Government Contracts Advisory

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Indictment of In-House Counsel Highlights Need For Caution In Responding to Government Inquiries

On November 9, the Department of Justice announced the indictment of a former GlaxoSmithKline ("GSK") attorney for obstruction and making false statements to the FDA. The indictment alleges that the attorney withheld incriminating documents and made numerous misrepresentations in a series of letters sent to the FDA. The indictment of an attorney for acts committed while representing a client is extremely rare and has provoked concerns about the chilling effect it will have on other attorneys.

Some commentators contend that this indictment targets zealous advocacy. Others maintain that such views are an alarmist overreaction to an indictment predicated on conduct that many experienced defense attorneys would consider improper or, at the very least, extremely ill-advised. Clearly, the indictment sends a strong message that has implications for how all attorneys should respond to government inquiries.

The GSK attorney is charged with six counts, including obstruction, concealment of documents, and making false statements. The case is being handled by the Civil Division of the United States Attorney's Office for the District of Massachusetts and the Department of Justice Office of Consumer Litigation. The charges relate directly to the attorney's failure to produce documents, and to the attorney's denials that GSK maintained programs to promote off-label uses of Wellbutrin or paid doctors to attend speaker programs. In a press release, U.S. Attorney Carmen Ortiz stated that "[t]here is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth. . ." Nonetheless, the indictment arguably implicates certain representations that most defense counsel would identify as proper advocacy, not an illegal cover-up or distortion of facts.

The government alleges that in 2002, the FDA notified GSK of possible off-label marketing of one of its products, Wellbutrin, and requested that GSK provide the FDA with all Wellbutrin-related promotional materials, including materials presented at any GSK-sponsored promotional programs, even if those materials were not created by or were not under the custody or control of GSK. GSK agreed to voluntarily produce the requested materials and said that it would make a good-faith effort to obtain and provide materials that were not under its custody and control.

In preparing to respond to the FDA's request, GSK's attorney requested promotional materials from 550 of 2,700 physicians who had given GSK-sponsored promotional talks about Wellbutrin. The attorney received materials from 40 promotional speakers, and after reviewing those materials, sent letters to 28 of the speakers stating that the materials they had sent included information about unapproved uses of Wellbutrin.

The indictment alleges that the attorney engaged in discussions with other attorneys to determine whether to produce the materials gathered from the promotional speakers. Based on public statements by her counsel, this may have involved use of an outside law firm. At the request of the GSK attorney, a memorandum was drafted highlighting the "pros and cons" of producing the materials to the FDA. The memorandum listed "pros" to be the production of the documents would respond to the FDA's request and could garner credibility with the agency. As

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"cons," however, the memorandum noted that the materials would provide “incriminating evidence about potential off-label promotion.”

The indictment alleges that the attorney did not provide the materials that came from the promotional speakers, but nonetheless sent a letter to the FDA stating that GSK had completed its document production in response to the FDA’s inquiry. The attorney also represented that “all of the documentation and materials we have reviewed and provided to you during the course of this inquiry” show that GSK has not “maintained any program or activity to promote, either directly or indirectly” the use of Wellbutrin for unapproved uses.

On their face, some of the false statement counts appear defensible. For example, the indictment alleges that the attorney falsely stated that GSK had not developed or maintained a program to encourage off-label use of Wellbutrin. The government further alleged that the attorney falsely stated that there were only “isolated deficiencies.” The attorney’s statements may well have been literally true. It is easy to imagine that GSK could properly advocate against off-label marketing charges despite isolated evidence that 28 of 2,700 promotional speakers posessed off-label materials not created by GSK. The indictment also alleges that the attorney lied when she told the FDA that doctors attending speaker programs were not “paid, reimbursed or otherwise compensated” because in fact they received “gifts and entertainment.” Here, too, one can see a reasonable factual dispute regarding whether doctors were “paid” to attend promotional events.

At the same time, however, experienced defense counsel may question the prudence of withholding responsive documents on the basis that they may be damaging (even if GSK had not already essentially promised to produce them). It seems unlikely that the government would have indicted if the GSK attorney had made the same representations after having produced the documents in question.

In the future, whether the government will charge defense attorneys with making false statements in the absence of seemingly egregious factual predicates remains to be seen. For now, the case serves as a valuable reminder of the level of care required in responding to government investigations. Particularly when representing clients in regulated industries, attorneys must have a clear understanding of their role as advocates; the ethical, legal and strategic limitations on that role; and their client’s responsibilities. Attorneys should also exercise extreme caution before volunteering to produce material that is not in the custody of the company and the content of which is not known.

Finally, it is prudent to articulate very clearly and carefully what is being produced in response to a government request, including how a production may vary from such a request.