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### DOJ Issues FCPA Guidance on Free Product Promotions with Foreign Government Customers

On August 3, 2009, the U.S. Department of Justice (DOJ) issued important guidance concerning the Foreign Corrupt Practices Act (FCPA) implications of providing free product samples to customers that are owned or controlled by foreign governments. In its first FCPA Opinion Procedure Release of 2009, DOJ said it would not take enforcement action against a medical device company for giving away nearly \$2 million worth of free product samples to foreign medical centers, primarily because the samples would be given to the centers directly rather than to individual doctors or other medical center employees. (*See FCPA Opinion Procedure Release No. 09-01, available at [www.usdoj.gov/criminal/fraud/fcpa/opinion/2009/0901.html](http://www.usdoj.gov/criminal/fraud/fcpa/opinion/2009/0901.html).*)

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Put simply, the FCPA prohibits offering, paying, or promising anything of value to a foreign government official for the purpose of securing an improper business advantage. In the context of medical centers owned or controlled by foreign governments, both the DOJ and the Securities and Exchange Commission (which has civil jurisdiction in FCPA cases) generally consider doctors and other employees of such centers to be foreign “officials” within the meaning of the FCPA. Thus, many companies—particularly those in the medical device and pharmaceutical industries—are rightly concerned about the FCPA risks presented by giving, promising or offering free samples to such foreign medical centers.

DOJ’s new guidance provides some clarity for companies in this context. It arises from a request under DOJ’s FCPA Opinion Release Procedure, which allows companies to obtain an opinion “as to whether certain specified, prospective—not hypothetical—conduct conforms with [DOJ’s] present enforcement policy regarding the antibribery provisions of the [FCPA].” 28 C.F.R. § 80.1.

In its request for an opinion release, the unidentified U.S. medical device company described a common scenario in which a senior official of a foreign government agency encouraged the company to



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provide free samples to several government medical centers to facilitate an evaluation of whether the company's products were worthy of endorsement by the foreign government for sale in that country. In order to ensure that the evaluation results would be valid and reliable, the foreign government and the company jointly determined that the optimal sample size would be 100 units distributed among ten health centers in the country. The total cost of the sample devices, including associated accessories and technical support, was \$1.9 million.

The company told DOJ that the 100 patient recipients would be selected under objective criteria by a working group comprised of health care professionals in the country along with the company's Country Manager, who had recently received FCPA training on two occasions. The company also represented that it had adopted procedures to ensure that close relatives of the government agency's officers or employees, working group members, or employees of the health centers would not obtain any favoritism in the selection of recipients. Moreover, the names of the selected recipients would be published on the government agency's website for two weeks in order to provide additional transparency.

Based on the company's representations, DOJ confirmed that it had no intention to take enforcement action with respect to the free sample proposal described in the company's request. Specifically, DOJ concluded that the proposal fell "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." Significantly, this focus on conferring the benefit directly to the government, rather than to individuals, is consistent with earlier DOJ opinion releases issued in other contexts back in 1997 and 2006.

Notwithstanding DOJ's opinion release in this case, companies should remain cautious when evaluating whether to provide free product samples to foreign officials or agencies. Like all opinion releases, this one has no binding application to any party other than the requesting company, and can be relied upon even by the requesting company only to the extent that its request was complete and accurate. However, the opinion release does suggest that risks can be reduced by, among other precautions, providing free samples directly to government entities rather than to individual government employees, and by selecting recipients through a fair and transparent process. Moreover, in establishing procedures and selection criteria, companies should consider involving employees with FCPA training and, to the extent practical, monitoring the process to confirm that recipients are in fact selected fairly and transparently. Finally, as with all transactions involving foreign counterparties, free sample promotions should be accurately described and accounted for in the company's books and records.

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