

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



Hybrid Onsite Conference & Internet Event – Live and Archived
October 25 – 27, 2023

And Featuring a Virtual Pharma and Med Device
Global Ethics and Compliance Day With Updates
from Around the World — Broadcast Virtually on
November 15, 2023

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All Times are EDT • Agenda Current as of October 2, 2023
Subject to regular updates

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WEDNESDAY, OCTOBER 25, 2023

SPECIAL INVITATION ONLY SESSION: CHIEF COMPLIANCE OFFICER ROUNDTABLE

The CCO Roundtable is an independent session organized and hosted by the Pharmaceutical Compliance Forum (PCF).

The Roundtable is a core part of PCF's mission, which is to provide a safe and confidential environment for senior compliance executives to openly discuss business challenges, strategies, and solutions to drive corporate compliance programs to even greater effectiveness.

This Roundtable is unlike others due to its closed door setting. Attendance at the Roundtable is strictly limited to invitation only, for industry senior compliance executives and expert panelists. The session is not recorded nor included as part of the Congress audio and video archives.

There is a modest charge of \$295 to attend the Roundtable.

Roundtable attendees are not required to attend the Congress, but those who do wish to attend the Congress may register at the discounted rate of \$995.

Roundtable attendees are not required to attend the Congress.

Qualifying CCOs may request more information about the Roundtable and, if appropriate, inquire about attending by emailing reginfo@hccconferences.com.

7:30 am Invitation-only Breakfast

8:00 am Closed CCO Roundtable Welcome



Jill Dailey, JD, Vice President and Chief Compliance Officer, Incyte; Executive Committee, Pharmaceutical Compliance Forum, New York, NY



Cheryl Lee, MBA, Vice President, Head of Major Markets Compliance & Ethics, Bristol Myers Squibb; Executive Committee, Pharmaceutical Compliance Forum, Princeton, NJ



Antitrust Admonition

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

8:15 am



What is the Role of Compliance in the Era of ESG?

Jim Massey, MS, Chief Sustainability Officer, Zai Lab; Author, Trust in Action: A Leaders Guide to ACT. Right. Now, Washington DC

9:15 am



The Rising Stakes of Data Governance and How Companies are Responding

Industry Cross Functional Expert Panelists: (Practical Advice from Experts)

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



Brett Harrison, Senior Managing Director, Head of Digital Forensics and Investigations, FTI Consulting; Former Computer Forensic Examiner, Federal Bureau of Investigation, Washington, DC



Shannon Capone Kirk, JD, Managing Principal and Global Head, Advanced E-Discovery and AI Strategy, Ropes & Gray, Boston, MA



Tim Loper, JD, Executive Director, Head of Compliance and Ethics Investigations and Integrity Line, Bristol Myers Squibb; Former Assistant Deputy Chief, US Department of Justice, Princeton, NJ



Jeffrey Scott, JD, Lead Compliance Counsel - Digital, Reporting, and Analytics, Pfizer, Philadelphia, PA



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

10:15 am

Break

10:30 am



A Fireside Chat on Whistleblowers with Kirsten Mayer, JD and Gregg Shapiro, JD

Kirsten Mayer, JD, Interim Legal Director, ACLU of Massachusetts; Former Head, US Compliance and Vice President Legal, argenx; Former Partner, Ropes & Gray, Boston, MA



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



Interviewed by:

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

11:30 am

Open Forum Q&A

12:00 pm

Adjournment

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

October 25 – 27, 2023

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Hybrid Onsite Conference & Internet Event – Live and Archived

AGENDA DAY I: WEDNESDAY, OCTOBER 25, 2023

7:00 am Congress Registration Opens;
Continental Breakfast

PHARMA CONGRESS MINI SUMMITS GROUP I (8:00 am – 8:50 am)

Mini Summit 1: Compliance Primer and How to Make the Most of Your Time at the PCF Congress

Are you new to compliance and feeling a little intimidated? Not sure how to make the most of your time at the Congress? Please join us for this fun and open session where all questions are good questions! We'll review:

- Some basic compliance fundamentals that provide the framework for everything you'll hear this week, including:
 - The Seven Elements
 - Basic laws and regulations that come into play like the Antikickback Statute, False Claims Act, Food Drug & Cosmetic Act, and Transparency Regulations
 - Recent DOJ and OIG Guidance that is "all the rage"
- Current trends in compliance that are driving the week's agenda, and what you need to know to understand why these issues are important
- How to best use your time here, from session selection to networking
- We'll have open Q&A throughout the session

8:00 am Introduction, Discussion and Q&A

Cristina List, CPA, Senior Manager Compliance Advisory Services, MedPro Systems, Mount Arlington, NJ

Maureen Ruane, JD, Director Compliance Advisory Services, MedPro Systems, Mount Arlington, NJ

Mini Summit 2: Data Analytic Strategies for Compliance

As companies look to grow and optimize their compliance programs, they are frequently faced with the challenge of how to best incorporate data analytics into compliance programs. This panel will discuss:

- Leveraging metrics to identify risks and trends to more strategically mitigate new and evolving risks.
- Example analytics used by organizations in the compliance program.
- Partnering with key stakeholders across the organization to leverage available data for analytics.

8:00 am Introduction, Discussion and Q&A

Rodrigo Grion, MS, MBA, CFA, FRM, Vice President, Compliance, McKesson, Milwaukee, WI

Akbar Pasha, CCEP, Director, Ethics and Compliance, Data Analytics & Automation and Digital Transformation, Baxter International, Deerfield, IL

Sapan Singh, MBA, Executive Director, Customer Engagement, Ethics, Risk & Compliance, Novartis, East Hanover, NJ

Jeffrey Garfield, Vice President, Forensic Services, Charles River Associates; Former Director, Forensic Services, Stryker, Indianapolis, IN (Moderator)

Mini Summit 3: Insights from Medical Device Corporate Integrity Agreements

This will be an enlightening and informative panel discussion that delves into the intricate world of compliance within the medical device industry. In an ever-evolving regulatory environment, medical device companies are under increasing scrutiny to ensure adherence to ethical and legal standards. Corporate Integrity Agreements, negotiated with government agencies, serve as a framework for companies to demonstrate their commitment to transparency, quality, and compliance. This panel discussion will shed light on the nuances of CIAs, exploring their impact on the industry, best practices, and the lessons learned from cases that have shaped the compliance landscape. Key discussion points will include:

- Lessons from real cases
- Navigating regulatory challenges
- Driving ethical corporate culture
- Embedding compliance in operations
- Looking ahead

8:00 am Introduction, Discussion and Q&A

Peter Jensen, JD, Vice President, Risk Management and Compliance, Arthrex, Naples, FL

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

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

Mini Summit 4: Update on Federal Government Pharmaceutical Price Negotiations

Join the panel in an interactive discussion on the most recent updates regarding the Inflation Reduction Act, which drugs are being targeted for price-setting negotiations, and the overall impact of the implementing regulations on the pharmaceutical industry.

8:00 am Introduction, Discussion and Q&A

Richard Bagger, JD, Partner and Executive Director, Christie 55 Solutions LLC; Adjunct Faculty, Rutgers University; Former Executive Vice President, Celgene Corporation, Morristown, NJ

Judith Haron, JD, Assistant General Counsel, PhRMA; Former Acting Chief Counsel, US Department of Health and Human Services, Washington, DC

Keren F. Bisnauth, JD, Associate Vice President, Legal & Regulatory, Porzio Life Sciences, an RLDatix Company, New York, NY (Moderator)

Mini Summit 5: The Latest in Social Media Enforcements

8:00 am Introduction, Discussion and Q&A

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

Elizabeth Hall, JD, Vice President, Commercial Counsel, Alkermes, Inc.; Former General Counsel, TG Therapeutics, Inc., Waltham, MA

Paul Silver, Principal and Corporate Intelligence Services Practice Leader, Deloitte Advisory, Atlanta, GA

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

8:50 am Transition Break

MINI SUMMITS GROUP II (9:00 am – 9:50 am)

Mini Summit 6: Government Enforcement Actions Piggy-Backing on Product Liability Litigation

At first blush, government investigations and consumer product liability lawsuits may have little in common. But increasingly, federal and state governments are seeking to leverage product liability lawsuits – including prior document productions pursuant to court-mandated discovery – into investigations and litigation under state and federal fraud and abuse laws and unfair/deceptive trade practices laws. This panel will survey examples of this phenomenon and discuss tips and best practices for handling such parallel matters.

9:00 am Introduction, Discussion and Q&A

Brenna Jenny, JD, Partner, Sidley Austin LLP; Former Principal Deputy General Counsel and Chief Legal Officer, Centers for Medicare and Medicaid Services, Washington, DC

Mini Summit 7: HCP Engagement: Business Needs Assessment, Contracting, and Activities Management

9:00 am Introduction, Discussion and Q&A

Rore Middleton, JD, Vice President, Compliance and Ethics, Blueprint Medicines; Member, Chief; Former Director, US Compliance and Ethics, Alexion, Boston, MA

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

Mini Summit 8: Preparing for Government Intervention in Drug Pricing

The significant growth of Federally funded health care programs has brought increased scrutiny at the Federal and State levels, as well as legislative actions to regulate drug pricing. With this intense scrutiny, as well as the complex requirements to satisfy government pricing requirements, the role of the Compliance Office is evolving to provide objective and independent oversight for a manufacturer's policies in the area as well as to support strategic decision making on Federal healthcare programs and government pricing operations. In this session we will discuss the role of the Compliance Office in establishing oversight and coordination of stakeholders across finance, contracting, market access, legal, etc. We will also delve into the IRA and key considerations for the Compliance Office in preparing for and implementing its requirements.

