



15th Advanced Forum on

FCPA & **ANTI-CORRUPTION** For the Life Sciences Industry

April 14, 2021 (Eastern Daylight Time)
Virtual Conference



A Virtual Event Done Right



True Interaction and Q&A



1:1 Networking



Benchmark with Audience Polling



Best Practices & Hypotheticals

Government Speakers:



David Last Assistant Chief, FCPA Unit. Fraud Section, Criminal Division **U.S. Department of Justice**



Robert I. Dodge Assistant Director, FCPA Unit **U.S. Securities and Exchange Commission**



Bernard J. Cooney Assistant United States Attorney U.S. Attorney's Office, **District of New Jersey**

Associate Sponsors:





Expert Speakers Include:



Ash Agarwal Senior Director, Compliance Excellence & Transformation **Astellas Europe**



Parth Chanda Founder & CEO Lextegrity



Derek A. Cohen Partner **Goodwin Procter**



Jill Dailey Vice President and Chief Compliance Officer Incyte Inc.



Partner **Clifford Chance** Kathleen M. Hamann Partner

Megan Gordon



Marc Hennes Executive Director & Senior Litigation Counsel



Peter G. Jensen Global Chief Compliance Officer **Arthrex**



Kate Kiesel Global Health Care Compliance Officer LifeScan



Partner **Morrison & Foerster LLP** Mariana Kurlat

James M. Koukios



Senior Director, Anti-Corruption Program Office Lead



Joseph Mack Senior Assistant General Counsel, Compliance and Investigations Baver U.S.



Mona Peterson Rosow Sr. Director, Global Auditing & Monitoring Medtronic



Jessica S. Pill VP. Chief Compliance Officer **Boston Scientific**



David H. Resnicoff **Riley Safer Holmes & Cancila LLP**



Jennifer Saperstein **Covington & Burling LLP**



Robert N. Sikellis Vice President & Head of U.S. Litigation Novartis



William Simmons Head of Global Investigations: Associate Director, Ethics & Compliance



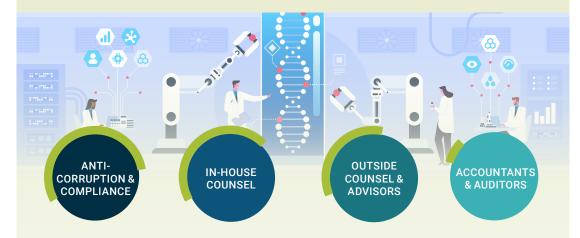
William B.F. Steinman Senior Partner Steinman & Rodgers LLP



Patrick Stokes Partner Gibson, Dunn & Crutcher LLP

Uniquely for the Life Sciences Community, Benchmark in 1:1, Small and Larger Groups.

WHO YOU WILL MEET:



Benefit from 1:1, large and smaller-group networking and benchmarking with senior in-house decision-makers from pharmaceutical, biotech and medical device companies, and CROs! Compare notes, share "war stories" and hear lessons learned for mitigating heightened global compliance risks.

Join the go-to event of the year for the life sciences industry!



Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

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For more information on **ACI's** CLE process for virtual events visit: www.americanconference.com/accreditation-instructions-for-virtual-attendance/

Join Us Virtually this April!

As the current global situation continues to unfold, we understand that it may not be possible to attend our events in person. At the same time, we also understand that collaboration is more vital than ever and for that, you can still rely on ACI to bring the industry together but in a different way. We are transforming quickly to ensure you can now connect virtually and continue to gain unparalleled access to market leading intelligence and to the facilitation of a global exchange of expertise.



What to Expect at Our New Virtual Conference



Enjoy an Easy to Use, Dynamic Online Platform



Engage with Attendees and Speakers in an Interactive Format



Immerse Yourself in Live Presentations ____ and Panel **Discussions**



Meet 1-on-1 with Your Fellow Attendees

Wednesday April 14, 2021 (EDT)

10:00

Opening Remarks from the Conference Co-Chairs



Mariana Kurlat Senior Director, Anti-Corruption Program Office Lead Pfizer



Jennifer H. Saperstein
Partner
Covington & Burling LLP

10:15 FCPA ENFORCEMENT IN THE LIFE SCIENCES ARENA

Emerging Liability Risks and New Enforcement Priorities Amid Covid-19



David Last
Assistant Chief,
FCPA Unit,
Fraud Section,
Criminal Division
U.S. Department
of Justice



Robert I. Dodge Assistant Director, FCPA Unit U.S. Securities and Exchange

Commission



Bernard J. Cooney Assistant United States Attorney U.S. Attorney's Office, District of New Jersey

