

The Responsible Corporate Officer Doctrine

A Re-emergent Threat to General Counsel and Corporate Officers

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THE CRIME OF DOING NOTHING

The “Responsible Corporate Officer doctrine” (RCO doctrine)¹ is a procedural contrivance that regulators and prosecutors have rediscovered and now are applying aggressively against businessmen in administrative, civil, and criminal actions. The RCO doctrine has been aptly described as the “crime of doing nothing”² because it largely focuses upon a person’s *position* in an entity as the basis for imposing liability and not whether he or she had a culpable intent, was aware of any wrongdoing, or had any direct involvement whatsoever.

Not surprisingly, regulators and prosecutors support this doctrine, which reduces or eliminates their burden of proof and gives them a *tremendous* negotiating or litigating advantage:

Given the difficulty in defending a charge under the RCO doctrine..., an individual thus could incur the time, expense, [and] risk...involved in a federal criminal trial...and still end up with an extraordinarily high likelihood of a conviction on a RCO misdemeanor. A conviction at trial...put[s] the individual in a position almost certainly no better (and probably worse) than if he or she had pleaded guilty to the RCO misdemeanor...³

The two seminal RCO doctrine cases, both of which involved misdemeanor violations of the Food, Drug, and Cosmetic Act (FDCA), are *United States v. Dotterweich*⁴ and *United States v. Park*.⁵ The rationale for applying the



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RCO doctrine was explained in this way by the *Park* Court: “The requirements of foresight and vigilance imposed on responsible corporate agents are...demanding, and perhaps onerous, but...no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in...enterprises whose services and products affect the health and well-being of the public...”⁶

In the years after *Dotterweich* and *Park*, courts have allowed prosecutors and regulators to expand the RCO doctrine to other “public welfare” laws — primarily environmental laws, but also securities laws, as well as “consumer fraud, deceptive mortgage lending practices, antitrust violations, failures in recordkeeping of controlled substances, sales tax violations, liability under the Sarbanes-Oxley Act, and others.”⁷ Significantly, although the *Park* court said that a defendant charged with misbranding a pharmaceutical product could assert a defense that he or she was “powerless” to prevent the violation,⁸ courts have been reluctant to permit the defense,⁹ lending credence to the claim that such violations effectively are *strict liability* crimes.

Although the *Dotterweich* court was willing to countenance the RCO doctrine because the violations were only *misdemeanors*,¹⁰ the doctrine now has been used in various *felony* environmental prosecutions. The RCO doctrine *presumes* that someone having a position of responsibility in a company also has the power and duty to prevent violations that may endanger the public. In short, RCO doctrine liability is based on a person’s *status*, and it is imposed *vicariously*. As such, by *imputing* a duty on a corporate officer to prevent a violation of a public welfare law, the RCO doctrine extends beyond those state statutes that criminalize a person’s *failure to act when a specific duty to act is imposed by statute*.¹¹

The reach of the doctrine also extends beyond various common law theories developed to impose *civil* liability against corporate directors and officers.¹² While having

such a broad reach makes the RCO doctrine an incredibly effective weapon for regulators and prosecutors, its fundamental premise conflicts with widely held concepts that undergird our criminal¹³ and corporate laws:

[T]he idea that liability can be imposed on an individual for corporate misconduct, in apparent disregard of the corporate form and without culpable involvement or even a requirement of a culpable state of mind, seems inconsistent with the most basic concepts surrounding the corporate form. The doctrine arguably imposes liability for nothing more than a person’s status. *The word “responsible” in the doctrine’s name does not mean that the individual is responsible for the misconduct, but... for the corporation.*¹⁴

It is hard to reconcile how the Supreme Court could approve the RCO doctrine to be used in criminal prosecutions while prohibiting the use of *mandatory presumptions* in such cases because they impermissibly remove the government’s burden of proof as to a statute’s required elements, and thereby offend due process.¹⁵ In fact, only for the very small category of offenses (*i.e.*, *strict liability* crimes¹⁶ that do not require proving that a defendant was culpable¹⁷) will the use of the RCO doctrine not conflict with the prohibition against using *mandatory presumptions* in criminal cases.

