

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

Hybrid Onsite Conference & Internet Event – Live and Archived

October 22 – 24, 2025

Washington, DC • Grand Hyatt Washington

All Times are EDT • Agenda Current as of August 25, 2025
Subject to regular updates



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

The Leading Forum on Pharmaceutical and Medical Device Ethics and Compliance Issues

Sponsored by the Pharmaceutical Compliance Forum (PCF)

October 22 – 25, 2025 • A HYBRID ONSITE CONFERENCE AND INTERNET EVENT

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AGENDA AT A GLANCE

DAY I: WEDNESDAY, OCTOBER 22, 2025

7:00 am

Registration Opens & Continental Breakfast

8:00 am – 11:50 am

MORNING MINI SUMMITS (CONCURRENT SESSIONS)

MINI SUMMITS GROUP 1

State Consumer Privacy Laws — Compliance Tips for Pharma and Med Device Companies	Pharmaceutical Compliance and AI: Government Pricing Compliance Transformation through Intelligent Automation	Compliance Considerations for Small Companies	Free ≠ Risk-Free: A Closer Look at the Free Goods Landscape	Compliance's Role in Digital Information Governance	Aligning Your Compliance Program Activities with the New Administration's Priorities
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MINI SUMMITS GROUP 2

Optimizing the Compliance Operating Model for the Future	Navigating Regulatory Uncertainties in Life Sciences	Government Pricing: Finding Compliance Zen	Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities	Building Smarter Monitoring Plans: Applying Enhanced Risk Segmentation	Leveraging Digital Compliance
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MINI SUMMITS GROUP 3

Annual Medical Device Ethics and Compliance Issues Roundtable	Elevating Compliance: Strategic Risk Leadership in a Global Landscape	Compliance Considerations, Enforcements, and Guidelines on Social Media Activities	Patient Advocacy Organization Relationships — Compliance Considerations for Developing and Maintaining Effective Partnerships	Navigating Legal and Political Risks in the New DEI Landscape	External Funding Risks and Mitigation — Latest Trends in Exhibit & Display and Sponsorship Requests
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MINI SUMMITS GROUP 4

What to Expect from a CMS Open Payments Audit	Integrating Compliance into Vendor/Consultant Engagements	What the Privacy? Live	Evaluating Compliance Training Effectiveness	Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success	Patient-Oriented Commercial Models: Legal and Market Access Considerations
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11:50 am – 1:00 pm

EXHIBIT HALL OPENS & NETWORKING LUNCHEON (Luncheon in Exhibit Hall of Mini Summit Rooms)

(LUNCHEON) MINI SUMMITS GROUP 5

Compliance Considerations for Rare Disease	AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future?	Update on Medical Device Investigations and Prosecutions	Update on the Status of FCPA Enforcement — Strategic Implications	Fighting Overcriminalization in Federal Regulations	Eyes Wide Open: Navigating the Global Complexities of Third Party Risk
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1:00 pm – 5:45 pm

OPENING PLENARY SESSION

PCF Board Welcome and Introductions

Keynote: OIG Update

US DOJ Keynote Fireside Chat

Medical Device C-Suite Keynote Fireside Chat

One Size Doesn't Fit All: Tailoring Compliance to Your Product

New Business Models to Meet Patients Where They Are

Chief Compliance Officer and Business Leader Roundtable

Adjournment

NETWORKING RECEPTION IN THE EXHIBIT HALL

5:45 pm

Agenda continued next page

AGENDA AT A GLANCE, CONTINUED

DAY II: THURSDAY, OCTOBER 23, 2025

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

CHIEF COMPLIANCE OFFICER (CCO) ROUNDTABLE *(PCF Sponsored Special Closed Morning Session, Invitation-only)*

7:30 am

Invitation-only Networking Breakfast

8:00 am – 11:45 am

Welcome, Introductions, and Antitrust Admonition

Passing the Baton: Reflections from Retiring CCOs

Fireside Chat with the Honorable Merrick B. Garland

Perspectives from Former Government Officials

Executive Breakouts

Breakout Takeaways & Open Forum

Wrap Up

8:00 am – 11:50 am MORNING MINI SUMMITS (CONCURRENT SESSIONS)

MINI SUMMITS GROUP 6

Case Studies in AI & Analytics for Monitoring & Investigations	Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights	Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success	Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk	Making Compliance Cool, Increasing Your Influence
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MINI SUMMITS GROUP 7

Telehealth for Life Sciences Companies: New Platforms, Old Risks	State of Confusion: The Overlooked State Laws in Pharma Compliance	Vaccines Under the Trump Administration	Compliance Considerations for Mergers and Acquisitions	Strategic Stewardship: Navigating Compliance and Corporate Responsibility in Life Sciences
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MINI SUMMITS GROUP 8

Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance	Implementing AI in Life Sciences Compliance: Strategies, Challenges, and Opportunities	Fair Market Value: Compliant Compensation Strategies	New Standards for Compliance Learning: What You Need to Know — Rethink's 2025 Benchmarking Report	Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements
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MINI SUMMITS GROUP 9

What Enforcement May Look Like in Trump 2.0	Sanctions — the Enterprise-Wide Risk and Compliance Nexus	SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies	Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI	Best Practices in Responding to Investigations
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11:50 am – 1:00 pm NETWORKING LUNCHEON WITH DESSERT AND COFFEE IN THE EXHIBIT HALL

1:00 pm – 5:30 pm

CLOSING PLENARY SESSION
PCF Board Welcome and Introductions
Annual AUSA Roundtable
Investigations, Enforcement and Prosecutions Roundtable
Strategies and Techniques for Compliance Conversations with the Business
Artificial Intelligence in Life Sciences Compliance: Real-World Case Studies
CMS Transparency Update
Updates from AdvaMed, BIO and PhRMA
Adjournment

