

# **AVOID FDA PROBLEMS: IMPLEMENTING A CORPORATE COMPLIANCE PROGRAM**



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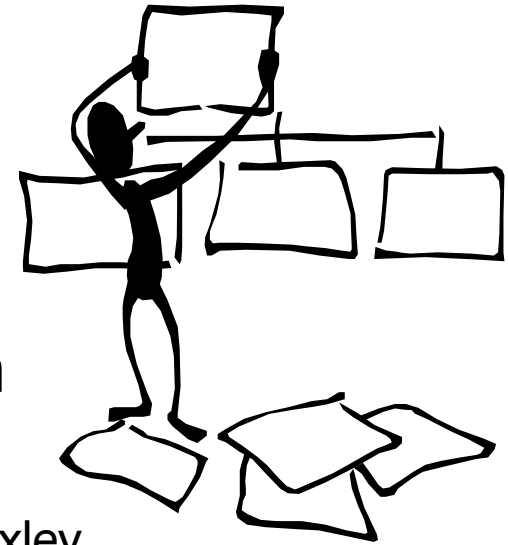
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**6<sup>th</sup> Annual FDA-ORCA Educational Conference – “FDA &  
ORCA: Understanding the Changing Landscape.”  
June 5, 2003**

# 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**



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# **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.”

67 Fed. Reg. 62,057, 62,060 (Oct. 3, 2002).



# 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:
  - U.S. v. C.R. Bard, Inc., 848 F.Supp. 287 (D. Mass. 1994).
    - ✧ 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.

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# Corporate Compliance Programs - Benefits



# Benefits Of Having An Effective Program:

## 1. Possibly avoid DOJ Prosecution if a problem arises.

- ◆ Larry D. Thompson, Deputy Attorney General memo. Jan. 20, 2003
  - 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

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## ◆ 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."

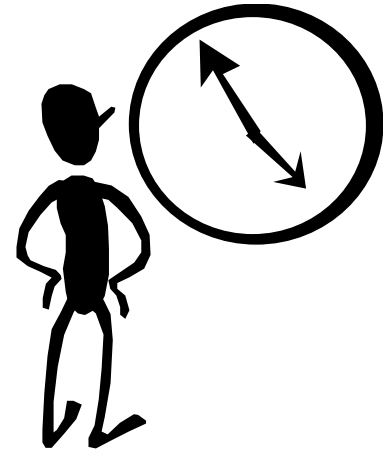
# Additional Benefits of a Compliance Program

- ◆ 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**

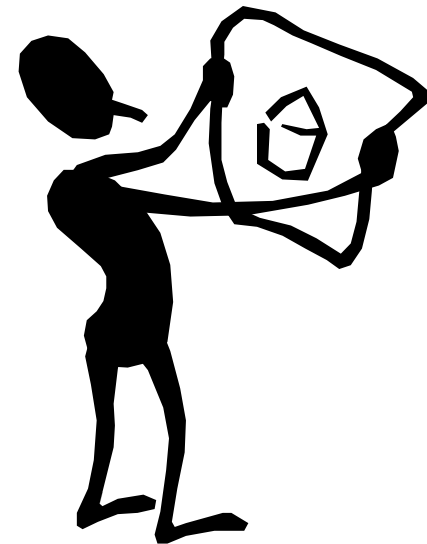
- FDA Enforcement Manual Monthly Bulletin, Apr. 1998 vol. 7, no. 2, reported a statement by Steven M. Solomon, Director of Medical Products Quality Assurance, in FDA's Office of Regulatory Affairs
  - ✧ FDA will "strategize according to the risk" when it comes to its inspection programs due to its limited 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.

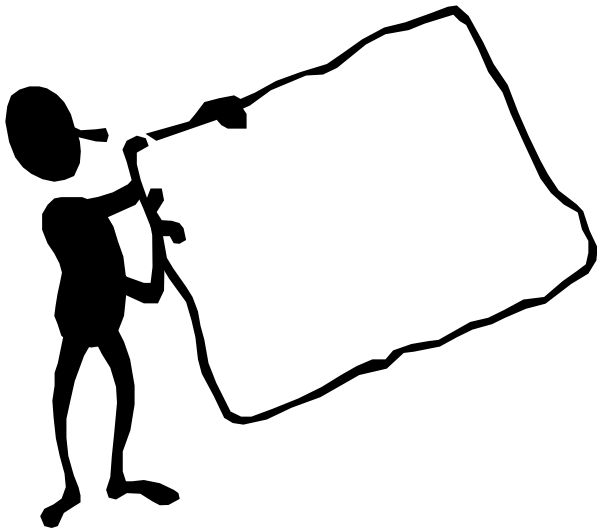
# Benefits of Compliance Program

## 5. Reduce Product Liability Exposure.





# Corporate Compliance Programs - Elements



# Elements Of A Successful Compliance Program

- ◆ HHS Office of Inspector General (OIG) Compliance Guidance for Pharmaceutical Manufacturers.

68 Fed. Reg. 23,731 (May 5, 2003).

- ◆ **It is a “set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one.”**

68 Fed. Reg. 23,731.



# 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

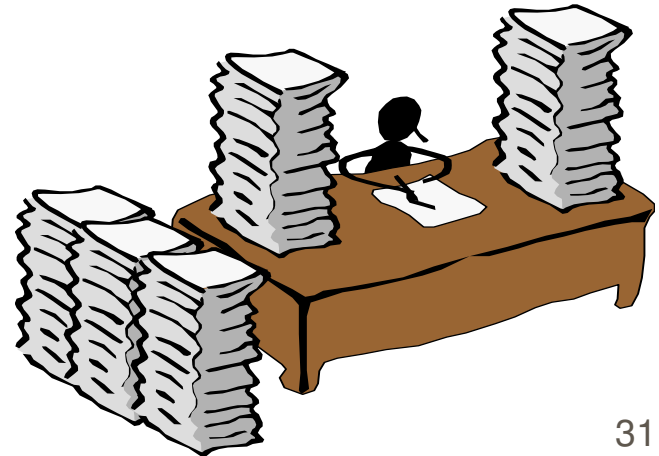
## 5. Hotline or other Reporting System to Receive Complaints

- 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.”  
68 Fed. Reg. 4862 (Jan. 30, 2003)
- ◆ 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.

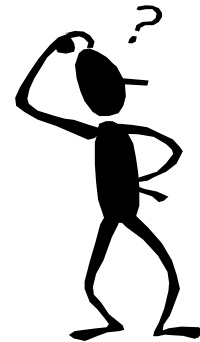
# Record Retention Policy

- ◆ FDA has additional record retention policies -
  - requirements depend on what type of product the company manufactures: drugs, devices, foods.
- ◆ The FDA record retention requirements are imposed on the company regardless of whether it is regulated by the SEC.

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# **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.”
  - Eric M. Blumberg. Deputy Chief Counsel of FDA, FDA Enforcement Manual, Mar. 2002 at 7.
- ◆ 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.

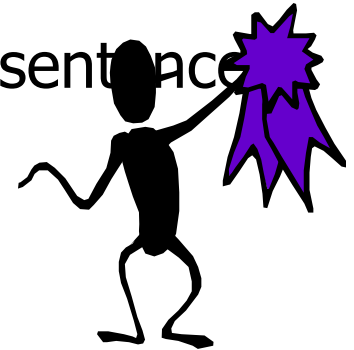
# Voluntary Disclosure

- ◆ 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?