Indictment of Former GlaxoSmithKline
In-House Attorney Highlights Risks and Provides Lessons for Handling Document Requests in Government Investigations

by Jessie K. Liu and Iris E. Bennett

A former in-house counsel at pharmaceutical company GlaxoSmithKline (“GSK”), Lauren Stevens, was indicted earlier this month for obstruction of a proceeding, false statements, and falsifying or concealing documents for her role in responding to a document request from the Food and Drug Administration (“FDA”).

According to the six-count indictment, in 2002, the FDA was investigating allegations that GSK had promoted the prescription antidepressant Wellbutrin for unapproved uses, such as to treat obesity. In the course of that investigation, the FDA sent a letter to GSK seeking documents related to the company’s promotion of Wellbutrin, as well as information regarding compensation GSK provided to promotional speakers. In a call with FDA representatives, Stevens agreed on behalf of GSK to collect and provide the requested materials. Stevens then led the team of lawyers and paralegals responding to the document request.

To prepare GSK’s response to the FDA:

• Stevens asked 550 of the approximately 2700 speakers who had given promotional talks about Wellbutrin on behalf of GSK in the relevant time period to send her their presentation materials. She received materials from 40 of the 550 speakers. Stevens determined that the materials used by 28 of the speakers contained references to unapproved uses of Wellbutrin. Stevens asked her legal team to prepare a memorandum for her identifying the “pros” and “cons” of providing these materials to the FDA. The memorandum identified “cons” that included the facts that the materials appeared to demonstrate promotion of off-label uses and that they contained incriminating evidence about such promotion that could be used against the company in the FDA’s investigation, or a future investigation.

• Stevens collected and reviewed presentation materials from two physicians who had spoken at GSK-sponsored events hundreds of times. Both physicians repeatedly promoted Wellbutrin as a weight-loss drug.

• Stevens obtained and reviewed a spreadsheet showing that attendees at Wellbutrin promotional events were not paid, but that they sometimes did receive gifts and entertainment.
The indictment alleges that:

- Stevens chose not to produce the materials used by 28 speakers that contained references to unapproved uses of Wellbutrin.
- Stevens falsely informed the FDA that GSK’s document production was complete, even though she had not provided promotional materials containing references to unapproved uses of Wellbutrin.
- Stevens wrote to the FDA falsely stating that GSK had not developed, devised, established, or maintained any program or activity to promote Wellbutrin as a weight-loss drug, even though she knew that numerous speakers, including two doctors who had spoken on GSK’s behalf hundreds of times, had promoted Wellbutrin for the treatment of obesity. Later, after she learned that a whistleblower had sent the FDA some GSK promotional materials referencing unapproved uses of Wellbutrin, she falsely told the agency that these materials represented only “isolated deficiencies.”
- Stevens falsely stated in a letter to the FDA that “Attendees [at promotional events] were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases,” even though she knew that GSK had provided gifts and entertainment to the attendees.

Commenting on the case, the U.S. Attorney prosecuting Stevens stated: “There is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth.” The Assistant Attorney General in charge of the Civil Division, which is also prosecuting the case, said: “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.”

Stevens’ attorney issued a statement saying that “[e]verything she did in this case was consistent with ethical lawyering and the advice provided her by a nationally prominent law firm retained by her employer specifically because of its experience in working with F.D.A.”

The case is notable for a number of reasons:

- It shows that attorneys must be extremely careful that all factual statements made to government agents are complete and accurate. Likewise, document collections and productions must be thorough, and must not be represented to be complete if they are not. Accuracy in such representations is required even if a subpoena is not at issue, such as in this case, where the company decided to respond voluntarily to a letter from the agency requesting documents.
- It shows that attorneys must be extremely cautious about the content even of privileged documents. Notably, the Stevens indictment quotes a memorandum that Stevens asked her legal team to prepare for her – an arguably privileged document.
- It shows that the government is serious about holding individuals accountable for a corporation’s conduct, even where the individual in question was not involved in the underlying activity under investigation.
- It shows that a regulatory inquiry can easily become a criminal matter if not handled properly. In addition, it demonstrates that the civil and criminal components of the Justice Department will work together to pursue such cases. The Stevens case is unusual in that both civil lawyers and criminal prosecutors signed the indictment.

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