DAY III: FRIDAY, OCTOBER 24, 2025

7:00 am

Registration Opens & Continental Breakfast

8:30 am – Noon

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.)
Welcome and Antitrust Admonition
The Gap isn't as Big as You Think — A Collaborative Learning Session: Pharma & Medical Device Focus
Benchmarking and Q&A Forum
Patient Engagement: Interactions & Advocacy Breakouts
Final Q&A, Wrap Up

Noon

CONGRESS ADJOURNMENT

AGENDA DAY I: WEDNESDAY, OCTOBER 22, 2025**7:00 am Registration Opens****PHARMA/DEVICE CONGRESS****MINI SUMMITS GROUP I (8:00 am – 8:50 am)****Mini Summit 1: State Consumer Privacy Laws — Compliance Tips for Pharma and Med Device Companies****8:00 am Introductions, Discussions and Q&A**

Erin Geygan, JD, Vice President Law, Patient Services Center/PECS, Johnson & Johnson, New Brunswick, NJ

Elizabeth Smith, JD, Senior Director, G&A Contracts and Data Privacy, Exelixis; Former Head of Global Privacy, Senior Director & Associate General Counsel, Privacy Law, Seagen, Alameda, CA

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)

Mini Summit 2: Pharmaceutical Compliance and AI: Government Pricing Compliance Transformation through Intelligent Automation**8:00 am Introductions, Discussions and Q&A**

Matt Berkle, JD, LL.M., Compliance Counsel, Head of US Compliance, Guerbet; Former Vice President, General Counsel, Head of Ethics & Compliance, Breckenridge Pharmaceutical; Former Head of North America Legal and Compliance, ALK-Abelló, Princeton, NJ

John Shakow, JD, Partner, FDA & Life Sciences Practice, King & Spalding, Washington, DC

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

Mini Summit 3: Compliance Considerations for Small Companies**8:00 am Introductions, Discussions and Q&A**

Jeffrey Kawalek, MBA, Chief Compliance Officer, Zambon US; Former Deputy Chief Compliance Officer US, Jazz Pharmaceuticals, Former Co-chair, PCF, New York, NY

Timothy Moore, JD, Vice President, Head of Legal & Compliance, Secretary, Corium; Former Assistant General Counsel - Commercial & Compliance, BD; Former Special Assistant US Attorney, United States Attorneys' Offices, Southern District of Florida; Former Assistant State Attorney, Assistant State Attorney, Miami-Dade State Attorney's Office, Miami, FL

Joseph Zimmerman, Senior Vice President, Chief Compliance & Privacy Officer, SpringWorks Therapeutics; Former Vice President, Chief Compliance & Privacy Officer, US, Head of Government Affairs, Ferring Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Executive Leadership Team Member, Allergan (FKA Actavis, Forest Laboratories), Former Co-chair, PCF, New York, NY

John E. 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 (Moderator)

Mini Summit 4: Free ≠ Risk-Free: A Closer Look at the Free Goods Landscape**8:00 am Introductions, Discussions and Q&A**

Steven B. Cohen, MBA, Vice President, Chief Ethics and Compliance Officer, North America, Eli Lilly, Fishers, IN

Alan G. Minsk, JD, Partner, Food and Drug Practice, Arnall Golden Gregory, Atlanta, GA

Heather Young, JD, Compliance Officer - Executive Director, Olympus Corporation of the Americas; Former Assistant District Attorney, Philadelphia District Attorney's Office, Philadelphia, PA

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

Mini Summit 5: Compliance's Role in Digital Information Governance**8:00 am Introductions, Discussions and Q&A**

Jennifer L. Joyce, CFE, CIPM, Principal, Forensic & Integrity Services, EY, Washington, DC

Jeff Lemay, JD, Former Executive Director, N.A. Compliance Officer, Jazz; Former Senior Director, US Compliance Officer, Greenwich Bioscience, Carlsbad, CA

Ravi Kumar Monangi, MCA, MBA, Founder & Chief Technology Officer, Celito Tech Inc., Redwood City, CA

Jeff Hyre, Regional Vice President, Global Relay, Denver, CO (Moderator)

Mini Summit 6: Aligning Your Compliance Program Activities with the New Administration's Priorities**8:00 am Introductions, Discussions and Q&A**

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

Robert Mascola, MA, JD, Chief Compliance Officer, Juul Labs; Professor, Fordham Law School, Program on Corporate Ethics & Compliance, Washington, DC

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

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

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)

8:50 am Transition Break

PHARMA/DEVICE CONGRESS

MINI SUMMITS: GROUP 2 9:00 am – 9:50 am

Mini Summit 7: Optimizing the Compliance Operating Model for the Future

9:00 am Introductions, Discussions and Q&A

Kevin L. Espinoza, MBA, Chief Integrity & Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo; Former SVP, Corporate Compliance and Privacy Officer, Boston Scientific; Former SVP, Chief Compliance and Privacy Officer, BTG, Richmond, VA

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

Russell Rose, Managing Director, Life Sciences Advisory, Deloitte & Touche, Dallas, TX

Clarissa Crain, Managing Director, Life Sciences Advisory, Deloitte & Touche, Phoenixville, PA (Moderator)

Mini Summit 8: Navigating Regulatory Uncertainties in Life Sciences

9:00 am Introductions, Discussions and Q&A

Dominick P. DiSabatino, JD, Partner, Life Sciences, FDA and Healthcare Regulatory Compliance, 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 9: Government Pricing: Finding Compliance Zen

9:00 am Introductions, Discussions and Q&A

Beth Krewson, JD, Vice President, Head of US Legal and Compliance, PharmaEssentia; Former General Counsel, Formation Bio; Former Senior Vice President, BlueRock Therapeutics, Philadelphia, PA

