Twenty Second PCF Virtual Pharmaceutical and Medical Device Ethics & Compliance Congress and Best Practices Forum

GHC LIFE SCIENCES Global Health Care, LLC

Virtual Online Event Live and Archived
www.PharmaCongress.com

November 2 – 5, 2021
All Times are EDT · Agenda Current as of November 5, 2021

CONTINUING EDUCATION CREDITS

COMPLIANCE CERTIFICATION BOARD CONTINUING EDUCATION UNITS (CCB CEUs): The Compliance Certification Board (CCB)® has approved this event for up to 22.6 live CCB CEUs based on a 50-minute hour. 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.

AGENDA DAY I: TUESDAY, NOVEMBER 2, 2021

MINI SUMMITS GROUP I AND II/ CHIEF COMPLIANCE OFFICER ROUNDTABLE

Welcome by:
Indrani Franchini, JD, *Co-chair, Pharmaceutical Compliance Forum; Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP I

(Open to all attendees)

MINI SUMMIT 1: Enforcement Action Updates

10:00 am Welcome, Introductions, Discussions and Q&A

Hear an update of recent government enforcement activities from industry experts and federal prosecutors. The panel will address how the government is scrutinizing conduct relating to speaker programs and consulting arrangements, Covid-related fraud, telehealth, clinical trials, research grants, opioid-related crimes and manufacturer and charitable patient assistance programs. In this session, the panel also will share their predictions about the government's enforcement priorities as we head into 2022.

Paul Kaufman, JD, *Assistant United States Attorney & Unit Chief, United States Attorney's Office, District of Massachusetts; Boston, MA*

David Lazarus, JD, *Assistant United States Attorney & Unit Chief, United States Attorney's Office, District of Massachusetts; Boston, MA*

Joseph Mack, JD, *Senior Assistant General Counsel, Bayer Pharma; Former Deputy Chief Healthcare and Government Fraud Unit, US Attorney's Office, District of NJ; Whippany, NJ*

Natalie A. Waites, MS, JD, *Assistant Director, United States Department of Justice, Civil Division/Fraud Section; Washington, DC*

Melissa Tearney, JD, *Partner and Co-chair, Litigation, Choate, Hall & Stewart LLP; Boston, MA (Moderator)*

11:00 am Transition Break

MINI SUMMIT 2: Case Study: Next Generation Compliance Risk Management using Advanced Analytics

10:00 am Welcome, Introductions, Discussions and Q&A

Learn how to get started in developing advanced analytics to support your compliance program

- Develop a problem statement, business case, and plan to address
- Expand practical uses cases for monitoring data
- Build a strategic plan to prioritize steps in the process

Learn how you can experiment with advanced analytics models to assess feasibility of generating risk-based insights to support compliance programs

- Quick wins that offer immediate risk mitigation value
- Opportunities to test the quality and connections of data in your organization
- Build credibility with the Business by informing the value and risk associated with key business activities

Walk through a case study that shows how data can be triangulated to deliver risk profiles for key business activities by market, therapeutic area, and individuals

Malini Natarajan, MS, *Executive Director, Monitoring, Analytics and Third Party Due Diligence, Bristol Myers Squibb; Princeton, NJ*

Hima Pavuluri, MBA, *Senior Director, Enterprise Risk Analytics, Bristol Myers Squibb; Princeton, NJ*

Michael L. Shaw, JD, *Principal, Global Head of Risk & Compliance, ZS; Former Vice President & Compliance Officer, Global Therapy Areas & US Pharma, GlaxoSmithKline; Former Senior Counsel, HHS Office of Inspector General; Princeton, NJ (Moderator)*

11:00 am Transition Break

MINI SUMMIT 3: Evolution of Investigations

10:00 am Welcome, Introductions, Discussions and Q&A

During this session, panelists will share insights on:

- Understanding the basics of investigations
- Techniques for conducting a virtual investigation.
- When should you seek outside resources?
- Policy and Procedures

Vineeta Dinesh, *Senior Director, Compliance Audits & Investigations, Global Audit & Assurance, Johnson & Johnson; New Brunswick, NJ*

Robert Ennis, JD, LLM, *Vice President and Lead Compliance Counsel, Global Science, Medicine, Manufacturing & North America Investigations Lead, Pfizer; New York, NY*

Giuseppe (Pino) Falbo, *Global Head, Ethics and Compliance Investigations, Takeda; Dubai, United Arab Emirates*

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

11:00 am Transition Break

MINI SUMMIT 4: Risk Assessments of the Future

10:00 am Welcome, Introductions, Discussions and Q&A

During this session, we will focus on four key themes driving risk assessments of the future: Resource Type and Allocation, Evolving Market Dynamics, Data Analytics and Modeling, and Frequency. We will also discuss how technology serves as a fifth theme, existing within and across the other four. Today is the Future. . .as companies continue to work out of the pandemic, these themes either existed before the pandemic and are now being given greater emphasis to improve how we work and/or these themes have been driven primarily by the changes in market dynamics associated with the pandemic. . . either way, they represent the direction pharmaceutical and medical device companies are moving to transform how we continuously assess and mitigate risk.

Kellie Fidler, MBA, PMP, *Director, Global Compliance Risk Assessment, Monitoring & Analytics, Bristol Myers Squibb; Princeton, NJ*

Mona Peterson Rosow, JD, MPH, *Senior Director, Global Compliance Auditing & Monitoring, Medtronic; Minneapolis, MN*

Alexis Stroud, CQA, CCEP, *Executive Director, Ethics and Compliance, Compliance Operations, Boehringer Ingelheim; Ridgefield, CT*

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

11:00 am Transition Break

INTERACTIVE WORKSHOP I: Harmonizing, Globalizing, and Digitizing Ethics and Compliance

10:00 am Moderated Interactive Discussion

Ethics and Compliance Programs have to address the dynamic risk landscape in a simplified, efficient way to secure a meaningful impact on changing business practices.

Based on an embedded sustainable compliance culture and a simplified but global compliance governance, digitized services will have to be delivered to enable these business needs.

Join us to discuss why and how Ethics and Compliance Programs will have to:

- Harmonize and simplify the Compliance and Ethics framework and processes to sustain excellence of Program management;
- Globalize Compliance and Ethics culture, strategy, organizational design and people development to secure impact; and
- Digitize the delivery models by integrating its offerings into business process wherever possible and provide a one stop shop digital Compliance and Ethics platform with self-services on demand for business clients.

Eva Gardyan-Eisenlohr, *Rechtsanwältin, DIAP (ENA, Paris), Global Chief Compliance Officer, Senior Vice President, Olympus Corporation; Tokyo, Japan (Discussion Co-Lead)*

Dana S. McMahon, JD, *Vice President, Global Chief Compliance Officer, Stryker; Former Assistant General Counsel, Novo Nordisk; Allendale, NJ (Discussion Co-Lead)*

11:00 am Transition Break

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP II

MINI SUMMIT 5: DOJ/SEC FCPA Panel

11:15 am Welcome, Introductions, Discussions and Q&A

Pharmaceutical and Medical Device companies have long been subject to scrutiny by both the Department of Justice and Securities and Exchange Commission under the Foreign Corrupt Practices Act. Yet the current global pandemic, and change in administrations means significant changes in corruption risk, compliance, and enforcement for both companies and for regulators. Join us as we discuss – from an enforcement perspective – risks facing the industry and compliance best practices.

