

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

SPONSOR:



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

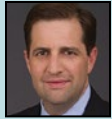
WiFi and Mobile  
App Information:  
See page 2

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

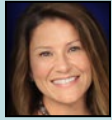
Agenda current as of  
October 30, 2023

[www.PharmaCongress.com](http://www.PharmaCongress.com)

## 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, 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,**  
*Independent Board Director,  
Emergent BioSolutions; Senior  
Advisor, Ethicist International*



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



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

## MEDIA PARTNERS



HARVARD  
health policy  
REVIEW

HealthAffairs

## PLATINUM GRANTORS



## GOLD GRANTORS



## SILVER GRANTORS



## BRONZE GRANTORS



## COVINGTON



## TUESDAY, OCTOBER 24, 2023

**4:00 pm** Early Registration Opens for Attendees, Speakers and Exhibitors

**WOODROW WILSON PREFUNCTION**

**6:00 pm** Early Registration Adjourns

## WEDNESDAY, OCTOBER 25, 2023

### SPECIAL INVITATION ONLY SESSION: CHIEF COMPLIANCE OFFICER ROUNDTABLE

**BALTIMORE 3,4,5**

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.

Qualifying CCOs may request more information about the Roundtable and, if appropriate, inquire about attending by emailing [reginfo@hconferences.com](mailto:reginfo@hconferences.com).

**7:00 am** Congress Registration Opens

**7:30 am** Invitation-Only Continental 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, Compliance and 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

**9:00 am**



#### The Rising Stakes of Data Governance and How Companies are Responding

#### Cross Functional Industry Expert Panelist Discussion

**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)

**10:10 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 Department of Justice, 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

PCF Co-Chairs

**11:55 am**

#### ADJOURNMENT

## COMPLIMENTARY WIRELESS ACCESS ONSITE

The Congress has arranged for complimentary wi-fi for attendees on the meeting floor. To access the wi-fi, connect to the Pharma-MedDevice Congress Network. **When prompted enter Group Code: PhMD2023**

## DOWNLOAD THE CONFERENCE APP

The Conference App is required to participate in polling questions. Scan the QR code for your device. If prompted enter **Event Code 24pc2023**

You should have received an email prior to the conference with your unique App Pin. Enter the pin when prompted. If you need the pin, please inquire at registration.



Apple QR Code



Android QR Code

## FOR POLLING QUESTIONS

To respond to a poll question in a session, go to the agenda button in your app and scroll to the session you are attending. Click on Poll. When the poll is live it will be visible on your screen. Respond to the poll and wait for the host to make the results available.



## AGENDA DAY I: WEDNESDAY, OCTOBER 25, 2023

**7:00 am Congress Registration Opens;  
Continental Breakfast**

**WOODROW WILSON PREFUNCTION**

### 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 **ANNAPOLIS 1-2**

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 **ANNAPOLIS 3-4**

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 and 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 **CAMELLIA 1**

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 **WOODROW WILSON B**

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 and Regulatory, Porzio Life Sciences, an RLDatix Company, New York, NY (Moderator)

#### Mini Summit 5: The Latest in Social Media Enforcements **BALTIMORE 1-2**

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

#### **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 SUMMIT TOPICS LISTED BY CATEGORIES

**NOTE:** This is only a guide to help organize and manage topics. Please refer to the brochure for an accurate description of each Mini Summit to facilitate your selections as topics may fall into multiple categories.

### GLOBAL/TPRM

- 25 Sanctions — Compliance Monitoring Approaches and Tools
- 28 New Levels of Transparency and Governance Across the Pharma and Device Ecosystems
- 31 Annual FCPA Update
- 39 Third Party Risk Management: Onboarding Diligence, Oversight and Exercising Audit Rights
- 40 Global Aspects and Challenges of FCPA/Compliance Investigations
- 43 Global Ethics and Compliance: Evolution of Legislation
- 50 Global Ethics and Compliance: ESG Governance
- 58 Building Fearlessness into Organizations

### HCP ENGAGEMENT

- 7 HCP Engagement: Business Needs Assessment, Contracting, and Activities Management
- 18 Contemporary Trends in Fair Market Value
- 21 The Role of Fair Market Value in Pharma and Medical Device Compliance Programs

### MARKET ACCESS & PATIENT SUPPORT

- 9 Alternative Funding Vendors: The Future and Options for Responding to New Challenges to Patient Support Programs
- 14 Compliance Considerations for Market Access Initiatives
- 16 All Things Patients
- 23 Is the “No Patient Left Behind” Approach to Patient Support Programs Viable?

