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Life Sciences Health Industry Alert

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Pharmaceutical Executives and In-House Counsel Beware: U.S. District Court Affirms Exclusion of Former Purdue Executives Under 'Responsible Corporate Officer' Doctrine

On December 13, 2010, the United States District Court for the District of Columbia affirmed the decision of Kathleen Sebelius, Secretary of the Department of Health & Human Services (the "Secretary"), excluding three former pharmaceutical executives for 12 years from participation in Medicare, Medicaid, and all other federal health care programs. The exclusion – the latest weapon in governmental assaults on pharmaceutical company wrongdoing – was imposed by the Office of Inspector General of the Department of Health & Human Services ("OIG"). The executives, who included the company's former general counsel, were excluded notwithstanding the fact that they asserted no knowledge of the misbranding conduct for which their former employer, Purdue Frederick Company ("Purdue"), previously settled with the government.

The decision illustrates the government's enhanced focus on individual liability and punishment in the context of fraud and abuse by health care entities, and it represents a significant development in enforcement activity in this area.

This Client Alert summarizes the court's opinion and related background. Now more than ever, we urge our health care clients – providers, suppliers, and manufacturers alike – to consider the potential impact of the OIG's permissive exclusion authority when defending against allegations of fraud or abuse involving federal health care programs. Moreover, as we have advised previously, the Food & Drug Administration ("FDA") has separately signaled its intention increasingly to bring criminal misdemeanor charges against responsible corporate officials; such charges, if proved, would then form the basis for an OIG exclusion action, as in this case.

For additional information regarding the OIG's permissive exclusion authority with respect to individuals, please see our Client Alert, "New Guidance on the OIG's Ability to Exclude Owners, Officers and Managing Employees; Related FDA Statements on Pharmaceutical Executives." http://www.healthindustrywashingtonwatch.com/2010/10/articles/other-oig-developments/oig-guidance-on-permissive-exclusion-authority/

Background on Exclusion of Purdue Executives

The Purdue executives' exclusion stems from a well-publicized government investigation and subsequent settlement related to Purdue's marketing of the pain medication, OxyContin. According to the court, from December 1995 until June 2001, certain Purdue supervisors and employees inappropriately marketed OxyContin with the intent to defraud or mislead. Specifically, they characterized the product as less addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal symptoms.

In May 2007, the government filed criminal charges against Purdue and the three executives, charging the company with misbranding a drug with intent to defraud or mislead, a felony under the Food, Drug, and Cosmetic Act ("FDCA"), and the executives as "responsible corporate officers" with misbranding the drug, a misdemeanor under the FDCA. Consistent with the Supreme Court's explanation of the "responsible corporate officer" doctrine in *United States v. Park*, 421 U.S. 658 (1975), the executives' liability was based on their responsibility and authority to prevent in the first instance, or promptly to correct, the violation complained of, regardless of whether they were aware of or intended to cause the violation. The executives held the following positions at Purdue: President and Chief Executive Officer; Executive Vice President of Medical and Scientific Affairs and Executive Vice President for Worldwide Research and Development; and Executive Vice President and Chief Legal Officer.

As part of a global settlement in May 2007, Purdue and the executives entered guilty pleas to violating the FDCA. Purdue agreed to pay a total of $600 million and entered a five-year Corporate Integrity Agreement with the OIG. The executives agreed to disgorge a total of $34.5 million, to be paid to the Virginia Medicaid Fraud Control Unit, and were sentenced to three years probation, 400 hours of community service, and a $5,000 fine. As part of their plea agreements, the executives submitted an Agreed Statement of Facts. The Statement specifies that none of the executives had personal knowledge of Purdue's misbranding of OxyContin, but acknowledges that the executives were responsible corporate officers of Purdue during the relevant time and therefore had responsibility and authority to prevent or promptly correct certain conduct resulting in misbranding.

Following the settlement, in March 2008, the OIG issued formal notices of exclusion to the Purdue executives. The OIG invoked both 42 U.S.C. § 1320a-7(b)(1), authorizing exclusion of individuals convicted of "a misdemeanor relating to fraud . . . in connection with the delivery of a health care item or service," and 42 U.S.C. § 1320a-7(b)(3), related to conviction of "a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." The OIG's initial exclusion was for a period of 20 years, an increase over the statutory period of three years, based on alleged aggravating circumstances. The OIG subsequently reduced the period of exclusion from 20 to 15 years after considering additional mitigating evidence related to the executives' cooperation with federal and state law enforcement officials.

