

Asian Pharmaceutical Compliance Congress September 12-14, 2011 Singapore

Whistleblower Provisions of Dodd-Frank:

Implications for Global Pharma Compliance Programs

John T. Bentivoglio

Skadden

Beijing Boston Brussels Chicago Frankfurt Hong Kong Houston London Los Angeles Moscow Munich New York Palo Alto Paris San Francisco São Paulo Shanghai Singapore

Sydney Tokyo Toronto Vienna Washington, D.C. Wilmington

Topics for Discussion



- What is the Dodd-Frank Law?
- The Whistleblower Provisions of Dodd-Frank
- Implications for Global Compliance Programs
- Practical Suggestions

Note: Presentation and Discussion Provide General Overview and Not a Complete Discussion of Dodd-Frank Law or Implementing Regulations

The Dodd-Frank Law



- Enacted on July 21, 2010 in response to 2008 financial crisis
- More than 2,000 pages regulating virtually every aspect of U.S. financial system
- Added new Section 21F to the Securities Exchange Act of 1934
 - Directed the U.S. Securities and Exchange Commission (SEC) to provide financial rewards to persons who provide the SEC with information about violations of U.S. securities laws that lead to successful enforcement efforts
 - Also protect whistleblowers against retaliation
 - SEC implementing regulations have become very controversial with supporters arguing strong incentives are needed to encourage reporting of violations and critics contending that generous financial rewards will encourage people to by-pass internal reporting systems – thereby undermining corporate compliance programs



Whistleblower Provisions of Dodd-Frank

- General Rule:
 - Requires SEC to provide financial awards
 - To any person
 - Who voluntarily provides the SEC
 - Original information
 - About a "possible" violation of U.S. securities laws
 - That leads to a successful enforcement action resulting in monetary sanctions exceeding \$1,000,000.
- Statute also prohibits retaliation against whistleblowers and allows them to sue in court for redress

Who May Be a Whistleblower



- Must be a natural person, not a company or entity
- Generally, not an attorney, auditor or compliance professional performing relevant services for a company
- Information must be provided voluntarily
- Information must not have been obtained in violation of U.S. or state criminal law

Submission Must Be Voluntary



- Not after request or inquiry from SEC
- Not if under a pre-existing legal or contractual duty to report to the SEC or certain other governmental agencies

Information Must Be "Original"

- Derived from independent knowledge or independent analysis;
- Not already known to the Commission from any other source;
- Not exclusively derived from an allegation made in a judicial or administrative hearing, in a governmental report, hearing, audit, or investigation, or from the news media, unless you are a source of the information; and
- Provided after July 21, 2010
- Note: Information still deemed original even if an investigation has been commenced and/or inquiry made to the relevant company – as long as other requirements are met.

Not An Original Source If ...



- Information was subject to attorney-client privilege or pursuant to a legal representation
- An officer, director, trustee, or partner of an entity who learns information from another person or pursuant to internal procedures
- An employee whose principal duties involve compliance or internal audit responsibilities (or employee or firm that performs such work)
- Employed by or otherwise associated with a firm retained to conduct an inquiry or investigation into possible violations of law; or
- Employee of a public accounting firm performing work required of an independent public accountant under the federal securities laws

Violation of U.S. Securities Laws



- Applies to information regarding a "possible" violation of U.S. securities law "has occurred, is ongoing, or is about to occur."
- Violations of U.S. securities laws not state or foreign laws
 - Violations of the FCPA are violations of U.S. laws
 - Whistleblower provisions of Dodd-Frank may apply to FCPA enforcement actions
- To recover, ultimate enforcement action must result in monetary recoveries of \$1,000,000 or more

Amount of Award



- Not less than 10% nor more than 30% of monies collected by SEC and in related actions
- Factors that would increase award:
 - Significance of the information
 - Assistance provided by the whistleblower (including whether s/he reported internally)
 - Law enforcement interest
- Factors that would decrease award:
 - Culpability in misconduct
 - Unreasonable delay in reporting
 - Interfering or impeding internal reporting or compliance system