### PRICING & PRIVACY

- 4 Update on Federal Government Pharmaceutical Price Negotiations
- 8 Preparing for Government Intervention in Drug Pricing
- 20 Drug Pricing — Considerations around Price Controls, Negotiation, and Access
- 30 Privacy and Data Protection: Changes in Laws and the Impact on Our Industry
- 47 Pixels and Privacy: Navigating the Litigation and Enforcement Landscape of Website and Mobile App Privacy

### R&D/MEDICAL

- 10 R&D and Clinical Trials Compliance Update
- 17 Evolving Risks in Medical Affairs
- 53 What Do Health Equity Initiatives Mean for Compliance?
- 60 Old Concepts New Risks: Trends in Medical Education Support Compliance

### REGULATORY & ENFORCEMENT

- 3 Insights from Medical Device Corporate Integrity Agreements
- 5 The Latest in Social Media Enforcements
- 6 Government Enforcement Actions Piggy-Backing on Product Liability Litigation

- 13 Insights and Actionable Deliverables in Response to the DOJ Self-Disclosure Policy
- 26 A Fireside Chat with Jim Sheehan, JD
- 27 Key Learnings from CMS Audits of Open Payments
- 33 Navigating M&A of FDA-Regulated Companies
- 44 DOJ Agreements, Dual Reporting and the Role of the Compliance Officer
- 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
- 57 Recent Developments in DOJ and FTC Enforcement Actions

### RISK ASSESSMENT, MONITORING, DATA ANALYTICS AND COMPLIANCE USE OF AI

- 2 Data Analytic Strategies for Compliance
- 15 Data Analytics to Monitor Payments to HCPs, HCOs, Distributors, and Other Third Parties
- 24 Assessing Compliance Priorities: Considerations for Conducting an Effective and Collaborative Compliance Risk Assessment
- 32 Developing an Effective AI Governance Model: What You Need to Know
- 34 Enterprise Communications Monitoring and the Recent DOJ Guidance
- 38 AI — Art of the Possible
- 45 Compliance in Life Science; Unleashing AI's Potential
- 48 The Modern Investigation: Current Best Practices for Investigations
- 59 Compliance Monitoring — Operational Insights and Lessons Learned

### CORPORATE COMPLIANCE AND TRAINING

- 1 Compliance Primer and How to Make the Most of Your Time at the PCF Congress
- 11 Proving the Value of Corporate Compliance
- 12 Internal Investigations: Best Practices to Address Compliance Concerns and Reduce Risk
- 29 Hiring and Developing Compliance Leaders
- 35 DEI Training: Why It Matters and How to Do It?
- 36 Outsourced Compliance Programs: How to Make them Work?
- 37 Fostering a Speak Up Culture at Your Organization
- 41 Compliance Considerations for Small and Emerging Companies
- 46 Engaging Your Board Effectively in an Era of Heightened Scrutiny and Enforcement Risk
- 49 Using Behavioral Compliance to Improve Your Compliance Program — Practical Implementation Suggestions
- 52 Compliance Considerations for Rare Disease
- 55 Evolving Board of Directors and Compliance Committees Oversight Obligations
- 56 Comedy & Compliance — Shifting Culture & Building Trust with Entertainment

### EMERGING RISK (INCL. BUSINESS USE OF AI)

- 19 Risk and Ethics Perspective of Artificial Intelligence
- 22 Responsibly Harnessing the Power of AI
- 42 Legal Risks Around Digital Health Technology
- 51 Navigating Compliance Challenges: Real-World Case Studies and Solutions

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

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

ANNAPOLIS 1-2

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

WOODROW WILSON B

This comprehensive workshop will delve into the critical aspects of engaging with health-care providers (HCPs), starting from initial business needs assessment to contracting and ongoing activities management. Experts will share best practices for ensuring compli-

ance with regulatory frameworks while optimizing HCP relationships. Attendees will gain actionable insights into risk mitigation, contract formulation, and effective management of HCP interactions. This session is a must-attend for those looking to elevate their compliance strategies in HCP engagement.

