AVOID FDA PROBLEMS: IMPLEMENTING A CORPORATE COMPLIANCE PROGRAM

John R. Fleder

Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW
Suite 1200
Washington, D.C. 20005
(202) 737-4580

June 5, 2003
Corporate Compliance Programs

Overview

- Benefits of a Corporate Compliance Program
- Elements of a Successful Corporate Compliance Program
- Record Retention Policy
  - Congress recently enacted the Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745-810. This statute mandated changes in the way companies make disclosures pursuant to securities laws, retain records, and it dramatically increased penalties for “white collar” offenses.

- Voluntary Disclosures
Corporate Compliance Programs - Generally
Code of Conduct

Create a Code of Conduct / Ethics

- A “document that details the fundamental principles, values, and framework for action within the organization.”

Code Of Conduct

Should provide specific guidelines on topics such as:

- Conflict of interest
- Bribes and kickbacks
- Gifts, gratuities, and entertainment
- Accuracy of books and records
- Statements/advertisements about products and services
- Protection of confidential and trade secret information
- Insider trading, antitrust rules
- Government relationships
- Sexual harassment
- Alcohol and drug use
Purposes of Corporate Compliance Programs:

1. Prevent Wrongdoing
2. Detect and Cure Misconduct
3. Comply with FDA Regulations
Enforcing The Program:

- Develop a procedure for enforcing the Compliance Program within your company.
- Determine which violations will require punishment and termination.
  - Establish clear rules with some flexibility.
- Design training for people not terminated after a violation.
- Document everything.
If You Don’t Have An Effective Program ...

◆ An example of what can happen:
  ✤ Corporation pled guilty to 391 felonies:
    ✤ conspiracy, mail fraud involving submissions to FDA, submitting false statements to FDA, shipping adulterated medical devices, and shipping unapproved medical devices.
U.S. v. C.R. Bard, Inc.

- The Court determined that all crimes were committed intentionally and that the plea agreement was reasonable.
- Plea Agreement:
  - $30.5 million in criminal fines
  - $78,200 special assessment
  - $30.5 million civil settlement
  - Bard had to implement specified corporate remedial measures for 4 years, through a corporate integrity agreement approved by court.
Corporate Compliance
Programs - Benefits
Benefits Of Having An Effective Program:

1. Possibly avoid DOJ Prosecution if a problem arises.
     - Lists several factors Department of Justice (DOJ) prosecutors should consider in making a decision about whether to prosecute.
Benefits: Possibly Avoid DOJ Prosecution

Among the factors DOJ considers in determining whether to prosecute:

“"The existence and adequacy of the corporation’s compliance program."
Benefits: Possibly Avoid DOJ Prosecution

- Critical Factors when DOJ evaluates a compliance program:
  - Is it “adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees”
  - “Whether corporate management is enforcing the program”
Benefits: Possibly Avoid DOJ Prosecution

- Ultimate Questions the DOJ asks:
  1. “IS THE CORPORATE COMPLIANCE PROGRAM WELL-DESIGNED?”
  2. “DOES THE PROGRAM WORK?”

- In order to ask these questions, DOJ considers several aspects of the program and makes certain determinations ...
Benefits: Possibly Avoid DOJ Prosecution

DOJ Considerations about the Compliance Program:

- Comprehensiveness
- Extent and pervasiveness of criminal conduct
- Number / level of corporate employees involved
- Seriousness / duration / frequency of misconduct
- Remedial actions taken - restitution, disciplinary action, revisions to compliance program
- Promptness of any disclosure
Benefits: Possibly Avoid DOJ Prosecution

◆ DOJ Determinations about the Compliance Program:
  ➢ Is the program merely a “paper program?”
  ➢ DOJ determines whether corporation has provided for a staff sufficient to audit, document, analyze, and utilize the results of the compliance program.
  ➢ DOJ also examines whether employees are adequately informed about the Compliance Program and are convinced of corporation’s commitment to it.
Benefits: Possibly Avoid DOJ Prosecution

- Designing a Corporate Compliance Program:
  - Should be designed to detect particular types of misconduct that are most likely to occur in the food and drug industry.
  - DOJ will speak with FDA about company’s program:
    - "Prosecutors should consult with relevant federal and state agencies with the expertise to evaluate the adequacy of a program’s design and implementation."
Additional Benefits of a Compliance Program

- After all of these determinations, DOJ may decide:
  - Charge only the corporation’s employees and agents, or
  - Not to charge at all.

- United States Sentencing Guidelines may also reward, at the time of sentencing, adequate corporate compliance programs if corporation is convicted. USSG § 8C2.5(f).
Benefits of a Compliance Program

2. Early warning to company of problems.

➢ There is time to correct the problem before FDA inspection, product liability suits, or safety or misbranding issues arise for customers.
Benefits of Compliance Program

3. Prevents whistleblower suits and complaints to FDA, including qui tam actions.

- Whistleblowers within the company are potentially the biggest threat.
- A procedure in place allows company to respond and cure problems before government hears about it.
- Corporate Compliance Programs can help company morale:
  - Employees know management listens.
  - No retribution for notifying management of problems.
Benefits Of A Compliance Program

4. A Compliance Program may help to avoid FDA Inspections

  - FDA will “strategize according to the risk” when it comes to its inspection programs due to its limited resources for inspections.
Benefits: Possibly Avoid FDA Inspections

“Strategize According to the Risk” means:

- Companies with comprehensive compliance programs are viewed as “lower-risk operations.”
- Solomon stated that this designation can help a company avoid close scrutiny by FDA
  - Although it will not be guaranteed to reduce inspectional coverage.
5. Reduce Product Liability Exposure.
Corporate Compliance

Programs - Elements
Elements Of A Successful Compliance Program


- It is a “set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one.”
OIG Elements In A Successful Compliance Program

1. **Formal Commitment by Board of Directors of Governing Body.**
   - Allocate adequate resources to program.
   - Follow a reasonable but firm timetable for implementation.
   - Identify an individual to serve as a Compliance Officer.
OIG Elements In A Successful Compliance Program

2. **Written Standards of Conduct, Written Policies, Procedures and Protocols.**

   ➢ This will serve as evidence of company’s commitment.

