DOJ's New Corporate Compliance Evaluation Guidance

Key Considerations and Updates for Life Sciences Companies

On April 30, 2019, the Criminal Division of the U.S. Department of Justice (DOJ) issued updated guidance for white-collar prosecutors on evaluating the effectiveness and adequacy of corporate compliance programs (DOJ Compliance Guidance).[1] This new guidance reorganizes, clarifies and adds details to the DOJ Fraud Section's February 2017 guidance addressing compliance program evaluation.[2] DOJ also seeks to better harmonize and consolidate existing Department standards with this new guidance.

These latest updates from DOJ now apply beyond the Fraud Section to the entire Criminal Division. They also serves as a roadmap for prosecutors, as well as boards of directors, management, compliance officers and legal counsel, in analyzing compliance programs.

<u>Roadmap to Compliance</u>

DOJ acknowledges that there is no one way or approach—no "rigid formula"—to evaluate the effectiveness of a compliance program. But DOJ recognizes that there are often common questions they may ask in the course of making an individualized determination.

As the Justice Manual notes, a prosecutor should ask three fundamental questions when evaluating a compliance program:

(1) Is the compliance program well designed?

(2) Is the compliance program effectively implemented?

(3) Does the compliance program work in practice?

The DOJ Compliance Guidance reorganizes the "sample topics and questions" from the 2017 guidance using these three fundamental questions as an outline and provides expanded detail, additional nuance and examples. DOJ uses this revised structure to simplify and provide greater clarity into what it means to have an effective compliance program. DOJ expresses a pragmatic theory of compliance, one
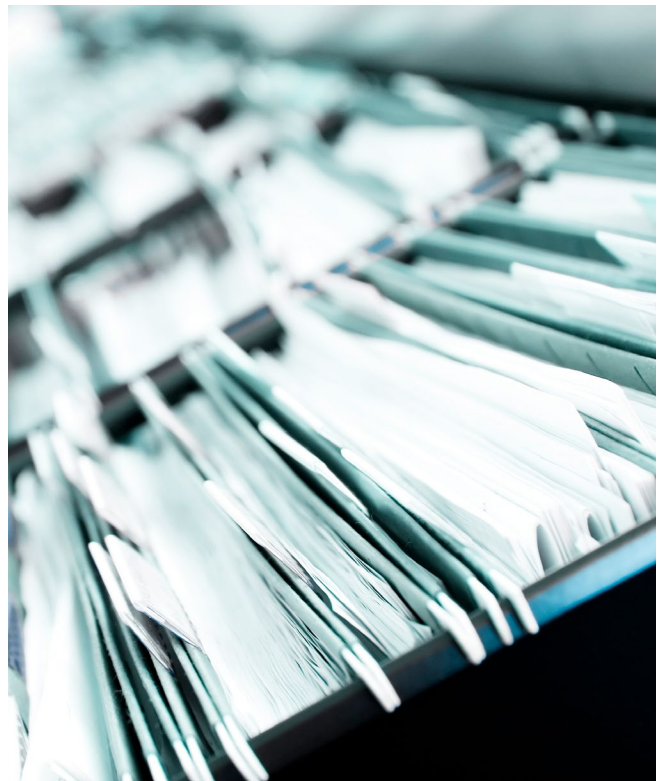
that emphasizes not only the "seven" (or 10 or 11, depending upon your source) elements of an effective compliance program but that also places importance on compliance incentives, cultural tone and practical training.

DOJ's position is that compliance should be an ongoing, evolving process. DOJ instructs to measure the adequacy and effectiveness of a compliance program at the time of the offense, as well as at the time of a charging decision and resolution. The guidance emphasizes process—whether a company learns from experience and makes changes and adjustments accordingly. The guidance also emphasizes that an effective compliance program is one that is based on and tailored to appropriate risk assessments as well as regular evaluation and assessment, improvement and testing.

We have prepared this booklet to summarize DOJ's guidance in a checklist format to help you assess your compliance program.

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1   U.S. Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs (Updated April 2019) (*available at* https://www.justice.gov/criminal-fraud/page/file/937501/download).

2   U.S. Department of Justice Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (February 2017).

Question 1: Is the Program Well-Designed?