#### 9:00 am Introduction, Discussion and Q&A

**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*

**Torrie Nagendran**, *Compliance Manager, HCP Interactions, Exact Sciences, Seattle, WA*

### Mini Summit 8: Preparing for Government Intervention in Drug Pricing CAMELLIA 1

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 ANNAPOLIS 3-4

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

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

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

### Mini Summit 10: R&D and Clinical Trials Compliance Update BALTIMORE 1-2

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 and 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 ANNAPOLIS 1-2

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 WOODROW WILSON CD

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.

*Session continued next page*

**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

WOODROW WILSON B

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**  
**Murad Hussain, JD**, Partner, Arnold & Porter Kaye Scholer, LLP, Washington, DC  
**Seth Whitelaw, JD, LL.M., 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

ANNAPOLIS 3-4

As companies seek to address increasing requirements, changes to, and updates in market access – from grappling with the Inflation Reduction Act's looming impact on drug pricing to addressing concerns with PBM and GPO relationships to contemplating the impact of alternative funding programs and similar entities – this panel will address the compliance considerations that pharmaceutical companies face, including how Legal and Compliance teams should think about these issues.

**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

BALTIMORE 1-2

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**  
**Patricia A. Etzold, CPA, CFF**, Partner, Resolution Economics LLC, New York, NY  
**Erin Brown Jones, MA, JD**, Partner, Latham & Watkins, Washington, DC  
**Parth Chanda**, Chief Executive Officer, 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

ANNAPOLIS 1-2

Join Clarissa and esteemed panelist's discussion on All Things Patients, including:

- Patient centricity and the evolution of patient interactions, engagement, go-to-markets model, risk profiles and ethical decision making
- Key considerations in engagement with patients across the patient journey
- Key learnings from recent enforcement actions and advisory opinions
- Ethics & Compliance role in advising on strategy and concepts for patient engagement and interaction

**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 Law; Adjunct Professor, Mitchell Hamline School of Law; Senior Lecturer, Carlson School of Management, University of Minnesota; Adjunct Professor, University of Minnesota Law School, Stillwater, MN  
**Clarissa Crain**, Managing Director, Deloitte & Touche, LLP, Phoenixville, PA (Moderator)

### Mini Summit 17: Evolving Risks in Medical Affairs

WOODROW WILSON CD

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. Doeblner, 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

ANNAPOLIS 3-4

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 and 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

BALTIMORE 1-2

GenAI is accelerating the AI revolution, and the companion risks and ethical considerations are incredibly relevant across industries. Tad and Dana bring a wealth of knowledge and practical experience to AI Risk & Ethics: governance, privacy, cyber security, emerging regulatory frameworks, etc. Tad was BCG's former CRO and oversaw the development of their Responsible AI policies and processes. He now leads BCG's Risk & Compliance practice in healthcare. Dana recently joined Medline and was tasked with developing immediate guidelines on use of generative AI. Join in an interactive discussion to address the questions:

- What are the risks that unfettered AI could create for your organization?
- How should you get started, what are the key challenges, and what does success look like?
- What is the role of compliance and how do you ensure a seat at the table?

### 11:00 am Introduction, Discussion and Q&A

**Dana Garbo, JD**, Chief Privacy Officer, Medline Industries, LP; Advisory Council Member, Stillman School of Business, Seton Hall University, Northfield, IL

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

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

WOODROW WILSON B

Join our panel discussion around the dynamic regulatory landscape including IRA and various considerations that impact pricing control, operational pressures and potential access strategies.

### 11:00 am Introduction, Discussion and Q&A

**Alexis Boaz, MPH, JD**, Associate Attorney, Health Care and Life Sciences, Epstein Becker & Green, P.C., Washington, DC

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

**Stephanie Trunk, JD**, Partner, Arent Fox LLP, 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

WOODROW WILSON A

## 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

ANNAPOLIS 3-4

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, Mozart 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

CAMELLIA 1

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 and Regulatory, PwC, Chicago, IL

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

ANNAPOLIS 1-2

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

BALTIMORE 1-2

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 **WOODROW WILSON BCD**

### 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 Geoff S. Martha, Chairman and Chief Executive Officer, Medtronic**



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

#### Interviewed by:

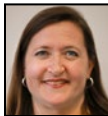


**Tara Shewchuk, JD**, Global Chief Ethics and Compliance Officer, Medtronic; Member, Pharma Congress Medical Device Steering Committee, Minneapolis, MN

### 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, LLM**, Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International; 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** **WOODROW WILSON A**

### 4:15 pm



### Prosecution and Enforcement Actions Update

**Jennifer L. 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 and 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 **WOODROW WILSON A**

