

GLOBAL DISPUTES AND INVESTIGATIONS

2017 COMPLIANCE UPDATE: DOJ AND OIG OFFER 2 NEW RESOURCES TO EVALUATE COMPLIANCE PROGRAM EFFECTIVENESS

Compliance professionals have received two pieces of informative guidance in 2017 that help define and communicate the government's expectations for an effective compliance program. The first, published by the Department of Justice (DOJ) in February, [lists "common questions"](#) the DOJ asks when it evaluates a company's compliance program as part of a criminal investigation.¹ The second guidance reflects a meeting between the U.S. Department of Health and Human Services' Office of Inspector General (OIG) and the Health Care Compliance Association (HCCA) and offers a [list of strategies](#) for measuring various compliance elements.² Both documents are useful tools for life sciences and healthcare organizations seeking to design effective compliance programs, as well as those looking to validate and improve upon their existing compliance controls.

BACKGROUND: "PAPER" COMPLIANCE PROGRAM

In recent years, the government has emphasized its distrust of "paper" compliance programs — policies and procedures that look good on paper, but are not reflected in daily practice at the company. The former head of the Justice Department's Criminal Division, Leslie Caldwell, summarized the DOJ's view, stating: "Unfortunately, a surprising number of companies still lack rigorous compliance programs. And even more companies have what appear to be good structures on paper, but fail in practice to devote adequate resources and management attention to compliance."³

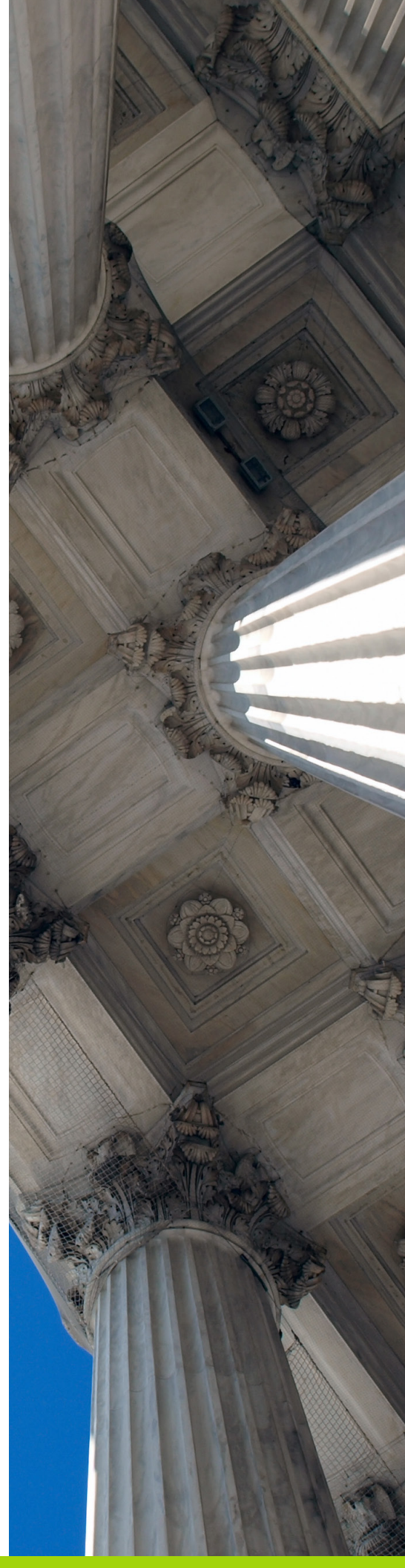
The DOJ's increased attention on how companies implement their compliance programs coincided with new compliance sophistication at the agency. In November of 2015, the DOJ hired the agency's first Compliance Counsel. The DOJ announced that this role would help prosecutors test the validity of a company's claims about its program, "such as whether the compliance program truly is thoughtfully designed and sufficiently resourced to address the company's compliance risks, or essentially window dressing."⁴

1. Department of Justice. "Evaluation of Corporate Compliance Programs," U.S. Dept. of Justice Criminal Division Fraud Section, Feb. 8, 2017.

2. HCCA-OIG. "Measuring Compliance Program Effectiveness — A Resource Guide," HCCA-OIG Compliance Effectiveness Guide, March 27, 2017.

3. Department of Justice. "Assistant Attorney General Leslie R. Caldwell Speaks at SIFMA Compliance and Legal Society New York Regional Seminar," Nov. 2, 2015.