The executives appealed the exclusion decision to an administrative law judge ("ALJ"), who affirmed the exclusion. The executives then appealed the ALJ's decision to the Departmental Appeals Board, which issued a decision sustaining the exclusions, but reducing the length of exclusion to 12 years.

Arguments Presented by the Executives

Ultimately, the executives filed a complaint against the Secretary in the United States District Court for the District of Columbia, challenging the OIG's exclusion decision on two grounds:

> (1) The OIG's permissive authority does not authorize exclusion of individuals who are convicted of misdemeanor misbranding under the "responsible corporate officer" doctrine because such convictions do not require any evidence of personal wrongdoing; and
>
> (2) The length of exclusion was unreasonable because of the executives' lack of culpability; the fact that the aggravating factors relied on by the OIG were not supported by substantial evidence; and because the OIG failed to consider additional mitigating evidence relating to the executives' efforts to prevent the abuse of prescription drugs.

Court's Decision and Analysis

Granting the Secretary's motion for summary judgment, the court concluded that the OIG's decision to exclude the executives based on their convictions for misdemeanor misbranding under the "responsible corporate officer" doctrine was supported by substantial evidence. The court therefore affirmed the order excluding the executives for 12 years from participation in all federal health care programs.

The court found that 42 U.S.C. § 1320a-7(b) authorizes the OIG to exclude individuals convicted of misdemeanor misbranding under the "responsible corporate officer" doctrine. By its plain terms, that section permits the exclusion of anyone convicted of an offense having a connection with or reference to fraud in the delivery of a health care item or service.

Similarly, the court rejected the executives' contention that their convictions resulted solely from their status as corporate officers rather than from their own conduct. The Agreed Statement of Facts they signed specifically acknowledged that the executives served as responsible corporate officers of Purdue over a time period during which they had responsibility and authority to prevent or promptly correct certain conduct resulting in the misbranding of a drug, but they failed to do so.

Finally, with respect to the length of exclusion, the Purdue executives argued that the "aggravating circumstances" relied on by the OIG did not apply, and that the OIG failed to give sufficient weight to the executives' cooperation as a mitigating factor. The court rejected these arguments, essentially refusing to second-guess the OIG's decision, since the statute affords the Secretary discretion in determining exclusion length.

Reed Smith Analysis

It remains to be seen whether the Purdue executives will appeal the court's decision. Nonetheless, the opinion serves as a reminder not only of the importance of providers, suppliers, and

manufacturers taking affirmative steps to avoid misconduct, but also of the critical necessity for individuals in management positions to undertake an active role in aggressive compliance efforts. As we pointed out in our earlier Alert, once misconduct is proved, halting or even delaying the exclusion process is difficult.

The *Purdue* decision comes in the wake of another developing case involving a former in-house counsel at a global pharmaceutical company.[1] On November 9, 2010, the Department of Justice indicted an attorney who previously served as inside counsel, charging her with obstruction and making false statements. The indictment alleges that, in response to FDA's inquiries, the lawyer signed and sent a series of letters from the company to the FDA falsely denying that the company had promoted a specific drug for off-label uses, even though she knew, among other things, that the company had sponsored numerous programs at which the drug was promoted for unapproved uses. The indictment alleges further that she knew that the company had paid numerous physicians to give promotional talks to other physicians that included information about unapproved uses of the drug.

These cases illustrate that the focus of governmental enforcement activity against manufacturers has expanded to include individual officers, employees, and counsel. For its part, the OIG intends increasingly to use its permissive authority to exclude individuals – whether with manufacturers or providers – in order to positively influence individual behavior and compliance with federal health care program requirements. The court in the *Purdue* case asserted that the consequences of exclusion are not dire because the executives remain free to seek private employment at a company that does not rely on federal or state funds. Nevertheless, the exclusion of an individual from participation in federal health care programs, including Medicare and Medicaid, and particularly for the length of time at issue here, is likely to result in ending such individual's career in health care – a dire consequence indeed for many who have spent their professional lives in the health care field.

In light of this potential outcome, the possibility of the permissive exclusion of individuals must be considered when negotiating a settlement of allegations of fraud or abuse against a health care provider, supplier, or manufacturer. In addition, the potentially conflicting interests of health care entities facing sanctions, and those individuals subject to sanctions by virtue of their role within the entity, may require earlier efforts to obtain separate legal representation, a situation sure to further complicate an already complex and difficult process.

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The contents of this Memorandum are for informational purposes only and do not constitute legal advice.

1 http://www.justice.gov/opa/pr/2010/November/10-civ-1266.html

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