

Compliance Strategies for Sample Management under PDMA

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Sample Management under PDMA

- Introduction
- Current Environment
- Compliance Program
- PDMA Overview
- PDMA Compliance
- PDMA Investigations & Audit

Compliance Programs - Two Sides of the Story

- After the Drexel thing exploded, there was a push to codify ethics. A big policy book came out. No one read it.

Anonymous Harvard MBA Alumnus

- Use your good judgment in all situations. There will be no additional rules.

Nordstrom, Inc., Employee
Handbook

Compliance - Dilemmas, Causes, Solutions

- Dilemma:
 - ◆ Do no harm v. To err is human
- Causes: ignorance, negligence, bad guidance
- Usual Solution: name, blame, shame
- ***Better Solution:***
 - ◆ ***Analyze root cause; Enhance process***
 - ◆ ***Monitor performance***

Current Environment

- U.S. government focus on pharmaceutical industry
- Public demands for greater corporate responsibility
- Enforcement actions pending against industry

Prosecutors Like The Criminal Remedy

- Lax or indulgent corporate cultures are a main reason why individuals engage in prohibited behavior.
- Indicting companies is the greatest, most effective means for changing the culture and deterring future violations.

Statements of the U.S. Attorney for the Southern District of N.Y.

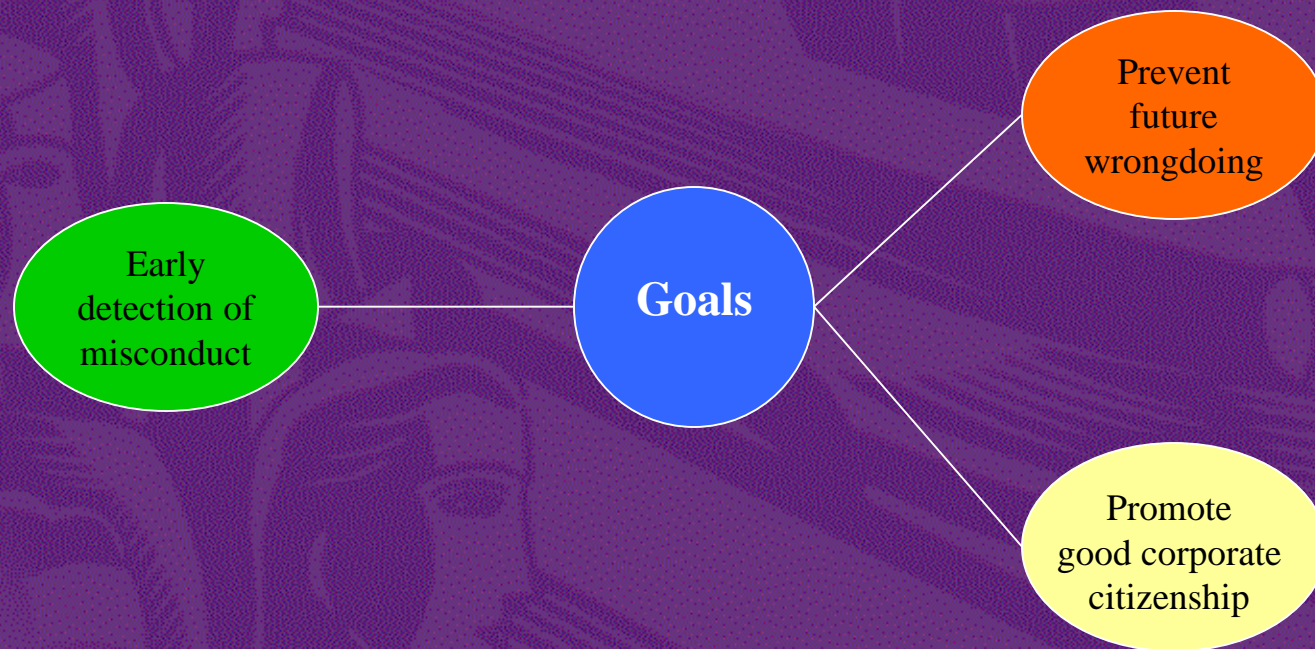
Bayer Corporate Integrity Agreement

- Alleged reporting of artificial AWP's
- Major Requirements of CIA:
 - ◆ Reporting of all sales prices for all customers
 - ◆ Compliance Officer
 - ◆ Compliance Committee with heads of Sales, Marketing, Contracting, HR, Audit
 - ◆ Code of Conduct with certification
 - ◆ Policies and procedures and training
 - ◆ Audits by independent organization
 - ◆ Penalties of \$1000-2,500 per day for failures

