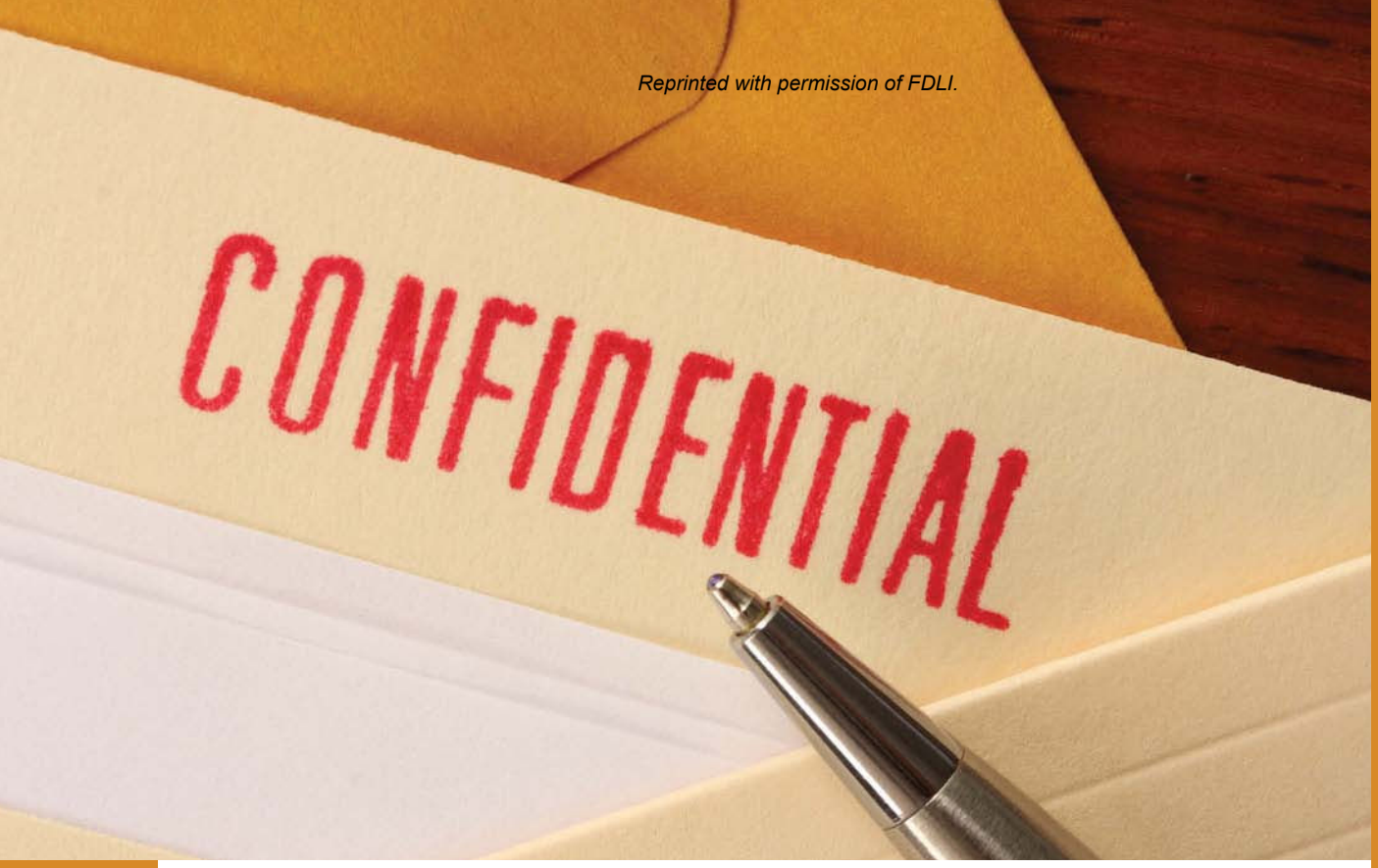

United States v. Lauren Stevens: How FDA's Questions about Off-Label Promotion Led to the Criminal Prosecution of a Company Lawyer

By William F. Gould and Michael M. Gaba[1]