## AGENDA DAY II: THURSDAY, OCTOBER 26, 2023

### 7:00 am **Registration Opens** **WOODROW WILSON PREFUNCTION** **Continental Breakfast in Exhibit Hall** **WOODROW WILSON A**

## 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 **BALTIMORE 1-2**

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**, Principal, Forensic & Integrity Services, EY, Boston, MA

**Chris Matteson**, Senior Manager, Forensic & Integrity Services, 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 **ANNAPOLIS 3-4**

Prominent life science ethics and compliance expert, Jacob T. Elberg, JD, Associate Professor and Faculty Director of Center for Health and Pharmaceutical Law, Seton Hall



University School of Law and Former Chief, Health Care and Government Fraud Unit; Assistant US, Attorney, US Attorney's Office, District of New Jersey, interviews iconic former Associate United States Attorney, Eastern District of Pennsylvania Jim 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, about his career and lessons learned in investigations, compliance, and prosecution of pharmaceutical and medical device cases.

#### 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 BALTIMORE 3,4,5

#### 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 and Pharma Ecosystems ANNAPOLIS 1-2

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, accountability is equally important for biopharma and medical device manufacturers. For example, new EUMDR and IVDR regulations reflect 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 pharmaceutical and medical device manufacturers' ecosystems, 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), Pittsburg, 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: Hiring and Developing Compliance Leaders WOODROW WILSON B

Compliance departments can be so focused on mitigating risk in their companies that they can sometimes neglect thinking enough about how to hire the right people and develop themselves and others in the department. Join us as we share best practices for hiring and developing compliance professionals. You will walk away with actionable ideas that you can use immediately, whether you are working on developing yourself or are an experienced compliance officer looking for ideas to develop your team. Time permitting, we'll even work on a short case study where you'll have a chance to work with your peers. We're looking forward to a lively session!

#### 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, Dermavent 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 ANNAPOLIS 1-2

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 CAMELLIA 1

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: Developing an Effective AI Governance Model: What you Need to Know **ANNAPOLIS 3-4**

As the life sciences industry continues to advance with the rapid adoption of artificial intelligence (AI) and machine learning technologies, organizations must also tackle the accompanying challenges related to risk management, regulatory compliance, and data privacy. In this presentation, we will explore the essential elements required for creating a robust AI Governance model, such as:

- Core Tenants of AI Governance
- Effective risk mitigation strategies
- Insights gleaned from the evolving regulatory landscape
- Data Privacy Considerations

This holistic approach will empower organizations to successfully navigate the complexities of AI and capitalize on the immense potential these technologies have to offer.

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

**John Gitas, MBA, Partner, Healthcare and Life Sciences, KPMG US, New York, NY**

**Bryan McGowan, Partner, Technology Risk, KPMG US, Overland Park, KS**

## Mini Summit 33: Navigating M&A of FDA-Regulated Companies **BALTIMORE 1-2**

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 **WOODROW WILSON CD**

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? **BALTIMORE 3,4,5**

- 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**

### 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? **WOODROW WILSON B**

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**

### Mini Summit 37: Fostering a Speak Up Culture at Your Organization **ANNAPOLIS 1-2**

- 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 **WOODROW WILSON CD**

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 a 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**, *Chief Ethics and Compliance Officer, UCB, Smyrna, 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

ANNAPOLIS 3-4

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 on 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*

**Chris Matteson**, *Senior Manager, Forensic & Integrity Services, EY; Former Senior Director Risk Mitigation and CIA Management, Johnson & Johnson, Marlton, NJ*

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

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

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

CAMELLIA 1

This session will not be about substantive FCPA and other Western requirements. Rather, we will focus on the complexities of conducting investigations in various countries, particularly in some of the more “difficult” jurisdictions. Challenges faced when conducting such investigations range from cultural differences, unfamiliar local laws and requirements, and language barriers, to conflicts of interest and even contradictory legislation. To name but a few typical issues, we will be discussing compliance with data protection regimes, cross-border data transfers, collection of evidence, remediation of compliance issues, mitigating the risk of exposure for local management, adapting global policies to local realities, and more.

This session will be interactive. We will use a “roundtable format” that should allow lively participation, rather than having the panel participants talk alone. Ultimately, we hope our session will help you conduct future multi-jurisdictional investigations in a smart way avoiding some of the cultural gaps and local pit-holes.