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

Mini Summit 10: Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities

9:00 am Introductions, Discussions and Q&A

Ethan Davis, JD, Chief Compliance Officer, Associate General Counsel, Vericel Corporation, Cambridge, MA

David J. Derusha, JD, Compliance Director, Vertex Pharmaceuticals; Former Assistant US Attorney, Boston, MA

Joseph E. Keeney, JD, Former US Head of Ethics and Compliance. Galderma Laboratories; Former Senior Director/Head, healthcare Compliance, Organogenesis, Dallas, TX

James (Jamie) Ravitz, JD, Partner and Chair, FDA Practice, McDermott Will & Schulte, Washington, DC (Moderator)

Mini Summit 11: Building Smarter Monitoring Plans — Applying Enhanced Risk Segmentation

9:00 am Introductions, Discussions and Q&A

Evan DaSilva, CPA, CFE, CAMS, US Business Ethics Monitoring & Operations, Ipsen Biopharmaceuticals, Boston, MA

Mona Peterson Rosow, JD, MPH, Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic, Minneapolis, MN

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

Kelly Listro, Senior Manager; Potomac River Partners, Chicago, IL (Moderator)

Mini Summit 12: Leveraging Digital Compliance

9:00 am Introductions, Discussions and Q&A

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

Erica Powers, Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals, Boston, MA

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

9:50 am Transition Break

PHARMA/DEVICE CONGRESS

MINI SUMMITS: GROUP 3 10:00 am – 10:50 am

Mini Summit 13: Annual Medical Device Ethics and Compliance Issues Roundtable

10:00 am Introductions, Discussions and Q&A

Terra Buckley, JD, Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene, Summit, NJ (Medical Device Executive Committee)

Brian Danahy, JD, Deputy General Counsel and Chief Compliance Officer, Exactech; Former, Compliance Program Manager, Zimmer, Gainesville, FL

Peter Jensen, JD, Vice President, Global Chief Compliance Officer, Arthrex; Former Chief Nominations Counsel, US Senate Judiciary Committee, Naples, FL

Tara Shewchuk, JD, LL.M., Senior Vice President, Chief Privacy, Integrity & Compliance Officer Medtronic; Former Senior Director, Ethics and Compliance, AbbVie, Minneapolis, MN (Medical Device Executive Committee)

Jonathan Stevens, JD, Partner, Litigation Department, Paul Hastings; Former Associate General Counsel, Exactech, Irvine, CA (Moderator)

Mini Summit 14: Elevating Compliance: Strategic Risk Leadership in a Global Landscape

10:00 am Introductions, Discussions and Q&A

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, Chicago, IL (Medical Device Executive Committee)

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

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

Mini Summit 15: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities

10:00 am Introductions, Discussions and Q&A

Wendy Goldstein, JD, MPH, Of Counsel, Litigation Department, Paul Hastings; Former Special Counsel to the Commissioner of Health, New York State Department of Health, New York, NY

Jill Mason, JD, Chief Compliance and Risk Officer, Orthofix; Former Senior Global Compliance Director, St. Jude Medical, Dallas, TX

Chad Morin, MBA, Senior Vice President, Chief Compliance Officer, Viridian Therapeutics; Former Senior Vice President, Chief Compliance Officer, Kiniksa Pharmaceuticals; Former Vice President, Chief Compliance Officer, bluebird bio, Waltham, MA

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

Mini Summit 16: Patient Advocacy Organization Relationships — Compliance Considerations for Developing and Maintaining Effective Partnerships

10:00 am Introductions, Discussions and Q&A

M. Cristina “Cris” Barba, MBA, CFE, CEP, Director, Compliance, Inmsed; Former Associate Director Global and NA Medical Affairs Compliance, Teva Pharmaceuticals, Jamison, PA

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

Sarah L. Whipple, JD, Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Former Vice President, Global Compliance & Privacy Officer, Aegerion, Boston, MA

Emily F. Hodge, JD, Partner, Choate, Hall & Stewart, Boston, MA (Moderator)

Mini Summit 17: Navigating Legal and Political Risks in the New DEI Landscape

10:00 am Introductions, Discussions and Q&A

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

Daryl Kreml, JD, Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Former US Compliance & Global Program Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific Boston, MA (PCF Board)

Richard Perry, M.Ed., Compliance Operations Manager, Incyte; Board Member, William Way LGBT Community Center; Former Corporate Compliance Specialist, Adaptimmune, Wilmington, DE

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

Mini Summit 18: External Funding Risks and Mitigation — Latest Trends in Exhibit & Display and Sponsorship Requests

10:00 am Introductions, Discussions and Q&A

Edgar H. Donohoe, JD, Vice President & Lead Compliance Counsel, Pfizer US, New York, NY

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

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

10:50 am Transition Break

PHARMA/DEVICE CONGRESS

MINI SUMMITS: GROUP 4 11:00 am – 11:50 am

Mini Summit 19: What to Expect from a CMS Open Payments Audit

11:00 am Introductions, Discussions and Q&A

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

Margaret K. Feltz, MA, JD, Vice President, Chief Compliance Officer, Purdue Pharma; Former Co-chair, PCF, Stamford, CT

Sara Kimball, JD, Assistant General Counsel, Daiichi Sankyo, Basking Ridge, NJ

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

Mini Summit 20: Integrating Compliance into Vendor/Consultant Engagements

11:00 am Introductions, Discussions and Q&A

Kimberly Ford, MBA, JD, Vice President, Chief Ethics & Compliance Officer Americas, Medtronic; Former Vice President Compliance, Americas, Smith+Nephew, Memphis, TN