Protections for Whistleblowers



- The Act prohibits employers from discharging, demoting, suspending, threatening, harassing, or otherwise discriminating against whistleblowers who provide information to enforcement authorities.
- Also creates a private right of action for employees who experience retaliation as a result of any lawful act done by the whistleblower "(i) in providing information to the [SEC] in accordance with [the incentive provisions]; (ii) in initiating, testifying in, or assisting in any investigation or judicial or administrative action of the [SEC] based upon or related to such information; or (iii) in making disclosures that are required or protected" under certain SEC-related laws and regulations."
- Protections do not depend on ultimate finding that a violation has occurred. Rather, protections apply if a whistleblower possesses a "reasonable belief that the information [they are] providing relates to a possible securities law violation"

SEC Efforts to Encourage Internal Reporting



- Final rule provides some incentives for internal reporting
 - SEC may pay larger awards to whistleblowers who report through internal compliance processes <u>before</u> providing information to the SEC (and smaller awards if they obstruct or interfere internal processes)
 - Whistleblowers can receive awards for reporting internally when the company subsequently self-reports a possible violation discovered as a result of whistleblowers information; whistleblowers would then be given credit for all of the information self-reported to the SEC by the company; and
 - Whistleblower reports to the SEC relate back to the date whistleblowers reported a possible violation internally, as long as the whistleblowers contact the SEC within 120 days of the internal report
- Many observers believe these incentives are not sufficient and that financial awards will encourage people to bypass or ignore internal compliance systems

Implications for Global Pharma Compliance Programs



- Prior to Dodd-Frank, whistleblower issues primarily confined to violations of the False Claims Act, which by definition is limited to violations involving U.S. government health care programs
- After Dodd-Frank, whistleblowers with information about bribes or corruption in foreign countries could recover millions or tens of millions of dollars from the SEC for such reports.
 - Numerous recent FCPA actions have resulted in fines and penalties exceeding \$100 million
 - Whistleblowers in future actions may receive 10% to 30% of such recoveries
- As a practical matter, will need to expand efforts to encourage internal reporting of problems to overcome the strong financial incentives to report outside the company.

Practical Tips to Address Heightened Risks – Internal Reporting



- Verify that hotline protocols ensure that reports of potential misconduct are escalated quickly and appropriately, and that employees can safely preserve their anonymity;
- Ensure and communicate that company policy obligates employees to report potential misconduct to appropriate company personnel (with heightened expectations for supervisory and management personnel);
- Use surveys or other tools to assess the effectiveness of the internal compliance and reporting system;
- Effectively communicate appreciation and support for internal reporting—and lack of tolerance for retaliation—from senior management;
- Train human resources personnel and line managers to recognize employee reports and complaints that may implicate whistleblower issues, and to quickly escalate them to legal and compliance personnel; and
- Assign high-level responsibility for ensuring internal allegations are handled appropriately, including appropriate remediation and discipline.

Practical Tips to Address Heightened Risks – Handling Whistleblowers



- Retaliation extends beyond simply firing a whistleblower, and may encompass other actions that are regarded as materially adverse to an employee—possibly including, for example, suspension or reassignment of duties;
- Recognize the need to fully investigate whistleblower claims and avoid dismissing such concerns where (1) some (or even most) of the claims lack merit, and/or (2) where the whistleblower is perceived as "difficult" or "not a team player."
 - While motives and other considerations may be relevant, the ultimate question should be: Are all (or even some) of the allegations true?
- Formalize disciplinary process to ensure adequate input from legal and/or compliance personnel;
- Develop internal procedures and/or guidelines to ensure a reasonable level of consistency in the application of disciplinary sanctions;
- Consider exit interviews and separation agreements to confirm that departing employees are not aware of possible violations.



.....

.....

Speaker Biography

Skadden



John Bentivoglio represents pharmaceutical, medical device, healthcare, and technology companies in government investigations and enforcement activities and in developing and implementing U.S. and global ethics and compliance programs. He has negotiated several Corporate Integrity Agreements for pharmaceutical companies and, increasingly, has worked with U.S. and foreign-based companies to implement global programs that address recent changes in U.S. and foreign law and enforcement relating to bribery and anti-corruption issues.

John previously served as Associate Deputy Attorney General and Special Counsel for Health Care Fraud at the U.S. Department of Justice and as Special Assistant in the front office of DOJ's Criminal Division. Earlier in his career, John served as a Professional Staff Member on the U.S. Senate Committee on the Judiciary for then-Chairman Joseph R. Biden, Jr. (D-Delaware).

He can be reached at john.bentivoglio@skadden.com or (202) 371.7560