

Assistant Attorney General Warns of Heightened FCPA Enforcement Against Pharmaceutical Industry

November 16, 2009

The Department of Justice is turning up the heat even further on the pharmaceutical industry to comply with the Foreign Corrupt Practices Act ("FCPA"). In a speech on November 12 to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, Lanny A. Breuer, Assistant Attorney General of DOJ's Criminal Division, bluntly warned an audience of pharmaceutical industry officials that "[o]ur focus and resolve in the FCPA will not abate, and we will be intensely focused on rooting out foreign bribery in your industry."

Breuer highlighted some of the key factors that increase FCPA liability risks for the pharmaceutical industry. First, he noted that "close to \$100 billion, or roughly one-third, of total sales for [U.S. pharmaceutical companies] were generated outside the United States, where health systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States" – thereby creating substantial interaction with foreign government officials to manufacture and market pharmaceutical products. Second, he highlighted the problem presented by interacting with foreign health care systems: namely, that foreign doctors, pharmacists, lab technicians, and other health professionals employed by state-owned facilities may constitute "foreign officials" for FCPA enforcement purposes. Indeed, Breuer commented that "under certain circumstances and in certain countries, nearly every aspect of the approval, manufacture, import, export, pricing, sales and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA." Third, he cited heightened FCPA risks for pharmaceutical companies arising from "fierce industry competition and the closed nature of many public formularies."

Breuer's new warning to the pharmaceutical industry is but the latest public manifestation of a trend in intensified FCPA enforcement by DOJ and the Securities and Exchanges Commission, which shares enforcement of the FCPA with DOJ. Since 2005, according to Breuer, the Criminal Division has "brought 57 cases – more than the number of prosecutions brought in the almost 30 years between the enactment of the FCPA in 1977 and 2005." Meanwhile, the FBI recently has created a squad of agents in its Washington, DC, field office who are dedicated to FCPA investigations, which, according to Breuer, "has grown exponentially, both in size and expertise, over the last two years." Consistent with public statements recently made by other Justice Department officials, Breuer disclosed that the government is "currently pursuing more than 120 FCPA investigations."

Nor did Breuer limit his remarks to the investigation and prosecution of corporations found guilty of FCPA violations. Citing recent enforcement actions against the former Chairman and CEO of Kellogg, Brown & Root and other corporate executives, Breuer warned of the "investigation and prosecution of senior executives and stated DOJ's belief that, "for our enforcement efforts to have real deterrent

effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant.”

Finally, Breuer called attention to the benefits of corporate cooperation in the event of a finding of misconduct, stating that “any pharmaceutical company that discovers an FCPA violation should seriously consider voluntarily disclosing the violation and cooperating with [DOJ’s] investigation.” Breuer noted that companies will receive “meaningful credit” if they voluntarily disclose a violation, cooperate with DOJ’s investigation, and take remedial measures to ensure that the conducting resulting in the violation does not recur.