But My Lawyer Told Me It Was Okay

by John R. Fleder

Introduction

We live in an era where it seems that just about everyone has legal counsel. This is especially true for companies whose activities are closely regulated by the Food and Drug Administration (FDA). As a result, it is commonplace for companies to seek advice from in-house and outside counsel regarding whether proposed conduct would violate the Federal Food, Drug, and Cosmetic Act (FDCA).

We hope that this process results in prudent decision-making by FDA-regulated companies. Sometimes, however, clients do not accept the legal advice they receive. In other instances, lawyers may simply give bad legal advice. In either case (and also other situations), it has become increasingly popular for federal prosecutors to target the legal advice that counsel renders to a company or individual who is under criminal investigation or has actually been indicted. Indeed, the government has been quite aggressive in prosecuting lawyers who the government believes are actually part of a fraudulent scheme.[1]

Calling a Lawyer to the Witness Stand

A more common situation occurs when the government either threatens or actually initiates a felony criminal prosecution because it believes that a company and/or one of its employees has intentionally violated the FDCA, but the government does not believe it can or will prosecute an attorney who provided legal advice to his client. If the Department of Justice (DOJ) and FDA believe that the alleged violation occurred after legal advice was sought and obtained, the government can seek to penetrate the secrecy of that advice by asserting that the client was seeking advice as a component of a fraudulent scheme. Courts have ruled that when a lawyer provides legal advice to assist a client with his ongoing fraud, the advice is not protected by the attorney-client privilege.[2]

Most FDCA criminal prosecutions that go to trial evolve into a battle regarding the defendant's intent. A defendant may claim that he was unaware of the activity that the government alleges was illegal. More common is a defense that the defendant believed his activity was lawful. A defendant may even argue that he took certain actions because his lawyer told the defendant that the actions were lawful, the so-called "advice of counsel defense." Some might ask who could be a better trial witness than the lawyer who prospectively advised the defendant that future activity is legal?

Courts have generally ruled that relying on a lawyer's advice is an absolute defense to a crime that requires the government to prove that a defendant committed an offense with wrongful intent.[3] A defendant can certainly testify in his own defense that the alleged illegal activity he is charged with committing was taken in good faith based on legal advice obtained from a lawyer. In some situations, defense counsel will try to strengthen that testimony by obtaining corroborating evidence from the lawyer who rendered that advice. In other instances, defense counsel may try to establish a defendant's good faith by calling his prior counsel as a witness, instead of calling the defendant to testify.

Calling a lawyer as a witness to demonstrate the client's good faith is a classical risk/ reward quandary. The obvious reward is that a defendant can obtain an acquittal if he can demonstrate all the elements of an "advice of counsel" defense. It is generally viewed that the elements of that defense are that the defendant: 1) fully disclosed all pertinent facts to counsel; 2) relied in good faith on counsel's advice; and 3) did not know that counsel's advice was erroneous.[4]

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The Harkonen Case

The difficult strategic issues presented when a defendant decides to call his counsel as a witness was recently illuminated in United States v. W. Scott Harkonen. In 2004, the DOJ began investigating InterMune, Inc. (InterMune) for the alleged marketing and promotion of its drug, Actimmune, for the treatment of idiopathic pulmonary fibrosis (IPF), an indication for which the drug had not received approval from FDA.[5] In March 2008, Dr. Harkonen, the company's former chief executive officer, was indicted on two counts for allegedly: 1) violating the federal wire fraud statute;[6] and 2) making false and misleading statements with "intent to defraud or mislead" concerning the efficacy of Actimmune, which allegedly resulted in the product being misbranded in violation of the FDCA.[7]

Central to the government's case was a press release announcing the results of a clinical trial involving Actimmune for the treatment of IPF. The government alleged that the defendant directed the company to issue a press release that misled the public on the benefits of Actimmune.

During the trial, the defense obtained testimony from the company's general counsel during the time period of the government's inquiry, Stephen Rosenfield. In his role as general counsel, Mr. Rosenfield was responsible for reviewing all press releases prior to publication. Once the defense called him as a witness, what would have been otherwise likely protected by the attorney-client privilege was open for cross examination testimony elicited by the prosecution, and was thus fair game for a full inquiry before the jury. Both the defense and prosecution inquired of Mr. Rosenfield regarding his changes to the draft press release.