Robert I. Dodge, JD, *Assistant Director, FCPA Unit, US Securities & Exchange Commission; Washington, DC*

David Fuhr, JD, *Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice; Washington, DC*

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

12:15 pm Break

MINI SUMMIT 6: Compliance Considerations for Rare Disease Products

11:15 am Welcome, Introductions, Discussions and Q&A

During this session, attendees will hear from industry leaders on several major areas of healthcare compliance in rare disease, including HCP interactions, the role of medical affairs, and patient organization and patient support considerations. The panel will also address strategies for managing and mitigating risk in the rare disease space and the role of outside consultants and legal counsel. Attendees will take away key points pertaining to understanding business objectives and structuring guidance based on real world scenario-based examples.

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

Tiffany Cummings-Damiani, MBA, *Vice President, Corporate & Healthcare Compliance, Insmed, Inc.; Bridgewater, NJ*

Angela Duger, JD, CCEP, *Compliance Manager, Servier Pharmaceuticals; Boston, MA*

Emily Hodge, JD, *Partner, Choate, Hall & Stewart LLP; Boston, MA (Moderator)*

12:15 pm Break

MINI SUMMIT 7: The Road Ahead for Device Enforcement

11:15 am Welcome, Introductions, Discussions and Q&A

The road ahead for device enforcement is a winding one, but the panelists will gaze through the windshield and offer some insights on hot topics in enforcement and compliance for the device industry. Of course, the road ahead is informed by the road behind us. We are emerging from a time that has involved particular enforcement focus on COVID-19 (providers, labs) and various pharmaceutical issues such as opioids and drug pricing. Accordingly, while device companies have had to maintain vigilance, the spotlight that we see in the rearview mirror has not been on them. But in the road ahead it might be.

Panelists will provide compliance insights on:

- Anti-Kickback Statute enforcement (Sunshine Act, PODs, value-based care safe harbors)
- Agency "good guidance" practices
- Identifying and remediating red flags during diligence
- Med tech and privacy
- Data in compliance programs
- Fostering an ethical culture

Terry Chang, MD, JD, *Vice President, Assistant General Counsel, and Director, Legal & Medical Affairs, Advanced Medical Technology Association (AdvaMed); Washington, DC*

Eva Gardyan-Eisenlohr, *Rechtsanwältin, DIAP (ENA,Paris), Global Chief Compliance Officer, Senior Vice President, Olympus Corporation; Tokyo, Japan*

Tara R. Shewchuk, JD, LLM, *Chief Ethics and Compliance Officer, Medtronic; Former Senior Director, Ethics and Compliance, Abbott; Former Vice President, Chief Compliance, Privacy & Security Officer, Resurrection Health Care; Minneapolis, MN*

Jonathan Turner, MSc, *Vice President, Compliance, Privacy & Governance, ZOLL Medical Corporation, Adjunct Faculty, Florida State University; Pittsburgh, PA*

Brenna Jenny, MPH, JD, *Partner, Sidley Austin LLP; Former Principal Deputy General Counsel & CMS Chief Legal Officer, US Department of Health and Human Services; Washington, DC (Moderator)*

12:15 pm Break

MINI SUMMIT 8: Fair Market Value Calculations, Benchmarks and New Standards in a Virtual World

11:15 am Welcome, Introductions, Discussions and Q&A

On behalf of Eric Bolesh, Cutting Edge Information, Donna White will moderate an esteemed panel from Pharmaceutical and Medical Device companies for an engaging discussion of FMV rates for HCPs. Learn best practices for making sure your company is staying within the acceptable range for payments and surrounding issues such as tiering, travel, rate distribution and more. Hear how your peers are handling the complications of the virtual "new normal".

Eric Bolesh, *Chief Operating Officer, Cutting Edge Information; Research Triangle Park, NC*

Antonio Caram, CCEP, *Regional Lead, Health Care Compliance - Consumer Health Canada & LatAm, Johnson & Johnson; Miami, FL*

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

Donna White, CCEP, *Vice President, Compliance, Chiesi, USA, Co-chair, Pharmaceutical Compliance Forum; Cary, NC (Moderator)*

12:15 pm Break

INTERACTIVE WORKSHOP II: Modernization of Third-Party Risk Management

11:15 am Moderated Interactive Discussion

Third parties are no longer just managing ancillary activities, but driving critical activities in core parts of the business—extending the walls of the enterprise. Our panelists discuss how organizations are modernizing their approach to third party risk management, including insights related to:

- Role of technology and analytics
- Responsible business practices
- Evolving regulatory landscape
- Modernization of cost reduction
- Renewed focus on risk management throughout the third-party lifecycle
- Response to third party incidents

Stephanie Meehan, *Senior Manager, Deloitte & Touche LLP; San Francisco, CA (Discussion Co-Lead)*

Dominique Donovan, MBA, *Senior Manager, Deloitte & Touche LLP; Conshohocken, PA (Discussion Co-Lead)*

12:15 pm Break

INTERACTIVE WORKSHOP III: Comedy & Compliance: Creative Training & Communications - Let's Discuss

11:15 am Moderated Interactive Discussion

In this interactive work session, we'll discuss and review a variety of creative, entertaining approaches for communication, awareness and burst learning to engage employees, brand ethics & compliance as welcoming and approachable, and promote speak up culture.

Ronald Feldman, MBA, *President & Creative Director, L&E Creative; Former Product Director, RealBiz Video Communications, Second City Works; Chicago, IL (Discussion Lead)*

12:15 pm Transition Break

CHIEF COMPLIANCE OFFICER ROUNDTABLE

Special Invitation Only, Closed-Door Chief Compliance Officer Round Table
Hosted by Pharmaceutical Compliance Forum. Session not recorded.

