, HI*

Zachary Coseglia, JD, *Co-Founder, Culture. Data. Ethics; Co-Founder & Former Managing Principal & Head of Innovation R&G Insights Lab, Ropes & Gray; Former Vice President & Assistant General Counsel, Global Compliance Monitoring, Analytics and Digital, Pfizer; Boston, MA*

11:00 am **Transition Break**

MORNING MINI SUMMITS: GROUP 4 (11:10 am – 12:00 pm)

Mini Summit 18: Risk Advantage: How Resilient Organizations are Capturing Opportunity through Uncertainty

11:10 am **Introductions, Discussions and Q&A**

Kate Godfrey, JD, CCEP, *Senior Vice President, Global Chief Compliance Officer, Chief Compliance Officer KSNA, Karl Storz North America; El Segundo, CA*

Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*

Russell Schaefer, MBA, *Managing Director, BCG; Washington, DC (Moderator)*

Mini Summit 19: View from the Top: Practical Advice for Accelerating Your Compliance Career

11:10 am **Introductions, Discussions and Q&A**

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

Christie Camelio, *Senior Vice President and Chief Compliance Officer, Insmed; Former Vice President & Deputy Global CCO, Celgene; Florham Park, NJ (PCF Board)*

Daryl Kreml, JD, *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise, Risk & Compliance Officer, Sage; Former US Compliance & Global Program Management, Biogen; Boston Scientific; Boston, MA (PCF Board Member)*

Daniel O'Connor, *Senior Vice President, NXLevel Compliance; Lambertville, NJ (Moderator)*

Mini Summit 20: Direct-to-Consumer (DTC) Models: Emerging Compliance Risks and Governance Considerations

11:10 am **Introductions, Discussions and Q&A**

Amy Bensten, JD, *Head of Investigations for Americas, Ethics & Compliance, Takeda; Cambridge, MA*

Michele Guerino, MS, *Executive Director, Ethics and Compliance Office, Merck; Former Senior Regional Business Director, Cubist Pharmaceuticals; Hopewell, NJ*

Edward "Ted" B. Diskant, JD, *Partner, McDermott Will & Schulte; Former Assistant US Attorney, Southern District of New York, US Department of Justice; New York, NY (Moderator)*

Mini Summit 21: Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks

11:10 am **Introductions, Discussions and Q&A**

Abe Kassis, MBA, PhD, *Global Head Compliance and Legal Operations, Bausch + Lomb; Former Director of Corporate Compliance (Ethics & Compliance); Former Global Compliance, Director of Compliance, Takeda; New York, NY*

Yelena Ferreira, JD, *Head of Compliance and Assistant General Counsel, Pharmacosmos Therapeutics; Former Senior Director, Associate General Counsel, Pacira BioSciences; Morristown, NJ*

Eric Bolesh, *Chief Executive Officer, Cutting Edge Information; Research Triangle Park, NC (Moderator)*

Mini Summit 22: Navigating the Evolving US Privacy Landscape

11:10 am **Introductions, Discussions and Q&A**

Tom Hiney, CIPP/US, CIPM, JD, *Head, Digital Ethics & Compliance, US Business Unit, Takeda; Former Privacy Counsel, Blueprint Medicines; Boston, MA*

Courtney Lyles, *Manager, Privacy and Data Protection, Dovetail Consulting Group, Atlanta, GA*

Erin Wagenberg, CIPP/US, CIPP/E, CIPT, FIP, *Director, Dovetail Consulting Group; Former Deputy Privacy Officer, Deloitte Global; Atlanta, GA (Moderator)*

Mini Summit 23: Agentic Risk Management: Transforming Compliance Across Key Business Processes

11:10 am **Introductions, Discussions and Q&A**

Kevin Espinoza, *Chief Integrity & Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo; Former Senior Vice President, Corporate Compliance, Boston Scientific; Richmond, VA*

Jeanille Gatta, MA, *Director, Compliance Business Partner, AstraZeneca, North America; Philadelphia, 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)*

12:00 pm **Networking Luncheon in Exhibit Hall**

NETWORKING LUNCHEON

(12:00 pm – 1:00 pm)

OPTIONAL SMALL AND MID-SIZED LIFE SCIENCE COMPANIES LUNCHEON

Grab your box lunch and join a luncheon discussion designed for emerging and smaller life science companies that have limited to no existing compliance program elements. The focus is on helping compliance leaders determine where to begin and how to build a program in a practical, risk-based way.

The discussion will address questions such as:

- Which risks should be prioritized first?
- When should key compliance program elements and control be implemented?
- How do you build a roadmap that aligns with the company's stage of growth?
- How do you maximize limited resources while establishing an effective compliance program?

