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Continuing The Trend: Biomet's FCPA Settlement

Law360, New York (April 09, 2012, 1:35 PM ET) -- On March 26, 2012, U.S. medical device maker Biomet Inc. agreed with the U.S. Department of Justice and U.S. Securities and Exchange Commission to settle charges related to alleged bribes paid to obtain business in Argentina, Brazil and China. This is the third — though almost certainly not the last — Foreign Corrupt Practices Act settlement with medical device manufacturers.

In the wake of recent setbacks in the Shot Show and Lindsey cases, the settlement serves as a reminder that the U.S. government is still aggressively enforcing the FCPA and broadly interpreting its provisions.

Background

Biomet, based in Warsaw, Ind., manufactures and sells orthopedic medical devices, including prosthetic joints. Until September 2007, Biomet's stock was traded on the NASDAQ; the company therefore was an "issuer" for purposes of the FCPA until that point in time and thus subject to SEC jurisdiction. (Under the FCPA, the SEC only has jurisdiction over issuers; the DOJ also maintains jurisdiction over U.S. companies and individuals, including any person physically located in the United States, regardless of nationality.)

The government brought an action against Biomet based on business conducted by the company's wholly owned subsidiaries in Argentina, Brazil and China. According to the charging documents, Biomet paid commissions of 10 to 20 percent per sale to doctors working for public health care providers in Argentina and Brazil. Through a Chinese distributor, Biomet apparently paid similar commissions to, or for travel by, Chinese doctors.

Biomet's internal auditors discovered the Brazil payments in 2002 and the Argentina payments in 2006. The auditors apparently notified Biomet personnel in the United States about these payments, yet the payments continued until around August 2008.

Biomet personnel appear to have learned of the China payments even earlier — in 2001 — through correspondence with the company's distributor for China. According to the government, in 2005, Biomet's director of internal audit instructed another auditor to classify improper payments made to doctors in connection with clinical trials as "entertainment."

Biomet was charged with conspiracy to violate the FCPA, three counts of violating the law's anti-bribery provisions, and one count of violating the law's books and records provisions. The company agreed to pay more than $5.5 million in disgorgement and prejudgment interest to the SEC, and more than $17 million in fines to the DOJ. Under the terms of the agreement, Biomet was also required to implement a compliance monitor for 18 months.

Analysis

As noted above, the Biomet settlement follows FCPA settlements with other medical device manufacturers (Johnson & Johnson in April 2011 and U.K.-based Smith and Nephew in February 2012). While based on similar patterns of conduct — payments to doctors in public health care systems — these settlements also demonstrate the U.S. government's focus on individual companies even in the context of an industry-wide investigation. For example, the settlements pertain to different regions: While the Johnson & Johnson and Smith and Nephew settlements focused on those companies' activities in Europe, the Biomet settlement is based on conduct in South America and China.

In addition, the punishment meted out to each company appears to vary based on the circumstances. In Biomet's case, management's failure to address compliance issues despite notification from the company's internal audit department and the apparent complicity of the audit department in certain misconduct likely contributed to the imposition of a compliance monitor.

By contrast, while it was required to appoint an internal chief compliance officer and other senior compliance personnel and maintain a rigorous compliance program that meets highly detailed requirements provided by the DOJ, Johnson & Johnson was not obligated to hire a compliance monitor with direct reporting obligations to the DOJ.

It remains to be seen whether the government may seek to impose penalties on individual employees of Biomet, though Biomet pledged in its deferred prosecution agreement with the DOJ to cooperate in any other investigation — whether by U.S. or non-U.S. enforcement authorities — of individual directors, officers, employees or other individuals affiliated with the company. (Based on the publicly reported facts, particularly given the government's recent settlement with the former head of internal audit for the Noble Corporation, it seems likely that Biomet's director of internal audit could be an enforcement target.)

Ultimately, while each settlement in these matters has varied, the government appears to have pursued enforcement under the theory that practices in an industry may not vary significantly between individual companies. For medical device manufacturers, it seems that it was common to make payments to orthopedic doctors or other health care professionals in exchange for use of devices. Notably, for the medical device industry, the government apparently gained insight into this practice through a voluntary disclosure (made by Johnson & Johnson), which then formed the basis for the government to inquire into similarly situated companies.

It also is notable that the government's theory of liability in the Biomet case is founded on a broad interpretation of what constitutes a "foreign official" under the FCPA. In this case, and indeed in each of the settlements in the medical device cases, the government has premised liability on its view that doctors affiliated with public health programs are themselves "foreign officials."

Correspondingly, under this view, payments made to such doctors have FCPA implications. While this is not a novel theory (for example, the DOJ brought an enforcement action against Syncor Taiwan Inc. in December 2002 based on payments to doctors at public hospitals in Taiwan), doctors are a particularly jarring example of the breadth of "foreign official" under the government's view of the statute. Continued enforcement involving doctors serves as a reminder that all personnel of state-run entities or businesses are likely to be deemed foreign officials under the government's current interpretation of the FCPA.

Takeaway

Predicting what industry the U.S. government may next target would be difficult to do and likely a waste of effort. But the Biomet settlement serves as a reminder that any company in an industry that has been targeted previously would do well to study past enforcement action in the industry and assess whether practices on which liability was based could be a problem for their own enterprise. A bit of time reflecting on conduct that created problems for competitors in the same industry may help companies avoid the fate of those competitors.

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