1:00 pm **Welcome**

Joe Zimmerman, *Vice President, Chief Compliance Officer & Privacy Officer, Ferring Pharmaceuticals, Inc.; Chair, Pharmaceutical Compliance Forum; Parsippany, NJ (PCF Chair)*

Indrani Franchini, JD, *Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

Joshua Marks, JD, *Vice President, Chief Ethics & Compliance Officer, Boehringer Ingelheim; Ridgefield, CT*

Margaret Sparks, JD, *Head of Compliance, Vaccines, North America Ethics and Business Integrity, Sanofi; Bridgewater, NJ*

Ann Marie Tejcek, MA, *Senior Director, Global Medical Strategy & Transformation Leader; Former Senior Director, Chief Compliance Officer North America, Eli Lilly; Indianapolis, IN*

Donna White, CCEP, *Vice President, Compliance, Chiesi, USA; Cary, NC*

Antitrust Admonition

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

1:10 pm **Open Forum with PhRMA and AdvaMed**

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

Nancy Schwalje Travis, MIA, *Vice President, Global Compliance and Governance, AdvaMed; Former Deputy Director, Office of Economic Policy, Asia-Pacific Bureau, US Department of State; Washington, DC*

Ann Marie Tejcek, MA, *Senior Director, Global Medical Strategy & Transformation Leader; Former Senior Director, Chief Compliance Officer North America, Eli Lilly; Indianapolis, IN (Moderator)*

1:50 pm **Chief Compliance Officer Connection Program – Partner Experience**

Dennis K. Barnes, JD, CPA, *Vice President, Global Governance, Risk & Compliance, Mayne Pharma, Raleigh, NC*

Cindy Cetani, LPEC, *Chief Integrity & Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis International AG; Richmond, VA*

Donna White, CCEP, *Vice President, Compliance, Chiesi, USA, Co-chair, Pharmaceutical Compliance Forum; Cary, NC (Moderator)*

2:00 pm **Break**

2:15 pm **The Pivotal Role of Chief Compliance Officers in Fostering a Strong Culture of Inclusion, Trust, and Psychological Safety**

- Inclusion in the workplace is more important than ever, psychological safety is at the root of inclusion and trust is at the root of psychological safety. Recent studies suggest that there is a connection between a company's focus on diversity, equity and inclusion and its culture of integrity and trust.
- Hear from CCOs from across industries on the role they play in fostering a culture of inclusion, trust and psychological safety. Discuss and share culture-influencing tactics and programs we can support as CCOs to promote a strong culture of trust and steps you can take to measure your culture's strength (or weakness).

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

Janet S. Holcombe, JD, *Vice President, Chief Compliance and Privacy Officer, The Children's Hospital of Philadelphia; Haverford Township, PA*

Katherine A. Lawler, JD, *Senior Vice President, Global Chief Ethics Officer, US Bank; Minneapolis, MN*

Jill Fallows Macaluso, JD, *Corporate Vice President, Chief Ethics, Compliance & Privacy Officer, Novo Nordisk; Princeton, NJ*

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

3:15 pm **"Evolving our Operating Model" Discussion Breakouts (Choice of one of the following)**

1. Scope and Structure of the Compliance Function

2. Ethics and Compliance - The Road Ahead

Welcome and Introductions:
Sujata Dayal, JD, *Vice President & Global Chief Compliance Officer, Medline Industries, Inc.; Former PCF Co-chair; Chicago, IL*

Hosted by PCF Co-Chairs and Facilitators:

Katherine Chaurette, *Vice President Healthcare Law & Compliance, Blueprint Medicines, Suffolk County; Cambridge, MA (Facilitator)*

Jeffrey Kawalek, MBA, *Executive Director, Global Strategic Compliance & Ethics Operations, Jazz Pharmaceuticals; Philadelphia, PA (Facilitator)*

Giota Papamarkou, *Vice President, Business Ethics, North America and Global Monitoring, Ipsen; Paris, France (Facilitator)*

Kristin Rand, JD, MA, *Head, Corporate Compliance and Global Risk Officer, Moderna; Former Vice President and Compliance Officer, Seattle Genetics; Cambridge, MA (Facilitator)*

4:00 pm **Optional Networking Opportunities Continue in the Breakout Rooms**

AGENDA DAY II: WEDNESDAY, NOVEMBER 3, 2021

DAY II MORNING MINI SUMMITS

Welcome by:
Indrani Franchini, JD, *Co-chair, Pharmaceutical Compliance Forum; Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP III

MINI SUMMIT 9: The New Rules of Compliance for Pharma and Medical Device Companies: What you Need to Know Now About Disclosure Requirements and Compliance

10:00 am Welcome, Introductions, Discussions and Q&A

Join this esteemed panel, who will discuss major areas regarding disclosure requirements including:

1. Background on disclosures in Pharma / Med Device
   b. When do we think about disclosing?
   c. Thoughts on government [DOJ / SEC / OIG] – when do they expect companies to disclose?
      i. Focus on the individual vs. company
2. What particular issues would lead to considering disclosure?
   a. Disclosable, material issues
      i. Types of scenarios
      ii. Remediated issues
   b. Materiality – government vs. public
      i. How do you determine when to disclose between the two?
   c. Case studies
      i. Gifts and payments, Speakers Program
      ii. Distributor kickbacks
      iii. Clinical trials
      iv. COVID-related (PPE, DOJ site for COVID-related fraud)
      v. Government contracts (Procurement task force)
      vi. ESG (SEC priority, future focus)
3. How are disclosure controls working? Are you seeing the issues that you may need to disclose?
4. Disclosure controls and compliance program updates
   a. Proactive
   b. Reactive
5. Key takeaways

Susan Markel, CPA, *Managing Director, AlixPartners; Former Chief Accountant—Division of Enforcement, US Securities and Exchange Commission; Clifton, VA*

Lynn A. Neils, JD, *Partner, Baker Botts; Former Assistant United States Attorney, Southern District of New York and District of New Jersey, US Department of Justice; New York, NY*

Mara Senn, JD, *Director & Senior Counsel, Global Compliance Investigations, Zimmer Biomet; Former Prosecutor, Money Laundering and Asset Recovery Section, US Department of Justice; Washington, DC*

Brooke Hopkins, *Managing Director, AlixPartners LLP; Dallas, TX (Moderator)*

11:00 am Transition Break

MINI SUMMIT 10: What's the Future of Drug Pricing?

10:00 am Welcome, Introductions, Discussions and Q&A

Join Meena Datta and industry leaders for an update on drug pricing legislations, next gen GPOs, considerations for rare disease and oncology products, the Medicaid final rule implementation, and key compliance strategies. The panel will provide insight on the Role of Compliance in Pricing Committee Discussions and how to get a seat at the table.

Alexandra M. Bonelli, *Principal, Government Contract Services, EY, New York, NY*

Jenna Cohen, *Senior Director, Market Access Strategy, Blueprint Medicines; Former Director, Global Oncology & Cell Therapy Lead, Government Affairs & Policy, Gilead Sciences; Boston, MA*

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

11:00 am Transition Break

MINI SUMMIT 11: The Role of Compliance In M&A Transactions: A Review of DOJ's Recent Expectations

10:00 am Welcome, Introductions, Discussions and Q&A

In June 2020, the US Department of Justice issued a significant revision and update to its "Evaluation of Corporate Compliance Programs" guidance. In addition to an overall increased focus on the compliance program's use of "data" and the emphasis on the ability of the compliance function to demonstrate that it is "adequately resourced and empowered to function effectively", DOJ provided some detailed expectations about the role that Compliance should play when a company is engaged in an M&A transaction

The objectives of this session are to:

