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# The Second Annual Pharmaceutical Industry Regulatory & Compliance Summit

Compliance 202: Assessing the Effectiveness of Your Compliance Program

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# What is Compliance?

- Specialized staff function responsible for oversight, monitoring and enforcement of particular legal requirements (e.g. securities, insurance industries)
- Programs developed to demonstrate the existence of the elements considered in mitigating sanctions under the Federal Sentencing Guidelines
- Programs addressing application of substantive legal requirements to corporate conduct, including laws with civil or criminal consequences
- Ethics or corporate integrity programs expressing/embodying corporate culture

# Approaches to Compliance Programs

- Rule-Based (or compliance-based; substantive law requirements)
  - Adherence to rules; dos and don’ts
  - Emphasizes deterrence of illegal conduct and avoiding punishment
  - Provides basis for deniability
- Ethics-Based (or integrity/values-based)
  - Stresses employee “awareness”; self-governance; accountability
  - Focuses on prevention
  - Aimed at improving decision-making/reasoning skills

# Why Do Companies Develop Corporate Compliance Programs?

(1996 Price Waterhouse Survey)

- Reduce liability exposure: deter and detect wrongdoing
  - For the company
  - For officers and directors
- Response to past problem
- Articulate ethics/integrity program as fundamental attribute of corporate culture
- Cover particular areas of the law presenting significant risk of exposure
- Response to Federal Sentencing Guidelines
- Reflection of specific industry practice/guidance (Best Practices)

# Legal and Enforcement Context

- Throughout the 1990s, federal and state law enforcement agencies focused unprecedented attention on alleged fraud and abuse in the health care industry
- Thousands of companies were charged with civil and criminal wrongdoing
  - More than $1.5 billion was collected under the False Claims Act alone
- Significant increase in the level of sophistication and confidence of enforcement officials
- Whistleblower (qui tam) lawsuits

# Legal and Enforcement Context (cont.)

- The “everybody does it defense” doesn’t work
  - This is what the clinical laboratory companies argued
  - SmithKline paid $325 million to DOJ/HHS and more to private insurance companies
  - PPS Transfer cases: potential liability under the False Claims Act
    - DOJ contacted almost 4,000 hospitals, out of 6,500 hospitals nationwide
    - Over 2,700 hospitals have entered into settlements
- For some investigators and prosecutors, the fact that a suspect practice is common or widespread within industry makes the case *more attractive*, particularly where the practice arguably might harm patients (e.g., drug switching)

# Major Cases: Criminal

- Caremark
- Columbia-HCA
- National Medical Care (now Fresenius)
- U.S. v. Anderson (hospital executives and lawyers)
- BC/BS of Illinois

# Major Cases: Civil and Administrative

- Liability: $5,000-10-000* per claim, plus treble damages
  - National Medical Care $385 million
  - NME $379 million
  - SmithKline $325 million
  - BC/BS of Illinois $140 million
  - TAP $800 million
- Mandatory/permissive exclusion and/or debarment
- Corporate Integrity Agreements
  - Generally 5 years or more
  - Requires periodic audits/reporting
  - OIG review of compliance with CIAs
- Shareholder and third-party lawsuits

# HHS OIG Model Guidance

- As part of its stepped-up enforcement efforts, the HHS OIG developed “voluntary” compliance guides for particular sectors of the health care industry
- To date, the HHS OIG has published 9 guides
- While voluntary, these guidelines have become de facto industry standards for compliance programs within particular sectors

# HHS OIG Model Guidance (cont.)

1) Clinical Labs (2/97)
2) Hospitals (2/98)
   - Most frequently cited
3) Home Health (8/98)
4) Third-Party Billing (12/98)
   - Drafted by TPB Association; adopted by OIG
5) Durable Medical Equipment (6/99)
6) Hospice (10/99)
7) Medicare and Choice (11/99)
8) Nursing Facilities (3/00)
9) Physician Practices (9/00)
   - New issues: Privacy; kickbacks from manufacturers

# Anti-Fraud Resources (1997-2003)

- Significant increase in resources for federal enforcement agencies
- Under HIPAA, the DOJ, FBI, and HHS OIG receive dedicated funding — the amount increases 15% per year through 2003.

| | 1997 | 2000 | 2003 | |
|---|---|---|---|---|
| • DOJ/HHS | $104 | $158 | $240 | |
| • FBI | $47 | $76 | $114 | (millions) |

- Congress does NOT need to take action — increases are automatic.

