

White Collar Criminal and Civil Litigation and Compliance

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DOJ Announces Enhanced Enforcement of Foreign Corrupt Practices Act in Pharmaceutical Industry

The Department of Justice has sent a clear warning to the pharmaceutical industry: FCPA enforcement is coming. At last week's Pharmaceutical Regulatory and Compliance Congress, Lanny Breuer, Assistant Attorney General of DOJ's Criminal Division, stated that "in the months and years ahead" DOJ will be focusing on investigating and prosecuting potential violations of the FCPA committed by U.S. pharmaceutical companies.

The FCPA prohibits U.S. companies and their employees from paying bribes to foreign officials, foreign political parties, and certain other individuals and entities. Payments that may constitute bribes under the Act include not only cash, but also gifts, charitable donations, travel and entertainment expenses, and other items of value. Companies and company officers may, in certain circumstances, be held criminally liable for acts of company employees, agents or consultants that violate the FCPA.

In recent years DOJ and the Securities and Exchange Commission have ramped up enforcement efforts under the FCPA, resulting in an unprecedented number of corporate convictions, multimillion-dollar fines and terms of imprisonment for individual offenders. The global nature of the U.S. pharmaceutical industry, in which many U.S. companies sell products overseas, renders those companies particularly susceptible to running afoul of the FCPA's prohibitions. Because government involvement in health care is significantly greater in most foreign countries than in the United States, "foreign officials" under the FCPA may include not only health ministers and customs officials, but also doctors, hospital officials and other relatively low-level health care workers.

The importance of understanding the FCPA's requirements and prohibitions, along with the implementation of a comprehensive FCPA compliance plan, cannot be overstated in the current enforcement environment. Companies must ensure that they have in place a regularly updated compliance plan that prevents violations of the FCPA and educates employees on the statute's prohibitions and exceptions.

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