TOSIOD Life sciences

A Polite Reminder: Preventing Fraud Before It Occurs by Inspiring a Culture of Compliance and Promoting Compliance Through Compensation

"The carrots and sticks of our corporate enforcement program are attempting to affect, punish, deter or change the decision-making and actions of individuals." - Assistant Attorney General Kenneth A. Polite Jr.

On Friday, March 3 the Department of Justice (DOJ) announced The Criminal Division's Pilot Program Regarding Compensation Incentives and Clawbacks. The Pilot Program is one of the DOJ's latest efforts to deter criminal conduct by incentivizing the development and implementation of effective compliance programs and promoting ethical corporate cultures.

During this Pilot Program, the Criminal Division's corporate resolutions will include a requirement for the organization entering the resolution to develop compliance-promoting criteria within its compensation and bonus system. Deputy Attorney General Lisa O. Monaco mentioned in her remarks that a failing score for compliance should now lead to failure to secure a bonus. This statement implies criteria should be developed to calculate a compliance performance score as part of an individual's performance evaluation. It also begs the question how else will scores impact an individual's bonus reward, for example, if a failing score results in no bonus, does a high score result in an additional bonus?

Before diving into the Pilot Program specifically, let's first highlight some of the key takeaways from the recent remarks by the Deputy Attorney General and Assistant Attorney General on the topic of incentivizing good compliance.

Key Takeaways

Lisa O. Monaco and General Kenneth A. Polite Jr. both discussed several topics related to addressing corporate crime during their remarks at the ABA Event, highlighting departmental commitments aimed at encouraging compliance within organizations:

- Plans to continue DOJ resource commitments to corporate criminal enforcement (to confront emerging risks, address victims' interests, and fight corporate crime)
- Commitments to Voluntary Self-Disclosure Programs (encouraging predictable and transparent disclosures from companies that can help minimize the harm to impacted individuals, such as patients)
- Focus on individual accountability (high priority placed upon holding individual wrongdoers accountable as people, not companies, commit crimes)
- > Interest in seeing Cultures of Compliance (recognition that the culture and the climate in an organization can influence good or poor ethical behavior)
- Pilot Program focused on Incentive Compensation and Clawbacks (encouraging employees to practice ethical behavior by ensuring individuals engaging in wrongdoing face proper consequences for their actions)

This Client Alert focuses on the topics of inspiring cultures of compliance and promoting compliance through compensation. For more information about the topics mentioned above, please read:

- > Monaco's remarks at the ABA
- > Polite's remarks at the ABA
- > Link to Pilot Program

"When you are asked about your compliance program and whether its adequately creating, maintaining and supporting an ethical culture, the question again goes to individual accountability. We want to know about your investment in compliance, not simply because we want you to hire more consultants or buy more sophisticated training software... I want to know whether you are doing everything you can to ensure that when that individual employee is facing a singular ethical challenge, he has been informed, trained and empowered to choose right over wrong.

Or, if he makes the wrong choice, you have a system that immediately detects, remediates, disciplines, and then adapts to ensure that others do not follow suit."
- Assistant Attorney General Kenneth A. Polite Jr.

Inspiring a Culture of Compliance

Both Monaco and Polite emphasized the DOJ's desire for organizations to commit to cultivating cultures of compliance. When assessing an organization, the DOJ will consider the environment: Is leadership modeling good or poor ethical behavior? Are there controls in place to detect misconduct? Are people rewarded solely on the bottom line?

Does the environment encourage positively intentioned misconduct? Ultimately, the department cares about your culture as they continue to attempt to "incentivize the development and implementation of effective compliance programs and promote ethical corporate cultures."²

No path to ethical corporate cultures is the same as it will be unique to each organization. However, to help promote an ethical and compliant corporate culture organizations may consider:

- > **Tone From the Top**: setting the tone at the top with executives, emphasizing the importance of compliance
- Embedding compliance into the fabric of the organization: promoting compliance through the mission, values, principles of the company, and methods of working
- > **Business Ownership**: encouraging employees to take ownership of compliance
- > **Develop Risk Intelligence**: educating and promoting a culture of risk awareness
- > Open Lines of Communication: enacting an open-door policy, encouraging employees to approach their managers and supervisors to report their grievances or issues fostering a culture where employees feel comfortable reporting concerns without any fear of retaliation, contributing to better detection and prevention of compliance issues

The DOJ has implemented the Pilot Program in the hopes that implementing compliance criteria in compensation and bonus decisions as one tool organizations may consider encouraging ethical and compliant corporate cultures.

Compensation systems that use affirmative metrics and benchmarks can reward compliance promoting behavior. Compensation systems that clearly and effectively impose financial penalties for misconduct can also deter risky behavior and foster a culture of compliance. - The Criminal Division's Pilot Program

- The Criminal Division's Pilot Program Regarding Compensation Incentives and Clawbacks



Promoting Compliance Through Compensation

The Pilot Program has been designed to "encourage companies who do not already factor compliance into compensation to retool their programs and get ahead of the curve."3 The DOJ is hoping to "empower general counsels and compliance officers to make the case to company management, to make the case in the boardroom that investment in a robust compliance program, including a forward-leaning compensation system, is money well spent."4 Furthermore, the department wants companies to ensure executives and employees are invested in promoting compliance and believes that "nothing grabs attention or demands personal investment like having skin in the game, through direct and tangible financial incentives."5

This talk of carrot and stick is important, and yet in many conference presentations, when challenged, DOJ and OIG representatives are quick to highlight the sticks but have very little to offer in terms of carrots.