# Congress

- Congressional investigations
  - AWP
  - Drug repackaging
  - Congress generally does not recognize non-constitutional privileges, including the attorney-client privilege
    - Possible disclosure of sensitive pricing data
- Close scrutiny is likely to continue, given upcoming debate on Medicare drug benefit
- Perception that pharmaceutical industry is gouging consumers and engaging in anti-consumer and fraudulent behavior

# April 2001
# Rep. Fortney H. “Pete” Stark (D-Calif.)

“It’s about time that we get tough on drug companies ripping off Medicare. This action is long overdue and I hope there are many more to follow. It is also a clear signal that we must be very careful when creating a broad Medicare prescription benefit in order to keep such rip-offs from becoming even more rampant and of even greater proportion.”

– commenting on news of the TAP investigation

# The Review Process
## Basic Steps

- Acquire understanding of organizational structure, business operations and business/contract practices (e.g. JVs; co-promotion)
- Risk Assessment:  Identify applicable laws and regulations
- Review existing policies and procedures/desk audit
- Conduct functional and operational interviews to assess business practices
- Prepare assessment report

# Questions Regarding Initiation of a Compliance Review

What is the purpose of the review?

- Business mapping (i.e., identify current practices
- Assess compliance with existing policies and procedures
- Determine whether there are existing policies and procedures
- Manage risk
- Assess “effectiveness” of existing programs based on Sentencing Guidelines criteria
- Demonstrate to outside observers that your program is working

# Questions Regarding Initiation of a Compliance Review

What are your key risk areas?

- Don't have resources to review everything
- Where have you been the subject of government enforcement actions? Private suits?
- What are high risk areas based on current government enforcement initiatives?
- In what areas are your competitors subject to suits?
- What are emerging areas of concern? (Congressional hearings, Administration announcements, comments by enforcement officials, press reports, etc.)

# Questions Regarding Initiation of a Compliance Review

Is senior management committed to the review?

- Is management prepared to devote resources necessary to implement recommendations?
- Does management understand the tension between providing "actionable" recommendations and creating a "roadmap"?
- At what level do you anticipate providing recommendations?
  - Business processes and controls?
  - Specific activities?

# Questions Regarding Initiation of a Compliance Review

- Have you considered the downside?
  - Expensive
  - Disruptive to company operations
  - Creates angst
  - Risk that problems will be identified
  - Increased risk of qui tam suits
  - Unlawful discharge suits by disciplined/terminated employees
  - Risk to customer relationships
  - Impact on sales

# Questions Regarding Initiation of a Compliance Review

Are you considering all elements of programs necessary to assess “effectiveness”:

- High Level responsibility
- Delegation of authority
- Policies and Procedures
- Communication
- Training
- Monitoring/auditing
- Disciplinary procedures
- Remedial process

# Assessment Tools

- Benchmarking/Best Practices
  - Healthcare industry: associations; companies
  - Other industries: Defense/aerospace industry (DII)
  - Consultant and academic studies
  - Government guidance: HHS OIG Guides
- Surveys
  - Assessing effectiveness of corporate communication
  - Assessing training
- Focus groups
- Training: post-training test of content knowledge

# Legal Guidance/Model Policies

- Fraud and Abuse (Anti-Kickback)
  - Safe Harbor regulations
  - Advisory Opinions
  - Fraud Alerts (1994: Special Fraud Alert on Prescription Drug Marketing Schemes)
  - CIAs
- Associations/Trade Groups
  - ACCA
  - EOA
  - HCCA
  - Ad Hoc Groups

# Government's Assessment of a Compliance Program's Effectiveness (HHS)

(March 1999 HHS/Industry Roundtable)