Because the scope of liability arising from applying the RCO doctrine is so striking, its use can lead to perverse results. Consider that while a director will be safe from *civil* liability by operation of the “business judgment rule”¹⁸ when he or she fulfills his or her *Caremark* oversight duties,¹⁹ the director can be held *criminally* responsible by operation of the RCO doctrine *even if* he or she did not know that company employees had violated public welfare laws.²⁰

This is because courts have rejected arguments by corporate officers and executives

that they delegated to subordinates the responsibility to stop such misconduct.²¹ In a larger organization, corporate officers and executives simply cannot have the same degree of “hands on” oversight as their peers in smaller ones. But because courts have held that responsible corporate officers have a *non-delegable duty* to prevent such violations, an unprincipled use of the RCO doctrine could easily undermine the effectiveness of corporate compliance programs:

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.²²

THE FDA RAMPS UP

In March 2010, following a critical Government Accountability Office (GAO) report,²³ the FDA Commissioner wrote to the Ranking Member of the Senate Committee on Finance, saying that her agency would try to increase the use of the RCO doctrine in prosecutions of pharmaceutical and food industry executives.²⁴ As a follow up, in January 2011, the FDA published new internal guidelines in its REGULATORY PROCEDURES MANUAL, entitled “Special Procedures and Considerations for Park Doctrine Prosecutions,”²⁵ describing seven factors the agency will consider in deciding whether to seek to have the RCO doctrine applied in a prosecution for FDCA violations:

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.

Before moving into the next part of this article, it is worth mentioning a prosecution of pharmaceutical executives that happened before these events since, as will next be explained, it has had important repercussions. In May 2007, as part of the settlement between the Purdue Frederick Company, Inc. and the government regarding the company's promotion of Oxycontin, three of the company's executives — its president and chief executive officer (CEO), its executive vice president (VP) and chief legal officer, and its former executive VP and chief scientific officer — pled guilty to misdemeanor misbranding charges under the FDCA.²⁶

THE OIG LOOKS TO TRANSFORM MISDEMEANOR FDCA CONVICTIONS INTO LENGTHY PERMISSIVE EXCLUSIONS

In October 2010, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) explained how it would leverage misdemeanor convictions obtained by applying the RCO doctrine in prosecutions of owners, officers, and executives of pharmaceutical and other health care providers into administrative exclusions from participating in federally funded programs. See the OIG's “Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b) (15) of the Social Security Act.”²⁷

HHS officials have said that exercising the agency's permissive exclusion authority against repeat offenders is necessary to stop repeat offenders.²⁸ As the guidance explains, the agency's statutory authority provides two distinct bases for imposing permissive exclusions:²⁹

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.*

Because the elements of these two provisions are so different, *our exclusion analysis differs depending on whether the individual... 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... 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.³⁰

The OIG says that it will consider the following factors in exercising its exclusion authority: (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.³¹

THE OIG EXCLUDES PURDUE'S GENERAL COUNSEL BASED ON THE MISDEMEANOR CONVICTIONS TIED TO THE RCO DOCTRINE: IS THIS A HARBINGER OF THINGS TO COME?

Not long after the DOJ obtained convictions of the three Purdue executives by applying the RCO doctrine to hold them responsible for Purdue's off-label promotion of Oxycontin, the OIG moved to exclude them from participating in federal health care programs for 20 years, which was reduced in the administrative appeal to 12 years.³² While it was harsh for the OIG to impose the 12-year government-wide exclusions derived from strict liability misdemeanors tied to the three men's *status* in Purdue, without evidence of knowledge or wrongdoing, more troubling was the exclusion of Purdue's former general counsel, "the first known general counsel to be debarred under the responsible officer doctrine."³³

In an amicus brief filed to support the appeal by Purdue's former general counsel and his colleagues, the Association of Corporate Counsel (ACC) argued, *inter alia*, that "[the exclusions are]...of direct and immediate concern to ACC's members. Among other things, [it]...inappropriately shifts liability and punishment...to those...obliged to provide legal counsel and advocate for their clients' positions."³⁴

THE OIG THREATENS TO EXCLUDE THE OWNER OF FORREST LABS, BUT RETREATS

On April 2011, the OIG took an even more aggressive posture with respect to its exclu-

sion powers, notifying Howard Solomon, the chairman, chief executive officer, and president of Forest Laboratories, Inc., that the agency would seek to exclude him from participating in federally funded health care programs. What made this threatened exclusion different is that the agency's basis wasn't tied to Solomon's underlying conviction, since there wasn't one, but because he was "associated with" Forest Laboratories.