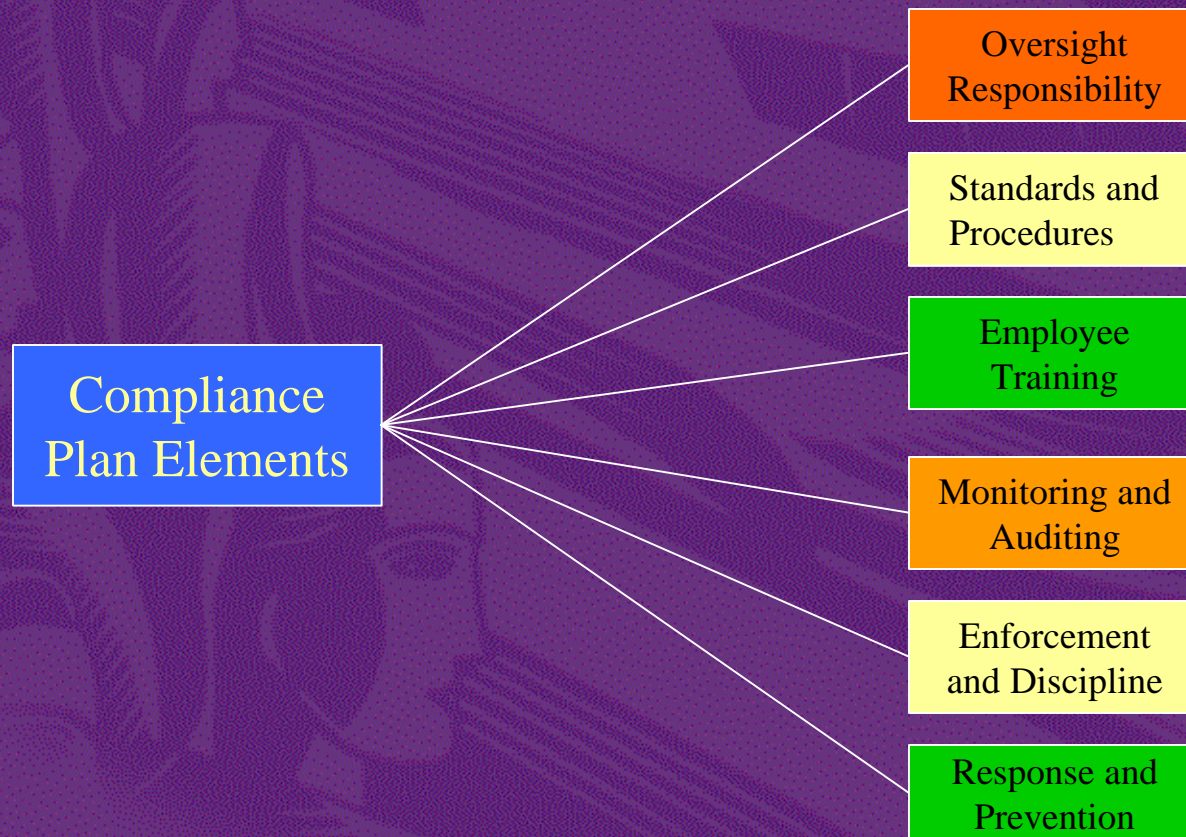
PDMA Enforcement

- TAP: Newspaper reports possible \$800 million settlement for alleged false claims, kickback and PDMA violations
 - ◆ Samples billed to government
 - ◆ Switching of patients for free samples
 - ◆ 3 doctors indicted, 1 pleads guilty

Compliance Program - Goals



Compliance Program - Government Guidelines



Indicators of Effectiveness

- Does management promote compliance with policies and procedures?
- Do employees believe management supports compliance?
- Are violators made accountable and disciplined?

PDMA Requirements - Compliance

- Written Policies and Procedures on:
 - ◆ Conducting inventory, preparing reconciliation
 - ◆ Implementing security and audit system
 - ◆ Identifying losses and notifying FDA
 - ◆ Electronic records must must meet Part 11
- Inventory and Reconciliation
 - ◆ Physical inventory at least annually
 - ◆ Reconcile results of current and past inventory
 - ◆ Fully investigate discrepancy or significant loss

PDMA Requirements - Compliance

- Drug Sample Storage
 - ◆ Maintain stability, integrity, and effectiveness
 - ◆ Comply with labeling requirements
- Samples by Mail
 - ◆ Must be requested by doctor
- Sales, purchase or trade of any drug purchased by hospital, healthcare entity or charity prohibited
 - ◆ Exceptions: returns, between affiliates

PDMA Requirements - Compliance

- Lot Numbers
 - ◆ Track lot number to practitioner level
- Drug samples, personal use, free goods
 - ◆ All samples and labeled as such
 - ◆ Indigent patient programs exempted

PDMA Requirements - Audit

- Manufacturers must have an audit system capable of detecting:
 - ◆ Diversion activities
 - ◆ Possible significant loss
 - ◆ Falsification
- The system must include “random” and “for-cause” audits
 - ◆ By personnel independent of Sales & Marketing

PDMA Requirements - Notification and Investigation

- Manufacturer who has “reasons to believe” that sample records are falsified or “becomes aware” of a significant loss or theft of samples is required to:
 - ◆ Notify FDA within 5 days
 - ◆ Immediately initiate an investigation
 - ◆ Provide a complete report within 30 days of the initial notification
- Representative convictions must also be reported to the FDA

PDMA Requirements - Third Parties

- Includes Contract Sales Organizations (CSOs) Shippers, and Fulfillment Companies
 - ◆ Must maintain separate accountability
 - ◆ Identifies them as separate entities
 - ◆ Manufacturers are ultimately responsible for their compliance activities, their ability of meet FDA requirements, and for any PDMA-related liabilities and penalties

PDMA Penalties

- Persons who knowingly sell, purchase or trade samples or offer to do so in violation of Act
 - ◆ \$250k / 10 yr or both
- Manufacturer whose rep. violates Act
 - ◆ \$50k for first 2 / \$1 million after second
- Manufacturer who fails to comply with Act
 - ◆ \$100k/ 1year
- Failure to report
 - ◆ \$100k

P D M A Waiver of Penalties

- Provide information leading to arrest and conviction of sales rep.
- Conduct investigation before beginning of criminal proceedings against sales rep. (exception – supervisor)
- Diligent implementation of audit and security system designed to detect drug sample violations.

PDMA Enforcement Focus

- Shift in focus toward companies and their compliance systems
- Looking for adequate audit/security measures to detect diversion
- Will review SOPs to determine that they align with PDMA and are being followed
- Will verify that FDA is being properly notified of irregularities

Just Remember

- When you find yourself in a hole, the first thing to do is to stop digging.

Anonymous

- The secret of life is honesty and fair dealing. If you can fake that, you've got it made.

Groucho Marx