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# **WHITE COLLAR PERSPECTIVES: A DAY IN THE LIFE OF A CHIEF COMPLIANCE OFFICER IN THE LIFE SCIENCES INDUSTRY**

April 26, 2022

# Speakers

## Meredith S. Auten

- White Collar Partner in the Philadelphia office of Morgan, Lewis & Bockius LLP
- Practice emphasizes all aspects of defending criminal and civil government and regulatory agency investigations and litigation with a particular emphasis on defending False Claims Act investigations and litigation in the life sciences and healthcare space



## John J. Pease III

- White Collar Partner in the Philadelphia Office of Morgan, Lewis & Bockius LLP
- Over 20 years of experience as a federal prosecutor, defense attorney, and in-house counsel focusing on complex criminal and civil investigations and trials, including in FCPA and False Claims Act litigation



## Timothy J. Geverd

- Associate in the Philadelphia Office of Morgan, Lewis & Bockius LLP
- Practice focuses on civil and criminal investigations, including in False Claims Act litigation



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# Guest Speakers

## Jeffrey Cohen

- Chief Compliance Officer and Regulatory Counsel, Globus Medical
- Jeffrey is responsible for Corporate Compliance at Globus where he has established and manages Globus' domestic and international compliance program
- He also provides counsel to Globus regarding healthcare regulatory and legal matters and manages Globus' state and federal government affairs initiatives

## Jill Dailey

- Vice President and Chief Compliance Officer, Incyte
- Jill has a diverse range of pharmaceutical experience in compliance, product legal support, business development transactions and manufacturing in both the innovative and generic pharmaceutical space
- She has spent over 20 years as a legal and compliance professional in the pharmaceutical industry, having worked at both large and mid-sized companies prior to joining Incyte Corp as the Chief Compliance Officer in 2017

## Kathy Gaddes

- Executive Vice President and Chief Compliance Officer, AmerisourceBergen
- Kathy has extensive experience in governance, securities, finance and corporate matters
- Prior to being named to her current position, Kathy was Executive Vice President and Chief Human Resources Officer since 2016

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# Agenda




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- I. US Department of Justice Guidance on Components of Effective Compliance Programs
- II. Emerging Compliance Challenges and Developments
  - A. The “Great Resignation”
  - B. Third-Party Auditing and Monitoring
  - C. Trade Sanctions
  - D. Data Analytics





# **US Department of Justice Guidance on Components of Effective Compliance Programs**

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# DOJ Guidance for Effective Compliance Programs

- The “Principles of Federal Prosecution of Business Organizations” reflected in the Justice Manual set out factors for prosecutors to consider when investigating, making prosecution decisions, and negotiating plea and other agreements.
- Those factors include assessing “the adequacy and effectiveness of the corporation’s compliance program at the time of the offense, as well as at the time of a charging decision” and any remedial efforts the corporation undertook “to implement an adequate and effective corporate compliance program or to improve an existing one.”
- The United States Sentencing Guidelines also instruct to consider whether the corporation had an effective compliance program in place at the time of the misconduct in determining an appropriate criminal fine for a corporation.

# DOJ Guidance for Effective Compliance Programs

- Prosecutors do not use a “rigid formula” for assessing the effectiveness of corporate compliance programs.
- Prosecutors assess the effectiveness of corporate compliance programs on an individualized basis, considering the company’s size, the industry in which the company does business, the regulatory landscape of the industry, the company’s risk profile, and other factors.
- This assessment is guided by three “fundamental questions”
  - Is the compliance program well-designed?
  - Is the compliance program applied in good faith?
  - Does the compliance program work in practice?



# Is the Compliance Program Well Designed?

- Requires understanding the company's business, how the company has defined its risk profile, how the compliance program addresses those risks, and how the compliance program has evolved over time.
- Prosecutors scrutinize the effectiveness of a company's risk assessment and whether the company's compliance program has been designed to detect and address the types of misconduct that are most likely to occur in the company's line of business.
- Prosecutors also scrutinize whether compliance programs devote appropriate resources to high-risk activities and whether the company makes revisions to its compliance program in light of any lessons learned or failures to detect or prevent infractions.

# Is the Compliance Program Well Designed?

- There should be formal policies and procedures establishing ethical norms to which employees must adhere, including a code of conduct setting forth the company's commitment to compliance.
- There should be "appropriately tailored" compliance trainings and communications to ensure that the company's compliance policies and procedures are implemented and integrated into the company's culture.
- Prosecutors look for a channel through which employees can anonymously report suspected breaches of the company's compliance program as such reporting structures are a "hallmark" of a well-designed compliance program.
- There should be a mechanism for conducting "risk-based due diligence" on the company's third-party partners or vendors.