4. Ibid.



The government's efforts were recently exemplified in a December 2016 complaint against Teva Pharmaceuticals. In this case, the Securities and Exchange Commission and DOJ investigated Teva for bribes to foreign government officials.⁵ The allegations resulted in a \$520 million settlement and a deferred prosecution agreement with the DOJ, and highlight the government's expectations that robust written standards be supported with full buy-in by the organization. "Teva executives approved policies and procedures that they knew were not sufficient to meet the risks posed by Teva's business and were not adequate to prevent or detect payments to foreign officials," the DOJ stated in its settlement announcement.⁶ "Teva also admitted that its executives put in place managers to oversee the compliance function who were unable or unwilling to enforce the anti-corruption policies that had been put in place."⁷ As a result of the allegations, Teva not only had to pay a steep settlement fee, but also retain an independent compliance monitor for three years.

The *Teva* case and the DOJ's stated emphasis on holding individuals accountable for misconduct⁸ appear to put added pressure on corporate compliance departments. However, the good news is that the government has provided recent guidance that helps define its expectations for an effective compliance program. While these two new guidances reiterate many principles the enforcement agencies have addressed before, the DOJ and OIG releases offer comprehensive and actionable direction that compliance departments should find very useful.

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DEPARTMENT OF JUSTICE'S EVALUATION OF CORPORATE COMPLIANCE PROGRAMS

The DOJ considers the "existence and effectiveness of the corporation's pre-existing compliance program" when determining whether to bring charges and in negotiating plea deals with corporate entities.⁹ On February 8, 2017, the DOJ's Fraud Section released a list of topics and sample questions the agency uses when evaluating the effectiveness of corporate compliance programs as part of an investigation. Though the agency notes that each compliance program must be evaluated in the specific context of the investigation, the guidance provides a list of 11 key topics and several underlying questions within each topic that are relevant to the DOJ's review.

The 11 "important topics" the DOJ's Fraud Section found relevant include:

1. Analysis and Remediation of Underlying Misconduct
2. Senior and Middle Management
3. Autonomy and Resources
4. Policies and Procedures: Design and Accountability and Operational Integration
5. Risk Assessment
6. Training and Communications
7. Confidential Reporting and Investigation
8. Incentives and Disciplinary Measures
9. Continuous Improvement, Periodic Testing, and Review
10. Third-Party Management
11. Mergers and Acquisitions

The DOJ's questions cover a broad spectrum, including targeting the conduct at issue in a particular investigation (e.g., "What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?"), as well as the broader compliance program (e.g., "How has the company incentivized compliance and ethical behavior?"). Compliance personnel will be familiar with many of DOJ's focal points—thoughtfully developed and implemented policies and procedures; effective training; autonomy and empowerment of the compliance function; confidential reporting of concerns. However, the guidance is a valuable resource that offers specific direction to companies in assessing the effectiveness of their compliance programs.

Notably, the DOJ's guidance offers the following insights into the agency's expectations of corporate compliance:

- The DOJ expects companies not only to test their controls, but also to collect, analyze, and track compliance data and any action items taken. The DOJ stresses continuous compliance improvements, and will look to whether such testing and analysis feed into a company's assessment and mitigation of risks.

5. *Securities and Exchange Commission v. Teva Pharmaceutical Industries Limited*, Case No. 1:16-cv-25298 (S.D. Fla. filed Dec. 22, 2016).

6. Department of Justice. "Teva Pharmaceutical Industries Ltd. Agrees to Pay More Than \$283 Million to Resolve Foreign Corrupt Practices Act Charges," Dec. 22, 2016.

7. *Ibid.*

8. Aponte, D. and Helman, S. "Individual Prosecutions for Corporate Misconduct: Impact of The Yates Memo on Big Pharma," Navigant, April 1, 2016.

9. Department of Justice. "Evaluation of Corporate Compliance Programs," U.S. Dept. of Justice Criminal Division Fraud Section, Feb. 8, 2017.