Hear from an esteemed panel of DOJ and SEC representatives on key topics, including:

- The agencies' views on subsidiary liability in light of the Novartis settlement
- Deficiencies that led to the first FCPA recidivist in the pharma industry
- · Deterring improper influence over foreign healthcare providers through sponsorship and hospitality
- Fostering a culture of compliance and adapting your anti-bribery/corruption program to the pandemic context

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11:00

INTERACTIVE DISCUSSION - AUDIENCE POLLING

The Newest, Unwritten Rules for Third Party Due Diligence: How to Resolve the Most Industry-Specific Dilemmas



Kathleen M. Hamann
Partner
Pierce Atwood LLP



Jill Dailey
Vice President and
Chief Compliance Officer
Incyte Inc.

With over 90% of FCPA enforcement actions involving third parties, ensuring adequate oversight of distributors and foreign subsidiaries continues to be a critical concern for life sciences companies.

Test your knowledge on the most vexing grey areas of third party due diligence. You will engage in 2 hypothetical exercises – participate in anonymous polling or turn on your audio and video to share your perspective with fellow participants.

PART I: SUB-DISTRIBUTORS

 How companies are tackling ongoing internal supply chain and vendor management challenges that preceded the pandemic

- Particular risks facing drug and medical device companies distributing products in key high-risk jurisdictions: Russia, China, and Brazil
- Mitigating bribery risks associated with the distribution of valuable Covid testing products and vaccines
- Due Diligence: How far to go and how much is enough

PART II: FOREIGN SUBSIDIARIES

- What constitutes adequate FCPA diligence in mergers and acquisitions?
- To what extent are companies responsible for the conduct of foreign subsidiaries and ongoing oversight of these entities?
- Upgrading your compliance program to better police your subsidiaries post-Novartis

12:00 Break



12:30

SPECIAL INTERVIEW WITH NOVARTIS

Reflecting on the 2020 Settlement and a Reimagined Approach to Ethics & Compliance



Robert N. Sikellis Vice President & Global Head of Investigations Novartis



Marc Hennes Executive Director & Senior Litigation Counsel Novartis



James M.
Koukios
Partner
Morrison &
Foerster LLP

- Navigating a multijurisdictional investigation
- Effectively communicating compliance enhancements to enforcement authorities
- Organizing a global investigations function



1:00

Digital Transformation for Anti-Corruption: Leveraging Data Analytics, Automation and Machine Learning to Prevent and Detect FCPA Violations



Ash Aggarwal Senior Director, Compliance Excellence & Transformation Astellas Europe



Parth Chanda Founder & CEO Lextegrity



Kate Kiesel Global Health Care Compliance Officer LifeScan

- Implementing end-to-end anti-corruption spend controls, from third party due diligence and HCP/HCO engagements to continuous spend monitoring
- How digital tools can drive greater effectiveness and efficiency in your FCPA compliance program
- How companies are working to satisfy the DOJ's data analytics expectations using technology
- How technology can break down perennial data silos across multiple systems, functions and geographies



1:1 Peer-to-Peer Networking

2:00 Break

JOIN THE CONVERSATION 2:15

How to Measure the Effectiveness of Your Compliance Program: Industry-**Specific Considerations**



Joseph Mack Senior Assistant General Counsel, Compliance and Investigations Bayer U.S.



William Simmons Head of Global Investigations; Associate Director, Ethics & Compliance Lonza



Mona Peterson Rosow Sr. Director, Global Auditing & Monitorina Medtronic



MODERATOR David H. Resnicoff Partner **Riley Safer Holmes** & Cancila LLP

- What the DOJ's June 2020 guidance changes and how life sciences companies are complying with it
- Perspectives on designing and operationalizing a compliance program that can resist prosecutorial
- Assessing your compliance controls in an era of remote work
- How to evaluate your training and controls by means other than audits
- Ensuring that your program is aligned on paper and in practice

Turn on your audio and video during the latter part of the session to chat, compare notes, and share "war stories" with the speakers and fellow participants!

