



# The Responsible Corporate Officer Doctrine: Ethical and Liability Issues for Corporate Officers

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# Hypothetically speaking...

- You are the CEO of a national food company with 36,000 employees, 900 retail stores, and 20 warehouses.
- You work out of the corporate headquarters in Philadelphia.
- You are notified of an FDA inspection in your Baltimore warehouse that uncovered evidence of rodent infestation and insanitary conditions.
- You take prompt action on this information, identify the relevant individuals at your company in charge of sanitation, and are advised by your General Counsel that the head of your Baltimore division is investigating the situation, will be taking corrective action, and will respond to FDA appropriately.
- In a subsequent inspection, the FDA finds that there were improvements in the conditions, but still evidence of rodent activity in the warehouse and rodent-contaminated lots of food items.
- **ARE YOU A CRIMINAL???**



# Responsible Corporate Officer Doctrine

- According to the Supreme Court, the answer is YES!
- Under the RCO or the *Park* doctrine, a defendant may be guilty if he had “by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct,” the violations of law.
- Actual knowledge of the violation is not required.



# Origin of RCO Doctrine

- *U.S. v. Park* (1975)
  - Acme Markets, Inc. and its CEO were charged with violation of FDCA for unsanitary warehouse conditions.
  - Acme pleaded guilty; the CEO (Park) did not.
  - In upholding CEO's conviction, Supreme Court stated that "corporate agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act bear a 'responsible relationship' to, or have a 'responsible share' in violations."



# Origin of RCO Doctrine

- The Supreme Court upheld the conviction because “the Act imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions.”
- Necessary to protect the public health & welfare; the FDCA imposes “a positive duty to seek out and remedy violations” and a “duty to implement measures that will insure that violations will not occur.”



## The RCO Doctrine

- “Provides that a responsible corporate official can be held liable for a . . . misdemeanor (and possible subsequent felony) under the FDCA without proof that [1] the corporate official acted with intent or even negligence, and [2] even if such corporate official did not have any actual knowledge of, or [3] participation in, the specific offense.”

FDA Regulatory Procedures Manual § 6-5-3 (2011).



# RCO Prosecutions

- A public danger is central for RCO prosecutions.
- Limited to regulatory or public safety and welfare crimes without a *mens rea* element.
  - *Mens rea* = mental state.
  - Can include food and drug safety regulations and environmental protection laws.
  - Charges against officer are wholly independent of charges against the company or its employees.



# FDA Regulatory Procedures Manual

- “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.”  
6-5-3 (2011).



# Factors for Misdemeanor Prosecution of a Corporate Official

- Individual's position in the company and relationship to the violation.
- Does the violation involve actual or potential harm to public?
- Is the violation obvious?
- Does the violation reflect a pattern of illegal acts or a failure to heed prior warnings?
- Is the violation widespread?
- Is the violation serious?
- The quality of the legal and factual support for proposed prosecution.
- Is the proposed prosecution a prudent use of agency resources?
- Does it appear that the responsible individual(s) put sales before safety?



# Limits on RCO Doctrine

- Used for strict liability offenses.
  - Strict Liability Misdemeanor: “Causing” the adulteration or misbranding of any drug or device in interstate commerce. 21 U.S.C. § 333(a)(1).
- Corporate officer must have been aware that the company places him “in a responsible relation to a public danger.”



## Limits on RCO Doctrine

- Corporate officer must have been aware that the company placed her “in a responsible relation to a public danger.”
- “A reasonable person should know that the conduct is subject to stringent regulation and may seriously threaten a community’s health and safety.”
- The burden is on a defendant “to ascertain at his peril whether [his conduct] comes within the inhibition of the statute.”



# Affirmative Defense to RCO

- Impossibility
  - FDCA does not require that which is “objectively impossible.”
  - Defendant can demonstrate that it would have been impossible to prevent or remedy the regulatory violations despite exercising “extraordinary care.”
    - Neither DOJ nor the courts have issued guidance on how the elements of this defense can be satisfied.



# Risk Mitigation

- An effective ethics and compliance program—that includes RCO training—can help prevent violations and can alert corporate officers to violations as soon as they occur.



# DOJ Corporate Compliance Guide

- Issued in February 2017
- Guidance that details how companies can avoid prosecution and mitigate penalties
- 11 key compliance topics designed to outline DOJ's expectations for effective corporate compliance programs
- Each topic supported by questions that DOJ considers relevant in evaluating a corporate compliance program



# DOJ Corporate Compliance Guide

- Analysis and Remediation of Underlying Misconduct
- Senior and Middle Management
- Autonomy and Resources
- Policies and Procedures
- Risk Assessment
- Training and Communications
- Confidential Reporting and Investigation
- Incentives and Disciplinary Measures
- Continuous Improvement, Periodic Testing, and Review
- Third Party Management
- Mergers and Acquisitions