



# When Pharmaceutical Marketing Crosses the Line: Best Practices For Investigation and Remediation





# Government's Emphasis on Health Care Enforcement



- ◆ Health care fraud and abuse issues are a top government priority.
- ◆ Cost of illegal health care schemes estimated at 10% of all health care spending.
- ◆ Federal government has responded by declaring war on health care fraud and abuse.



# Impact on the Health Care Industry

## FY 2000

- ◆ More than \$1.232 billion in criminal fines, civil judgments, settlements, and administrative sanctions.
- ◆ 3,350 exclusions from federal health care programs.
- ◆ 414 criminal convictions.
- ◆ 357 civil actions.



## Impact on the Health Care Industry (cont.)

10/01/01- 3/31/02

- ◆ More than \$728.7 million in civil settlements.
- ◆ 1,472 OIG-administered sanctions, in the form of program exclusions or civil actions on individuals and/or entities.
- ◆ 1,366 exclusions from health care programs.



# Risk Areas

## 1) Intentional and Obvious Conduct

- **Marketing the “spread,” and other AWP violations.**
- **Overcharging or mischarging on government contracts.**
- **Product substitution or delivery of nonconforming goods.**
- **Material misrepresentation regarding goods/services supplied.**
- **Re-sale of drug samples –PDMA concerns**



## Risk Areas (Cont.)

### 2) More Subtle Potential Violations

- **Use of free goods, discounts to incent purchases – i.e. anti-kickback violations.**
- **Misuse of samples, grants, or educational funds.**
- **Improper allocation of indirect costs (overhead) to government.**
- **Misreporting actual levels of contract performance.**



# What Is My Corporation's Potential Exposure?

- ◆ Corporations are derivatively liable for most acts of employees and authorized agents under very broad civil and criminal standards.
  - **Civil** : An employer is liable for acts of employees within the scope of their employment even without culpable intent by the employer.
  - **Criminal**: A corporation is criminally liable if an officer, employee or agent commits a crime within the scope of his actual or apparent authority with the intent to benefit the corporation, regardless of whether the corporation actually benefited and regardless of whether the employee also intended to benefit himself.





# What's at Stake?



- ◆ Monetary Fines/ Penalties / Sanctions
- ◆ Exclusion from Health Care Participation
- ◆ Criminal Convictions
- ◆ Imprisonment
- ◆ Highly publicized results



# What's at Stake?

Example: Anti-Kickback Violations.

- Criminal statute
- Five years of jail
- Criminal fines of \$250,000
- Civil fines up to \$50,000 and treble damages.
- Exclusion (criminal or civil)





# How do we prepare for Government Investigations?







## Step 1: Develop A Good Compliance Program



- ◆ Key step in preparing for government investigations is to prevent government investigations.
- ◆ Look to OIG Draft Compliance Guidelines for help on developing compliance program.



# OIG Compliance Guidance: Seven Fundamental Elements of an Effective Compliance Program

- ◆ Implementing written policies and procedures
- ◆ Designating a compliance officer and committee
- ◆ Conducting effective training and education
- ◆ Developing effective lines of communication
- ◆ Conducting internal monitoring and auditing
- ◆ Enforcing standards through well-publicized disciplinary guidelines
- ◆ Responding promptly to detected problems and undertaking corrective action.



## Step 2: Familiarize with “Hot Topics” Where to Look?

### Statutes and Regulations

- Federal Anti-kickback statute
- State Anti-kickback statutes
- Stark II
- False Claims Act
- HIPAA
- Draft OIG Compliance Guidance

### Voluntary Guidelines

- OIG 2003 Workplan
- PhRMA Code
- AMA Guidelines on Gifts to Physicians from Industry
- OIG Advisory Opinions
- Other industry codes pending





I suspect a problem:

Should I conduct an  
Internal Investigation?



# The Benefits and Associated Risks of Conducting Internal Investigations

- ◆ Benefits of Prompt and Thorough Internal Investigations
  - Evaluating potential liability
  - Gaining control
  - Minimizing criminal exposure
  - Minimizing civil exposure
  - Minimizing likelihood of exclusion, debarment, or other adverse regulatory actions
  - Public relations
  - Sarbanes-Oxley Act Compliance



# The Benefits and Associated Risks of Conducting Internal Investigations (cont.)

- ◆ Associated Risks of Internal Investigations
  - Increasingly difficult to preserve confidentiality
  - Justice Department increasingly demanding disclosure of results of internal investigations, including privileged materials, in settlement negotiations with corporations
    - ◆ Holder Memorandum (June 1999)
      - “Timely and voluntary disclosure of wrongdoing” and “willingness to cooperate” are among specified factors prosecutors must consider in evaluating “proper treatment of corporate targets.”



# The Benefits and Associated Risks of Conducting Internal Investigations (cont.)

- Voluntary disclosure includes identifying culpable and knowledgeable personnel who may no longer work for the corporation and disclosing the findings of internal investigations.
- An additional factor in the “completeness” of a corporation’s disclosure is whether it has agreed to waive the attorney-client and work product privileges, “both with respect to its internal investigation and with respect to communications between specific officers, directors, and employees and counsel.”



# The Benefits and Associated Risks of Conducting Internal Investigations (cont.)

- ♦ An additional related factor is whether the corporation appears to be protecting its culpable employees and agents. Factors to consider include:
  - advancing legal fees
  - joint defense arrangements
  - retaining employees without sanction



# The Benefits and Associated Risks of Conducting Internal Investigations (cont.)

- Consequences of the DOJ's Aggressive Stance on Privilege Waiver
  - ◆ Conflicts between corporation and employees
  - ◆ Chilling investigative inquiries/limiting reports
  - ◆ Deprives corporations of fully-informed legal advice
  - ◆ Vitiates individual's Fifth Amendment protections
  - ◆ May disclose unknown wrongdoing
  - ◆ Collateral consequences of privilege waiver



# Best Practices – Conducting Internal Investigations so as to Maximize Benefits and Minimize Risks

- ◆ Inside vs. outside counsel
- ◆ Maintaining confidentiality – cloak investigation with privilege
- ◆ Witness interviews
- ◆ Document review
- ◆ Interacting with simultaneous government investigations
  - Responding to document subpoenas
  - Preparing employees for government interviews



## Best Practices – Conducting Internal Investigations so as to Maximize Benefits and Minimize Risks (cont.)

- ◆ Using experts
- ◆ Representing employees – conflict concerns
- ◆ Preparing the investigative report
- ◆ Disclosure of the investigative report