

Emerging Threats from the Responsible Corporate Officer Doctrine

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Overview of the Doctrine

- ❖ The RCO doctrine *presumes* that someone with a position of responsibility in a company has the power and duty to prevent violations that may endanger the public.
- ❖ Liability is based on a person's *status* and imposed *vicariously*. By *imputing* a duty to prevent a violation of a public welfare law, the doctrine goes beyond state statutes that criminalize the *failure to act when a specific duty to act is imposed by statute*.

Overview of the Doctrine (Cont'd.)

- ❖ The RCO doctrine extends liability beyond various common law theories that impose *civil* liability against directors and officers. While a director will be safe from *civil* liability by operation of the “business judgment rule” when s/he fulfills the *Caremark* oversight duties, he or she can be *criminally* responsible by operation of the RCO doctrine *even if* s/he didn't know that employees violated public welfare laws.

Overview of the Doctrine (Cont'd.)

- ❖ Courts have rejected arguments by officers that they delegated to subordinates responsibilities to stop such misconduct. Under the RCO doctrine, delegation is not a defense. A corporate officer can be convicted without knowing that a specific violation is occurring. *Cf. State v. Rollfink*, 475 N.W.2d 575, 580 (Wis. 1991) (“Since delegation is done by those with a broad range of responsibilities, [it] shows that the defendant was responsible for the overall operation of [the company’s] facility”).

Scope of the Doctrine

- ❖ The RCO doctrine is particularly dangerous to individuals working in industries that involve the public welfare, such as pharmaceuticals and other healthcare entities; over the years it has expanded to cover environmental crimes as well.
- ❖ In the *Nature's Sunshine* case, the SEC imposed liability under the FCPA's books and records provisions using the RCO doctrine against individuals without knowledge of wrongdoing by employees of a foreign subsidiary
- ❖ Criminal, civil and administrative liability based on Responsible Officer Doctrine can be applied in theory for organizational violations of the health care Anti-Kickback and Self-Referral laws and/or the submission of false and fraudulent claims.

Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices

- ❖ Congressional and Executive Branch officials have been concerned that organizations are considering fines and penalties and Deferred Prosecution and Corporate Integrity Agreements in the health care industry as the cost of doing business and are not deterring fraudulent and abusive conduct.
- ❖ Consequently recent enforcement actions have targeted organization executives in a number of ways for criminal, civil and administrative liability based on organizational misconduct
 - Assumption is that organizational misconduct cannot occur without individual involvement
 - What individuals are responsible for organizational misconduct?
 - Responsible Corporate Officer Doctrine.

Responsible Corporate Officer Doctrine

- ❖ *U.S. v. Dotterweich* and *U.S. v. Park* (1975) originally established Responsible Corporate Officer Doctrine
- ❖ Corporate misconduct and violations of law can result in conviction of organization executives without individual involvement in wrongdoing or even knowledge that wrongdoing was taking place.
 - Recent application in cases involving violations of law which protects the health and safety of Medicare and Medicaid Program beneficiaries (i.e. Purdue Frederick, Inc. – promotion of “off-label” use of Oxycontin).

Responsible Corporate Officer Doctrine (Cont'd.)

- Individual criminal (i.e. plea to misdemeanor conviction), civil (i.e. individual multi million dollar fines) and administrative (Federal health program exclusion) liability for CEO, GC and CMO.
- ❖ Individual criminal, civil and administrative liability against Purdue executives not based on personal involvement or even knowledge of organization wrongdoing
- ❖ Based on Responsible Corporate Officer doctrine whereby each executive had “responsibility and authority to prevent or to promptly correct the organizational misconduct.”

Responsible Corporate Officer Doctrine and Program Exclusion

- ❖ Responsible Corporate Officer Doctrine – Strict liability application – without need for establishing personal involvement in wrongful conduct-criminal and administrative liability – misdemeanor and exclusion
- ❖ Pharma and Medical Device Industry for violations of Food, Drug & Cosmetics Act (Purdue Frederick and Synthes, Inc.)
- ❖ Exposure for health care organization and Board Members and upper level management.
 - Responsibility for and authority to prevent or correct non-compliant activity.

Responsible Corporate Officer Doctrine and Program Exclusion (Cont'd.)

- ❖ Federal Health Care Program Exclusion also based on Responsible Corporate Officer Doctrine
 - No knowledge of or participation in core activity
 - Twelve year exclusion of CEO. GC, CMO upheld. See *Friedman v. Selbelius*, 2010 U.S. Dist. Lexis 131465 (D.D.C. December 13, 2010), pending before D.C. Court of Appeals

Responsible Corporate Officer Doctrine and Program Exclusion (Cont'd.)

- ❖ Board Members – knew or should have known;
Managers – strict liability
 - Individual exclusion liability based solely on position in organizational hierarchy
 - Sufficient nexus and common sense connection to misconduct
 - See Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act; available at <http://oig.hhs.gov/fraud/exclusions/asp>.

