

***Pharmaceutical Regulatory and
Compliance Congress --
Pre-Conference Workshop
November 13, 2002***

Sarbanes-Oxley:

**What It Means for Pharmaceutical
Compliance Professionals**

John T. Bentivoglio

john_bentivoglio@aporter.com

202.942.5508

Overview

- Why Is Sarbanes-Oxley Important to Compliance Professionals?
- Requirements Affecting the Board of Directors and Audit Committee
- Requirements for Senior Executives
- Document Retention, Whistleblowers, Hotlines
- New Criminal Penalties
- Codes of Conduct, NYSE Listing Standards

Board and Audit Committee

- New Corporate Governance Standards
- Changes to Audit Committee Structure and Composition
- Increased Audit Committee Oversight Responsibilities
- New Auditor Independence Requirements

Provisions Affecting the Board of Directors and Audit Committee

- Audit Committee and Independent Directors given new roles, responsibilities for corporate governance, oversight, and compliance

- New Focus on Qualifications of Audit Committee:
 - Independence: All Audit Committee members must be independent and accept no fees from the Company.
 - Financial Expertise: Audit Committee must include at least one “financial expert.”

Provisions Affecting the Board of Directors and Audit Committee (cont'd)

- Audit Committee Resources:
 - Can hire independent counsel
 - Company must provide funding
 - Audit Committee can hire auditors

- Audit Committee Responsibilities:
 - Directly responsible for “appointment, compensation and oversight” of auditors
 - Complaint Procedures: Must establish procedures to receive and address complaints regarding accounting, internal accounting controls and auditing issues.

Provisions Affecting the Board of Directors and Audit Committee (cont'd)

- Procedures include providing mechanism for employees to submit concerns -- on a confidential, anonymous basis -- regarding questionable auditing or accounting matters.
- Must pre-approve all auditing and non-auditing service to be performed by outside auditors.

- New Auditor Independence Requirements
 - Registered public accounting firms will be prohibited from providing eight types of non-audit services to audit clients

Provisions Affecting the Board of Directors and Audit Committee (cont'd)

- Auditor Independence (cont'd)
 - Mandatory auditor rotation: Partner cannot be lead or review partner for more than 5 consecutive years
 - Auditor must timely report to Audit Committee:
 - All critical accounting policies and practices to be used in financial reports
 - All alternative treatments of financial information within GAAP that have been discussed with management, ramifications of their use, and treatment preferred by the auditor
 - Other material written communications with management

Provisions Affecting Senior Management (cont'd)

- Act requires an internal control report in company's annual reports
- Internal control report must:
 - (1) State management's responsibility for establishing and maintaining an adequate internal control structure and procedures for financial reporting, and
 - (2) Contain an assessment of the effectiveness of those controls, as of the end of the company's most recent fiscal year.
- Is internal control structure limited strictly to financial reporting issues?

Special Issues for Lawyers and Compliance Professionals

- Document retention and destruction
- Whistleblowers
- Special rules for SEC Lawyers

Documents (cont'd)

- 18 U.S.C. § 1519: “Whoever knowingly alters, destroys . . . with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any [U.S.] department or agency . . . or in relation to or contemplation of any such matter or case . . .”
- Highlighted language raises questions:
 - Could common document retention/destruction policies result in violations where they call for destruction of documents relevant to a matter that could arise in the future?
 - Potential problem if a document retention program is set up with the intent to avoid future Government liability.

Documents (cont'd)

- Need to develop a business justification for every element of the document destruction plan
- Document destruction program should exempt from destruction all documents that could be used in future investigations
- Company's e-mail policy and document retention policies should be reviewed and revised to accord with new statutory requirements.

SEC Lawyers

- New Lawyer Disclosure Obligation: SEC has issued proposed rule implementing new statutory obligation on lawyers practicing before the Commission.
- Two-tiered disclosure obligation:
 - (1) Rules will require in-house and outside counsel to report securities law violations to company's CEO or chief legal officer;
 - (2) If they don't respond appropriately, lawyer must report directly to Board of Directors or designated Board committee

SEC Lawyers (cont'd)

- **Materiality standard:** Statute requires “an attorney to report evidence of a material violation of securities law or breach of fiduciary duty or similar violation by the company or any agent thereof ”
- Good news
 - “Materiality” limitation
 - No reporting outside the company is required
- Troublesome issues:
 - “Practicing before the Commission” is a broad standard
 - What kind of “evidence” should an attorney have?

