

Miller & Chevalier

Distributor Risk Under the FCPA

OCTOBER 20, 2016

FCPA: Anti-Bribery Provisions

- Prohibits:
 - Offer, pay, promise or authorize to pay
 - A bribe (anything of value)
 - To a foreign official (broadly defined)
 - To obtain or retain business or improper advantage (*e.g.*, award of contract, favorable tax or customs treatment)
- Does not require:
 - Direct payment (improper payments through distributor prohibited)
 - Actual payment
 - Active participation
- Reasonable expenses may be permitted

Key Concept: Foreign Official

- FCPA defines “foreign official” very broadly, to include:
 - Employee of any government agency or instrumentality
 - Employee of government-controlled company, university, hospital or research institutes
 - Party officials, elected officials, political parties and candidates for office
 - Judge or legislator
 - Private person acting officially
 - Official of public international organizations (e.g., the World Bank)
 - Members of royal family
 - Close relative or dependent of an official
- US law definition of foreign official is not contingent on whether one is deemed a government official under local law
- Bottom Line: ***Foreign officials can be hard to identify***

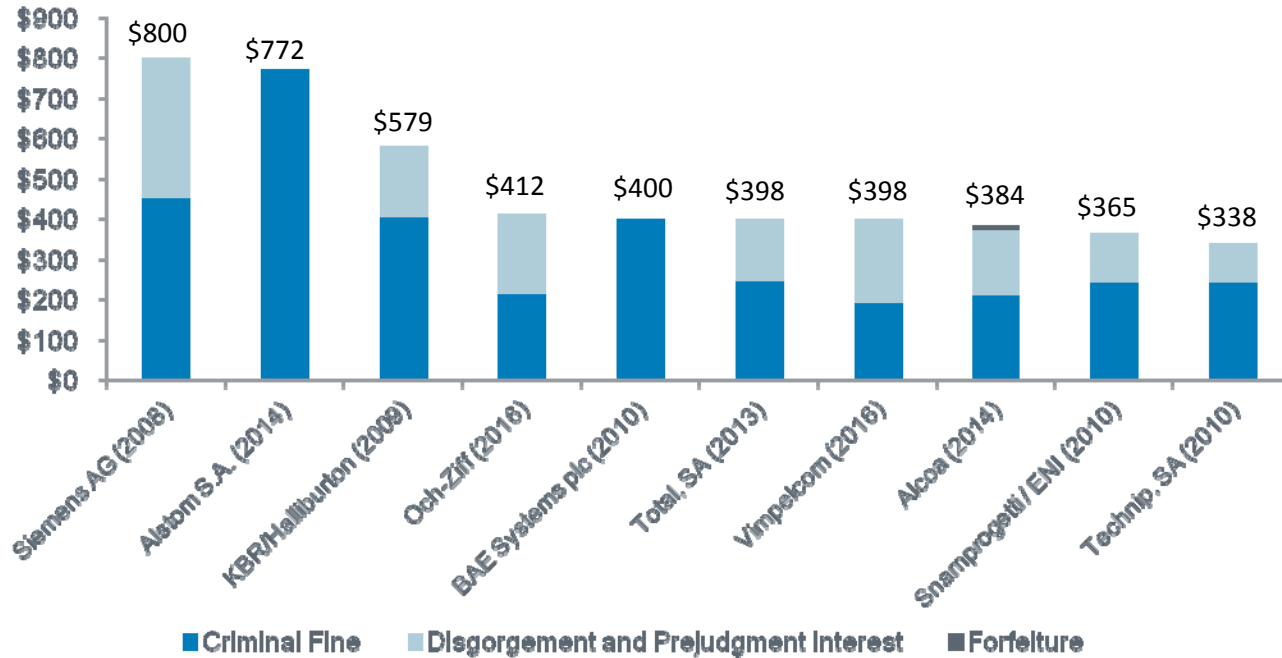
FCPA: Accounting Provisions

- Requires publicly-traded companies to maintain:
 - Books and records (accurate, detailed)
 - Internal controls (adequate to ensure accountability for assets)
- Because of the anti-bribery and accounting provisions, issuers should:
 - Maintain anti-corruption and accounting policies
 - Assess anti-corruption risk posed by any distributors engaged
 - Evaluate sufficiency of distributors' compliance and accounting controls
 - Accurately and fully document transactions with distributors
 - Provide adequate training to employees and ensure distributors are trained