- Management's Commitment to and good faith efforts to implement
- Funding and legitimate support provided
- Background of the individual designated as the compliance officer
- Sufficiency of training and availability of guidance on policies and procedures
- Evidence of open lines of communication and appropriate use of information lines to address employee concerns
- A documented practice of refunding overpayments and self-disclosing non-compliance

# The Compliance Organization

— It's not simply a legal function

- Corporate Compliance Officer
- Compliance Committee/Task Force
- Functional Support:
  - Legal Department
  - Human Resources
  - Internal Audit
  - Finance
  - Sales/Marketing
  - Corporate Communications/Public Relations
  - Manufacturing/Operations

# Subjects Covered by Compliance Programs

(1996 Price Waterhouse Survey)

- Ethics, conflicts of interest and gifts
- Employment/labor law
- Antitrust, trade regulation and procurement
- Environmental, health and safety
- Lobbying, government relations and political contribution
- Securities law
- Intellectual Property
- International Business practices
- Fair trade and advertising

# Six Risks Most Terrifying to Legal Departments —

(KPMG Peat Marwick's Business Ethics Institute)

1. Sexual harassment
2. Environmental contamination
3. Antitrust infractions
4. Foreign payments
5. Fraudulent financial reporting
6. Race issues

# Department of Justice/Regulatory Enforcement

(Docket, Journal of the American Corporate Counsel Association, July/August 1996)

Settlements including compliance measures:

- Antitrust violations
- Environmental offenses
- Health care fraud
- Government contracts/defense procurement fraud
- Security law violations
- Civil rights
- Federal wage and hour laws
- Consumer fraud
- Consumer banking

# Program Content --
# Risk Areas: Practices Under Scrutiny
## Sales and Marketing Practices

- Gifts, Business Courtesies, Entertainment and Other Inducements
- Free or Nominally-Priced Goods/Samples
- Reporting Discounts, Rebates and Similar Pricing Practices
- Manipulation of AWP
- Consulting Fees to Physicians and Other Providers/Advisory Boards
- Research and Medical Education Grants/Sponsorships
- Drug Switching/PBM Arrangements
- Repackaging
- Off-Label Promotion
- Marketing Practices Implicating Antitrust Laws

# Identify and Document Proper/Laudable Objectives

— It's not only about ferreting out misconduct

- Patient benefit
- Physician education/advance the practice of medicine
- Clinical/scientific research
- Charitable purpose

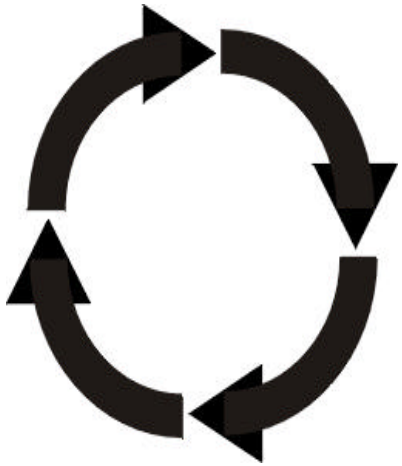
# Implementation Strategy for Effective Compliance Programs

## Plan

**Develop and Adopt Policies/Standards and Corporate Compliance System**

## Act

**Correct Deficiencies, Revise Policies/Standards/ Compliance Systems, Improve Systems and Procedures**



## Do

**Communicate; Provide Training; Implement Standards; Implement Violation Reporting and Follow-Up System; Discipline Violators**

## Check

**Monitor, Conduct Self-Audits vs. Standards, Conduct Audits by Corporate and External Auditors, Submit Annual Letters of Assurance to Board**

# Beyond the Guidelines

- *Message must come from the top*
  - Communication
  - Commit resources to support the compliance function
- Communicate a simple, clear message
- Buy-in at all levels
- Training
- Oversight:  Monitoring/Auditing
- Factor in performance evaluations
- Enforce/Discipline
- Evolve
  - Content
  - Methods
- Document/auditable
- *Message must come from the top*