9:00 am Introduction, Discussion and Q&A

Chris Cobourn, MS, Principal Business Consultant, Chris Cobourn Consulting, LLC, Placida, FL

Matthew E. Wetzel, JD, Partner, Life Sciences, Goodwin Procter; Former Chief Compliance Officer, Grail, Washington, DC

Julie DeLong, MA, CFA, Senior Managing Director, Ankura Consulting Group, LLC, Atlanta, GA (Moderator)

Mini Summit 9: Alternative Funding Vendors: The Future and Options for Responding to New Challenges to Patient Support Programs

“Health plans – often with the assistance of “alternative funding vendors” – are revising benefit designs or otherwise implementing practices that seek to reduce their drug costs by leveraging patient assistance programs offered by pharma companies or charitable organizations. This session will provide an overview of established and emerging practices that seek to use patient assistance programs as alternative funding sources and outline options for responding to the practices.

1. Update on status of health plan policies involving copay accumulators and maximizers, regulation of the policies and legal challenges

a. Key legal challenges

b. Compliance considerations, including in light of government price reporting

2. Overview of emerging alternative funding vendor practices and examination of impact on copay assistance and free drug programs, and lawfulness of practices

a. Reclassifying drugs as “non-essential health benefits”

b. Selectively limiting or denying coverage for drugs and re-directing patients to free drug programs

3. Outline of potential options for mitigating the impact or otherwise responding to the new practices

a. Revisions to patient assistance program policies

b. New health plan contracting models

c. Legal challenges

9:00 am Introduction, Discussion and Q&A

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

Alison Fethke, JD, Counsel, Ropes & Gray; Former Counsel, Legal Regulatory & Compliance, Abbvie, Chicago, IL

Margaux J. Hall, JD, Partner, Ropes & Gray, Washington, DC

Mini Summit 10: R&D and Clinical Trials Compliance Update

An effective R&D compliance program is essential for life sciences companies to ensure successful clinical development and must adapt to new technologies and changing government enforcement priorities. During this session, we will discuss:

• Enforcement updates related to R&D and clinical trials

• Best practices for developing and implementing an effective clinical compliance program to mitigate risk

• Emerging trends and the future landscape of clinical trial compliance, including the implications of artificial intelligence, decentralized trials and remote monitoring, and digital patient engagement

9:00 am Introduction, Discussion and Q&A

David Baker, MBA, Senior Director, R&D Compliance, Zai Laboratory, Wilmington, DE

Natasha Trifun, JD, Executive Director, Head of Compliance, R&D, Global Medical, External Funding & Global Functions, Alexion Pharmaceutical, Boston, MA

Benjamin Correa, JD, Partner, Sidley Austin, LLP, Washington, DC (Moderator)

9:50 am Transition Break

MINI SUMMITS GROUP III (10:00 am – 10:50 am)

Mini Summit 11: Proving the Value of Corporate Compliance

Depending on who you ask, corporate compliance is either the most valuable initiative a company can invest in, or simply a type of insurance policy purchased to avoid legal liability. This divergence is problematic because it leaves the compliance community—companies, regulators, compliance scholars—guessing as to whether and how much should be invested in compliance programs. There are two reasons for this ideological disagreement. One is that most compliance scholarship has thinly defined value, focusing on how compliance programs save companies money through legal liability avoidance or by generally improving corporate culture that will result in far off and ill-defined corporate benefits. The other is that when there have been attempts to measure the value of corporate compliance, they have largely suffered from a lack of empirical rigor. This article seeks to address both deficiencies. First, we provide a more robust concept of corporate compliance value by focusing on how compliance can provide the potential for increased consumer sales revenue, a metric business leaders and regulators can easily understand and internalize. Second, by utilizing a validated statistical method called choice based conjoint analysis, we directly and rigorously measure the revenue generation value of corporate compliance programs. Our article is the first to provide empirically sound, direct evidence that corporate compliance can create positive revenue enhancing value for companies. This more complete conception and measurement of compliance value has important implications for corporate stakeholders, including managers who design and implement compliance programs, regulators who monitor and enforce such programs, and legal scholars who research optimal compliance policy.

10:00 am Introduction, Discussion and Q&A

Suneal Bedi, JD, PhD, Assistant Professor of Business Law and Ethics, Kelley School of Business, Indiana University; Co-author, *Valuing Corporate Compliance*, Bloomington, IN

Todd Haugh, JD, Associate Professor of Business Law and Ethics, Kelley School of Business, Indiana University; Co-author, *Valuing Corporate Compliance*, Bloomington, IN

Mini Summit 12: Internal Investigations: Best Practices to Address Compliance Concerns and Reduce Risk

Internal investigations play a critical role in protecting companies from legal liability and reputational harm. When done properly, they can help identify potential misconduct and help companies devise strategies to mitigate risk. Poorly managed investigations, however, can actually create more problems than they solve. This presentation will discuss best practices for identifying potential areas of concern through the use of technology and data analytics, conducting proper investigations to meet the nature of the risk (including the use of outside counsel to better preserve privilege), and developing appropriate remediation plans to mitigate future risk.

10:00 am Introduction, Discussion and Q&A

Eric Hertrich, CPA, CFE, CAMS, Senior Manager, Compliance and Internal Investigations, Olympus Corporation of the Americas, Bethlehem, PA

Heidi Teresi, CHRC, Region Head Americas, SpeakUp Office, Novartis, East Hanover, NJ

Martin J. Healy, JD, Principal, Porzio, Bromberg & Newman, PC, New York, NY (Moderator)

Mini Summit 13: Insights and Actionable Deliverables in Response to the DOJ Self-Disclosure Policy

Beyond announcing new certifications for Chief Compliance Officers, the Justice Department has updated and expanded its policies for organizations seeking credit for voluntary self-disclosure and cooperation. This session will explore these new expectations as well as changes and best practices life science compliance professionals should consider to meet the new expectations before and during a government enforcement action.

10:00 am Introduction, Discussion and Q&A

Seth Whitelaw, JD, LLM, SJD, President and Chief Executive Officer, Whitelaw Compliance Group, LLC, Senior Fellow and Adjunct Professor, Life Sciences Compliance, Mitchell Hamline School of Law; Editor, *Policy & Medicine Compliance Update*, Philadelphia, PA

Suneeta Hazra, JD, Partner, Arnold & Porter Kaye Scholer, LLP; Former Chief, Criminal Division, US Attorney's Office, District of Colorado, Denver, CO (Moderator)

Mini Summit 14: Compliance Considerations for Market Access Initiatives

10:00 am Introduction, Discussion and Q&A

Stephanie Garfield, JD, Senior Legal Counsel, Rhythm Pharmaceuticals, Boston, MA

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

Matthew E. Wetzel, JD, Partner, Life Sciences, Goodwin Procter; Former Chief Compliance Officer, Grail, Washington, DC (Moderator)

Mini Summit 15: Data Analytics to Monitor Payments to HCPs, HCOs, Distributors, and Other Third Parties

This panel brings together outside counsel, inside counsel, and technology professionals who have overseen the implementation of advanced data analytics to monitor payments to HCPs, distributors, and high-risk third parties, including under the watchful eye of enforcement agencies. Learn how advanced analytics can mitigate the risks of kickbacks, corruption, fraud, sanctions violations, and channel stuffing and how they can be implemented in reality.

This panel will discuss:

- The need for advanced data analytics to ensure your compliance program is effective and meets the evolving expectations of enforcement agencies
- Examples of advanced analytics in third-party payment monitoring and how to achieve them
- Common challenges of data readiness, completeness, and cleanliness
- Translating analytics findings into action
- How to get started on your data analytics journey

10:00 am Introduction, Discussion and Q&A

Carrie Pennington, MBA, MA, PhD, Former Vice President, Global Compliance, Monitoring & Controls, Zimmer Biomet; Former Global Compliance Manager, Books & Records, GE Healthcare; Culver, IN

Erin Brown Jones, MA, JD, Partner, Latham & Watkins; Washington, DC

Parth Chanda, CEO, Lextegrity; Former Chief Compliance Counsel Global Oncology, Pfizer; Former Global Anti-Corruption Lead Counsel, Pfizer; New York, NY (Moderator)

10:50 am Transition Break

MINI SUMMITS GROUP IV (11:00 am – 11:50 am)

Mini Summit 16: All Things Patients

11:00 am Introduction, Discussion and Q&A

Daniele Capasso, Compliance Lead, US Oncology Business Unit, AstraZeneca Pharmaceuticals LP, Gaithersburg, MD

Mark Gardner, MBA, JD, Directing Attorney, Gardner, FDA Law Firm, Senior Lecturer University of Minnesota, Carlson School of Management, Stillwater, MN

Clarissa Crain, Managing Director, Deloitte & Touche, LLP, Phoenixville, PA (Moderator)

Mini Summit 17: Evolving Risks in Medical Affairs

This session will explore how companies are using medical affairs personnel to communicate emerging scientific information about their products, including proactively and using new technologies. In recent years, there has been a trend away from the reactive medical silo structures that many companies historically employed. Panelists will discuss ways medical personnel are communicating with stakeholders and will consider various compliance controls intended to mitigate the risks associated with these interactions.

