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A Primer on Conducting Effective Compliance Investigations

By Gary Messplay and Sharon Bradley

The pharmaceutical and medical device industry is among the most heavily regulated in the U.S., subject to numerous laws, regulations, and guidelines that federal, state, and local government entities and prosecutors are especially eager to enforce. With government enforcement actions against pharmaceutical/device companies regularly resulting in multi-million and even multi-billion dollar settlements, industry's compliance with applicable laws, regulations, and guidelines has never been more critical. As a consequence, companies of all sizes have become increasingly dependent on their internal compliance functions to prevent, detect, investigate, and redress non-com-

pliant behavior before it reaches a magnitude likely to attract government attention. This article offers practical suggestions for conducting internal compliance investigations and addressing detected misconduct in a manner that reduces an organization's overall compliance risk.

Follow Procedure

Pharmaceutical and device companies may receive reports of non-compliant behavior through a variety of channels, including direct reports by employees to management or compliance personnel, anonymous tips submitted to the company's internal compliance hotline, and complaints received from competitors.



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Regardless of the source, every report of non-compliance must be taken seriously and subjected to a prompt, thorough, and objective investigation.

One way to ensure uniform and appropriate handling of all compliance complaints is to establish a formal, written policy that governs the management of all compliance reports and investigations. At a minimum, the policy should require the tracking of all compliance reports, development of an investigation plan, reporting of investigation results, and taking appropriate corrective actions. The policy should also require the investigation to be conducted in a manner that adequately protects the confidentiality of the individuals and information involved.

Document Everything

It is imperative for the company to extensively and accurately document each step of a compliance investigation. By doing so, it creates a record that potentially will be scrutinized by outside parties, such as the government or private litigants. An investigation will be questioned if it is not seen as fair and impartial. The development of an extensive record will assist the company in establishing timeliness, completeness, fairness, and impartiality.

Define and Redefine the Scope

At the outset of a compliance investigation it is important to define the scope of the inquiry, taking into account both the extent and the severity of the alleged misconduct. For example, an investigation into an allegation that a single entry-level employee violated an internal company policy will initially have a much narrower scope than an allegation that the entire sales force is routinely engaging in off-label

promotion at the direction of a member of senior management. That being said, the former type of investigation may uncover evidence of systemic misconduct, thereby necessitating expansion of the investigation's initial parameters. Because the scope of an investigation is inherently dynamic, it should be continually reassessed throughout the course of the investigation.

Have a Plan

After determining the preliminary scope of the investigation, the next essential step is to create a written investigation plan that identifies the potential misconduct, the internal and external resources that will be involved in conducting the investigation, the areas of inquiry to be pursued and the individuals responsible for pursuing them, and each step that will be taken during the course of the investigation. Almost all investigation plans will call for collecting and reviewing documents, as well as conducting interviews.

Document Review. Oftentimes the first step in an investigation is to review the documents of the individual(s) involved in the alleged misconduct. At a minimum, this will include conducting a targeted search of each individual's email, shared files, phone messages, and computer hard drive. Depending on the nature of the allegations, it may also be necessary to review expense reports, call notes, and phone records, among other things.

After this initial review of documents, it is important to reevaluate the investigation plan and determine whether the documents of additional employees should be collected and reviewed.

Interviews. Generally interviews should be conducted after reviewing and analyzing pertinent documents, which often will help with selecting

interviewees. However, in some circumstances there may be time constraints that prohibit the collection and review of all documents prior to conducting interviews. In addition to company employees, it may be necessary and appropriate to interview third parties. The decision whether to interview third parties should take into account the need for confidentiality.

Determining the interview sequence is almost as important as deciding whom to interview; typically interviews should begin with the individuals who are likely to be the most forthcoming (i.e., those who have the least to lose), with the goal of obtaining information that will be useful during interviews of the individuals who have the most at stake and therefore may have an incentive to obfuscate the truth. In this regard, it is imperative to obtain buy-in from the highest levels of the organization; the message from the top should be an expectation of complete cooperation with the investigation. It is equally important to ensure confidentiality so that interviewed employees do not discuss the investigation or their interview with other employees. One way to minimize this risk is to conduct the key interviews in a single day or at least on a compressed timeline.

As with the scope of the investigation, the investigation plan should be continually reexamined and modified as needed.

Bring in Reinforcements When Needed

Both at the beginning of an investigation and throughout its duration, staffing is an important consideration. It is essential that an investigation be conducted in an expeditious, thorough, and objective manner. In some instances, assistance from outside counsel may

be required depending on a number of factors, including the following:

Adequacy of internal resources. If the scope of an investigation exceeds the available internal resources, an outside firm should be brought in to assist with the speed of the investigation. Inadequacy of internal resources does not excuse the company from its obligation to conduct a prompt, thorough, and objective investigation into all compliance complaints. This is particularly important if the non-compliant activity may be ongoing.

Need for demonstrating independence. Seeking assistance from an outside firm is also advisable if the nature of the investigation is one that would call into doubt the objectivity of an internal review. For example, if the alleged misconduct is attributed to one of the company's top sales representatives, third parties including the government may be more likely to give credence to an investigation conducted by outside counsel rather than internal compliance personnel.

Resistance from within. Due to the particularly sensitive nature of some compliance investigations, such as those involving allegations of executive wrongdoing, compliance personnel may face resistance when attempting to conduct the investigation. In such instances, hiring outside counsel to conduct the investigation may be preferable because outsiders are less likely to succumb to internal pressures. In some instances, outside counsel may be retained by a corporate board of directors to bolster the authority of the outside lawyers.

Severity of the misconduct. Minor violations of internal company policies most often can and should be investigated by internal compliance personnel. But if the alleged misconduct is particularly egregious, such as a violation

that could lead to criminal and/or civil penalties, hiring outside counsel to conduct the investigation is likely in the company's best interests.

