A Case Study: How to Conduct an Effective and Compliant Internal Investigation

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HYPOTHETICAL FACT PATTERN
Hypothetical Fact Pattern

Scientific Drug Company of Columbus, Ohio, is excited to announce today it has received FDA approval for a breakthrough lung cancer drug called Freedom. Dr. Frank Johnson, Medical Director and PhD, has worked on the development of Freedom for 15 years. Dr. Johnson intended Freedom to be used for dementia and not lung cancer. Despite Dr. Johnson’s work for the past 15 years, the FDA would not approve dementia as a permitted use for Freedom.

Hypothetical Fact Pattern

Once the FDA approved Freedom for lung cancer, the Scientific Drug Company’s Compliance Department began training the Marketing Teams throughout the United States on the appropriate uses of the drug, Freedom. Compliance Trainer, Jack Paul, put together extensive training materials for the Marketing Department for the appropriate use of Freedom. Jack conducted training for all marketing employees. Jack specifically trained all marketing employees not to sell the drug, Freedom, for dementia despite Dr. Johnson’s clear dissatisfaction with Jack’s training materials.

Hypothetical Fact Pattern

In January Jack took a training trip to the Chicago office to train the Marketing staff on the appropriate uses of the new drug, Freedom. While in Chicago, Jack took his two nephews, ages eight and nine, to the Bulls game and expensed three Bulls’ tickets as a Scientific Drug Company Marketing Compliance Teambuilding Activity. Jack also posted pictures of the Bulls game on Facebook.
Hypothetical Fact Pattern

In April, Jack went to visit his primary care physician for his routine physical. Jack’s primary care physician commented that Freedom was having a dramatic effect on two of his patients who are suffering from dementia. At Jack’s primary care physician’s comment as to the remarkable results that he was seeing, Jack inquired as to how it came about that the primary care physician was using Freedom for dementia. Jack’s doctor explained that the Marketing Team from Scientific Drug Company had been in the office in February to explain the dementia use of the drug, Freedom.

Hypothetical Fact Pattern

Jack immediately reported this to the Chief Compliance Officer of Scientific Drug Company, Brett Bender. Jack reviewed with Brett that he had instructed all Marketing Departments to sell Freedom only for lung cancer and never for dementia. Brett decided to hire outside counsel in order to conduct an Internal Investigation. Outside counsel, Joe Jackson, began interviews and interviewed the Vice President of Marketing, Tom Smith, regarding the Marketing Department’s sales activity regarding the drug, Freedom. Mr. Jackson gave Mr. Smith an Upjohn Warning. Mr. Smith indicated he was willing to cooperate with Scientific’s investigation of this matter; however, he wanted personal counsel paid for by the company and wanted an Indemnification Agreement for discussing any matters.

Hypothetical Fact Pattern

A Finance Department employee, who was a friend of Jack, was processing the expenses for Jack’s Chicago trip and had seen on Facebook that Jack had taken his two nephews to the Bulls game. The date of the post on Facebook corresponded with the same expense for a Marketing Compliance Teambuilding Activity. The Finance Department employee reported this to the Chief Compliance Officer.
Hypothetical Fact Pattern

Jack became disillusioned as the Internal Investigation dragged on and no direct order was issued to stop the Marketing Department from marketing Freedom as a dementia drug. Jack sought outside counsel and filed a False Claim Act Complaint under seal regarding the off-label marketing and sales of Freedom.

Hypothetical Fact Pattern

The Chief Compliance Officer confronted Jack regarding his expense account of the Bulls game. Jack refused to answer any questions until Jack received answers as to the progress of the Internal Investigation. Jack indicated he would answer all questions if Scientific Drug Company paid for counsel to represent him regarding this matter and provided him an Indemnification Agreement. Scientific terminated Jack for falsification of the expense report and failing to cooperate with an Internal Investigation.

Hypothetical Fact Pattern

Jack immediately file an Amended Complaint alleging retaliation in his False Claim Act filed under seal.

The Department of Justice subpoenaed scientific drug company and requested the internal investigation report from outside counsel. The Department of Justice demands the names of all employees responsible for the off label marketing of Freedom.
WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

Directors
Committee Representation
- Special Litigation Committee
- Compliance Committee

Individual Representation
- Potential Caremark Issues
- Potential Breaches of Other Fiduciary Duties
  - Duty of Care
  - Duty of Loyalty

RESPONSIBLE CORPORATE OFFICER DOCTRINE

- AKA the “Park Doctrine” – United States v. Park, 421 U.S. 658 (1975)
- Concept – officer stood in “responsible relation” to the underlying violative act or omission
- Origins
- Statutory Bases
  - Food Drug & Cosmetic Act
  - Has since expanded
- Bottom Line: Essentially Strict Liability Based Solely on Being in a Position of Control

THE “YATES MEMO”

- Issued in September 2015 by the now famous (or infamous) former Acting Attorney General, Sally Yates, when she served as Deputy AG under Eric Holder. (insert video clip from “The Apprentice” of Donald Trump saying, “You’re fired.”)
- DOJ Response to political and public outcry out of lack of individual accountability for the 2008-2009 “Great Recession”
- Gist: Any corporate entity hoping to obtain cooperation credit from DOJ had better be prepared to throw one or more individual wrong-doers under the bus.
- Result: Along with RCO, heightened emphasis by DOJ on holding individuals accountable for corporate wrongs.
WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