The company rallied behind Mr. Solomon, criticized the OIG's threat, and said that, if necessary it would back him in seeking relief from the courts.³⁵ Subsequently, the OIG changed its position in a letter to Solomon dated August 5, 2011, explaining only that "[b]ased on a review of information in our file, and consideration of the information your attorneys provided to us both in writing and in an in-person meeting, we have decided to close this case."³⁶ This OIG's change in position, as one commentator pointed out, should not be interpreted as a change in the OIG's mindset:

The closing of Mr. Solomon's case has been reported by some...as a retreat by the government from the pursuit of responsible corporate officers who were not directly responsible for the sanctioned conduct. Unfortunately, it would be a mistake to interpret the OIG's action in Mr. Solomon's case as a change in direction in its efforts to hold corporate employees responsible for conduct occurring on their watch. Both the letter to Mr. Solomon and the OIG's press release indicated, without providing meaningful explanation, that the decision in Mr. Solomon's case was based solely on the facts of that case.³⁷

OTHER ADMINISTRATIVE USES OF THE RCO DOCTRINE BY HHS

Although the RCO doctrine first arose in criminal misdemeanor prosecutions of

FDCA violations, its use has expanded to administrative proceedings, including not only the exclusion proceedings which have been discussed, but also in other administrative proceedings, including the imposition of civil monetary penalties (CMPs). Illustrative is *TMJ Implants, Inc. v. United States Department of Health & Human Services*,³⁸ in which the Tenth Circuit upheld the agency's imposition of CMPs for violating reporting requirements imposed by the FDCA.

As the *TMJ Implants, Inc.* Court explained, "[u]nder 21 U.S.C. § 333(f)(1)(A), 'any person who violates [the medical device report (MDR) reporting requirements] shall be liable to the United States for a civil penalty' which requires proof that the violation was either a significant or knowing departure from the law, or...posed a risk to public health."³⁹ While inspecting the company's facilities and its MDR files, FDA employees discovered that TMJ had not submitted MDRs for 22 events related to a medical device or antibiotic treatment.⁴⁰ FDA issued a Warning Letter to Robert W. Christensen, TMJI's founder and president, explaining that written MDRs had to be submitted for the events within 15 days and that the failure to do so could result in regulatory action without further notice, including seizure, injunction, and civil penalties.⁴¹

This led to a series of disagreements between the FDA and Dr. Christensen, who claimed that the agency did not understand the scientific issues and thought it may be using Warning Letters to retaliate against TMJI.⁴² Instead of submitting the MDRs, Dr. Christensen and TMJI continued to send letters to the FDA and request meetings to express their concerns; after a while, the director of the FDA's Center for Radiological Health even offered to treat the explanations in the letters as MDRs that satisfied the statutory and regulatory obligations, but his offer was refused.⁴³ Consequently, the FDA filed a CMP against Dr. Christensen and TMJI for failing to submit the MDRs, which led to a hearing before an administrative law judge, who imposed

sanctions of \$170,000 on both TMJI and Dr. Christensen, individually.⁴⁴

After perfecting their administrative appeals, TMJI and Dr. Christensen sought judicial review. Dr. Christensen argued that only the device manufacturer, not an individual, could be subject to civil money penalties, which argument, the court held, was not supported by 21 U.S.C. § 333(f) (“any person who violates a requirement of this chapter...related to devices shall be liable... for a civil penalty”) or by 21 U.S.C. § 321(e) (which defines the term “person” to include an “individual, partnership, corporation, and association”).⁴⁵

The court explained that, in analogous circumstances, the Supreme Court upheld the imposition of liability on corporate officers for FDCA violations, citing *Park* and *Dotterweich*.⁴⁶ It further wrote that “the rationale for holding corporate officers criminally responsible for acts of the corporation, which could lead to incarceration, is even more persuasive where only civil liability is involved, which at most would result in a monetary penalty,” citing *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 561 (6th Cir. 1985).⁴⁷

USES OF THE RCO DOCTRINE BY OTHER AGENCIES

Commentators have noted that, in at least one proceeding, the U.S. Securities and Exchange Commission (SEC) has used Section 304 of the Sarbanes-Oxley Act⁴⁸ as a basis for seeking a claw-back of compensation from a CEO after a restatement of earnings without alleging that the executive knew about the violation.⁴⁹ Under Section 304 of the Sarbanes-Oxley Act (“Forfeiture of Certain Bonuses and Profits”),⁵⁰ the SEC can seek to recover claw-backs of executive bonuses or other incentive- or equity-based compensation received in a 12-month period before a publicly traded company had to prepare an accounting restatement to address a material noncompliance. As the commentators point out:

Although the statute requires that the accounting restatement be “a re-

sult of misconduct,” it does not state *whose* misconduct creates liability. At least one court, in *SEC v. Jenkins*, [718 F. Supp. 2d 1070 (D. Ariz. June 9, 2010)] has held that the misconduct need not have been committed by the defendant officer. In reaching its decision, the District Court of Arizona reasoned that Sarbanes-Oxley’s plain meaning requires only “the misconduct of corporate officers, agents or employees acting within the scope of their agency or employment,” not the specific misconduct of the issuer’s CEO or CFO.” [*Jenkins*, 718 F. Supp. 2d at 1074].⁵¹

Section 954 of the Dodd-Frank Act⁵² has greatly extended the scope of claw-back authority. It requires *issuers* to pursue claw-backs of executive compensation not only against CEOs and chief financial officers (CFOs) (as compared to Section 304 of the Sarbanes-Oxley Act) but against current or former “executive officers” and covers the three-year period before the restatement; notably, it also does not require proof of any misconduct by the executive to seek a claw-back.⁵³

The SEC also has relied upon the RCO doctrine in one noteworthy civil action brought pursuant to its authority under the books and records provisions of the Foreign Corrupt Practices Act (FCPA).⁵⁴ In the *Nature’s Sunshine Product* case,⁵⁵ the Commission charged Nature’s Sunshine Products Inc. (NSP), its CEO, and its former CFO for violations relating to cash payments made eight years before by a Brazilian subsidiary to import unregistered products into Brazil and the subsequent falsification of the books and records to conceal these payments.⁵⁶

Nowhere in its complaint⁵⁷ did the Commission allege that the CEO or CFO knew or participated in the illegal actions; rather it alleged that, “in their capacities as *control persons*,⁵⁸ [they] violated the books and records and internal controls provisions of the securities laws in connection with the Brazil-

ian cash payments.”⁵⁹ Specifically, it alleged that [the CEO] “failed to adequately supervise NSP personnel in 2000 and 2001 to make and keep books and records that accurately reflected in reasonable detail the state of registration of NSP products sold in Brazil and to supervise [them]...in devising and maintaining a system of internal controls sufficient to have provided reasonable assurance that the registration of NSP products sold in Brazil was adequately monitored in 2000 and 2001.”⁶⁰

Almost identical allegations were lodged against the CFO.⁶¹ NSP and the two executives settled the case without admitting or denying the allegations, by agreeing to the entry of an order enjoining them from committing further violations and paying fines (NSP paid a civil penalty of \$600,000, while each individual paid a civil penalty of \$25,000).

CONCLUSION

The impact of the RCO doctrine is potentially far reaching for business owners, officers, and directors — particularly those connected to companies that manufacture or handle products widely used by the public. The key takeaways for such individuals, and for those who regularly provide counsel to them, is that it's probably best to consider how a motivated regulator or prosecutor would later view their actions or inactions when trying to determine who should be held responsible when things go wrong.

Unfortunately, in today's world, the line between what constitutes an administrative, civil, or criminal violation has become blurred, and regulators and prosecutors are willing to assert novel and expansive theories in ways hardly imagined. While some commentators advocate that the best protection is to always “super” comply, that may not be realistic or necessary. Rather, regulators and prosecutors should understand the need for some scalability with compliance activities and that compliance is a *good faith* endeavor, not one to be viewed as providing *insurance* against wrongdoers or wrongdoing.

While enterprise liability may make sense in the context of civil liability issues,

it does not seem fair or appropriate to apply outlier doctrines, such as the RCO doctrine, against those who are powerless to prevent wrongdoing, as the *Park* court long ago noted. Perhaps all is not gloom-and-doom as relates to the RCO doctrine because, as one commentator points out:

Recent case law suggests that at least some courts have become reluctant to expand the RCO doctrine's reach. In a particularly noteworthy development, the Supreme Court has now distanced itself from the very doctrine it once created. In *Meyer v. Holley* [537 U.S. 280 (2003)], declining to hold the president of a real estate corporation liable for an employee's violations of the Fair Housing Act, the Court expressed its desire to curb future judicial uses of the RCO doctrine. Suggesting that *Dotterweich* and *Park* established “unusually strict” and nontraditional principles of vicarious liability, the Supreme Court emphasized that this type of liability would only be justified in cases of clear Congressional intent. [*Meyer*, 537 U.S. at 287, 289]⁶²

In the meantime, however, it remains to be seen if, how, or when courts will begin to curtail the otherwise expanding threats from regulators and prosecutors who seek to rely upon the RCO doctrine in innovative ways against owners, officers, and company directors.