Discussion Facilitators:

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

Jeffrey Kawalek, MBA, *Chief Compliance Officer, Zambon US; Former Deputy Chief Compliance Officer US, Jazz Pharmaceuticals; New York, NY (Former PCF Board Chair)*

PHARMACEUTICAL AND MEDICAL DEVICE CONGRESS OPENING PLENARY SESSION

1:00 pm **Welcome and Introduction: PCF Board**

Donna White, CCEP, *Vice President, Compliance Officer, America Region, Chiesi Farmaceutici S.p.A.; Cary, NC (PCF Board Chair)*

1:15 pm **C-Suite Congress Welcome**

Albert Bourla, DVM, PhD (Invited), *Chairman and Chief Executive Officer, Pfizer; Co-Chair, Partnership for New York City; Former Chair of the Pharmaceutical Research and Manufacturers of America (PhRMA); Former President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); New York, NY*

1:25 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*

2:15 pm **Keynote US DOJ Criminal Division Update Fireside Chat**

Jacob Foster, JD, *Acting Chief, Health Care Fraud (HCF) Unit, Criminal Division, Fraud Section, US Department of Justice (DOJ); Former Trial Advocacy Project Deputy District Attorney, Los Angeles County District Attorney's Office; Washington, DC*

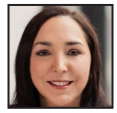
Gary F. Giampetruzzi, JD, *Partner & Global Chair Life Sciences, Paul Hastings; Former Vice President and Acting General Counsel, Head of Government Investigations, Pfizer; New York, NY (Moderator)*

2:45 pm **Tech & Human-in-the-Loop Compliance (Why Human Judgment Matters More Than Ever)**

Jason DiPietro, *Senior Manager Compliance Analytics & Transparency Compliance, Lundbeck; Lake Zurich, IL*

Rawan Fusisi, *Head, Transparency and Third Party Compliance, Indivior; Former Transparency and Analytics Manager, Stryker; Washington, DC*

John Poulin, *Chief Technology Officer and Partner, HELIO; Boston, MA (Co-Moderator)*

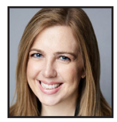


Marci Juneau, MBA, *A Founding Partner, HELIO, Atlanta, GA (Co-Moderator)*

3:15 pm **Networking Break in Exhibit Hall**

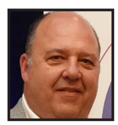
3:45 pm **The Next Generation of Compliance: Leveraging Data to Stay Ahead of Risk**

David M. Blank, JD, *Partner, Arnall, Golden, Gregory; Former Senior Counsel, US Department of Health and Human Services (HHS); Former Special Assistant US Attorney, US Attorney's Office Southern District of Mississippi; Washington, DC*



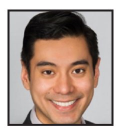
Lindsey LaMoria Gavin, *Senior Director, Deputy Compliance Officer, Lundbeck; Former Compliance Director, Meetings & Events International; Deerfield, IL*

Al Park, *Senior Compliance Officer, Global Monitoring, Auditing and Third-Party Risk Management, Global Ethics and Compliance, Jazz Pharmaceuticals; Former Global Program Effectiveness & Insights Leader, Worldwide Compliance & Business Ethics, Amgen; Phoenix, AZ*



Robert Melillo, JD, *Co-founder and Managing Director, G&M Health; Cocoa Beach, FL (Moderator)*

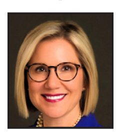
4:15 pm **Integrated Risk Transformation in Pharma/Medical Device: From Compliance Burden to Strategic Advantage**



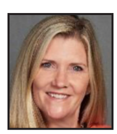
Michael Reyes, *Director, Risk & Regulatory Consulting, PwC; Former Analyst, Compliance Analytics, Edwards Lifesciences; Dallas, TX*

Brian Riewerts, MPA, *Partner, Pharmaceutical and Life Sciences Risk and Regulatory Leader, PwC; Washington, DC (Moderator)*

4:45 pm **Annual Chief Compliance Officers Fireside Chat**



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



Christine Gordon, JD, *Vice President, Risk, Assurance, & Compliance and Chief Compliance Officer, Americas; RAC Business Partner, Global SIS Division, Olympus Corporation of the Americas; Former Assistant District Attorney, Philadelphia District Attorney's Office; Bethlehem, PA*

Melissa T. Lozner, JD, *Senior Vice President, Chief Compliance Officer, Regeneron; Former Chief Compliance & Ethics Officer and Special Counsel, Rafael Holdings; Former Vice President, Head of Ethics, Risk & Compliance, Novartis; Tarrytown, NY (PCF Board Member)*

Paul J. Silver, *Principal, Life Sciences Regulatory, Compliance, and Legal Leader, Deloitte Consulting, Atlanta, GA (Moderator)*

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

THURSDAY, OCTOBER 15, 2026

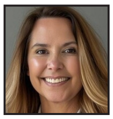
PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 3

7:00 am **Registration Opens: Breakfast Buffet**

CHIEF COMPLIANCE OFFICER ROUNDTABLE

PCF-Sponsored, Exclusive Invitation-Only, Closed-Door session

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



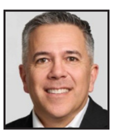
Jill Dailey, JD, *Vice President, Chief Compliance Officer, Oncology, Menarini Stemline; Former Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer; New York, NY (PCF Board Member)*

Antitrust Admonition
Kristin Graham Koehler, JD, *Managing Partner, DC Office & Executive Committee Member, Sidley Austin; Washington, DC*

8:15 am **Future of the Compliance Profession in an AI Driven Environment**

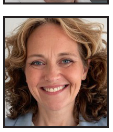
AI is reshaping how compliance functions operate, how teams are structured, and what skills tomorrow's leaders must bring to the table. This panel brings together organizations of varying sizes to explore how AI is changing expectations, budgets, staffing models, and the competencies required for the next generation of compliance leadership.

