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LAW UPDATE

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For additional information on this or any white collar criminal law related issue, please contact RMF's White Collar Crime & Investigations co-chairs: Alexander G. Bateman, who can be reached at 516-663-6589 or abateman@rmfpc.com or Gregory J. Naclerio, who can be reached at 516-663-6633 or gnaclerio@rmfpc.com Sept

GOOD WORKS OVERCOME OIG'S EXCLUSION PRESUMPTION FOR FOREST LABS' CEO

Forest Laboratories, Inc. (NYSE: FRX)("Forest Labs") recently avoided a devastating sanction from the Health and Human Services Office of the Inspector General ("OIG"). The OIG announced August 5, 2011 that it would not take any action pursuant to its permissive exclusion authority against Howard Solomon, Forest Labs' CEO. If the OIG had imposed the sanction, Mr. Solomon and any company he worked for or owned would have been barred from participating in any federal health care program, including Medicare Part D. Forest Labs is a pharmaceutical company with a \$9 billion market capitalization, and Mr. Solomon has been its CEO for the past 30 years. The OIG's announcement provides prescient guidance to help other companies from losing key executives.

The threat to Forest Labs highlights the peril that companies reliant upon participation in federal health care programs face when charged with crimes. Even misdemeanor pleas may result in corporate executives facing OIG's equivalent of the death penalty: exclusion from participation in federal health care programs. If an executive is excluded, a company may no longer employ that individual. This can have devastating consequences.

The Criminal Case

As detailed in a September 15, 2010 DOJ release found here, Forest Labs pleaded guilty to one felony obstruction charge and two misdemeanors related to two drugs it illegally marketed. All together, Forest Labs paid \$313 million to resolve all criminal and civil liability, including a 2009 False Claims Act case. Mr. Solomon was never charged with any crimes.

OIG's Exclusion Authority

Under Section 1128(b)(15) of the Social Security Act, the OIG is permitted, but is not required, to exclude an individual from participation in federal health care programs if the individual: (i) has a direct or indirect ownership or control interest in a "sanctioned entity" and knows or should know of the action constituting the basis for the entity's conviction or exclusion or (ii) is an officer or managing employee of such an entity. A "sanctioned entity" is defined as any entity that has been convicted of a pertinent crime or that has been excluded from participation. In this case, Forest Labs qualifies as a sanctioned entity, which triggered Mr. Solomon's eligibility for exclusion under 1128(b)(15)(ii).

OIG's Exclusion Guidance

In October 2010, the OIG issued a "Guidance for Implementing Permission Exclusion Authority Under Section 1128(b)of the Social Security Act," (the "Guidance") which may be found here. The Guidance states that, under certain circumstances, OIG will operate under a presumption in favor of exclusion when dealing with owners, officers, and managing employees of sanctioned entities. For owners, if the evidence shows that an owner knew or should have known of conduct that formed the basis for the sanction, it will trigger the exclusion presumption. For officers and managing employees, as defined in SSA § 1126(b), the statute does not require knowledge of wrongdoing, and the OIG has the authority to exclude every officer and managing employee of a sanctioned entity.

The OIG's published guidance says that it does not wish to exclude every officer and

managing employee of a sanctioned entity, and it will operate with the exclusion presumption primarily in cases in which the officer or managing employee knew or should have known of the sanctioned conduct.

Once the presumption is triggered, an individual must present mitigating evidence to the OIG to overcome the presumption. Factors that the OIG will evaluate are:

- Circumstances of the Misconduct and Seriousness of the Offense
- The Individual's Role in the Sanctioned Entity
- The Individual's Actions in Response to the Misconduct
- Information About the Entity

Forest Labs' Mitigating Factors

Using the above four factors, Mr. Solomon's attorneys argued that his minimal involvement in the sanctioned conduct as well as his scrupulous implementation of a robust compliance plan even before criminal charges were filed overcame OIG's exclusion presumption. Considering the swift corrective action that Mr. Solomon took and the devastation his loss would cause to Forest Labs, the OIG issued its determination not to exclude Mr. Solomon.

Forest Labs' example highlights the pivotal role that counsel conversant in both white collar criminal defense as well as health law can play to avoid potentially devastating OIG sanctions that can follow even minor criminal cases.

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