



Did Drug Company Lawyer Make False Statements to FDA?

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When regulatory agencies ask major corporations to hand over documents to them as part of an ongoing investigation, there's normally a pretty clear understanding of how things work: if the agency doesn't receive the full set of documents it is asking for, it negotiates with the company, or ratchets up the urgency of the request, or goes to court to enforce a subpoena.

What it hardly ever does is ask the Justice Department to step in, years later, and seek an indictment of a high-ranking corporate in-house counsel for obstruction of a legal proceeding, making false statements, and concealment of documents.

But this may be changing. On November 9, 2010, the Justice Department announced the indictment of Lauren Stevens, a now-retired vice president and associate general counsel at GlaxoSmithKline, the British pharmaceutical giant, in connection with Stevens' actions back in 2003 when the FDA was investigating GSK for allegedly promoting one of its drugs for unapproved uses.

The indictment says Stevens led a team of lawyers and paralegals responding to the FDA's request for documents about GSK's promotion of Wellbutrin, an anti-depressant, for weight loss and other uses that the FDA hadn't approved. (Actually, the indictment doesn't name the company or the drug, but many sources confirm their identity.)

Stevens, according to the indictment, knew that GSK had set up marketing programs to promote the use of the drug against obesity and that it had paid many physicians to make speeches about that use to other doctors. But Stevens told the FDA that GSK had done nothing of the sort. She wrote to the FDA, for example, that GSK "has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of [the drug] to achieve weight loss or treat obesity."



And Stevens allegedly had seen slide presentations that physicians had put together about such unapproved uses, but she didn't hand those over to the FDA. Any off-label uses, she said, were "isolated deficiencies" in GSK's compliance program.

Interestingly, neither the company itself nor any of its other lawyers or officials were indicted. Could Stevens, as the head of a team of lawyers and paralegals that reported to top management, have acted on her own in withholding these documents and information? If GSK really planned to lie to the government, didn't other people have to be part of the scheme as well? Shouldn't they or the company itself have been indicted – if there really was such a conspiracy within the company?

Also, Stevens' statements sound to us more like legal posturing on behalf of a client than like a criminal attempt to deceive the FDA and withhold information. It seems that she was telling the agency that GSK had no intent to promote the off-label uses, while knowing that individual doctors probably did so without the company's permission.

If that's the basis of the dispute – and both sides clearly think they have the better of it, with Stevens' lawyers pledging that she will be exonerated – the criminal courts are the wrong place to work it out. The facts may eventually show that Stevens did in fact violate the federal criminal laws, of course. But ordinarily, this kind of discovery dispute is worked out behind the scenes, between the federal agency and the company, with harsh words perhaps but without a criminal case against an attorney. That seems the best place to handle it.

At the very least, lawyers who respond to federal agencies' demands now had better look very carefully at what they say.

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