

KING & SPALDING LLP

Pharmaceutical Compliance Congress

November 15, 2004

Washington, DC

Internal Investigations: Key Issues for Pharmaceutical Companies

**John T. Bentivoglio
jbentivoglio@kslaw.com
202.626-5591**

Key Issues in Conducting Internal Investigations

- Why it is important to investigate potential wrongdoing
- Responsibility for conducting the investigation
- Telling employees about the investigation
- Collecting and handling documents
- Conducting interviews
- Deciding whether (and how) to disclose the results of the investigation
- **Practical tips on how to avoid going to jail**
- The importance of policies and procedures

1. Why Conduct an Internal Investigation?

- Corporations are liable (criminally and civilly) for the acts of their agents within the scope of their employment and that are intended in part to benefit the corporation
- Prosecutors and enforcement agencies expect companies to investigate allegations of wrongdoing. Examples:
 - U.S. Sentencing Guidelines
 - Memo by Deputy Attorney General (Jan. 2003) on Prosecution of Business Organizations (the “Thompson Memo”)

Why Conduct an Investigation? (cont'd)

- Respond to any government investigation
 - Keep track of what the government knows or may discover
 - Present facts in proper context
 - Document company's investigation and response
- Minimize potential adverse consequences
 - Recall or halt distribution of product
 - Avoid or limit regulatory action, including suspension or debarment
 - Prepare to defend shareholder, qui tam, or criminal actions
- Identify and fix any problems:
 - Learn if there is a problem and estimate its scope and potential liabilities
 - Identify wrongdoers
 - Fix it and make sure it doesn't happen again
- Comply with disclosure obligations imposed by statute or agreement

Responsibility for the Investigation

- In most cases, investigation should be under the direction of lawyers:
 - Counsel is more experienced on the appropriate way to conduct, document an investigation
 - Investigations often involve difficult legal issues
 - Preserves the option of asserting privileges to prevent disclosure
- Inside or outside counsel?
 - There may be advantages to both

Responsibility for the Investigation (cont'd)

- Advantages of inside counsel:
 - Often experienced in conducting investigations
 - More familiar with the company and legal environment
 - Known to management/employees
 - Less likely to disrupt operations
 - Less expensive

Responsibility for the Investigation (cont'd)

- Advantages of outside counsel
 - Outside perspective of the facts
 - Greater credibility with government (sometimes viewed as more independent)
 - May facilitate assertion of privileges
 - Inside counsel may have reviewed relevant events
 - Prevents/insulates inside counsel from “obstruction” and other issues

Informing Employees About the Investigation

- If there is a government investigation, employees need to be told about it:
 - Avoid damaging rumors and uncertainty
 - Government agents may show up at their homes without warning

Informing Employees (cont'd)

- Generally, the best approach is to send a letter or memo:
 - Brief description of the nature of government investigation and its subject (to extent known)
 - Company intends to cooperate
 - Agents may try to interview employees
 - Consider whether or not to note that employee has right to talk or to refuse to talk
 - Employees should be fully truthful
 - Don't discuss facts with others

Handling Documents

- Instruct employees in writing to collect and preserve all relevant documents
 - Don't alter or add documents either
- Electronic documents require specific instructions to ensure that they are retained:
 - Suspend normal document destruction procedures
 - Stop recycling backup tapes
 - Back up network servers
 - Consider imaging hard drives
- Here again: Think these issues through in advance - Know what you have.

Documents (cont'd)

- Have a designated, uninvolved employee (or outside person) be responsible for gathering documents
- Review documents before interviews
- Review documents before producing them to the government
 - Remove privileged documents
 - Mark commercially sensitive documents

How Should Interviews Be Conducted?

- Begin with “warnings”:
 - What you’re investigating
 - Interview is for the purpose of rendering legal advice
 - You are the company’s lawyers, not the individual’s
 - Privileges can be waived by the company
- Why is this necessary?
 - Fairness to employee
 - Ethical issues
 - Avoid possible disqualification of counsel
 - Avoid problems with subsequent decision to disclose

Conducting Interviews (cont'd)

- Employee should keep interview confidential to preserve privilege
- More than one person should be present to conduct the interview
- Thorough, accurate notes
- Consider issues involved in creating formal interview memoranda

Should a Report Be Prepared? Should It Be Disclosed?