Endnotes:

1. The RCO doctrine also is sometimes called the “Responsible Relation doctrine” based on verbiage in *Dotterweich and Park*. See, e.g., Todd S. Aagaard, *A Fresh Look at the Responsible Relation Doctrine*, 96 J. CRIM. L. & CRIMINOLOGY 1245, 1246 (2006) (“The responsible relation doctrine holds individuals criminally liable for failing to prevent or correct violations that occur within their area of responsibility and control in a business organization.”)
2. Brent J. Gurney, et al., *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA* (2007) available at www.wilmerhale.com/files/Publication/7b1c0866-

- a547-48c7-86d0-04d0449c03d7/Presentation/PublicationAttachment/c5eda281-2dae-4154-a0f8-13b817f25b52/The_Crime_of_Doing_Nothing.pdf.
3. Gregory L. Poe, *The Responsible Corporate Officer Doctrine: Defending Individuals in FDCA Cases*, 21st Annual National Institute on Health Care Fraud (ABA, April 2011), at D-5.
 4. 320 U.S. 277 (1943).
 5. 421 U.S. 658 (1975).
 6. *Park*, 421 U.S. at 672.
 7. Martin Petrin, *Circumscribing the "Prosecutor's Ticket to Tag the Elite": A Critique of the Responsible Corporate Officer Doctrine* (Sept. 10, 2011), at 10-11 (internal citations omitted); available at ssrn.com/abstract=1808344.
 8. See *Park*, 421 U.S. at 673 ("The [FDCA]... does not require that which is objectively impossible. The theory upon which responsible corporate agents are held criminally liable for 'causing' violations of the Act permits a claim that the defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits.'").
 9. See R.J. Cinquegrana and Diana K. Lloyd, *Liability Without Fault: New Enforcement Trends Against Corporate Executives*, BLOOMBERG LAW REPORTS (Feb. 2011) ("[A]lthough an impossibility defense may be available if an executive can show he exercised extraordinary care but nevertheless was powerless to stop the violation, this standard is difficult to meet") (citing *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980), an adulterated foods prosecution under the FDCA). In *New Eng. Grocers Supply Co.*, the judge discussed whether the defense is an *affirmative defense* "satisfied by evidence that the corporate officer exercised 'extraordinary care' and was still unable to prevent the violations," or a rebuttal defense that "relates only to the power of the corporate officer, by virtue of his position in the corporation, to correct or prevent violations of the Act," before deciding it is a non-affirmative defense. 488 F. Supp. at 235-36.
 See also Stephen N. Landsman, *Criminal Liability for Corporate Actions: The Responsible Share Doctrine*, 9 DCBA BRIEF (1997) (pointing out that, in *United States v. Starr*, 535 F.2d 512 (9th Cir. 1976), an appeal of a corporate officer's conviction for rodent infestation of a warehouse in violation of the FDCA's ban on food contamination, the judge rejected the proffered impossibility defense (that the defendant couldn't prevent the infestation because his subordinate didn't follow his orders), ruling that reasonable vigilance required anticipation of the shortcomings of subordinates; the judge also noted that, in *United States v. Y. Hata & Co., Ltd.*, 535 F.2d 508 (9th Cir. 1976), which arose from a bird infestation, the defendant had unsuccessfully argued that he was entitled to the defense since a wire cage hadn't arrived. That judge found that the defendant hadn't acted promptly enough in ordering the materials); available at www.dcbabrief.org.

www.dcbabrief.org/backissues/vol91997.html.

10. It is worth including part of the strong dissent in *Dotterweich* (authored by Murphy, J., and joined by three other justices) which pointed out serious issues with the majority's opinion:

Our prime concern... is whether the criminal sanctions of the... [FDCA] plainly and unmistakably apply to the respondent... as a corporate officer. He is charged with violating § 301(a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. *There is no evidence... of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed... solely on the basis of his authority and responsibility as president and general manager of the corporation.*

It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal, and that it ought not lightly to be imputed to a citizen who... has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But, in the absence of clear statutory authorization, it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen, the legislative mandate must be clear and unambiguous...

Dotterweich, 320 U.S. 285-86 (emphasis supplied).