Extent of the misconduct. Some investigations begin with a single allegation of wrongdoing that, once investigated, leads to the discovery of additional violations that are so pervasive that internal compliance personnel cannot demarcate the wrongdoing—in other words, they cannot identify a boundary within which the misconduct is contained. In such instances, involving outside counsel is particularly advisable.

Need for specialized expertise. Certain types of violations may require specialized expertise that internal compliance personnel do not possess. For example, investigations into potential violations of the Foreign Corrupt Practices Act may require consulting an outside firm to help navigate the nuances of this area of law. Similarly, an issue involving data integrity may require the expertise of an outside law firm.

Privilege. In some instances, the company may want to attempt to conduct the investigation in a manner that is protected by the attorney-client privilege, which is another reason for retaining outside counsel to conduct the investigation.

Government involvement. If the conduct in question is likely to be disclosed to, or discovered by, the government, it may be in the company's best interest to involve outside counsel from the outset.

Report Findings

The company's compliance officer (or equivalent) should report the findings of each compliance investigation to the Chief Executive Officer, the Board of Directors, and/or the Compliance Committee, as appropriate. The report should include the compliance officer's

recommendations regarding corrective measures to be taken, if any.

With respect to the timing of these reports, findings of confirmed wrongdoing should be reported as soon as practicable after concluding the investigation. For investigations that conclude that a violation did not occur, it would be appropriate to deliver such reports on a quarterly basis or during the next scheduled compliance update.

In addition, the results of compliance investigations—either individually or at least in the aggregate—should be reported to the entire organization. By doing so, the company assures employees that if they voice compliance concerns, those concerns will be addressed. Such assurance is essential to building and maintaining a culture of compliance. Conversely, failure to communicate the results of the investigation can lead to a number of unfortunate consequences including the belief that the company permits or even condones non-compliance.

Finally, the company should consider whether to report the misconduct to federal or state authorities and/or make a repayment of any kind to the government or another entity. According to the oft-cited compliance guidance issued by HHS' Office of Inspector General,¹ prompt voluntary reporting demonstrates good faith and will also be considered as a mitigating factor if the company becomes the subject of an OIG investigation. But there are numerous factors to consider before deciding whether to self-report and it is advisable to consult with outside counsel before reporting.

Take Corrective Actions

When an investigation uncovers wrongdoing—and sometimes even when it does not—the final step is to develop and undertake corrective actions. Companies should assume that one day

the government will learn about the misconduct and will inquire about the company's response to the non-compliant activity. How the company addresses misconduct will directly influence the government's response to the situation. An inadequate investigation or insufficient corrective action to redress the misconduct is more likely to result in government enforcement or a more severe government response. In general, corrective actions fall into one of the following five categories: (1) disciplinary actions, (2) training, (3) policy revisions, (4) corrective communications, and (5) culture adjustments.

Disciplinary Action. In almost all cases, some form of disciplinary action should be taken against the wrongdoer. It also may be necessary to take disciplinary action against managers who failed to use reasonable care to detect the misconduct, employees who refused to cooperate with the investigation, supervisors who condoned the malfeasance, or anyone who attempted to retaliate against the reporter of the misconduct.

Disciplinary action can take one or more of the following forms: employee counseling, verbal or written warning, verbal or written reprimand, probation or suspension without pay, demotion, salary decrease, bonus reduction or forfeiture, and/or termination. Every company should have in place a "disciplinary matrix" that guides the determination of which form or forms of discipline to impose. The matrix should take into account the nature and severity of the violation at issue; whether the employee

acted intentionally, recklessly, negligently, or accidentally; whether the employee has committed any prior violations, and if so the nature and severity of those violations; whether the employee voluntarily disclosed the violation; and the extent to which the employee cooperated with the compliance investigation.

Training. In lieu of or in addition to disciplinary action, misconduct often signals the need for additional compliance training, whether for the wrongdoer individually, a specific department within the company, or the organization as a whole.

Even in instances where an investigation into alleged misconduct concludes that no wrongdoing occurred, additional compliance training may be warranted. For example, the allegation of wrongdoing may reflect that the reporter himself does not understand the rules that govern his conduct and therefore needs additional training.

Policy Revisions. Sometimes the occurrence of misconduct signifies the need to develop new internal policies and/or to revise existing ones. By way of example, a company policy could be misconstrued by employees to permit the conduct at issue and therefore needs to be revised for clarity to prevent similar behavior in the future.

Corrective Communications. Where the misconduct at issue reaches health-care providers and potentially has a deleterious impact on patient health, it may also be necessary to disseminate corrective communications to affected third parties.

Culture Adjustments. Finally, a compliance investigation might uncover wrongdoing that is attributed, at least in part, to the lack of a "culture of compliance" within the company. In such instances, it is imperative that senior management in the organization work with the compliance department to address these cultural issues. The compliance department cannot be expected to achieve this alone.

The adequacy of a company's corrective action plan depends on the extent to which it addresses the pervasiveness and severity of the improper conduct, and its effectiveness in preventing misconduct in the future. While disciplinary action alone may be sufficient in the case of misconduct by a single rogue employee, systemic problems may warrant all five types of corrective action. In all cases, it is important to subsequently evaluate whether the corrective actions were effective.

Conclusion

In light of the intense scrutiny faced by pharmaceutical and medical device companies, ensuring that allegations of non-compliance are properly investigated and corrected must be a top priority of the compliance function. Following these guidelines will assist companies with this important task.

1. Office of Inspector General, Department of Health and Human Services, [Compliance Program Guidance for Pharmaceutical Manufacturers](#), 68 Fed. Reg. 23731, 23742 (May 5, 2003).