Sam Pietropaolo, JD, Lead Counsel US Commercial, Takeda; Former Senior Legal Counsel, Shire Pharmaceuticals; Former Senior Corporate Counsel, Smith & Nephew, Lexington, MA

Erica Powers, Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals, Boston, MA

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

Mini Summit 21: What the Privacy? Live

11:00 am Introductions, Discussions and Q&A

Liz Fortier, JD, Chief Privacy & Data Governance Officer, LivaNova, Minneapolis, MN

Tom Hiney, JD, CIPP/US, CIPM, Privacy Counsel and Senior Director, Blueprint Medicines, Boston, MA

Patrick Santiago, MBA, CIPM, Director, Global Data Privacy, Genmab; Former Associate Director, US Data Privacy Operations, Boehringer Ingelheim, Plainsboro, NJ

Courtney Lyles, Manager, Dovetail Consulting Group, Atlanta, GA

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

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

Mini Summit 22: Evaluating Compliance Training Effectiveness

11:00 am Introductions, Discussions and Q&A

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

Kelley Medeiros, MPP, Compliance Officer, Neuromodulation, LivaNova; Former Global & US Oncology Compliance Officer, EMD Serono; Former BU Ethics & Compliance Advisory Operations, Takeda Oncology, Houston, TX

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

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

Mini Summit 23: Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success

11:00 am Introductions, Discussions and Q&A

Fred Gibbons, Principal, Life Sciences Digital Quality & Compliance, Deloitte & Touche, New York, NY

Kelly J. Tope, JD, MBA, Head of Ethics and Business Integrity Governance, Operations & Risk MGMT-NA & Global Specialty Care, Sanofi; Former Head of UBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Former Global Director, Compliance Transparency, Monitoring, Systems, Data Analytics & Process Improvement, Zimmer Biomet, Boston, MA

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

Mini Summit 24: Patient-Oriented Commercial Models: Legal and Market Access Considerations

- 11:00 am** **Introductions, Discussions and Q&A**
Eve M. Brunts, JD, LLM, Partner, Ropes & Gray, Boston, MA
Tess Carey, PharmD, Senior Pharmacist, Amazon Pharmacy, Philadelphia, PA
Alison Fethke, JD, Counsel, Ropes & Gray; Former Division Counsel, Legal Regulatory & Compliance, AbbVie, Chicago, IL
Margaux J. Hall, JD, Partner, Ropes & Gray, Washington, DC

11:50 pm **Transition to Networking Luncheon**

EXHIBIT HALL OPENS, NETWORKING LUNCHEON AND LUNCHEON MINI SUMMITS

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

PHARMA/DEVICE CONGRESS MINI SUMMITS: GROUP 5 Noon – 12:50 pm

Mini Summit 25: Compliance Considerations for Rare Disease

- Noon** **Introductions, Discussions and Q&A**
Tracy Berns, JD, Senior Vice President, Chief Compliance & Quality Assurance Officer, Ionis Pharmaceuticals; Former Chief Compliance Officer, Akcea Therapeutics; Former Vice President, Chief Compliance Officer & Legal Affairs, AMAG Pharmaceuticals, Boston, MA
Tara D'Orsi, JD, Executive Vice President, General Counsel, Kyowa Kirin North America, Princeton, NJ
Laura Hunter, JD, Senior Associate, Healthcare Regulatory, Hogan Lovells, Washington, DC
Eliza L. Andonova, JD, Partner, Life Sciences Global Regulatory, Hogan Lovells, Washington, DC (Moderator)

Mini Summit 26: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future?

- Noon** **Introductions, Discussions and Q&A**
Aur lie Ercoli, LLM, PhD, Partner, Life Sciences Practice Group, DLA Piper, Washington, DC
Lucy Muzzy, JD, Vice President Enterprise Lead Responsible AI, Digital and Privacy Compliance Counsel, Pfizer; Former Assistant US Attorney, US Attorney's Office, New Jersey, New York, NY
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
Kim Tyrrell-Knott, JD, Senior Vice President, Chief Compliance Officer, Enovis; Former Associate General Counsel, GE HealthCare, San Diego, CA
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 27: Update on Medical Device Investigations and Prosecutions

- Noon** **Introductions, Discussions and Q&A**
Terra Buckley, JD, Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast; Former Executive Director, Head, Business Advisory, Center of Excellence, US Healthcare Compliance, Celgene, Summit, NJ (Medical Device Executive Committee)
Kate Godfrey, JD, CCEP, Senior Vice President, Global Chief Compliance Officer, Karl Storz, US; Former Vice President, Chief Compliance and Privacy Officer, Veracyte, Seattle, WA
Kristen Perriello, JD, Principal, Choate, Hall & Stewart; 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 28: Update on the Status of FCPA Enforcement — Strategic Implications

- Noon** **Introductions, Discussions and Q&A**
Adam Falkowitz, Head of Legal, North America, Getinge; Former Deputy General Counsel, Olympus Corporation of the Americas; New York, NY
Christina Hud, JD, Global Investigations Senior Counsel, Pfizer Inc.; Former Health Care Fraud Acting Unit Chief and Senior Trial Counsel at U.S. Department of Justice, U.S. Attorney's Office for the District of New Jersey, New York, NY
Alexandria (Alex) Lav, Director Risk & Compliance, Dow Jones, New York, NY
Allan Medina, JD, Partner, Goodwin Procter; Former Senior Deputy Chief, Criminal Division, US Department of Justice, Washington, DC (Moderator)

Mini Summit 29: Fighting Overcriminalization in Federal Regulations

- Noon** **Introductions, Discussions and Q&A**
Lee M. Cortes, Jr., Partner, Arnold & Porter; Former Executive AUSA, US Attorneys' Offices, District of NJ; Former AUSA, Chief, Health Care Fraud Unit, and Former Deputy Chief, Special Prosecutions Division, US Attorney's Office, District of New Jersey, Newark, NJ
Lisa Re, MS, JD, Retired Assistant Inspector General for Legal Affairs, Office of Inspector General, US Department of Health and Human Services, Chevy Chase, MD