According to DOJ, the initial question is whether a company has a **well-designed compliance** program. This means a program tailored the company's business, its risk profile and how the company has constructed its program to address these risks. DOJ includes the following questions for evaluation:

Risk Assessment	Examines the scope and nature of compliance risk assessment, including whether the program has **incorporated lessons learned** and appropriately **allocates resources among risk areas** based on severity	**Process** ☐ Methodology used to identify, analyze and address risk? ☐ How has the information informed the compliance program? **Resource Allocation** ☐ Does the company devote too many resources to policing low-risk areas (ex: routine hospitality, entertainment) vs. high-risk areas (corporate transactions)? **Updates** ☐ Is the risk assessment current? Subject to periodic review? ☐ Have there been updates in light of lessons learned or risks discovered?
Policies and Procedures	Assesses whether the company has policies andprocedures that **incorporate a culture of compliance** Looks at whether policies are **accessible to employees**, including in terms of linguistic and other barriers that might prevent access Inquires specifically into **training "gatekeepers"** (i.e., individuals with approval authority)	**Code of Conduct** ☐ Code of Conduct sets forth commitment to full compliance with relevant laws? Accessible to all company employees? **Design** ☐ Process for designing and implementing new policies and procedures? ☐ Has that process changed? ☐ Who is involved? ☐ Have business units been consulted prior to roll out? **Comprehensiveness** ☐ How does the company monitor and implement policies and procedures that reflect spectrum of risks? **Accessibility** ☐ How has the company communicated its policies and procedures to all employees and relevant third parties? ☐ If the company has foreign subsidiaries, are there linguistic or other barriers to foreign employees' access? **Responsibility for Operational Integration** ☐ Who is responsible for integrating policies and procedures? ☐ Have they been rolled out in a way that ensures employees' understanding? ☐ In what specific ways are compliance policies and procedures reinforced through the company's internal control systems? **Gatekeepers** ☐ What, if any, guidance and training has been provided to key gatekeepers in the control processes (e.g., those with approval authority or certification responsibilities)? ☐ Do they know what misconduct to look for? ☐ Do they know when and how to escalate concerns?

Training and Communication	Pays additional attention to accessibility of training, training of supervisory employees and **high-risk and control employees** Emphasizes real-life training and messaging, including **lessons learned**, **examples** of disciplinary action and **case studies**	**Risk-Based Training** ☐ What training have employees in relevant control functions received? ☐ Tailored training for high-risk and control employees, addressing risks in the area where the misconduct occurred? ☐ Have supervisory employees received different or supplementary training? ☐ What analysis has the company undertaken to determine who should be trained and on what subjects? **Form/Content/Effectiveness of Training** ☐ Has the training been offered in a form and language appropriate for the audience? ☐ Is the training provided online or in-person? Why? ☐ How does the company measure the effectiveness of the training? ☐ Have employees been tested? ☐ How has the company addressed employees who fail testing? ☐ Does the training include real-life advice? Case studies? Lessons learned? ☐ Does the training include guidance on how to obtain ethics advice? **Communications about Misconduct** ☐ What has senior management done to let employees know the company's position concerning misconduct? ☐ Communications with discipline or termination? **Availability of Guidance** ☐ What resources are available to employees to provide guidance relating to compliance policies? ☐ How has the company assessed whether employees know when to seek advice and whether they would be willing to do so?
Confidential Reporting and Investigations	Focuses primarily on the comprehensiveness and **effectiveness of the investigative structure**	**Effectiveness of the Reporting Mechanism** ☐ Does the company have an anonymous reporting mechanism? ☐ How is the reporting mechanism publicized to employees? ☐ Has it been used? ☐ How does the company assess the seriousness of the allegations it received? ☐ Has the compliance function had full access to information? ☐ Does the process include proactive measures to create a workplace atmosphere without fear of retaliation? **Properly Scoped Investigations by Qualified Personnel** ☐ How does the company determine which complaints or red flags merit further investigation? ☐ How does the company ensure that investigations are properly scoped? ☐ What steps does the company take to ensure investigations are independent, objective, appropriately conducted and properly documented? ☐ How does the company determine who should conduct an investigation? **Investigation Response** ☐ Does the company apply timing metrics to ensure responsiveness? ☐ Does the company have a process for monitoring the outcome of investigations and accountability for findings? **Resources and Tracking of Results** ☐ Are the reporting and investigating mechanisms sufficiently funded? ☐ How has the company collected, tracked, analyzed and used information from its reporting mechanisms? ☐ Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?

