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The Rise of Government Action Against the Individual

By Christine C. Levin and Evan W. Davis – October 11, 2012

A year has passed since Judge Roger Titus in the U.S. District Court for the District of Maryland granted a judgment of acquittal for Lauren Stevens, the GlaxoSmithKline (GSK) lawyer accused of obstruction of justice for her handling of the response to a U.S. Food and Drug Administration (FDA) letter request. Now is an opportune time to step back and consider whether the Stevens prosecution was an aberration or whether it fits into a broader pattern of the federal government's increased focus on individual responsibility as a means of deterring wrongdoing. Below we discuss other recent enforcement actions by the government against individuals, the lessons to be learned, and suggestions for how to avoid having your name unwillingly appear in print.

Recent Prosecutions and Enforcement Actions

The Criminal Prosecution of Lauren Stevens by the U.S. Department of Justice

In November 2010, the Department of Justice indicted Lauren Stevens, an in-house lawyer at GSK, on six counts of obstructing justice, concealment, and making false statements to the FDA. *See United States v. Stevens*, Crim. No. 10-694 (D. Md. Mar. 23, 2011). The government accused Ms. Stevens of failing to produce documents that she had previously agreed to produce, altering documents that she did produce, and making legal arguments premised on factual statements that she knew to be false. The case went to trial in the District of Maryland last year, and although the judge ultimately awarded Stevens a judgment of acquittal, this prosecution vividly demonstrates the federal government's increasing willingness to take criminal action against both corporations and individuals.

The case against Stevens went back nearly a decade. In 2002, as part of an investigation into whether GSK had promoted the drug Wellbutrin for off-label purposes, the FDA requested that the company produce all materials "presented or distributed at or in connection with any program, seminar, discussion, conference or other presentation" about Wellbutrin by a physician on behalf of GSK. Although the request was voluntary and not compulsory process, Stevens agreed that GSK would produce such documents and further agreed to make a good-faith effort to obtain copies from third-party physicians who had made presentations about the drug to other health care professionals. She solicited documents from 550 third parties and received responses from 40. Of these, Stevens sent follow-up correspondence to 28 physicians noting that their presentations inappropriately contained material promoting Wellbutrin for off-label uses.

In spite of Stevens's apparent awareness of these third-party actions, she made a series of representations to the FDA that were, in the eyes of federal prosecutors, criminally false and misleading. When producing documents for the FDA, Stevens withheld presentations received

from third parties—despite her promise to produce them—but told the FDA that GSK had "complete[d] [its] production of information and documents in response" to the FDA's request. She went on to tell the FDA that the company has not "established or maintained any program or activity to promote, either directly or indirectly, the use of [Wellbutrin] to achieve weight loss or treat obesity," further stating that "[a]ll of the documentation and materials we have reviewed and provided to you during the course of this inquiry support this conclusion."

Stevens consulted with outside counsel concerning this correspondence, but her own handwritten notes, which were found in a related proceeding to be subject to the crime-fraud exception to the attorney-client privilege, contained statements such as "find a way not to provide." Similarly, outside counsel's opinion noted that the withheld presentations "provide incriminating evidence about potential off-label promotion of [Wellbutrin]," which is a statement at odds with Stevens's implication that GSK's documents reflected no wrongdoing.

Some months later, Stevens learned that a GSK employee had provided the FDA with copies of two third-party physicians' presentations that included references to Wellbutrin's off-label uses. She then produced these presentations for the FDA and continued to withhold other presentations, while characterizing any physicians' references to the drug's off-label uses as mere "isolated deficiencies."

The government charged that Stevens's letters to the FDA, in which she stated definitively that GSK had not "developed, devised, established or maintained any program or activity" that promoted off-label uses of Wellbutrin, were criminally false. Stevens made no mention of withholding any documents and made legal arguments that were, in the government's eyes, based on factual underpinning she knew to be false.

At the close of the prosecution's case, the district judge granted Stevens's motion for a judgment of acquittal. He noted that correspondence between Stevens and GSK's outside counsel showed that Stevens "sought and obtained the advice and counsel of numerous lawyers" and that while some of Stevens's statements to the FDA may not have been "literally true, it is clear that they were made in good faith which would negate the requisite element [of intent] required for all six of the crimes charged in this case."

