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U.S. v. Lauren Stevens Case Dismissed: What Now for In-House Attorneys?

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Federal prosecution of attorneys is a rare, but riveting, event for other attorneys. The criminal trial of former GlaxoSmithKline (GSK) in-house counsel, Lauren Stevens, is the most recent reminder that attorneys are not immune from federal investigation and charges.[1] Stevens was indicted for allegedly withholding documents and making numerous materially false

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[1] The last in-house counsel at a pharmaceutical company charged with a crime was the former general counsel of Purdue Frederick, who along with two other executives of the company, pled guilty to a misdemeanor violation of the Food, Drug and Cosmetic Act's misbranding provisions under the responsible corporate officer doctrine. *See* "District Court Upholds 12-Year Bans From Federal Programs for Drug Executives," BNA's Pharmaceutical Law & Industry Report (8 PLIR 1575, 12/17/10). In May, 2007, Howard Udell admitted to having a position of responsibility and failing to prevent, detect, and correct misbranding of Oxycontin, which was promoted beyond its FDA-approved label. *Id.* Udell did not admit to committing any illegal act himself or to any knowledge or awareness of the illegal acts of others in the company.

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statements in letter responses to a Food and Drug Administration inquiry. As a result, the government charged her with obstructing an official proceeding,[2] concealing documents in an FDA proceeding,[3] and four counts of false statements.[4] Stevens defended her responses to FDA, asserting that they were based on advice she received from a combined legal team of in-house and outside counsel. The Stevens prosecution was over May 10, after the U.S. District Court for the District of Maryland granted Stevens's motion for judgment of acquittal on all six counts. Still, attorneys who advise corporations for whom federal criminal misdemeanor and felony charges have become nearly commonplace must ask, ''Why did the government target this lawyer?'' and ''How do I advise my client and avoid risk of exposure to prosecutorial interest myself?''

Following a fleeting victory for Stevens in March when the district court dismissed her indictment without prejudice because the government incorrectly instructed the grand jury on the relevance of advice of counsel, the government re-indicted her on April 13. Trial commenced April 26, during which the government offered numerous documents and ''extensive testimony of both FDA and GSK officials,'' including Stevens's paralegal and a GSK vice president who was granted immunity. Stevens promptly filed a Rule 29 motion for judgment of acquittal at the end of the eight-day government case.

Giving context to the gravity of the district court's ruling, Judge Roger W. Titus reported that in his seven and one-half years as a jurist he had never granted such a motion. In making this his first, Judge Titus singled out the volumes of documents offered into evidence by the government, ''very significant portions'' of which ''were what would otherwise be privileged attorney-client documents.'' This evidence demonstrated the bona fides of Stevens's legal representation of GSK and that she acted in good faith reliance on both external and internal lawyers in responding to FDA's inquiry. As a result, Judge Titus concluded that the advice of counsel defense applied and negated ''the requisite element required for all six of the crimes charged in this case.''

Counsel in similar positions will breathe a collective sigh of relief. Yet, the story line of this case is a cautionary tale for lawyers who practice their craft inside a corporation or advise corporate counsel from outside an organization.

The Setting

Context is everything. Lauren Stevens's pharmaceutical manufacturing client and employer received an FDA inquiry in October of 2002 to evaluate whether GSK engaged in the promotion of Wellbutrin SR for weight loss or as a treatment for obesity. The drug was approved only for adult major depressive disorder. At the time of the inquiry, neither FDA nor the Department of Justice (DOJ) had aggressively pursued companies for misbranding pharmaceutical products.[5] Indeed, it is highly probable that DOJ was not involved with the FDA's October 2002 inquiry. In 2002, federal criminal charges were not commonplace occurrences in the pharmaceutical or medical device industries; these industries were not accustomed to the almost routine SEC filings of companies announcing federal criminal investigations that seem so prevalent today.