11:00 am Introduction, Discussion and Q&A

Ann-Marie Tejcek, Associate Vice President, Global Medical Affairs, Strategy and Transformation, Eli Lilly and Company, Indianapolis, IN

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

Sarah A. Franklin, JD, Partner and Vice-chair, Life Sciences Investigations Practice, Covington & Burling, LLP, Washington, DC (Co-moderator)

Mini Summit 18: Contemporary Trends in Fair Market Value

Join Eric Bolesh from Cutting Edge Information for an engaging discussion of FMV rates for HCPs. Learn best practices for making sure your company is staying within acceptable ranges for payments and surrounding issues such as tiering, travel, rate distribution and more. Hear how your peers are handling the complications of inflation, rate changes around the globe, and other current issues such as HCP pushback and influencer compensation. Leave this session with new insights and approaches to consider.

11:00 am Introduction, Discussion and Q&A

Kimberly Kwak, *Director, Corporate Compliance, Medline Industries, Northfield, IL*

Abe Kassiss, MBA, PhD, *Senior Director, Global Head of Compliance and Legal Operations, Bausch + Lomb, New York, NY*

Gus Papandrikos, MBA, *Executive Director, Internal Audit & Monitoring Risk Detection, Daiichi Sankyo, Inc., Basking Ridge, NJ*

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

Mini Summit 19: Risk & Ethics Perspective of Artificial Intelligence

11:00 am Introduction, Discussion and Q&A

Tad Roselund, MBA, *Managing Director and Senior Partner, The Boston Consulting Group, Montclair, NJ (Moderator)*

Mini Summit 20: Drug Pricing — Considerations around Price Controls, Negotiation, and Access

11:00 am Introduction, Discussion and Q&A

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

Garrett N. Pape, JD, *Senior Manager, Forensic & Integrity Services, EY, Chicago, IL (Co-Moderator)*

Kevin Tran, CPA, *Senior Manager, Forensic & Integrity Services, EY, New Orleans, LA (Co-Moderator)*

11:50 am NETWORKING LUNCHEON IN EXHIBIT HALL AND LUNCHEON MINI SUMMITS

DAY I LUNCHEON MINI SUMMITS GROUP V

(12:15 pm – 1:05 pm; Mini Summit rooms set in rounds for comfortable luncheon seating.)

Luncheon Mini Summit 21: The Role of Fair Market Value in Pharma and Medical Device Compliance Programs

From data acquisition to modality specific technology, in the Pharma and Medical device industry the need for Fair Market Value support extends beyond Key Opinion Leaders. In this session, gain an understanding of how organizations are strengthening their compliance and documentation with FMV opinions to support a broad range of arrangements.

12:15 pm Introduction, Discussion and Q&A

Joseph Keeney, *Head of US Compliance, Galderma Laboratories, LP, Dallas, Texas*

Mona Peterson Rosow, JD, MPH, *Chief Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic, Minneapolis, MN*

Donna White, CCEP, *Vice President, Compliance Officer, Chiesi; Executive Committee, Pharmaceutical Compliance Forum, Cary, NC*

Emma Miller, *Managing Director, Health Solutions, FTI Consulting, Denver, CO (Moderator)*

Luncheon Mini Summit 22: Responsibly Harnessing the Power of AI

AI is changing the world as we know it—bringing with it inherent challenges around trust and accountability. Your stakeholders, including board members, customers, and regulators, will likely have many questions about your use of AI and safeguarding data. You not only need to be ready to provide the answers, but you should also demonstrate ongoing governance and regulatory compliance.

- Learn more about emerging regulations and where you are on your Responsible AI journey
- Hear perspectives from data ethics professionals
- Explore the role of the Compliance Professionals in both harnessing and governing AI

12:15 pm Introduction, Discussion and Q&A

Michael Haughney, JD, *Director, Global Compliance Monitoring and Analytics, Bristol Myers Squibb; Former Associate Director, Ethics and Compliance, Auditing/Monitoring, Novartis, Philadelphia, PA*

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

Luncheon Mini Summit 23: Is the “No Patient Left Behind” Approach to Patient Support Programs Viable?

Patient support programs are ubiquitous and a critical aspect of successful product launches and securing patient access to life-saving therapies. But often there is a temptation to implement every conceivable support program without considering the barriers to access that are specific to the therapy, disease state or patient population. This program will explore recent HHS-OIG Advisory Opinions, litigation and enforcement developments as well as emerging industry trends related to free drug programs (quick start/bridge, free trial, PAPs), copay support, and other support programs.

12:15 pm Introduction, Discussion and Q&A

Julie Kilcoyne, JD, *Senior Director, Healthcare Law, Blueprint Medicines; Former Director, Corporate Counsel, Sage Therapeutics, Boston, MA*

Mike Rivas, MBA, *Former Director, Ethics and Compliance Functional Advisor, Market Access Patient Services, Novartis, Oakland, NJ*

Amy Wilson, MBA, MSJ, *Vice President, Chief Compliance Officer, Esperion, Boston, MA*

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

Luncheon Mini Summit 24: Assessing Compliance Priorities: Considerations for Conducting an Effective and Collaborative Compliance Risk Assessment

Whether your company is new or established, large, midsize or small, pre-commercial or commercial, or preparing for your first or next product launch, conducting effective and collaborative compliance risk assessments is critical. However, compliance assessments are not one size fits all. During this session, we will discuss:

- The importance of a targeted approach for any compliance risk assessment
- Identifying key risk areas to focus your efforts
- How to develop priorities and timelines that make sense for your company

12:15 pm Introduction, Discussion and Q&A

Yvonne Clark, *Head of Corporate Compliance, Spark Therapeutics, Inc., Philadelphia, PA*

Thomas Federici, MBA, *Compliance Officer, North America, Olympus Corporation of the Americas, Center Valley, PA*

Noah C. Goldstein, JD, *Counsel, Porzio, Bromberg & Newman, PC, Westborough, MA*

Sara R. Simon, JD, *Counsel, Porzio, Bromberg & Newman, PC, New York, NY*

1:05 pm Transition Break

OPENING PLENARY SESSION

1:15 pm



Welcome and Introduction: PCF Co-Chairs

Joe Zimmerman, Senior Vice President and Chief Compliance Officer, SpringWorks Therapeutics; Chair, Pharmaceutical Compliance Forum (PCF Chair)

1:30 pm



Keynote Fireside Chat with Geoffrey S. Martha, Chairman and Chief Executive Officer, Medtronic

Geoff S. Martha, Chairman and Chief Executive Officer, Medtronic, Minneapolis, MN



Interviewed by:

Tara Shewchuk, JD, Global Chief Ethics and Compliance Officer, Medtronic; Member, Pharma Congress Medical Device Steering Committee, Minneapolis, MN

2:00 pm



Keynote: OIG Update

Robert K. DeConti, JD, Chief Counsel to the Inspector General, Office of Counsel to the Inspector General, US Department of Health and Human Services, Office of Inspector General, Washington, DC



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

2:45 pm



US DOJ Keynote

Lisa Miller, JD, Deputy Assistant Attorney General, Fraud and Appellate Sections, Criminal Division, US Department of Justice, Washington, DC

3:15 pm



Strategic, Behavioral Compliance, and Economic Considerations Regarding DOJ's Pilot Program

Michael R. Clarke, JD, CCEP, Vice President, Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior; Former Vice President, Ethics and Compliance, Americas, Actavis; Former Vice President and Compliance Officer, Biomet Spine & Bone Healing Technologies, Bridgewater, NJ



Sujata Dayal, JD, LL.M., Former Vice President and Global Chief Compliance Officer, Medline Industries, Inc.; Independent Board Director, Emergent BioSolutions; Member, Pharma Congress Medical Device Steering Committee, Chicago, IL



Yogesh Bahl, MBA, Partner and Leader, Life Sciences and Healthcare Practice, Resolution Economics, New York, NY (Moderator)

3:45 pm

NETWORKING BREAK IN EXHIBIT HALL

4:15 pm



Prosecution and Enforcement Actions Update

Jennifer Bragg, JD, Partner, Life Sciences and Health Care; Litigation, Skadden; Former Associate Chief Counsel for Enforcement, Food and Drug Administration (FDA), Washington, DC



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



Emily Hodge, JD, Partner, Choate, Hall & Stewart, LLP; Former Special Assistant District Attorney, Suffolk County District Attorney's Office, Boston, MA



Tom Gregory, MBA, CPA, Partner, Forensic & Integrity Services, EY, New York, NY (Moderator)