The conversation will focus on practical realities: what companies are doing, where pressures are emerging, and how to prepare talent for a future where AI is embedded in every workflow.



Kevin Espinoza, *Chief Integrity & Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo; Former Senior Vice President, Corporate Compliance, Boston Scientific; Richmond, VA*

Jim Gibney, *Vice President, Global Compliance Operations, Corporate Compliance, Regeneron; Former Director, Worldwide Programs and US Investigations, Pfizer; Ridgewood, NJ*



Rebekah Latchis, JD, *Vice President, Risk Intelligence & Investigations, Office of Privacy, Integrity & Compliance, Medtronic; Former Corporate Responsibility Director, Bon Secours; Washington, DC*

Natasha Trifun, JD, *Head of Enterprise Compliance & Risk and Privacy, AstraZeneca; Former 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*

Joy Dowdle, JD, *Partner, Litigation Department, Paul Hastings and Co-Chair of the Houston Office; Houston, TX (Moderator)*

9:00 am **Executive Breakout by Company Size - Part 1**

In this breakout, discussions will build on the previous session by shifting from high-level trends to practical, real-world implementation. Participants will share how AI is actually being used inside their organizations, what's working, what's stalled, and where the biggest opportunities and risks emerge.

Daniel Spicehandler, JD, *Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Pharma Congress Medical Device Executive Steering Committee)*

9:40 am **Networking Break in Exhibit Hall**

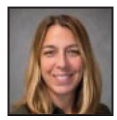
10:00 am **Executive Breakout by Company Size - Part 2**

Mona Peterson Rosow, JD, MPH, *Former Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Steering Committee)*

10:40 am **Board Oversight of Compliance: What Audit Firms Observe and What Regulators Require**

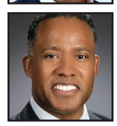
As regulatory expectations intensify and AI accelerates business risk, Boards are reexamining what "good" compliance looks like—and whether their organizations are structured to deliver it. Yet many Boards still misunderstand the purpose, scope, and value of Compliance, creating gaps in oversight and weakening independence.

This session offers an inside look at what audit firms are seeing in board governance and cultural attitudes toward compliance. We will also explore the government's perspective on why robust compliance programs matter, and the oversight behaviors regulators expect Boards to demonstrate in the boardroom.

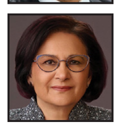


Katherine Buckley, MBA, *Partner, Pharmaceutical and Life Sciences Risk & Regulatory Consulting Solutions, PwC; Philadelphia, PA*

Saul B. Helman, MD, *President and Managing Director, Epsilon Life Sciences; Chicago, IL*

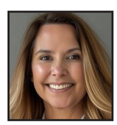


Kenneth A. Polite, Jr, JD, *Partner & Global Co-leader, White Collar Defense, Sidley Austin; Former Assistant Attorney General, Criminal Division, US Department of Justice; Washington, DC*



Sujata Dayal, JD, LLM, *Independent Board Director, Emergent BioSolutions; Former Vice President & Global Chief Compliance Officer, Medline; Former Vice President Health Care Compliance & Privacy, Johnson & Johnson; Chicago, IL (Moderator)*

11:30 am **Open Forum: Opportunities for Benchmarking and Peer-driven Q&A. Bring your questions!**



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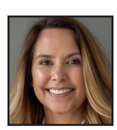
Mona Peterson Rosow, JD, MPH, *Former Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Steering Committee)*

Daniel Spicehandler, JD, *Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Pharma Congress Medical Device Executive Steering Committee)*

11:55 am **Wrap-up**



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

Noon **Chief Compliance Officer Roundtable Adjournment**

MORNING MINI SUMMITS: GROUP 5 (8:00 am - 8:50 am)

Mini Summit 24: Identifying and Managing Risk Associated with AI

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

Brent Boeckmann, MBA, *Strategic Advisor, Commercial Immunology Lead, US & Global Specialty Care, Sanofi; Boston, MA*

Kari Czeszewski, CHC, *Associate, Epsilon Life Sciences; New York, NY*

Mini Summit 25: A Look Under the Hood: Exploring PBM and Payer Arrangement Risks and Emerging Reporting Requirements

