White Paper

Some issues for pharmaceutical companies under the FCPA

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Some issues for pharmaceutical companies under the FCPA

The pharmaceutical industry has had its fair share of Foreign Corrupt Practices Act (FCPA) enforcement actions. One of the more significant reasons is because such entities sales practices involve payments of some sort to doctors, in exchange for recommendations for their products or actual sales. As doctors overseas tend to work in socialized medicine, this mean that they work in government owned or managed hospitals and are considered to be 'foreign officials' under the Foreign Corrupt Practices Act, those payments may create offenses under the U.S. law. As noted by the FCPA Blog, "Unfortunately for the pharmas, their overseas sales practices seem to satisfy every element of an FCPA offense." This article will look at some of the bribery and corruption schemes which have gotten various pharmaceutical companies into trouble.

I. Use of false expense reports to cover improper gifts and cash payments

In China, one company's employees used the classic system of submitting inflated expense reports and using the excess reimbursements to pay bribes. The list of gifts that were provided to Chinese government officials was as wide ranging as it was creative. There were gifts consisting of specialty foods, wines and a jade bracelet. There were paid trips to bath houses, karaoke bars and spas. There was money paid to purchase "door prizes and publication fees to government employed physicians." It was even noted that bribes were paid consisting of cigarettes. In the SEC complaint it stated that "Although the dollar amount of each gift was generally small, the improper payments were wide-spread across the [China] subsidiary."

II. Use of distributor discounts to fund bribes

In Brazil, companies have gotten into trouble through the use of to distributors to sell products. These distributors then resold the products to both public and private entities. It was the classic distributor model where products are sold to the distributors at a discount and then the distributors would resell the products at a higher price and then took their discount as compensation. A standard discount given to the distributors which generally ranged between 6.5% and 15%, with the majority of distributors in Brazil receiving a 10% discount; however in early 2007, one company awarded an unusually high discount of between 17% and 19% to a distributor for the sale of a product to the government of one of the states of Brazil.

The distributor used approximately 6% of this additional discount to create a fund to pay Brazilian government representatives to purchase the products from him. Moreover, this increase in the discount was approved by the company with no further inquiry as to the reason for the request or to substantiate the basis for such an unusually high discount. If there were any internal controls they were not followed.

III. Use of charitable donations to obtain sales of drugs

There have been two FCPA enforcement action based entirely upon charitable giving. In the first, a US company's Polish subsidiary made improper payments to a charitable organization named the Chudow Castle Foundation, which was headed by an individual who was the Director of the Silesian Health Fund during the time period in question. Schering-Plough is a pharmaceutical company and the Director of the Health Fund provided money for the purchase of products manufactured by Schering-Plough as well as influencing medical institutions, such as hospitals, in their purchase of pharmaceutical products through the allocation of health fund resources. In addition to the above, the SEC found that Schering-Plough did not accurately record these charitable donations on the company's books and records.

Amazingly enough, the second enforcement action involves the same charitable entity, the Chudow Castle Foundation. The thing that got the second company into trouble was that its donations were made to an entity controlled by the person whose position allowed him to exercise "considerable influence over the pharmaceutical products local hospitals and other health care providers in the region purchased."

Just how did this bribery scheme camouflaged as a charitable donation work? The Director actually made a request for a donation directly to representatives of The Company. Thereafter, the Foundation itself made "subsequent requests" for donations. In addition to this obvious red flag, The Company did no due diligence on the Foundation and falsely described the nature of the payments not once but three separate times with three separate descriptions. The Company turned some of the monies over not to the Foundation, but to the Director for use at his "discretion". Interestingly, the donations were not only made at or near the time of a contract execution, with one donation being made two days after the Director authorized the purchase of the drugs from The Company. Internally The Company even discussed the size of a donation, calling it a "rebate" and said "it will depend on the purchases of medicines."

The FCPA Blog further reported that when asked about the guidelines regarding requests for charitable giving and the FCPA then Deputy Chief of the Criminal Division's Fraud Section at the DOJ Mark Mendelsohn, said that any such request must be evaluated on its own merits. He advocated a "common sense" approach in identifying and clearing Red Flags. This would include determining if a governmental decision maker held a position of authority at the charity to which the donation would be made, whether the donation was consistent with a company's overall pattern of charitable giving, who made the request for the donation and how was it made.