5:00 pm



Annual Chief Compliance Officer Fireside Chat

Michael R. Clarke, JD, CCEP, Vice President, Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior; Vice President, Ethics and Compliance, Americas, Actavis; Former Vice President and Compliance Officer, Biomet Spine & Bone Healing Technologies, Bridgewater, NJ



Jake DeBoever, JD, Vice President, Chief Compliance Officer, Dermavant Sciences; Former Vice President, Compliance & Ethics, McKesson; Former Vice President, Chief Compliance Officer, Americas, Galderma, Dallas, TX



Anisa Dhalla, Chief Ethics and Compliance Officer, UCB, Smyrna, GA



Melissa Lozner, JD, Senior Vice President, Chief Compliance Officer, Regeneron; Former Chief Compliance and Ethics Officer and Special Counsel, Rafael Holdings Inc; Former Vice President, Head of Ethics, Risk and Compliance, Novartis, Tarrytown, NY



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

6:00 pm

ADJOURNMENT AND NETWORKING RECEPTION

AGENDA DAY II: THURSDAY, OCTOBER 26, 2023

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

BREAKFAST MINI SUMMITS – GROUP VI

**(7:10 am – 7:50 am; Mini Summit rooms set in rounds
for comfortable breakfast seating.)**

Breakfast Mini Summit 25: Sanctions — Compliance Monitoring Approaches and Tools

Discuss regulator expectations/requirements of an effective Sanction Program along with the methodologies, tools, and resources used to effectively and efficiently monitor and respond to changes in risk.

7:10 am **Introduction, Discussion and Q&A**

Roberto J. Gonzalez, JD, Partner, Paul, Weiss, Rifkind, Wharton & Garrison LLP; Former Deputy General Counsel, U.S. Treasury Department, Washington, DC

Jason Macias, JD, Head of Risk Assessment and Monitoring COE, Viatrix Inc., New York, NY

Jeremy Osinski, CAMS, CFE, ERMm, Principal, Forensics & Integrity Services, EY, Boston, MA

Chris Matteson, Senior Manager, EY; Former Senior Director Risk Mitigation and CIA Management, Johnson & Johnson, Marlton, NJ (Moderator)

Breakfast Mini Summit 26: A Fireside Chat with Jim Sheehan, JD

7:10 am **Introduction and Discussion**

James Sheehan, JD, Chief, Charities Bureau at Attorney General of New York; Former Chief Integrity Officer, City of New York Human Resources Administration; Former NY Medicaid Inspector General; Former Associate United States Attorney, Eastern District of Pennsylvania, New York, NY

Interviewed by:

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

Breakfast Mini Summit 27: Key Learnings from CMS Audits of Open Payments

7:10 am **Introduction, Discussion and Q&A**

Is your company prepared for an Open Payments audit? CMS has begun auditing manufacturers, and it is important to be prepared to demonstrate your company's commitment to compliance and provide documentation that supports your reporting determinations. This session will discuss important learnings and practical considerations for preparing for and navigating an Open Payments audit. We will discuss:

- CMS's Open Payments audit authority
- The Open Payments auditing process
- Practical considerations for navigating an Open Payments audit
- Steps to take now to prepare for an Open Payments audit

Margaret Feltz, MA, JD, Vice President, Ethics and Compliance, Purdue Pharma LP; Former Co-chair, Secretary, Pharmaceutical Compliance Forum, Stamford, CT

Masha Goodman-Khan, MSJ, Director, Compliance and Legal Operations, Vericel Corporation, Cambridge, MA

Sara A. Kimball, JD, Assistant General Counsel, Corporate Business Functions, Legal Affairs, Daiichi Sankyo, Inc., Basking Ridge, NJ

Brian A. Bohnenkamp, JD, MHA, Partner, FDA and Life Sciences, King & Spalding, Washington, DC (Moderator)

Breakfast Mini Summit 28: New Levels of Transparency and Governance Across the Device Ecosystem

As evidenced by recent discussions and presentations with the FDA, the agency has endorsed a deeper focus on supplier quality. CDRH presented with representatives from the device industry to lay out MedAccred, a program fashioned after similar supplier certification programs in aerospace where transparency now extends down to tier 3 and tier 4 suppliers. Looking downstream, new EUMDR and IVDR regulations stress the importance of transparency and responsibility for "Economic Operators", the importers, distributors and authorized representatives who handle medical device products in European states.

The panel will discuss the requirements, challenges and benefits of increasing the integrity of the medical device manufacturer's ecosystem, both upstream and downstream.

7:10 am **Introduction, Discussion and Q&A**

Jeremiah Genest, Head of Quality Management Systems, Amylyx Pharmaceuticals, Cambridge, MA

Justin McCabe, MS, Operations Manager, MedAccred, Performance Review Institute (PRI), Pittsburgh, PA

Patterson (Pat) Shafer, Managing Director, FTI Consulting, Ridgefield, CT (Moderator)

7:50 am **Transition Break**

MINI SUMMITS GROUP VII (8:00 am – 8:50 am)

Mini Summit 29: Practical Guidance for Developing Tomorrow's Compliance Leaders

Compliance departments can be so focused on mitigating risk throughout their companies that they can neglect to develop themselves and others in the department. We're reminded of the classic saying about the shoemaker's children (You can look it up if you've not heard it). Join NXLevel Compliance (formerly PharmaCertify) and three of our clients to delve into the topic of developing compliance professionals. Walk away with practical tools and information that you can use immediately, whether you are new to compliance and working on developing yourself, an experienced compliance officer looking for ideas to develop your team, or somewhere in between.

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

Jill Dailey, JD, Vice President and Chief Compliance Officer, Incyte; Executive Committee, Pharmaceutical Compliance Forum, New York, NY

Jake DeBoever, JD, Vice President, Chief Compliance Officer, Dermavant Sciences; Former Vice President, Compliance and Ethics, McKesson; Former Vice President, Chief Compliance Officer, Americas, Galderma, Dallas, TX

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

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

Mini Summit 30: Privacy & Data Protection: Changes in Laws and the Impact on Our Industry

Join Dovetail Consulting Group for an interactive panel discussion focusing how life sciences companies are planning to address recent changes to the Privacy and Data Protection Landscape. This session will cover:

- Recent developments in US Privacy and Consumer Protection Laws
- Updates on EU/US Data Privacy Framework
- Steps to address new / emerging privacy requirements
- Privacy Program Development – Strategic Considerations

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

Katherine A. Chaurette, Senior Vice President, Healthcare Law and Compliance, Blueprint Medicines, Boston, MA

Tiago Garrido, Chief Compliance Officer, Seres Therapeutics; Former Vice President, Chief Compliance Office, Verastem Oncology, Cambridge, MA

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

Mini Summit 31: Annual FCPA Update

Pharmaceutical and medical device companies have long been subject to scrutiny by both the Department of Justice and the Securities and Exchange Commission under the Foreign Corrupt Practices Act. This year alone, companies must decide how they will navigate the DOJ's updated Corporate Enforcement and Voluntary Disclosure Policy and the DOJ's revised Evaluation of Corporate Compliance Programs guidance. We will discuss the implications for voluntary self-disclosures, the relevance to incentive compensation and clawbacks systems, employee communications, including ephemeral messaging, and much more.

8:00 am Introduction, Discussion and Q&A

Keith Edelman, JD, Principal Assistant Chief, FCPA Unit, Criminal Division, US Department of Justice, Washington, DC

Tracy L. Price, JD, Deputy Chief, FCPA Unit, US Securities and Exchange Commission, Washington, DC

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

Mini Summit 32: Data Analytics for Prospective Compliance Monitoring

8:00 am Introduction, Discussion and Q&A TBD

Mini Summit 33: Navigating M&A of FDA-Regulated Companies

Join us as industry experts converge to share insights, strategies, and real-world experiences in a panel discussion on mergers and acquisitions within the FDA-regulated sector. Gain valuable perspectives on due diligence activities focusing on compliance, privacy, and regulatory considerations in this dynamic exchange of knowledge and expertise.

8:00 am Introduction, Discussion and Q&A

JJ Kuhn, JD, Vice President and Chief Counsel, Global Investigations, Medtronic, Minneapolis, MN

Gregory S. Moss, JD, Chief Corporate Strategy and Legal Officer, Evomunne; Former Executive Vice President, General Counsel and Corporate Secretary, Chief Compliance Officer, Kadmon Holdings, Inc., Palo Alto, CA

Scott Way, JD, General Counsel and Chief Compliance Officer, Impulse Dynamics, Marlton, NJ

Amanda Johnston, JD, R.A.C., Managing Attorney, Gardner Law; Adjunct Professor of Law, Mitchell Hamline School of Law, St. Paul, MN (Moderator)

Mini Summit 34: Enterprise Communications Monitoring and the Recent DOJ Guidance

Communications monitoring has become a renewed focus for the life sciences industry based on regulator guidance, recent settlements outside of life sciences as well as initial DOJ guidance targeting the topic. This panel will review some key considerations and hurdles related to communication monitoring including:

- Highlights of addressing DOJ updated guidance reviewing of three main factors: Communication Channels, Policy Environment and Risk
- Review high level results of recent survey related to communications monitoring
- Types of methods of communications monitoring
- Options and approaches to communications monitoring
- Discussion of navigating internal politics of communications monitoring
- Risk based analysis for communications monitoring
- Considerations of BYOD monitoring

8:00 am Introduction, Discussion and Q&A

Rachel Batykefer, Vice President, CIA and Compliance Operations, Mallinckrodt Pharmaceuticals, Bridgewater, NJ

Sarah A. Franklin, JD, Partner and Vice-chair, Life Sciences Investigations Practice, Covington & Burling, LLP, Washington, DC

Nichole Pinard, CPA, Senior Director, Global Monitoring, Analytics and Digital Capabilities, Bristol Myers Squibb; Former Senior Director, Digital Transformation, Audit and Compliance, Princeton, NJ

Alexis Shaw, Executive Director, Compliance, Paratek Pharmaceuticals, Malvern, PA

Marci Juneau, MBA, Partner, Helio Health Group, Atlanta, GA (Moderator)

Mini Summit 35: DEI Training: Why It Matters and How to Do It?