- Whether or not to prepare a report depends on the particular context
- Decision is up to the client (Senior Management, Board, or Board Committee)
- In many cases company will want to disclose:
 - Most pharmaceutical companies often can't risk fighting over disclosure issues
 - May be statutory obligations to disclose
 - E.g., 42 U.S.C. § 1320a-7b(a)(3) (retention of federal health care program overpayments by providers)
 - E.g., FDA or SEC may require disclosure of certain matters
 - Companies operating under CIAs

Should the Report Be Disclosed? (cont'd)

- Companies operating under a Corporate Integrity Agreement may be required to disclose “reportable events” to the HHS OIG
- Some agencies have voluntary disclosure programs
 - Affirmative disclosure of fraud/abuse (particularly potential anti-kickback issues) presents serious issues
- U.S. Sentencing Guidelines:

Sentence of a convicted corporation can be reduced if it promptly and before threat of disclosure reported the offense to appropriate authorities and cooperated fully in the investigation (U.S.S.G. § 8C2.5(g)(1))
- Thompson Memo

Should the Report Be Disclosed? (cont'd)

- Waiver of privileges:
 - Department of Justice is increasingly taking the position that full cooperation requires corporation to waive privileges
 - Most courts hold that voluntary production of a report of an internal investigation to the government waives any otherwise applicable privileges, so that the report will have to be produced to plaintiffs in civil litigation
 - Risk can be mitigated through use of confidentiality agreements with government
- Disclosure to third parties:
 - Disclosing the results of an investigation to auditors, banks or public relations personnel (or any other third party) may waive the privilege as against the government and others
 - Don't disclose within company except to those with need to know

Practical Tips on Obstruction of Justice

- Obstruction of justice: 18 U.S.C. § 1512(b):

“Whoever knowingly . . . engages in misleading conduct towards another person, with intent to . . . influence, delay or prevent the testimony of any person” can go to jail for up to ten years

Exception for “solely...lawful conduct” when the “sole intention” is to encourage truthful testimony

Federal obstruction of justice statutes do not reach “the providing of lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding.”

Obstruction Issues (cont'd)

- Be careful in talking to employees:
 - Don't suggest that they not cooperate with the government
 - Don't tell them what to say (except to tell the truth)
 - Don't mislead them as to the facts
 - Keep a written record
 - Have two members of the investigative team in attendance

Obstruction Issues (cont'd)

- Document Retention Obligations:
 - Sarbanes-Oxley added new § 1519:

“Whoever knowingly alters, destroys . . . [or] conceals . . . any record [or] document . . . with the intent to impede, obstruct or influence . . . [any federal investigation] or in relation to or contemplation of any such matter or case,” can go to jail for 20 years.
 - What does it mean?
 - Can you make changes in a draft memo?
 - Can you have a document retention policy?
 - Ensure that any such policy is justified by considerations other than protecting documents from discovery, and is tailored accordingly

Obstruction Issues (cont'd)

- Document Retention (cont'd):
 - Take steps to ensure that relevant documents are preserved and produced if requested
 - Electronic documents are a particular problem
 - Suspend normal document retention procedures
 - Obstruction of justice can occur even before a subpoena is served

Obstruction Issues (cont'd)

- What to do about the whistle-blower employee?
 - Discipline or termination can look like retaliation
 - Sarbanes-Oxley gives extra protection to whistle-blowers in public companies
 - Bonuses, promotions, or generous severance packages can look like a payoff or bribe
 - Follow normal procedures

Obstruction Issues (cont'd)

- What to do about the employee that has engaged in wrongdoing?
 - Government expects you to discipline the employee(s) (up to an including termination)
 - Government expects you not to provide legal fees or cooperate through a joint defense
 - However, discipline can create other risks
 - Employment litigation
 - Whistleblower claims

Policies and Procedures Can Reduce Risks

- Written policies and procedures on when and how to conduct internal investigations can provide substantial benefits
 - Establish internal expectations about matters will be handled
 - Expedite decisions when events may be unfolding rapidly
 - Protect the company and lawyers against changes of *ad hoc* decision-making

Policies and Procedures (cont'd)

- Key Provisions for Policies and Procedures:
 - Employee hotline and/or other reporting procedures
 - Company policy is to investigate allegations of wrongdoing
 - And cooperate with investigators and regulators
 - Employees should report wrongdoing through appropriate channels
 - Employees must cooperate with internal investigations
 - Assign responsibility for receiving, documenting and investigating allegations or complaints
 - Coordination with legal counsel
 - Use of additional internal or external resources
 - Establish responsibility for identifying corrective actions to prevent future wrongdoing

Policies and Procedures (cont'd)

- Policies and procedures:
 - Establish obligations and procedures to report results of investigations
 - Sarbanes-Oxley rules
 - Prohibit retaliation against good-faith whistleblowers
- Drafts of key documents should be prepared in advance. Examples:
 - Memo directing employees to hold documents
 - Memo to employees re: government investigation
 - Internal checklists for counsel

Fine Print

- Views expressed in these slides and the accompanying oral presentation represent personal views of the presenters and not necessarily those of our clients or King & Spalding LLP.
- Moreover, slides and presentation provide a general summary of legal and regulatory requirements and do not constitute legal advice.