# Is the Compliance Program Applied in Good Faith?

- Prosecutors will ask whether the compliance program has sufficient resources and authority to “function effectively.”
- Key question for prosecutors is whether the company’s culture of compliance is “top down,” – i.e., whether the “company’s top leaders . . . set the tone” of compliance “for the rest of the company.”
- Prosecutors also ask whether compliance personnel act independently, including by ensuring that compliance personnel are sufficiently senior within the company, have sufficient resources to carry out their mission, and have independence from the company’s management (for instance, by having direct access/a direct reporting line to the board of directors).
- Prosecutors also assess whether the company has in place incentives to encourage compliance and disciplinary measures for any non-compliance.

# Does the Compliance Program Work in Practice?

- That misconduct might have occurred does not necessarily mean that the compliance program did not work or was not effective at the time that misconduct occurred.
- Prosecutors consider whether and how misconduct was detected, what resources were available to the company to investigate suspected misconduct, and “the nature and thoroughness” of any remedial efforts.
- Prosecutors also consider whether the compliance program “evolved over time to address . . . compliance risks” and whether the company conducted “an adequate and honest root cause analysis” to understand the cause of the misconduct and assess the need for any remedial efforts.
- “Hallmarks” of effective compliance programs that work in practice are monitoring and testing to facilitate continuous improvement, mechanisms to conduct timely and throughout investigations of suspected misconduct, and the conduct of “thoughtful” root cause analyses of misconduct.



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# EMERGING COMPLIANCE CHALLENGES AND DEVELOPMENTS



# Other Hot Topics on Life Sciences Compliance

- The “Great Resignation”
- Third Party Auditing and Monitoring
- Trade Sanctions
- Data Analytics



# Questions?

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# THANK YOU

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# Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

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To help keep you on top of developments as they unfold, we also have launched a resource page on our website at [www.morganlewis.com/topics/coronavirus-covid-19](http://www.morganlewis.com/topics/coronavirus-covid-19)

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to [subscribe](#) using the purple "Stay Up to Date" button.

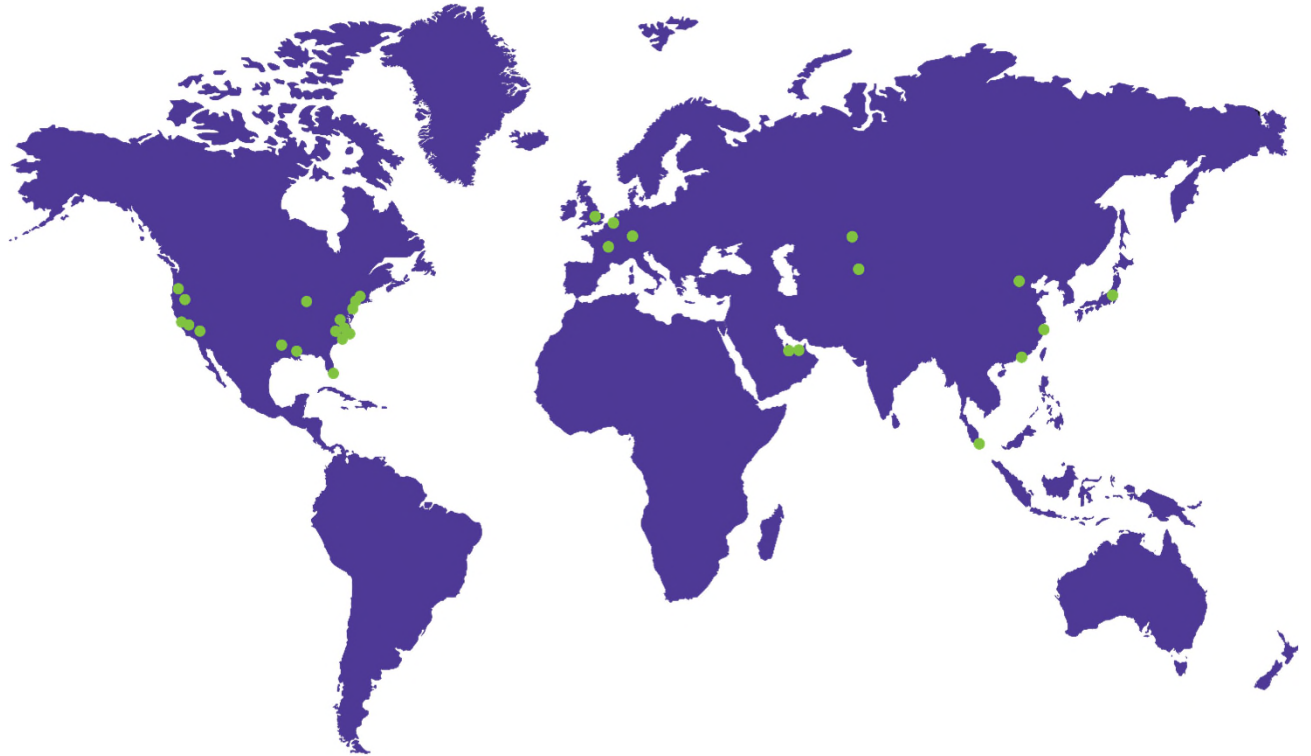


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