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PROFESSIONAL CONDUCT

Indictment Raises Questions About Proper Role of In-House Counsel

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Special to the Legal

On Nov. 9, a federal grand jury in Maryland handed up an indictment charging Lauren Stevens, a retired GlaxoSmithKline (GSK) attorney and vice president, with obstruction, concealment and false statements. The charges arose out of Stevens' representation of GSK in connection with a Food and Drug Administration investigation into the company's marketing and promotion of the prescription drug Wellbutrin. Without question the indictment, which includes one count of obstruction of an official proceeding, one count of falsification/concealment of documents, and four counts of false statements, has sent shockwaves through the ranks of in-house and outside counsel alike.

Stevens' counsel has issued a public statement proclaiming her innocence and her resolve to take the matter to trial if need be to obtain vindication. In the same statement, counsel also stated that Stevens' actions were fully consistent with "the advice provided her by a nationally prominent law firm retained by her employer specifically because of its experience in working with FDA."

Some of the commentary generated in response to the indictment has tilted heavily against the prosecution, depicting it as an attempt to intimidate those working in heavily regulated industries. Whatever the prosecution's motives or goals, the indictment raises serious questions about in-house counsel's proper roles and involvement with compliance issues and internal investigations. The indictment also signals a new era of aggressive pursuit of prosecutions against corporate officers and employees — including in-house counsel — that prosecutors suspect of improperly impeding or falsely responding to its investigative requests.

As for what precipitated this extraordinary prosecution, at this point we have only the Justice Department's side of the story as



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set forth in the indictment. According to the indictment, in October 2002 the FDA sent a letter to GSK notifying the company that the FDA had received information that GSK may have promoted the anti-depressant drug Wellbutrin for weight loss, an "off-label" use not approved by the FDA and therefore prohibited by "new drug" and "misbranding" provisions of the Food, Drug and Cosmetic Act. The FDA requested materials related to GSK's promotional programs for the drug, including "copies of all slides, videos, handouts, and other materials presented or distributed at any [company] program or activity" related to the drug. The indictment further alleges that Stevens sent a letter to the FDA on behalf of GSK voluntarily agreeing to make "a good-faith effort" to obtain and provide to the FDA copies of materials and documents presented at GSK-sponsored promotional programs between January 2001 and October 2002, "even if

not created by, or under the custody or control" of the company. And in a subsequent teleconference with representatives from the FDA, Stevens is alleged to have agreed to send a letter asking all of the health care professionals who gave promotional talks on behalf of the company concerning Wellbutrin during the specified time frame to provide GSK with copies of their presentation slides and other materials.

According to the indictment, Stevens sent letter requests to approximately 550 of the speakers GSK identified; the company received slides and other materials from approximately 40 of them. Stevens is alleged to have sent a follow-up letter to 28 of those speakers informing them that their slides and other materials contained "information about unapproved uses of [Wellbutrin]," and that any affirmative representation in a GSK-sponsored speaker program suggesting that a GSK drug was effective for treatment of a medical condition not yet approved by the FDA would be inconsistent with the FDA's requirements, GSK policy, and the speaker's contract with the company. The indictment further alleges that Stevens "gathered information" demonstrating that two health care professionals, each of whom spoke at several hundred promotional events sponsored by GSK in 2001 and 2002, "repeatedly" promoted Wellbutrin for unapproved uses including weight loss. The indictment alleges that Stevens "withheld documents she recognized as incriminating" and made false statements to the FDA with the goal of "curtailing further FDA investigation and avoiding or minimizing any FDA regulatory action" against the company.

Specifically, Stevens has been accused of improperly withholding the slides and other presentation materials gathered from 40 of the health care professionals who participated in GSK-sponsored promotional programs concerning Wellbutrin, while at the same time representing to the FDA in letter correspondence that the company's production in response to the agency's requests for documents and information was

complete. In addition, the indictment alleges that Stevens falsely represented to the FDA that “all of the documentation and materials we have reviewed and provided to [the FDA] during the course of this inquiry” supported the conclusion that GSK did not develop, devise, establish or maintain any program or activity to promote Wellbutrin to achieve weight loss or treat obesity.

