The Biomet Case:
Lessons from the latest FCPA settlement involving Latin America

http://mattesonellislaw.com/fcpamericas/
March 30, 2012

Earlier this week, a former colleague and skilled attorney, Lisa Prager, offered thoughts on compliance priorities in her article for Forbes entitled, "FCPA Compliance: Don't Blow Your Budget Just Yet." She advises companies to implement straightforward compliance programs and to target compliance efforts to the areas of business posing the highest corruption risks.

Companies need go no further than this week's $22.8 million FCPA settlement with the Indiana medical device maker Biomet Inc. to understand what Lisa is talking about. Had Biomet created a straightforward compliance program and targeted its compliance efforts to the following four key areas in Argentina, Brazil, and China, history would probably be much different:

1. Training. Throughout the SEC's complaint, it is apparent that, not only was the company engaged in consistent FCPA violations over the span of eight years by making improper payments to public doctors, but multiple people in the company were aware of the activity, participated in the activity, and did nothing to stop it. A Managing Director, an Associate Regional Manager, a Director of Internal Audit, a President of International Operations, senior vice presidents, operations managers, and lower-level employees and auditors throughout the company all played a role. Maybe they did not realize that public doctors are considered "foreign officials" under the FCPA? Maybe they knew they were doing something wrong but did not understand the consequences? Had Biomet instituted a training program to educate its personnel on its compliance rules, including the acts prohibited by the law and the consequences of violations to employees and the company, these wide-scale practices probably would have been avoided.

2. Due Diligence on Distributors: Biomet's Brazilian and Chinese subsidiaries were aware that their distributors were paying doctors between 5 and 25 percent of the value of the medical devices in exchange for the purchases. Had the subsidiaries conducted appropriate anti-corruption due diligence on the distributors, they would probably have identified such practices before they started. The subsidiaries could have worked to ensure that the distributors were aware of and agreed to their compliance guidelines, could have included anti-corruption terms and conditions in their written agreements, and could have verified that the distributors were not giving kickbacks to doctors anyway. In fact, when Biomet conducted appropriate acquisition due diligence on the Brazilian distributor in 2008, it identified cash payments to doctors and other expenses "that raised red flags of bribery" and then terminated the relationship. The process eventually worked – it just happened too late.

3. Effective Internal Audits: In his article "Lessons for Internal Audit," Tom Fox shows how Biomet's internal audit department failed to fulfill basic compliance functions, thereby enabling violations to persist. It did not review documentation supporting why commission payments were made. It did not review whether the doctors performed services that would have entitled them to such payments. It did not correctly classify payments so that the books and records of the company accurately reflected the expenses. Had it done these functions, the violations could have likely been avoided.

4. Stand-Alone Travel and Entertainment Policy: Biomet's Chinese subsidiary sponsored the travel of twenty surgeons to Spain for training, and a "substantial portion" of the trip included sightseeing and other entertainment. A stand-alone FCPA Travel and Entertainment policy, if in place, would have clarified that the primary purpose of trips for foreign officials should have been legitimate business, not leisure. The most prudent approach for companies is not to offer any sightseeing at all to officials when they travel with the company. Minor sightseeing, however, might be permissible, especially if it is designed to further the business relationship between the parties. It would not be permissible, however, as part of a *quid pro quo* with a specific official. If sightseeing does occur, the overall trip should not be disproportionately related to pleasure, like it was in the Biomet case. Moreover, if a company allows officials to sightsee, it should ensure that the activity is properly authorized internally. Detailed records of the activity should be kept, including the travel schedule, itinerary, names of company officials doing the sightseeing, and the rationale for the sightseeing activities.

Lisa Prager references a recent survey that found, among other things, that 46% of respondents said their companies had inadequate staffing to do appropriate training and due diligence. These companies will surely not want to find themselves in the position of Biomet right now.