According to his testimony on direct examination, Mr. Rosenfield, who was on vacation at the time the press release was being prepared, testified that he nonetheless approved the press release before it was issued after learning that company officials were euphoric after reviewing the results of a clinical trial. He maintained that he relied on statements made by the defendant and other internal employees in verifying the accuracy of the press release. For instance, Mr. Rosenfield approved language indicating that Actimmune had "demonstrated" clinical benefit in treating certain patients with IPF after discussions with company employees, including the defendant.[8] Additionally, he testified that during his time away from the office he was in contact with the defendant had in drafting the press release.

On cross-examination, Mr. Rosenfield claimed that the defendant withheld information that may have been relevant to Mr. Rosenfield's assessment of the press release. He thought that Dr. Harkonen had consulted with certain other company officials about the wording of the press release. Mr. Rosenfield also testified that he was unaware of informal communications regarding the study outcomes the defendant and other company employees had with FDA staff members, who had expressed their concerns regarding the data and results.[9]

Anticipating that it would call Mr. Rosenfield as a trial witness, the defense submitted a proposed jury instruction before trial on an advice of counsel defense. That proposed instruction would have instructed the jury to absolve the defendant of having criminal intent if the defendant acted upon the advice of counsel. The final instructions that the trial court gave the jury, however, did not contain any such instruction, even though both the defense and the prosecution relied on Mr. Rosenfield's testimony. On September 29, 2009, the jury convicted the defendant of wire fraud but acquitted him of the FDCA misbranding charge.

Without commenting on the particular facts of the decision to call Mr. Rosenfield as a witness, the Harkonen case highlights risks presented in any case where counsel is called to the witness stand. First, many legal commentators believe that lawyer/witnesses generally do not make compelling witnesses because they try to outsmart the prosecutor, which is quite risky for any witness. Second, by raising that defense, a defendant may have to provide the government with all the legal advice sought by the client and later provided by the lawyer, not just the advice on which the defendant wants to rely. Further, as described above, the advice of counsel defense will likely fail if the defendant did not make full disclosure of all relevant facts when the advice was sought. This is a difficult burden for any defendant to meet.

There are at least two other very sticky points that arise in these situations. First, in the FDA-regulated arena, companies sometimes seek advice about the regulatory risks involved if a company undertakes certain activity. The government may claim that such advice is not legal advice, but is instead business advice, and therefore not protected by the attorney-client privilege. Although that claim should be rejected, particularly when a client has sought advice from an outside law firm, there is no guarantee that a court would accept the defendant's assertion that his lawyer provided *legal* advice.

Second, another quagmire is presented when a company official obtains legal advice from the company's counsel and the official is thereafter prosecuted under the FDCA. Although in that situation the official can probably assert an advice of counsel defense, he may be presented with a number of difficult hurdles. For instance, what if the company does not want the lawyer to testify and does not authorize the official to waive the attorney-client privilege by raising an advice of counsel defense?

Conclusion

In this era of heightened enforcement activity, it is becoming increasingly common for a corporation under investigation to cooperate with the government by waiving its attorney-client privilege and produce legal advice rendered by counsel. Waiver of attorney-client privilege, however, may open the floodgates to criminal prosecution of current and former employees. Whether an employee wants to assert that his actions were based on legal advice received from company counsel or his own legal counsel and possibly calling counsel to testify at a trial involves careful assessment of the risks and benefits.

1 See The Curious Case of the Prosecution of Lawyer Paul Kellogg, FDLI Update, (Mar./Apr. 2009), available at http://www.hpm.com/devitem.cfm?RID=149.
2 See e.g., U.S. v. Martin, 278 F.3d 988 (9th Cir. (2002)).
3 See e.g., U.S. v. Ragsdale, 426 F.3d 765 (5th Cir. (2005)).
4 See e.g., U.S. v. Lindo, 18 F.3d 353 (6th Cir. (1994)).
5 In Oct. 2006, InterMune entered into a deferred prosecution agreement with the U.S. Attorney's Office for the Northern District of California and agreed to pay approximately $36.9 million to resolve criminal and civil liabilities in connection with the alleged promotion and marketing of Actimmune® for IPF. Additionally, the company entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.
6 18 U.S.C. § 1343.
7 21 U.S.C. §§ 331(k), 333(a)(2), and 352(a).
8 Rosenfield Test. 3135-3138, (Sept. 17, 2009).
9 Rosenfield Test. 3385-3387, (Sept. 18, 2009).