

*Periodically, we will send you a **concise** update on current events in the healthcare compliance arena **as it relates specifically to pharmaceutical and medical device manufacturers** that may have an impact upon your business and operating procedures. These news items and analyses are intended for informational purposes only.*



After conveying numerous signals to warn the pharmaceutical community, last week the Justice Department criminally charged a former executive in connection with off-label marketing allegations. Former in-house counsel for GlaxoSmithKline Lauren Stevens has been charged with obstruction and making false statements during a probe of Wellbutrin SR marketing. The “smoking gun” in this case appears to be a March 2003 memo from Steven’s staff providing a list of the pros and cons of submitting physician presentations on Wellbutrin to the FDA, which was subsequently not tendered during the investigation. You can view the indictment at <http://freepdfhosting.com/58c3122373.pdf>. The charges could carry a sentence of up to 20 years in prison. Assistant AG Tony West said of the indictment, “the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations”.

FDA’s Deputy Chief Counsel Eric Blumberg was quoted in several venues providing warnings of an impending indictment, and his comments lead one to conclude that more indictments will be imminent.

- August 24<sup>th</sup> - *“Very soon and I have no one particular in mind, some corporate executive is going to be the first in a long line ... so it's going to happen. Do what you can and do the right thing before we find out about it”.*
- October 13<sup>th</sup> - *“It's clear we're not getting the job done with large, monetary settlements. Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion.”*
- October 31<sup>st</sup> – in an interview appearing in the Philadelphia Inquirer, *“One thing that will get executives' attention is a few cases in which we have convicted two-legged defendants.”*

Further, in response to requests made by HHS OIG Chief Counsel Lewis Morris, the House introduced HR 6130 on September 15<sup>th</sup> whereby execs at companies that are convicted of fraud can be excluded from federal health care programs, including banning execs even if they later work elsewhere. The House voted and passed the bill a week later.

On October 20<sup>th</sup> the OIG published a new guidance document listing factors it will consider in implementing its permissive exclusion authority under Section 1128(b)(15) of the Social Security Act, which authorizes the exclusion of owners, officers or managing employees of an entity that has been excluded or convicted of certain offenses. Officers and managing employees may be held to a higher standard of conduct than owners. Significantly, officers and managing employees may be excluded even in the absence of evidence demonstrating knowledge of the underlying misconduct.

Today, Marc Hermelin, former chairman of the board of KV Pharmaceutical Co., has become the first drug company executive to be banned from participating in federal health care programs. Mr. Hermelin was reportedly removed as CEO in December 2008 for cause; something he disputed as he maintained

he had retired. The company announced his resignation from the board effective today. The exclusion follows a KV subsidiary's conviction on criminal charges earlier this year for shipping oversized morphine tablets.

Executive prosecutions via criminal indictments, or the use of permissive exclusions appear to be a DOJ enforcement tool that we will continue to see in the near future. Aside from a stern warning to Compliance Departments of the need for a robust and proactive compliance program, this new trend should at the very least provide support for your Compliance Department budgeting process.

*As always, if you have any questions, comments, or concerns we can be reached at [sreardo23@independent-commercial-compliance.com](mailto:sreardo23@independent-commercial-compliance.com) or at (908) 370-4085.*