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# Risky Business: The Pursuit Of Healthcare Industry Executives And Managers

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This week's indictment of a former vice president and associate general counsel of GlaxoSmithKline PLC is causing a stir in the healthcare industry and beyond. This case is making waves in part because a company's in-house counsel faces allegations of obstruction and false statements in connection with her analysis and advice related to an off-label promotion investigation. However, the prosecution of a healthcare industry executive is itself no surprise to those who have been following recent statements by federal officials. Although the Department of Justice (DOJ) indictment is getting substantial coverage, the manner in which the Department of Health and Human Services (HHS) is ramping up enforcement efforts against individuals offers even greater insight into the risks facing today's healthcare executives.

Recently issued guidance from the HHS Office of Inspector General (OIG) seeks to target a broad range of individuals, setting forth nonbinding factors that the OIG says it may use to decide whether to apply its federal healthcare program exclusion authority to an officer or a managing employee of an excluded or convicted entity. *See* OIG, *Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act* (October 20, 2010) *available at* *http://www.oig.hhs.gov/fraud/exclusions.asp*. The breadth of the authority asserted in the guidance reflects the OIG's recent commitment to pursuing individuals, including any uncharged healthcare industry executives and managers the OIG deems responsible for the actions of their companies. Similarly, Food and Drug Administration (FDA) officials are stressing their intent to increase the number of cases in which they refer misdemeanor misbranding charges against individuals under the responsible corporate officer doctrine of *United States v. Park,* 421 U.S. 658 (1975), to USDOJ for prosecution.

Going forward, the ability of compliance programs to prevent healthcare fraud and other regulatory offenses may have greater personal significance for key officers and managing employees in the healthcare industry.

**OIG's Permissive Exclusion of Officers and Managing Employees**

Under Section 1128 of the Social Security Act (Act), the OIG has authority to exclude individuals and entities from participation in federal healthcare programs. The Act identifies certain types of criminal convictions and other derivative grounds upon which the OIG, in its discretion, may base exclusion. One ground for permissive exclusion, Section 1128(b)(15), authorizes the OIG to exclude an individual based upon the individual's role or interest in a sanctioned entity. Specifically, Section 1128(b)(15) authorizes the OIG to exclude officers or managers of any entity that is excluded, convicted of, or pleads to particular healthcare offenses. The healthcare offenses that can trigger this exclusion authority include the increasingly common plea to a misdemeanor misbranding violation of the Food, Drug and Cosmetic Act.

The OIG's new guidance effectively announces its intention to make greater use of this authority to exclude a wide array of individuals based on their relationship to sanctioned corporations—regardless of whether the individuals themselves have been convicted or even charged in the underlying case. Within a company, the new guidance claims OIG has the authority to exclude all "officers" as well as any "managing employees"—defined as individuals with operational or managerial control over the entity or who directly or indirectly conduct day-to-day operations. Under its newly articulated standard, the OIG will apply a *presumption* in favor of exclusion if the OIG determines there is evidence that the officer or managing employee knew "or should have known" of the conduct that formed the basis for the corporate sanction. The presumption may be overcome if the OIG determines that unidentified "significant factors weigh against exclusion." The new guidance also describes a second basis for exclusion of officers and managers in the absence of evidence triggering the presumption of exclusion and identifies the set of factors the OIG will consider to determine whether to exclude such individuals.

The OIG guidance explains that when assessing whether to impose a derivative permissive exclusion on an officer or managing employee where there is no evidence that the individual knew or should have known of the misconduct, the OIG will consider four categories of factors: (1) information about the entity; (2) individual's role in entity; (3) circumstances of the misconduct and seriousness of the offense; and (4) individual's actions in response to the misconduct. While exclusion is intended to be a prophylactic remedy protecting federal healthcare programs and beneficiaries from harm the excluded person could cause, the OIG's categories focus primarily on the conduct and character of the convicted corporation and not the individual who may be excluded—the first two

categories look at the company and the individual's position in the organization, and the third focuses on the *company's* misconduct and the resolution. It is only the fourth category that looks at the individual's relationship to the company's misconduct. These factors emphasize that the OIG is willing to exclude officers and managing employees based on the misconduct of others in a corporation, even if the individual being excluded was reasonably unaware of the wrongdoing.

The new guidance is aggressive not only because it seeks to hold executives accountable for the misconduct of others but also because of the scope of what is considered relevant misconduct. The OIG has interpreted misconduct to include not only the factual basis for the corporate sanction, but also "any other conduct OIG considers relevant." The OIG specifically identifies allegations in criminal, civil, or administrative matters, as well as conduct that formed the basis for any criminal, civil, or administrative investigation, to be relevant in its consideration. Taken to its extreme, the OIG's guidance arguably claims the authority to exclude an individual based on allegations of misconduct of which the individual was not only unaware but are also unsubstantiated.

**Other Enforcement Efforts Against Individuals**

The OIG's guidance is paired with efforts by DOJ and the FDA to focus increasingly on seeking sanctions against healthcare industry executives and employees. In a March 4, 2010 letter, FDA Commissioner Margaret Hamburg told Senator Grassley that the agency has developed criteria for use in selecting appropriate cases for charging executives with misdemeanor misbranding. In recent weeks, Eric Blumberg, Deputy Chief for Litigation, Office of the Chief Counsel FDA, reiterated the agency's intention to pursue *Park* doctrine misdemeanor prosecutions against industry executives. In one notable recent case in which Hogan Lovells represents the individuals involved, the OIG extended its exclusion authority to executives convicted of strict liability misdemeanors under that doctrine.

**Ramifications**

The headlines may focus on the efforts of DOJ; however, activities of HHS offer more robust insight into the likelihood of expanded future enforcement and sanctions against individuals. Notably, the OIG seems committed to continued expansion of its authority to reach executives and managers whether or not those individuals are charged in criminal investigations or had any reason to know of the misconduct in question. Corporate leadership would do well to reassess their organizations' compliance infrastructure in light of the potential for personal exposure. Where ignorance (or even responsible oversight) is no defense to conviction and exclusion when any misconduct occurs, the only available safeguards may be robust compliance operations that demonstrate "extraordinary care."