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New FCPA Settlement Involving Medical Device Manufacturer

On March 26, 2012, the US Department of Justice ("DOJ") and Securities Exchange Commission ("SEC") announced a settlement with Biomet, a medical device manufacturer, regarding allegations of improper payments made by its subsidiaries and distributors in China as well as Argentina and Brazil. Under a deferred prosecution agreement ("DPA"), Biomet will pay a criminal penalty of US $17.28 million and is required to implement "rigorous internal controls, cooperate fully with the [DOJ] and retain a compliance monitor for 18 months." In Biomet's settlement with the SEC, Biomet agreed to pay $5.4 million in disgorgement of profits, including pre-judgment interest.

The DOJ and SEC's allegations regarding China include that two of Biomet's wholly-owned subsidiaries, Biomet China and Scandimed AB, sold medical devices through a distributor in China who provided publicly-employed doctors with money and travel in exchange for their purchases of Biomet products. Beginning as early as 2001, the distributor exchanged e-mails with Biomet employees that described the bribes he was arranging on the company's behalf.

The SEC alleges that some e-mails described the way that vendors would deliver cash to surgeons upon completion of surgery, and others discussed the amount of payments. The distributor explained in one e-mail that 25 percent in cash "rebates" would be delivered to a surgeon upon completion of surgery. Biomet sponsored travel for 20 Chinese surgeons in 2007 to Spain, where a substantial part of the trip was devoted to sightseeing and other entertainment. In connection with field visits, Biomet senior managers and employees paid "commissions" or 10-15% "consulting fees" to doctors for conducting clinical trials and in one instance instructed an auditor to classify the improper payments made in connection with certain clinical trials as "entertainment."

In addition to the substantive bribery counts, the DPA includes counts for failing to implement internal controls and keeping inaccurate books and records by incorporating the false characterizations of bribes into the year-end financial statements filed with the SEC.

The Biomet case is the third case that US authorities have brought against medical device manufacturers since January 2011. The Biomet case, as well as the two earlier

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cases against Johnson & Johnson and Smith & Nephew, demonstrate the importance of conducting due diligence of and monitoring a company's distribution and sales and marketing network. In all three of these cases, companies were charged with, among other things, making improper payments through their sales intermediaries. The DOJ and SEC have made clear that they consider companies to be responsible for conducting a reasonable amount of due diligence into their distribution and sales and marketing network, including conducting a review of sales intermediaries' qualifications and business reputation, providing a rationale for using the sales intermediary, and addressing risk areas under the FCPA. The DOJ and SEC have also made clear that they consider companies to be responsible for ongoing monitoring of the distribution network.

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