A DOJ inquiry into GSK's off-label promotional conduct joined with the FDA's inquiry, but when that commenced will not be known. One of Stevens's filings revealed that by April 2003 ''FDA ceded to DOJ primary responsibility for the GSK/Wellbutrin investigation.''[6] By 2004, DOJ was pursuing a broader investigation of numerous GSK products out of the District of Massachusetts. DOJ has a wide variety of tools and alternative sources from which to obtain information, such as cooperative witnesses, grand jury subpoenas, and voluntary production of materials—including privileged materials for which the owner has waived the privilege for a number of reasons ranging from the advice of counsel defense to voluntary waiver. And, as the Stevens case vividly demonstrates, such a separate investigation can arise at any time or be ongoing in parallel to a regulatory investigation.

Here, the previously sealed investigative material made public in the Stevens trial revealed that much of the evidence the government used to charge and try Stevens was not from its traditional sources or tools. Rather, as Judge Titus discussed in his May 10 hearing, the U.S. Attorney successfully petitioned a federal magistrate judge in Massachusetts for compulsory access to otherwise privileged information at GSK under the crime-fraud exception, alleging that GSK perpetrated or intended to perpetrate a crime or fraud and that the attorney-client communications were made in furtherance of such a crime or fraud.

Whether these aggressive investigative steps and charges filed in November 2010 would have been brought against an individual attorney in a different year in a different industry is open to debate. But, there is little question today that after a decade in pursuit of pharmaceutical corporations, the government intends to prosecute individuals, including attorneys. The FDA's chief counsel[7] and the HHS Office of Inspector General[8] each announced earlier in 2010 their intentions to bring individuals to account for the conduct of manufacturers who have, in their view, failed to heed

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[2] 18 U.S.C. § 1512(c).

[3] 18 U.S.C. § 1519.

[4] 18 U.S.C. § 1001.

[5] Only one reported major judicial resolution predated this FDA inquiry, *United States v. Genentech* (N.D. Cal. 1999) (alleged misbranding of human growth hormone, Protropin). It was not until the announcement of the guilty plea and civil settlement in *United States v. Pfizer, Parke-Davis, Warner-Lambert*, (D. Mass. 2004) (alleged misbranding of anti-seizure drug, Neurontin), that these issues came to the forefront of industry attention.

[6] *United States v. Stevens*, Memo. in Supp. of Def's Mot. to Compel Discovery and Disclosure of Material and/or Exculpatory Information, at 2-3, 10-CR-0694, D.E. 140 (D. Md. March 30, 2011).

[7] Remarks of Eric Blumberg at the Food and Drug Law Institute (FDLI) Enforcement Conference, Washington, D.C. (Oct. 13, 2010) (urging federal prosecutors ''to criminally charge individuals at all levels in the company'').

[8] Efforts to Combat Fraud, Waste, and Abuse in Medicare: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means Comm., 111th Cong. (June 15, 2010) (testimony of Lewis Morris, Jr., chief counsel to the HHS inspector general); press release, Rep. Pete Stark, Ways and Means Hearing Focuses on Efforts to Combat Fraud, Waste, and Abuse In Medicare (June 15, 2010), available at http://www.stark.house.gov/index.php?option=com_content&view=article&id=1948.

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and respect FDA's regulatory scheme and mandate. DOJ Assistant Attorney General Tony West of the Civil Division similarly embraced this approach, stating that ''where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations'' when the indictment of Stevens was first announced.[9] The Stevens acquittal will not likely slow this initiative against responsible corporate officers, for the charges against her were of a different nature than that legal theory, requiring proof of knowing and willful conduct.

The Response to FDA

In October 2002, Stevens assembled a team of inside and outside counsel to assist in GSK's response to FDA's request and over the course of 13 months wrote numerous letters to FDA with accompanying disclosures. According to the indictment, the team identified 2,700 health care professionals hired by GSK as speakers on Wellbutrin SR, wrote to 550 of them, and obtained slide sets from 40. It also was alleged that GSK wrote to 28 of the 40 speakers to advise them that their slides contained information outside approved product labeling and asked them to cease this activity.

During the course of compiling this information and communicating with its speaker-consultants, GSK wrote to FDA more than once to describe particular speakers who had included information about weight loss on their slides in talks and about a problematic slide set used at one of its speaker training programs and distributed to speakers with information for their education about weight loss effects of the drug. GSK described to FDA the steps taken in December 2002 and thereafter to retrieve the slide sets from physicians and to instruct those trained with these slides not to use them in their affirmative presentations, replacing the slides in question with compliant slides. GSK also noted to FDA that it had previously required all speakers to sign an agreement to confine their affirmative presentations to approved product indications.