11. See, e.g., V.T.C.A. PENAL CODE § 6.01 (Requirement of Voluntary Act Or Omission):

(a) A person commits an offense only if he voluntarily engages in conduct, including an act, an omission, or possession.

* * *

(c) A person who omits to perform an act does not commit an offense unless a law as defined by Section 1.07 provides that the omission is an offense or otherwise provides that he has a duty to perform the act.

(Emphasis added).

See also V.T.C.A. PENAL CODE § 7.02 (Criminal Responsibility for Conduct of Another):

(a) A person is criminally responsible for an offense committed by the conduct of another if: * * * (3) having a legal duty to prevent commission of the offense and acting with intent to promote or assist its commission, he fails to make a reasonable effort to prevent commission of the offense.

(Emphasis added).

12. See Martin Petrin, *The Curious Case of Directors' and Officers' Liability for Supervision and Management-*

Exploring the Intersection of Corporate and Tort Law, 59 AM. U.L. REV. 1661, 1667 (2010) (“[A]t common law, directors and officers are not personally liable for the torts of a corporation or of any other agent merely because of their position. Instead, some additional connection is required. Courts have developed various approaches to test whether a director or officer has a sufficient enough connection... to hold him personally liable. For the most part, the different theories or approaches overlap... and courts can apply combinations or variations of the theories. Nevertheless, the theories can be roughly divided into three approaches: first, and most common, where the court focuses on the defendant’s participation in a tort; second, where the court focuses on whether a personal duty was breached; and third, where the court pierces the corporate veil.”) (internal citations omitted).

13. See *id.* at F-9 (“Generations of law students have learned that under the common-law every crime has two elements: (1) a bad act (the actus reus), and (2) a culpable state of mind (mens rea), generally intent or recklessness”). See also Sir Wm. Blackstone, COMMENTARIES ON THE LAWS OF ENGLAND (“[T]o constitute a crime against human laws, there must be, first, a vicious will; and, secondly, an unlawful act consequent upon such vicious will.”).
14. Kevin M. LaCroix, *More about the Responsible Corporate Officer Doctrine*, THE D & O DIARY (March 8, 2010), available at www.dandodiary.com/2010/03/articles/corporate-governance/more-about-the-responsible-corporate-officer-doctrine. (Emphasis added).
See also Petrin, *Circumscribing the “Prosecutor’s Ticket to Tag the Elite”: A Critique of the Responsible Corporate Officer Doctrine*, at 3 (“For prosecutors, the responsible corporate officer doctrine... [is] an... effective tool to hold individuals liable who would normally not be responsible under traditional criminal, tort, or agency law principles”) (internal citations omitted).
15. See *In re Winship*, 397 U.S. 358, 364 (1970) (prosecution must prove every fact necessary to constitute the crime charged beyond a reasonable doubt); *Mullaney v. Wilbur*, 421 U.S. 684, 701-04 (1975); and *Sandstrom v. Montana*, 442 U.S. 510, 524 (1979).
16. See, e.g., John T. Bentivoglio and Jennifer L. Bragg, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 FOOD & DRUG L.J. No. 3, 525, 529 (2010) (because various provisions of the FDCA are silent as to any required mental state, courts have interpreted them as being strict liability offenses).
17. See *Dotterweich*, 320 U.S. at 281.
18. See generally, Stephen M. Bainbridge, *The Business Judgment Rule as Abstention Doctrine* (July 29, 2003). UCLA, School of Law, LAW AND ECON. RESEARCH PAPER NO. 03-18; available at ssrn.com/abstract=429260. As Professor Bainbridge explains, the business judgment rule insulates directors

from liability for claims of negligence “by providing a presumption that the directors or officers of a corporation acted on an informed basis, in good faith, and in the honest belief that the action taken was in the best interests of the company. As a result, even clear mistakes of judgment will not result in personal liability.” Bainbridge, *The Business Judgment Rule as Abstention Doctrine*, at 6-7 (internal notes omitted).