SEC Lawyers (cont'd)

- What is a “similar violation?”
 - What is an “inappropriate” response on the part of the CEO or Chief Legal Officer, that would require the attorney to go to the Audit Committee or full Board?
 - What if the Audit Committee or Board are complicit in the wrongdoing, or refuse to take remedial action?
-
- Legal department may want to articulate and disseminate standards to staff as to when they must come forward to the General Counsel

Whistleblowers (cont'd)

- Sweeping new protections for whistleblowers--
 - Modeled after protections for airline employees reporting safety violations

- Two new criminal provisions to protect whistleblowers
 - 18 U.S.C. § 1513
 - 18 U.S.C. § 1514A

Whistleblowers (cont'd)

- 18 U.S.C. § 1513: “Whoever knowingly, with the intent to retaliate, takes any action harmful to any person . . . for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense . . .”
- Elements added to 18 U.S.C. § 1513(e):
 - Knowing and intentional action to retaliate
 - Against any person (not just an employee)
 - Providing truthful information relating to commission or possible commission
 - A law enforcement official (not just a Federal agent)
 - Regarding any Federal offense

Whistleblowers (cont'd)

- Elements of 18 U.S.C. § 1514A:
 - Prohibits a company from sanctioning an employee because of any lawful act to provide information about “fraud against shareholders” to (1) a Federal agency, (2) Congress, or (3) employee’s supervisor.
 - Authorizes civil action for damages and equitable relief, including reinstatement, back pay, attorneys’ fees, etc.
 - 90-day statute of limitations: employee must file claim within 90 days of retaliation.
 - Provision construed narrowly: applies only to information provided in connection with an ongoing proceeding.

New Felonies and Increased Criminal Penalties

- Substantive new offenses added by the Act:
 - 18 U.S.C. § 1348: Scheme or artifice to defraud
 - 18 U.S.C. § 1350: Knowing violations involving new CEO/CFO certifications

- Enhanced Penalties:
 - Multiple directives to U.S. Sentencing Commission to boost penalties for obstruction of justice, criminal fraud, accounting and securities fraud, and the new “white collar” provisions in the Act related to document destruction or tampering

New Felonies and Increased Criminal Penalties (cont'd)

- Enhanced penalties for conspiracies (from 5 years to same level as underlying offense)
- Stiffer penalties for criminal ERISA violations
- Doubles the penalties for criminal violations of Securities Act of 1934

Codes of Conduct and NYSE Listing Standards

- Section 406 of Sarbanes-Oxley Act requires adoption of “Code of Ethics” for senior financial officers
 - Code is applicable to principal financial officer and controller or principal accounting officer, or persons performing similar functions
 - The term “code of ethics” is defined broadly to mean standards reasonably necessary to promote
 - (1) honest and ethical conduct,
 - (2) full, fair, accurate, timely, and understandable disclosure in periodic reports the company is required to file, and
 - (3) compliance with applicable Government laws and regulations.

Codes of Conduct and NYSE Listing Standards (cont'd)

- NYSE Listing Standards changes include:
 - Independent directors must comprise a majority of a Board of Directors
 - Company's Nominating Committee, Compensation Committee and Audit Committee must be comprised solely of independent directors
 - Non-management directors must meet without management in regular executive sessions
 - To be "independent," Board must affirmatively determine that director has no material relationship with the company (either as a shareholder or officer of an organization that has a relationship with the company)

Codes of Conduct and NYSE Listing Standards (cont'd)

- Independence also requires a 5-year “cooling off” period for former employees of the company or its independent auditor (increase from previous 3-year period)
- Every listed company must have an internal audit function
- For Audit Committee members, director’s compensation must be sole remuneration from the company
- Listed companies must adopt a code of business conduct and ethics, and must promptly disclose any waivers of the code for directors or executive officers
- Listed company’s CEO must certify annually that he/she is not aware of any violation by the company of the NYSE corporate governance standards

Codes of Conduct and NYSE Listing Standards (cont'd)

- NYSE may issue a public reprimand letter for violation of a corporate governance standard, in addition to existing penalty of de-listing
- NYSE will develop a Directors Institute (first-ever formalized program designed for directors)

Summary of Issues for Compliance Professionals

- Clarification of responsibility for compliance with, oversight of financial reporting rules
- New requirement of process for internal reporting of financial fraud -- coordination with existing hotlines and internal reporting procedures
- Code of Conduct for financial executives -- develop separate Code or incorporate into existing Codes

Summary of Issues for Compliance Professionals (cont'd)

- Whistleblowers -- review in light of heightened risks, ensure appropriate coordination
- Document retention -- review in light of heightened risks, establish and document business justification
- Implications of direct reporting to Board, Audit Committee of compliance issues outside traditional mechanisms

Action Items for In-House Lawyers (cont'd)

- Establish internal procedures for reporting securities law issues -- and clarifying lawyer disclosure obligations -- in light of forthcoming SEC rules for lawyers
- Draft or review Code of Ethics for senior financial officers
- Assist in developing Code of Conduct under NYSE standards
- Determine role of Legal Department in meeting new corporate governance standards
 - Relationship with internal audit
 - Relationship with Audit Committee