The particular statements Stevens's letters made that the government charged as false were

- GSK ''has not . . . maintained any activity to promote or encourage, either directly or indirectly, the use of [the drug] as a means to achieve weight loss or treat obesity'';
- GSK had only two types of advisory boards when the records show that Stevens knew of special issue boards;
- ''GSK did not pay the audience to attend these events or reimburse their expenses'' when the records show that Stevens and her team were aware this had happened;
- GSK provided FDA with ''extensive information and supporting documentation regarding GSK's promotional and non-promotional activities relating to Wellbutrin SR and weight loss'' and ''[w]ith this final submission, . . . complete[d] [GSK's] production of information and documents'' to FDA's inquiry when Stevens knew that the company had not provided all material information that contradicted the company's representation that it had not engaged in off-label promotion; and
- the activities of certain physicians who spoke off label were ''isolated instances'';[10]

A number of the statements sound very much like legal advocacy and careful factual characterization in the light most favorable to the client. But, the government did not see it that way. Despite the context of Stevens's statements as counsel for GSK and the availability to her of the advice of counsel defense, the government must have assessed that defense as likely to fail. The magistrate judge's ruling that the crime-fraud exception permitted waiver of privilege over her deliberations with other counsel reinforced this view. Thus, the government believed the evidence would show (and argued so in its filings) that (1) Stevens did not act in good faith in making these statements given her knowledge, (2) she did not provide full information to outside counsel, and (3) that the legal advice was designed to justify the false statements and thereby further the crime or fraud.[11] The implications of the government's last argument is the most worrisome for attorneys, as it suggests that a lawyer may not advocate or characterize a client's conduct as lawful—and a lawyer may not deliberate or seek legal advice about that decision in confidence—if there may be facts that potentially contradict the argument without risking criminal prosecution. Indeed, rather than see this type of conduct as lawful advocacy, the government took a criminal view of Stevens's actions:

> The defendant's lack of good faith has been established by the contrast between what she knew and what she told the FDA, demonstrated most starkly by her own notes and the notes of other participants that reflect the calculated way in which she chose to deceive the FDA and not follow through on her commitments to provide information covered by the FDA's request, while telling the FDA that the responses were final and complete.[12]

For example, the prosecutors cited to Stevens's claim that GSK is ''not engaged in the promotion of Wellbutrin SR for weight loss.'' As an initial matter, what constitutes promotion is a legal determination, and, in this case, the statement was made in the context of numerous communications that disclosed other relevant information, which the government sought to discount entirely. Evaluating the government's argument, the court described the prosecution as seeking ''to take that statement . . . in isolation, and the Court simply will not do that and cannot permit a jury to do that.''

Indeed, Judge Titus acknowledged that Stevens's responses ''may not have been perfect; they may not have satisfied the FDA.'' But the court found that ''even if some of these statements were not literally true, it is clear that they were made in good faith, which would

[9] *See* http://www.justice.gov/civil/ocpl/cases/cases/Stevens/DOJ_Press_release_11-9-10.pdf. West made this same statement approximately a month earlier at the 11th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum. *See* ''Top DOJ Official Says Feds Will Pursue Individuals as Aggressively as Companies,'' BNA's Health Care Fraud Report (14 HFRA 877, 11/3/10).

[10] *See Stevens*, Indictment, Counts Three-Six, D.E. 149 (D. Md. April 13, 2011).

[11] *See*, *e.g.*, *Stevens*, United States' Motion to Preclude Advice of Counsel Defense to 18 U.S.C. § 1519 and for Hearing Regarding Applicability of the Defense to Other Charges, D.E. 19 (Dec. 17, 2010).

[12] *Id.*, United States Initial Response to Defendant's Motion for Judgment of Acquittal, at 2, D.E. 185 (May 9, 2011).

negate the requisite element required for all six of the crimes charged in this case.'' The court considered the alleged false statements of Stevens in the context of all of GSK's responses, noting other communications which clearly disclosed to FDA that GSK inadvertently gave speakers an off-label slide deck, that approximately 75 speaker presentations had off-label topics, and that particular doctors had discussed Wellbutrin SR's effect on body weight ''that some might consider as outside the product's approved indication.''