3:30 PUBLIC PROCUREMENT

Engaging with Foreign Governments and Providers Amid Covid-19: Special Considerations for the Sale of Medical Supplies and Vaccine Procurement



Derek A. Cohen Partner **Goodwin Procter**



Megan Gordon Partner **Clifford Chance**

The global pandemic has triggered unprecedented levels of negotiation with foreign governments. From Covid testing products to personal protective equipment, therapeutics, and vaccines, lack of access and critical need for these products creates fertile ground for bribery and corruption around the world. This session will address:

- · Anticipated scrutiny of emergency spending that did not follow regular public bidding procedures
- The implications of the bribery schemes that occurred in relation to the Covid response
- Challenges facing vaccine manufacturers, suppliers, and their procurement intermediaries as they balance the need for speedy distribution with compliance considerations

- Additional bribery risks facing vaccine companies as they compete for market share
- Operational challenges in countries with national healthcare systems, where there is heightened contact with government officials in sales and licensing
- Considerations for retaining sub-distributors and tender agents for assistance in winning tenders
- Overseeing interactions with customs officials seeking bribes in light of pandemic-induced financial pressures on government

4:15 Break

SPOTLIGHT ON CLINICAL TRIALS 4:30

Determining When (and When Not) to Proceed with Clinical Trials Abroad: Managing Unique, Evolving Bribery Risk Factors



Jessica S. Pill VP, Chief Compliance Officer **Boston Scientific**



William B.F. Steinman Senior Partner Steinman & Rodgers LLP

- What the Novartis settlement teaches us about FCPA liability resulting from clinical trials
- Developing processes to determine the legitimacy of and need for clinical trials
- How to go about bridging the legal/technical divide
- Mitigating bribery risks when engaging local doctors in your clinical trials

TEST YOUR KNOWLEDGE - AUDIENCE POLLING

The Nuances of Sponsorship, Hospitality, and Advisory Board Membership of Foreign Healthcare Providers: What Companies are Now Doing to Strengthen Compliance



Peter G. Jensen Global Chief Compliance **Arthrex**



Patrick F. Stokes Partner Gibson. Dunn & Crutcher LLP

Respond to panel questions confidentially in a user-friendly digital polling system. An effective way to compare your compliance and investigations practices to your peers across the globe!

- The impact of Covid-19 on the life sciences industry and practices for interacting with healthcare professionals and patient associations
- Responding to scrutiny over improper influence of healthcare providers through travel, gifts, entertainment - particularly in sponsorship of educational meetings and conferences
- Discerning when it is appropriate to retain a foreign healthcare provider for advisory services and compensate for their time
- Best practices for mitigating FCPA risk while staying on top of local legal requirements
- What level of due diligence is now required before outreach to an HCP?
- How companies are operationalizing controls around HCP conflicts of interest

6:00 **Conference Concludes**

Navigating the Virtual Conference

On Our HopIn Platform



The **Lobby** is your starting point...

iii View the Schedule

See What is 'Happening Now"

Reference Conference Materials

Accreditation Information

Check Out our Sponsors

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The **Sessions** area contains the majority of the conference programming and some networking events.

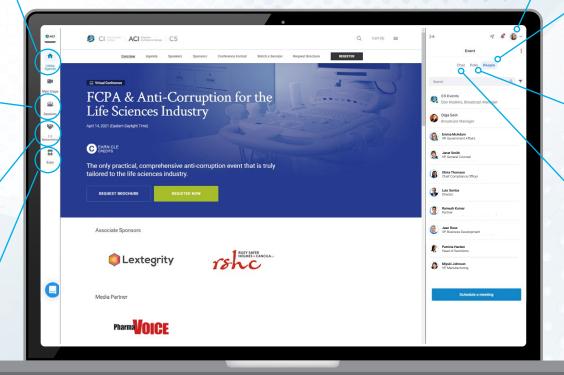
Here, you can attend live sessions, ask questions comment in the chat function, and take part in live polling.

The 1:1 Networking is a fast-paced opportunity to meet new people and expand your professional network.

Enter this area to be paired up at random with another attendee for a quick video connection.

Plan to visit the **Expo** often. It will be open before, during, and after the conference.

Use this opportunity to explore new products and services from leading providers as well meet with new and existing partners over video chat.



Maximize Your Conference Experience



Update your profile

Review your profile, upload a picture and connect your social media accounts to personalize your presence.



People tab

You can also engage with other attendees directly. Find a person in the attendee list to send a message and/or an invitation to a video chat.



Polling

Weigh in and seize the opportunity to benchmark with industry peers in real-time on leading issues.



Use the Chat feature

to engage with fellow attendees, speakers and sponsors.



Turn your camera on

for roundtable sessions, networking events and video chats for a more personal virtual connection.

Make Connections



Join scheduled "1:1

Networking" sessions. They are an interactive way to expand your network of peers.



Engage with solution providers of all kinds by visiting the "Expo" to watch video and live demonstrations and for face to face conversations.



Use the "People" tab to create new relationships and strengthen existing ones within your industry.

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