Impact on Compliance and Governance

- ❖ Agencies' reliance on the responsible corporate officer doctrine *directly impacts compliance programs and corporate governance oversight responsibilities.*

Compliance programs enhance the RCO doctrine's deterrence objectives because they are a sharper instrument for achieving accountability. The RCO doctrine casts its net so broadly that it risks diluting its underlying policy objectives by making so many individuals potentially responsible that no individual perceives himself as invested in ensuring compliance.

Douglass, *The (Ir)Responsible Corporate Officer Doctrine and Contemporary Corporate Compliance: Protecting Responsible Corporate Officers from Irresponsible Prosecution* (Jan. 2011).

FDA's Guidance on the RCO Doctrine

- ❖ FDA's recently posted guidance entitled "Special Procedures and Considerations for *Park* Doctrine Prosecutions" lists seven factors that agency will consider in determining whether to recommend the RCO doctrine be applied.

FDA's Guidance (Cont'd.)

- ❖ The seven non-exclusive factors are:
 - Whether the violation involves actual or potential harm to the public;
 - Whether the violation is obvious;
 - Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
 - Whether the violation is widespread;
 - Whether the violation is serious;
 - The quality of the legal and factual support for the proposed prosecution; and
 - Whether the proposed prosecution is a prudent use of agency resources.

OIG's Guidance on the RCO Doctrine

- ❖ In October 2010, the OIG for HHS explained how it would leverage misdemeanor convictions obtained by applying the RCO doctrine in prosecutions of owners, officers, and executives of healthcare providers into administrative exclusions from participating in federally-funded programs. *See* Guidance for Implementing Permissive Exclusion Authority.

OIG's Guidance on the RCO Doctrine (Cont'd.)

- ❖ As explained in the Guidance, the agency's statutory authority provides two distinct bases for imposing permissive exclusions:
 - Individuals who have an **ownership or a control interest** in a sanctioned entity may be excluded. . .if they knew or should have known of the conduct that led to the sanction. **Officers and managing employees. . .may be excluded. . .based solely on their position within the entity.**

See Section 1128(b)(15)(A)(ii) of the Social Security Act, codified at 42 U.S.C. § 1320A-7(b)(emphasis supplied).

OIG's Guidance on the RCO Doctrine (Cont'd.)

- ❖ Factors that the OIG says that it will consider in exercising its exclusion authority are: (1) the circumstances of the misconduct and seriousness of the offense; (2) the individual's role in sanctioned entity; (3) the individual's actions in response to the misconduct; and (4) information about the entity.

6-5-3 - Special Procedures and Considerations for Park Doctrine Prosecutions

Recommending Park Doctrine Prosecutions

The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A Park Doctrine prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to the Department of Justice. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead. Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

Other factors to consider include but are not limited to:

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread;
5. Whether the violation is serious;
6. The quality of the legal and factual support for the proposed prosecution; and
7. Whether the proposed prosecution is a prudent use of agency resources.

As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act. In addition, these factors are intended solely for the guidance of FDA personnel, do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evident.

When a district office is considering initiating a referral for a Park Doctrine prosecution, the district is required to consult with the appropriate center to ensure that the referral will align with agency priorities and that the center will support the referral and provide expert witnesses or other litigation support when necessary. Centers and district offices are also encouraged to consult with OCC and OCI HQ Special Agent in Charge (SAIC) and/or the Assistant Special Agent in Charge (ASAIC) Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If the district or center is seeking a misdemeanor prosecution under the Park Doctrine, the initial referral to OCI should clearly indicate that a Park Doctrine prosecution is being sought and the reasons that a Park Doctrine prosecution would be beneficial. At the same time that the district refers a Park Doctrine prosecution to an OCI Field Office, notice of the referral also should be sent to the SAIC and/or the ASAIC OCI HQ IOD, and the applicable center. Notice of all Park Doctrine referrals, whether initiated by the district office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in the Office of Chief Counsel (OCC), and the director of the Office of Enforcement.

Upon receipt of a Park Doctrine referral, OCI will promptly review the referral and will communicate with OCC and the referring office to obtain any information or assistance needed to present the matter for prosecution. In appropriate cases, the assigned OCC attorney and/or a representative from the Office of Enforcement or other component should participate in the initial presentation of the Park Doctrine matter.

Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act

SUMMARY: This notice sets forth nonbinding factors the Office of Inspector General (OIG) will consider in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.

SUPPLEMENTARY INFORMATION

I. Purpose and Rationale

Section 1128(b)(15) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude an individual owner, officer, or managing employee of a sanctioned entity, as defined in section 1128(b)(15)(B) (i.e., an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs). Exclusions under section 1128(b)(15) of the Act are derivative in nature and are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. Exclusions under section 1128(b)(15) are permissive, that is, the Secretary has the discretion whether to exclude or not to exclude. OIG's exercise of this discretion is not subject to administrative or judicial review.

Section 1128(b)(15) of the Act provides two different bases for exclusion. Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction. Officers and managing employees, as defined in section 1126(b) of the Act, may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity.