This difficulty is also reflected in the life sciences industry, with many companies struggling to identify what a carrot might be when "ethics and compliance is a basic expectation of everyone," so rewarding for compliance feels peculiar.

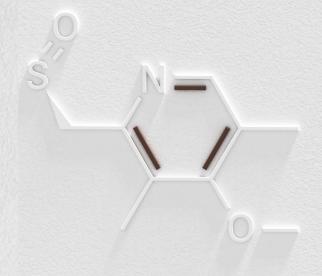
Epsilon Life Sciences has worked with a number of clients on this very question - how do we incentivize good compliance? Consider for example, sales representatives, who are hired with an expectation to sell as much of the company's product(s) as is possible and appropriate, and yet, they are incentivized to sell through various forms of carrots - bonuses, kickers, competitions, President's awards etc. The old cliché "what gets measured gets done" often comes to mind in the context of performance review, but maybe that should be updated to "what is rewarded/ incentivized gets done." If sales incentives can encourage sales, then shouldn't incentivizing and rewarding ethical and compliant behavior encourage more ethical and compliant behavior?

Another common explanation is that it is difficult to come up with objective measures of good compliance. However, corporate jobs often require employees to establish SMART goals to measure success in their role, couldn't the same be done for compliance-specific objectives?

Please see the **following page** for example criteria and actions related to compliance in compensation and bonus systems that companies may consider.

Another frequently seen challenge is figuring out how to effectively incentivize and acknowledge good compliance practices. Organizations may consider:

- > Recognition senior leadership acknowledging individuals who have supported compliance efforts (e.g., during a town hall meeting or award ceremony, executives can examine a case study or recognize business personnel in secondary roles who have supported compliance)
- > Rewards Rewards can take place through performance management (e.g., rewards for regions that perform the best on a compliance metric during monitoring and auditing, recognizing tests results demonstrating understanding during compliance trainings)
- > Awards/ Competitions Incentivizing compliance behaviors (e.g., spot awards distributed for the best region with documenting a recent compliance observation trend such as failure to provide a package insert)



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Actions

Prohibition on Bonuses

A prohibition on bonuses for employees who do not satisfy compliance performance

- > What compliance metrics are employee's being held accountable to through performance metrics?
- > Would non-compliance delay or prohibit incentive compensation?

Disciplinary Measures

Disciplinary measures for employees who violate applicable law and others who both: had supervisory authority over the employee(s) or business area engaged in the misconduct, and knew of, or were willfully blind to, the misconduct

- > What compliance training are you providing to employees with supervisory responsibilities?
- > How accessible are the supervisors?
- > Do supervisors have required review of/ certification for their departments work?
- > What monitoring activities are being conducted? How are you using analytics to detect red flags or misconduct?

Incentives

Incentives for employees who demonstrate full commitment to compliance processes

- > How is good compliance being recognized?
- > Do you have rewards for compliant behaviors?
- > How do you recognize, acknowledge, and champion commitment to compliance processes?
- > Do you explain the business impact of compliant actions?

Our industry often looks for signals from the government such as guidance documents, settlement agreements, and speeches for what is considered best practice. Therefore, this new Pilot Program is likely not just a new requirement for future resolutions, but a signal from the DOJ as to what they expect as best practice for organizations. Furthermore, the updated guidance document from the DOJ states:

Compensation structures that clearly and effectively impose financial penalties for misconduct can deter risky behavior and foster a culture of compliance. At the same time, providing positive incentives, such as promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership, can drive compliance. Prosecutors should examine whether a company has made working on compliance a means of career advancement, offered opportunities for managers and employees to serve as a compliance "champion", or made compliance a significant metric for management bonuses. - U.S. Department of Justice Criminal Division Evaluation of Corporate Compliance Programs

How Epsilon Life Sciences Can Help

Our professionals have expertise in assisting organizations in creating a positive culture of compliance and designing recognition and reward programs – key areas of focus by the DOJ as evidenced by the implementation of the Pilot Program and reinforced by Monaco's and Polite's remarks. Our experts:

- > Conduct compliance effectiveness reviews to assess the effectiveness and maturity of a company's compliance program.
- > Conduct compliance culture assessments to review the culture of ethics and compliance across a company.
- > Assist in the development of company programs and performance metrics to help incentivize "good compliance."
- > Work with internal and external counsel to assess the effectiveness of compliance programs at the time of alleged misconduct, to develop independent compliance program enhancement strategies, and evaluate the effectiveness of compliance program enhancements during settlement negotiations between corporations and enforcement authorities.





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