



## Life Sciences Health Industry Alert

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### New Guidance on the OIG's Ability to Exclude Owners, Officers and Managing Employees; Related FDA Statements on Pharmaceutical Executives

On October 20, 2010, the Office of Inspector General (OIG) of the Department of Health and Human Services issued significant new guidance for implementing its permissive exclusion authority under Section 1128(b)(15) of the Social Security Act. As background, "exclusion" refers to the ability of the OIG to exclude individuals or entities from participating in the federal health care programs. Section 1128(b)(15) specifically authorizes the OIG to exclude an owner, officer or managing employee of a sanctioned entity, i.e., health care provider, supplier, or manufacturer, from participation in federal health care programs.

The OIG's new guidance sets out non-binding factors which the OIG intends to consider in deciding whether to impose exclusion on owners, officers and managing employees. This memorandum summarizes the OIG's new guidance and encourages our clients to take proactive measures against potential abuses and misconduct, as exclusion likely precludes an individual from employment with any health care provider or supplier. We have also noted below recent statements by officials of the Food & Drug Administration concerning the bringing of misdemeanor charges against executives of entities that promote off-label uses of their products. Taken together, these OIG and FDA developments clearly signal that increasing investigative and enforcement activity is forthcoming regarding the owners, officers and managing employees of providers, suppliers, and manufacturers alike.

#### New Guidelines on Permissive Exclusion

Where evidence indicates that an owner, officer, or managing employee of a sanctioned entity knew or should have known of the prohibited conduct resulting in the sanction, the OIG will operate with a presumption in favor of exclusion of the individual from participation in federal health care programs. This presumption may be overcome if the OIG finds that significant factors weigh against exclusion.

In addition, officers and managing employees may be held to a higher standard of conduct than owners. Significantly, officers and managing employees may be excluded *even in the absence of evidence demonstrating knowledge of the underlying misconduct*. The guidance sets out factors to guide the OIG's determination of exclusion for officers and managing employees, based on (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) the history and structure of the entity itself.

#### Background on Permissive Exclusion Authority

An entity that has been convicted of certain offenses, such as patient abuse, fraud or program-related crimes such as kickbacks and false claims, may be excluded from participation in federal health care programs. By virtue of their role or interest in an excluded entity, an individual owner, officer, or managing employee of a sanctioned entity may also be excluded from participation through their association with the entity. Such exclusions are subject to the discretion of the Secretary, and by delegation, the OIG. According to its new guidance, the OIG's exercise of its discretion to exclude an officer or managing employee is not subject to administrative or judicial review.

The standards for exclusions vary significantly depending on the individual's status as (1) an owner or (2) an officer or managing employee.<sup>1</sup>

## **Exclusion of Owners**

Individuals with a direct or indirect ownership or control interest in a sanctioned entity may be excluded only if they knew or should have known of the conduct that formed the basis of the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the prohibited conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome if the OIG finds that significant factors weigh against exclusion. The OIG does not describe those factors that are sufficiently significant to weigh against exclusion of an owner, and the factors described below *do not* affect the determination of whether an owner may be permissively excluded.

## **Exclusion of Officers and Managing Employees**

In contrast, officers and managing employees of a sanctioned entity may be excluded based on their position within the entity alone. Officers and managing employees need *not* have knowledge of the conduct that led to sanction of the entity. Because there is no required showing of knowledge to be subject to exclusion, officers and managing employees are at much greater risk of being excluded than owners. In its guidance, the OIG indicates that it will operate with a presumption in favor of exclusion where the evidence indicates that an owner knew or should have known of the prohibited conduct. Again, the presumption may be overcome if the OIG finds that significant factors weigh against exclusion.

## **Factors in Determining Whether to Exclude Officers and Managing Employees**

The factors outlined below describe the considerations the OIG may utilize to determine whether to exercise its permissive exclusion authority with respect to officers and managing employees of a sanctioned entity. However, the OIG makes clear in its new guidance that the presence or absence of any or all of these factors does not constitute the sole grounds for determining whether the OIG will pursue exclusion.

### **1. Circumstances of the misconduct and seriousness of the offense, including:**

- a. Nature and scope of the misconduct for which the entity was sanctioned;
- b. Nature and scope of other relevant misconduct;
- c. Level of the entity at which the misconduct occurred;
- d. The criminal sanction imposed against the entity, the amount of criminal fine, forfeiture or penalty imposed, the amount of civil or administrative payment, or the length of exclusion, as applicable;
- e. Whether the misconduct resulted in actual or potential harm to patients or financial harm to any federal health care program; and
- f. Whether the misconduct was an isolated incident or part of a pattern of wrongdoing over a significant period of time.