- Review DOJ's specific guidance on the role of Compliance in pre-acquisition due diligence
- Review DOJ's guidance on Compliance's role post-acquisition
- Discuss why Compliance due diligence should matter to the deal-makers and the business
- Discuss real-world examples of Compliance due-diligence and post-acquisition auditing
- Consider how additional general principles from DOJ's guidance document might also inform Compliance's role in M&A transactions

Punkaj T. Amin, MBA, CFE, *Compliance Officer & Privacy Officer, Compliance Officer - Global Wound Management Division, Office of Ethics and Compliance (OEC), Smith & Nephew; Fort Worth, TX*

Cheryl Lee, *Vice President, Global Market Compliance and Compliance Committees at Bristol Myers Squibb; Former Vice President, Worldwide Markets Healthcare Compliance, Celgene; Summit, NJ*

Jenny McVey, MS, PHD, *North America Compliance Officer, bioMérieux, Inc., Adjunct Professor, Fordham University School of Law; Former Compliance Risk Strategy & Management, Novo Nordisk, Compliance Lead, Hands International, Editorial Board Member, Policy & Medicine Compliance Update; Salt Lake City, UT*

Timothy Roberts, MSJ, *Vice President, Chief Compliance Officer, Amneal Pharmaceuticals; Bridgewater, NJ*

Craig Bleifer, JD, *Principal, Craig B. Bleifer, LLC; Former Corporate Vice President, General Counsel North America, Novo Nordisk; Former Senior Vice President, General Counsel and Secretary, Daiichi Sankyo; Summit, NJ (Moderator)*

11:00 am Transition Break

MINI SUMMIT 12: Latest Developments in Electronic Discovery

10:00 am Welcome, Introductions, Discussions and Q&A

This panel will share insights and experiences around the latest developments in electronic discovery, including how COVID has required adjustments to electronic discovery processes. Hear from industry, law firm and consulting practitioners talk about how changing technology, including mobile applications, is shifting where compliance investigations are focusing efforts to monitor and analyze high-risk activity, including cross border considerations.

Jennifer Joyce, CFE, CIPM, *Senior Manager, Forensic & Integrity Services, EY; Washington, DC*

Jeffrey Salling, JD, *Global Director of eDiscovery, Novartis, Adjunct Professor, The John Marshall Law School; East Hanover, NJ*

Michael C. Zogby, JD, *Trial Partner, Deputy Practice Leader, and Co-Chair, Life Sciences Litigation Team, Faegre Drinker; Florham Park, NJ*

Edward Glynn, MBA, *Principal, Forensic & Integrity Services, EY; Iselin, NJ (Moderator)*

11:00 am Transition Break

MINI SUMMIT 13: Applying Automation to Risk Management: Fundamentals of a Successful HCP Engagement Strategy and Platform Implementation

10:00 am Welcome, Introductions, Discussions and Q&A

Hear from in house experts on how they have accelerated their HCP engagement strategies through automation

- Understand the problem statement, devise a plan to address
- Obtain buy in for your vision
- Decide where automation makes sense in your current process
- Identify key risk areas to address
- Understand HCP engagement lessons learned from experts
- Learn how automation is beneficial to your compliance organization

Deb Horwitz, JD, *Global Director of HCP Compliance, Merz North America; Raleigh, NC*

Karen Lowney, CIA, *Head of the Office of Ethics and Compliance, Sun Pharma; Princeton, NJ*

Ryan Macpherson, JD, *Senior Director, Chief Compliance Officer, Dexcom; San Diego, CA*

Michael T. O'Connor, MS, *Chief Product Officer, Porzio Life Sciences, LLC; Former Global Head Compliance and Ethics Operations, Alexion Pharmaceuticals, Inc.; New York, NY (Moderator)*

11:00 am Transition Break

INTERACTIVE WORKSHOP IV: Hot Topics In Medical Device

10:00 am Moderated Interactive Discussion

Role of compliance in medical device given the often complex, fragmented business model. Evolution of external expectations related to M&A and best practices. The importance of a proactive model focused on ethical culture.

Sujata Dayal, JD, *Vice President & Global Chief Compliance Officer, Medline Industries, Inc., Chair Chief Compliance Officer Group, AdvaMed; Chicago, IL (Discussion Co-Lead)*

Perri Pomper, JD, *Senior Director - Compliance Governance & Strategy, Stryker, Allendale, NJ (Discussion Co-Lead)*

11:00 am Transition Break

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP IV

MINI SUMMIT 14: Pharma Congress Regulatory Updates and Industry Shifts

11:15 am Welcome, Introductions, Discussions and Q&A

FDA regulatory oversight and enforcement has never been so front and center as it is currently in the COVID-19 environment. Pharmaceutical and medical device companies work diligently to navigate and adhere to their regulatory compliance obligations, stay abreast of and adapt to changes in the laws, regulations and guidance and promptly address any enforcement issues that may arise. This panel will draw insights and updates from attorneys who work in the FDA regulatory space, including in-house attorneys from a pharmaceutical company and medical device company, focusing on shifts in the industry prior to and as a result of the pandemic, the compliance environment, and the impact and potential impact on the industry.

Tina Beamon, JD, *Chief Compliance Officer, MEI Pharma; New York, NY*

Christine Hunt, MSPH, JD, *Associate Chief Counsel, Office of the Chief Counsel, Food and Drug Administration; Washington DC*

Na'Im Moses, MHSA, JD, *Executive Director, Regulatory Law, Alcon Vision, LLC; Former Regulatory Counsel, FDA; Fort Worth, TX*

Tiffany Humphries, JD, *Senior Associate, Baker & McKenzie LLP; Former Associate Chief Counsel, FDA; Washington, DC (Moderator)*

12:15 pm Break

MINI SUMMIT 15: Optimize Your Compliance Training: A Practical Approach to the DOJ's Guidance

11:15 am Welcome, Introductions, Discussions and Q&A

During this session, the panelists will provide practical approaches for aligning your compliance training with guidance from the Department of Justice as outlined in their publication Evaluation of Corporate Compliance Programs (June 2020). We will examine the obvious (e.g., training based on risk) as well less-obvious factors that should be considered when devising compliance training plans.

We will share practical examples to give you real-world guidance that you can apply immediately no matter the budget and internal capabilities at your company. Key takeaways will include:

- Guidance for analyzing your compliance training needs.
- The effects of the forgetting curve on compliance – and how to overcome these effects.
- How to employ the Risk-Frequency Framework to make compliance training decisions.
- How to apply the Compliance Training Portfolio model to optimize your time and budget.
- Practical ways to evaluate the effectiveness of your training.

Please join us for this dynamic and interactive session!

