No.: 09-01

Date: August 3, 2009

Foreign Corrupt Practices Act Review

Opinion Procedure Release

The Department has reviewed the FCPA Opinion request of a U.S. company (the "Requestor") that was submitted on June 26, 2009, along with supplemental materials submitted on July 6, 2009, and July 31, 2009. The company is a "domestic concern" within the meaning of the FCPA. The facts and circumstances are as follows:

Requestor designs and manufactures a specific type of medical device. Requestor is one of only a small number of major global companies to design and manufacture this type of medical device. Requestor's competitors already operate and sell their products to the government of a certain foreign country, but Requestor is not well known to that country's government because its sales in that country to date have been mainly in the private sector.

In or about March 2009, representatives of Requestor visited the foreign country to meet with a senior official ("Senior Official") of a government agency ("Government Agency"). During that visit, the Senior Official described the foreign government's plan to provide a specific type of medical device for patients in need in the country and what the Senior Official believed Requestor should do in order to participate successfully in that program. The Senior Official explained that the government intends to purchase the medical devices, and then subsidize the cost of such devices when it resells them to patients. The Senior Official informed Requestor that all major manufacturers would be allowed to participate in tenders for government purchases of the medical devices, but not all products would be endorsed by the government. The Senior Official explained that the government would only endorse products that it has technically evaluated with favorable results.

Because the foreign government is not familiar with the performance of Requestor's devices, the Senior Official advised Requestor that in order for Requestor's devices to be endorsed by the government, they would need to be evaluated by the government. The Senior Official asked Requestor to provide sample devices to government health centers for evaluation of the technology, measured outcomes, and feedback from the top physicians at each center following the use of the devices in patients. The foreign government and Requestor jointly determined that the optimal sample size for such a study was 100 units distributed among ten experienced health centers in the country. The number was determined based on the size of the overall potential patient population in the country and the government's experience with other similar medical devices. Requestor and the foreign government determined that providing ten medical devices each to ten different centers would ensure valid results free from anomalies that may result from a smaller sample size or sampling at a smaller number of centers. Requestor will select the centers that will participate in order to ensure that the participating centers have the requisite expertise, resources, and experience to successfully participate in the evaluation.

Requestor will also provide accessories for the medical devices free of charge, as well as standard

follow-on support. Requestor will not be responsible for the costs of any associated medical procedures. The approximate value of the devices and related items and services to be provided by Requestor is $19,000 per device, or $1.9 million for all 100 units.

The 100 recipients will be selected from a list of candidates provided by the participating medical centers. The centers have long lists of candidates but will be expected to nominate candidates that best meet certain objective criteria, which Requestor provided with its letter of request. In addition, all candidates will be required to present a certificate of economic difficulty from the relevant local government authority establishing the candidate's inability to pay. The 100 recipients will be selected from the list of candidates by a working group of health care professionals who are experienced in the use of this type of medical device. Requestor's country manager in the foreign country, a physician ("Country Manager"), will also participate in the working group that evaluates and selects patients who will receive the donated devices. This will enable Requestor to ensure that the selection criteria are met. The Country Manager received FCPA training from Requestor in January 2008 and March 2009.

In order to ensure fairness and transparency in the selection process, the names of the 100 recipients will be published on the Government Agency's web site for two weeks following the selection. In addition, close family members (meaning immediate relatives, as well as nieces, nephews, cousins, aunts, and uncles) of the Government Agency's officers or employees, working group members, or employees of the health centers who are participating in the selection process or in testing and evaluating the medical devices will be ineligible to be recipients under the program unless (a) the government-employed relatives of such recipient hold low-level positions and are not in positions to influence either the selection or testing process; (b) the government-employed relatives of such recipient clearly meet the requisite economic criteria; and (c) the recipient is determined to be a more suitable candidate than candidates who were not selected based on technical criteria. Requestor agrees to provide a report of any such determination to the Department. In addition, the Country Manager will specifically review the selection of any immediate family members of any other government officials (e.g., those unaffiliated with the medical device project or the Government Agency) to make certain that the criteria were properly and fairly applied and will report his determination to Requestor's legal counsel.

The evaluation of the donated medical devices will be based on objective criteria that are standard for this type of medical device and that have been provided to the Department. The results of the evaluation will be collected by the Country Manager, who will enlist the help of two other medical experts to review the results and provide an overall report, as well as individual objective results, to a senior health official in the foreign country who will share his assessment with the Government Agency. The Government Agency will then evaluate the results of the evaluation and the report by the Country Manager, along with the senior health official's assessments, to determine the suitability of Requestor's technology for the medical device program. If the results of the evaluation are favorable, Requestor's device will be identified by the Government Agency as eligible for the subsidized medical device program, along with the devices of Requestor's competitors, which have already been declared eligible. The foreign government has advised the Requestor that none of the companies' devices will be promoted by the foreign government above any of the other qualified devices.

Requestor expects that more than thirty government health centers throughout the country will receive the evaluation results, which will in large part determine whether those centers will purchase Requestor's products as part of the government's medical device program. As a result of the anticipated success of the proposed evaluation, Requestor expects that its products will meet all

technical criteria for this program and that its opportunities for participation in the program will be greater as a result of the awareness among government physicians of the performance of Requestor's devices.

Finally, Requestor states that it has no reason to believe that the Senior Official who suggested providing the devices will personally benefit from the donation of the devices and related items and services.

Based upon all of the facts and circumstances, as represented by Requestor, the Department does not presently intend to take any enforcement action with respect to the proposal described in this request. This is because, based on Requestor's representations, the proposed provision of 100 medical devices and related items and services fall outside the scope of the FCPA in that the donated products will be provided to the foreign government, as opposed to individual government officials, for ultimate use by patient recipients selected in accordance with specific guidelines, as described above.

This FCPA Opinion Release has no binding application to any party which did not join in the request, and can be relied upon by the requestor only to the extent that the disclosure of facts and circumstances in its request is accurate and complete and continues to accurately and completely reflect such facts and circumstances.