Current Issues in Pharmaceutical and Medical Device Compliance Management

Introductory Comments

Pharma, Medical Device & Biotech Colloquium
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Steve Mohr, Esq.
Deputy Compliance Officer
AstraZeneca
Pre-Conference Co-Chair

Overview

- The Evolving Role of Compliance in the Pharma and Device Industries
- New Challenges
  - Revised Sentencing Commission Guidelines
  - Scrutiny Beyond Sales and Marketing Activities
  - State Laws and Enforcement
- Today's Goals
- Today's Agenda

Evolving Role of Compliance

- Ten years ago, regulatory compliance was focused on FDA issues and was addressed through existing functions (Legal, Finance, etc.)
- Today, compliance is addressing multiple regulatory issues at the federal, state and international levels, and is emerging as a separate function and discipline
- As compliance programs expand, and scrutiny intensifies, some companies are moving toward a "regulatory risk management" approach

New USSC Guidelines

- Recent amendments (effective November 1, 2004) strengthened each of the seven elements (and arguably added a new element)
- Amendments include important changes (partial list):
  - Compliance programs should be designed to reasonably prevent and detect all violations of law (not just crimes)
  - Significantly expands responsibility of "governing authority," including a requirement to "otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance …" (emphasis added)
  - Requires adequate resources to implement the program
  - Requires periodic evaluation of program effectiveness
- The amendments reflect – and in some instances go beyond – the suggestions in the HHS OIG Guidance

Going Beyond Sales & Marketing

- Legal and regulatory scrutiny – which has focused to date largely on sales and marketing areas – is moving into new areas.

- These areas include:
  - **Clinical research**
  - **Adverse event reporting and drug safety**
  - **GMP**
  - **International**

- Management in many companies is looking to the Compliance Department to leverage existing resources (e.g., web-based training platforms, Compliance Helpline, etc.) to address these areas

State Law Compliance

- Proliferation of state laws targeting pharma/device marketing and promotion is a relatively new challenge
- Six states currently have laws on the books
  - California
  - Maine
  - Minnesota
  - Vermont
  - Washington, DC
  - West Virginia
- Legislation pending in more than a dozen other states
- These laws are particularly challenging due to slight differences in approach and requirements

Today's Goals

- Our goal is to discuss and provide practical tips and insight on some of the toughest challenges facing compliance professionals in the pharmaceutical and medical device industries

- We hope to touch on the issues that you can't look up
  - How to engage Senior Management in compliance issues
  - How to motivate employees (and keep them motivated) on compliance issues
  - How to tackle multiple issues with limited resources

Today's Agenda

- First panel: Primer on Compliance Program Issues for Pharma and Device Companies
- Second Panel: Discussion of Key Risk Areas for Pharma and Device Companies
- Third Panel: Roundtable Discussion of Ten of the Toughest Challenges Facing Pharma and Device Compliance Professionals