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

Craig B. Bleifer, JD, *Partner, McGuire Woods; Former Corporate Vice President, General Counsel North America; Novo Nordisk; Former Senior Vice President, General Counsel & Secretary, Daiichi Sankyo; New York, NY*

Jeffrey Low, RPh, MHA, *Director, Ankura; Former Vice President, Clinical Services, Magellan Health; Former Director, Medicare Services, CVS/Caremark; Phoenix, AZ*

Katherine C. Norris, MPA, *Senior Managing Director, Life Sciences Compliance, Disputes & Economics, Ankura; Washington, DC (Moderator)*

Mini Summit 26: From Speak-Up to Proof: Turning DOJ and OIG Expectations into Defensible, AI-Enabled Compliance Operations

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

Allison Benkert, MBA, *Senior Director, Compliance Policies, Training & Investigations, Jazz Pharmaceuticals; Former Senior Director, Global Investigations, Pfizer; Former Head of Global Compliance Investigations, Seagen; Doylestown, PA*

Melissa (Missy) Kaschak, CPA, CFE, CISA, *GRC Operations, Olympus Corporations of the Americas; Center Valley, PA*

Aaron Lewis, MBA, *Director, Legal and Compliance Operations, Cordis; Former Director, Compliance Insights and Technologies, Cardinal Health; Miami Lakes, FL*

Brook Mishler, RN, MSN, *Global Director of Compliance Solutions, Life Sciences, Case IQ; Former Compliance Officer for the Americas, Cordis; Ontario, Canada (Co-Moderator)*

Shannon Walker, *Executive Vice President, Thought Leadership & Strategy, Case IQ; Founder and President, WhistleBlower Security; Ontario, Canada (Co-Moderator)*

Mini Summit 27: Manufacturer–Specialty Pharmacy Relationships: Managing Compliance Risk in Specialty and Rare Disease Commercial Models

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

Elizabeth Conti, JD, *Senior Legal Counsel, Nestlé Health Science; Arlington, VA*

Aaron P. Maskery, CPA, CIA, *Senior Director, Compliance Operations, Mighty Therapeutics; Former Senior Director, Compliance, Karuna Therapeutics; Former Director, Compliance Auditing & Monitoring, Idorsia; Wilmington, DE*

Eliza L. Andonova, JD, *Partner, Global Regulatory, Hogan Lovells Cadwalader; Washington, DC (Moderator)*

Mini Summit 28: The Future of Compliance Monitoring: AI Agents, Risk Intelligence and Practical Adoption

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

Kristiana Bankova, MS, *Senior Manager, Forensics, EY; New York, NY*

Libby M. Rosenberry, *Senior Manager, Forensic & Integrity Services, EY; Boston, MA*

8:50 am **Transition Break**

MORNING MINI SUMMITS: GROUP 6 (9:00 am - 9:50 am)

Mini Summit 29: Building the Compliance Operating Model for What's Next

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

Monica Schroeter, CPA, CISA, *Head of Compliance Operations and Risk, LivaNova; Former Head of Compliance, F2G; Former Head of Compliance & Privacy, SK Life Sciences; Goshen, NY*

Clarissa Crain, *Managing Director, Life Sciences Regulatory, Compliance, and Legal Leader, Deloitte Consulting; Phoenixville, PA (Moderator)*

Mini Summit 30: Leveraging AI for More Efficient and Effective Investigations

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

Mike D'Alessandro, CFE, *Senior Manager, Forensics and Integrity Services, EY; Former Chief Ethics and Compliance Officer, ahma Rx; New York, NY*

Susana Franco, MBA, *Director, Field Compliance and Investigations, Lundbeck; Former Director of Compliance Operations, Orthofix; Dallas, TX*

Tracey Tran, *Senior Manager, Forensic and Integrity Services, EY; New York, NY*

Erin Brown Jones, MA, JD, *Partner, Latham & Watkins; Washington, DC (Moderator)*

Mini Summit 31: Compliance Considerations, Enforcements and Guidelines on Social Media Activities

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

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

Nikki Reeves, JD, *Partner, FDA & Life Sciences Practice Group, Co-Chair, Government Matters & Regulatory Practice Group, King & Spalding; Washington, DC (Moderator)*

Mini Summit 32: Building a Compliance Roadmap: Practical Strategies for Scaling Compliance Programs

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

Geeta Kaveti, MHA, JD, *Chief Compliance Officer & US General Counsel, Nyxoah; Former Vice President, Chief Compliance & Privacy Officer, Nevro; Former Division Counsel - Legal Regulatory & Compliance, Abbott; Vernon Hills, IL*

Eric Ortman, MBA, *Senior Director, Legal Operations & Healthcare Compliance, 4D Molecular Therapeutics; Former Senior Director, Legal Operations, BeiGene; Former Director, Legal Operations, Ultragenyx Pharmaceutical; Walnut Creek, CA*

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

Mini Summit 33: Fair Market Value in Flux: Navigating Complex Fee Arrangements, HCP & Patient Engagement, and Influencer Compensation Risks

