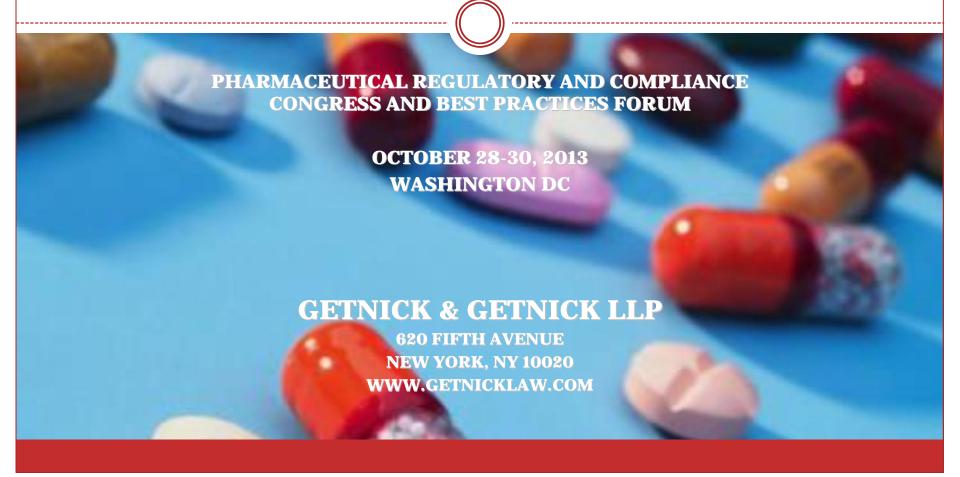
Blowing the Whistle on cGMPs: the Next Big Challenge for Compliance

The SEC Whistleblower Law and Pharma Manufacturing in the US and Abroad Neil V. Getnick



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.
 - 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?



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" Getnick & Getnick LLP

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 antibusiness—potential for businesses to use these laws as a tool to level the playing field, reform markets