
Implementing Effective Training:

Lessons from the DOJ Guidance on
Evaluating Effective Compliance Programs

Informa Connect - Pharmaceutical Compliance Congress

September 28, 2021



Introductions



Madeline Scherwitzky

US Compliance
Biohaven Pharmaceuticals



Jon Wilkenfeld

President
Potomac River Partners

Agenda

- **About DOJ Guidance**
- **Strategic Plan**
- **5 Key Takeaways:**
 1. Targeted and Tailored
 2. Get Real
 3. Ask Away
 4. Measure Knowledge
 5. Evaluate Outcomes

About DOJ Guidance

- How DOJ assesses Compliance Programs
- Structured by Element
- This session focuses on Training & Communications
 - Revised June 2020 Guidance provides further indication of what the DOJ expects training programs to look like
 - Shorter, more targeted and risk-based trainings
 - An increase focus on the ability to ask questions, measuring knowledge and retention, and evaluating the impact of training on behaviors

<https://www.justice.gov/criminal-fraud/page/file/937501/download>

U.S. Department of Justice
Criminal Division
Evaluation of Corporate Compliance Programs
(Updated June 2020)

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "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 the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. See U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled "Selection of Monitors in Criminal Division Matters" issued by Assistant Attorney General Brian Benczkowski (hereafter, the "Benczkowski Memo") instructs prosecutors to consider, at the time of the resolution, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future" to determine whether a monitor is appropriate.

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three "fundamental questions" a prosecutor should ask:

Strategic Plan

Questions to consider:

- What are the learning objectives?
- What is the best delivery format?
- Who is the audience?
- What is the optimal duration and frequency?
- Does the content need to be translated?



1. Targeted and Tailored

Questions Posed by the DOJ

- Has the company provided tailored training for high-risk and control employees?
- Has the training been offered in the form and language appropriate for the audience?

Key Takeaways

- ✓ Create shorter, more frequent role-based training
- ✓ Maintain accurate user data within the LMS to define narrow curricula
- ✓ Ensure training matches the employee's sophistication and language capabilities



2. Get Real

Questions Posed by the DOJ

- Has the company provided training that addresses risks in the area where the misconduct occurred?
- What has senior management done to let employees know the company's position concerning misconduct?
- Has the training addressed lessons learned from prior compliance incidents?

Key Takeaways

- ✓ Develop real-world scenarios and case studies that show how to apply the policy
- ✓ Directly address areas of previously identified misconduct (appropriately anonymized)
- ✓ Track statements made by senior management about the importance of ethical conduct



3. Ask Away

Questions Posed by the DOJ

- Whether online or in-person, is there a process by which employees can ask questions arising out of the training?
- Have supervisory employees received different or supplementary training?
- What resources have been available to employees to provide guidance relating to compliance policies?

Key Takeaways

- ✓ Identify mechanism for Compliance to receive follow-on questions
- ✓ Train line management separately on how to respond
- ✓ Consistently communicate availability of compliance resources and how to access them



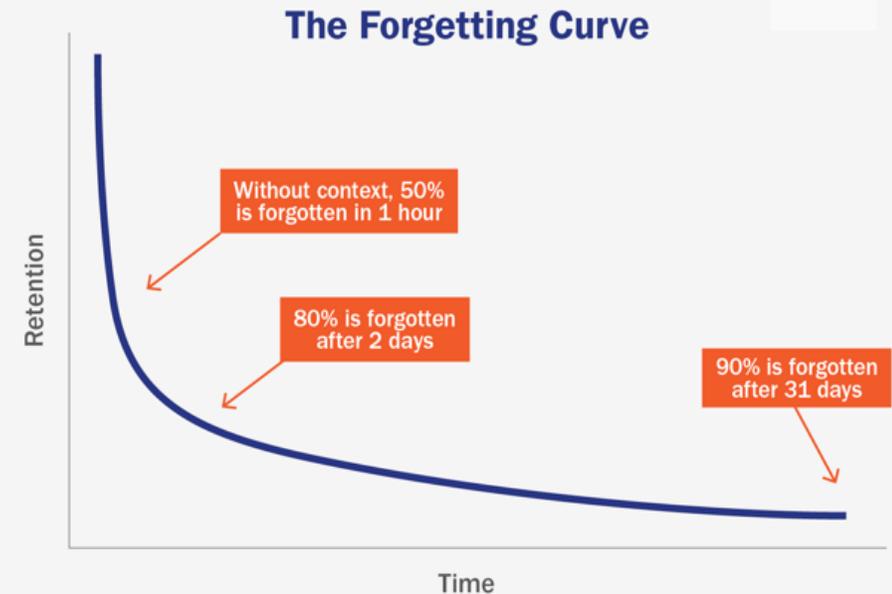
4. Measure Knowledge

Questions Posed by the DOJ

- How has the company measured the effectiveness of the training?
- Is the training provided online or in person (or both), and what is the company's rationale for its choice?
- Have employees been tested on what they have learned?
- How has the company addressed employees who fail all or a portion of the testing?

Key Takeaways

- ✓ Test knowledge regularly following the training
- ✓ Require employees who do not understand the content to take additional remediation training; allow learners who know it well to place out
- ✓ Track the data and evaluate patterns to identify areas to strengthen compliance controls



5. Evaluate Outcomes

Questions Posed by the DOJ

- Has the company evaluated the extent to which the training has an impact on employee behavior or operations?

Key Takeaways

- ✓ Evaluate whether training is effective by measuring outcomes
- ✓ Auditing and monitoring often provide inputs on comprehension of training
- ✓ Survey employees on comfort level in seeking advice and company expectation



Conclusion

- Effective Training = Understood Compliance Program
- Relevant training on most important topics
- Expectations are clear
- Data is paramount

Questions



Contact Information



Madeline Scherwitzky

Biohaven Pharmaceuticals

267-337-0921

madeline.scherwitzky@biohavenpharma.com



Jon Wilkenfeld

Potomac River Partners

610-470-7616

jwilkenfeld@potomacriverpartners.com