Mini Summit 30: Eyes Wide Open: Navigating the Global Complexities of Third Party Risk

- Noon** **Introductions, Discussions and Q&A**
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
Daniel Spicehandler, JD, Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Medical Device Executive Committee)
David Fisher, MS, President, TDI, Washington, DC (Moderator)

12:50 pm **Transition Break**

PHARMA/DEVICE CONGRESS OPENING PLENARY SESSION

1:00 pm



PCF Board Welcome and Introduction

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

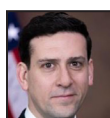
1:15 pm



Keynote: OIG Update

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

2:00 pm



US DOJ Keynote Fireside Chat

Matthew R. Galeotti, JD, Head, Criminal Division, US Department of Justice; Former Acting Deputy Chief, Business & Securities Fraud Section, US Attorney's Office, Eastern District of New York, Washington, DC



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

2:30 pm



Medical Device C-Suite Keynote Fireside Chat

Spencer Stiles, MBA, Group President, Orthopaedics, Stryker; Director, Chart Industries (GTLS); Director, Medical Device Manufacturers Association (MDMA); Director, Business Leaders for Michigan (BLM), Kalamazoo, MI



Interviewed by: Daniel Spicehandler, JD, Vice President Compliance, Commercial Divisions, Stryker, New York, NY (Medical Device Executive Committee)

3:00 pm

Networking Break

3:30 pm

One Size Doesn't Fit All: Tailoring Compliance to Your Product



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



Reanna Carver, JD, Assistant General Counsel, Accord BioPharma, Raleigh, NC



Steven B. Cohen, MBA, Vice President, Chief Ethics and Compliance Officer, North America, Eli Lilly, Fishers, IN



Kristin Comer, JD, General Counsel, RVL Pharmaceuticals; Former General Counsel and Chief Compliance Officer, RedHill Biopharma, Inc; Former Vice President and Assistant General Counsel, Syneos Health, Bridgewater, NJ



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

4:15 pm



New Business Models to Meet Patients Where They Are

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



David Dopf, JD, Executive Director & Executive Counsel, US Human Pharma Business Law, Boehringer Ingelheim, Ridgefield, CT



Stefanie A. Doeblner, 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)

4:45 pm



Chief Compliance Officer and Business Leader Roundtable

Brent Boucher, Senior Vice President, Americas, Solvntum; Former Executive Vice President, Global Commercial, NuVasive, St. Paul, MN



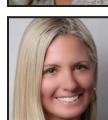
Anisa Dhalla, Vice President, Global Head, Ethics and Business Integrity, UCB; Board, Pharmaceutical Compliance Forum, Acworth, GA



JJ Kuhn, JD, Senior Vice President, Chief Ethics & Compliance Officer, Solvntum; Former Vice President Chief Counsel, Global Investigations, Medtronic, St. Paul, MN



Colleen Kempf, Head of Ethics & Compliance, US Biopharmaceuticals, AstraZeneca Wilmington, DE



Meredith Odell, Executive Director Marketing, AstraZeneca; Former Specialty Sales Representative, GSK, Wilmington, DE



Jeffrey Stark, MD, Vice President & Head of Medical Immunology, UCB, Smyrna, GA



Paul J. Silver, Principal, Life Sciences Regulatory, Legal, & Compliance Leader, Deloitte & Touche, Atlanta, GA (Moderator)

5:45 pm

ADJOURNMENT AND NETWORKING RECEPTION

AGENDA DAY II: THURSDAY, OCTOBER 23, 2025

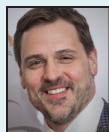
7:00 am **Registration Opens:
Continental Breakfast in Exhibit Hall**

CHIEF COMPLIANCE OFFICER ROUNDTABLE

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

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

8:00 am **Welcome and Introductions**



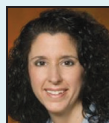
Daryl Kreml, JD, Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific, Boston, MA (PCF Board)



Antitrust Admonition:

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

8:15 am **Passing the Baton: Reflections from Retiring CCOs**



Cindy Cetani, LPEC, NACD.DC®, Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia, Glen Allen, VA (PCF Board)



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

8:45 am **Fireside Chat with the Honorable Merrick B. Garland**



Merrick B. Garland, JD, Partner, Arnold & Porter; Former 86th United States Attorney General, Chief Judge of the US Court of Appeals, DC Circuit and Chair, Executive Committee, US Judicial Conference, US Department of Justice, Washington, DC



Interviewed by: Mahnu Davar, JD, Partner and Co-chair Life Sciences & Healthcare Regulatory Practice, Arnold & Porter, Washington, DC

9:15 am **Perspectives from Former Government Officials**



Robert K. DeConti, JD, Partner, King & Spalding; Former Chief Counsel, Inspector General, Office of Inspector General, US Department of Health and Human Services, Washington, DC



Joshua S. Levy, JD, Partner, Ropes & Gray; Former US Attorney for the District of Massachusetts, US Department of Justice, Boston, MA



Lisa H. Miller, JD, Partner, Sidley Austin LLP; Former Deputy Assistant Attorney General, Fraud and Appellate Sections, Criminal Division, US Department of Justice, Washington, DC



Tara Shewchuk, JD, LLM, Senior Vice President, Chief Privacy, Integrity & Compliance Officer Medtronic; Former Senior Director, Ethics and Compliance, AbbVie, Minneapolis, MN (Medical Device Executive Committee) (Moderator)

10:00 am **Break**

10:15 am **Executive Breakouts**

Attendees will choose two topics of interest and engage in facilitated breakout discussions designed for active collaboration and shared learning.

