White Collar Defense and Investigations Update

June 2011

GODFREY & KAHN S.C.
ATTORNEYS AT LAW

Sean Bosack
(414) 287-9431
sbosack@gklaw.com

Eric J. Wilson
(608) 284-2603
ewilson@gklaw.com

The following is based on a summary of legal principles. It is not to be construed as legal advice. Individuals should consult with legal counsel before taking any action based on these principles to ensure their applicability in a given situation.

©2011 Godfrey & Kahn, S.C.

United States v. Lauren Stevens: A Defense Victory And An Opportunity For In-House Counsel To Reflect

On May 10, 2011, a Maryland federal district court judge did something that rarely happens in federal criminal cases: he granted a defense motion for acquittal at the conclusion of the prosecution's case in chief. The defendant on trial was Lauren Stevens, an in-house lawyer at GlaxoSmithKline ("GSK"), accused of concealing information, falsifying records, and making false statements to the FDA while representing GSK in responding to an FDA inquiry regarding alleged off-label marketing of the anti-depressant drug Wellbutrin.

The charging and disposition of this case are significant to both in-house corporate and white collar defense lawyers alike. Notably, the in-house lawyer was not accused of participating in any of the underlying wrongdoing—the alleged off-label marketing—but rather, she was accused with obstructing an FDA investigation by concealing and falsifying records, and making false statements to the FDA. In contrast to many obstruction cases, Stevens' alleged conduct arose in the context of advising GSK in connection with a voluntary response to an informal FDA letter inquiry—not any compulsory process such as an administrative summons or grand jury subpoena. Further, the prosecution evidence at trial included communications between Stevens and outside counsel retained to assist her in responding to the FDA inquiry that the government obtained in a separate proceeding in the District of Massachusetts pursuant to the crime-fraud exception.

Generally, the indictment alleged that Stevens concealed and/or falsified evidence by failing to reveal information regarding gifts and entertainment given to physicians who attended promotional events sponsored by GSK when she knew, and GSK records revealed, that attendees at certain events received gifts and entertainment. The indictment also alleged that Stevens falsely asserted in correspondence to the FDA that GSK did not promote Wellbutrin for off-label purposes when she knew that, during promotional presentations, certain doctors asserted that Wellbutrin was appropriate for off-label uses such as weight loss. Based on these allegations, the government charged Stevens with one count of obstructing an official proceeding in violation of 18 U.S.C. § 1512(c)(2), one count of falsification and concealing of documents with intent to obstruct an FDA investigation in violation of 18 U.S.C. § 1519, and four counts of making false statements to the FDA in violation of 18 U.S.C. § 1001. Remarkably, all of this conduct arose in the context of GSK's voluntary response to an informal letter inquiry from the FDA.

Although it is tempting to view the judge's decision to acquit Ms. Stevens as a victory for both in-house and outside counsel who represent corporations in government investigations, the government's decision to charge the case in the first place should serve as a sobering warning and learning opportunity as to the risks government investigations present, especially for in-house counsel.

On a positive note, the Court determined that Stevens' actions were protected under a safe harbor provision set forth in 18 U.S.C. § 1515(c), which makes it clear that the obstruction of justice statute does not apply to "lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding." The Court found that Stevens' letters to the FDA were prepared in the context of her bona fide representation of a client, and in good faith reliance on advice of outside counsel. As a result, it held that the safe harbor served as an absolute bar to conviction.

As significantly, the Court strongly supported the importance of preserving the sanctity of the attorney-client privilege. The evidence the government presented included numerous privileged documents GSK was ordered to produce under the crime-fraud exception. The judge opined that "access should not have been granted to the documents because the crime

GODFREY & KAHN S.C.
ATTORNEYS AT LAW

fraud exception did not apply." He determined that it was clear that GSK did not approach Stevens and ask her to assist it in committing a crime or fraud. Rather, it came to her for assistance in responding to a letter inquiry from the FDA.

The court believed the evidence established that Stevens obtained advice from numerous lawyers, including outside counsel, and made sufficient disclosure to those lawyers to elicit informed legal advice. The judge concluded that Stevens conducted a "studied, thoughtful analysis of an extremely broad request from the Food and Drug Administration and an enormous effort to assemble information and respond on behalf of a client." After analyzing the privileged material, he agreed with defense arguments that her communications to the FDA were the product of consensus reached with outside counsel regarding what constituted adequate and appropriate disclosure to the FDA in light of its specific requests. In this regard, the court found that the record demonstrated that disclosures were sufficient to prompt additional inquiry by the FDA, and that Stevens initiated communications to schedule follow-up meetings to which the FDA failed to respond. According to defense submissions, privileged documents included talking point memos, prepared with the assistance of outside counsel, that supported the proposition that Stevens intended to disclose much, if not all, of the allegedly concealed information at anticipated meetings with the FDA, which unfortunately never occurred. Accordingly, the Court held that Stevens' disclosures to the FDA were made in good faith.

Despite the favorable outcome, the case provides a stark illustration of the risks associated with representing a client in a government investigation. The mere fact that a lawyer is preparing a voluntary response to an informal inquiry does not relieve the lawyer of the obligation to make complete and accurate disclosures once he or she advises the client to cooperate with an investigation. Lawyers must exercise extreme caution when initiating elective or compulsory responses to the government, particularly when responding to an inquiry or subpoena that is in any way vague, ambiguous or overly broad. Counsel must discipline themselves to draw clear distinctions between factual representations, and advocacy. If communication in response to any government inquiry, formal or informal, is anything other than a complete response to such inquiry, a lawyer should say so, assert appropriate objections, or otherwise articulate why information may have been withheld. Similarly, counsel must diligently take appropriate measures to clarify the scope of government requests for information in order to identify potential disputes, avoid misunderstandings and develop strategies that may resolve any ambiguity. Indeed, lawyers can never help a client commit or cover up a crime or fraud. As the judge made clear in the Stevens case: "[L]awyers do not get a free pass."

Finally, the case illustrates the need to vigorously maintain control and protection over attorney-client privileged communications. While in this case the release of such information was compelled, the use of the privileged materials at trial illustrates the importance of vigorously protecting attorney-client privileged material in parallel civil and criminal proceedings. As evidenced here, the disclosure of privileged material in one proceeding allows it to be used against the protected party in another. In this case, the information was used by the prosecution against a defendant—the in-house lawyer. In other circumstances, however, the release of privileged information to the government could lead to civil plaintiffs using such information in litigation against the corporation seeking damages.

Conclusion

In-house counsel should reflect on the events leading up to the indictment of this case, rather than simply taking solace in the outcome. Often, in-house counsel are generalists who are not regularly called upon to fashion responses to government investigations. At times, in-house counsel may feel pressure from their constituents—the business people—to expeditiously (or hastily) take measures to get the government "off the company's back." In these situations, outside counsel experienced in managing government investigations, and advocating on behalf of corporate clients, can provide in-house counsel objective advice necessary to successfully and safely navigate the storm by appropriately balancing the need for candor and advocacy in a manner that protects the corporation's interest and the integrity and reputation of in-house counsel.

White Collar Defense and Investigations Team Members

Appleton office:
Daniel Flaherty
(dflaherty@gklaw.com)

Madison office:
Frank Tuerkheimer
(ftuerkheimer@gklaw.com)
Andrew Turner
(aturner@gklaw.com)
Eric Wilson
(ewilson@gklaw.com)

Milwaukee office:
Daniel Blinka
(dblinka@gklaw.com)
Sean Bosack
(sbosack@gklaw.com)
Nelson Phillips III
(nphillips@gklaw.com)