   ➢ Include “adherence to compliance program” as an element in evaluating employees.
OIG Elements In A Successful Compliance Program

3. Designation of Corporate Compliance Officer and Corporate Compliance Committee
   - Responsible for developing, operating, and monitoring the program
   - Authority to report directly to Board of Directors or CEO (not General Counsel)
   - Sufficient funding, resources and staff to fully perform duties
OIG Elements In A Successful Compliance Program

4. **Regular, Effective Education and Training Programs for all affected employees.**
   - Effectively communicate company standards and procedures
   - Train new employees immediately
   - Document any formal training undertaken by the company
OIG Elements In A Successful Compliance Program

5. **Hotline or other Reporting System to Receive Complaints**

- Ensures lower level employees have access to supervisors and compliance officer
- Develops a method to keep complaints anonymous
- Allows company to investigate and respond to complaints
- Company should document all relevant correspondence
- Obtain information through effective employee exit interview program
- Should you list the government hotline number?
OIG Elements In A Successful Compliance Program

6. **Use of Audits** to monitor compliance and identify problem areas
   - Ongoing monitoring of compliance program
   - The monitoring should be documented
OIG Elements In A Successful Compliance Program

7. Policies to **Terminate Violators of the program**
   - Should have consistency across the company
   - Discipline a responsible employee who fails to detect a violation due to negligence or reckless conduct
   - Further training if an employee violates a policy and is not terminated
OIG Elements In A Successful Compliance Program

8. Develop Policies for Investigation of Complaints and Non-Compliance

- Respond to complaints
- Initiate corrective action and preventative measures
- Reporting system for discovered violations
Record Retention Policy

- For drug and medical device companies, certain records must be maintained for a certain number of years. 21 C.F.R. § 211.180

- Sarbanes-Oxley mandated SEC Final Rule “Retention of Records Relevant to Audits and Reviews.”

- Applies to Sec. 10A(a) companies:
  ✦ Issuers of securities and any “registered investment company.”

- Requires accountants to retain certain records for 7 years.
Record Retention Policy

- Records that need to be retained pursuant to SEC Rule:
  - Workpapers and other documents forming basis of audit or review,
  - Memos, correspondence, communications, other documents and records:
    - Created, sent, or received in connection with the audit or review, and
    - Containing conclusions, opinions, analyses, or financial data related to audit or review.
Record Retention Policy

- Awareness of Sarbanes-Oxley requirements is beneficial, even if they don’t apply to your company ...
- They may be an indication of future FDA rules and requirements.
Record Retention Policy

FDA has additional record retention policies -

- requirements depend on what type of product the company manufacturers: drugs, devices, foods.

- The FDA record retention requirements are imposed on the company regardless of whether it is regulated by the SEC.
Corporate Compliance Programs - Voluntary Disclosure

After misconduct has been discovered, should you voluntarily disclose to FDA?
Voluntary Disclosure

FDA does not currently have a formal incentive program for voluntary disclosure. However, FDA has said it is an “idea [that] is worth exploring .... I wish more corporations would self-report. Companies can either self-report and correct the problem, or they can wait for FDA to catch them.”


FDA will generally “reward” companies who self-report their own violations of law.
Voluntary Disclosure - DOJ Policies

- DOJ considers a corporation’s willingness to “cooperate” in determining whether to charge:
  - “Cooperation” may include willingness to waive attorney-client privilege
  - “Cooperation” may also include not advancing attorney’s fees in support of culpable employees or agents
    - This will not be a consideration in states which require corporations to pay the legal fees of officers under investigation.
Voluntary Disclosure

- Some agencies, such as SEC and EPA, have programs where voluntary self-reporting, coupled with remedial measures, can qualify the corporation for amnesty and reduced sanctions.
- FDA does not, but even in the absence of a formal program, some of the same procedures may be followed.
Voluntary Disclosure

- U.S. Sentencing Guidelines may also “reward voluntary disclosure and cooperation with a reduction in the corporation’s offense level.”
  USSG § 8C2.5(g).

- However, this reward is rarely granted.
  - As of 1998, only 1 corporation out of 400 sentenced under the Sentencing Guidelines.
Voluntary Disclosure: Issues to Consider

◆ Considerations for making a voluntary disclosure:
  ➢ Does FDA want to hear about these things?
  ➢ What are the risks of self-reporting?
  ➢ Does FDA typically find out about these problems anyway?
  ➢ If reported, when?
    ♦ Before or after investigation?
Voluntary Disclosure: Issues to Consider

- Considerations for setting up a voluntary disclosure program:
  - Written or oral reporting?
  - To whom should the disclosure be made?
  - Who makes the report - Counsel or Company?
  - Should there be a meeting?
    ✷ What do you ask for in a meeting?
    ✷ Who attends, who speaks?
    ✷ Follow-up letter sent?
Voluntary Disclosure: Issues to Consider

Considerations for setting up a voluntary disclosure program:

- Tell all or make selective disclosure?
- Will FDA expect privilege to be waived?
- What promises should be made by company?
- What benefits should FDA give -
  - Testifying in private cases, amicus brief?