

White Collar and Health Care Enforcement Defense Alert: In-House Counsel Indicted in Responding to Government Inquiry

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Having investigated and prosecuted, sometimes unsuccessfully, pharmaceutical and biotech companies and their executives for years, the government this week has turned its might on a pharmaceutical company's associate general counsel. Lauren Stevens, a former in-house attorney for GlaxoSmithKline, was charged with one count of obstructing an official proceeding, one count of concealing and falsifying documents to influence a federal agency, and four counts of making false statements to the Food and Drug Administration (FDA), for arguably doing her job. Her indictment spotlights the importance of being extremely cautious when responding to governmental inquiries and investigations and the need for "gatekeepers"—those deemed to be responsible for ensuring that a company acts legally—to be especially careful. Every statement to the government must now be evaluated with this in mind.

According to [the indictment](#), Stevens coordinated the company's response to an FDA investigation into whether the company had engaged in or encouraged off-label promotion of its anti-depressant drug, Wellbutrin. In the course of the company's internal investigation, Stevens allegedly obtained materials used by speakers hired by the company. Those materials allegedly indicated that the speakers had engaged in off-label promotion of the drug. Despite having previously told the FDA that this kind of material would be turned over to the FDA, Stevens allegedly decided that the company did not need to produce the documents. She then sent a cover letter representing that she had turned over everything she had agreed to turn over. Stevens also allegedly represented to the FDA that the company had not engaged in off-label promotion, despite allegedly being aware that it had. If convicted, she now faces a maximum penalty of 20 years in prison for each obstruction count and five years for each of the false statement counts.

Counsel representing companies under investigation must determine which documents need to be produced in response to a subpoena. They owe a duty to their clients to produce only those materials properly called for by the subpoena. They also have an obligation to zealously advocate their client's position. The Stevens indictment reminds us that in these situations, counsel must be prepared to justify their statements and decisions based on what they know, what they should have known, and what they have agreed upon. Aggressive prosecution of individual "gatekeeper" conduct requires gatekeepers to take extra care when dealing with regulators, including seeking opinions of independent counsel where possible and appropriate.

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