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

Ravneet Talwar, MBA, *Senior Manager, Life Sciences & Healthcare Consulting Group, Paul Hastings; New York, NY*

Laura A. Skinner, MBA, *Managing Director, Life Sciences & Healthcare Consulting Group, Paul Hastings; Managing Director, Rare Disease Compliance Consortium; New York, NY (Moderator)*

Mini Summit 34: Future Proofing the Compliance Function: Operating Models for an AI-Enabled World

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

Craig B. Bleifer, JD, *Partner, McGuire Woods; Former Corporate Vice President, General Counsel North America; Novo Nordisk; Former Senior Vice President, General Counsel & Secretary, Daiichi Sankyo; New York, NY*

Brett Barlag, MBA, *Senior Managing Director, Healthcare Risk Management and Advisory, FTI Consulting; New York, NY (Moderator)*

9:50 am **Networking Break**

MORNING MINI SUMMITS GROUP 7 (10:10 am – 11:00 am)

Mini Summit 35: Unstructured Data and Advanced Monitoring Strategies

10:10 am **Introductions, Discussions and Q&A**

Christina Woods, MHA, *Partner, Pharmaceutical and Life Sciences Risk & Regulatory Consulting, PwC; New York, NY*

Jeff Hyre, *Vice President Sales, Healthcare and Life Sciences, Global Relay; Denver, CO (Moderator)*

Mini Summit 36: Leading Practices for Managing Investigations Panel

10:10 am **Introductions, Discussions and Q&A**

John S. Rah, JD, *Counsel and Head, Life Sciences Compliance Practice, Potter & Murdock; Potomac, MD*

Olga Zinavenka, CPA, MBA, *Head of Compliance Operations, Keenova; Former Executive Director, Head of Compliance Operations, Endo; Former Compliance Officer – Europe, Middle East and Africa; Paoli, PA*

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

Mini Summit 37: Navigating Regulatory Uncertainties in Life Sciences

10:10 am **Introductions, Discussions and Q&A**

Dominick P. DiSabatino, JD, *Partner, Sheppard Mullin Richter & Hampton; Washington, DC*

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

Mini Summit 38: Compliance Considerations for Rare Disease Products

10:10 am **Introductions, Discussions and Q&A**

Craig B. Bleifer, JD, *Partner, McGuire Woods; Former Corporate Vice President, General Counsel North America; Novo Nordisk; Former Senior Vice President, General Counsel & Secretary, Daiichi Sankyo; New York, NY (Moderator)*

Mini Summit 39: From Oversight to Partnership: Strengthening Collaboration Between Compliance and the Business

10:10 am **Introductions, Discussions and Q&A**

Jessica Constant, MS, *Associate Director, Compliance & Business Controls, AstraZeneca; Former Global Compliance Business Partner, Commercial Operations, QIAGEN; Washington, DC*

Mini Summit 40: Digital Ecosystem Considerations for Pharmaceutical Companies

10:10 am **Introductions, Discussions and Q&A**

Christine Moundas, JD, MPH, *Healthcare and Data Partner, Co-Head, Digital Health Initiative, Ropes & Gray; Former Analyst, Office of Inspector General, US Department of Health and Human Services; New York, NY (Moderator)*

11:00 am **Transition Break**

MORNING MINI SUMMITS GROUP 8 (11:10 am – 12:00 pm)

Mini Summit 41: Holistic, Ongoing Monitoring Case Studies in Compliance

11:10 am **Introductions, Discussions and Q&A**

John Gitas, MBA, *Principal, US Advisory, Healthcare and Life Sciences, KPMG; New York, NY (Moderator)*

Mini Summit 42: Emerging Commercial & Market Access Risk in Life Sciences: Navigating Innovation, Compliance, and Evolving Access Models

11:10 am **Introductions, Discussions and Q&A**

Anthony S. Greco, MBA, *Managing Director, Pharmaceutical & Life Sciences Advisory Services, PwC; Philadelphia, PA (Moderator)*

Mini Summit 43: Effectively Leveraging Post-Investigation Mitigation to Create a Narrative of Continuous Improvement

11:10 am **Introductions, Discussions and Q&A**

Aurélie Ercoli, LLM, PhD, *Partner, Life Sciences Practice Group, DLA Piper; Washington, DC*

Emily Treanor, JD, *Head of Global Investigations & Enterprise Risk Management, Alnylam Pharmaceuticals; Washington, DC*

Jeffrey Scott, JD, *Of Counsel, Life Sciences Practice Group, DLA Piper; Former Lead Compliance Counsel, Digital, Reporting, and Analytics, Pfizer; Philadelphia, PA (Moderator)*

Mini Summit 44: Transparency Reporting; Update on the Centers for Medicare and Medicaid Services Open Payments Program

11:10 am **Introductions, Discussions and Q&A**

Veronika Peleshchuk Fradlin, MPP, *Director, Transparency & Data Group, Centers for Medicare & Medicaid Services, US Department of Health and Human Services; Washington, DC*