On November 9, 2010, the Department of Justice issued a press release titled "Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements."[2] This press release discussed the six count indictment against Lauren Stevens that subjected her to a maximum of 60 years in federal prison. This potential criminal penalty was specifically referenced in the government's press release. When she was indicted, Stevens was a retired vice president and former in-house attorney for GlaxoSmithKline (GSK). The Department's press release was extensive and aggressive. It included quotes from Tony West, the Assistant Attorney General for the Civil Division; Carmen Ortiz, the U.S. Attorney for Massachusetts; Dara Corrigan, FDA's Associate Commissioner of Regulatory Affairs; Susan Waddell from HHS, OIG; the FBI Special Agent in Charge in Boston; and the Defense Criminal Investigative Services

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Resident Agent in Charge in Boston. Mr. West said, "[w]here the facts and the law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations." The Department was vigorous indeed in its prosecution of Stevens.

The Maryland federal indictment charged Stevens with two counts of obstruction and four counts of making material false statements during an FDA investigation into whether GSK improperly introduced a misbranded drug into interstate commerce. On May 10, 2011 United States District Judge Roger Titus dismissed the government's indictment for the *second* time. Judge Titus's Order granting Stevens' Rule 29 Motion discusses the appropriate parameters of attorney-client privilege and the importance of advice of counsel extensively.

All in-house and outside counsel should read Judge Titus' Rule 29 Order dismissing the case for three important reasons. First, it reminds us all of how important privileged and candid communications are between lawyer and client. Second, it demonstrates how aggressively and effectively the government can prosecute a case, including seizing clearly privileged documents against a company's wishes. Third, it serves to illustrate that there are times when a zealous, albeit respectful, defense is the best tactic, particularly when confronted with some of the government's theories concerning enforcement under FDCA and its implementing regulations.

In his Rule 29 Order, the Judge concluded that Stevens "should never have been prosecuted and that she should be permitted to resume her career." It was the first time he had granted a Rule 29 Order in his almost eight years on the bench.

The FDA Investigation

The FDA began its investigation into whether GSK improperly promoted the anti-depressant drug Wellbutrin SR for weight loss, an off-label use,[3] in late 2002, almost a decade before Stevens was indicted. The factual underpinnings of the case are extensive, but a brief background may be helpful. On October 9, 2002, FDA sent GSK an initial letter requesting "copies of all slides . . . and other materials presented or distributed at any program or activity related to Wellbutrin" and "all compensation provided to individuals involved in programs or activities related to Wellbutrin." FDA's lengthy subsequent letters to GSK requested a number of other facts and explanations.

Stevens, GSK's Vice President and Associate General Counsel for U.S. Legal Operations at the time, headed up the company's response to FDA's inquiries. GSK agreed to make a good faith effort to voluntarily provide FDA with materials presented at GSK-sponsored promotional programs, including those presented by outside consultants. Stevens, aided by in-house GSK lawyers and outside counsel, initiated an internal investigation. This team solicited documents from 550 out of over 2,000 consultants and received 40 responses from the doctors who worked with GSK. Twenty-eight of the slide decks received from these doctors discussed off-label uses for Wellbutrin. Stevens and her team sent follow-up letters to these physicians stating that she had "reviewed the content of your presentations and determined that they contained material relating to GSK products (e.g. Wellbutrin SR) and uses that are not currently FDA-approved indications for those products. Any affirmative presentation in a GSK-sponsored non-independent program suggesting that a GSK product is effective in conditions that are not approved indications is inconsistent with FDA requirements, GSK policy and your contract with GSK." GSK responded to FDA's inquiry in a number of separate written communications in the first half of 2003. GSK, among many other things, represented that:

- GSK had not developed a program or activity to encourage the use of Wellbutrin as a means to achieve weight loss.
- GSK had not developed or maintained promotional plans to promote Wellbutrin for weight loss.
- GSK had two types of advisory boards: national and local (omitting any mention of GSK's "special issues boards").
- Attendees were not paid, reimbursed or otherwise compensated to attend GSK's speaker programs, "with the exception of reimbursement for parking fees in some cases."

