Advisory

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WIGGIN AND DANA

Counsellors at Law

Recent Developments Highlight The Breadth of OIG's Exclusion Authority

If you have any questions about this Advisory, please contact:

Maureen Weaver
203.498.4384
mweaver@wiggin.com

James I. Glasser
203.498.4313
jglasser@wiggin.com

Joseph Martini
203.498.4310
jmartini@wiggin.com

The authority of the Office of the Inspector General of the Department of Health and Human Services ("OIG") to exclude individuals who themselves engage in wrongdoing from participation in health care programs is well-established. Indeed, exclusion under those circumstances is viewed as a logical consequence of a criminal conviction based on an individual's personal involvement in health care fraud. But what of situations where there is no evidence that an individual personally engaged in wrongdoing? Can OIG exclude an individual whose only offense was serving as an officer of an entity that is convicted of a crime, or whose individual conviction is founded solely on a theory that as a "responsible corporate officer" the individual had an obligation to prevent the offense but failed to do so? Recent developments have made it abundantly clear that exclusion is not only available but will be sustained upon judicial review.

Exclusions of Purdue Pharma Executives Upheld

On December 13, 2010, a federal judge upheld an order that barred three Purdue Pharma executives – the President and CEO, the Chief Medical Officer, and the Chief Legal Officer – from participating in Medicare, Medicaid and all other federal health care programs for 12 years.[1] The exclusion followed the officers' guilty pleas to misdemeanor violations involving the misbranding of Oxycontin entered as part of a global settlement of the government's investigation of a subsidiary of Purdue Pharma L.P.

Significantly, the misdemeanor offense to which the guilty pleas were entered did not require, as an essential element of the offense, proof that the officers personally engaged in any wrongdoing, or were otherwise aware of or intended conduct resulting in the violation. Rather, the officers' liability was founded solely on the "responsible corporate officer" doctrine developed by the U.S. Supreme Court in its decisions in United States v. Dotterweich and United States v. Park. In essence, the "Park doctrine" provides that business executives can be held strictly liable upon a finding that they were in a position to prevent, detect or correct the violation, but failed to do so. Applying the Park doctrine, the Judge found that exclusion of the three Purdue Pharma officers was authorized despite the fact that they had not directly participated in any criminal activity. The court relied on the officers' convictions as "responsible corporate officers" at Purdue and found that the convictions bore a "nexus or common sense connection to fraud or financial misconduct in the delivery of a health care item or service."

This recent decision stems from an October 2009 federal lawsuit filed by the executives seeking to vacate the debarment order or to have it remanded to the Department of Health and Human Services for further administrative review. The executives made two principal arguments, based on the wording of the exclusion statutes and based on the propriety of exclusion of those convicted under the Park doctrine. The court rejected both arguments.

In making its exclusion decision, OIG relied on a statute that permitted exclusion of individuals convicted of a misdemeanor (1) "related to fraud . . . in connection with the delivery of a health care item or service," and (2) "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

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See 42 U.S.C. § 1320a-7(b)(1) and (3). The officers argued that "their convictions related neither to fraud nor the unlawful distribution of a controlled substance because the convictions were based solely on their positions within the corporate hierarchy during the relevant time period." In other words, they argued that the exclusion statutes should be applied only where the underlying offense involved an individual's own fraudulent conduct. The court rejected the officers' interpretation of the exclusion provisions as flying in the face of the plain meaning of the exclusion statute which permits the exclusion of anyone convicted of an offense "having a connection with or reference to fraud or financial misconduct in the delivery of a health care item or service."

With respect to their argument based on the Park doctrine, the officers contended that their guilty pleas were founded solely on their "status" as "responsible corporate officers," and as such did not reflect any personal wrongdoing. Exclusions from participating in all federal health care programs under such circumstances, they argued, was simply improper. The federal district court rejected this claim. In the court's view, the misdemeanor convictions were not solely the by-product of the officers' "status" within Purdue Pharma. Rather, the court found that while their position within the company was relevant, it was simply one link in the causal chain needed to establish liability under the Park doctrine.

According to the court, a "responsible corporate officer" conviction is viable only if the officer had a "responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce . . . misbranded drugs." While recognizing that the doctrine "dispenses with the conventional requirement for criminal conduct, [that is,] awareness of some wrongdoing," the court found that the imposition of criminal responsibility was not boundless. The government had to establish that each defendant had the "power ... to prevent or correct the prohibited condition" but failed to do so. According to the court, "[c]orporate officials are thus subject to prosecution under the doctrine only if they stand in some 'responsible relationship' to a specific violation of the Act, meaning that their 'failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation complained of.'" Put another way, "to establish a prima facie case, the government must introduce evidence demonstrating that 'the defendant 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.'"

OIG Has Applied the Park Doctrine to Its Permissive Exclusion Analysis

In October 2010, OIG published a guidance document that made clear its view that it has the authority to "exclude every officer and managing employee of a sanctioned entity" based solely on their position within the entity, and regardless of whether they knew or should have known of the misconduct.[2] However, OIG has determined not to go that far, but rather to apply a number of factors in determining whether to exclude "officers and managing employees" based solely on their positions within the sanctioned entity. While it is refreshing to see that OIG, as a matter of published guidance, has pulled back from a position of blanket exclusions of corporate officers based solely on "status," a review of OIG's factors shows that there is still reason for concern.

OIG's guidance document states that its factors were derived from several sources, including "the responsible corporate official doctrine established [in] U.S. v. Park." In fact, a review of the factors reveals that the Park doctrine had a significant influence on

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OIG's guidance document. In particular, none of OIG's listed considerations focus on the prospective excluded individual's knowledge of, or participation in, the wrongdoing. Instead, OIG indicates that it will consider the "circumstances of the misconduct and seriousness of the offense," and "information about the entity." When it comes to factors that get closer to consideration of individualized conduct, however, OIG limits its inquiry to the "individual's role in sanctioned entity," and the "individual's actions in response to the misconduct." That is, OIG is concerned about the individual's current and former position in the sanctioned entity, and whether the misconduct occurred "within the individual's chain of command," and not with whether the individual was involved in the wrongdoing. Similarly, OIG is focused on whether the individual attempted to stop the misconduct or mitigate its "ill effects," and whether the individual disclosed the misconduct to the authorities and cooperated with them.

In fact, lack of evidence that an individual participated in the misconduct is not a defense to permissive exclusion, according to OIG. Seemingly, an individual's only defense to exclusion is "[i]f the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct." Still, even if such a showing could be made, OIG will consider it only as a "factor weighing against exclusion."

Conclusion

The government's prosecution of the Purdue Pharma officers is just one example of the government's renewed interest in the "responsible corporate officer" doctrine, a development that portends an expansion of potential criminal liability. While it is comforting to read that the federal judge in the Purdue Pharma case recognized that there are limits to expansion of criminal liability, those limits seemingly are evanescent when it comes to exclusion from health care programs. Indeed, notwithstanding what the judge said in her opinion, there was little beyond the officers' "status" that supported a decision to exclude the three Purdue Pharma executives for 12 years. And, in its recent guidance, OIG does not even bother to list an individual's personal involvement – or lack thereof – as a factor that enters into its determination whether to exclude an officer of a sanctioned entity. These two developments should serve as a stark reminder of the power and reach of the Park doctrine, and of the need for health care executives to carefully consider the compliance implications of the decisions they make in carrying out their responsibilities.

1 OIG initially debarred the three executives for 20 years. Through appeals, that debarment period was reduced to 12 years.

2 By contrast, exclusion of an "owner" of a sanctioned entity requires evidence that the owner knew or should have known of the misconduct.