

**Blowing the Whistle on cGMPs:
the Next Big Challenge for Compliance**

**The SEC Whistleblower Law and Pharma
Manufacturing in the US and Abroad**

Neil V. Getnick



**PHARMACEUTICAL REGULATORY AND COMPLIANCE
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GETNICK & GETNICK LLP

**620 FIFTH AVENUE
NEW YORK, NY 10020
WWW.GETNICKLAW.COM**

SEC Whistleblower Law



- The SEC whistleblower program, created by Dodd-Frank in 2010, offers rewards for original information regarding violations of securities laws, rules and regulations
- Whistleblower can receive 10-30% of any amounts recovered

SEC Whistleblower Program



- SEC paid its first whistleblower award in Aug. 2012, one year after program was created
- Oct. 1, 2013: SEC announced \$14 million award
- SEC whistleblower program “turbocharges the enforcement program” and will produce “incredibly impactful cases” with “some extremely significant whistleblower awards.”
 - Stephen Cohen, Assoc. Director of Enforcement, SEC, June 2013

How does the SEC Whistleblower Law apply to drug manufacturing?



- In the US:
 - Manufacturer is publicly traded and serious cGMP violations material to share price
 - May be FCA if sold to government, e.g., Rx
 - Whether or not FCA, may be SEC, e.g., OTC
 - ✦ J&J cGMP violations and recalls regarding children's OTC products 2010: 13% drop in share price

Materiality



- Companies listed on US exchange or required to file reports with SEC can be liable under securities laws for concealing information from investors where the information concealed is **material** (i.e. a reasonable investor would consider the information significant in deciding whether to buy or sell shares in the company)

How does the SEC Whistleblower Law apply to drug manufacturing?



- Outside the US:
 - Dodd-Frank extra-territoriality
 - Foreign Corrupt Practices Act violations

Securities Violations Abroad I: Dodd-Frank Extends Reach of US Securities Laws



- Dodd-Frank expanded territorial reach of US securities laws to allow jurisdiction where the violation involves conduct outside the US that has a “foreseeable substantial effect within the United States”

Violations at foreign drug plants may be “material”



- Company listed on US exchange violates cGMPs at foreign plant, if those violations would materially affect share price, a whistleblower could file a tip with the SEC
- Consider Ranbaxy: FDA announced import ban on Ranbaxy drugs following cGMP FCA whistleblower case; Ranbaxy’s stock price fell by over 30% in one day
- e.g., India has largest number of FDA-registered plants outside the US and is emerging as the largest exporter of generic drugs to the US

SEC Whistleblower Tips



- In 2012, the SEC received 3001 tips from whistleblowers
- 18.2% (547 tips) involved failure to disclose material information to investors: the No. 1 category
- 10.8% (324 tips) originated from foreign countries

Securities Violations Abroad II: FCPA



- FCPA prohibits bribery of foreign government officials by US persons or companies
- “US companies” includes companies listed on US exchange or required to file reports with the SEC
- FCPA provides for fines of twice the gross profits from business attributable to the bribes
- Largest FCPA recovery to date: \$800M (Siemens AG)

FCPA SEC Whistleblower Tips



- 115 tips received by SEC in 2012 involved violations of the FCPA
- “We have a number of investigations involving foreign whistleblowers in the FCPA space. It’s a fertile ground for whistleblowers because it’s an area that we don’t have any natural visibility into.”
 - Stephen Cohen, Assoc. Director of Enforcement, SEC, June 2013

FCPA and Pharma: A High Risk Combination



- More than 3,500 FDA-registered manufacturing plants abroad
- Employees routinely interact with foreign officials in matters affecting drug inspections, approvals, release, recalls, clinical trials, import/export, etc.
- DOJ has used FCPA aggressively against health care companies in recent years

Can Your Company Meet This Challenge?



- **Business-driven integrity vs. law-driven compliance**
- **Whistleblower laws are anti-fraud, not anti-business—potential for businesses to use these laws as a tool to level the playing field, reform markets**