#### 9:00 am Introduction, Discussion and Q&A

**Michael Buckner, JD**, *Vice President and Deputy General Counsel, Danaher Corporation, Washington, DC*

**Peter Dieners, JD**, *Partner and Head, Global Risk and Compliance; Head, Global Healthcare and 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*

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

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

### Mini Summit 41: Compliance Considerations for Small and Emerging Companies

BALTIMORE 1-2

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

BALTIMORE 3,4,5

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, FDCA, 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 CAMELLIA 1

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 WOODROW WILSON CD

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

**Kate Godfrey, JD, CCEP**, *Chief Compliance Officer, KARL STORZ; Member, Chief, El Segundo, CA*

**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*

**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 ANNAPOLIS 1-2

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 and 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 ANNAPOLIS 3-4

The past several years have seen a heightened period of enforcement risk and public, private, and government scrutiny. During this time, traditional compliance concerns have become magnified and new areas of interest have come into focus for Boards of Directors of both public and private companies. Our panel will discuss what topics remain, and have more recently become, top of mind for Boards of Directors. Additionally, they will discuss strategies, examples, and recommendations for effectively engaging and liaising with Board members, managing these relationships, and navigating a Board's perception of risk. The panel will also discuss topics such as:

- The TikTok/Twitter/X effect on a Board's perception of risk and risk tolerance;
- A Board's evolving view of the CCO's remit and whether that scope should expand (e.g., sanctions, privacy);
- A CCO's involvement in product pricing and/or government pricing oversight; and
- The DOJ Criminal Division's Pilot Program Regarding Compensation Incentives and Clawbacks.

#### 10:30 am Introduction, Discussion and Q&A

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

**Timothy Roberts, MSJ**, *US Compliance and Privacy Officer, Ferring Pharmaceuticals, Parsippany, NJ*

**Marella Thorell**, *Chief Financial Officer, Evelo Biosciences; Board Member, Essa Pharmaceuticals, Cambridge, MA*

**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 BALTIMORE 1-2

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 Investigation **BALTIMORE 3,4,5**

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 **WOODROW WILSON B**

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 Spicandler, 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 **CAMELLIA 1**

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 **BALTIMORE 1-2**

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

**Erinee Endrawis**, Vice President, Accounts, G&M Health, Somerset, NJ

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

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

**Ihab Ghaly, MBA**, Managing Director, G&M Health, LLC, Matawan, NJ (Moderator)

### Mini Summit 52: Compliance Considerations for Rare Disease **ANNAPOLIS 1-2**

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

### 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, Sentyln, Los Angeles, CA

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

**Elaina McEwan**, Senior Manager, Life Sciences Consulting Group, Litigation Department, Paul Hastings, New York, NY (Moderator)

### Mini Summit 53: What Do Health Equity Initiatives Mean for Compliance? **ANNAPOLIS 3-4**

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**, Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International; Member, Pharma Congress Medical Device Steering Committee, Chicago, IL

**Danielle Pelot, JD**, Partner, Choate, Hall & Stewart, LLP; Former Special Assistant District Attorney, Middlesex District Attorney's Office, Boston, MA

## 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 **WOODROW WILSON CD**

Leading life sciences attorney and former Deputy Chief, DPJ Criminal Division Kirk Ogrofsky interviews former leading government officials Greg Demske, JD, Partner, Goodwin Procter, and former Chief Counsel to the Inspector General, HHS Inspector General, and Kevin McAnaney, JD, Law Office of Kevin McAnaney, and former Chief, Industry Guidance Branch, HHS Office of Counsel to the Inspector General, who were instrumental in the implementation of the False Claims Act on its 50th anniversary.

### 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 Ogrofsky, 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 **BALTIMORE 3,4,5**

- 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

**Maureen Nagelberg, JD**, Associate Compliance Officer, Otsuka Pharmaceutical Companies US, Princeton, NJ

**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 **WOODROW WILSON B**

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

# EXPERTS WITH IMPACT™

FTI Consulting is an independent global business advisory firm dedicated to helping organizations manage change, mitigate risk and resolve disputes: financial, legal, operational, political & regulatory, reputational and transactional.



[www.fticonsulting.com](http://www.fticonsulting.com)

©2023 FTI Consulting, Inc. All rights reserved.