• WHO PAYS LEGAL FEES AND COSTS?
  • ADVANCEMENT
  • INDEMNIFICATION
  • D&O INSURANCE
  • SOURCES OF AUTHORITY
    • State general corporation law
    • Company Articles of Incorporation and By-Laws
    • Contracts (e.g., Indemnification Agreements)
  • See Johnston, McFadden, et al. *Indemnification and Insurance for Directors and Officers*, BNA Bloomberg Corporate Practice Portfolio Series, No. 84-3rd.

WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

• DECISION IS NOT ENTIRELY WITHIN CONTROL OF CORPORATE ENTITY AND ITS COUNSEL
  • Irrespective of Company’s decision, certain individuals may insist on separate counsel.
  • Typically the genesis of the biggest fights over advancement, indemnification, and insurance.

WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

• FORGING ALLIANCES – JOINT DEFENSE AND COMMON INTEREST AGREEMENTS
  • CONCEPT: US v. Them => Privileged Communications
  • The Bane of Every Prosecutor or Plaintiff’s Attorney
  • Written or Unwritten?
  • What happens when one member decides to that the best course is to save his/her own skin?
  • Navigating Conflicts
PLANNING THE INVESTIGATION

• STEP 1: ISSUE IDENTIFICATION AND POTENTIAL EXPOSURE ASSESSMENT
  • What is at stake here? What is the worst-case scenario?
    • Administrative exposure – Exclusion
    • Civil exposure
      • False Claims Act
      • Shareholder’s Derivative Suit
    • Criminal exposure
      • Kickbacks
      • Fraud
      • Statutory violations
      • RCO

PLANNING THE INVESTIGATION

• Step 2: Collecting Documents
  • Legal Hold Notice
  • Identification of Custodians
  • Development if Keyword Search Protocols
    • E-mails are the nail that seals the coffin
  • E-discovery Plan and Process
    • Creation of a searchable database
    • What are the inputs?
      • Backup tapes? Other media?

PLANNING THE INVESTIGATION

• Step 3: Witness Interviews
  • Identification of Key Witnesses
    • Document Review
    • High-Level Discussions with Control Group
  • Preparation of Witness Binders
  • Resolution of Representation Issues
  • Resolution of Privilege Issues
    • Former Employees
PLANNING THE INVESTIGATION

• FORM OF REPORT
  • Oral v. Written
  • Level of Detail
  • THE KEY CONSIDERATION: DISCOVERABILITY

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PLANNING THE INVESTIGATION

• ASSESSING THE PROS AND CONS OF SELF-DISCLOSURE AND “COOPERATION CREDIT”
  • Regulatory Self-Disclosure Requirements
  • Yates memo revisited
  • Sentencing Guidelines

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CONDUCT OF THE INVESTIGATION

• DETERMINATION OF THE CONTROL GROUP, POINTS OF CONTACT, AND LIMITATIONS ON COMMUNICATION
  • Maintaining independence as the internal investigator, and the importance of being able to demonstrate it later.
CONDUCT OF THE INVESTIGATION

• WITNESS INTERVIEWS
    • Gist
      • This conversation is covered by the attorney-client privilege
      • That privilege belongs to one entity and one entity only: the Company
    • WE DO NOT REPRESENT YOU
      • The Company, and only the Company, can decide whether to waive or maintain the privilege

CONDUCT OF THE INVESTIGATION

• A REPRESENTATIVE UPJOHN Warning
  • Identify yourself as an attorney; identify your client
  • Make clear that you represent NO ONE OTHER THAN THE CLIENT: "I do not represent you."
  • State the purpose of the interview
    • Obtain facts, in confidence, in furtherance of providing legal advice to the client = the Company. Classic elements of the attorney/client privilege
  • Make clear to whom the privilege belongs and who can waive it.

CONDUCT OF THE INVESTIGATION

• A CLASSIC QUESTION FROM THE WITNESS: “Do I need my own lawyer?”

• THE NECESSARY AND ONLY RESPONSE.

• ORDER OF INTERVIEWS (typically bottom to top)
**The Yates Memo: Background**

“In the most basic ways, though, corporate misconduct isn’t all that different from everything else DOJ investigates and prosecutes.

[Crime is crime.]

And it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom. In the white-collar context, that means pursuing not just corporate entities, but also the individuals through which these corporations act.”

Sally Quillian Yates, Deputy Attorney General, September 10, 2015

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<thead>
<tr>
<th>The Yates Memo: Background</th>
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<tbody>
<tr>
<td><strong>Issued:</strong> September 9, 2015</td>
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<tr>
<td><strong>Author:</strong> Sally Quillian Yates, Deputy AG</td>
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<td><strong>Goal:</strong> Consistency across all DOJ departments in holding individuals accountable for illegal corporate conduct.</td>
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**The Yates Memo: Significance**

- Principles revised to reflect Yates Memo expanded focus on individuals
- Prosecutors rely on Principles in determining whether and what charges to bring
- Principles provide important guidance to corporations regarding compliance programs and cooperation during investigations
The Yates Memo: 6 Key Steps

1. Eligibility for any cooperation credit requires corporations to provide DOJ with all relevant facts about the individuals involved in the misconduct.