Third Party and Distributor Risks

- Distributors can be directly liable or cause liability for companies
 - Under the FCPA, a company can be liable for “indirect” payments made by a distributor if that company has “knowledge” of pass-through to officials
 - No actual knowledge required – can be liable for “conscious disregard” of red flags
 - Non-US distributors could be prosecuted under the FCPA under certain circumstances
 - If a distributor is implicated in an FCPA prosecution, this could constitute a compliance red flag for other foreign companies
- Distributors may present heightened risks:
 - Potential close relationships and frequent interactions with foreign officials
 - Potential gifts, entertainment and trips for foreign officials
 - Challenging local compliance environment and history

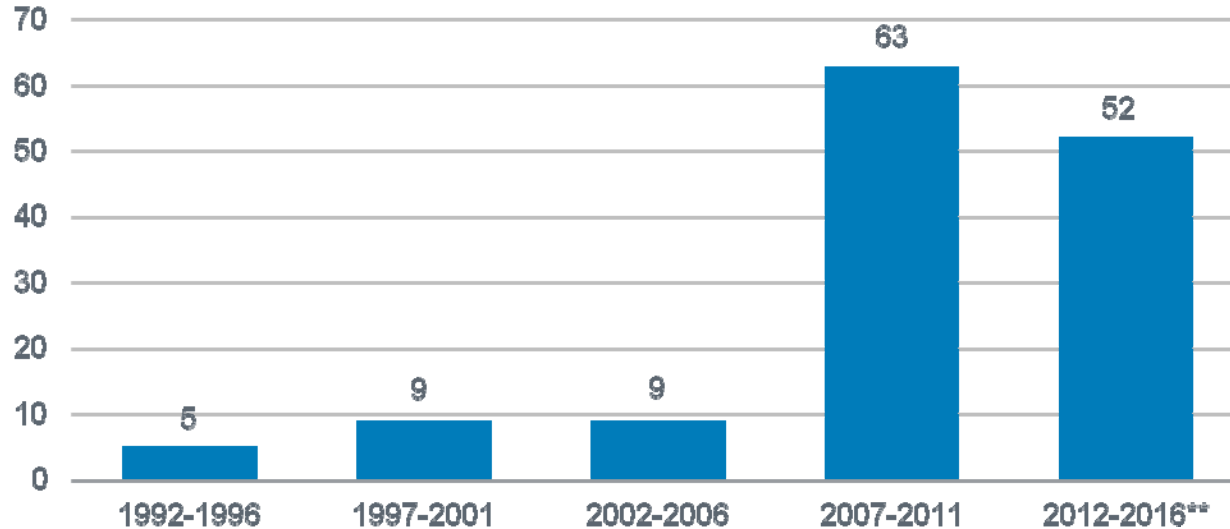
Top Ten U.S. Corporate Settlement Amounts (Combined Penalties, Disgorgements, and Interest)



Note: Updated through October 17, 2014. Where a matter involved more than one action brought against a particular company and its subsidiaries and affiliates, those actions are “combined” and counted as one.