**Deloitte.**

**We have your back,  
and the way forward**

Regulatory compliance and legal services that help you lean in

Learn more at [www.deloitte.com](http://www.deloitte.com)

Copyright © 2023 Deloitte Development LLC. All rights reserved.

## 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 ANNAPOLIS 1-2

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 and 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 BALTIMORE 1-2

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 BALTIMORE 3,4,5

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 and Monitoring, Medtronic, Orlando, FL

**Karen Lowney**, Head of the Office of Ethics and 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 and Compliance Monitoring, Boehringer Ingelheim USA Corporation, Ridgefield, CT

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

**Award-Winning**  
**COMPLIANCE CONTENT**  
**FOR YOU**



 **Rethink**  
Compliance

**HEALTHCARE & LIFE SCIENCES**

**Ankura's Global Team of Experts and Advisors Helps Life Sciences Clients to Protect, Create, and Recover Value in Moments of Change and Disruption**

- | Compliance
- | Disputes & Investigations
- | Fair Market Value
- | Government Pricing
- | Privacy & Cybersecurity
- | Operations & Supply Chain
- | Valuation
- | M&A and Due Diligence Support

Learn more at [ankura.com](https://ankura.com)

**ankura**  | PROTECT, CREATE, AND RECOVER VALUE



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

ANNAPOLIS 3-4

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** WOODROW WILSON BCD

**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

Session continued on page 18

**Cutting Edge INFORMATION**

**The world's most accurate, market-based FMV rate data for HCP engagements**

<b>125+</b> Countries	<b>110+</b> General & Non-MD HCP Titles
<b>135+</b> Specialist Titles	<b>25+</b> Non-HCP Titles

**+1 800.864.2063**  
**www.cuttingedgeinfo.com**

**COMPLIANCE AND PRIVACY CONSULTING**  
for life science companies

We make compliance work.

**highlighted service offerings**

- Program Strategy, Design and Development
- Responding to Regulatory and Legal Challenges
- Developing Balanced Policies and Procedures
- Providing Interim Staffing Solutions
- Creating Engaging Training and Education Solutions

**Come visit us at booth #105.**

**DOVETAIL**  
CONSULTING GROUP LLC

+1 617 383 3864 dovetailcg.com • info@dovetailcg.com





FOR MORE INFORMATION VISIT  
LIFESCIENCES.RLDATIX.COM



Partnering with Life Sciences clients to navigate evolving regulations, manage risk, and achieve business goals.

**PORZIO**  
Bromberg & Newman

Visit us at Booth #104  
pbnlaw.com

# 24<sup>th</sup> Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

**Purchase your Media at the Conference and Save!**



**\$129**

on-site

**\$195**

post-conference

## ONLINE ARCHIVE ACCESS

- ✓ Access from any computer or mobile device with internet connection
- ✓ Contains video, audio and synchronized Powerpoint slides\*
- ✓ Includes presenter slides in PDF format\*
- ✓ 6 months access from date of purchase



**\$129**

on-site

**\$195**

post-conference

## CONFERENCE FLASH DRIVE

- ✓ Easy navigation of all sessions
- ✓ Contains video, audio, and synchronized Powerpoint slides\*
- ✓ Includes presenter slides in PDF format\*
- ✓ No internet access required

Visit the Registration Desk to order your media onsite.



**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**  
**WOODROW WILSON A**

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 and 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

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**

# HelioChat is revolutionizing the compliance world.

**Sales Rep:** Can I mention our expected approval date in a company post on LinkedIn?

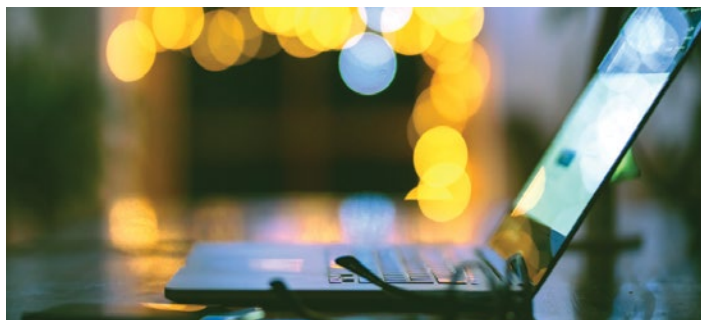
**HelioChat:** No. You should not mention a launch date when the product has not yet been approved. You do not want to promise a date that is not guaranteed. Refer to POL-Helio1275 and SOP-Helio-1287

HelioChat can answer your organization's compliance questions.