The court did not discuss a legal memorandum charged in the indictment and presumably obtained from GSK's counsel after the magistrate judge's ruling, which because of its prominence in the indictment, must have played a significant role in the decision to seek charges against her. This internal document memorialized a discussion among GSK counsel as to whether GSK should produce the slide sets collected from all of the 40 speakers, stating:

> *Pros*: Responds to FDA's request . . . for copies of all materials presented by individuals identified . . . and relating to [the drug]; Potentially garners credibility with the FDA *Cons*: Provides information that appears to promote off-label uses of [the drug] for weight loss . . . ADHD, sexual dysfunction . . .; Provides incriminating evidence about potential off-label promotion of [the drug] that may be used against [GSK] in this or in a future investigation.[13]

Prosecutors would argue this evidenced Stevens's intent to avoid providing responsive but incriminating evidence, and thus her intent to violate the law. But Judge Titus squarely ruled that the statements Stevens made on behalf of GSK cannot ''be taken as false when you consider it in the context in which it was given.'' It is ''only with a jaundiced eye and with an inference of guilt that's inconsistent with the presumption of innocence [that] a reasonable jury [could] ever convict this defendant.''

The Advice of Counsel Defense

Stevens defended the charges, asserting that she relied upon her employer's outside counsel in formulating her response, and, indeed, that GSK's outside counsel had written the language in the letters charged as false. The district court agreed that as an individual employee she could rely on corporate counsel's advice, refusing to grant the government's pretrial motion to deny her this defense. The court found Stevens's responses were sent to 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.'' Therefore, it applied the safe harbor provision in the obstruction of justice chapter, 18 U.S.C. § 1515(c), to hold that Stevens's charged conduct was bona fide legal advice and that she did not assist in any effort to commit a crime or fraud, precluding conviction on counts one and two. The court also ruled that the common law advice of counsel defense applied to the four remaining false statement charges.[14] In short, the court held Stevens ''should never have been prosecuted.''

Access to Privileged Evidence Under the Crime-Fraud Exception

Stevens's indictment was made possible because a federal magistrate judge in Massachusetts, presiding over a related investigation, ordered a large volume of attorney-client privileged, GSK documentary evidence to be produced to the United States. This order presumably followed a government motion arguing that the crime-fraud exception worked a waiver of privilege because (1) the client, presumably GSK, was engaged in or planning a criminal or fraudulent scheme when it sought legal advice to further the scheme, and (2) the privileged materials bore a close relationship to the existing or future criminal or fraudulent scheme.[15] This exception to the attorney-client privilege is seldom granted.

Judge Titus was clearly so troubled by its use here to prosecute Stevens that he opened the hearing in lament of the ''profound implications for the free flow of communications between a lawyer and client when the privilege is abrogated.'' Having viewed the documents ''paraded in front of'' him at trial, he found they ''demonstrate[d] that access should not have been granted in the first place.'' Rather than criminal purpose, they showed ''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.''

While Judge Titus's ruling soundly rejected the government's view of Stevens's conduct, it will not preclude the government from seeking attorney-client privileged materials on the same crime-fraud theory in other cases where it believes that a lawyer falsely characterized her client's conduct as lawful. But in situations like this case, where the lawyer deliberated and sought legal advice about how to characterize a client's conduct and about what evidence to turn over in response to a government inquiry, one can presume that the government will take greater care in making this argument. In the absence of access to the government's motion, the record shows and the indictment charges that GSK produced slides sets from one physician only after learning that a GSK employee had separately given them to the FDA. This troubled the government. But after hearing all the evidence, the trial judge was convinced that when Stevens decided on GSK's behalf to seek a meeting with the FDA and produce many other documents, even if not all documents she gathered that could be construed as problematic for the client, this was sufficient to satisfy the purpose of the FDA's inquiry and sufficient to show the lack of criminality in Stevens's words and actions.

Guideposts for Lawyers Whose Clients are in the Midst of the Fray

Many uncommon issues played out in this hard-fought case. The court accepted the notion that an in-house attorney relies upon advice given by her employer's attorney when acting in the course and scope of her own employment. A court other than the trial court

[13] *Stevens*, Indictment, ¶ 36.