- Understand the full scope of DEI training and culture building.
- Learn techniques to market your values internally.
- Consider your key collaborators.
- Inspire vulnerability and brave conversations.

8:00 am Introduction, Discussion and Q&A

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

Kirsten Liston, Principal and Founder, Rethink Compliance, Westminster, CO (Moderator)

8:50 am Transition Break

MINI SUMMITS GROUP VIII (9:00 am – 9:50 am)

Mini Summit 36: Outsourced Compliance Programs: How to Make them Work?

As corporate budgets shrink amid global economic belt-tightening, life science companies, especially start-up companies looking to launch their first or second product, struggle to strike the right balance between economic efficiency and compliance effectiveness. To strike that balance, many companies have turned to outsourcing their compliance function as the right solution. With the COVID pandemic making virtual support a "New Normal," an outsourced compliance solution is more viable than ever. The latest updated Department of Justice Compliance Program Guidance clearly recognizes this as an option. Listen to experienced practitioners and in-house counsel who have implemented this option. They will share their views on how best to do so to be truly effective and cost-efficient from both a legal/compliance and business perspective.

9:00 am Introduction, Discussion and Q&A

Jocelyn Lafond, LLB, LLM, Vice President, General Counsel and Corporate Secretary, Theratechnologies, Montreal, Quebec, Canada

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

Mini Summit 37: Fostering a Speak Up Culture at Your Organization

- Use effective, targeted, creative messaging to foster and improve Speak-Up culture.
- See strategies for removing roadblocks to help employees feel comfortable raising concerns.
- Is your reporting system working? Learn how to collect the right data to prove it.

9:00 am Introduction, Discussion and Q&A

Nanette Almeida, CHC, Compliance Director, Azurity Pharmaceuticals; Former Director of Compliance, Kaléo, Richmond, VA

Nereyda Garcia, JD, Vice President, Head Ethics and Compliance US Business Unit, Takeda Pharmaceuticals, Boston, MA

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

Mini Summit 38: AI — Art of the Possible

AI — Art of the Possible: an interactive panel to discuss the relevant compliance considerations and foundational questions that Compliance professionals should consider when delving into the world of AI, including topics such as:

- How can AI accelerate compliance automation and support various business use cases
- How can AI leapfrog traditional self-serve capabilities to become an one-stop shop for intelligent and targeted compliance inquiries from the Field
- Opportunities for targeted compliance monitoring inquiries vs. traditional dashboard approach
- What are potential operational/ethical challenges and the key compliance standards that need to be navigated

9:00 am Introduction, Discussion and Q&A

Gary DelVecchio, *Healthcare Compliance Officer, CVM, Janssen; Former Executive Director US Pharmaceutical Compliance and Ethics, Bristol Myers Squibb, Pennington, NJ*

Anisa Dhalla, *Global Head, Ethics and Compliance, UCB, Acworth, GA*

Emily Mason, JD, *Vice President, Worldwide Compliance and Business Ethics, Amgen, Los Angeles, CA*

Faiz Merchant, MS, *Principal (Partner), ZS, San Mateo, CA (Co-moderator)*

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

Mini Summit 39: Third Party Risk Management: Onboarding Diligence, Oversight and Exercising Audit Rights

Our panel of experts will share their experience and approach related to: third-party risk assessment and classification; identification of needs and regulatory requirements, efforts undertaken from on-boarding to monitoring with limited resources (i.e., prioritization); use of technology to provide results and flexibility; lessons learned/pit falls and success stories.

9:00 am Introduction, Discussion and Q&A

David Falcone, MS, *Associate Vice President Global Compliance, Merz Aesthetics, Raleigh, NC*

Christopher McCavitt, MA, *Managing Director, Business Intelligence, EY, Boston, MA*

Blair Shaw, JD, CIPP/US, HCCP, CCEP, *Vice President, Corporate Compliance, Fortrea; Former Senior Director, Vendor/Third Party Compliance, Otsuka, Jenkintown, PA*

Gildas Durand, *Partner/Principal, Forensic & Integrity Services, EY, Miami, FL (Moderator)*

Mini Summit 40: Global Aspects and Challenges of FCPA/ Compliance Investigations

9:00 am Introduction, Discussion and Q&A

Peter Dieners, JD, *Partner and Head, Global Risk & Compliance; Head, Global Healthcare & Life Sciences Group, Clifford Chance; Member, Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany*

Dominique Laymand, *Of Counsel, Clifford Chance; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Torsten Syrbe, JD, *Partner, Clifford Chance, Düsseldorf, Germany (Moderator)*

Mini Summit 41: Compliance Considerations for Small and Emerging Markets

Who should attend:

- Are you a one-person Compliance team supporting the entire business?
- Or part of a small team, constantly juggling different responsibilities?
- Or maybe someone considering switching from a big company to a smaller one?

Join our experienced panel for a discussion on Compliance considerations specific to small and emerging companies. Each panel member is currently navigating the excitement and challenges of smaller companies. Some main topics include:

- Optimizing resources to efficiently plan and design the Compliance team
- Identifying the appropriate timeline for certain actions — what should be done before launch, at launch, or can wait until after launch?
- Post-launch challenges for companies that have limited resources but the same list of responsibilities
- Partnering with the business to increase Compliance buy-in and functional area support
- Tricks and techniques for optimizing each of the Seven Elements

And bring your questions with you. This is a great opportunity to leverage the experience of a group of industry experts!

9:00 am Introduction, Discussion and Q&A

William Hrubes, MS, *Senior US Compliance Manager, PharmaEssentia USA Corporation, Columbia, MD*

Aaron Leskow, MS, *Manager, Healthcare Compliance, Immunocore, Conshohocken, PA*

Madeline Scherwitzky, *Vice President, Head of Compliance, US, Idorsia Pharmaceuticals US Inc., Philadelphia, PA*

Daniel Koerner, *Senior Director, Potomac River Partners, New York, NY (Moderator)*

Mini Summit 42: Legal Risks Around Digital Health Technology

In recent years, Pharmaceutical and Medical Device companies have taken steps toward developing new digital health tools that have the potential to transform how companies operate in the digital space with respect to healthcare. As companies look to advancements in the Digital Healthcare space, the legal risks facing companies are changing as a result of new and innovative strategies companies are developing to transform business to meet the age of digitization. This shift will translate into a different litigation landscape in the future.

One development of interest was EHR company Practice Fusion's \$145 million civil and criminal settlement with the Department of Justice on January 27, 2020. DOJ alleged that Practice Fusion solicited and received payments that violated the Anti-Kickback Statute in connection with its clinical decision support ("CDS") alert arrangements. The settlement signaled that the development and implementation of CDS alerts will be closely scrutinized by DOJ going forward. Other EHR companies have entered into relevant settlements with DOJ to resolve False Claims Act and Anti-Kickback Statute allegations in recent years (e.g., athenahealth Inc. (Jan. 2021) and Modernizing Medicine, Inc. (Nov. 2022)). Future actions against pharmaceutical companies related to the development of EHR tools may be forthcoming, with a focus on whether something of value was provided to anyone who could influence the selection of reimbursable items and services and whether there was an intent to induce that decisionmaker. Implementing digital health tool-specific systems will involve companies navigating risk areas such as the AKS, fraud and abuse, FDA, privacy, and security and data related risks.

