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5 Tips For In-House Counsel Handling Gov't Inquiries

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Law360, New York (August 30, 2013, 12:07 PM ET) -- When Lauren Stevens, former vice president and associate general counsel of GlaxoSmithKline PLC, was indicted in 2010 on charges of misleading the U.S. Food and Drug Administration about the pharmaceutical giant's off-label promotion of its anti-depression drug Wellbutrin, it sent chills down the spine of in-house lawyers. Stevens was the in-house lawyer responsible for responding to a letter inquiry from the FDA to provide promotional materials for Wellbutrin.

The government, determining that she had been less than forthright, charged her with obstruction of justice, making false statements, and concealment of documents. Many lawyers believed that the prosecution was misguided and that the U.S. Department of Justice was, as Stevens herself characterized it, "criminalizing the practice of law." Those lawyers were vindicated when U.S. District Judge Roger Titus took the unusual step of dismissing the indictment against Stevens even before the defense had presented its case, admonishing the Department of Justice that it "should never have been prosecuted."

How much solace a lawyer can take from Judge Titus' dismissal is still very much an open question. At a recent forum hosted by the New England Chapter of the Association of Corporate Counsel and the law firm of Nutter McClennen & Fish LLP, Sara Bloom, an assistant United States attorney and the lead prosecutor in the Stevens case, stated that she continues to believe that the DOJ acted properly in bringing criminal charges against Stevens.

Bloom contended that Stevens' notes demonstrated that she knew she was lying to the government and understood that this was unlawful behavior. Given the opportunity to revisit the decision to charge Stevens, Bloom made it clear that she stands by her decision: Stevens was "not held responsible for giving advice … she was held responsible for making false statements, … knowingly making false statements to the government is a crime."

Given that Bloom continues to believe that Stevens' conduct was criminal and that she would make the same decision today, the recent ACC/Nutter forum revisited what about Stevens' actions offended the prosecutor, and with the benefit of hindsight and perspective, what lessons might be learned by in-

house counsel in order to avoid the government's crosshairs when responding to an inquiry or subpoena.

Below are five "best practices" that in-house counsel, and regulatory affairs people, should consider when interacting with and responding to inquiries from the government.

1) Evaluating the Nature of the Inquiry

Companies frequently receive formal and informal government inquiries and requests for information from the FDA, the U.S. Securities and Exchange Commission and other agencies. Care must be taken to figure out what an agency is looking for: Information about another company or about an individual employee? Information that goes to the operations of the company and how it conducts its business? If the inquiry goes to the core of the company's business itself, then in-house counsel need to be aware that this kind of inquiry has the potential of crossing from a regulatory request for information into a law enforcement action.

Figuring out what the government is really after and what it is investigating is often no small feat — even a grand jury subpoena may not inform the recipient of the nature of the investigation. In-house counsel need to recognize the difference between routine requests for information and those that have wider and more serious implications.

In the Stevens case, an FDA inquiry about the marketing and off-label promotion of GSK's drugs should have raised red flags. If the scope of the inquiry is not clear, in-house counsel should seek help from someone who has an expertise in the particular area and who has experience working with the government in order to figure out what the government is looking at and how best to proceed.

Frequently, in-house counsel's initial reaction to a government inquiry is that it is just a request for documents and therefore not a big deal. In-house counsel might figure that they can curry favor with the powers-that-be in the company by handling it themselves and thereby show their competence while at the same time sparing the litigation budget the cost of hiring outside counsel. Some in-house counsel view regulators as bureaucrats who are just pushing paper and who can be easily mollified or steamrolled. In-house counsel underestimate the government regulator at their peril.

Even though in-house counsel work in the company, he or she may not be in a position to know the full scope of the conduct at issue. Stevens' initial promise to "obtain and provide to [the FDA] materials and documents presented at GSK-sponsored promotional programs" was overbroad given her limited knowledge of GSK promotional activities. Her subsequent failure to produce much of the promotional materials she promised and her willingness to make sweeping denials on behalf of the company, according to Bloom, contributed to the decision to prosecute Stevens. Don't overpromise to the government. Thus, it is crucial to figure out what the government is looking at, how serious it might be, and what is the scope of potential impact.

