

## E-ALERT | Anti-Corruption

March 29, 2012

### **BIOMET, INC. PAYS \$22.88 MILLION TO SETTLE FCPA ALLEGATIONS** **Improper Payments Made to Public Doctors in State-run Hospitals in China and Two Other Countries**

On March 26, 2012, Biomet, Inc. (“Biomet”) agreed to pay \$22.88 million to settle allegations that Biomet employees and distributors made improper payments to publicly-employed health care providers in China, Argentina, and Brazil to sell products. According to a complaint filed by the US Securities and Exchange Commission (“SEC”) (the “[SEC Complaint](#)”) and a [press release](#) issued by the US Department of Justice (“DOJ”), Biomet employees and distributors made improper payments and then recorded the payments as “commissions,” “royalties,” “consulting fees,” or “scientific incentives.” To settle the charges, Biomet agreed to pay \$17.28 million in criminal penalties, retain a compliance monitor for 18 months, and pay \$5.6 million in disgorgement of profits and prejudgment interest.

#### **Alleged Misconduct**

Biomet, which is based in Indiana and listed on the NASDAQ, manufactures and sells medical devices worldwide. Biomet’s products are primarily used by orthopedic surgeons.

Biomet conducts business in China through two wholly owned subsidiaries: Biomet China, a Chinese company, and Scandimed AB, a Swedish company. Prior to 2006, these subsidiaries contracted with an unnamed Chinese distributor (identified in the SEC Complaint as “Chinese Distributor”) for product distribution in China.

According to the SEC Complaint, Biomet China and Scandimed both used the Chinese Distributor to funnel bribes to doctors employed at public hospitals. These doctors were provided with cash and travel benefits by the Chinese Distributor in exchange for selecting Biomet medical device products.

The SEC Complaint stated that from at least 2001, certain senior Biomet business managers, executives, and auditors in China and the US learned that surgeons in China were receiving “commissions” or “rebates” of 5% to 25% of the price of Biomet’s products. In 2005, Biomet’s director of internal audit reportedly instructed an auditor to classify improper payments made to physicians in connection with clinical trials as “entertainment.”

In late 2006, Biomet decided for business reasons to cease working with the Chinese Distributor and to hire its own sales team to promote its products in China. According to the SEC Complaint, however, despite this change, improper payments reportedly continued. In October 2007, Biomet China reportedly paid for 20 surgeons to travel to Barcelona and Valencia, Spain, for training. According to the SEC complaint, “a substantial portion” of that

time was devoted to “sightseeing and other entertainment at Biomet’s expense.” Toward the end of the trip, a product manager for Biomet China sent an email to the associate regional manager of Biomet International in Hong Kong, describing efforts by the Chinese government to halt corruption in the health care sector, and proposing four methods by which Biomet could avoid the regulation, including falsifying invoices.

The SEC Complaint also alleges that Biomet’s Argentine subsidiary, Biomet Argentina, obtained phony invoices from doctors for consulting services that were never performed in order to comply with local regulations required that required companies to report all payments to doctors. When this law was amended in 2000 to forbid tax-free payments to surgeons, Biomet Argentina continued paying doctors approximately 15% to 20% of each sale under the guise of “royalties” or “other sales and marketing” expenses.

In Brazil, Biomet’s local distributor reportedly paid bribes to doctors of 10% to 20% of each sale price and masked the payments as “commissions” or “rebates.” Analyses of company emails in Argentina and Brazil found that Biomet employees had been warned by company auditors about the corrupt practices, but had failed to take timely remedial measures.

## Consequences

Biomet agreed to pay a \$17.28 million criminal penalty as part of a deferred prosecution agreement with the DOJ. The DOJ press release noted Biomet’s cooperation and remedial efforts, which led to Biomet receiving “a reduction in its penalty as a result of its cooperation in the ongoing investigation of other companies and individuals.”

The SEC charged Biomet with violations of the FCPA’s anti-bribery, books and records, and internal controls provisions. Biomet consented to the entry of a court order requiring payment of \$4,432,998 in disgorgement of tainted profits and \$1,142,733 in prejudgment interest. The SEC also ordered Biomet to retain, at Biomet’s expense, an “independent compliance consultant” for 18 months to review its compliance program.

## Implications

The SEC [press release](#) noted that the Biomet settlement was part of SEC’s and DOJ’s “ongoing proactive global investigation into medical device companies bribing publicly-employed physicians,” which has already resulted in settlements with two other medical device companies.

This enforcement action reinforces lessons learned from other FCPA and anti-corruption cases, including the need for:

- careful oversight, monitoring, and control of both company employees and third-parties that represent the company, including distributors and sales agents;
- ensuring that recommendations by internal audit are followed-through;
- scrutiny from an anti-corruption perspective, and careful control of, payments such as sales commissions and rebates; and

- proactively addressing specific risks in the healthcare sector, including interactions with physicians in state-owned hospitals (travel benefits, entertainment, and payments made for clinical trials, consulting, etc.).

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