Mini Summit 45: Can Learning Data Reduce Risk? Using Measurement to Drive Defensible, Risk-Based Compliance Training

11:10 am **Introductions, Discussions and Q&A**

A.D. Detrick, CPTM, *President, Founder, MetriVerse Analytics; Columbus, OH*

Jaya Saigal, *Senior Director, C&E Policy, Education, Communications, Culture of Integrity and Ombuds, Bristol Myers Squibb; Princeton, NJ*

Lily Zimmerman, *Learning Solution Architect, Tier1 Performance; Covington, KY (Moderator)*

Mini Summit 46: AI in Clinical Practice: Compliance, Governance & FDA Oversight

11:10 am **Introductions, Discussions and Q&A**

Julie K. Taitsman, MD, JD, *Managing Director, BDO, US; Former Chief Medical Officer, Office of Inspector General (OIG), US Department of Health & Human Services; Former Special Counsel for Health & Science, United States Senate Committee on Finance; Washington, DC*

Georgia Ravitz, JD, *Partner, FDA & Healthcare Regulatory, Orrick, Herrington & Sutcliffe; Washington, DC; (Moderator)*

12:00 pm **Networking Luncheon**

NETWORKING LUNCHEON

11:50 am **Networking Luncheon with Dessert and Coffee in the Exhibit Hall and Luncheon Mini Summits**

LUNCHEON MINI SUMMITS GROUP 9 (12:10 pm – 1:00 pm)

Mini Summit 47: Direct-to-Consumer (DTC) Models in the Pharmaceutical Space

12:10 pm **Introductions, Discussions and Q&A**

Kala Shankle, JD, *Vice President, Regulatory Affairs, Healthcare Distribution Alliance; President Elect, American Society for Pharmacy Law; Washington, DC*

Alison J. Fethke, JD, *Member of the Firm, Epstein Becker Green; Former Division Counsel, Legal Regulatory & Compliance, AbbVie; Chicago, IL (Moderator)*

Mini Summit 48: ROI of AI: Separating Value from Hype

12:10 pm **Introductions, Discussions and Q&A**

Stephanie Macholtz, JD, MBA, *Adjunct Faculty, Suffolk University Law School; Former Vice President, Healthcare Compliance, Organogenesis; Former Senior Director Global Compliance and Deputy General Counsel, Clinical Affairs, Apellis Pharmaceuticals; Cambridge, MA*

Omar S. Richardson, MBA, *Executive Director, Compliance, Shionogi; Former Compliance Officer, Grünenthal Group; New York, NY*

Kelly J. Tope, JD, MBA, *Head, Ethics & Business Integrity Governance, Operations & Risk Management-North America & Global Specialty Care, Sanofi; Former Head, USBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Boston, MA*

Katie Jacyna, *Chief Product Officer, HELIO; Denver, CO (Moderator)*

Mini Summit 49: Lean, Credible, Defensible: Compliance Programs That Work Without Big Budgets

12:10 pm **Introductions, Discussions and Q&A**

Reetu Dandora, *Senior Vice President, Quality & Regulatory Compliance, AVEO Oncology; Boston, MA*

Julian Gabbard, JD, *Associate General Counsel, Meso Scale Diagnostics; Former Head of Legal and Compliance, Corporate Counsel, Kolon TissueGene; Former Senior Director, Arcellx; Washington, DC*

Elizabeth Weiss, JD, *Vice President, Chief Compliance & Privacy Officer, Invivyd; Former Head of Compliance for Americas & EMEA, Lupin; Former Senior Director, US Risk and Compliance, LEO Pharma; Former Assistant General Counsel, Compliance Lead, Global Health & Patient Access, Pfizer; Livingston, NJ*

Robert A. Wells, JD, *Health Care Regulatory Shareholder, Chair, Health Law and Government Solutions, Baker, Donelson, Bearman, Caldwell & Berkowitz; Baltimore, MD (Moderator)*

Mini Summit 50: Data Analytics & Compliance Monitoring in an AI-Powered World

12:10 pm **Introductions, Discussions and Q&A**

Ignatius Grande, JD, *Of Counsel, Winston Taylor; New York, NY*

Roberta Rima, MS, *Vice President, Global Compliance Audit, Monitoring & Analytics, Zimmer Biomet; San Francisco, CA*

Stephanie M. Lewko, CFE, *Managing Director, Healthcare Disputes & Economics, Ankura; Washington, DC (Moderator)*

Mini Summit 51: Collaborating to Create Lasting Solutions During and After Monitoring or Investigations

12:10 pm **Introductions, Discussions and Q&A**

Katherine "Kate" Dyson, JD, *Head of US Compliance, Alexion Pharmaceuticals; Former Head of Assurance, Alexion, AstraZeneca RDU; Former Senior Director, Neurology Compliance Business Partner; Alexion Pharmaceuticals; Boston, MA*

