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Enforcement Focus on Individuals: The HHS OIG's Multifaceted Assault





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The Department of Health and Human Services Office of Inspector General (OIG) is in the midst of an aggressive push to redefine its role.

Through a multi-faceted assault, the OIG is using the theory underlying the responsible corporate officer doctrine of *United States v. Park*, 421 U.S. 658 (1975) to expansively interpret its authority to pursue the individuals it deems responsible for abuses in the health care industry.

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In 2008, the OIG began by excluding, for the first time ever, health care industry executives from participation in federal health care programs based on their pleas to strict liability misbranding offenses under the responsible corporate officer doctrine.

Since then, the termination of executives and managers deemed responsible by the OIG has become a frequent sticking point in the negotiation of corporate integrity agreements.

In October, the OIG set forth nonbinding factors it will consider in deciding whether to exclude an officer or a managing employee of an excluded or convicted entity—regardless of whether these individuals have themselves been convicted or even charged in the underlying case. *See* Guidance on Implementation of Permissive Exclusion Authority (October 2010) available at http://www.oig.hhs.gov/fraud/exclusions.asp.

Now, the OIG is soliciting recommendations for supplements to its 1999 Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs. 75 Fed. Reg. 69,452, 69,452-53 (Nov. 12, 2010).

This expansion of the OIG's authority, when taken together with the far-reaching ramifications of exclusion,

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creates an unprecedented level of exposure for industry executives and employees.

''[W]e recognize that the way we are going to change corporate cultures is by focusing on individuals.''

LEWIS MORRIS, CHIEF COUNSEL, HHS OIG
TESTIMONY BEFORE A JOINT HEARING OF THE HOUSE WAYS AND MEANS SUBCOMMITTEES ON HEALTH AND OVERSIGHT

Exclusion: ''The Nuclear Option''

Under Section 1128 of the Social Security Act (Act), the secretary of health and human services, and by delegation the OIG, has authority to exclude individuals and entities from participation in federal health care programs. Exclusion is often referred to within the industry as the ''nuclear option'' based on its devastating effect on the excluded party.

The OIG has made clear that the exclusion of an individual or entity means that no federal health care program may make a payment for any items or services furnished, ordered, or prescribed by the excluded individual or entity. The prohibition on payments applies to the excluded person or entity, and to anyone who employs or contracts with the excluded person or entity, any hospital or other provider where the excluded person provides services, and anyone else.

In 1998, the OIG stated that indirect providers such as pharmaceutical or medical device manufacturers may be subject to exclusion. 63 Fed. Reg. 46676, 46678 (Sept. 2, 1998).

The ramification of exclusion for officers or executives of pharmaceutical or medical device manufacturers, as elaborated in OIG guidance, is that those individuals cannot work in the health care industry unless: 1) their work is wholly separate from any item or service (including administrative and management services) reimbursable by federal health care program; and 2) their salary (or consulting fee) is paid from funds wholly separate from any monies that can be tied to, or that are commingled with, direct or indirect federal health care program funds. *See* HHS-OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (Sept. 1999), *available at* http://www.oig.hhs.gov/fraud/alerts/effect_of_exclusion.asp.

(Note, however, that the OIG has taken a much broader view in public fora, questioning why the government would want to do business with any company that seeks to employ a convicted individual in any capacity. *See* Comments of Lewis Morris, HHS OIG, ABA White Collar Crime Conference, Feb. 26, 2010.)

The current solicitation for comments offers industry an opportunity to share its concerns about the disproportionate impact on indirect providers such as employees of manufacturers. Even if the OIG elects to narrow its interpretation of the impact on exclusion on indirect providers, it remains the case that going forward, the OIG will seek to apply this and related enforcement tools aggressively.

OIG Follow-On Enforcement

The opening salvo in the OIG's current efforts to target individuals was rooted in Food and Drug Administration and Department of Justice enforcement actions.

Under *Park*, an individual can be held liable for a strict liability Food Drug and Cosmetic Act (FDCA) violation even absent knowledge of or intent to cause the violation if at the time of the misconduct, the individual ''had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.'' *Park*, 421 U.S. at 673-74.

