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U.S. Cracks Down On Pharmaceutical and Medical Device Companies Doing Business Abroad

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Actions against pharmaceutical and medical device companies under the Foreign Corrupt Practices Act (FCPA) and export control laws are on the rise. The U.S. Department of Justice (DOJ), the FCPA group, the Health Care Fraud Group at the DOJ and officials at the Securities and Exchange Commission are teaming up to crack down on pharmaceutical companies that take shortcuts and are attempting to obtain business through illegal means. According to Lanny A. Breuer, the Assistant Attorney General for the Criminal Division of the DOJ, more agents have been dedicated to FCPA enforcement at the Federal Bureau of Investigation's Washington, D.C. field office, and the criminal division of the DOJ is currently conducting 120 investigations under the FCPA.

Because foreign health care systems tend to be government-run, every U.S. pharmaceutical company conducting business abroad should have a well-enforced FCPA compliance program to reduce the potential for violations. As companies continue to work more frequently with foreign governments and their officials who finance, regulate and operate foreign health care systems, chances that corrupt payments will make their way into transactions will increase. U.S. FCPA enforcement will focus on pharmaceutical companies and their senior officials. Common violations include customary practices like gifts, meals and entertainment and incorrect accounting entries that improperly record the activities. Companies doing business abroad should take steps to ensure employees, agents and sales representatives understand the FCPA provisions, educate local agents and subsidiaries, and study the list of red flags to avoid possible violations.

If companies voluntarily disclose information on violations they will receive "meaningful credit for that disclosure" according to Breuer. Some of this "credit" may include the U.S. government not requesting or obliging the company to disclose privileged material. Companies that fail to disclose FCPA violations may face considerable ramifications. Non-disclosing companies may suffer criminal fines, civil actions, negative publicity, plummeting stock prices and possible exclusion from Medicare and Medicaid programs. For example, Shering-Plough settled an FCPA matter based upon a donation to a legal foreign charity by a subsidiary. The U.S. government asserted the payments were made to influence the director of the charity to buy its products and none of the payments were "accurately" reported in the accounting records. Shering-Plough settled at \$500,000 back in 2004. The U.S. Treasury's Office of Foreign Asset Control (OFAC) fined Philips Electronics \$128,750 as a penalty in a settlement with DOJ because one employee traveled to Cuba to discuss a sale of medical equipment. Phillips was fined because under the law, a license was required. There are many case examples and the recent cases have differed in prosecution agreements with fines in the hundreds of millions of dollars. The most recent and largest settlement came this year against Siemens, resulting in global fines of \$1.6 billion, of which \$800 million went to U.S. authorities. Siemens failed to properly maintain books and records and will have an independent monitor for four years to supervise its reworking of the internal compliance system to prevent future bribes it paid and recorded as "consultant" or "legal" fees around the world.

Companies should perform internal audits of their global sales to discover any potential violations before the government comes knocking. The money spent on implementing an adequate compliance program is a far better option for the senior executives and compliance officers than the stress of worrying about future penalties and possible personal criminal liability.

For more information about FCPA compliance programs, please contact your Baker Donelson attorney.