### **2. Individual's role in sanctioned entity, including:**

- a. The individual's current position and positions held throughout his tenure, particularly at the time of the underlying misconduct;
- b. Relation of the individual's position to the underlying misconduct; and
- c. Whether the misconduct occurred within the individual's chain of command.

### **3. Individual's actions in response to misconduct, including:**

- a. Whether the individual took steps to stop the underlying misconduct or mitigate the ill effects (*e.g.*, executed appropriate disciplinary action against the individuals responsible for the sanction);
- b. Whether the corrective action took place before or after the individual had reason to know of an investigation into the misconduct;
- c. Whether the individual can demonstrate the misconduct was unpreventable or that the individual exercised extraordinary care, but still could not prevent the misconduct;
- d. Whether the individual disclosed the misconduct to the appropriate federal and/or state authorities;
- e. Whether the individual cooperated with investigators and prosecutors; and

- f. Whether the individual responded in a timely manner to lawful requests for documents and evidence regarding the involvement of others in the misconduct.

#### 4. Information about the entity, including:

- a. Whether the sanctioned entity or a related entity has previously been convicted of a crime;
- b. Whether the sanctioned entity or a related entity has previously been found liable, civilly or administratively, or resolved a civil or administrative case with the federal government, state government, or a government entity;
- c. If the sanctioned entity has been previously convicted or held civilly liable, the prior conduct that formed the basis of that action;
- d. The size of the entity, including number of employees, revenues, and number of product lines/divisions; and
- e. The corporate structure of the entity, including number of subsidiaries, sizes of the subsidiaries, and reporting relationships between the subsidiaries.

It is worth noting that of these four categories of factors, an officer or managing employee can only impact one – the individual's actions in response to the alleged misconduct of his or her employer.

#### Related FDA Statements on Charging Executives

The Deputy Chief for Litigation of the Food & Drug Administration (FDA), Eric Blumberg, recently indicated that the FDA may pursue misdemeanor criminal charges against executives of pharmaceutical companies that promote off-label uses of their products. Mr. Blumberg suggested in a speech at the Food and Drug Law Institute's October 13, 2010 "Enforcement and Litigation Conference," that such charges may be necessary to change industry culture and deter off-label promotion since, he alleges, large monetary settlements have not done so. Mr. Blumberg's statements echo statements earlier this year by FDA Commissioner Margaret Hamburg that the agency intends to increase individual prosecutions under the responsible corporate officer theory.

Charging company executives with misdemeanors relies on the Park doctrine, named after the U.S. Supreme Court decision in *United States v. Park*, 421 U.S. 658 (1975), which allows the government to seek criminal convictions against company officials for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA). In *Park*, the Court upheld the conviction on misdemeanor charges of John Park, the president of a national retail food chain. The Court stated that an executive could be convicted, based on violations of the FDCA, even if the executive had no knowledge or involvement in the offense as long as he or she was a "responsible corporate officer" and was in a position to correct or prevent the violation. The Park doctrine is based on the theory that executives who manage companies that make and market products regulated by FDA have an affirmative duty to ensure the safety of those products. .

The use of the Park doctrine waned but has reemerged and was evident in the 2007 prosecution of several current and former Purdue Frederick Company, Inc. officials, who pleaded guilty to misdemeanor charges as "responsible corporate executives" under *Park* for misbranding OxyContin. In 2009, two executives of the Chemnutra, Inc. company pled guilty to misdemeanor charges for adulterating and misbranding food in a case involving wheat gluten tainted with melamine that was used in pet food.

#### Conclusion

One of the OIG's goals in implementing the new guidance on permissive exclusion is to positively influence individual behavior and compliance with federal health care program requirements – a goal also stated quite explicitly by the FDA officials cited above.

As shown, once proven misconduct occurs, there is little that can be done to avoid exclusion. Therefore, it is more critical than ever that providers, suppliers, and manufacturers alike take affirmative steps to avoid misconduct in the first place. The OIG has long urged that management be integrally involved in compliance efforts, and these recent developments underscore the need for such involvement. Health care practitioners and entities operating today must do so in a culture of ongoing compliance, both with documented internal policies and procedures, and with external laws, regulations, and guidelines.

The potential impact of the OIG's permissive exclusion authority must necessarily be considered when defending a health care entity against allegations of fraud or abuse of the federal health care

programs. The OIG intends increasingly to use its permissive authority to exclude owners, officers and managing employees – an outcome likely to result in ending an individual's career in health care, or, at the very least, to result in an extended absence from the health care arena for the exclusion period, unless and until the individual is reinstated. This potential outcome must be considered when negotiating a settlement of allegations of fraud or abuse against a health care provider, supplier, or manufacturer.

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

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<sup>1</sup> A "managing employee" includes a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity. 42 U.S.C. § 1320a-5.

## About Reed Smith

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