

UNDER SCRUTINY:
**SHB's Government Enforcement
& Compliance Update**



**GOVERNMENT ENFORCEMENT
& COMPLIANCE**

Our clients face unprecedented enforcement scrutiny and novel legal theories. Today, government enforcement actions can include civil as well as criminal investigations and litigation. They can involve a host of independent actors including federal and state prosecutors, regulators, whistleblowers and their counsel, and class-action attorneys. These cases must be defended under the watchful eye of investors and the public.

Our Government Enforcement & Compliance Practice consists of former prosecutors – including a former U.S. Attorney, former Justice Department officials and even former corporate executives – who counsel and defend companies, their executives and employees in the full range of criminal, civil and regulatory government enforcement actions at the state and federal level. We counsel clients on how to avoid enforcement scrutiny. When investigations do arise, however, we work with our clients to resolve it as efficiently, cost-effectively and quietly as possible.

WANT TO PROVIDE FREE PRODUCT SAMPLES?

FCPA Opinion Procedure Release Offers Guidance

The Department of Justice (DOJ) recently issued its first FCPA Opinion Procedure Release (OPR) of 2009, and it has implications for companies that wish to provide free product samples to state-owned or controlled customers. In Release 09-01,¹ the DOJ stated that it would not take enforcement action against a medical device company for donating \$1.9 million in free product samples to government health centers as part of its effort to introduce its product to a foreign government.²

The OPR explains that a senior foreign government official informed the medical device company of the foreign government's plan to provide a specific medical device to needy patients. The official further explained that while all manufacturers would be invited to participate in tenders to the government, not all products would be endorsed by the government; only those products favorably evaluated by the government would be endorsed. The senior official asked the medical device manufacturer to provide samples to government health centers for an evaluation of the technology. The parties decided on a sample size of 100 units distributed among 10 health centers. The total cost of the devices and support was \$1.9 million. The patient recipients would be selected using objective criteria with care taken to ensure no favoritism was shown to government employees' close relatives.

Based on the information provided to the DOJ in the OPR process, the DOJ decided not to take enforcement action because the samples were to be "provided to the foreign government, as opposed to individual government officials, for ultimate use by patient recipients selected in accordance with specific guidelines." An FCPA offense requires a corrupt payment to a "foreign official." The law defines "foreign official" as a human being, not a government entity. No foreign official, no FCPA offense.³

1 FCPA Opinion Procedure Release No. 09-01, available at: <http://www.usdoj.gov/criminal/fraud/fcpa/opinion/2009/0901.html>.

2 Similar questions have been addressed in previous releases: No. 97-02 (November 5, 1997) and No. 06-01 (October 16, 2006).

3 Simply because there is no FCPA violation does not excuse a company from complying with other anti-fraud laws and relevant U.S. export control regimes.

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Notwithstanding this release, companies must tread cautiously when providing free samples to foreign officials or government agencies. While OPRs are non-binding, this release confirms that free product samples may be provided directly to foreign government entities rather than individual government officials. Merely having a government entity as the party to the transaction, however, is not entirely dispositive. An effective compliance plan should be in place to protect against all risks associated with sales to government entities. If agents or distributors are involved, they too must also be aware of the compliance obligations. Lastly, as with all transactions with foreign governments, the free samples must be accurately described and accounted for in the company's books and records.

The medical device and pharmaceutical industries have come under increased scrutiny from the DOJ and SEC regarding their overseas sales practices, and this is a trend that will likely continue. Given the extent to which these sectors have come under investigation, it is not surprising that the medical device company played it safe and submitted an OPR request. The OPR procedure, which is drastically under-used, allows companies to obtain an opinion as to whether specified, prospective—not hypothetical—conduct conforms to the DOJ's FCPA enforcement policy.

While the OPR process can be a useful tool, there are downsides to submitting a request: (i) the opinion expresses only the DOJ's opinion, not the SEC's; (ii) the procedure takes time, and the proposed business conduct may be time-sensitive; (iii) the request may needlessly raise a company's FCPA profile; and (iv) submitting OPR requests is time-consuming and expensive. These are all important considerations in deciding whether to use the OPR process. ■

Analysis provided by Carol Poindexter and Matthew Benov.