



Please contact any of the attorneys listed below if you have any questions regarding this alert.

Geoffrey R. Garinther
grgarinther@Venable.com
202.344.4919

W. Warren Hamel
wwhamel@Venable.com
410.244.7563

Winifred M. Weitsen
wmweitsen@Venable.com
202.344.8224

Matthew L. Beville
mlbeville@Venable.com
202.344.4487

Government Puts In-House Counsel in its Cross-Hairs

Confirming recent statements by Department of Justice (“DOJ”) and Food & Drug Administration (“FDA”) officials that the government will increasingly target individual executives for criminal prosecution, DOJ has indicted a former Associate General Counsel for pharmaceutical giant GlaxoSmithKline (“GSK”) on two counts of obstruction of justice and four counts of making false statements during an FDA investigation.

The indictment – filed on November 9, 2010 in the District of Maryland, where the FDA’s main offices are located, but brought by the United States Attorney’s Office for the District of Massachusetts – alleges that the in-house lawyer obstructed an FDA investigation into whether GSK promoted its anti-depressant Wellbutrin for off-label purposes. While the indictment does not specifically name GSK or the drug, a GSK spokesperson confirmed that the in-house lawyer, Lauren Stevens, was a former employee. According to the indictment, Stevens authored several letters during the investigation denying that GSK promoted Wellbutrin for off-label purposes, despite allegedly knowing that the company had sponsored events at which Wellbutrin was improperly marketed. The indictment further alleges that Stevens failed to provide the FDA with slides used by physicians to promote Wellbutrin, despite committing to produce them. Instead, Stevens allegedly concluded that the slides were “incriminating” and informed the FDA that GSK’s production was “final” and “complete.”

Stevens has denied liability. The obstruction charges each carry a maximum penalty of 20 years imprisonment and the false statement charges each carry a maximum penalty of 5 years imprisonment. The indictment is unrelated to the \$750 million settlement that GSK announced on October 26, 2010.

This case is an example of the FDA’s and DOJ’s recent coordinated interest in prosecuting individual executives for corporate misconduct. At the Annual Food and Drug Law Institute Enforcement Conference last month in Washington, DC, many speakers discussed the focus on prosecutions of individuals, including strict-liability prosecutions of responsible corporate officials under the so-called Park doctrine (*United States v. Park*, 421 U.S. 658 (1975)), even if there is no proof that the employee directly participated in or knew of the violations.

Commenting on the Stevens indictment, Tony West, Assistant Attorney General for the Civil Division of the DOJ, forewarned that, “Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations.” The indictment is undeniable proof that DOJ believes individual prosecutions are necessary to deter corporate wrongdoing, and is no longer content to obtain convictions solely against entities. It is also further warning that, like the Martha Stewart and Scooter Libby cases, the government will prosecute individuals for obstructing investigations with the same zeal that it pursues the underlying violations.

If you have friends or colleagues who would find this alert useful, please invite them to subscribe at www.Venable.com/subscriptioncenter.

CALIFORNIA MARYLAND NEW YORK VIRGINIA WASHINGTON, DC

1.888.VENABLE | www.Venable.com