IV. Use of offshore agents who performed no services

Here a company can get into FCPA hot water by entering into an agreement with a third party other than the distributor who was selected by the government official making decisions on the purchase of products; where the other third parties were usually not domiciled in Russia, nor did they have bank accounts in Russia. In other words, they were Offshore Agents who were paid a flat fee or percentage of the total sales with no discernible work or services performed.

What about the services that these Offshore Agents provided by these agents? First and foremost, they all had their own special "Marketing Agreement" which was actually a template contract prepared by the US entity. The services allegedly provided by these Offshore Agents included "immediate customs clearance" or "immediate delivery" of the product. There were other equally broad and vague descriptions such as "promotion of the products" and "marketing research". But not only was there little if no actual evidence that these Offshore Agents provided such services.

V. GSK in China

GSK recently got into anti-corruption hot water for another set of bribery schemes in China. In an FT article, entitled "Bribery built into the fabric of Chinese healthcare system", reporters Jamil Anderlini and Tom Mitchell wrote about the 'nuts and bolts' of how bribery occurs in the health care industry in China. They opened their article by noting that the practice of bribing "doctors, hospital administrators and health officials is rampant." They quoted an unnamed senior health official in Beijing for the following, "All foreign and domestic pharmaceuticals operating in China are equally corrupt". The authors also quoted Shaun Rein, a Shanghai-based consultant and author of "The End of Cheap China", for the following "This is a systemic problem and foreign pharmaceutical companies are in a conundrum. If they want to grow in China they have to give bribes. It's not a choice because officials in health ministry, hospital administrators and doctors demand it."

Their article included a diagram which visually represented two methods used to pay bribes in China, which were designated the direct incentives and indirect incentives methods. Whichever method is used, the goal is the same—to boost sales.

In the direct incentives method, a third party representative of a company would provide cash to the department head of a clinic or hospital. The department head would in turn pay it to the individual physicians to encourage them to prescribe the company's medical products. But a third party representative could also contact a physician directly and reward them with "gifts such as store cards, vouchers and travel" expenses. Other direct methods might include the

opening of bank accounts or charge accounts at luxury goods store and then the company would hand "the debit card or VIP card directly to the recipient."

The FT noted that the indirect incentives method tended to be "used by larger pharmaceutical groups with stricter governance procedures." Under this bribery scheme there were two recognized manners to get benefits into the hands of prescribing physicians. The first is to have cash incentives paid to a third party representative, such as a travel agency, which would then "pass on some of these rewards to the physician directly." Another method was for the company itself to make a "lump sum sponsorship paid to hospitals". The hospitals would then distribute perks "to the doctors as a monthly or annual bonus." Another indirect method noted was that companies might organize overseas conferences and site visits, which might also include first class travel arrangements with stays at "five-star accommodations."

Anderlini and Mitchell reported that "The 2012 annual reports of half a dozen listed Chinese pharmaceutical companies reveal the companies paid out enormous sums in "sales expenses", including travel costs and fees for sales meetings, marketing "business development" and "other expenses". Most of the largest expenses were "travel costs or meeting fees and the expenses of the companies' sales teams were, in every case, several multiples of the net profits each company earned last year." They cited the example of the company Guizhou Yibai Pharmaceutical which earned a net profit last year of Rmb333.3m. However its "sales expenses came to a total of Rmb1.25bn, including meetings expenses of more than Rmb295m and wages of just Rmb88m." Indeed the "largest expense for the company's sales team of 2,318 people was Rmb404m spent on travel, for an average of more than Rmb174,000 per sales representative for the year. That is roughly what it would cost every single sales representative to fly 10 times a month between Beijing and Guiyang, where the company is based." Pharmaceutical companies have drawn and will continue to draw scrutiny from regulators regarding anti-bribery and anti-corruption. They need to robust compliance programs in place to meet these challenges.

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