19. *In re Caremark Int’l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996); *Graham v. Allis-Chalmers Mfg., Co.*, 188 A.2d 125, 130 (1963) (“absent cause for suspicion there is no duty upon the directors to install and operate a corporate system... to ferret out wrongdoing which they have no reason to suspect exists”; corporate directors must exercise “that amount of care which ordinarily careful and prudent men would use in similar circumstances”).
20. See Martin Petrin, *Circumscribing the “Prosecutor’s Ticket to Tag the Elite”: A Critique of the Responsible Corporate Officer Doctrine*, at 33 (Sept. 10, 2011); available at ssrn.com/abstract=1808344 (“[A] responsible corporate officer may well satisfy his internal corporate duties with regards to oversight and be safe from shareholder claims, but still incur civil and criminal liability under RCO doctrine principles.”).
21. See Barbara DiTata, *Proof of Knowledge under RCRA and Use of the Responsible Corporate Officer Doctrine*, 7 FORDHAM ENVTL. LAW J. 795, 814-14 (1996) (“[A]lthough the courts are unwilling to find that corporate officers possess the requisite knowledge for conviction under § 6928(d) of RCRA merely because of their position within the corporate hierarchy, it is clear that corporate managers can no longer insulate themselves from criminal liability by delegating their responsibility for compliance to others or by closing their eyes to the problem”). Accord, Washington Legal Foundation, SPECIAL REPORT : FEDERAL EROSION OF BUSINESS CIVIL LIBERTIES Second Edition 2010), at 1-13 (“The [Clean Water Act’s] and [Clean Air Act’s] definition of ‘person’ raises potential due process issues because the definition includes ‘responsible corporate officer[s],’ under 33 U.S.C. 1319(c)(6); 42 U.S.C. § 7413(c)(6). This would mean that a person could be responsible for crimes that she neither committed nor knew about. CEOs have no choice but to delegate responsibility for compliance with environmental laws and regulations to corporate environmental managers and attorneys. But under the responsible corporate officer doctrine, such delegation of responsibility is no defense; a responsible corporate officer can be convicted even without knowledge 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, the delegation shows that the defendant was responsible for the overall operation of [the company’s] facility”).
22. David L. Douglass, *The (Ir)Responsible Corporate Officer Doctrine and Contemporary Corporate*

- Compliance: Protecting Responsible Corporate Officers from Irresponsible Prosecution (Jan. 2011).
23. See Government Accountability Office, "Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen oversight of Criminal Misconduct Investigations," GAO-10-221 (March 4, 2010); available at gao.gov/products/GAO-10-221.
 24. See Letter from Margaret A. Hamburg, MD, Commissioner of Food and Drugs, to Sen. Charles F. Grassley, Senate Committee on Finance (March 4, 2010), at p. 2, ¶13: "A third recommendation from the committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. *Criteria now have been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions.*" (emphasis added). Dr. Hamburg wrote this letter to Sen. Grassley since he had asked the GAO to review the FDA's investigations, including its investigative policies and procedures, and its resources for investigations. See Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations," at 2.
 25. See FDA, REGULATORY PROCEDURES MANUAL 6-5-3, available at www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm.
 26. Michael A. Rogoff, et al., A Perfect Storm: Prosecutors' Increasing Focus on Individual Liability in the Drug and Device Sectors and the Responsible Corporate Officer Doctrine, 8 PHARM LAW & IND. REPORT, 1480, at 2 (Nov. 19, 2010).
 27. The OIG's Guidance, issued on September 24, 2010, is available at oig.hhs.gov/exclusions/files/permisive_excl_under_1128b15_10192010.pdf.
 28. See, e.g., Testimony by Lewis Morris, Chief Counsel, Office of Inspector General, U.S. Department of Health and Human Services, before the Subcommittee on Oversight, Committee on Ways and Means, U.S. House of Representatives (March 2, 2011), explaining, *inter alia*, that:

***We are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business. As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue. For example, some major pharmaceutical corporations that have been convicted of crimes and paid hundreds of millions of dollars in False Claims Act settlements continue to participate in the Federal health care programs, in part because of the potential patient harm that could result from an exclusion.

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk. For example, in 2008, we excluded three former executive officers of the pharmaceutical company Purdue Frederick based on their convictions for misbranding of the painkiller OxyContin. Each of the executives was convicted based on his status as a responsible corporate officer.