9:00 am Introduction, Discussion and Q&A

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

Rim El Kassaby, *Director US Business Counseling and Support, Organon, New York, NY*

Sean Kennedy, JD, *Senior Director, Healthcare Compliance Strategy and Operational Risk, Bristol Myers Squibb, Princeton, NJ*

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

9:50 am NETWORKING BREAK IN EXHIBIT HALL

MINI SUMMITS GROUP IX (10:30 am – 11:20 am)

Mini Summit 43: Global Ethics and Compliance: Evolution of Legislation

Present and discuss the legal evolution on key matters, from an European and US perspective and discuss how this could impact the companies risks assessment and their compliance programs

10:30 am Introduction, Discussion and Q&A

Peter Dieners, JD, *Partner and Head, Global Risk & Compliance; Head, Global Healthcare & Life Sciences Group, Clifford Chance; Member, Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany*

Jennifer McGee, JD, *Senior Vice President, Global Chief Ethics and Compliance Officer, Otsuka Pharmaceutical Companies (U.S.) Rockville, MD*

Steve Nickelsburg, MSE, JD, *Partner, Clifford Chance US LLP, Washington, DC*

Dominique Laymand, *Of Counsel, Clifford Chance; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France (Moderator)*

Mini Summit 44: DOJ Agreements, Dual Reporting and the Role of the Compliance Officer

DOJ, especially Main Justice's Consumer Protection Branch, is taking an increased role in developing compliance agreements and monitoring them following corporate resolutions with healthcare and life sciences companies. DOJ has suggested that Chief Compliance Officers should be signatories on such agreements, regardless of whether the Chief Compliance Officer has responsibility for compliance in the part of the company responsible for the alleged violative conduct. (For example, in resolutions of alleged violations of current good manufacturing practices where the quality unit may not report to the Chief Compliance Officer, DOJ has suggested the Chief Compliance Officer should nevertheless take responsibility.) In addition, resolutions of certain kinds of conduct can involve multiple lines of reporting—to DOJ and to other agencies. Finally, DOJ has made it very clear that it will take an expansive approach to considering past compliance history when crafting terms of a resolution. This discussion will address the increased risk associated with the evolution in DOJ's role in compliance agreements and post-resolution compliance monitoring and will provide recommendations to mitigate this risk.

10:30 am Introduction, Discussion and Q&A

Ryan Brown, JD, *General Counsel, Sarepta Therapeutics, Cambridge, MA*

Michelle Scharfenberg, JD, *Senior Vice President, Chief Ethics and Compliance Officer, Avanos Medical, Alpharetta, GA*

Tara Shewchuk, JD, *Global Chief Ethics and Compliance Officer, Medtronic; Member, Pharma Congress Medical Device Steering Committee, Minneapolis, MN*

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

Mini Summit 45: Compliance in Life Science: Unleashing AI's Potential

Join us for an exploration of the intersection between compliance in the life sciences industry and the transformative power of artificial intelligence (AI). In this conversation, we will discuss the ways AI is reshaping how pharmaceutical compliance is approached, presenting both opportunities and potential challenges. Our experts will guide you through real-world applications, regulatory considerations, and the path forward for leveraging AI's potential to elevate compliance practices.

Key Discussion Points:

- AI in Regulatory Landscape: Understand how AI is revolutionizing compliance processes in life science industries, providing efficient solutions for navigating complex regulations.
- Predictive Compliance: Discover how AI algorithms can predict potential compliance issues, enabling proactive measures to ensure adherence.
- Streamlined Monitoring & Auditing: Explore the use of AI in automating auditing procedures, reducing manual effort, and enhancing audit accuracy.

- Collaboration of AI and Human Intelligence: Understand how AI augments human expertise, fostering a harmonious synergy for more effective compliance outcomes

10:30 am Introduction, Discussion and Q&A

Paul Steele, MBA, *Founder and Consultant, Paul Steele, LLC; Former Director, Transparency & Compliance Monitoring, Sunovion Pharmaceuticals, Marlborough, MA*

Neeraj Gupta, MBA, *Managing Partner, Cresen Solutions, Chester Springs, PA (Moderator)*

Mini Summit 46: Engaging Your Board Effectively in an Era of Heightened Scrutiny and Enforcement Risk

10:30 am Introduction, Discussion and Q&A

Barry Boise, JD, *Partner, Troutman Pepper, Cheltenham, PA*

Timothy Roberts, MSJ, *Chief Compliance Officer, North America, Ferring Pharmaceuticals, Parsippany, NJ*

David Berger, JD, *Senior Managing Director and Life Sciences Practice Lead, Ankura, New York, NY (Moderator)*

Mini Summit 47: Pixels and Privacy: Navigating the Litigation and Enforcement Landscape of Website and Mobile App Privacy

In an increasingly digitized world, the intersection of technology, privacy, marketing, and legal compliance has never been more critical. Delve into the intricate web of challenges faced by Life Sciences organizations as we explore the realm of website and mobile app privacy. Our panel of experts will dissect the complexities of class action litigation that arise from data privacy breaches and enforcement actions from regulators such as the FTC and HHS. We will guide you through real-world case studies and sharing insights on effective mitigation strategies.

But fear not, we won't drown you in technical jargon. Our panel bridges the gap between legal intricacies and technological nuances, ensuring that legal and compliance teams can confidently navigate the nuances of data privacy in the digital marketing landscape. Don't miss this opportunity to empower your organization with actionable knowledge. Join us for a dynamic session that promises to demystify the pixels and privacy puzzle, equipping you to proactively steer your organization clear of potential pitfalls.

10:30 am Introduction, Discussion and Q&A

Christine Moundas, MPH, JD, *Partner, Ropes & Gray; Former Program Analyst, US Department of Health and Human Services, Office of Inspector General, New York, NY*

Elizabeth Smith, JD, *Senior Director, Data Privacy and Associate General Counsel, Seagen, Bothell, WA*

Katy Van Pelt, JD, *Vice President and Head Of Ethics and Compliance, Data Protection Officer, Arcus Biosciences, Brisbane, CA*

Brian Segobiano, *Managing Director and Chief Privacy Officer, Epsilon Economics, Chicago, IL (Moderator)*

Mini Summit 48: The Modern Investigation: Current Best Practices for Investigations

Panelists will discuss the evolution of investigations, including:

- Use of data and analytics in investigations, including the identification of key risk areas.
- Managing the split between remote and in-person procedures in a post-covid environment.
- Considerations for data collection in a remote environment, including managing the potential use of non-approved corporate technologies.

10:30 am Introduction, Discussion and Q&A

JJ Kuhn, JD, *Vice President and Chief Counsel, Global Investigations, Medtronic, Minneapolis, MN*

Colleen Doyle, ACFE, *Director, Audit and Remediation, Sage Therapeutics, New York, NY*

Terra Reynolds, JD, *Partner and Local Co-chair of the Litigation and Trial Department, Latham & Watkins, LLP; Former Assistant US Attorney, Northern District of Illinois, US Attorney's Office, Chicago, IL*

John Rademacher, *Principal, Forensic Services, Charles River Associates, Chicago, IL (Moderator)*

Mini Summit 49: Using Behavioral Compliance to Improve Your Compliance Program — Practical Implementation Suggestions

Have you heard about Behavioral Compliance but thought it was more conceptual than practical? Would you like to learn and walk away with practical suggestions as to how you can use Behavioral Psychology to enhance your compliance program?

As a follow-up on the Strategic, Behavioral Compliance, and Economic Considerations Regarding DOJ's Pilot Program plenary session, come listen to a roundtable discussion on Behavioral Compliance methods and practical steps that can be taken by organizations to make their compliance programs more impactful.

10:30 am Introduction, Discussion and Q&A

Joseph Calarco, MSS, Senior Director, Compliance, SpringWorks Therapeutics; Former Senior Director, US Compliance, Idorsia Pharmaceuticals, Stamford, CT

Michael R. Clarke, JD, CCEP, Vice President, Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior; Former Vice President, Ethics and Compliance, Americas, Actavis; Former Vice President and Compliance Officer, Biomet Spine & Bone Healing Technologies, Bridgewater, NJ

John S. Rah, JD, Partner, Potter & Murdock, Washington, DC

Daniel Spicehandler, JD, Vice President Compliance, Commercial Divisions, Stryker; Former US Compliance Officer, Sanofi Pasteur; Former Director, Risk and Accountability, Novo Nordisk; Member, Pharma Congress Medical Device Steering Committee, Somerset, NJ

Jonathan Hecht, CPA, CFF, CFE, Director, Resolution Economics, LLC, New York, NY (Moderator)

11:20 am Transition Break

MINI SUMMITS GROUP X (11:30 am – 12:20 pm)

Mini Summit 50: Global Ethics and Compliance: ESG Governance

The Mini Summit introduces into the legal criteria for structuring the governance in view of "E" and "S." It also provides practical guidance to avoid the allegation of organizational failure.

11:30 am Introduction, Discussion and Q&A

Dominique Laymand, Of Counsel, Clifford Chance; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France

Jennifer McGee, JD, Senior Vice President, Global Chief Ethics and Compliance Officer, Otsuka Pharmaceutical Companies (U.S.), Rockville, MD

Steve Nickelsburg, MSE, JD, Partner, Clifford Chance US LLP, Washington, DC

Peter Dieners, JD, Partner and Head, Global Risk & Compliance; Head, Global Healthcare & Life Sciences Group, Clifford Chance; Member, Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany (Moderator)

Mini Summit 51: Navigating Compliance Challenges: Real-World Case Studies and Solutions

Join us for Mini Summit 51 as we delve into the intricate world of compliance with industry experts. Discover how to tackle high-risk compliance issues through real-life case studies and gain insights into effective solutions. Our panel and audience interactive discussion will focus on the following critical topics:

- CMS Transparency Audits
- Specialty Pharmacy
- Hub Services: Delve into the complexities of hub services compliance, including
 - Speaker programs
 - HCP engagements
 - PDMA (Prescription Drug Marketing Act)

11:30 am Introduction, Discussion and Q&A

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

Christopher Fletchall, MBA, Vice President of Compliance, G&M Health, LLC; Former Senior Director, Ethics and Compliance Global Operations, Eli Lilly, Indianapolis, IN

Ihab Ghaly, MBA, Managing Director, G&M Health, LLC, Matawan, NJ

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

Mini Summit 52: Compliance Considerations for Rare Disease

11:30 am Introduction, Discussion and Q&A

Tiffany Cummings-Damiani, MBA, Head of Global Compliance, Insmid Incorporated, Philadelphia, PA

Michael G. Hercz, JD, Senior Vice President and General Counsel, Sentynl, Los Angeles, CA

Ronald L. Wisor, Jr., JD, Partner, Hogan Lovells, Washington, DC

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

Mini Summit 53: What Do Health Equity Initiatives Mean for Compliance?