The government charged all four of these statements as federal felonies. GSK's final letter to FDA in May 2003 included a spreadsheet containing titles of doctors' presentations and noted that some appeared to contain information regarding off-label uses of Wellbutrin. Stevens and her team of lawyers did not provide the actual physician presentations to FDA at that time. It is worth noting that Stevens signed all of the letters to FDA. Nevertheless, the first drafts were done by outside counsel, and the final submissions were the yield of a collaborative process that included two other in-house lawyers and GSK's outside counsel. The advice that she received from these lawyers would prove to be the most significant pillar of her defense strategy.

The Government's Case

Before Stevens' November 8, 2010 indictment was returned by a grand jury in Maryland, the government convinced a Massachusetts federal magistrate judge

to order that attorney-client privileged documents from the time when GSK was interacting with FDA on the Wellbutrin matter be released to the government. This was ordered pursuant to the crime fraud exception to the attorney-client privilege. When he dismissed the government's case, Judge Titus said that "with the 20/20 vision of hindsight . . . the Massachusetts Order was an unfortunate one." He went on to say that the government should not have been "permitted to forage through confidential files to support an argument for criminality of the conduct of the defendant." It is worth reflecting here for a moment on some of Judge Titus' words. When he dismissed the case, he stated:

"Very significant portions of the documents placed before the Court were what would otherwise be privileged attorney-client documents. They were obtained by the United States as a result, as I've learned, of an order of a magistrate judge in the District of Massachusetts who ordered them produced under what's known as the Crime Fraud Exception. There are, of course, profound implications for the free flow of communications between a lawyer and client when the privilege is abrogated, as it was in this case. The Crime Fraud Exception is designed to overcome the privilege only when the evidence established that the client intended to perpetuate a crime or fraud and the communications at issue between the attorney and the client were made in furtherance of such crime or fraud." Titus Rule 29 Order at 3-4 (May 10, 2011).

There is a vast gulf between the views of DOJ in this case against Stevens and those of many in-house and outside counsel in the life sciences industry. One area where this divergence is especially glaring regards the level of respect given the attorney-client privilege and attorney-client communications. Two examples of communications that the government viewed as part of a crime serve to effectively illustrate this difference in viewpoints. First, the government attempted to prove the element of "corrupt intent" with excerpts from Stevens' handwritten notes that weighed possible benefits of, and problems caused by, producing the doctors' slide decks to the FDA. These were notes that she took in meetings with witnesses and with the lawyers with whom she was working to conduct the internal investigation. They reflected her thoughts and legal conclusions. They included summaries of information she received from other lawyers and how she viewed such information. These notes were actually quoted in the indictment against her. Second, the government believed that the memorandum excerpted below, which was developed by GSK's outside counsel, demonstrated that Stevens knew she was obstructing justice. The memo balances the pros and cons of producing the slide decks.

"Pros

- Responds to FDA's request 5(a) for copies of all materials presented by individuals identified in response to item 3 and relating to Wellbutrin
- Potentially garners credibility with FDA

Cons

- Provides information that appears to promote off-label uses of Wellbutrin for weight loss
- Potentially demonstrates GSK's lack of control over GSK sales reps
- Potentially demonstrates GSK's lack of control over physician speakers
- Provides incriminating evidence about potential off label promotion."

The "unfortunate," to borrow Judge Titus' word, use of the crime fraud exception to force disclosure of clearly privileged documents is not the only illustration of how aggressively the government prosecuted this case. After the government attempted mightily to prevent Stevens, and even the District Court, from reviewing the grand jury transcripts, the Judge finally required the government to turn over these transcripts for his *in camera* review. Then, on March 23, 2011, Judge Titus, dismissed the government's case *for the first time* citing the government's incorrect legal instructions to the grand jury regarding how the grand jurors were to evaluate the fact that Stevens relied on other attorneys in her decision-making. Judge Titus determined that "[t]here can be little doubt that the instruction given the grand jury [by both prosecutors] regarding the advice of counsel defense was erroneous."

