

## Internal investigations as an effective compliance tool

One of the overarching themes of the post-Enron, Sarbanes-Oxley era is the imperative that corporations self-police, self-report and self-remediate wrongdoing by management and other employees. As a result, internal investigations, often under the auspices of a special committee of the board of directors, have become a relatively common corporate governance practice.

Most internal investigations are defensive in nature. That is, they are in response to claims of wrongdoing coming from outside the company such as shareholder demands or litigation, government investigations or press reports. However, internal investigations can also be used proactively by companies to identify and address internal issues before they become public and ahead of government enforcement efforts. Doing so can provide greater control over potentially difficult situations and possibly mitigate the ultimate consequences.

The pharmaceutical industry is among the most highly regulated. As such, compliance is a critical component of its governance structure. Proactive internal investigations can play a constructive role in compliance. Whether and how to conduct an internal investigation depends upon the facts and circumstances at hand. Accordingly, companies should seek legal advice, from in-house or outside counsel, in connection with particular investigations.

Some common questions and considerations include:

- When is an internal investigation warranted?
  - Whistleblower complaint
  - Internal audit
  - Materiality considerations
  - Changes in DOJ/OIG enforcement priorities or outlook
  - Reporting requirements
- What types of issues in the pharmaceutical industry may trigger the need for an internal investigation?
  - Gifts to healthcare professionals/decision makers
  - Aggressive tactics in the field, particularly related to potential “off-label” communications
  - Conferences/honoraria
  - Preceptorships
  - Product samples
  - Drug pricing and discount arrangements
  - Grants/research arrangements
  - PBM contracts
  - Exclusive or preferential formulary selections

- Who should conduct the investigation? (This will vary depending upon the nature of the investigation.)
  - In-house counsel/outside company counsel/independent counsel
  - Independence considerations must be considered
  - Likelihood of subsequent assessment of investigation is a factor
  
- Should the government be informed?
  
- Who should oversee the investigation?
  - Board/audit committee/special committee?
  
- How should the investigation be reported?

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