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Overview of the United States' Regulatory Environment

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Regulatory Overview

- Pharmaceutical manufacturers in the United States are subject to numerous regulatory schemes
  - Health Care
  - Food and Drug
  - Government Contracting
  - Antitrust
  - Environmental
  - Corporate Governance
  - Numerous others

Regulatory Overview

- Health Care Laws
  - Financial relationships between manufacturers and those in a position to purchase or prescribe
    - Wholesalers, distributors, GPOs, PBMs, managed care organizations, pharmacies, physicians
  - Submission (or causing the submission) of “false claims”
    - Pricing of products reimbursed by the federal health care programs (Medicare and Medicaid)
    - Price reporting, for purposes of certain reimbursement and Medicaid rebates
  - Privacy of personal health information

Regulatory Overview

- Food and Drug Laws
  - Conduct of clinical trials
  - Drug approval and labeling
  - Manufacturing of drug products
  - Content of promotional messages

Regulatory Overview

- Government Contracting Laws
  - Special government pricing
  - Financial relationships with government employees

Regulatory Overview

- Overlapping jurisdiction
  - Examples:
    - Off-label/false claims
    - Kickback/false claims
    - Off-label/kickback
    - Fraud-on-the-FDA/false claims
- The issue generally is not “what statute was violated,” but rather did the conduct:
  - Injure patients or put them at risk?
  - Affect patients’ privacy rights?
  - Harm the government in some way?
  - Adversely affect a competitor or investors?
  - Corrupt the judgment of a government official or physician in some way?

Regulatory Authorities

- Wide range of sanctions
  - Criminal penalties for corporate entities as well as individuals
  - Civil penalties
  - “Injunctive" relief
    - Consent decrees
    - Corporate Integrity Agreements

Regulatory Authorities

- Department of Health and Human Services
  - Office of Inspector General
- Food and Drug Administration
- Department of Justice
- State prosecutors

"Regulations by enforcement"

Regulatory Authorities

- Increasing role of whistleblowers in driving enforcement
  - Statutory “qui tam” provisions that allow whistleblowers to collect up to 30% of any financial recovery by the government
  - Whistleblower laws being used to attack conduct far beyond actual submission of false claims
    - Kickbacks
    - Off-label promotion

The Cost of Non-Compliance

- Since 2001, government has entered into settlements with pharmaceutical manufacturers exceeding $350 million

Pharmaceutical Company	Settlement Amount
TAP Pharmaceutical Products	$875 million
Serono	$704 million
Abbott Pharmaceuticals	$600 million
Pfizer	$430 million
AstraZeneca Pharmaceuticals	$355 million

Emergence of Compliance as Key Corporate Function

- United States Sentencing Guidelines
- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
- PhRMA Code
- Corporate Integrity Agreements

Emergence of Compliance as Key Corporate Function

- Formalization of compliance structures and organizations
- Enhanced authority/statute for compliance officers
- Integration of disparate compliance functions within organizations
- Shift from “policy/training” perspective to “audit/verify” perspective
- Proactive approach to problems

END