

Indicted—Not Once, But Twice! Former GlaxoSmithKline In-House Counsel, Lauren Stevens, Tells Her Harrowing Story And Hard Lessons Learned From Being Indicted

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Imagine, one of the worst things that could happen to any person, especially an attorney—being indicted. This not only happened to former GlaxoSmithKline (“GSK”) Vice President and Associate General Counsel, Lauren Stevens (“Stevens”) once—but twice! On November 8, 2010, a federal grand jury in the District of Maryland returned an indictment charging Stevens with one count of obstructing an official proceeding in violation of 18 U.S.C. §1512, one count of falsification and concealment of documents in violation of 18 U.S.C. §1519, and four counts of making false statements in violation of 15 U.S.C. §1001. On March 23, 2011, the District Court dismissed the indictment without prejudice due to erroneous and prejudicial legal advice that the prosecutors gave to the grand jury. However, on April 13, 2011, Stevens was indicted again, based on the same charges in the earlier indictment. For more than 18 months, Stevens lived this harrowing ordeal, and eventually was exonerated of any wrong doing. Stevens will discuss the events leading up to the indictment, the grueling court proceedings, and the lessons she learned at the National Association of Women Lawyers’ Ninth Annual General Counsel Institute on November 8, 2013 at the Intercontinental Hotel in New York City.

The indictments against Stevens arose out of a letter from the Food and Drug Administration (“FDA”) to GSK stating that it had information that GSK possibly promoted the use of Wellbutrin (a drug approved by the FDA to treat depression) for an unapproved use (namely, weight loss). The FDA requested that GSK *voluntarily* provide numerous materials and information related to the promotion of Wellbutrin.

GSK assembled a team, led by Stevens, which included in-house attorneys, a former FDA reviewer, and employees from GSK’s marketing, compliance, regulatory affairs and medical divisions, to respond to the FDA’s request. GSK also retained an outside law firm to conduct an internal review and advise GSK how to respond to the inquiry. Ultimately, GSK submitted six substantive letters, all signed by Stevens, in which she denied that GSK promoted Wellbutrin for an unapproved use and/or paid doctors to give promotional talks that included information on the unapproved use. On December 17, 2010, the government filed a motion to bar Stevens from relying on the defense of advice of counsel on the basis that it was not a defense to a charge of violating 18 U.S.C. §1519 because, the government argued, the statute is not a specific intent crime. That same day, Stevens filed a motion to disclose the government’s presentation to the Grand Jury relating to the advice of

counsel defense. She also filed two motions to dismiss Count II of the indictment. In the first motion, Stevens sought dismissal for unconstitutional multiplicity and for failure to state an offense, arguing that Counts I and II violated her due process rights because they sought to impose multiple punishments for the same offense. She also argued that the government's case was legally flawed because the government did not allege that she altered or falsified any pre-existing documents. In her second motion, Stevens sought dismissal of Count II on the basis that the charges were unconstitutionally vague.

On February 25, 2011, Stevens filed her opposition to the motion to exclude, arguing that where a defendant relies in good faith on the advice of counsel, she lacks the intent necessary to be found guilty of making false statements and obstructing justice, which required proof that she "knowingly" submitted false information. She also argued that she met the prerequisites for asserting the defense because outside counsel was aware of all material facts as evidenced by over 350 drafts of the six response letters to the FDA and 1,300 pages of notes regarding the matter.

On March 23, 2011, the Court denied the government's motion to prohibit Stevens from asserting the advice of counsel defense. The Court then dismissed the indictment without prejudice due to erroneous and prejudicial legal advice the prosecutors gave to the grand jury.

On April 13, 2011, a federal grand jury re-indicted Stevens. The trial commenced thirteen days later, and proceeded through May 6, 2011, at which time the government rested its case. Stevens filed a Rule 29 Motion for Acquittal on the basis that the government failed to present evidence sufficient to prove beyond a reasonable doubt any of the six counts. On May 10, 2011, the Court granted Stevens' Motion and dismissed the indictment. The Court determined that the government was given access to attorney-client privileged communications, which formed the basis of the government's case, as the result of an erroneous decision by a Massachusetts magistrate judge that the communications were evidence of a scheme to perpetrate a crime of fraud. However, the documents revealed a "studied, thoughtful analysis of an extremely broad request from the [FDA] and an enormous effort to assemble information and respond on behalf of the client." Although GSK's responses may not have satisfied the FDA, they were sent to the FDA in the course of Stevens' bona fide representation of a client and in good faith reliance on both external and internal lawyers for GSK. The Court concluded: "the defendant sought and obtained the advice of counsel of numerous lawyers. She made full disclosure to them. Every decision that she made and every letter she wrote was done by consensus." Further, although some statements were not literally true, they were made in good faith which would negate the requisite element of intent required for the charged crimes.

Stevens learned many lessons from this ordeal including: (1) when hiring outside legal counsel, make sure they know all of the facts; (2) make sure other parties know you have hired outside counsel; (3) take clear, accurate notes, knowing they could end up in Court; and (4) be careful in correspondence with adverse parties.

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