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FAST BREAK: **DOJ COMPLIANCE GUIDANCE**

Jonelle Saunders and Jake Harper
June 27, 2019



Agenda

- Background of DOJ Guidance on Compliance Programs
- Summary of key questions and factors DOJ will examine
 - (1) Is the Compliance Program well-designed?
 - (2) Is the Compliance Program being implemented effectively?
 - (3) Does the Compliance Program actually work in practice?
- Incentives to Companies
- Case Studies

DOJ Refreshes Guidance Document on Evaluation of Corporate Compliance Programs



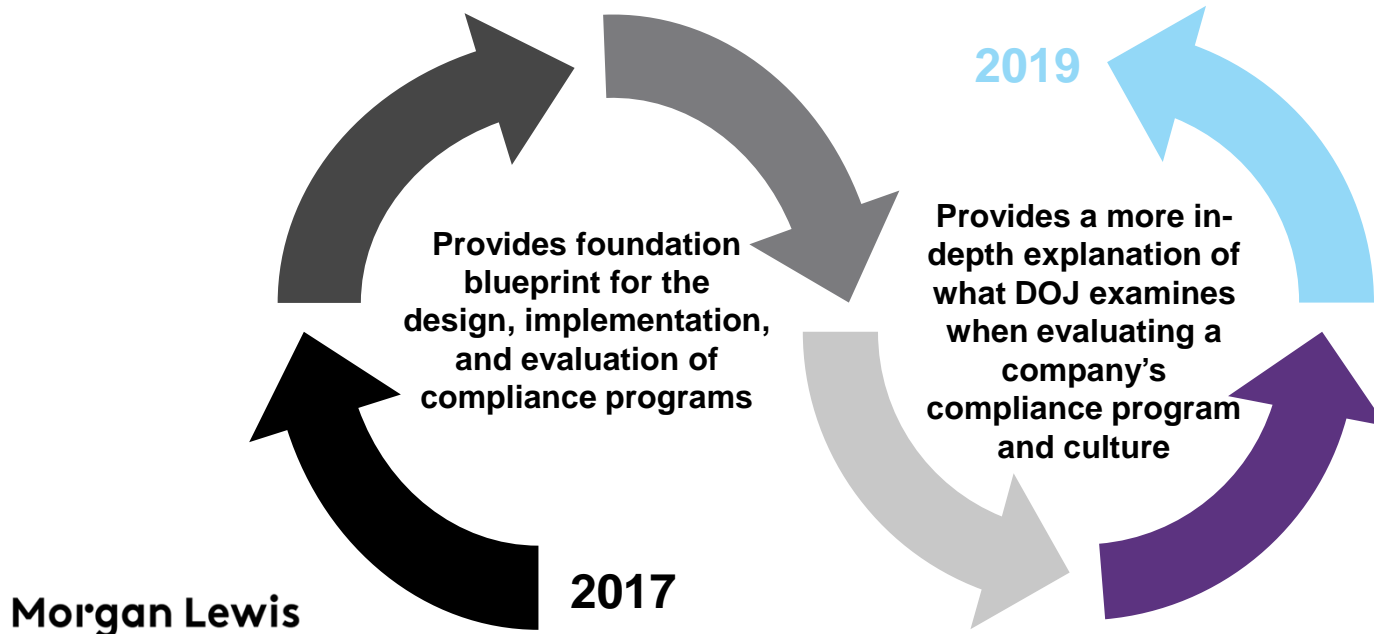
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Guidance from the U.S. Department of Justice (DOJ) Fraud Section provides useful insight into how it evaluates corporate compliance programs and can inform other criminal and civil enforcement actions. The DOJ Fraud Section has large corporate fraud and health care fraud units.

The 2019 Guidance was provided during a speech at the Ethics and Compliance Initiative 2019 Annual Impact Conference – training for DOJ prosecutors. This guidance is part of DOJ's broader effort to promote predictability and transparency in enforcement actions.

DOJ Refreshes Guidance Document on Evaluation of Corporate Compliance Programs

- The “Evaluation of Corporate Compliance Programs,” published on April 30, 2019, updates guidance previously released on February 8, 2017, and provides companies with increased clarity on the government’s evaluation of corporate compliance programs. The DOJ Fraud Section places effectiveness at the epicenter of its factors to be utilized when evaluating a company’s compliance program in the context of a criminal investigation