A grand juror asked the prosecutors, who are the grand jury's legal advisors during an investigation, how the grand jury should evaluate the advice Stevens was given by the lawyers on her team. The prosecutors incorrectly told the grand jury that advice of counsel was a defense for the trial judge and jury to evaluate, and it was not to be considered by the grand jury in evaluating whether there was probable cause to return the indictment against Stevens. Judge Titus, referring to this astute grand juror's question as "akin to asking about an elephant in the room," dismissed the first indictment in its entirety. About three weeks later, on April 13, 2011, the government reindicted Stevens with a substantially similar indictment. This second indictment included the excerpts from her above-described legal notes.

One additional interesting and unusual aspect of the government's

advocacy should be mentioned. Well before the trial began in this matter, Stevens' lawyers suggested that the parties waive the jury and try the case with the Judge as fact finder. Shortly after this offer by the defense, the government declined and insisted on its right to try the case to a jury.

Stevens' Legal Arguments

The obstruction of justice counts against Stevens were premised to no small extent upon the failure of Stevens to produce the physician slide decks. The defense argued that there was in fact no concealment, as GSK was not under any legal compulsion, such as a subpoena, to produce the decks. The defense also argued that Stevens and her team of lawyers never claimed that it produced them or that they did not exist. The defense pointed out that Stevens provided FDA with a list of presentation titles, which should have put FDA on notice that slide decks existed that GSK had not produced during the FDA investigation. Stevens and her team of lawyers also tried to call FDA to discuss the slide decks. These repeated calls were never returned by the agency.

The obstruction counts were also based on the spreadsheet provided to FDA that listed the speakers' presentations, from which a column listing gifts and entertainment provided to speakers was removed. On this point, the defense argued that FDA did not request information relating to entertainment. Stevens also argued to the court that she never claimed to have provided these data and that she chose not to provide them based on advice of counsel.

Finally, the government alleged that several of the statements made in GSK's 2003 responses to FDA constituted false statements. The government claimed that these statements supported the obstruction counts, but a number of them also served as the basis of stand-alone material false statements crimes. A number of these statements were quite clearly literally true, and others were written by Stevens' team of lawyers after careful and studied deliberation. Judge Titus found that they could not withstand Stevens' advice of counsel defense.

The Judge's Order

Judge Titus stated in his Rule 29 Order at the conclusion of the government's case that "a lawyer should never fear prosecution because of advice that he or she has given to a client who consults him or her . . . . There is an enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice." This statement is directly tied to the very basic notion in the Preamble to the Model Rules of Professional Conduct that "it is a lawyer's obligation to zealously protect and pursue a client's legitimate interests, within the bounds of the law." Judge Titus was quite clear that the life-line that drove his decision on Stevens' Rule 29 Motion was her advice of counsel defense. The Judge determined that Stevens was not committing crimes. Rather, she was practicing law by zealously representing her client.

As noted above, Judge Titus said that there are "profound implications for the free flow of communication between a lawyer and client when the privilege is abrogated, as it was in this case." Although the judge clearly indicated in his ruling that he felt the Massachusetts magistrate judge's decision to allow the government access to privileged documents was incorrect, the use of the crime fraud exception to the attorney-client privilege should be carefully considered by our industry going forward. Vigilant communication must be practiced, even in written product that is clearly at the core of the privilege.

Some Practical Recommendations

Life science companies and their in-house counsel should consider the following:

- Involve the company's legal department.
- In complicated high-risk interactions with any agency, corporate lawyers should ensure they work "shoulder-to-shoulder" with a multi-disciplinary team of attorneys who understand the government entity with which they are dealing.
- Encourage company counsel to carefully consider whether outside counsel should sign any submission.
- Keep the dialogue civil, even when the company views the government as being unfair.
- Draft any written product with an eye toward how a criminal investigator would interpret the writing with the full benefit of hindsight. This is particularly true of all submissions to the government, although it is a warning that should be heeded for all documents, even those that most lawyers would never expect to receive public scrutiny.

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2. See http://www.justice.gov/civil/ocpl/cases/cases/Stevens/DOJ_Press_release_11-9-10.pdf.
3. It is interesting to note that potential weight loss is a precautionary statement on the Wellbutrin SR label, making its reference a necessary component of any balanced presentation.