[14] The Supreme Court recognized this defense first in *Williamson v. United States*, 207 U.S. 425, 453 (1908).

[15] A lawyer's ethical constraints prevent her from helping a client commit a fraud, Model Rules of Prof'l Conduct R. 1.2(d), and a lawyer must withdraw from representing a client if the client intends to use the attorney to commit a fraud. Model Rules of Prof'l Conduct R. 1.16.

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granted the government access to privileged materials under a narrow exception to attorney-client confidentiality based on arguments of criminal purpose. The defendant sought access to grand jury materials based on a showing that ''a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury.''[16] In March, the court asked to conduct *in camera* review of material normally out of bounds to the defense—not the testimony of particular witnesses—but the questions grand jurors posed to prosecutors and the responses prosecutors gave them. The court based its decision upon revelations in the prosecution briefing that one of the grand jurors had asked about the advice of counsel defense. After its review of this section of the transcripts, the court released it to the defense, which then successfully showed that the government provided erroneous legal instruction to the grand jurors warranting dismissal of the indictment. Undeterred, the prosecution sought renewed charges. The trial judge granted a motion to acquit for the first time in his judicial career.

Everyday lessons can be drawn from this saga. As the government viewed it, GSK, through Stevens and others, committed voluntarily to provide information and materials responsive to an FDA inquiry and made representations concerning the nature and scope of GSK's response. Having done so, neither GSK nor Stevens (or anyone else) was ''free to mislead the government'' or to ''promise but then not provide information when it turns out to be damaging'' regardless of the nature of the government's request.[17] The government takes seriously any perceived attempt to ''crippl[e] the ability of a myriad of government regulators to carry out their mission.''[18] As illuminated in this case, the government believed that line had been crossed in numerous ways:

– Stevens and GSK voluntarily agreed to provide the information to FDA, rather than being compelled to do so by subpoena. The form of the request is irrelevant, in the government's view, to the obligations of the company and individual employees. Once a company undertakes to respond, it must do so truthfully and accurately. While the government took a more rigid view of what those duties required, the district court recognized that GSK disclosed material information that was responsive to FDA's request, and truthful when viewed as a whole. When responding to a government inquiry, counsel must consider the entirety of the portrayal of a client's conduct and whether additional information may need to be disclosed to give the government an accurate picture and to ensure that select statements are not taken out of context.

– Stevens committed to FDA to make ''good faith efforts'' to get information to the government from third parties, even though it was not in the control of her employer. When taking on a similar endeavor, the extent of efforts to obtain that information internally and from third parties must be carefully documented. Decisions to produce or not to produce must be framed with a view to the accuracy of the whole response.

– Stevens expressly told FDA if she became ''aware of additional or new information that materially alters the accuracy of [the company's] responses,'' the company would inform FDA.[19] Counsel must be aware that FDA and DOJ take these representations seriously. Again, counsel must keep detailed records of information as it comes into the investigative effort and as it flows out to the government. Even if counsel does not affirmatively commit to supplement responses, the government will assume that material changes in facts as represented to the government should and will be made.

– Before deciding to withhold information that arguably may be responsive to a government inquiry, measured analysis is essential. If the terms of a government request are either ambiguous or capable of legal interpretation, such as ''did not promote'' or ''in accordance with the label,'' a response must be crafted with the established meaning of terms firmly in mind, and with the assistance of either internal or external counsel on questions of ambiguity, legal interpretation, and privilege.

The resolve of FDA and DOJ to enforce FDA's regulatory scheme is beyond doubt. That individual executives and now corporate counsel are squarely in the prosecutorial sights is equally clear. But the court's dismissal of these charges against a pharmaceutical company's in-house lawyer has altered the seemingly inexorable prosecutorial march.

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[16] Fed. R. Crim. P. 6(e)(3)(E)(ii).

[17] *Stevens*, United States Initial Response to Defendant's Motion for Judgment of Acquittal, at 6.

[18] *Id.*

[19] *Stevens*, Def's Reply Brief in Supp. of Mot. for Bill of Particulars, Ex. 1, D.E. 80-1 (Letter from Lauren Stevens to Lesley R. Frank, Regulatory Counsel, FDA (Dec. 23, 2002)).