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Criminal Action Against In-House Lawyer Underscores Risks in Dealing With Government Investigations

Lawyers who deal with government investigators and regulators should take note of a recent federal criminal action charging a former in-house lawyer at GlaxoSmithKline for statements she made while representing the company in a government investigation.

Lauren Stevens, a former Associate General Counsel, was indicted earlier this month in the District of Maryland in connection with alleged false statements to Food and Drug Administration ("FDA") investigators.

The case is provoking widespread concern among lawyers because it involves charges for conduct by a company lawyer in response to an investigation, which often is viewed as advocacy in an adversary system. The U.S. Attorney contends that certain statements and actions by Ms. Stevens crossed the line between advocacy and factual misrepresentation.

The indictment asserts counts against Ms. Stevens for obstruction of an official government proceeding, falsification and concealment of documents to influence a government investigation, and making false statements to the FDA.

The FDA in 2002-03 was investigating whether Glaxo was promoting a drug for unapproved use in violation of the Federal Food, Drug, and Cosmetic Act. The drug was Wellbutrin, approved for use as an anti-depressant; at issue in the FDA probe was whether Glaxo was promoting it for "off-label" use as a weight-loss drug or other unapproved purposes. In response to an FDA request for voluntary production, the indictment charges, Ms. Stevens, on behalf of Glaxo, agreed to search for and provide the FDA with documents presented at Glaxo promotional programs that would reflect whether the company was in fact promoting the drug for unapproved use.

Key facts alleged against Ms. Stevens include:

- She gathered documents and information reflecting that Glaxo's drug was indeed marketed and promoted for unapproved uses, and that Glaxo had compensated doctors who promoted the drug for such uses, but did not provide them to the FDA.
- She collected information from two unnamed doctors revealing that they had repeatedly promoted the drug for unapproved uses.
- She asked "other lawyers" (the indictment does not make clear whether this refers to other in-house or to outside counsel) representing Glaxo to prepare a memorandum summarizing the "pros and cons" of producing the harmful documents to the government. It lists "pros" such as "responds to FDA's request 5(a) for copies of all materials presented by individuals ... relating to" the drug; among the "cons" were "provides incriminating evidence about potential off-label promotion" of the drug "that may be used against" Glaxo. The FDA apparently obtained the memorandum from someone other than Ms. Stevens.
- Rather than producing the documents, Ms. Stevens wrote to the FDA saying that Glaxo had completed its document production. In her letter, she affirmatively stated that the company's "promotional material and activities ... are consistent with the approved Prescribing Information and the supporting clinical data." She further represented that "all of the documentation and materials we have reviewed and provided to you during the course of this inquiry support this conclusion."

In a press release issued by the Department of Justice, Assistant Attorney General Tony West stated, "Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations. Criminal charges are appropriate when false statements such as those alleged here are made to the FDA." Carmen Ortiz, the U.S. Attorney for the District of Massachusetts added, "There is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth."

The investigation was led by the Boston U.S. Attorney's Office, but filed in Maryland, where the FDA is located. Glaxo's name was not mentioned in the indictment, but published reports identified Ms. Stevens as a former Glaxo attorney and Glaxo as the company being investigated by the FDA for promoting "off-label" uses of Wellbutrin.

It remains to be seen whether the government will be able to support its allegations against Ms. Stevens and prevail in the criminal action against her. The facts may not turn out to be as the indictment alleges, and the jury could take a different view of the evidence. Further, the Stevens case is a relatively unusual one: prosecutors do not regularly bring cases against lawyers for statements they have made in an investigation.

Nevertheless, both in-house and outside counsel who deal with government investigators should take heed of this case. Since Enron and the passage of the Sarbanes-Oxley Act, prosecutors and regulators from agencies like the SEC have focused greater attention on lawyers and other "gatekeepers" and brought criminal and civil enforcement actions against them. The mere fact that a lawyer is speaking on behalf of a client does not immunize a lawyer from prosecution. If a lawyer's conduct is such that a prosecutor believes the lawyer was intentionally making false factual statements, as, for example, about the findings

of a document review, the lawyer's conduct could be portrayed as obstruction, or the making of false statements to government officials, which are crimes.

For questions or further information, please speak to your Bryan Cave contact, a member of our White Collar Defense and Investigations or Securities Litigation and Enforcement groups, or the author of this client alert:

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