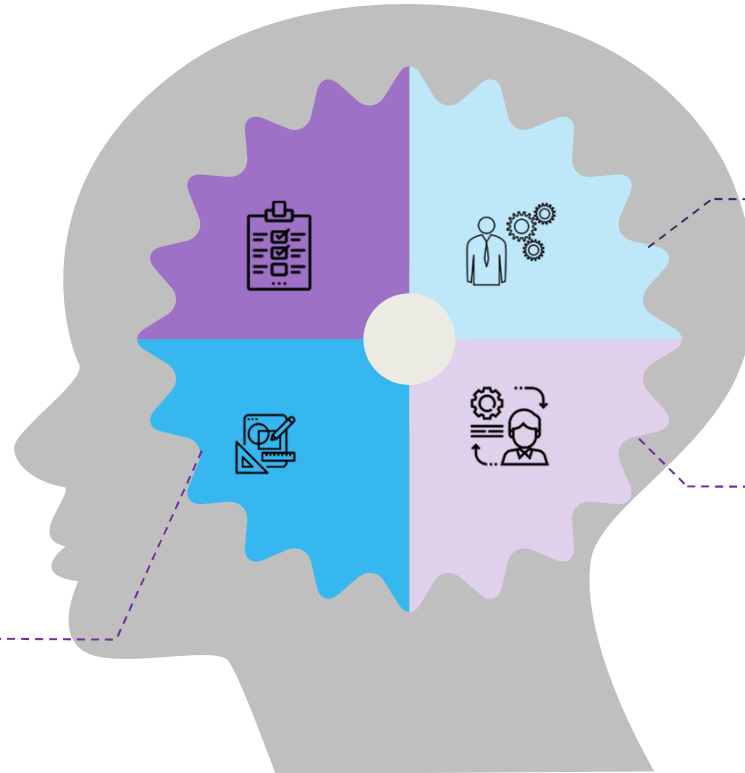


How does DOJ examine corporate compliance programs?

Prosecutorial Mindset

The 2019 guidance expands on the “fundamental questions” previously provided to prosecutors to evaluate whether a corporate compliance program is adequately identifying and preventing wrongful conduct. The 2019 Guidance is primarily structured around three questions:

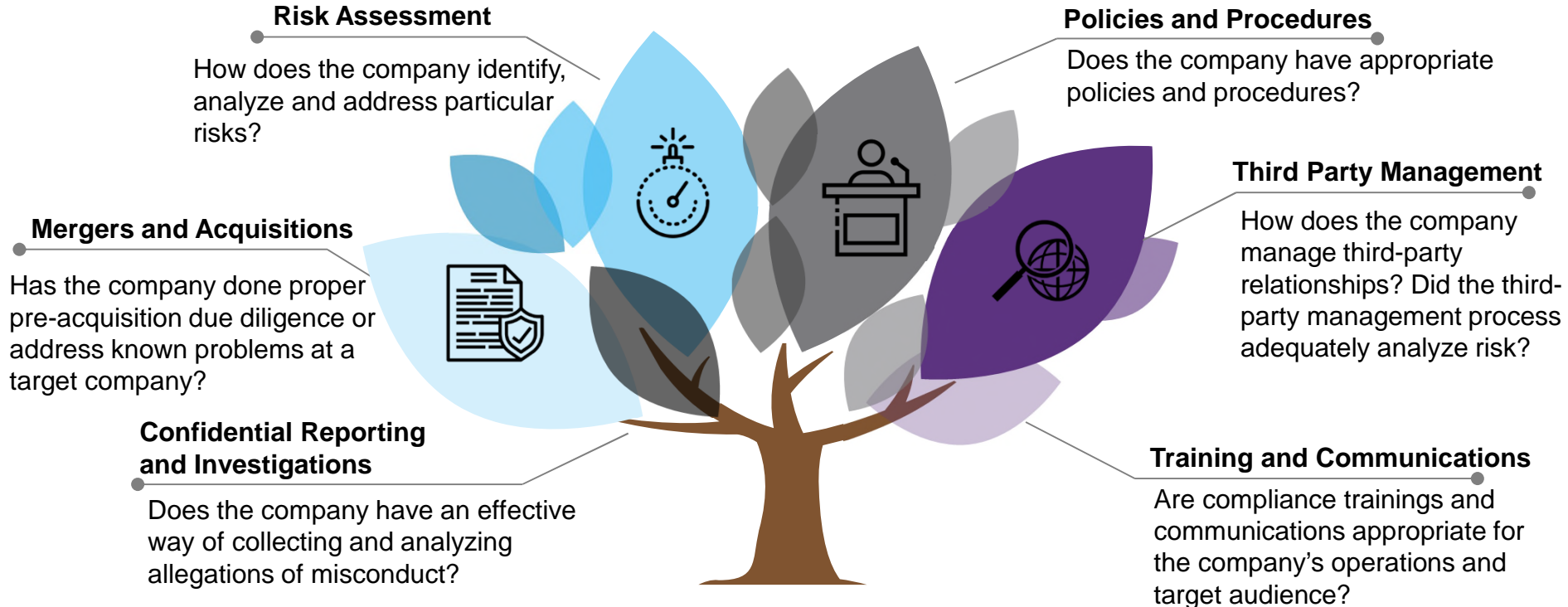
1. Is the Compliance Program Well-Designed?