Breakout Topics:

- 1. Strengthening Board Effectiveness Through Impactful Engagement**
- 2. Navigating the Crossroads: Legal & Compliance Collaboration**
- 3. Empowering Leadership: Growth Strategies for You and Your Team**



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

11:30 am **Breakout Takeaways & Open Forum**

Key insights from executive breakout sessions, followed by interactive opportunities for benchmarking and peer-driven Q&A.

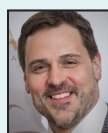


Christie Camelio, Senior Vice President and Chief Compliance Officer, Insmid; Former VP & Deputy Global CCO, Celgene, Florham Park, NJ (PCF Board)



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

11:55 am **Wrap Up**



Daryl Kreml, JD, Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Former US Compliance & Global Program Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific, Boston, MA (PCF Board)

Noon

Adjournment

MORNING MINI SUMMITS PHARMA/DEVICE CONGRESS

MINI SUMMITS GROUP 6 8:00 am – 8:50 am

Mini Summit 31: Case Studies in AI & Analytics for Monitoring & Investigations

8:00 am Introductions, Discussions and Q&A

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

Aaron Lewis, MBA, *Director, Legal and Compliance Operations, Cordis; Former Director, Compliance Insights and Technologies, Cardinal Health, Columbus, OH*

Jon Tan, LLB, MSC(Fin), *Director, Compliance and Ethics Investigations, Bristol Myers Squibb, Singapore*

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

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

Mini Summit 32: Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights

8:00 am Introductions, Discussions and Q&A

Ayushman Hazarika, CA, MBA, CFE, *Managed Markets Finance, Novartis; Former US SEC and Management Reporting, Merck and Schering-Plough, Berkeley Heights, NJ*

Samantha Sutherland, *Director, Digital Health and Transformation Practice, Baker Tilly, Jersey City, NJ*

Darren R. Jones, CIA, *Principal, Life Science Industry Leader, Baker Tilly, New York, NY (Moderator)*

Mini Summit 33: Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success

8:00 am Introductions, Discussions and Q&A

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

Christian Malias, MBA, *Associate Director, Compliance Operations, Monitoring & Systems, Sage Therapeutics; Former Global Corporate Compliance Manager, Investor Relations & Corporate Communications, Adaptimmune, Cambridge, MA*

Adam Price, JD, *Vice President, US Chief Compliance & Integrity Officer, Boehringer Ingelheim, Ridgefield, CT*

Michael T. O'Connor, MS, *Chief Executive Officer, qordata; Former Global Head Compliance and Ethics Operations, Alexion Pharmaceuticals; Former Executive Director, Global Head, IS Business Consulting, Boehringer Ingelheim, New York, NY (Moderator)*

Mini Summit 34: Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk

8:00 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 Science, Goshen, NY*

Rita K. Warfield, JD, *Director of Global Trade Legal & Compliance, Medtronic; Former Associate General Counsel, Regulatory Law Group, BD; Former Assistant General Counsel, Ferring Pharmaceuticals, Livingston, NJ*

Benjamin Correa, JD, *Partner Food, Drug & Medical Device, Sidley Austin, Washington, DC (Moderator)*

Mini Summit 35: Making Compliance Cool, Increasing Your Influence

8:00 am Introductions, Discussions and Q&A

Virginia MacSuihbne, JD, CCEP, *The Compliance Fairy Godmother; Executive Director, Legal Compliance, Alumis; Former Vice President, Global Chief Compliance & Privacy Officer, Agilent Technologies, Santa Clara, CA*

Ronnie Feldman, *Founder, Chief Executive Officer and Creative Director, L&E: Comedians Who Improve Compliance, Chicago, IL*

8:50 am Transition Break

PHARMA/DEVICE CONGRESS MINI SUMMITS GROUP 7 9:00 am – 9:50 am

Mini Summit 36: Telehealth for Life Sciences Companies: New Platforms, Old Risks

9:00 am Introductions, Discussions and Q&A

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

Stefanie A. Doeblner, 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*

Mini Summit 37: State of Confusion: The Overlooked State Laws in Pharma Compliance

9:00 am Introductions, Discussions and Q&A

Thomas Daly, JD, *Associate Director of Compliance, Biocon Biologics, New York, NY*

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

Mini Summit 38: Vaccines Under the Trump Administration

9:00 am Introductions, Discussions and Q&A

Richard H. Hughes IV, JD, MPH, *Partner, Epstein Becker & Green; Lecturer, George Washington University Law School; Member, Board of Directors, Vaccinate Your Family; Former Vice President, Moderna, Washington, DC (Moderator)*

Mini Summit 39: Compliance Considerations for Mergers and Acquisitions

9:00 am Introductions, Discussions and Q&A

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

Patrick Gibson, JD, *Former Associate Vice President, Global Compliance Counseling, Organon; Former Special Assignment – Global Compliance Separation Lead, Merck, Villanova, PA*

Tiffany Rivard, MBA, *Senior Director, Compliance and Privacy Operations, Medtronic, Minneapolis, MN*

Kiley Smith Kelly, MBA, *Partner/Principal, Forensic & Integrity Services, EY, Philadelphia, PA (Moderator)*

Mini Summit 40: Strategic Stewardship: Navigating Compliance and Corporate Responsibility in Life Sciences

9:00 am Introductions, Discussions 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

Suj Patel, Director, Digital, Healthcare Strategy and Transformation Practice, Baker Tilly, Tampa, FL

Perri Pomper, JD, Vice President, Global Compliance Program Management, Stryker; Former Vice President, Compliance & Legal Affairs, Clinical Genomics; Former Director, Ethics and Compliance Strategy & Education, Novo Nordisk, New York, NY