Third-Party Management	Considers the application of **risk-based due diligence to third-party** partners Encourages understanding third-party partners' **reputations and relationships** with foreign officials as well as business rationale Highlights need to track and **address red flags** that arise in diligence	**Risk-Based and Integrated Processes** ☐ How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company? ☐ How has this process been integrated into the relevant procurement and vendor management processes? **Appropriate Controls** ☐ Appropriate business rationale for the use of third parties? ☐ Mechanisms to ensure that contract terms describe the services to be performed; payment terms are appropriate; the described work is performed; and compensation is commensurate with services rendered? **Management of Relationships** ☐ How has the company considered and analyzed the compensation and incentive structures for third parties against compliance risks? ☐ How does the company monitor its third parties? ☐ Does the company have audit rights to analyze the books and accounts of third parties? Has the company exercised those rights? ☐ How does the company train its third-party relationship managers about compliance risks? ☐ How does the company incentivize compliance and ethical behavior by third parties? **Real Actions and Consequences** ☐ Does the company track red flags that are identified from due diligence? How are those red flags addressed? ☐ Does the company keep track of third parties that do not pass the company's due diligence? ☐ Does the company take steps to ensure that those third parties are not hired or re-hired later? ☐ Has a similar third party been suspended, terminated or audited as a result of compliance issues?
Mergers and Acquisitions	Expresses the concept that that effective compliance includes comprehensive **due diligence of acquisition targets**	**Due Diligence Process** ☐ Was the misconduct or the risk of misconduct identified during due diligence? ☐ Who conducted the risk review for the acquired/merged entities and how was it done? ☐ What is the M&A due diligence process generally? **Integration in the M&A Process** ☐ How has the compliance function been integrated into the merger, acquisition and integration process? **Process Connecting Due Diligence to Implementation** ☐ What has been the company's process for tracking and remediating misconduct identified during the due diligence process? ☐ What has been the company's process for implementing compliance policies and procedures at new entities?

Question 2: Is the Program Applied Earnestly and in Good Faith?

The DOJ Compliance Guidance is notable in that it defines an "effective compliance program" as one that is applied "**earnestly and in good faith**."[1] This is an important departure from previous government guidance on compliance programs, which associates an "effective" compliance program with one that meets the so-called "seven elements." Here, DOJ looks broadly and holistically beyond a check-the-box or paper program and encourages prosecutors to assess **how** the program has been applied as another measure of its effectiveness. Importantly, DOJ focuses on both corrective action and incentivizing compliant behavior.

Commitment by Senior and Middle Management	Looks to senior and middle **management to model compliant behavior** and to encourage compliance through messaging and actions Asks **whether leadership commitment to compliance waivers** depending on competing interests	**Conduct at the Top** ☐ How have senior leaders' words and actions encouraged or discouraged compliance? ☐ What concrete actions have they taken to demonstrate leadership in compliance efforts? ☐ How have they modelled proper behavior to subordinates? ☐ Have managers tolerated greater compliance risks in pursuit of new business or greater revenues? ☐ Have managers encouraged employees to act unethically or impeded compliance personnel from implementing their duties? **Shared Commitment** ☐ What actions have senior leaders and middle-management taken to demonstrate commitment to compliance? ☐ Have they kept that commitment in the face of competing business objectives? **Oversight** ☐ What compliance expertise has been available on the board of directors? ☐ Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions? ☐ What types of information have the board of directors and senior management examined in their oversight?

Autonomy and Resources	Explores the **integrity of the compliance function's structure** and how it compares to other critical functions within the company	**Structure** ☐ Where is the compliance function housed (within legal, under a business function or independent)? ☐ Is compliance run by a designated chief compliance officer or another executive? ☐ Do compliance personnel have non-compliance responsibilities? ☐ Why has the company chosen the compliance structure it has in place? **Seniority and Stature** ☐ How does the compliance function compare with other strategic functions in the company in terms of stature, compensation, rank, reporting line, resources and access to decision-makers? ☐ What has been the turnover rate for compliance and relevant control function personnel? ☐ What role has compliance played in the company's strategic and operational decisions? ☐ How has the company responded to specific instances where compliance raised concerns? ☐ Have there been transactions or deals that were stopped, modified or further scrutinized as a result of compliance concerns? **Experience and Qualifications** ☐ Do compliance and control personnel have the appropriate experience and qualifications for their roles and responsibilities? ☐ Has the level of experience and qualifications in these roles changed over time? ☐ Who reviews the performance of the compliance function and what is the review process? **Funding and Resources** ☐ Has there been sufficient staffing for compliance personnel to effectively audit, document, analyze and act on the results of the compliance efforts? ☐ Has the company allocated sufficient funds? ☐ Have there been times when requests for resources by compliance and control functions have been denied? Why? **Autonomy** ☐ Do the compliance and relevant control functions have direct reporting lines to anyone on the board of directors and/or audit committee? ☐ How often do they meet with directors? ☐ Are members of the senior management present for these meetings? ☐ How does the company ensure the independence of the compliance and control personnel?

Autonomy and Resources	Explores the **integrity of the compliance function's structure** and how it compares to other critical functions within the company	**Outsourced Compliance Functions** ☐ Has the company outsourced all or parts of its compliance functions to an external firm or consultant? ☐ If so, why, and who is responsible for overseeing or liaising with the external firm or consultant? ☐ What level of access does the external firm or consultant have to company information? ☐ How has the effectiveness of the outsourced process been assessed?