2. Both criminal and civil corporate investigations should focus on individuals from the investigation's inception.

3. Criminal and civil DOJ attorneys handling investigations should be in routine communication with one another.

4. No corporate resolution will provide protection from criminal or civil liability for individuals, except in “extraordinary circumstances.”

5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.

6. Civil attorneys should consistently focus on individuals and evaluate whether to bring suit against an individual based on considerations beyond the ability to pay.

The Yates Memo: Implications

- Increased pressure on prosecutors to pursue individuals
- Possible increases in civil actions due to the increased communication requirement
- More cooperation deals with lower level executives in order to reach highest level leaders
- Chilling effect on corporate cooperation with federal prosecutors due to “all or nothing” approach
The Yates Memo: Implications

- Chilling effect on self-reporting by corporations
- Chilling effect on personal cooperation with internal compliance investigations
- Conflicts of interest:
  - Legal representation (personal/corporate)
  - Involvement of personal stakeholders in internal corporate investigation
- Waivers of attorney-client privilege?

The Yates Memo: Action Items

Proactive
- Review and enhance compliance program
- Make leadership aware of Yates Memo
- Document efforts to remain compliant

Reactive
- Retain counsel experienced in criminal investigations (particularly in dealing with DOJ)
- Promptly deal with conflicts of interest

DRAFTING THE REPORT
DRAFTING THE REPORT

Case Information
- Investigative Team Details (names, position/roles, contact information)
- Name of Legal Counsel (if involved)
- Complainant/Referral Source Details (names, position/roles, contact information, date report or complaint was submitted, manner in which report was made (hotline, in-person meeting with CCO, exit interview, etc.))
- Summary of Allegations (description, seriousness, type, dates of alleged violation(s), names of parties involved)

DRAFTING THE REPORT

Scope of Investigation
- Succinctly state the scope of the investigation
- Summarize the objective of the investigation

DRAFTING THE REPORT

Investigation Plan
- List of documents to be collected
- Litigation holds
- List of referral source(s) and witnesses to be interviewed
- Order of interviews
DRAFTING THE REPORT

- Communication plan and outline for interviews
  - Upjohn warnings
  - Introduction/case overview
  - Investigator’s role
  - Overview of non-retaliation policy
  - List of general and specific questions
  - Concluding Messages: reiterate confidentiality, non-retaliation policy, preserve all documents and abide by litigation holds, call investigator with further information
- List of legal issues to be researched
- List of applicable company policy and/or legal authorities

DRAFTING THE REPORT

Documentation of Interviews
- Promptly and accurately memorialize interviews
- Be complete
- Document all parties who were present during interview
- Be consistent in format and organization of interview notes
- Summarize how key concepts were explained (see previous slide)
- Include "word-for-word" quotes, especially on important points

DRAFTING THE REPORT

Document Investigator Impression of Interviews (separate from summaries of interviews)
- Credibility assessments
- Interviewer’s notes/impressions section
DRAFTING THE REPORT

Document Evidence
• Attach key documents
• Attach interview summaries
• Attach key company policies, code of ethics provisions, or legal authorities

DRAFTING THE REPORT

Factual Findings
• Summarize the facts that decision makers need to know
• Business units and functions, individuals involved
• Dismiss facts that are irrelevant
• If 2 or more positions are at issue, discuss both sides
• Weigh the facts
• Finance related findings

Example of Factual Findings
• “Mr. X logged onto a government web portal with another employee’s log-in credentials.”
• “Mr. X’s supervisor was aware that Mr. X logged onto a government web portal with another employee’s log-in credentials.”
• “There is no company policy or procedure for the use of log-on credentials on government web portals.”
DRAFTING THE REPORT

Examples of Conclusions (note how conclusions and recommendations track factual findings).

- “Mr. X violated ___ CFR Section ___ and may have violated 18 U.S.C. § 1001
- “Mr. X’s supervisor failed to supervise Mr. X’s adherence to the company’s log-in policies”
- “The company’s internal controls regarding use of log-on credentials is in adequate.”

DRAFTING THE REPORT

Examples of Recommendations

- “Mr. X should be disciplined or terminated.”
- “Mr. X’s supervisor should be disciplined or moved to a non-supervisory position.”
- “The company should develop internal IT controls and retain an outside IT security consultant to assist it in doing so.”

DRAFTING THE REPORT

- Summarize follow-up steps
- Corrective Action/Process Improvement
- Determine if voluntary disclosure should be made
- Determine if overpayments were made and must be repaid
- Determine if fines are to be paid
- Determine if licensing bodies or regulators must be notified
- Notify complainant that appropriate action is being taken
PRESENTING THE REPORT

- Status reports (how frequent and audience)
- Reports to management
- Reports to audit and compliance committees
- Reports to governing boards