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The U.S. Government's Recent Efforts to Ban Pharmaceutical Executives from the Industry Without Due Process

BY THE WHITE COLLAR CRIME AND REGULATORY ENFORCEMENT PRACTICE

Earlier this month, as part of the Obama Administration's effort to make the case that it will pursue individual high-level executives and CEOs in addition to the companies they run, the Office of the Inspector General, Department of Health and Human Services ("HHS-OIG") informed the Chairman, CEO and President of Forest Laboratories Inc. ("Forest Labs") that it intends to exclude him from doing business with the federal government. Such an exclusion of Forest Labs' top executive could prevent Forest Labs from selling its drugs in connection with government programs such as Medicare, Medicaid and the Veterans Administration, which could amount to a corporate death sentence, unless the company drops the executive. One would think that the executive must have been found guilty of criminal activity, or found liable for misconduct in a civil lawsuit, but that is not the case. The executive has never been accused of or charged with any wrongdoing.

According to a press release by Forest Labs,[1] this potential action stems from a global settlement in September 2010 with the U.S. Department of Justice ("DOJ"), as part of which the company, among other things, pled guilty to two no-intent, strict liability misdemeanor violations of the federal Food, Drug and Cosmetic Act (FDCA) relating to conduct that occurred almost a decade ago involving the distribution and marketing of Levothroid and Celexa. Forest Labs' settlement with the DOJ included no acknowledgment of wrongdoing by the now targeted executive.[2]

The HHS-OIG has not yet made a final decision concerning its potential action against the Forest Labs executive; however, the agency is widely expected to act on its threat to invoke its permissive exclusion authority under Section 1128(b)(15) of the Social Security Act.[3] The permissive exclusion authority permits the HHS-OIG to exclude certain entities and individuals, including officers or managing agents of a company convicted of certain offenses, from participation in any federal health care program. While owners of the entity may be excluded only if they knew or should have known about the conduct that led to the sanction, officers or managing employees may be excluded based solely on their position within the entity, whether or not they knew or should have known about the bad conduct.[4] In October 2010, the HHS-OIG issued a notice which provided guidance regarding the factors that it would consider in deciding whether to exclude individuals.[5] The factors that the HHS-OIG will consider include the circumstances of the misconduct, seriousness of the violations, the individual's role within the entity and the individual's response to the misconduct.

The action against the Forest Labs executive, if taken, represents an aggressive use of sanctions to exclude an executive who has not been personally accused of or charged with any wrongdoing. Despite the HHS-OIG's seemingly broad power to exclude, in prior HHS-OIG permissive exclusion actions against pharmaceutical executives, criminal or civil charges against the individuals themselves have preceded or closely followed such actions. For example, in 2007, three Purdue Frederick Co. executives who had previously pled guilty to criminal misdemeanor misbranding charges were excluded by the HHS-OIG.[6] More recently, in November 2010, Marc Hermelin, an owner/operator of KV Pharmaceutical, was excluded by the HHS-OIG prior to civil or criminal charges, but such charges were clearly contemplated at the time, and Hermelin pled guilty to two criminal misdemeanor violations shortly thereafter.[7]

The HHS-OIG's stated intent to exclude executives against whom the government has insufficient evidence to charge criminally or civilly is a troubling development, because it provides little meaningful opportunity for the individuals to defend against the exclusion. It is the HHS-OIG's view that there is no opportunity for administrative or judicial review, although this view will likely be tested in courts. Without an effective way to challenge the HHS-OIG's discretionary exclusions, the HHS-OIG has a powerful tool that is susceptible to abuse.

Moreover, the trend toward more aggressive use of the exclusion tool could impact companies outside the health care industry as well. For instance, the exclusion might also impact companies which do business with the Defense Department or the Environmental Protection Agency, as these entities have exclusion powers similar to the HHS-OIG permissive exclusion authority.

When dealing with civil and criminal investigations and cases, it is critical to develop a comprehensive strategy at the outset which addresses all risks, including new elevated risks such as the exclusion tool.

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[1] Forest Laboratories, Forest Laboratories Chairman and CEO to Challenge "Unwarranted and Unprecedented" Potential Action to Exclude Him from Federal Healthcare Programs (April 13, 2011), available at http://www.frx.com/news/PressRelease.aspx?ID=1550242 (last visited on Apr. 26, 2011).

[2] *See supra* note 1.

[3] The Section states, "The Secretary may exclude the following individuals and entities from participation in any Federal health care program… Any individual—(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or (ii) *who is an officer or managing employee of such an entity.*" (emphasis added)

[4] "With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity." *Id.*

[5] Office of Inspector General, *Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act* (Oct. 19, 2010), available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited on Apr. 26, 2011).

[6] Office of Inspector General, *Administrative Law Judge Upholds HHS-OIG Exclusions Imposed Against Responsible Corporate Officers in OxyContin Case,* Office of Inspector General News (January 23, 2009), available at http://oig.hhs.gov/publications/docs/press/2009/hhs_oig_press_01232009.pdf (last visited on Apr. 26, 2011).

[7] Harris, Andrew and Joe Whittington, *Ex-KV Pharmaceutical CEO Hermelin Pleads Guilty to Drug Label Law Breach*, Bloomberg.com (March 10, 2011), available at http://www.bloomberg.com/news/2011-03-10/ex-kv-pharmaceutical-ceo-hermelin-pleads-guilty-to-drug-label-law-breach.html (last visited on Apr. 26, 2011).