Mark Scallon, MHA, Principal, Life Sciences Consulting, Baker Tilly, Richmond, VA (Moderator)

9:50 am Transition Break

PHARMA/DEVICE CONGRESS

MINI SUMMITS GROUP 8 10:00 am – 10:50 am

Mini Summit 41: Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance

10:00 am Introductions, Discussions and Q&A

Michelle D. Axelrod, JD, Principal, Porzio, Bromberg & Newman; Former Assistant General Counsel, Sunovion, Westborough, MA

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

Eddie Underwood, PharmD, Medical Science Liaison, argenx; Former Lead Medical Science Liaison (Southeast), NOVAVAX; Former Regional Director of Scientific Affairs, AcelRx Pharmaceuticals; Former Medical Science Liaison, Ironwood Pharmaceuticals, Crestview-Fort Walton Beach-Destin, FL

Jennifer A. Romanski, JD, Principal, Porzio, Bromberg & Newman, Morristown, NJ (Moderator)

Mini Summit 42: Implementing AI in Life Sciences Compliance: Strategies, Challenges, and Opportunities

10:00 am Introductions, Discussions and Q&A

Rebekah Latchis, JD, Vice President, Global Investigations, Data and Governance, Medtronic; Former Corporate Responsibility Director, Bon Secours Health System, Washington, DC

Jennifer McGovern, JD, Risk, Operations & Data Lead, AstraZeneca, Wilmington, DE

Saraswatha Lalitha Putcha, MS, Associate Director, Product Delivery & AI Implementations, Cresen Solutions, Exton, PA

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

Mini Summit 43: Fair Market Value: Compliant Compensation Strategies

10:00 am Introductions, Discussions and Q&A

Abe Kassis, PhD, Senior Director, Global Head Compliance and Legal Operations, Bausch + Lomb; Former Global Compliance - Director of Compliance, Takeda; Former Associate Director, Ethics and Compliance - CIA Auditing and Monitoring & Risk Management Oversight, Takeda, New York, NY

Matt Zebley, Senior Manager, Compliance, Transparency and HCP Engagement, Incyte Corporation, Wilmington, DE

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

Mini Summit 44: New Standards for Compliance Learning: What You Need to Know - Rethink's 2025 Benchmarking Report

10:00 am Introductions, Discussions and Q&A

Kirsten Liston, Founder and Chief Executive Officer, Rethink Compliance, Boston, MA

Jamie McKillop, Vice President for Advisory Services, Rethink Compliance, Reading, MA

Mini Summit 45: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements

10:00 am Introductions, Discussions and Q&A

Jamie E. Darch, JD, Partner, Life Sciences Practice Group, Ropes & Gray, Chicago, IL

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

10:50 am Transition Break

PHARMA/DEVICE CONGRESS

MINI SUMMITS GROUP 9 11:00 am – 11:50 am

Mini Summit 46: What Enforcement May Look Like in Trump 2.0

11:00 am Introductions, Discussions and Q&A

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

Perham Gorgi, JD, Partner, DLA Piper; Former Deputy Chief Counsel for Litigation, US Food and Drug Administration; Former Trial Attorney, Consumer Protection Branch, Department of Justice; Former Assistant United States Attorney, United States Attorney's Office, District of Columbia; Washington, DC

Gabriel Scannapieco, JD, Partner; Co-Chair Life Sciences, Arnall Golden Gregory; Former Assistant Director, Consumer Protection Branch, US Department of Justice, Washington, DC

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

Mini Summit 47: Sanctions — the Enterprise-Wide Risk and Compliance Nexus

11:00 am Introductions, Discussions and Q&A

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

David Amendola, Director, ResEcon Life Sciences & Healthcare; Former Global Compliance Risk Evaluation and Management, ConvaTec, New York, NY (Moderator)

Mini Summit 48: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies

11:00 am Introductions, Discussions and Q&A

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

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

Rupa Joshi, JD, Vice President, Legal and Head of Compliance, Astria Therapeutics; Former Vice President, General Counsel, Vaccines Business Unit, Takeda; Member, Board of Directors, Executive Committee and Personnel and Governance Committee, Massachusetts Technology Collaborative; Former Deputy General Counsel and Chief Compliance Officer, Stealth BioTherapeutics; Cambridge, MA

Jacob T. Elberg, JD, Professor & Faculty Director, Center for Health & Pharmaceutical Law, Seton Hall University School of Law; Former AUSA, US Attorney's Office, District of New Jersey, Newark, NJ (Moderator)

Mini Summit 49: Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI

11:00 am Introductions, Discussions and Q&A

Michael Curran, CPA, CFE, Manager, Forensics, KPMG US, New York, NY

Ronald Strauss, Vice President Compliance, MIMedx; Former Executive Sales Representative, Osteo Specialty, Eli Lilly and Company; Marietta GA

Joseph Zimmerman, Senior Vice President, Chief Compliance & Privacy Officer, SpringWorks Therapeutics; Former Vice President, Chief Compliance & Privacy Officer, US, Head of Government Affairs, Ferring Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Executive Leadership Team Member, Allergan (FKA Actavis, Forest Laboratories), Former Co-chair, PCF, New York, NY

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

Mini Summit 50: Best Practices in Responding to Investigations

11:00 am Introductions, Discussions and Q&A

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

Sarah diFrancesca, JD, Executive Director, Compliance Lead, Immunology & Dermatology, Incyte, Wilmington, DE

David C. Tolley, MA, JD, Partner, Chair, Boston Litigation and Trial Department, Latham & Watkins, Boston, MA

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

11:50 am Transition to Networking Luncheon

NETWORKING LUNCHEON

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

SPECIAL LUNCHEON SESSION ON GLOBAL COMPLIANCE (OPTIONAL)