Incentives andDisciplinary Measures	Looks at whether the company **dis-incentivizes bad behavior** through disciplinary action and whether the company **incentivizes good behavior** through rewards	**Human Resources Process** ☐ Who participates in making disciplinary decisions, including for the type of misconduct at issue? ☐ Is the same process followed for each instance of misconduct? ☐ Are the actual reasons for discipline communicated to employees? ☐ Are there genuine legal or investigation-related reasons for restricting information? **Consistent Application** ☐ Have disciplinary actions and incentives been fairly and consistently applied across the organization? ☐ Are there similar instances of misconduct that were treated disparately? **Incentive System** ☐ Has the company considered the implications of its incentives and rewards on compliance? ☐ How does the company incentivize compliance and ethical behavior? ☐ Have there been specific examples of actions taken (e.g., promotions or awards denied) as a result of compliance and ethics considerations? ☐ Who determines the compensation (including bonuses), discipline and promotion of compliance personnel?

Question 3: Does the Compliance Program Work in Practice?

Here, the DOJ emphasizes that a compliance program is not ineffective simply because of the existence of misconduct. Rather, according to DOJ:

- To assess a compliance program **at the time of misconduct**, a prosecutor or compliance officer should examine whether and how the misconduct was detected, what investigation resources were in place and the thoroughness of remedial efforts; and

- To assess a compliance program **at the time of the charging decision**, a prosecutor or compliance officer should consider whether the program evolved over time to address evolving risks, whether an adequate root cause analysis was undertaken and whether the company undertakes continuous review to ensure the program is not stale.

Continuous Improvement, Periodic Testing and Review	Examines the **substance and logistics of internal audits**, including decisions about audit scope, board and management reporting, evolution in internal controls based on findings and measuring the culture of compliance	**Internal Audit** ☐ What is the internal audit process, and what is the rationale behind that process? ☐ How are audits executed? ☐ What types of audits would have identified issues relevant to the misconduct? ☐ What were the findings? ☐ What types of relevant audit findings and remediation progress have been reported to management and the board on a regular basis? ☐ How have management and the board followed up? How often does internal audit conduct assessments in high-risk areas? **Control Testing** ☐ Has the company reviewed and audited its compliance program in the area relating to the misconduct? ☐ What testing of controls, collection and analysis of compliance data, and interviews of employees and third parties does the company undertake? ☐ How are the results reported and action items tracked? **Evolving Updates** ☐ How often has the company updated its risk assessments and reviewed its compliance policies, procedures and practices? ☐ Has the company undertaken a gap analysis to determine if particular areas of risk are not sufficiently addressed in its policies, controls or training? ☐ What steps has the company taken to determine whether policies/procedures/practices make sense for particular business segments? **Culture of Compliance** ☐ How often and how does the company measure its culture of compliance? ☐ Does the company seek input from all levels of employees to assess senior and middle management's commitment to compliance? ☐ What steps has the company taken in response to its measurement of the compliance culture?

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Investigation of Misconduct	Focuses on the scope, execution and follow-up from **internal investigations**	**Properly Scoped Investigation by Qualified Personnel** ☐ How has the company ensured that investigations are properly scoped, independent, objective, appropriately conducted and properly documented? **Response to Investigations** ☐ Have investigations identified root causes, system vulnerabilities and accountability lapses? ☐ What has been the process for responding to investigative findings? ☐ How high up in the company do investigative findings go?
Analysis and Remediation of Underlying Misconduct	Looks at **post-misconduct follow-up**, including root cause analysis, source of control failures and how remediation and disciplinary action have been used to advance compliance	**Root Cause Analysis** ☐ What is the company's root cause analysis of the misconduct at issue? ☐ Were any systemic issues identified? ☐ Who in the company was involved in making the analysis? **Prior Weaknesses** ☐ What controls failed? ☐ If policies or procedures should have prohibited the misconduct, were they effectively implemented, and have functions that had ownership of these policies and procedures been held accountable? **Payment Systems** ☐ How was the misconduct in question funded (e.g., purchase orders, employee reimbursements, discounts, petty cash)? ☐ What processes could have prevented or detected improper access to these funds? ☐ Have those processes been improved? **Vendor Management** ☐ If vendors were involved in the misconduct, what was the process for vendor selection and did the vendor undergo that process? **Prior Indications** ☐ Were there prior opportunities to detect the misconduct in question? ☐ What is the company's analysis of why such opportunities were missed? **Remediation** ☐ What specific changes has the company made to reduce the risk that the same issues will not occur in the future? ☐ What specific remediation has addressed the issues identified in the root cause analysis? **Accountability** ☐ What disciplinary actions did the company take in response to the misconduct and were they timely? ☐ Were managers held accountable for misconduct that occurred under their supervision? ☐ Did the company consider disciplinary actions for failures in supervision? ☐ What is the company's record (e.g., number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue? ☐ Has the company ever terminated or otherwise disciplined anyone (reduced or eliminated bonuses, issued a warning letter, etc.) for the type of misconduct at issue?

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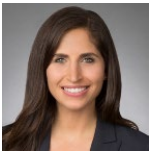
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