Katrina Church, JD, *Senior Vice President, Chief Compliance Officer, Bioventus, Durham, NC*

Matt Hill, JD, *Vice President, Ethics & Compliance, Novo Nordisk, Inc.; Former Senior Counsel—Regulatory Law, Johnson & Johnson; Cherry Hill, NJ*

Karen Snyder, JD, *Associate Director, Compliance, Ironwood Pharmaceuticals; Braintree, MA*

Daniel O'Connor, *Senior Vice President, PharmaCertify; New York, NY (Moderator)*

12:15 pm Break

MINI SUMMIT 16: Patient Assistance Programs

11:15 am Welcome, Introductions, Discussions and Q&A

In this session we explore recent developments for patient assistance and support programs. Pharmaceutical and biotech manufacturers implement a variety of patient support programs to assist patients secure access to their prescribed therapies. The session will explore recent legal developments, enforcement actions, and practical challenges in implementing these programs. We will explore developments related to manufacturer copay assistance programs for commercially-insured patients, as well as recent legal actions and enforcement settlements related to manufacturer donations to independent charitable foundations who provide patient support. The panel will also discuss the implications of three recent positive advisory opinions from the Office Of Inspector General for the Department of Health and Human Services related to manufacturer support of patient travel and lodging in connection with the administration and post-administration monitoring of innovative therapies. Finally, we will touch on issues related to patient assistance programs that provide free product to financially needy patients.

Noor Haq, CCEP, MS, MBA, CIA, *Executive Director, Compliance, Amgen; Oak Park, CA*

Michael Hercz, JD, *Senior Vice President and General Counsel, Sentynl; Former Vice President, Law & Chief Compliance Officer, Victory Pharma; Former Executive Director, Enterprise Risk Management, Amgen; Solana Beach, CA*

Kevin Ryan, MS, JD, *Vice President, Chief Compliance Officer, ACADIA; Former Senior Director, Ethics & Compliance, Novo Nordisk; San Diego, CA*

Eliza Andonova, JD, *Partner (Healthcare Regulatory), Hogan Lovells; Washington, DC (Moderator)*

12:15 pm Break

MINI SUMMIT 17: Changing Dynamics of State Price Transparency and Reporting Requirements

11:15 am Welcome, Introductions, Discussions and Q&A

The State price transparency landscape has evolved. Currently, 20 states have state price transparency reporting requirements, there are 58 pending bills around the country and state legislatures regarding these issues, and there are eight bills pending in Congress now. John Oroho, Katherine and Donna will review the different types of price transparency and price reporting requirements (i.e., periodic, quarterly, and annual reports) as well as reporting focused on price increases above a certain trigger point. In addition, some states require price notification on branded products and justification for the price and/or price increase. The panel addresses concerns raised on publishing this information and whether it is considered proprietary or trade secrets. What's next and should we be concerned this will follow the path of sunshine reporting.

Katherine Chaurette, *Vice President Healthcare Law & Compliance, Blueprint Medicines, Suffolk County; Cambridge, MA*

Donna White, CCEP, *Vice President, Compliance, Chiesi, USA; Cary, NC*

John Patrick Oroho, JD, *Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC, Principal, Porzio, Bromberg & Newman; Morristown, NJ (Moderator)*

12:15 pm Break

MINI SUMMIT 18: The Evolving Role of Compliance in Environmental Social & Governance (ESG) Initiatives

11:15 am Welcome, Introductions, Discussions and Q&A

Organizations are tackling an expanding set of responsibilities as environmental, social, and governance (ESG) becomes a critical priority within US life sciences companies. Legislation and enforcement signals across the globe are driving ESG action plans. Hear from our panel comprised of CCO, outside counsel and forensic advisory perspectives on internal approaches, enforcement postures and actions your teams can take to stay ahead of this critical, and expanding issue.

Dixie L. Johnson, MBA, JD, *Partner, Securities Enforcement and Regulation/Special Matters and Government Investigations, King & Spalding LLP; Washington, DC*

Chris Matteson, *Senior Manager, Forensic & Integrity Services, EY; Philadelphia, PA*

Lori Queisser, *Senior Vice President, Global Chief Compliance Officer, Teva Pharmaceuticals; Parsippany, NJ*

Chandan Sarkar, MS, JD, *Principal, Forensic & Integrity Services, EY; New York, NY (Moderator)*

12:15 pm Break

INTERACTIVE WORKSHOP V: How to Establish Risk Tolerance in an Emerging Organization

11:15 am Moderated Interactive Discussion

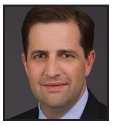
Emerging organizations face novel compliance challenges and risks. In this interactive workshop you'll join experienced thought leaders to discuss common archetypes, dive into what drives risk and risk tolerance, and share best practices for educating about and mitigating risks.

Terra Buckley, JD, *Vice President, Head of Compliance Advisory Services, MedPro Systems; Vice President, Head of Compliance, Mesoblast, Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Mount Arlington, NJ (Discussion Lead)*

12:15 pm Break

OPENING PLENARY SESSION

1:00 pm Welcome and Introduction:



Joe Zimmerman, *Vice President, Chief Compliance Officer & Privacy Officer, Ferring Pharmaceuticals, Inc., Chair, Pharmaceutical Compliance Forum; Parsippany, NJ (PCF Chair)*

1:15 pm Keynote: Fireside Chat with Giovanni Caforio

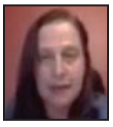
Giovanni Caforio, MD, *Chairman and Chief Executive Officer, Bristol Myers Squibb; New York, NY*

Interviewed by:
Adam Dubow, JD, *Senior Vice President, Chief Compliance and Ethics Officer, Bristol Myers Squibb; Princeton, NJ*

1:45 pm Keynote: OIG Update

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

2:30 pm US DOJ Keynote



Jamie Yavelberg, JD, *Director, Fraud Section, Civil Division, US Department of Justice; Washington, DC*

Interviewed by:
Gejaa T. Gobena, JD, *Partner, Hogan Lovells; Former Deputy Chief, Fraud Section, Criminal Division; Former Trial Attorney, Civil Division, Fraud Section, US Department of Justice; Washington, DC (Moderator)*

3:00 pm Break and Visit Virtual Exhibit Hall

3:15 pm

Response to OIG Special Fraud Alert and PhRMA and AdvaMed Code Update

Meenakshi Datta, JD, *Partner and Global Co-leader, Healthcare Practice, Sidley Austin LLP; Washington, DC*

Sujata Dayal, JD, *Vice President & Global Chief Compliance Officer, Medline Industries, Inc.; Former PCF Co-chair; Chicago, IL*

Jennifer McGee, JD, *Senior Vice President and Global Chief Compliance Officer, Otsuka America Pharmaceutical Inc.; Rockville, MD*

Nancy Schwalje Travis, MIA, *Vice President, Global Compliance and Governance, AdvaMed; Former Deputy Director, Office of Economic Policy, Asia-Pacific Bureau, US Department of State; Washington, DC*

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

Justin Will, JD, *Global Commercial Compliance Consulting, & Managed Services Practice Leader, IQVIA; Former Senior Compliance Officer, North America & EMEA, Arthrex; Former Regional Compliance Officer, Americas, bioMérieux; Philadelphia, PA (Moderator)*