Enforcement Actions: Third Parties

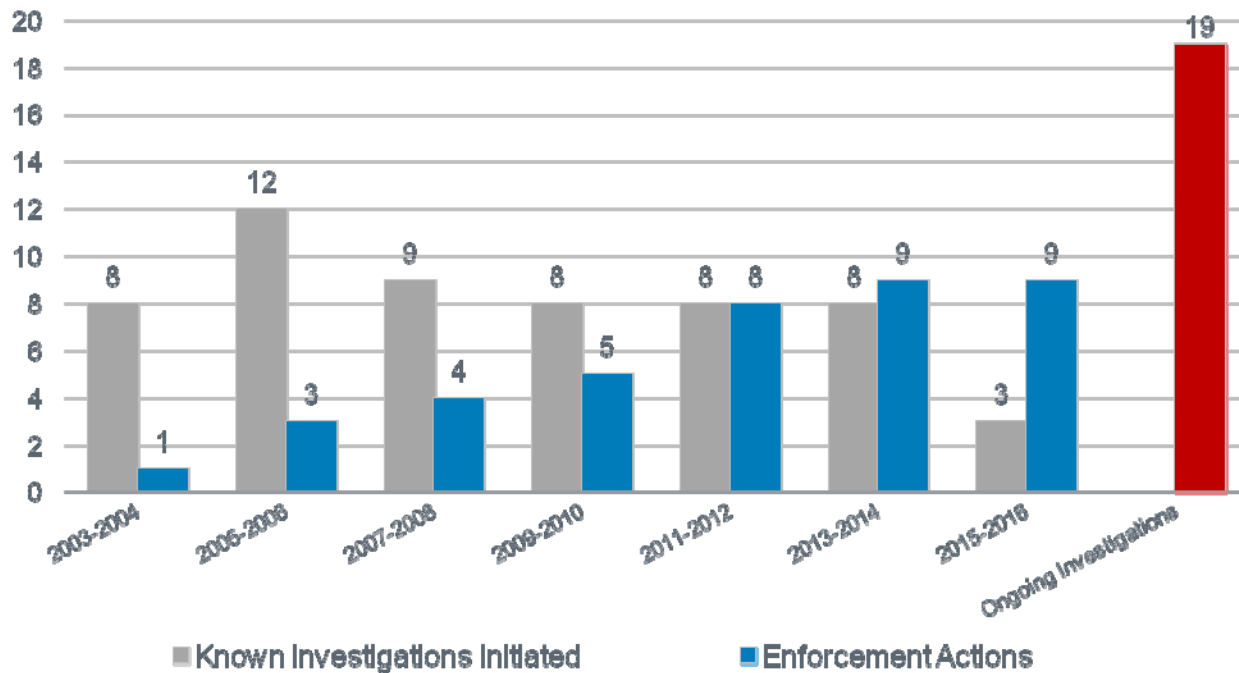
Combined Corporate Enforcement Actions Involving Third Parties*
1992 through 2016



* These statistics combine all related resolved enforcement actions involving each company and its subsidiaries and affiliates.

**2012-2016 numbers are based on enforcement actions through October 17, 2016.

Life Sciences Industry in the Crosshairs: FCPA Scrutiny of Healthcare Companies from 2003-2016



Note: Chart updated October 17, 2016. These statistics track related investigations of or resolutions with a company and its affiliates as one. The resolutions tracked include declinations.

Recent Enforcement: Mead Johnson Nutrition Co. (2015)

- Allegations:
 - Chinese subsidiary of infant formula manufacturer, Mead Johnson provided improper discounts to certain distributors tasked with performing marketing services.
 - Via such discounts, Mead China amassed a slush fund of over \$2 MM that it directed distributors use to pay to state-employed HCPs to (a) recommend Mead infant formula products; and (b) supply contact information for new or expectant mothers
 - These discounts were then mischaracterized as "distributor allowances" in books-and-records consolidated by Mead Johnson, which had inadequate internal accounting controls at Mead China to prevent these illicit payments.
- Outcome:
 - SEC administrative action: Combined \$12.03 MM settlement (ie, \$7.77 MM in disgorgement, \$1.26MM in prejudgment interest, and \$3 MM civil penalty)

Recent Enforcement: Analogic Corp. (2016)

- Allegations:
 - Medical device manufacturer Analogic's Danish subsidiary, BK Medical ApS, colluded with distributors in Russia and elsewhere to make improper payments to unknown third parties and shell companies (allegedly including, among others, HCPs at state-owned hospitals)
 - In Russia, the distributor would overpay BK Medical via a scheme involving a second set of fabricated invoices with inflated prices. BK Medical would then funnel these excess funds into its account for the distributor and disperse at the distributor's direction
 - Because BK Medical's CFO personally approved about 150 such payments (of more than 250 made) despite knowing that the payments violated BK Medical's internal accounting controls, the DOJ accused the subsidiary of willful falsification of Analogic's books, records and accounts.
- Outcome:
 - DOJ NPA with BK Medical: \$3.4 million penalty assessed against BK Medical
 - SEC administrative action:
 - Imposed \$7.7 million in disgorgement and \$3.8 million in prejudgment interest on Analogic
 - Imposed \$20,000 civil penalty on BK Medical CFO Lars Frost (Danish citizen/resident)

Contact Information:

Marc Alain Bohn

Miller & Chevalier
900 16th Street NW
Washington, D.C. 20006

(202) 626-5559
mbohn@milchev.com