The panel will explore compliance risks and considerations implicated by industry trends in initiatives addressing health equity and social determinants of health.

11:30 am Introduction, Discussion and Q&A

Sujata Dayal, JD, Former Vice President and Global Chief Compliance Officer, Medline Industries, Inc.; Independent Board Director, Emergent BioSolutions; Member, Pharma Congress Medical Device Steering Committee, Chicago, IL

Danielle Pelot, JD, Partner and Deputy Leader, Government Investigations and White Collar Defense Practice Group, Choate, Hall & Stewart, LLP; Former Special Assistant District Attorney, Middlesex District Attorney's Office, Boston, MA (Moderator)

Mini Summit 54: Fireside Chat: Reflections on the Role of the False Claims Act Liability over the past 50 Years into a Major Force in the Regulation of the Pharmaceutical and Medical Device Industries

11:30 am Introduction, Discussion and Q&A

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

Kevin McAnaney, JD, Law Office of Kevin McAnaney; Former Chief, Industry Guidance Branch, US Department of Health and Human Services Office of Counsel to the Inspector General, Bethesda, MD

Interviewed by:

Kirk Ogrosky, JD, Partner, Goodwin Procter, LLP; Former Deputy Chief, Criminal Division, US Department of Justice, Washington, DC

Mini Summit 55: Evolving Board of Directors and Compliance Committees Oversight Obligations

- Review expectations of BOD and Compliance Committee considering recent DOJ guidance
- Identify what should (and should not) be brought to different oversight bodies
- Learn how best to educate stakeholders on their roles and responsibilities

11:30 am Introduction, Discussion and Q&A

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

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

Mini Summit 56: Comedy & Compliance — Shifting Culture & Building Trust with Entertainment

Psychological safety can be defined as the belief that you won't be punished for speaking up about mistakes, ideas, questions or concerns. Achieving this in your organization involves not only shifting the cultural dynamics around Speaking Up and how the E&C team is perceived, but also ensuring that the organization has the communication, collaboration and listening skills to respond appropriately. People do not speak up when they are bored, annoyed or afraid. Trust has to be earned and shifting the culture requires regular, ongoing engagement and reinforcement.

This program will focus on how the philosophies, tools and techniques from the world of improv and entertainment can increase airtime and exposure without message fatigue, improve accessibility and stickiness of learning and make the program and its resources more engaging and approachable so people are more likely to speak up to ask questions, report concerns and seek out your advice and support.

11:30 am Introduction, Discussion and Q&A

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

Ronald N. Feldman, *President and Creative Director, Learnings & Entertainments, Chicago, IL*

12:20 pm NETWORKING LUNCHEON

DAY II LUNCHEON MINI SUMMITS GROUP XI (12:30 pm – 1:20 pm)

Luncheon Mini Summit 57: Recent Developments in DOJ and FTC Enforcement Actions

This panel will explore the compliance and legal implications of recent DOJ and FTC enforcement actions that impact the life sciences industry, as well as the impact to industry of the increasing role played by Main Justice's Consumer Protection Branch in both enforcing FTC provisions and developing and enforcing compliance agreements.

12:30 pm Introduction, Discussion and Q&A

Karen Day, JD, *Senior Counsel, Pfizer, New York, NY*

Terri L. Ledva, MS, *Director, Ethics and Compliance, Aurobindo Pharma LTD, Philadelphia, PA*

Raegan A. McClain, JD, LLM, *Chief Compliance & Privacy Officer, Eye Care Division, Viatris, Inc., Princeton, NJ*

Avia M. Dunn, JD, *Partner, Skadden, Arps, Slate, Meagher & Flom, LLP, Washington, DC (Moderator)*

Luncheon Mini Summit 58: Building Fearlessness into Organizations

Building off the work from Amy Edmondson, this presentation will focus on how to bring DEI, Ethical Culture, and the business desires for innovation together within organizations. In a time when more and more organizations are going global and virtual, tools, tips, and techniques used to unlock the potential for both innovation and building a speak-up culture will be highlighted.

12:30 pm Introduction, Discussion and Q&A

Adriana Davies, JSM, *Vice President Compliance and Privacy, USA, Smith & Nephew, Jacksonville, FL*

Mona Peterson Rosow, JD, MPH, *Chief Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic, Minneapolis, MN*

Luncheon Mini Summit 59: Compliance Monitoring — Operational Insights and Lessons Learned

Blending insights from a panel representing a diverse set of Life Sciences companies, this panel will discuss the opportunities and challenges associated with compliance monitoring in today's environment. Some of the topics to be covered will include how to best leverage risk assessment outputs, determining the types of monitoring to conduct given varying risk activities and profiles, optimizing internal and external resources and leveraging technology solutions to create greater efficiencies and effectiveness in your program.

12:30 pm Introduction, Discussion and Q&A

William Anders, *Director, Global Compliance Auditing & Monitoring, Medtronic, Orlando, FL*

Karen Lowney, *Head of the Office of Ethics & Compliance (OEC), Sun Pharmaceutical Industries, Inc., Taro Pharmaceutical Industries Ltd., Princeton, NJ*

Noah Mallon, JD, *Director, US Promotional Monitoring Lead, Pfizer, Birmingham, MI*

Dawn Snyder, *Manager, Ethics & Compliance Monitoring, Boehringer Ingelheim USA Corporation, Ridgefield, CT*

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

Luncheon Mini Summit 60: Old Concepts New Risks: Trends in Medical Education Support Compliance

Are you new to the world of independent medical education (IME), which consists of both accredited continuing education (CE) for various healthcare professionals (HCPs), and non-accredited, non-promotional educational programs? Or are you a seasoned professional that is increasingly seeing new types of educational providers, funding requests, and novel ideas? This panel will cover several emerging risks in Medical Education, including:

- Recent government interest in medical education, including OIG Advisory Opinion 22-14
- What types of risks are associated with non-accredited education involving Medical Affairs
- Use of IME outcomes data
- IME in the rare disease and pre-approval space

12:30 pm Introduction, Discussion and Q&A

William L. Aprea, JD, *Vice President, Healthcare Compliance, Phathom Pharmaceuticals, Florham Park, NJ*

Christine Gordon, JD, *Chief Compliance Officer and Head of GRC, Privacy, and Information Security, Olympus Corporation of the Americas, Bethlehem, PA*

LB Wong, RN, MSN, MBA, *Executive Director, Global Lilly Grant Office, Eli Lilly and Company, Indianapolis, IN*

Abraham Gitterman, JD, *Senior Associate, Arnold & Porter Kaye Scholer, LLP, Newark, NJ (Moderator)*

1:20 pm Transition Break

CLOSING PLENARY SESSION

1:30 pm Welcome and Introduction: PCF Co-Chairs

1:45 pm Keynote Fireside Chat with Richard Simkin, Chief Commercial Officer, Indivior



Richard Simkin, Chief Commercial Officer, Indivior; Former President North America, Reckitt Benckiser Pharmaceuticals, Richmond, VA

Interviewed by:



Cindy Cetani, LPEC, Chief Integrity and Compliance Officer, Indivior; Former Group Integrity and Compliance, Head, Compliance Operations, Novartis, Glen Allen, VA

2:15 pm The Future Chief Compliance Officer



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



Shannon Kelley, JD, Head of Ethics & Business Integrity, North America and Global Specialty Care, Sanofi; Former Assistant US Attorney and Deputy Chief of Litigation, Boston U.S. Attorney's Office, Cambridge, MA



Daryl Kreml, JD, Vice President and Chief Compliance Officer, SAGE Therapeutics, Boston, MA



Gregory S. Moss, JD, Chief Corporate Strategy and Legal Officer, Evomunne; Former Executive Vice President, General Counsel and Corporate Secretary, Chief Compliance Officer, Kadmon Holdings, Inc., Palo Alto, CA



Tad Roselund, MBA, Managing Director and Senior Partner, The Boston Consulting Group, Montclair, NJ (Moderator)

3:00 pm NETWORKING BREAK IN THE EXHIBIT HALL

3:30 pm FDA Keynote



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

4:00 pm Updates from AdvaMed and PhRMA



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



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

4:30 pm Strategic Resource Management for Optimized Compliance



Ann Beasley, JD, Chief Compliance Officer, Zai Lab, Boston, MA



Christie Camelio, Chief Compliance and Risk Officer, EQRx, Executive Committee, Pharmaceutical Compliance Forum, Florham Park, NJ



Terra Buckley, JD, Vice President, Head of Compliance Advisory Services, MedPro Systems, Mount Arlington, NJ (Moderator)

5:00 pm



What's Next in Pharma: Confronting a Challenging Macroeconomic Environment with Innovation

Tim Canonico, Principal, Pharmaceutical and Life Sciences and Managed Services Leader, Managed Services Platform, Chief Technology Officer, PwC, New York, NY



Brian Riewerts, Principal, Pharmaceutical and Life Sciences, Cyber Risk and Regulatory Leader, PwC, Washington, DC

5:30 pm

ADJOURNMENT

AGENDA DAY III: FRIDAY, OCTOBER 27, 2023

INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

(Industry-only session for pharmaceutical company compliance professionals and in-house counsel only)

8:00 am

Welcome



Christie Camelio, Chief Compliance and Risk Officer, EQRx; Executive Committee, Pharmaceutical Compliance Forum, Florham Park, NJ



Donna White, CCEP, Vice President, Compliance Officer, Chiesi; Executive Committee, Pharmaceutical Compliance Forum, Cary, NC



Antitrust Admonition

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

8:15 am

AI, ChatGPT, and Machine Learning — What Every Compliance Professional Needs to Know!



