

KIRKLAND ALERT

November 2009

DOJ Vows to Scrutinize Pharmaceutical Companies under the FCPA

In a November 12, 2009 speech, Lanny Breuer, Assistant Attorney General for the Criminal Division at the U.S. Department of Justice, sternly warned that the Department would begin (indeed, has already begun) to use the Foreign Corrupt Practices Act (“FCPA”) to police the overseas dealings of the pharmaceutical industry. The FCPA broadly prohibits companies from giving anything of value to a foreign official in order to obtain a business advantage, which can include merely acquiring market intelligence. As pharmaceutical companies do increasing business abroad, especially in countries with heavily regulated healthcare industries (where foreign officials are commonplace), they face a substantially greater risk of becoming targets of FCPA investigations and prosecutions.

In recent years, the Government has made increasing use of the FCPA. Earlier this year, for example, the Government fined Halliburton and its former subsidiary, Kellogg, Brown & Root (“KBR”), \$579 million under it. FCPA prosecutions often have prompted parallel enforcement proceedings from foreign governments, as well as civil suit from the United States Securities and Exchange Commission. In his speech, Mr. Breuer stressed that FCPA enforcement has become a top priority and that the FBI has special agents dedicated to FCPA investigations. Mr. Breuer expressly noted that the Criminal Division’s FCPA and healthcare-fraud units have already begun to work together in the pharmaceutical context.

Mr. Breuer also stated that the Criminal Division will not be content merely to seek criminal fines against companies. Rather, he explained that “[e]ffective deterrence” requires “investigat[ing] and prosecuti[ng] . . . senior executives,” even seeking prison sentences. He specifically noted that the former president and chief executive officer of KBR pleaded guilty and agreed to serve seven years in prison. Mr. Breuer’s recent statement mirrored statements of other Department officials that they hope to increase the number of prosecutions against individuals, as opposed to companies, in the healthcare marketplace.

This news comes at a time in which healthcare costs are front and center in the political debate and in which the Department has obtained record settlements against pharmaceutical companies for alleged off-label marketing of drugs. For example, just months ago, Pfizer agreed to plead guilty to such an allegation and to pay a fine of \$2.3 billion. Likewise, earlier this year, Eli Lilly agreed to pay a criminal fine of more than \$1.4 billion for alleged off-label marketing.

Pharmaceutical companies should take very seriously the combined efforts of the Division’s FCPA and healthcare-fraud units. Specifically, pharmaceutical companies should ensure that they have in place robust FCPA compliance programs, including appropriate training for executives and sales personnel. If a company believes it may have violated the FCPA, it should strongly consider hiring outside counsel to perform a prompt internal investigation and to advise the company on the best approach to resolving any issues.

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