- The DOJ also expects companies to hold wrongdoers accountable. The DOJ's Compliance Evaluation guidance demonstrates the agency's desire to determine individual culpability. For example, the DOJ may ask whether managers were held accountable for misconduct that occurred under their supervision. They also may ask whether the company has ever "terminated or otherwise disciplined anyone (reduced or eliminated bonuses, issued a warning letter, etc.)" for misconduct.
- The DOJ highlights the significance of "conduct at the top," including whether senior leaders, "through their words and actions," have "encouraged or discouraged the type of misconduct in question." The DOJ indicates that they will look for "concrete actions" taken by leadership to demonstrate commitment to compliant behavior. Furthermore, the DOJ will ask questions related to the board of directors' oversight and engagement into the compliance and control functions. The emphasis on board-level compliance responsibility is a common theme from enforcement agencies. The OIG, for example, may include settlement terms in its Corporate Integrity Agreements requiring the board to make a reasonable inquiry into the company's compliance program, including evaluating compliance effectiveness. Read more about board expectations in Navigant's article entitled "Compliance Effectiveness Review: What's a Board to Do?" [here](#).¹⁰

OIG AND HCCA: MEASURING COMPLIANCE PROGRAM EFFECTIVENESS – A RESOURCE GUIDE

Released March 27, 2017, the [Compliance Program Resource Guide](#) is a jointly prepared document by the OIG and HCCA that outlines "ways to measure the effectiveness of compliance programs."¹¹ Similar in structure to the DOJ's Compliance Evaluation guidance, the Resource Guide begins with a short list of overarching elements and provides specific details under each element to support companies' evaluation of their compliance programs.

The starting point for the OIG's resource is structured around the classic, well-known seven elements of compliance:

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors, and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems

6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

Under each element, the guidance details ways the company can effectively evaluate their compliance program by suggesting "what to measure" and "how to measure." For example, under the first element, "Standards, Policies, and Procedures," an important metric is whether such standards are accessible to employees who are expected to comply with them. The Resource Guide lists measurements to help evaluate this metric, including reviewing the link to the employee-accessible intranet that includes the Code of Conduct; surveying employees to determine whether and how they access the policies and procedures; testing key word searches to determine whether the written standards are searchable; and auditing/interviewing staff to show policies.

Another example, under the "Monitoring, Auditing, and Internal Reporting Systems" category, describes measurements around a company's risk assessment process. The OIG poses questions around risk assessment mapping: who participates; how are topics prioritized; what is the process; how are mitigation steps determined; is education provided; and how are the risk assessment results reported?

The OIG states that the Resource Guide was designed to provide a "large number of ideas for measuring the various elements of a compliance program."¹² Indeed, the examples above are two of *over four hundred metrics and measurement ideas* that were intended "to give health care organizations as many ideas as possible, to be broad enough to help any type of organization, and let the organization choose which ones best suit its needs."¹³

The OIG confirms that the Resource was not drafted as a "best practice" or "checklist to be applied wholesale to assess a compliance program."¹⁴ However, the list offers a high level of detail that provides companies with a helpful road map for measuring the effectiveness of their compliance program. The measurements laid out in the Resource Guide are useful to demonstrate Navigant's key elements of compliance effectiveness, including for example:

- That employees understand and can apply compliance standards, and that training evolves based on newly identified risk areas, monitoring results, and questions from employees that indicate additional clarity is needed.
- That operational leaders who own functions that present compliance risk are involved in the development and execution of periodic monitoring protocols.

10. Helman, S. "Compliance Effectiveness Review: What's a Board to Do?," Navigant, 2016.

11. OIG-HCCA. Compliance Program Resource Guide, March 27, 2017.

12. *Ibid.*

13. *Ibid.*

14. *Ibid.*

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- That compliance infractions are tracked and handled consistently, and any trends in noncompliant activities inform the compliance program.
- That the compliance office is providing the board of directors with consistent, actionable metrics related to compliance and controls.

CONCLUSION

Life sciences and healthcare organizations operate in a heavily regulated environment and remain under intense scrutiny from the Department of Justice and Office of Inspector General, as well as various state-level agencies. As the government continues to gain expertise in evaluating compliance effectiveness, it remains focused on whether a company has truly “bought-in” to the compliance program — from top to bottom. The recent DOJ Compliance Evaluation guidance and the OIG-developed compliance resource provide companies with insight into the government's thought process prior to being at the center of an investigation.

Additionally, the recent guidance documents promote third-party assessments of compliance effectiveness. Boards of directors and compliance committees should consider an independent evaluation of their compliance program, incorporating the DOJ and OIG guidances as appropriate.

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