Katie Jacyna, Vice President of Product Management, Helio Health Group, Denver, CO (Co-Moderator)



John Poulin, Chief Technology Officer and Partner, Helio Health Group, Boston, MA (Co-Moderator)

9:15 am

Key Takeaway Table Discussions

9:35 am

Break

9:45 am

Best Practice Sharing: Latest DOJ Guidances: How Is Your Company Preparing?

10:15 am

How to be a Wildly Effective Compliance Officer?



Kristy Grant-Hart, JD, CCEP-I, Founder and Chief Executive Officer, Spark Compliance; Author, How to be a Wildly Effective Compliance Officer; Former Chief Compliance Officer, United International Pictures; Director of Compliance, Europe, MEA, Carlson Wagonlit Travel, Los Angeles, CA

11:15 am

Key Takeaway Table Discussions

11:35 am

Open Forum

12:00 pm

CONGRESS ADJOURNMENT

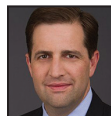
VIRTUAL GLOBAL PHARMA & MEDICAL DEVICE ETHICS & COMPLIANCE DAY

A Special Virtual Session of the 24th Pharmaceutical & Medical Device Ethics & Compliance Congress

(Complimentary access to this virtual Congress event is included in both onsite and online Congress registrations.)

MORNING PLENARY SESSION

10:00 am Pharmaceutical Compliance Forum Welcome



Joe Zimmerman, Senior Vice President and Chief Compliance Officer, SpringWorks Therapeutics; Chair, Pharmaceutical Compliance Forum, Parsippany, NJ (PCF Chair)

10:15 am Global Co-chair Welcome and Introductions



Imelda Alvarez, LLB, MBA, Chief Executive Officer & Founder, Comply Latam, SC; Former Regional Integrity & Compliance Head, Latin America and Canada, Novartis, Mexico City, Mexico



Maija Burtmanis, LLB, LLM, General Counsel & Chief Compliance Officer, Zuellig; Former Compliance Director, Japan/Asia Pacific, Shire; Former Healthcare CO, Asia Pacific Medical Sciences, Johnson & Johnson, Former Associate GC, Alcon Russia, Singapore



Dominique Laymand, Of Counsel, Clifford Chance; Former Executive Vice President, Ethics & Social Responsibility Officer, Ipsen; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France

10:30 am Keynote Address: Challenges in Developing a Truly Global Ethics and Compliance Program

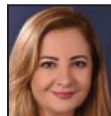


N. Craig Smith, PhD, INSEAD Chaired Professor of Ethics and Social Responsibility, Programme Director, Healthcare Compliance Implementation Leadership Programmes, at INSEAD, Fontainebleau, France

11:00 am EU, CEE and MEA Ethics and Compliance Developments Update Roundtable



Anne-Sophie Bricca, Deputy General Counsel & Senior Director Legal Affairs & Compliance, Terumo BCT; Chair, Ethics and Compliance Group and Seat at Code Committee, MedTech Europe, Brussels, Belgium



Laura Nassar, PharmD, Vice President, Head of Ethics & Business Integrity, AEME Region, Sanofi; Former Head of Compliance Middle East, Roche Pharmaceuticals; Former Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon



Roeland Van Aelst, EMEA Lead, Third Party Intermediary, Ethics & Compliance, Johnson & Johnson; President, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Europe Code Committee, Brussels, Belgium



Dominique Laymand, Of Counsel, Clifford Chance; Former Executive Vice President, Ethics & Social Responsibility Officer, Ipsen; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France (Moderator)

12:00 pm LUNCHEON BREAK

AFTERNOON PLENARY SESSION

1:00 pm



Asia Pac Ethics and Compliance Developments Update Roundtable

Campbell Clark, LLB, MJ, Vice President, Compliance Officer & Senior Legal Counsel, APAC, Zimmer Biomet, Former VP, Legal & Compliance, APAC, Medtronic; Chair, Compliance Committee, APACMed, Singapore



Lei Li, LLM, Partner, Sidley Austin; Former Third Secretary, Ministry of Commerce, People's Republic of China, Beijing, China

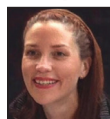


Maria Eugenia (Maru) Quindimil, MA, MBA, Founder and Chief Executive Officer, Socrates Healthcare; Former Executive Director JAPAC Regional Compliance, Amgen; Former APAC Ethics and Compliance Head, UCB, Kapolei, HI



Maija Burtmanis, LLB, LLM, General Counsel & Chief Compliance Officer, Zuellig; Former Compliance Director, Japan/Asia Pacific, Shire; Former Healthcare CO, Asia Pacific Medical Sciences, Johnson & Johnson, Former Associate GC, Alcon Russia, Singapore (Moderator)

2:00 pm



LatAm Ethics and Compliance Developments Update Roundtable

Katia Rosenstein Laurents, JD, Compliance Director, Fresenius Medical Care, Mexico City, Mexico



Irma García Morales, Regional Head of Compliance México and LatAm, Laboratorios Sanfer, Mexico City, Mexico



Sergio Albert Pinto, MBA, Senior Director, TPEC Lead Americas, Health Care Compliance, Johnson & Johnson, São Paulo, Brazil



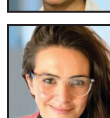
Imelda Alvarez, LLB, MBA, Chief Executive Officer & Founder, Comply Latam, SC; Former Regional Integrity & Compliance Head, Latin America and Canada, Novartis, Mexico City, Mexico (Moderator)

3:00 pm



A Fireside Chat on Navigating the Cultural Challenges in Global Compliance Programs with Hui Chen, JD

Hui Chen, JD, Senior Adviser, Ropes & Gray Insights Lab; Former Compliance Counsel Expert, US Department of Justice; Former Assistant General Counsel, Pfizer, Honolulu, HI



Interviewed by:

Caitlin Handron, MSP, PhD, Senior Lab Consultant and Behavioral Scientist, R&G Insights Lab; Former Research Scientist, Stanford University, Stanford, CA

3:30 pm

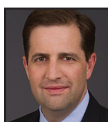
Adjournment

CONGRESS SPONSOR

The Congress is sponsored by the Pharmaceutical Compliance Forum (PCF) www.pharmacomplianceforum.org. 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. Our Vision is to be the leading forum in the pharmaceutical and biotech industry for promoting excellence in the compliance profession and advance effective risk-based compliance programs through solutions-oriented collaboration and innovative best practice sharing.

CONGRESS LEADERSHIP

PCF EXECUTIVE COMMITTEE



Joseph Zimmerman, Senior Vice President and Chief Compliance Officer, SpringWorks Therapeutics (PCF Chair)



Christie Camelio, Chief Compliance and Risk Officer, EQRx



Jill Dailey, JD, Vice President and Chief Compliance Officer, Incyte



Cheryl Lee, MBA, Vice President and Head of Major Markets Compliance and Ethics, Bristol Myers Squibb



Joshua Marks, JD, Global Head, Ethics and Compliance Program and Governance, Takeda



Donna White, CCEP, Vice President and Compliance Officer, Chiesi

MEDICAL DEVICE EXECUTIVE STEERING COMMITTEE



Sujata Dayal, JD, Former Vice President and Global Chief Compliance Officer, Medline Industries, Inc.



Tara Shewchuk, JD, Global Chief Ethics and Compliance Officer, Medtronic



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

CONTINUING EDUCATION CREDITS

COMPLIANCE CERTIFICATION BOARD (CCB) CREDIT

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

CONTINUING LEGAL EDUCATION

Update to read "pending approval for 35 Pennsylvania CLE credits.

CERTIFICATE OF ATTENDANCE

Both onsite and online attendees may complete and submit certificates of attendance to file with appropriate certifying bodies which accept such. Blank certificates of attendance may be downloaded on the Pharma Congress website, www.PharmaCongress.com, Continuing Education page.