Naveen Ganesh, MA, JD, *Vice President, Global Head of Investigations, Ethics & Compliance, Takeda; Former Head of Investigations & Monitoring, North America & Global Specialty Care, Sanofi; Former Compliance Assurance & Investigations (Lead), Verily;; Boston, MA*

Kathryn Harris, JD, *Head of US Compliance, Galderma; Former Senior Director, Global Compliance, Emergent BioSolutions; Former Compliance Business Partner (Market Access, Patient Services, and Strategic Accounts); Alexion Pharmaceuticals; Boston, MA*

Audrey DeGuarde, MSJ, *Vice President, General Manager, Commercial Compliance, MediSpend; Morristown, NJ (Moderator)*

Mini Summit 52: Annual FDA Office of Prescription Drug Promotion Update

12:10 pm **Introductions, Discussions and Q&A**

Twyla Mosey, PharmD, RPh, *Director, Division of Advertising & Promotion Review, US Food and Drug Administration; Washington, DC*

Joshua (Josh) Oyster, JD, *Partner, Life Sciences Regulatory & Compliance Practice, Ropes & Gray; Former Counsel, Humana; Washington, DC (Moderator)*

1:00 pm **Transition Break**

CLOSING PLENARY SESSION

1:10 pm **Welcome and Introduction: PCF Board**

1:15 pm **Keynote Annual DOJ Civil Division Update Fireside Chat**

Brenna Jenny, JD, MPH, *Deputy Assistant Attorney General, Commercial Litigation Branch, Civil Division, US Department of Justice; Former Principal Deputy General Counsel & Chief Legal Officer, Centers for Medicare & Medicaid Services, US Department of Health and Human Services; Washington, DC*

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

1:45 pm **Investigations, Enforcement and Prosecutions Roundtable**

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

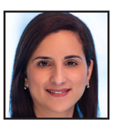
Greg Demske, JD, *Partner, Goodwin Procter; Former Chief Counsel, Office of Inspector General, US Department of Health and Human Services; Washington, DC*

Preeya Noronha Pinto, JD, *Partner, DLA Piper; Former Acting General Counsel, US Department of Health and Human Services; Washington, DC*

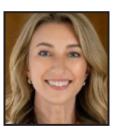
Kip F. Ebel, MBA, *Principal, Forensic & Integrity Services, EY; New York, NY (Moderator)*

2:15 pm **Updates from AdvaMed, BIO and PhRMA**

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



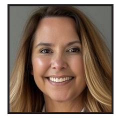
Ida Nassar, JD, *Vice President, Assistant General Counsel, Ethics & Compliance, AdvaMed; Former Senior Attorney, Office of Chief Counsel, US Drug Enforcement Administration; Washington, DC*



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

Mark C. Scallon, MHA, *Principal, Risk Advisory, Life Sciences Consulting, Compliance and Ethics Market Leader, Baker Tilly; Richmond, VA (Moderator)*

2:45 pm **Market Access in 2026 and Beyond: A Shifting Compliance Landscape**



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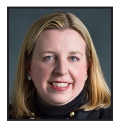
Christian Scognamillo, JD, *Associate General Counsel, US Market Access & Pricing, Abbvie; Former Senior Corporate Counsel, Market Access & Commercial Transactions, Exelixis; Former Senior Director, Legal, Access & Transactions, Alnylam, San Francisco, CA*

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

3:15 pm **Networking Break in Exhibit Hall**

3:45 pm **Burgeoning Compliance Risks**

Brian C. Barry, JD, *Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Chief Compliance Officer & Compliance Counsel, EMD Serono; Boston, MA*



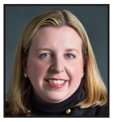
Jennifer Dubas, JD, *Chief Ethics and Compliance Officer, Jazz Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Cencora; Former Senior Vice President, Chief Compliance Officer, AmerisourceBergen; Ambler, PA*

Shannon Kelley, JD, *Executive Vice President, Chief Legal Officer, Madrigal; Former Vice President, Head of Compliance; North America and Global Specialty Care GBU, Sanofi; Former Assistant US Attorney & Deputy Chief of Litigation, US Attorney's Office District of Massachusetts; Boston, MA*

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

4:15 pm **AI and the Evolving Compliance Function**

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



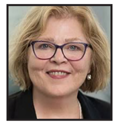
Jennifer Dubas, JD, *Chief Ethics and Compliance Officer, Jazz Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Cencora; Former Senior Vice President, Chief Compliance Officer, AmerisourceBergen; Ambler, PA*

Rebekah Latchis, JD, *Vice President, Risk Intelligence & Investigations, Office of Privacy, Integrity & Compliance, Medtronic; Former Corporate Responsibility Director, Bon Secours; Washington, DC*

Neeraj Gupta, MBA, *President, Chief Technology Officer, Cresen Solutions; Chester Springs, PA (Moderator)*