The Office of Inspector General's Investigation of Howard Solomon
In April 2011, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services notified Howard Solomon, chief executive officer (CEO) of Forest Laboratories, that he may be personally excluded from participating in any federal health care program, meaning that Solomon would effectively be barred from continuing his employment in the health care field.

Solomon's potential exclusion was not premised on any alleged wrongdoing on his part, but on the part of others within the company. The year before, a Forest subsidiary pled guilty to obstructing justice and distributing unapproved and misbranded drugs. The OIG informed

Solomon that its permissive exclusion authority under section 1128(b)(15) of the Social Security Act allowed the agency to exclude "an officer or managing employee" of a sanctioned entity based solely on that individual's position of authority.

The OIG ultimately closed its case against Solomon without imposing any penalties, but it offered no explanation for its decision and at no point suggested that its theory was flawed or untenable. Given the office's October 2010 Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, which states that "[w]ith respect to officers and managing employees, the statute includes no knowledge element" and that "when there is evidence that an officer or a managing employee knew or *should have known* of the conduct, OIG will operate with a presumption in favor of exclusion" (emphasis added), there is little doubt that individuals risk exclusion under this provision even in the absence of any personal wrongdoing. There is also a strong likelihood that the OIG will notify others of their potential exclusions for similarly attenuated reasons.

The Securities and Exchange Commission's Proceeding Against Ted Urban
In 2009, the Securities and Exchange Commission (SEC) sought to sanction Ted Urban, the general counsel of a broker-dealer, for his inadequate supervision of a broker who had engaged in misconduct. Order Instituting Administrative Proceedings, *In re Urban*, No. 3-13655 (Oct. 19, 2009). Upon the company's initial determination of the employee's misconduct, Urban recommended the employee be terminated. He was overruled, however, and ultimately agreed that the employee could remain with the company if placed under special supervision—with someone else in management having direct supervisory responsibilities.

Finding that the employee continued to engage in wrongdoing, the SEC sought to sanction Urban based on his failure to adequately supervise the employee, stating that while Urban was not the employee's most direct supervisor, as general counsel he had the "requisite degree of control to affect the conduct of the employee." In September 2010, an administrative law judge ultimately disagreed with the SEC, finding that those who were most immediately supervising the employee were sufficiently experienced and that Urban reasonably believed that this special supervision was sufficient to prevent further wrongdoing. Initial Decision, *In re Urban*, No. 3013655 (Sept. 8, 2010).

On appeal, the agency's commissioners split 1–1, leaving intact the administrative law judge's ruling but providing little clarity on how it will enforce the notion of "supervisory liability" down the road. Order Dismissing Proceeding, *In re Urban*, No. 3-13655 (Jan. 26, 2012).

Lessons Learned
A Common Theme
At first glance, these enforcement actions seem to have little in common. The prosecution's theory against Lauren Stevens included individual wrongdoing, the OIG's targeting of Howard

Solomon did not focus on Solomon's actions, and the proceeding against Ted Urban can be viewed through a securities-specific lens. All three share a common theme, however. In each case, the individual in question could have objectively felt as though he or she was simply doing his or her job. In the government's eyes, simply doing one's job may not be good enough.

Whether one's job is to advocate on a company's behalf, ensure regulatory compliance, or oversee operations, all such employees have an individual responsibility to avoid personal wrongdoing and ensure that those for whom they bear ultimate responsibility also steer clear of illicit activities. Lewis Morris, chief counsel to the Inspector General of the U.S. Department of Health and Human Services, made the following statement in testimony before Congress in June 2010:

> Although there are challenges to building a criminal case against a high-level executive—there's a lot of plausible deniability built into these large companies—it's an area where we and our partners at the Department of Justice are focusing on, because we recognize that the way we are going to change corporate cultures is by focusing on individuals.

Press Release, Office of Congressman Pete Stark, "Ways and Means Hearing Focuses on Efforts to Combat Fraud, Waste, and Abuse in Medicare" (June 15, 2010).

In Stevens's case, a lawyer's primary responsibility is to advocate on behalf of the lawyer's clients. Indeed, there exists a safe harbor for counsel charged in obstruction of justice cases, which immunizes from such a charge "the providing of lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding." 18 U.S.C. § 1515(c). As the trial judge noted, this provision recognizes "the obligation that every lawyer has to zealously represent his or her client and place their position in the most favorable possible light." Stevens no doubt felt through her communications with the FDA that she was simply doing her job—zealously advocating on behalf of her client. As the court ultimately recognized, although her attempt to do so may have been flawed, it was unquestionably made in good faith, given Stevens's regular reliance on outside counsel.