In 2007, DOJ revived the long-dormant *Park* doctrine to prosecute three pharmaceutical industry executives for strict liability misdemeanor misbranding violations of the FDCA.

The OIG excluded the executives under Section 1128(b)(1) of the Act, which allows for exclusion as a result of a misdemeanor conviction ''relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.'' 42 U.S.C. § 1320a-7(b)(1).

The OIG concluded that these convictions were sufficient to trigger its permissive exclusion authority even though the convictions were based solely on the executives' positions in the company and not on any individual misconduct or fraudulent intent.

High-ranking officials from the FDA have stressed that the agency intends to increase the number of cases in which they pursue misdemeanor misbranding charges against individuals under the *Park* responsible corporate officer doctrine.

Accordingly, the OIG will likely have increasing opportunities to assert its exclusion authority over executives convicted pursuant to the *Park* doctrine.

OIG-Initiated Enforcement

More recently, the OIG has taken upon itself the responsibility to identify individuals it deems responsible for corporate misconduct and pursue its own remedies. Informally, the OIG has begun to use the settlement negotiation process as a venue to query companies about key individuals it believes may have been involved, or could have prevented, the alleged corporate misconduct.

In an interview with PBS, Lewis Morris, chief counsel with the HHS OIG, explained: ''We have been talking to some companies, even as we speak, about executives within their current power structure who we would like to know what responsibility they had when the misconduct took place, what opportunities did they have to stop the problem and why they didn't affirmatively step in and prevent the abuse of our program.'' *High-Level Execs Accountability for Corporate Health Care Crimes* March 19, 2010, *available at* http://www.pbs.org/nbr/site/features/special/archives/pharmaceutical_companies/final_health_care_push_100319/.

Mary Riordan, senior counsel in the Office of Counsel to the Inspector General, speaking at the March 4, 2010, Second Annual Summit on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies in Washington, D.C., alluded to the

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possible corporate ramifications for a company choosing to retain relationships with individuals of interest to the OIG, stating ''it gives [the OIG] pause to continue doing business with that company on a going forward basis.''

We are aware of a number of negotiations in which companies have agreed to separate themselves from individuals of interest to the OIG. Indeed, divesting of such individuals appears increasingly important for the corporation itself to avoid the ''nuclear option.''

In addition to removing individuals through negotiation, the OIG has issued new guidance announcing its intention to make greater use of its existing authority to exclude uncharged individuals based on their relationship to corporations convicted of healthcare offenses under Section 1128(b)(15) of the Act.

Section 1128(b)(15) authorizes the OIG to exclude officers or managers of any entity that is excluded, convicted of, or pleads to particular health care offenses. Within a company, the new guidance claims the 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 misconduct forming 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. Under existing exclusion authority, individuals excluded based on this guidance have no right to challenge the OIG's determination until after the exclusion has been imposed.

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 the 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 health care 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.

In the end, it is only the fourth category that looks at the individual's relationship to the company's misconduct.

Notably, the OIG has interpreted misconduct to include not only the factual basis for the corporate sanction but also ''any other conduct OIG considers relevant.'' 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.

How broadly the OIG will seek to apply the authority claimed in the guidance remains to be seen. That it will use this authority is beyond question.

Within weeks of the guidance, the OIG excluded the former chairman of the board and chief executive officer of a specialty pharmacy company, who was uncharged in the prosecution leading to the conviction of a corporate subsidiary. Such actions may foreshadow the fate of many other health care executives and managers.

Implications

In sum, the OIG is continuing to expand its authority through informal and formal methods to reach health care industry executives and managers whether or not those individuals are charged in criminal investigations. Where the OIG pursues exclusion, the professional impact of becoming an OIG target is profound.

Indeed, the willingness of the OIG to apply the ''nuclear option'' to individuals where there is no evidence that they should have known of corporate misconduct could have a detrimental impact on the ability of responsible manufacturers to hire compliance-focused managers and officers.

Companies may be well advised to use the comment period on the impact of exclusion to highlight this and other potential unintended consequences of the OIG's pursuit of individuals.