**Are you an innovator?**



Contact Us: [info@heliohealthgroup.com](mailto:info@heliohealthgroup.com)



## Optimize your compliance programs

CRA has deep experience evaluating compliance program frameworks and advising on the design and implementation of compliance program elements.

**We focus our compliance solutions on five areas:**

- **Compliance strategy** integrating into an organization's mission and vision
- **Design & optimization** preventing, detecting, and responding to instances of non-compliance
- **Ethical culture** assessments helping mitigate reputational and integrity risks
- **Investigations** responding to allegations of fraud, misconduct, and non-compliance
- **Monitorships** as Independent Compliance Monitor, Independent Consultant, or Independent Review Organization

**Jeff Garfield**, Vice President, Forensic Services  
+1-317-931-8353 | [jgarfield@crai.com](mailto:jgarfield@crai.com)

**John Rademacher, CPA, CFE**, Principal, Forensic Services  
+1-312-283-2990 | [jrademacher@crai.com](mailto:jrademacher@crai.com)

Learn more at [www.crai.com](http://www.crai.com)



## AGENDA DAY III: FRIDAY, OCTOBER 27, 2023

**7:00 am** Registration for Industry-Only Compliance Best Practices Think Tank  
**WOODROW WILSON PREFUNCTION**

**7:30 am** Breakfast **WOODROW WILSON BCD**

## INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

**WOODROW WILSON BCD**

(On the morning of Friday, October 27, 2023, the Congress is offering an Industry-only Closing Plenary Session. This is a closed session that may be attended only by ethics, compliance and legal employees of medical device and pharmaceutical companies who have registered for the Congress. The Industry-only Closing Plenary Session is not being broadcast live or recorded and will not be available on the Congress video/audio archive.)

**8:00 am** Welcome and Introductions



**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



**John Poulin**, Chief Technology Officer and Partner, HELIO Health Group, Boston, MA

**9:15 am**

**Key Takeaway Table Discussions**

**9:30 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**

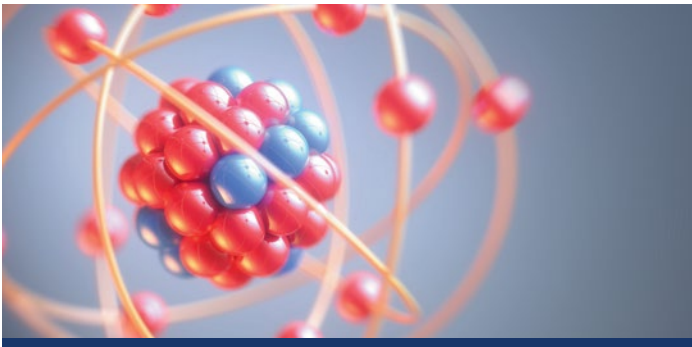
**11:30 am**

**Open Forum — Q&A and Best Practice Sharing**

**12:00 pm**

**CONGRESS ADJOURNMENT**

**CHOATE**



Pharmaceutical and medical device companies trust **Choate** with high-stakes investigations and government enforcement and compliance matters.

**CHOATE HALL & STEWART LLP**

To learn more, visit [choate.com](http://choate.com)

© Copyright 2023 CHOATE HALL & STEWART LLP. "CHOATE" is a registered trademark of CHOATE HALL & STEWART LLP.

**epsilon**  
life sciences

Disputes | Investigations  
Strategy | Compliance | Privacy  
Cybersecurity | Economics



## 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 and Senior Director, Legal Affairs and 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 and 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 and 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 and Social Responsibility Officer, Ipsen; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France (Moderator)

#### 12:00 pm

#### LUNCHEON BREAK



PwC's Pharmaceutical and Life Sciences Group is dedicated to delivering effective business and digital solutions to help solve the complex strategic, operational and financial challenges facing pharmaceutical, biotechnology and medical devices companies. We provide industry-specific services and solutions focused on transformation, cloud and digital, tax, cyber, risk and regulatory, deals, R&D, and more. We help our clients build public trust, make informed decisions, and enhance value for their business and their stakeholders. No matter how big you are, public or private, we can help you work smarter and reach your goals.

EXPERT  
ADVICE.

SMART  
SOLUTIONS.

COMPLIANCE  
SUCCESS.