Similarly, Solomon and Urban faced threats to their reputations and livelihoods for simply carrying on their day jobs. In Solomon's case, during his oversight of a large company—his tenure as CEO had lasted for over 30 years—the company's subsidiary had engaged in wrongdoing that was not connected to Solomon and, by all accounts, contrary to the atmosphere of compliance that Solomon had promoted. In Urban's case, he brought the broker's initial misconduct to light and asked that the broker be terminated. Only after his recommendation was denied did Urban agree that the broker could remain under the direct supervision of management, but under Urban's ultimate supervision as general counsel. As was the case with Solomon, at no point did the government allege that Urban himself had engaged in any wrongdoing.

Tips for Keeping Your Good Name
Having your name in the *New York Times* or *Wall Street Journal* is rarely an insignificant occurrence. While news items reflecting your professional accomplishments, editorials showcasing your brilliant insights, and even wedding announcements publicizing your marital bliss can all put a huge smile on your face, there is another side of the coin. Stories that call into question your personal or professional reputation can have a disastrous effect on your career, and as many have come to know, the Internet and its prolific search engines have a way of promulgating such stories quickly, broadly, and permanently.

The Stevens case in particular offers a number of teachable moments. One such takeaway is to *remember that you are dealing with the government and not a private adversary*. For any lawyer involved in responding to a government request, it is crucial that you be clear, frank, and transparent when producing documents and making communications related to these productions. When dealing with private litigants, motions to compel and requests for sanctions are typically the most extreme repercussions that an attorney may face when he or she gets "too cute" in construing document requests or uses language in a production letter that while technically true, may also be quite misleading. When the federal government is on the other side, however, obstruction of justice charges are, as Lauren Stevens found out, also a possibility. For this reason, it is important that when producing documents, a lawyer state exactly what is being produced and, in the event that it is something less than what was previously promised, what is *not* being produced. Similarly, to the extent that your "good faith" effort could conceivably be questioned, consider defining the scope of your undertaking—for example, to locate documents, interview third parties—in the letter accompanying your production.

Another important lesson that the Stevens case highlights is to *be careful what you put on paper*. Nothing is private anymore—even the attorney-client privilege may be pierced in certain circumstances, as it was in the Stevens matter. Although it was ironically Stevens's correspondence with GSK's outside counsel that helped lead to the court's judgment of acquittal, it is doubtful that the case against Stevens would have even been brought had her own handwritten notes— including talking points to discuss with outside counsel—not been created.

A related suggestion is to *recognize the important role that outside counsel can play*. In granting Stevens's motion for a judgment of acquittal, the trial judge emphasized the role that outside counsel played in consulting with Stevens, drafting and reviewing the correspondence that Stevens sent to the FDA and helping Stevens determine whether to produce documents obtained from third-party physicians. The judge noted that "the defendant sought and obtained the advice and counsel of numerous lawyers. She made full disclosure to them, and every decision that she made and every letter she wrote was done by a consensus." He concluded that Stevens had engaged in "a studied, thoughtful analysis of an extremely broad request from the Food and Drug Administration and an enormous effort to assemble information and respond on behalf of the client," and that any responses to the FDA were made "in the course of her bona fide legal representation of a client and in good faith reliance of both external and internal lawyers for

GlaxoSmithKline." In short, by engaging outside counsel, an in-house lawyer takes great strides in demonstrating his or her "good faith effort" toward compliance.

For those in upper management, *pay great attention to how your job responsibilities are defined*.Agreeing to have numerous employees under your supervision, even indirectly, can lead to the government holding you ultimately accountable for their actions. If you do carry this responsibility, make sure that you do *actively supervise* those for whom you are responsible or that you at least have a means of checking in with those who are doing the supervising. When wrongdoing occurs, the government will look to see what steps you took to prevent such an occurrence, and a well-documented list of supervisory activities can go a long way to convince the government that supervision, while not ultimately effective, was attempted.

Finally, regardless of your "official" job responsibilities, do your best to *establish and cultivate a culture of compliance*. The message of compliance must be strong and clear from the top down. Affirmative steps to monitor compliance and prevent wrongdoing play a similarly important role in persuading the government to target only the individual wrongdoer, and not those who were simply unfortunate enough to be listed above him or her on company organizational charts.

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