In support of both accusations, the government points to a memorandum that Stevens allegedly had “other lawyers involved in the response to the FDA” prepare concerning the “pros and cons” of producing the speaker presentation slide sets and other materials. According to the government, the memorandum stated as “pros” that producing the presentation slides and other materials would respond to the FDA’s request for the materials and potentially garner credibility with the FDA, but stated as “cons” that the materials “provide[] information that appears to promote off-label uses of [Wellbutrin],” “potentially demonstrates [GSK’s] lack of control over physician speakers,” and “provides incriminating evidence about potential off-label promotion of [Wellbutrin] that may be used against [the company] in this or in a future investigation.” The indictment alleges that after receiving the memorandum, Stevens “determined not to produce any of the slide sets” and instead represented to the FDA that the company’s production was complete. And finally, in what we would characterize as “throw-in” allegations, the indictment accuses Stevens of making false statements to the FDA concerning Wellbutrin advisory boards and “special issue boards” and whether physicians were “paid, reimbursed or otherwise compensated” to attend Wellbutrin speaker programs.

In a press release issued by the DOJ’s Office of Public Affairs on the same day the indictment was filed, U.S. Attorney for the District of Massachusetts Carmen Ortiz stated “there is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth.” In the same press release, Tony West, an assistant attorney general for the Civil Division of the DOJ, stated that “where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations.”

The Stevens indictment highlights a number of issues for in-house and outside counsel to corporations and other entities subject to significant government regulation and investigation. We believe the indictment reflects a government policy to step up

prosecutions of individual employees, especially in the pharmaceutical arena. These individual prosecutions may be based on perceived obstructive conduct, as in this case, or on strict liability as defined by the “responsible corporate officer doctrine.” Pursuant to the doctrine, a responsible corporate officer may be held criminally liable for the wrongful acts or omissions of the corporation if he or she had the responsibility and ability to prevent such acts but failed to do so. (See *United States v. Park*, 421 U.S. 658 (1975).)

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Federal law enforcement officials’ heightened focus on individuals in this area should prompt corporate officers, in-house counsel and involved outside counsel to consider whether their compliance systems and infrastructure are sufficient in this environment. Robust corporate compliance at every level has never been more important as a risk management tool. While mistakes and issues may arise, concerted efforts to prevent them, report them, and correct them are critical to protect companies of every size. The existence and enforcement of compliance programs that perform these functions are also important factors in the government’s assessment of wrongdoing and culpability. (See U.S. Attorneys Manual, Title 9, Chapter 9-28.000, Principles of Federal Prosecution Of Business Organizations.) If you represent a company that is subject to government regulation, you should advise your client to update and evaluate its compliance plan.

The indictment also raises the thorny question of how responsibilities should be best divided among in-house counsel, outside counsel and compliance personnel involved in internal investigations and related communications and negotiations with government agencies. It seems clear that, at least partially, Stevens’ defense will be that her decisions and actions conformed with sound legal advice obtained from outside counsel. While there is no one-size-fits-all

approach, consideration of the roles, responsibilities, and limitations of the participants is necessary to avoid missteps and to advance the best interests of the corporation with the government.

The indictment places Stevens front and center in the company’s communications, negotiations, disclosures and productions to the FDA. In addition, quoted portions of her correspondence with the FDA appear to suggest that Stevens was juggling two roles: acting as the face of GSK’s cooperative efforts, and also acting as a zealous advocate on behalf of the company. In-house counsel trying to balance these two roles may find themselves facing a conflict and have difficulty determining how best to proceed. We note that the conduct alleged in the indictment occurred between seven and eight years ago and that based on our experience, there has since been an increase in the use of both compliance officers and outside counsel to manage these investigations and related communications with the government.

As the Stevens prosecution proceeds, it will undoubtedly yield many interesting ethical, practical and legal issues and provide opportunities for discussion in future columns. •