Noon

Special Luncheon Session — Bringing the Outside In: Global Ethics & Compliance Trends and US Implications



Aleksej Daineko, MA, Vice President, Chief Ethics & Compliance Officer, Lundbeck; Former CCO, Sobi - Swedish Orphan Biovitrum AB; Former Director, Head of Global Compliance & Risk Business Partnering, LEO Pharma, Copenhagen, Denmark



Anisa Dhalla, Vice President, Global Head, Ethics and Business Integrity, UCB; Board, Pharmaceutical Compliance Forum, Acworth, GA



Gary Kalman, Executive Director, Transparency International US; Former Executive Director, Financial Accountability and Corporate Transparency (FACT) Coalition; Founder, Americans for Financial Reform; Former Director, Federal Legislative Office, US Public Interest Research Group (PIRG), Washington, DC



Mwana Lugogo, JD, MPP, Chief Ethics and Compliance Officer, Takeda Pharmaceuticals International GmbH; Former Senior Counsel, Baxter Healthcare, Zurich, Switzerland



Lisa K. Miller, JD, LLM, Head, Integrity Compliance, Integrity Vice Presidency, World Bank Group, Washington, DC



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

12:50 pm

Transition Break

CLOSING PLENARY SESSION

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

1:15 pm Annual AUSA Roundtable



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



Abraham George, JD, Assistant US Attorney and Chief, Civil Division, US Attorney Office, District of Massachusetts, Boston, MA



Mackenzie Queenin, JD, Assistant US Attorney and Chief, Health Care Fraud, US Attorney Office, District of Massachusetts; Adjunct Professor, Boston College of Law, Boston, MA



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

1:45 pm Investigations, Enforcement and Prosecutions Roundtable



Jennifer L. 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



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

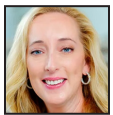


Lisa H. Miller, JD, Partner, Sidley Austin; Former Deputy Assistant Attorney General, Fraud and Appellate Sections, Criminal Division, US Department of Justice, Washington, DC



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

2:30 pm Strategies and Techniques for Compliance Conversations with the Business



Susan Williamson, MBA, Senior Vice President & Chief Compliance Officer, Endo; Former Senior Manager, WEBB Finance, Operational Risk Management, Pfizer, Malvern, PA



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



Shoshanna Clark, JD, Vice President, Ethics & Compliance, Kailera Therapeutics; Former Vice President, Chief Compliance Officer, Caravel Therapeutics; Former Head of UBU Ethics & Compliance Operations, Takeda, 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)

3:15 pm Transition Break

3:30 pm



Artificial Intelligence in Life Sciences Compliance: Real-World Case Studies

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



Omar Richardson, MBA, Senior Director of Compliance, Shionogi Inc.; Former Compliance Officer, Grünenthal Group; Former Director, Corporate Compliance, New York, NY



Kelly J. Tope, JD, MBA, Head of Ethics and Business Integrity Governance, Operations & Risk MGMT-NA & Global Specialty Care, Sanofi; Former Head of UBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Former Global Director, Compliance Transparency, Monitoring, Systems, Data Analytics & Process Improvement, Zimmer Biomet, Boston, MA



Manny Tzavlakakis, Managing Partner, HELIO, Morristown, NJ (Moderator)

4:15 pm



CMS Transparency Update

Veronika Peleshchuk Fradlin, MA, Director of Division of Transparency Projects, Centers for Medicare and Medicaid Services, Baltimore, MD



Amy L. Bedsaul, Open Payments Communications, Data Analytics & Systems Group, Centers for Medicare & Medicaid Services, Baltimore, MD

4:45 pm



Updates from AdvaMed, BIO and PhRMA

John Delacourt, JD, Deputy General Counsel, Vice President Health, Regulatory & Commercial Operations, 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



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

5:30 pm

ADJOURNMENT

AGENDA DAY III: FRIDAY, OCTOBER 24, 2025

INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

PHARMA/DEVICE CONGRESS DAY III

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

7:00 am Continental Breakfast

8:00 am Welcome



Cindy Cetani, LPEC, NACD.DC®, Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia, Glen Allen, VA (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 The Gap isn't as Big as You Think — A Collaborative Learning Session: Pharma & Medical Device Focus

Discover the nuanced intersections between two dynamic industries—Pharma and Medical Devices. While they operate in distinct regulatory and clinical spaces, they share more common ground than many realize. This session will demystify the medical device landscape and spotlight career pathways that bridge both worlds.



Tracy Berns, JD, Senior Vice President, Chief Compliance & Quality Assurance Officer, Ionis Pharmaceuticals; Former Chief Compliance Officer, Akcea Therapeutics; Former Vice President, Chief Compliance Officer & Legal Affairs, AMAG Pharmaceuticals, Boston, MA



Daniel Spicehandler, JD, Vice President Compliance, Commercial Divisions, Stryker, New York, NY (Medical Device Executive Committee)



Terra Buckley, JD, Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene, Summit, NJ (Medical Device Executive Committee/Moderator)

9:00 am Benchmarking and Q&A Forum

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



Terra Buckley, JD, Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene, Summit, NJ (Medical Device Executive Committee/Moderator)



Cindy Cetani, LPEC, NACD.DC®, Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia, Glen Allen, VA (PCF Board)



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)



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

9:45 am Break

10:00 am TBD

10:45 am Patient Engagement: Interactions & Advocacy Breakouts

We'll kick things off with an overview to tee up the key patient engagement themes, then shift into breakout discussions to surface insights from diverse perspectives. Finally, we'll reconvene to share collective learnings and actionable takeaways.



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)



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

11:45 am



Final Q&A, Wrap Up & Adjournment

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)

Noon

CONGRESS ADJOURNMENT