MedPro Compliance Advisory Services

Learn more at [MedProSystems.com/MCA](https://www.MedProSystems.com/MCA)

MedPro SYSTEMS

MedPro Compliance  
Advisory Services

## AFTERNOON PLENARY SESSION

1:00 pm

### Asia Pac Ethics and Compliance Developments Update Roundtable



**Campbell Clark, LLB, MJ**, Vice President, Compliance Officer and Senior Legal Counsel, APAC, Zimmer Biomet, Former Vice President, Legal and 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 and 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 and Founder, Comply Latam, SC; Former Regional Integrity and 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



ResEcon

Life Sciences & Healthcare

A FULL-SERVICE FIRM

[www.resecon.com](http://www.resecon.com)

**ResEcon Life Sciences & Healthcare is proud to sponsor the 24th Annual Pharmaceutical Compliance Congress**



**Investigations and Due Diligence**



**Compliance and Risk Management**



**Labor & Employment Advisory and Analytics**

## Exhibitor

Exhibitor	Location
Resolution Economics LLC	101
PwC	102
Ankura Consulting Group	103
Porzio, Bromberg & Newman PC	104
Dovetail Consulting Group	105
RLDatix Life Sciences	106
HELIO Health Group	107
G&M Health LLC	108
Clifford Chance	110
Deloitte	111
icuc Social	112
Charles River Associates	113
ZS	114
Lextegrity	116
Paul Hastings	118
Cutting Edge Information	200
MedPro Systems	201
FTI Consulting	204
Seton Hall University School of Law	205
Potomac River Partners	206
MedCompli	209
MediSpend	210
Baker Tilly	211
NxLevel Compliance	212
qordata, Inc	213
Trestle Compliance	215
Cresen Solutions	217
ReThink Compliance	309
Learnings & Entertainment	317



## Exhibit Viewing Hours

<b>WEDNESDAY, OCTOBER 25, 2023</b>	11:50 am – 7:00 pm
<b>THURSDAY, OCTOBER 26, 2023</b>	7:00 am – 3:30 pm

## Events in the Exhibit Hall

### WEDNESDAY, OCTOBER 25, 2023

Networking Luncheon:	12:00 pm – 1:00 pm
Networking Break:	3:45 pm – 4:15 pm
Networking Reception:	6:00 pm – 7:15 pm

### THURSDAY, OCTOBER 26, 2023

Continental Breakfast:	7:00 am – 8:00 am
Networking Break:	9:50 am – 10:30 am
Luncheon Mini Summits:	12:20 pm – 1:20 pm
Networking Break:	3:00 pm – 3:30 pm

## CONGRESS SPONSOR



**Debra Scanlon,**  
PCF Administrator

The Congress is sponsored by the Pharmaceutical Compliance Forum (PCF) [www.pharmacomplianceforum.org](http://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.

## CONTINUING EDUCATION CREDITS & CERTIFICATE OF ATTENDANCE

### COMPLIANCE CERTIFICATION BOARD (CCB)<sup>®</sup>:

**In-Person, Web, and Archived Event:** The Compliance Certification Board (CCB)<sup>®</sup> has approved this event for up to **26.0 Live and 21.0 Non-Live CCB CEUs each** based on a 50-minute hour, each. Continuing Education Units are awarded based on individual attendance records. Granting of prior approval in no way constitutes endorsement by CCB of this event content or of the event sponsor.

**Global Day Credits:** The Compliance Certification Board (CCB)<sup>®</sup> has approved this event for up to **4.8 Non-Live CCB CEUs each based** on a 50-minute hour, each. Continuing Education Units are awarded based on individual attendance records. Granting of prior approval in no way constitutes endorsement by CCB of this event content or of the event sponsor.

**CONTINUING LEGAL EDUCATION:** The Pharmaceutical and Medical Device Ethics and Compliance Congress has been approved to offer 35 Pennsylvania CLE Credits. **For more information visit the conference website at [www.pharmacongress.com](http://www.pharmacongress.com)**

**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](http://www.PharmaCongress.com), Continuing Education page.

BCG partners with clients across the health care sector to address the industry's most critical challenges, transform enterprises, and improve patient outcomes.

Our transformational approach ensures that our clients achieve sustainable competitive advantage, empower their organizations to grow, and drive positive societal impact.





Building a better  
working world

How do you keep  
today's risks from  
becoming tomorrow's  
headlines?

Learn more at [ey.com/us/forensics](https://ey.com/us/forensics).



The better the question.  
The better the answer.  
The better the world works.