Because the elements of these two provisions are so different, our exclusion analysis differs depending on whether the individual in question is: (1) an owner or (2) an officer or a managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity. A “managing employee” is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. While OIG does not intend to exclude all officers and managing employees, when there is evidence that an officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. As with the presumption relating to owners, the presumption may be overcome when OIG finds that significant factors weigh against exclusion.

OIG will consider the factors set forth below in deciding whether to exclude an officer or a managing employee in the absence of evidence that the person knew or should have known of the misconduct. We believe that these factors will serve a number of useful purposes: (1) they will allow for the development of effective investigations and investigative plans by OIG and its law enforcement partners, (2) they will establish and publicize a framework that will serve as a basis for OIG’s permissive exclusion decisions, (3) they will allow for the appropriate allocation of OIG’s finite resources to actions that have the most remedial and deterrent effect, and (4) they will positively influence individuals’ future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility.

These factors are internal agency guidelines that may be subject to modification at any time. They are not intended to limit OIG’s discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal health care programs or program beneficiaries, nor do they create any rights or privileges in favor of any party. Further, these factors do not supplant or modify, in any way, the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

These factors were derived from multiple sources, including: (1) the regulations governing exclusions under sections 1128(b)(15) and 1128A of the Act (42 CFR parts 1001 and 1003); (2) the factors for implementation of permissive exclusion under section 1128(b)(7) (62 Fed. Reg. 67392 (Dec. 17, 1997)); (3) the responsible corporate official doctrine established in case law, including *U.S. v. Park*, 421 U.S. 658 (1975); and (4) decisions of the Departmental Appeals Board in exclusion matters.

II. Factors To Be Considered in Implementing OIG’s Permissive Exclusion Authority Under Section 1128(b)(15)(A)(ii)

OIG may use the following factors to determine whether to impose a permissive exclusion under section 1128(b)(15)(A)(ii) of the Act in a particular case. They are

informal and nonbinding. The presence or absence of any or all of these factors does not constitute the sole grounds for determining whether OIG will pursue exclusion.

When considering whether to exclude an individual under section 1128(b)(15), OIG will consider the basis for the criminal conviction and/or exclusion of the entity, as well as any other conduct that formed the basis for criminal, civil, or administrative investigations, cases, charges, or resolutions. In addition, OIG will consider matters that involve entities that are or were related to the convicted or excluded entity. For example, OIG will consider the conduct alleged by the Government in a civil False Claims Act settlement with a corporate parent of the convicted or excluded entity. As used in the following factors, the term “misconduct” includes the factual basis for the criminal conviction or exclusion that underlies the potential 1128(b)(15) exclusion as well as any other conduct OIG considers relevant, including allegations in criminal, civil, and administrative matters involving the convicted or excluded entity or any related entity.

A. Circumstances of the Misconduct and Seriousness of the Offense

1. What were the nature and scope of the misconduct for which the entity was sanctioned? What were the nature and scope of any other relevant misconduct? At what level of the entity did the misconduct occur (e.g., violation by one field employee of company policy versus headquarters’ involvement and/or direction)?
2. What was the criminal sanction imposed against the entity (or related entities) or any individuals? What was the amount of any criminal fine, forfeiture, or penalty imposed? What was the amount of any civil or administrative payment regarding related or similar issues? What was the length of any period of exclusion imposed?
3. Was there evidence that the misconduct resulted in (1) actual or potential harm to beneficiaries or other individuals or (2) financial harm to any Federal health care program or any other entity? If financial loss to the programs or other persons occurred, what was the extent?
4. Was the misconduct an isolated incident or part of a pattern of wrongdoing over a significant period of time? Has the entity previously had similar problems with OIG, the Centers for Medicare & Medicaid Services or its contractors, or any other Federal or State regulatory agency? What was the nature of these problems?

B. Individual’s Role in Sanctioned Entity

1. What is the individual’s current position? What positions has the individual held with the entity throughout his or her tenure, particularly at the time of the

underlying misconduct? What degree of managerial control or authority is involved in the individual's position?

2. What was the relation of the individual's position to the underlying misconduct? Did the misconduct occur within the individual's chain of command?

C. Individual's Actions in Response to the Misconduct

1. Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)? Did these actions take place before or after the individual had reason to know of an investigation? If 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, OIG may consider this as a factor weighing against exclusion.
2. Did the individual disclose the misconduct to the appropriate Federal or State authorities? Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?

D. Information About the Entity

1. Has the sanctioned entity or a related entity previously been convicted of a crime or found liable, civilly or administratively, or resolved a civil or administrative case with the Federal or State Government or a government entity? If so, what was the prior conduct that formed the basis for these actions?
2. What is the size of the entity (e.g., how many employees does the entity have, what are the revenues, how many product lines/divisions are there within the entity)? What is the corporate structure of the entity (e.g., how many subsidiaries (operating and nonoperating) are there, what are the sizes of the subsidiaries, and what are the reporting relationships between the subsidiaries)?