4:15 pm

Back to the Future: Marking the 20th Anniversary of the TAP Case—the Compliance Case that Forever Changed the World of Pharmaceutical Sales and Marketing Practices—Applying Key Lessons Today That Have Stood the Test of Time

L. Stephan Vincze, JD, LLM, MBA, *President & Chief Executive Officer, TRESTLE Compliance, LLC., Author, "Winning with Compliance" —How To Inspire & Motivate Compliance To Propel Commercial Growth; Former Vice President, Ethics & Compliance Officer, TAP Pharmaceuticals; Boston, MA*

4:30 pm

Annual Chief Compliance Officer Fireside Chat

Ann E. Beasley, JD, *Chief Compliance Officer, Zai Lab; Former Director, Life Sciences, Governance, Risk & Compliance, Guidehouse; Former Senior Vice President, Chief Compliance Officer, Biogen; Boston, MA*

Shefali Kothari, JD, *Vice President, Chief Compliance Officer (US), Novartis; East Hanover, NJ*

Angela Main, JD, *Senior Vice President, Global Chief Compliance Officer & Associate General Counsel, Asia Pacific, Zimmer Biomet; Washington, DC*

Kristin Rand, JD, MA, *Head, Corporate Compliance and Global Risk Officer, Moderna; Former Vice President and Compliance Officer, Seattle Genetics; Cambridge, MA*

Latarsha Stewart, JD, MS, *Vice President, Head of Compliance, Servier Pharmaceuticals; Former Head of Compliance, Global Oncology Business Unit, Takeda Oncology; Boston, MA*

Tom Gregory, *Partner, Forensic & Integrity Services, EY; Atlanta, GA (Moderator)*

5:30 pm

Day II Recap & Adjournment

Joshua Marks, JD, *Vice President, Chief Ethics & Compliance Officer, Boehringer Ingelheim; Ridgefield, CT*

(All Day II sessions available on demand)

AGENDA DAY III: THURSDAY, NOVEMBER 4, 2021

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP V

Welcome by:
Indrani Franchini, JD, *Co-chair, Pharmaceutical Compliance Forum; Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

MINI SUMMIT 19: SEC Compliance Update: Managing Material Non-Public Information

10:00 am Welcome, Introductions, Discussions and Q&A

Pharmaceutical and medical device companies remain a significant focus for the US Securities and Exchange Commission. A life sciences company's treatment of material non-public information, as a disclosure issue and from a securities trading standpoint, can present significant potential liability exposure and reputational risks. In this session, we will consider MNPI from a variety of aspects: including determinations of materiality, ongoing and transactional disclosure considerations, insider trading policies and procedures, current thinking on 10b5-1 plans. And what happens when it all goes wrong.

Carol B. Stubblefield, JD, LLM, *Partner, Baker & McKenzie LLP; New York, NY*

Scott A. Thompson, JD, *Co-Acting Regional Director, Philadelphia Regional Office, United States Securities and Exchange Commission; Philadelphia, PA*

Amy J. Greer, JD, *Co-Chair, North America Financial Regulation and Enforcement Practice, Baker & McKenzie LLP; Former Regional Trial Counsel (Philadelphia), US Securities and Exchange Commission; New York, NY (Moderator)*

11:00 am Transition Break

MINI SUMMIT 20: Improving Training and Measuring Effectiveness: A Case Study

10:00 am Welcome, Introductions, Discussions and Q&A

As compliance professionals, we are required to train our organizations in a way that reflects the effectiveness of our compliance programs. We ourselves may question that effectiveness while conducting an investigation or reading a communication written by a trained member of our organization. Join us as we explore a case study addressing the importance of measuring employee knowledge, and getting the most out of just-in-time training. In this session, we will cover:

- Ensuring training is "right sized" for the audience – duration, level of experience etc.
- Developing training that appropriately addresses the areas of risk faced by the organization
- The importance of measuring knowledge, understanding, and training effectiveness
- Identifying needs for supplemental training and resources based on the knowledge employees display

Aurea Alexander, JD, *Senior Director & Head, Global Oncology Business Unit, Ethics & Compliance Advisory, Takeda Oncology; Former Compliance Business Partner, Patient Services, Global Compliance & Risk Management, Shire; Boston, MA*

Carla-Marie Ulerie, JD, CFE, CRCMP, MBA, *Director, Potomac River Partners; Washington, DC (Moderator)*

11:00 am Transition Break

MINI SUMMIT 21: Interactions with Health Care Professionals

10:00 am Welcome, Introductions, Discussions and Q&A

In this session industry leaders discuss the changing landscape of interacting with HCPs by exploring different perspectives from panelists representing key areas across the business who interact with HCPs. On today's panel, we have representatives from medical affairs, legal and compliance, and compliance operations.

Kimberly Ford, MBA, JD, *Vice President, Compliance Americas, Smith+Nephew; Former Senior Director US Compliance Programs; Memphis, TN*

Sharon Muscato, *Director, Global Compliance Operations, Moderna; Former Director, Transparency & Compliance Operations, Alexion Pharmaceuticals, Inc.; Cambridge, MA*

Holly Schachner, MD, *Chief Medical Officer, DoubleRainbow Biosciences; Former Senior Vice President, Clinical Development & Therapeutic Area Head, MyoKardia; New York, NY*

Regina Alvarado, *Principal, US Compliance Consulting Lead, IQVIA; Plymouth Meeting, PA (Moderator)*

11:00 am Transition Break

MINI SUMMIT 22: Future-Proofing Your Compliance Program with Data Analytics and Automation

10:00 am Welcome, Introductions, Discussions and Q&A

In the wake of new and evolving ABAC and healthcare compliance risks, and the DOJ's updated compliance guidance, organizations are increasingly looking to leverage the power of data analytics and automation within their own compliance programs. Featuring an expert panel from Lextegrity, Alexion, Stryker, Vertex and Bristol Myers Squibb, this session will offer a deep-dive into how several companies have approached this challenge. They will explain:

- What motivated them to embrace and adopt a data-driven approach
- Their approach and how to get started
- How they communicated the benefits and business case to their organization
- Future state and opportunities for improvement

Paul Ham, EdM, JD, *Senior Director, Office of Business Integrity and Ethics, Vertex; Boston, MA*

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

Piyush Sharma, JD, *Senior Vice President, Head of Compliance, Alexion Pharmaceuticals, AstraZeneca Rare Disease; New Haven, CT*

Sapan Singh, MBA, *Senior Director, Compliance Monitoring & Analytics, Stryker; Mahwah, NJ*

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

11:00 am Transition Break

MINI SUMMIT 23: Qui Tam/Whistleblower Update

10:00 am Moderated Interactive Discussion

The Justice Department recovered over $1.8 billion in False Claims Act settlements and judgments last year with the largest recoveries coming from the pharmaceutical and medical device industry. Whistleblowers played a critical role in those recoveries and continue to identify new and evolving theories for criminal and civil investigation and enforcement actions. Join us for a moderated interactive discussion featuring updates on 2021 whistleblower actions and perspectives from relator's counsel, former and current federal prosecutors and defense counsel concerning trends for 2022. Topics will include:

- Recent developments in Anti-Kickback Statute law
- Anti-Kickback Statute horizon spotting:
  - free genetic testing;
  - medical device royalty payments;
  - consulting payments; and
  - price-fixing.
- Admissions, denials, and silence in FCA settlement agreements
- Agency guidance: the Brand and Garland Memo

Danielle Corcione, JD, *Practice Group Leader, White Collar & Government Investigations Group, Chiesa Shahinian & Giantomasi PC; Former Assistant United States Attorney, Criminal Division, US Attorney's Office for the District of New Jersey; West Orange, NJ*

Augustine Ripa, JD, *Trial Attorney, U.S. Department of Justice; Washington, DC*

Maria R. Durant, JD, *Partner and Office Managing Partner, Hogan Lovells; Boston, MA (Co-moderator)*

Gregg Shapiro, JD, *Partner, Newman & Shapiro; Former Assistant US Attorney and Chief, Affirmative Civil Enforcement Unit, US Attorney's Office, District of Massachusetts, US Department of Justice; Boston, MA (Co-moderator)*

11:00 am Transition Break

INTERACTIVE WORKSHOP VI: Evolution of Ethics & Compliance

10:00 am Moderated Interactive Discussion

Participate in an active discussion on the future of health care compliance. Benchmark with colleagues and join a moderated discussion, including:

- How are the roles and responsibilities of compliance changing and expanding?
- What role should compliance play in an organization's DEI efforts?
- What is the impact of evolving business models on compliance?
- How does patient-focused healthcare change the focus of compliance professionals?
- How will recent legal developments influence company compliance priorities and/or operations?

Jacob Elberg, JD, *Associate Professor, Seton Hall University School of Law; Former Chief, Health Care & Government Fraud Unit, and Assistant US Attorney US Attorney's Office, District of New Jersey; Newark, NJ (Discussion Co-Lead)*

Richard Liner, JD, *Senior Assistant General Counsel, Bayer; Whippany, NJ (Discussion Co-Lead)*

Daniel Spicehandler, JD, *Vice President Compliance - Commercial Divisions, Stryker; Somerset, NJ (Discussion Co-Lead)*

11:00 am Transition Break

MINI SUMMITS/INTERACTIVE WORKSHOP GROUP VI

MINI SUMMIT 24: Comedy & Compliance! Creating a Speak Up/Listen Up Culture With Entertainment

11:15 am Welcome, Introductions, Discussions and Q&A

"Ethics" and "Compliance" are often toxic words to employees. The traditionally boring, bloated training methods exacerbate the problem. Why? People don't speak up to ask questions and report concerns if they are annoyed, apathetic or afraid. People won't go to the office of "no." When it comes to ethics, compliance and speaking up, "culture eats training for breakfast." E&C's reputation matters. This program will focus on strategies and techniques to generate a speak up / listen up culture and how entertaining training and comms can help.

Regina Gore Cavaliere, JD, *Former Chief Ethics and Compliance Officer, Esperion; New York, NY*

Nick Gallo, *Chief Servant, Co-Chief Executive Officer, ComplianceLine; Host & Creator, The Ethics Experts; Charlotte, NC*

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

Ronald Feldman, MBA, *President & Creative Director, L&E Creative; Former Product Director, RealBiz Video Communications, Second City Works; Chicago, IL*

12:15 pm Break

MINI SUMMIT 25: Trends in FDA Advertising/Promotion Enforcement: Know the Risk Areas

11:15 am Welcome, Introductions, Discussions and Q&A

Join Nikki Reeves, Partner, King & Spalding LLP and industry leaders on recent trends in FDA advertising and promotion enforcements, including:

- Boxed Warning Products: Top Targets?
- Repeat Offenses - Take Heed When Warned of Regulatory Risks (i.e., Advisory comments, Enforcement letters, Other communications)
- BadAd Program - Increased scrutiny by healthcare providers
- Ongoing Focus on Investigational Drugs
- Risk Presentation: OPDP's Highest Priority
- Risk Disclosure in Broadcast TV and Radio Ads, Spokespersons and Influencers

Casandra George, JD, *Deputy General Counsel, Ocular Therapeutix, Inc.*

Gregory S. Moss, LLB, *Executive Vice President, General Counsel and Corporate Secretary, Chief Compliance Officer, Kadmon Holdings; New York, NY*

Nikki Reeves, JD, *Partner, King & Spalding LLP; Washington, DC (Moderator)*

12:15 pm Break

MINI SUMMIT 26: Interactions with Patients

11:15 am **Welcome, Introductions, Discussions and Q&A**

Join the panel discussion on interactions with patients including:

- The rise in social media and PATIENT INFLUENCERS being used in this space, which poses a kickback risk when you engage patients.
- PATIENT FAIR MARKET VALUE considerations for their participation in Ad Boards, etc. Most companies have landed on some basic rates, but then there's this question of if they're speaking on a company's behalf, should they be paid more. Should there be a tiering for patients?
- One key question is how you would engage a patient to do disease awareness (sharing info on their own experience). own experience to kind of do a disease campaign.

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

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

Michael Joachim, JD, *Head of Ethics & Business Integrity, Specialty Care, Sanofi Genzyme; Cambridge, MA*

Jeff Lemay, JD, *Executive Director, North America Compliance Business Partnering, Jazz Pharmaceuticals; Former Director, U.S. Healthcare Compliance—Bone and Cardiovascular BU, Gov Affairs/Policy and GHE, Amgen; Carlsbad, CA*

Mario Prohasky, *Principal, Global Commercial Compliance Consulting, IQVIA; Philadelphia, PA*

12:15 pm **Break**

MINI SUMMIT 27: Hot Topics in Research and Development Compliance Programs

11:15 am **Welcome, Introductions, Discussions and Q&A**

Mahnu Davar and industry leaders in Research & Development discuss latest trends including:

- Clinicaltrials.gov/ Trial registration
- Patient Advocacy Org Interactions
- Fair Market Value in R&D
- COVID-19 issues
- Biobanking

Masha Chestukhin, MSJ, *Associate Director, Compliance Officer R&D, IA, FMV, Sanofi Genzyme, Former Senior Manager NA Compliance, Sanofi; Jamaica Plain, MA*

Paul M. Quinones, JD, MBA, *Vice President, Corporate Counsel - Development Legal, Incyte Corporation; Wilmington, DE*

Mahnu Davar, MBe, JD, *Partner, Arnold & Porter Kaye Scholer LLP, Adjunct Professor of Law, University of Pennsylvania Law School; Washington, DC (Moderator)*

12:15 pm **Break**

INTERACTIVE WORKSHOP VII: Taking the Fear Out of Data Analytics

11:15 am **Welcome, Introductions, Discussions and Q&A**

In this interactive session, you will have the opportunity to speak with your peers about the realities of building and maintaining a data analytics program. Hosted and attended by leading compliance and data analytics experts, you're invited to contribute your experience, ask questions and discuss ideas in a collaborative setting that aims to take the fear out of data analytics.

