

It's Getting Personal: The Government Loses First Round in Campaign Targeting In-House Lawyers and Corporate Executives

Pharmaceutical Law Update

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Dissatisfied with the feeble deterrent effects of conventional investigations, commonly resulting in settlement agreements, corporate integrity policies and millions of dollars in accompanying fines, the federal government is sending a message to the industry: "Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations." (Press Release, Department of Justice (DOJ), *Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements*, quoting Tony West, Assistant Attorney General (Nov. 9, 2010)). The effects of this message can be felt across the entire drug and medical device industry.

The In-House Lawyer as Criminal Defendant

United States v. Lauren Stevens (8:10-cr-00694, D. Md.) signals a recent and disturbing trend by the federal government to initiate criminal, civil and administrative actions against individuals for the alleged wrongdoings of their employers.

Stevens, GlaxoSmithKline's (GSK) former Vice President and Associate General Counsel, was charged last November with six criminal counts stemming from her alleged obstruction of a Food and Drug Administration (FDA) investigation into GSK's marketing practices. Specifically, she was accused of making false statements and withholding incriminating documents from FDA during the agency's 2002-2003 investigation of GSK for its alleged off-label promotion of the drug Wellbutrin SR®. For six months, Stevens was forced to defend herself against these criminal charges for simply doing what lawyers do each day – lawfully and zealously representing their clients.

Ultimately, last month, the U.S. District Court for the District of Maryland found that the evidence presented at trial showed a "studied, thoughtful analysis of an extremely broad request from FDA and an enormous effort to assemble information and respond on behalf of the client." The Court explained that while Stevens' responses to FDA were not perfect, they were sent in the course of her *bona fide* legal representation of GSK, and in good faith reliance upon the advice of numerous external and internal lawyers for GSK. Every decision she made, every letter she wrote, was made by consensus of GSK's legal team. Accordingly, the Court, on a Motion for Judgment of Acquittal, dismissed the case against Stevens, cautioning that "[t]here is an enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice."

While the *Stevens* ruling is a significant blow to the efforts of FDA and DOJ to target individuals for the alleged misconduct of an entire corporation, it appears that the government's fierce campaign may have only just begun.

The Government Unleashes New Tactics – Resurrecting Old Laws

To enlarge the scope of its enforcement actions, the government has resurrected the *Park Doctrine* (*United States v. Park*, 421 U.S. 658 (1975)), an old and seldom used law that allows it to charge a corporate official for alleged violations of the Food, Drug and Cosmetic Act (FDCA) if the official had the authority and responsibility to prevent and correct violations, but failed to do so. Under this doctrine, an official may be

charged regardless of whether he/she participated in, or was even aware of, the alleged violations. In fact, FDA recently updated its Regulatory Procedures Manual (Manual) to add a new chapter specifically addressing criminal prosecutions, including use of the *Park Doctrine*. The Manual sets forth factors to be considered by FDA personnel when recommending misdemeanor prosecution against a corporate official.

As if individual criminal prosecutions were not enough, FDA is also exercising its "exclusion authority" to further target specific company executives. Under this authority, the government may ban a corporate leader from federal healthcare programs if the company has been found guilty of criminal misconduct, regardless of whether the executive even had knowledge of the actions. By way of example, following a settlement wherein Forest Laboratories pled guilty to certain promotional misconduct, the Department of Health and Human Services unexpectedly notified Forest of its intent to preclude the company's CEO from conducting future business with the federal government. The CEO was never personally accused of any wrongdoing during the investigation. This measure by the government would thwart the sales of Forest's drugs to Medicare, Medicaid and even the Veterans Administration – a substantial revenue loss.

While the industry continues its struggle to understand the full scope and ramifications of federal laws and FDA regulations, one thing remains clear – the government's recent strategies place in-house counsel, as well as top executives, under intense scrutiny.

Strategies for the Next Round

If the government holds true to its promise of personal prosecution, it is vital for companies to have a well-thought-out strategy to defend themselves, as well as their lawyers and executives. A comprehensive team of both in-house and outside counsel with experience handling government investigations and insight into the underlying issues that form the basis of the probe must be assembled. This advisory council should be intimately involved in every decision throughout the process.

Prior to commencing discussions with the government, companies must also conduct an immediate and thorough internal investigation of any alleged wrongdoing. While it is imperative to cooperate with the government, a hasty response could result in unintentionally inaccurate or incomplete responses, and could also lead to the inadvertent disclosure of privileged information. In this era, individuals must also face the sobering reality that they may require separate counsel to protect themselves. Ultimately, every company subject to FDA regulation must consider the severe implications of its response to any government investigation - including any plea bargain or settlement - and carefully evaluate the risks created by any response, including now the potential for future criminal charges against the corporation and its executives, the government's possible exercise of its exclusion authority, as well as the obvious potential for future civil litigation and/or negative impact upon pending civil litigation.

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