4:45 pm **Managing Risk in Unsettled Times**

Deborah A. Curtis, JD, *Partner & Co-Chair, White Collar Defense & Investigations Practice, Arnold & Porter; Former Deputy General Counsel, Central Intelligence Agency; Former Deputy Chief, Counterespionage Section, National Security Division, US Department of Justice; Former Deputy Chief, National Security Section, District of Columbia US Attorneys' Office; Washington, DC*



Ambassador Barbara A. Leaf, JD, *Senior International Policy Advisor, Arnold & Porter; Former Special Assistant to the President and Senior Director for the Middle East and North Africa; Former Assistant Secretary of State for Near Eastern Affairs, and Former US Ambassador to the United Arab Emirates, US State Department; Washington, DC*

5:15 pm **ADJOURNMENT**

FRIDAY, OCTOBER 16, 2026

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 4

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)

8:00 am **Welcome and Introductions**

Daryl Kreml, JD, *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise, Risk & Compliance Officer, Sage; Former US Compliance & Global Program Management, Biogen; Boston Scientific; Boston, MA (PCF Board Member)*

Antitrust Admonition

Brian A. Bohnenkamp, MHA, JD, *Partner, FDA and Life Sciences, King & Spalding; Washington, DC*

8:15 am **Inside the New DOJ Initiative: The Rising Importance of Data Miners**

The DOJ has added a powerful new tool to its enforcement toolbox: Data Miners. Under its new initiative, the Department is partnering with select data-miner relators who can sift massive public datasets to uncover statistical anomalies, hidden patterns, and potential False Claims Act violations. We'll break down what this initiative means for compliance teams, how data driven allegations are likely to evolve, and the practical steps organizations should take now to strengthen monitoring, documentation, and response readiness.

This session features insights from Corey Amundson, a former Acting U.S. Attorney, Section Chief in DOJ's Criminal Division, head of DOJ's internal affairs, and longtime Assistant U.S. Attorney specializing in healthcare fraud and other white-collar crimes. In these roles, Corey led multiple crisis-response efforts and developed proactive enforcement initiatives aligned with DOJ priorities—including one of the nation's first healthcare fraud strike forces, the Criminal Division Corporate Whistleblower Awards Pilot Program, and a financial-fraud task force built around data-mining analytics.

Featuring:

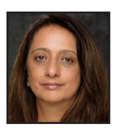
Corey R. Amundson, JD, *Partner, Special Matters & Government Investigations Practice Group, King & Spalding; Former Head, Public Integrity Section, US Department of Justice; Former Acting US Attorney, Middle District of Louisiana; Washington, DC*

Mark A. Jensen, JD, *Co-Chair & Partner, Special Matters & Government Investigations, King & Spalding; Washington, DC*

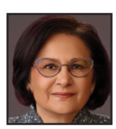
8:45 am **Wins & Losses in the Early Days of AI – Audience Discussion Session**

AI has entered compliance workflows with remarkable speed—and with uneven results. Some teams are already seeing meaningful efficiency gains, while others are wrestling with adoption challenges, accuracy concerns, governance gaps, or cultural resistance.

We'll discuss early wins, early failures, and the real-world lessons learned from attendees implementing AI in compliance programs. This is a candid, practical discussion about what's working, what isn't, and how organizations are navigating the realities of building AI-enabled compliance functions. Come prepared to share!



Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*



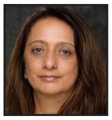
Sujata Dayal, JD, LLM, *Independent Board Director, Emergent BioSolutions; Former Vice President & Global Chief Compliance Officer, Medline; Former Vice President Health Care Compliance & Privacy, Johnson & Johnson; Chicago, IL*

Daryl Kreml, JD, *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise, Risk & Compliance Officer, Sage; Former US Compliance & Global Program Management, Biogen; Boston Scientific; Boston, MA (PCF Board Member)*

Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

9:15 am **Benchmarking and Q&A Forum**

Opportunity for polling, asking questions and benchmark against peers for valuable insights-Come prepared with questions!



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10:00 am **Networking Break**

10:20 am **Customer Centric Complexity: Field Pressures, Patient Expectations and Digital Health Governance**

Customer expectations, patient behavior, and field realities are shifting faster than traditional governance models can absorb. Field teams are navigating mounting office restrictions, expanding reimbursement responsibilities, all with an increasing need for data amidst existing firewalls and privacy constraints. At the same time, patients are turning to AI-driven information sources and digital therapeutics, thus blurring long-standing boundaries between education, support, and medical advic

Panelists will unpack these rising pressures and share practical strategies to sustain disciplined, coordinated, and trustworthy customer engagement in an accelerating landscape.

Michelle Murphy, *Executive Director, Compliance, Regeneron; New York, NY*

11:00 am **Breakouts by Company Size**

Topics Include:

- **Cross-Functional Account Planning – roles, permissible topics, frequency and guardrails**
- **TBD**

11:30 am **Last Minute Questions – Wrap Up – Adjournment**

Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*

Noon **CONGRESS ADJOURNMENT**