

The OIG Backs Off Intended Exclusion of Forest Laboratories' CEO

On August 5, 2011, the Office of the Inspector General, U.S. Department of Health and Human Services (the "OIG"), notified Howard Solomon, the CEO of Forest Laboratories, that the OIG would take no action against him under the permissive exclusion authority accorded the OIG by Section 1128(b)(15) of the *Social Security Act* ("SSA"). This decision is perhaps the final coda to the September 2010 resolution of criminal and civil allegations against Forest Laboratories and its wholly-owned subsidiary Forest Pharmaceuticals for *Food, Drug and Cosmetic Act* ("FDCA") violations, which resulted in a misdemeanor plea by Forest Pharmaceuticals. Although the OIG's decision this month provides a measure of solace that the OIG will use its authority to exclude officers and directors of sanctioned entities judiciously, the fact that Mr. Solomon—an individual with no direct involvement in the alleged wrongdoing—had to litigate this issue at all may signify an enforcement trend by the OIG that should be considered in the course both of resolving federal investigations and of conducting routine compliance activities.

Legal Background

Section 1128(b)(15) of the SSA permits, but does not require, the OIG 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" in this context is any entity that has been convicted (including by a plea of guilty) of a pertinent crime or that has been excluded from participation.

Although this section of the SSA dates back to 1996, it has rarely been used, and it was not until October 2010 that the OIG issued [guidance](#) on this provision, announcing that the OIG would now "operate with the *presumption in favor* of exclusion" of officers, directors and senior managers (the "Guidance"). The Guidance focuses on whether owners of sanctioned entities had knowledge of the conduct that gave rise to the sanctioning of the entity. However, with respect to officers and other "managing employees," the OIG considers a series of "informal and nonbinding" mitigating factors to determine whether exclusion is warranted. These include: "(1) the circumstances of the misconduct and seriousness of the offense; (2) the individual's role in the sanctioned entity; (3) the individual's actions in response to the misconduct; and (4) information about the entity." As the presumption is now in favor of exclusion, officers and directors targeted for exclusion by the OIG now bear the burden of establishing and presenting favorable mitigating information.

The OIG's First Exclusion Under its New Guidance

Barely one month after announcing the Guidance, the OIG used its Section 1128(b)(15) authority to exclude the former Chairman of the Board, CEO and controlling shareholder of KV Pharmaceutical Co., Marc Hermelin. Although Mr. Hermelin was the first pharmaceutical company board member and CEO to be excluded under the new Guidance, the fact that Mr. Hermelin was convicted of two misdemeanor FDCA offenses meant that his exclusion did not answer important questions raised by the Guidance about the OIG's view of the potential scope and reach of section 1128(b)(15). Mr. Hermelin was sentenced to 90 days imprisonment for his strict liability "Park" conviction. The OIG Notice of Intent to Exclude Mr. Solomon, by contrast, was the first time that the OIG initiated proceedings under Section 1128(b)(15) against an executive who had neither been convicted nor even alleged to have been directly involved in a criminal offense.

Basis for Exclusion of Howard Solomon

In September 2010, Forest Pharmaceuticals pled guilty to one felony for obstructing an FDA inspection, one FDCA misdemeanor for distributing an unapproved drug (Levothroid), and one FDCA misdemeanor for distributing a misbranded drug (Celexa). As part of a global settlement to resolve these criminal charges and civil liability under the *False Claims Act*, Forest paid a total of \$313 million and entered into a five-year corporate integrity [agreement](#).

Shortly after the company's plea was accepted by the court on March 2, 2011, the OIG sent written notice of its intent to exclude Mr. Solomon under 1128(b)(15) of the SSA. This notice triggered a 6-month effort by Mr. Solomon, Forest and their counsel to persuade the OIG—under the principles announced in the Guidance—not to exclude Mr. Solomon.

Factors Mitigating Against Exclusion

1. The circumstances of the misconduct and seriousness of the offense

Mr. Solomon's counsel argued that the conduct that gave rise to Forest's misdemeanor pleas was unique and narrow in scope. Forest's misconduct relating to Levothroid and Celexa was either minimal (not generating a significant percentage of off-label sales), based on reasonable interpretations of FDA guidance or not sufficient to raise issues of patient safety.

2. Individual's Role in the Sanctioned Entity

Counsel further argued that Mr. Solomon promoted compliance at Forest and had limited involvement in the misconduct at issue. They stressed his past involvement in Forest's compliance program, his consistent promotion of compliance and ethical behavior and his instrumental role in implementing and enhancing Forest's compliance program. With respect to Levothroid, Mr. Solomon's counsel argued that he reasonably relied on the advice of experienced FDA regulatory experts in the promotion of that drug. As to Celexa, the incidence of off-label prescriptions was such a small percentage of sales and below the market average that Mr. Solomon's counsel argued that there was no reason to believe that Mr. Solomon would be aware of off-label promotion in the field being a problem—especially considering Forest's policy and training against off-label promotion.

3. Actions in Response to the Misconduct

In addition to developing a robust compliance program prior to the start of the investigation, counsel argued that Mr. Solomon responded swiftly to the conduct uncovered by the investigation. Physicians who may prescribe predominantly outside of an approved indication were removed from call panels, policies were strengthened, employees were disciplined and a review of sales representative call notes and physician recall statements for indications of improper sales messaging was initiated.

4. Information about the Entity

Mr. Solomon's counsel argued that Forest was not a recidivist, was subject to a comprehensive Corporate Integrity Agreement and would suffer significant collateral consequences if Mr. Solomon were excluded. Mr. Solomon had been CEO at Forest for over thirty years and had also recently assumed the roles of President and Chief Operating Officer when his presumed successor unexpectedly retired.

Lessons Learned

The OIG's decision to take no action against Mr. Solomon shows that the OIG will give careful consideration to the mitigating factors enumerated in the Guidance, and that a compelling presentation on those factors may effectively rebut the presumption in favor of exclusion. Despite Mr. Solomon's success, however, the circumstances that may trigger a Notice of Intent to Exclude and what the OIG will deem sufficient to rebut the presumption in favor of exclusion in other contexts remains uncertain.

Nonetheless, some things are clear. First, companies that plead guilty to a health-care related offense may find that business-critical executives or board members face administrative proceedings in the wake of that plea. While Mr. Solomon's case shows that the initiation of such proceedings does not necessarily mean that exclusion will result, the pendency of the proceeding itself can have a significant impact on the business during a critical time. Second, Mr. Solomon's successful reliance on his ongoing involvement in Forest's compliance program and the actions he took in response to the conduct uncovered by the investigation show that proactive involvement by key individuals in compliance will not only strengthen a company's compliance program, but it will also help address the OIG's concerns about such individuals' continued participation in federal health care programs at a later date.

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