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Five Lessons Learned (the Hard Way?) for In House Counsel

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You may have wondered what became of the indicted in house counsel from GlaxoSmithKline (GSK) in *United States v. Stevens*, No. 10-CR-0694 (D. Md. Mar. 23, 2011). The case was enough to make most in house counsel sit up and take notice. The good news—Laura Stevens, Vice President and Associate General Counsel of GSK, was cleared of all charges. The bad news—this may not be the last case, if the government has its way. With attorney-client privilege on the minds of in house counsel, Stevens also demonstrates the importance of the advice of counsel defense. Below is a summary of the facts that may seem all too familiar to those in house counsel involved in government investigations, as well as five lessons we can all learn from *Stevens*.

The Facts

In *Stevens*, the United States Food and Drug Administration (FDA) opened an investigation to determine whether GSK had promoted its Wellbutrin drug for weight loss, a use not approved by the FDA. As part of its run-of-the-mill investigative inquiry, the FDA asked GSK to submit documents and other materials related to GSK's promotional programs of Wellbutrin. Laura Stevens, GSK's then Vice President and Associate General Counsel, served as lead throughout the investigation. Stevens also retained the law firm King & Spalding to assist with the investigation. GSK submitted responsive documents and six formal letters in reply to the government's inquiries. Stevens signed the documents on behalf of GSK. She was later indicted for this very act.

The Attorney General's office indicted Stevens and charged her with obstruction of justice, falsification and concealment of documents, and making a false statement. The federal government alleged that Stevens withheld relevant documents from the FDA, the most important of which were documents showing that GSK promoted off-label uses of Wellbutrin. Additionally, the government alleged that Stevens, as

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signatory of the letters, made materially false statements by not including what the government saw as all the relevant documents.

Stevens' primary defense to the charges was that she relied in good faith on the advice of counsel in responding to the FDA's investigation, and that such reliance negated the requisite intent to obstruct the FDA's investigation. Good faith reliance on the advice of counsel, when proven by the defendant, negates the element of wrongful intent that is required for a conviction. Relying on the advice of counsel defense, Stevens moved for judgment of acquittal at the conclusion of the prosecution's case and the judge agreed. Below find five lessons to take from Stevens when faced with a government investigation in the hopes of avoiding similar prosecution.

The Lessons

▪ Lesson 1: Know When to Engage Outside Counsel

We all know that when a matter arises that exceeds in house counsel's expertise, we should engage outside counsel with the requisite skill and expertise to provide advice and direct the investigation. Importantly, retaining outside counsel solidifies the attorney-client privilege. As Stevens makes clear, the advice of counsel defense is yet another reason to retain outside counsel. In fact, following the logic of the judge's reasoning in Stevens may keep an in house counsel from facing prosecution in the first place. In house counsel should make clear to government officials from the outset that they will be relying, in good faith, on the advice of outside counsel throughout the investigation, since it appears that their own guidance as in house counsel may not be enough in the eyes of government investigators.

▪ Lesson 2: Engage Counsel Early On

When served with a formal or informal government investigatory demand, engage counsel and specifically outside counsel early on in the investigation to take advantage of the attorney-client privilege and the advice of counsel defense from the get go. Indeed, in house counsel should take these steps to alleviate the risk of government charges upon receiving an investigation inquiry. The following passage from Stevens is instructive:

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The responses that were given by the defendant [in response to the FDA's inquiries] in this case may not have been perfect; they may not have satisfied the FDA. They were, however, sent to the FDA in the course of her bona fide legal representation of a client and in good faith reliance of both external and internal lawyers for GSK.

In house counsel's good faith reliance on outside counsel is an element of the advice of counsel defense. To ensure that such reliance is in good faith, in house counsel should engage outside counsel upon receipt of a government investigation demand rather than wait until later when the investigation is already underway.

- **Lesson 3: Review the Engagement Letter Carefully**

At the outset, the scope of representation by outside counsel should be well defined in a detailed engagement letter. To that end, in house counsel should ensure that the engagement letter with outside counsel defines the scope of the bona fide representation. Make sure to state explicitly in the letter the extent to which in house counsel will rely on the advice of outside counsel. For example, the letter should clearly state whether outside counsel will submit documents to the government on the client's behalf.

- **Lesson 4: Create a Paper Trail**

Create a paper trail that documents the investigation process followed by in house counsel at the advice of outside counsel. Documentation alleviates the risk of an investigation going awry. In *Stevens*, the judge specifically relied on favorable evidence found in house counsel's correspondence with outside counsel. The documents showed that outside counsel was intimately involved with GSK's document production that triggered Steven's indictment. With respect to the advice of counsel defense, Judge Titus found probative the fact that

[Stevens] sought and obtained the advice and counsel of numerous lawyers. She made full disclosure to them. Every decision she made and every letter she wrote was done by a consensus.

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For example, the judge pointed to letters and emails between in house counsel and outside counsel that showed that in house counsel was diligently relying on outside counsel's advice. Taking Judge Titus' reasoning at face value, in house counsel should heed his advice and be confident in making full disclosures to outside counsel as a matter of good public policy. Doing so will help to ensure that the free flow of information from in house to outside counsel is well documented. The court did not go as far as to address the free flow of information when outside counsel is not engaged.

- **Lesson 5: GCs - Educate Your In House Counsel**

Although we all know the importance of the attorney-client privilege, in house counsel may view their role in an investigation differently than government investigators. Indeed, the privilege is perhaps the single most important doctrine for in house lawyers when faced with a government investigation. The advice of counsel defense, on the other hand, is likely not at the forefront of their minds. To that end, and in light of Stevens, the advice of counsel defense is worthy of a refresher for in house counsel. Taking precautions on the front end and educating your in house attorney staff can protect against criminal allegations.

Could It Happen Again?

In some ways, we all knew it was coming. Over the years, in house counsel felt increased pressure to turn over privileged documents during a government investigation. Add to this pressure the uncertainty related to the role of in house counsel in an investigation compared to their outside counsel counterparts. For those interested, take a look at Steven's [indictment \[PDF\]](#) and the [trial court opinion \[PDF\]](#). Read for yourself and decide if a similar indictment of a health care in house counsel may come in the future.