Responsibilities of drug and medical devices companies

Andrew Jack
Financial Times
PCC, Budapest, May 2012
RELAX! I'LL TAKE JUST ENOUGH TO SAVE THE ECONOMY!...
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE
Friday, April 8, 2011

Johnson & Johnson Agrees to Pay $21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations

Company to Pay Total Penalties of $70 Million in Resolutions with Justice Department and U.S. Securities and Exchange Commission (SEC)

WASHINGTON – Johnson & Johnson (J&J) has agreed to pay a $21.4 million criminal penalty as part of a deferred prosecution agreement with the Department of Justice to resolve improper
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE  Monday, February 6, 2012

Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation

Agrees to Pay $16.8 Million Penalty Related to Bribery in Greece

WASHINGTON – Smith & Nephew Inc. has entered into a deferred prosecution agreement with the Department of Justice to resolve improper payments by the company and certain affiliates in violation of the Foreign Corrupt Practices Act (FCPA), the Department of Justice announced today. The matter is part of an investigation into bribery by medical device companies of physicians employed by government institutions.
21. On or around February 23, 2002, VP International sent an email from Memphis, Tennessee to Greek Distributor, proposing that the “marketing” payments to Shell Company A should also be reduced.

22. On or around March 8, 2002, Greek Distributor sent an email from Athens to VP International in Memphis, Tennessee, copying Greece Sales Manager, stating, “the [Shell Company A] commission cannot be reduced for the time being, since it is already not sufficient to cover my company’s cash incentive requirements at the current market level, with major competitors paying 30-40% more than [Greek Distributor]. As I explained to you in Memphis (as well as during your last visit to Athens) I absolutely need this fund to promote my sales with surgeons, at a time when competition offers substantially higher rates. [Shell Company A]’s only reason for being is the need for cash incentives, a real pain in the neck but an unavoidable fact of Greek life;” Greek Distributor goes on to state, “In case it is not clear to you, please understand that I am paying cash incentives right after each surgery....” (Emphasis in original.)
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, March 26, 2012

Third Medical Device Company Resolves Foreign Corrupt Practices Act Investigation

Indiana-Based Biomet Inc. Agrees to Pay $37.2 Million for Bribes in Latin America and China

WASHINGTON – Biomet Inc. has entered into a deferred prosecution agreement with the Department of Justice to resolve improper payments by the company and its subsidiaries in violation of the Foreign Corrupt Practices Act (FCPA), announced the Justice Department’s Criminal Division.
24. On or around January 10, 2006, the managing director of Biomet Argentina sent an email to Latin America Auditor in Indiana that attached a monthly list of payments to doctors that were a percentage of the cost of products purchased by the doctor during the month.

25. On or around February 22, 2006, Latin America Auditor circulated an internal report on the audit, which stated, “Other allegations being investigated by Biomet’s legal team include fraudulent product registration certificates, bribery of customs officials, and other charges as reported to legal via electronic media. It was later determined that certificates were fraudulent and bribes were made [sic].”

26. In or around November 2006, Latin America Auditor sent her report on the audit of Biomet Argentina to Vice President, Operations Manager, and others in Indiana, which stated, “The commission expense recorded on the income statement is actually royalties paid to doctors for using Biomet products. This account should be renamed to royalty’s [sic] expense.”
Pfizer Pays $2.3 Billion to Settle Marketing Case

WASHINGTON — The pharmaceutical giant Pfizer agreed to pay $2.3 billion to settle civil and criminal allegations that it had illegally marketed its painkiller Bextra, which has been withdrawn.

It was the largest health care fraud settlement and the largest criminal fine of any kind ever.
Completed Cases

AUTH/2100/2/08 - Financial Times/Director v Roche

**Case Number:** AUTH/2100/2/08  
**Case Ref:** Financial Times/Director v Roche  
**Description:** Supply of Xenical and support for a slimming clinic  
**Breach:** Breaches Clauses 2, 9.1 and 18.1. Public reprimand, and suspended from membership of the ABPI for a minimum of six months.  
**Appeal:** Appeal by the respondent  
**Review:** Published in the August 2008 Review  
**Complaint Received:** 19 February 2008  
**Complaint Completed:** 17 June 2008
Announcement: Moody's says Abbott's DOJ settlement for Depakote is credit negative; ratings unaffected

Global Credit Research - 10 May 2012

New York, May 10, 2012 -- Diversified healthcare company, Abbott Laboratories' (A1 negative) on 7 May reached an agreement with US federal and state authorities, which includes $1.6 billion in payments to resolve an outstanding investigation of previous sales and marketing practices related to Depakote, a neurological drug. This development is credit negative because of the relatively large settlement amount and acknowledged criminal violation of law, but does not affect Abbott's ratings at this time. For additional information, please see Moody's Issuer Comment on Abbott available at Moodys.com.

Please see ratings tab on the issuer/entity page on Moodys.com for the last Credit Rating Action and the rating history.

Abbott Laboratories, headquartered in Abbott Park, Illinois is a global, diversified healthcare company focused on pharmaceuticals and medical products, including nutritionals, devices and diagnostics.

Diana Lee
Sex drug campaign ‘violated rules’

Andrew Jack

 Eli Lilly is to be reprimanded by the UK pharmaceutical industry watchdog for an “unbalanced” promotion of its anti-erectile dysfunction drug Cialis, in violation of ethical rules.

The Prescription Medicines Code of Practice Authority has ruled that the US-based company “brought discredit” on the industry through a marketing campaign on television, the internet and in brochures in GP surgeries in the UK.

It said the company had presented information on its medicine that failed to cite the side-effects or risks, and in a way that would have encouraged patients to seek a prescription for Cialis.
Drug firm censured for lapdancing junket

Sarah Boseley, health editor
The Guardian, Tuesday 14 February 2006

One of the world's largest drug companies has been disciplined by the industry's UK watchdog after admitting that its staff entertained doctors to ground-level racing, lapdancing and Centre Court tickets at Wimbledon.
## Local Stories Based on This Data

Interested in getting our Dollars for Docs data for use in your research or reporting? [Find out here.](#)

- **The Tribune**: *Doctors face dilemma over compensation from drug companies*
- **Daily Hampshire Gazette**: *Rules shine light on drug firms' ties to doctors, raising questions about ethics*
- **Democrat and Chronicle**: *URMC gets better grade in conflict-of-interest report card*
- **Providence Journal**: *Doctors' ties to drug makers get scrutiny*
- **KOAA.com**: *If your doctor was getting money from drug companies would you want to know about it?*
- **KOAA.com**: *Local doctors paid $1.5 million by drug companies*
- **KTRE ABC**: *East Texas docs paid by drug companies*
- **San Rafael Patch**: *How Much Does Your Doctor Take from Drug Companies?*
- **Berkeley Patch**: *How Much Does Your Doctor Take from Drug Companies?*
- **Santa Cruz Patch**: *How Much Does Your Doctor Take from Drug Companies?*

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The new portal featuring the first MedTech event clearance system

MedTech is a platform dedicated to ethics and compliance projects in the European MedTech industry and is led by Eucomed, the European medical technology industry association. EthicalMedTech currently focuses...