Paul Ham, EdM, JD, *Senior Director, Office of Business Integrity and Ethics, Vertex; Boston, MA*

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

Sapan Singh, MBA, *Senior Director, Compliance Monitoring & Analytics, Stryker; Mahwah, NJ*

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

12:15 pm **Break**

CLOSING PLENARY SESSION

1:00 pm **Welcome and Introduction**

Daniel Spicehandler, JD, *Vice President Compliance - Commercial Divisions, Stryker; Somerset, NJ*

1:15 pm **Medical Device Keynote**

Antoinette Gawin, MSc, *President and Chief Executive Officer, Terumo BCT; Chair, AdvaMed Board Ethics and Healthcare Compliance Committee; Denver, CO*

1:45 pm **Keynote: "Wrighting" the Ship with Operational Integrity**

Tim Wright, *Chief Executive Officer, MiMedx; Marietta, GA*

Interviewed by:
Mark P. Graves, JD, MBA, *Senior Vice President and Chief Compliance Officer, MiMedx; Former Director, Global Patient Experience & Value, UCB; Former Senior Director, Pharmaceutical Products Division, Abbott; Marietta, GA*

2:15 pm **Keynote Fireside Chat with Rady Johnson**

Rady Johnson, JD, *Executive Vice President and Chief Compliance, Quality & Risk Officer, Pfizer Inc.; Westport, CT*

Interviewed by:
Indrani Franchini, JD, *Co-chair, Pharmaceutical Compliance Forum; Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

3:15 pm **Break**

3:30 pm **FDA Keynote**

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

4:00 pm **AUSA Roundtable**

Matthew J. Lash, JD, *Assistant Director, Consumer Protection Branch, Civil Division, US Department of Justice; Washington, DC*

Abraham George, JD, *Assistant US Attorney, US Attorney's Office, District of Massachusetts, US Department of Justice; Boston, MA*

Nicholas Grippo, JD, *Chief, Criminal Division, US Attorney's Office, District of New Jersey, US Department of Justice; Trenton, NJ*

John T. Bentivoglio, JD, *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud, and Chief Privacy Officer, US Department of Justice; Washington, DC (Moderator)*

4:30 pm **Ethical Interactions with Patient Advocacy Groups**

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

Jill Dailey, JD, *Vice President and Chief Compliance Officer, Incyte; Former Assistant General Counsel and Asia Pacific Compliance Lead, Pfizer; Wilmington DE*

Michael Hercz, JD, *Senior Vice President and General Counsel, Sentynl; Former Vice President, Law & Chief Compliance Officer, Victory Pharma; Former Executive Director, Enterprise Risk Management, Amgen; Solana Beach, CA*

Elizabeth Jobes, JD, *Senior Vice President, Global Chief Compliance Officer, Amryt Pharma plc; Former Senior Vice President, Chief Compliance Officer North America, EMD Serono; Former Head of Corporate Compliance and Legal Counsel, Spark Therapeutics; Cambridge, MA*

Gary F. Giampetruzzi, JD, *Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigation, Pfizer; Washington, DC (Moderator)*

5:15 pm **Compliance During and After a Crisis**

Cindy Cetani, LPEC, *Chief Integrity & Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis International AG; Richmond, VA*

Margaret Feltz, MA, JD, *Vice President, Ethics & Compliance, Purdue Pharma LP; Stamford, CT*

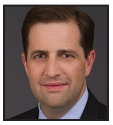
Christine Gordon, JD, *Chief Compliance Officer, Olympus Corporation of the Americas; Center Valley, PA*

Mark P. Graves, JD, MBA, *Senior Vice President and Chief Compliance Officer, MiMedx; Former Director, Global Patient Experience & Value, UCB; Former Senior Director, Pharmaceutical Products Division, Abbott; Marietta, GA*

Eric Siegel, MBA, JD, *Vice President, Head of Compliance US, Idorsia Pharmaceuticals US Inc.; Former Chief Compliance Officer, Jazz Pharmaceuticals; Former Senior Investigator, Office of the Inspector General, City of Philadelphia; Philadelphia, PA*

Paul Silver, *Principal, Regulatory & Compliance Life Sciences Leader, Deloitte & Touche LLP; Atlanta, GA (Moderator)*

6:15 pm **Day III Recap & Adjournment**



Joe Zimmerman, *Vice President, Chief Compliance Officer & Privacy Officer, Ferring Pharmaceuticals, Inc., Chair, Pharmaceutical Compliance Forum; Parsippany, NJ (PCF Chair)*

(All Day III sessions available on demand)

AGENDA DAY IV: FRIDAY, NOVEMBER 5, 2021

INDUSTRY ONLY BEST PRACTICES THINK TANK

Hosted by Pharmaceutical Compliance Forum

(Industry-only session for pharmaceutical and medical device industry ethics and compliance professionals and in-house counsel. Session not recorded.)

10:00 am **Welcome**

Indrani Franchini, JD, *Co-chair, Pharmaceutical Compliance Forum; Former Executive Vice President Chief Compliance Officer, Alexion Pharmaceuticals; New York, NY*

Anti-trust Admonition

John T. Bentivoglio, JD, *Partner, Skadden Arps LLP; Former Special Counsel for Healthcare Fraud and Chief Privacy Officer, US Department of Justice; Washington, DC*

10:10 am **Insights from a Former US Attorney, with Live Q&A**

Craig Carpenito, JD, *Partner, Special Matters and Government Investigations, King & Spalding; Former US Attorney for the District of NJ, US Department of Justice; New York, NY*

Margaret Sparks, JD, *Head of Compliance, Vaccines, North America Ethics and Business Integrity, Sanofi; Bridgewater, NJ (Moderator)*

10:45 am **Break**

11:00 am **Compliance Challenges in Operationalizing the Special Fraud Alert and Open Q&A**

Rore Middleton, JD, *Senior Director, Compliance and Privacy, Blueprint Medicines; Fairfield, CT*

Daniel Spicehandler, JD, *Vice President Compliance - Commercial Divisions, Stryker; Somerset, NJ*

Heather Young, JD, *Compliance Officer & Director, Olympus Corporation of the Americas; Center Valley, PA*

Joshua Marks, JD, *Vice President, Chief Ethics & Compliance Officer, Boehringer Ingelheim; Ridgefield, CT (Moderator)*

11:45 am **Interactive Discussion Groups/Breakouts:**

Keeping Up with the Frenzied Pace to Operationalize Your Compliance Program

Welcome by:

Donna White, CCEP, *Vice President, Compliance, Chiesi, USA, Co-chair, Pharmaceutical Compliance Forum; Cary, NC*

Hosted by PCF Co-Chairs

Ed Sleeper, MS, *Ethics and Compliance Officer, HutchMed International; Former Ethics and Compliance Officer, The Lipid Management Company; Bridgewater, NJ (Facilitator)*

12:30 pm **Congress Adjournment**