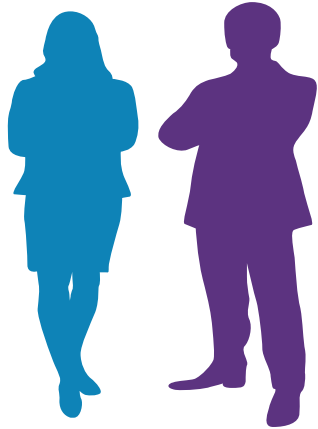
(2) Is the Compliance Program Being Implemented Effectively?

(3) Does the Compliance Program Actually Work in Practice?

1. Is the Compliance Program Well Designed



2. Is the Compliance Program Being Implemented Effectively?



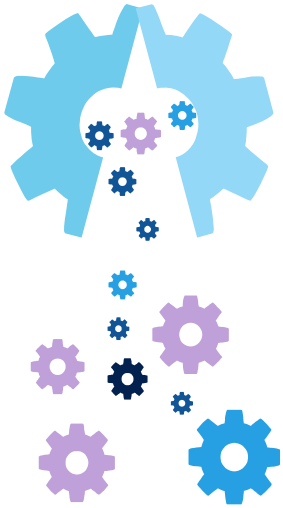
- Commitment by Senior and Middle Management
 - Instead of a check-the-box approach, the Compliance Program Guidance instructs prosecutors to look for examples of management setting the tone for the rest of the company and which communicates to employees that senior management is serious about compliance.
 - Senior management should go beyond just messaging and take concrete actions to model and encourage proper behavior. This would include not “tolerating compliance risks in pursuit of new business” or “encouraging employees to act unethically to achieve a business objective.”

2. Is the Compliance Program Being Implemented Effectively?



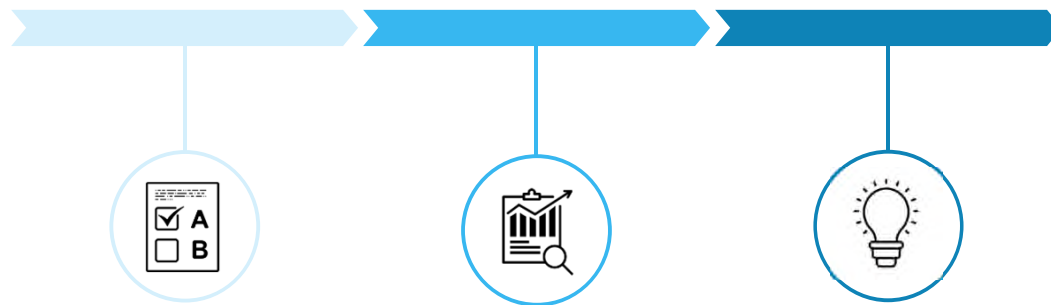
- Autonomy and Resources
 - DOJ emphasizes the importance of ensuring that a corporation's compliance function is adequately resourced and valued within the organization.
 - DOJ will evaluate whether compliance expertise has been available to the company's board of directors. Companies should consider how they will address the question of board oversight regarding the compliance function, and how that oversight has been documented over time.

2. Is the Compliance Program Being Implemented Effectively?



- Incentives and Disciplinary Measures
 - Different strategies work best for different companies.
 - Publicizing disciplinary actions internally, where appropriate, can have valuable deterrent effects.
 - Positive incentives may be a better approach for some companies, such as personnel promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership.

3. Does the Compliance Program actually work in practice?



- Should misconduct be identified, the Compliance Program Guidance calls for a company to undertake “an adequate and honest root cause analysis to understand both what contributed to the misconduct and the degree of remediation needed to prevent similar events in the future.”
- Companies should make modifications and enhancements where needed based on these “lessons learned.”

Incentives to Companies



Companies must examine the risk calculus in deciding how much to invest in their corporate compliance programs.

- DOJ reminds companies that prosecutors “may reward efforts to promote improvement and sustainability” within the company’s compliance program, and highlights some of the ways DOJ will make that determination.
- While favorable consideration from DOJ in the course of a government investigation is achievable for companies that have implemented effective compliance programs, “more importantly, [companies] may avert problems down the line.”

Thanks!



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Jonelle C. Saunders focuses her practice on healthcare and litigation matters, as well as governmental and internal corporate investigations. Jonelle advises clients on general litigation strategy, regulatory enforcement, and compliance counseling. She also provides counsel to stakeholders across the healthcare industry including hospitals, health systems, large physician group practices, chain pharmacies, and global pharmaceutical and medical device manufacturers on US federal and state fraud and abuse matters and False Claims Act (FCA) actions.

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Join us next month!

Please join us for next month's webinar:

Fast Break: FCA Hardball - Critical Strategic Considerations

Featuring Katie McDermott and Matt Hogan

➤ Tuesday July 30, 2019 3:00 PM (EST)