2) Consulting With/Hiring Outside Counsel

How can in-house counsel get their arms around the issues? Sometimes it is absolutely appropriate for in-house counsel to handle the response themselves. However, even at this early stage, in-house counsel needs to give serious thought to consulting with outside counsel. Consulting with outside counsel has significant upsides, especially when that person has a relationship with the government agency making the inquiry or request:

- Counsel who has experience with the government agency can provide insight into what the government is really looking at and the potential implications of the inquiry;

- Such counsel can more easily negotiate with the agency or prosecutor to narrow the scope of the subpoena and the timing of production. Often, a lawyer familiar with an agency or prosecutor is in a better position to get the agency to discuss what is driving the inquiry;

- Outside counsel interfacing with the agency creates a buffer for in-house counsel and shows the company is relying on advice of outside counsel; bringing in outside counsel and informing government regulators of your reliance on outside counsel strengthen the advice of counsel defense in the event of government prosecution — this defense proved critical in Judge Titus' decision to dismiss the case against Stevens; and

- Outside counsel can also advise on the appropriateness of the company conducting an internal investigation to learn more about what the government is interested in.

In-house counsel may be reluctant to hire outside counsel for fear of sending the wrong signal to government regulators. But this possible downside is mitigated by the fact that regulators are accustomed to dealing with outside counsel and when an inquiry has enforcement ramifications, counsel should err on the side of consulting with outside counsel.

What made Stevens a target was that she was seen as the mouthpiece for the company. As the Stevens case made clear, consulting with outside counsel may not insulate in-house counsel from liability, but having outside counsel serve as the point of contact may afford some protection.

3) Need to be Candid

It sounds obvious — you should not say something to government personnel that you know to not be true. Bloom's No. 1 issue with Lauren Stevens was that she believed Stevens lied to the government. It is always the lie or the attempt to hide something that gets folks into trouble. It is still what sticks in Bloom's craw. As Bloom stated at the ACC panel, what she is still focused on is her belief that Stevens lied "deliberately to make the FDA go away."

Lots of otherwise law-abiding professionals make this mistake and end up being defendants in a criminal case. They figure that if they can offer an innocuous explanation to a situation or not produce problematic documents, the inquiry will just go away.[1] This is a really bad idea, because when the inquiry does not go away, the hole they've dug is already very deep. Resist this temptation.

4) Don't Play Games with Production of Documents.

Unless there is a claim of privilege, you need to produce all the documents that are responsive to the request or subpoena. Bloom believed that Stevens chose which documents to produce based on whether she believed them to be harmful or helpful. This did not sit well with the prosecutor. All responsive, nonprivileged documents need to be produced.

5) Document Everything

In-house counsel should create a paper trail of all interactions with the government, the conduct of any internal investigations, all steps taken to respond to a government inquiry, interactions with outside counsel and all records of advice from both internal and outside counsel. You want to make sure that you carefully document your communications with outside counsel — your advice of counsel defense will depend on such documentation.

But think about what you are putting in writing.

Ill-considered emails are the prosecutor's best friend — and as many times as this is said, people just do not hear it. As Stevens herself has remarked: "They got all the privilege notes from me and from the senior paralegals. ... Although you think what you're writing will never see the light of day, you should write as if you might need to defend it on the front page of the New York Times. ... I wouldn't put in writing any personal musings or statements that could be subject to interpretation." WSJ, Law Blog, Oct. 1, 2012.

This is sound advice that Stevens only recognized in the wake of the government's criminal prosecution of her because she anticipated that many of these documents were privileged and confidential. In an era when the government has made it a priority to aggressively pursue criminal actions against in-house counsel, it is probably wise to confine discussions to legal strategy. Having a written record of your understanding of the facts can put you in harm's way — as Bloom stated, factual statements are very different from legal arguments and zealous advocacy.

Two years after the government prosecution was abruptly terminated, prosecutors in the Lauren Stevens case continue to believe that her actions went beyond zealously representing her client and she got away with lying to the government about GSK's program of off-label promotion.

The Stevens case illustrates the dangers to in-house counsel when responding to inquiries by government agencies, especially during this period when the DOJ is widening its net by increasingly targeting corporate executives or lawyers who it sees as contributing to fraud.

While Stevens ultimately was acquitted, had she in fact been more cautious in her approach to the FDA's initial inquiry, she may have avoided prosecution with all its attendant professional and personal costs.

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[1] Ms. Bloom stated: "she made sweeping and broad factual statements deliberately to make the FDA go away. And she signed those letters because she wanted the FDA to trust her and because she worked with them, she knew the people, she chatted with them and so that was a deliberate obstruction and it was her intent … I think the evidence shows to make the FDA go away by deceiving them about what she knew to be true. I don't see how that can't be a crime."