Testimony available at www.hhs.gov/asl/testify/2011/03/t20110302h.html.
 29. See Section 1128(b)(15)(A)(ii) of the Social Security Act, codified at 42 U.S.C. § 1320A-7(b).
 30. Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, at 1-2 (emphasis added).
 31. *Id.* at 3-4.
 32. See *In re Goldenheim*, Final Decision on Review of Administrative Law Judge Decisions, Decision No. 2268, Department of Health and Human Services, DAB, App. Div. Nos. A-09-56, A-09-57, A-09-58 (Aug. 28, 2009) and *Freidman v. Sibelius*, No. 1-09-cv-02028 (D.D.C., Dec. 13, 2010).
 33. See generally Sue Reisinger, *Bitter Pill: Did Purdue Pharma GC Get Due Process in Debarment?*, CORPORATE COUNSEL (July 01, 2011) (citing arguments advanced by the Washington Legal Foundation, which has filed an amicus brief with the D.C. Circuit in support of Udell in his appeal).
 34. Amicus Curiae Brief of ACC, *Friedman v. Sibelius*, No. 11-5028, U.S. Court of Appeal for the District of Columbia Circuit, at 1; available at www.acc.com/vl/public/AmicusBrief/upload/ACCAmicusFriedmanvSibelius.pdf. As the ACC also points out in its brief, a corporate counsel's role is markedly different from other officers and directors of a business entity and the OIG's sanction could have long range, counterproductive, effects:

[W]hether styled as a Chief Legal Officer, General Counsel or otherwise, corporate counsel is a lawyer rendering advice and representing his or her client. Imposition of liability on 5 such legal advisors based not on personal misconduct but on the wrongdoing of the corporate client ignores that traditional, and critical, distinction. A lawyer is charged by well-established ethical rules to represent his or her client without personal conflict of interest. This is essential to their ability to provide objective legal advice. If, however, such a lawyer is haunted by the specter of the loss of his or her career because of the actions of the client, that lawyer, however well-intentioned, can no longer provide untainted advice.

Id. at 4-5.
 35. Press Release, "Forest Laboratories Chairman and CEO to Challenge 'Unwarranted and Unprecedented' Potential Action to Exclude Him from Federal Healthcare Programs" (April 13, 2011) ("The potential action emanates from matters...settled by Forest in 2010 with no finding of knowledge or wrongdoing by Mr. Solomon. The only basis...is that he is 'associated with' Forest. The letter gives Mr.

- Solomon 30 days to respond and say why he should not be excluded"); *available at* www.frx.com/news/PressRelease.aspx?ID=1550242.
36. See Anthony J. Burba, *OIG Ceases Exclusion Efforts Against Forrest Labs CEO — Not All Corporate Officers*, OBER KALER HEALTH LAW ALERT (Summer 2011); *available at* www.ober.com.
37. *Id.*
38. 584 F.3d 1290 (10th Cir. 2009).
39. 584 F.3d at 1296.
40. *Id.*
41. *Id.*
42. *Id.* at 1297.
43. *Id.* at 1299.
44. *Id.*
45. *Id.* at 1302-03.
46. *Id.* at 1303.
47. *Id.* The case involved a civil penalty action filed against Hodges X-ray, Inc. and James J. Hodges, the company's major shareholder and president, who argued that he couldn't be held individually liable for the statutory violations asserted by the government since he wasn't a "manufacturer" within the meaning of the Radiation Control for Health and Safety Act of 1968. Civil penalties were assessed against Hodges and the company for violating certain FDA regulations because x-ray equipment that they manufactured didn't comply with regulations requiring a display of exposure time on the control panel in seconds and that each machine terminate exposure at a preset time.
48. Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745.
49. Cinquegrana and Lloyd, *Liability Without Fault: New Enforcement Trends Against Corporate Executives*, BLOOMBERG LAW REPORTS (page references not available).
50. 107 Pub. L. 204, Title III, § 304, 116 Stat. 745 (July 30, 2002).
51. Cinquegrana and Lloyd, *Liability Without Fault: New Enforcement Trends Against Corporate Executives* (internal citations omitted; page references not available).
52. Dodd-Frank Wall Street Reform and Consumer Protection Act, H.R. 4173, 111th Cong., at § 954(b)(2) (2010).
53. Cinquegrana and Lloyd, *Liability Without Fault: New Enforcement Trends Against Corporate Executives* (internal citations omitted; page references not available).
54. 15 U.S.C. §§ 78dd-1, *et seq.*
55. See SEC v. Nature's Sunshine Products, Inc., SEC Litig. Rel. No. 21162 (July 31, 2009); *available at* www.sec.gov/litigation/litrelases/2009/lr21162.htm.
56. *Id.*
57. The complaint is *available at* www.sec.gov/litigation/complaints/2009/comp21162.pdf.
58. Section 20(a) of the Securities Exchange Act of 1934 ("Liabilities of Controlling Persons and Persons Who Aid and Abet Violations"), while providing for joint and several liability for control persons, also doesn't impose liability for those who act in good faith:
Every person who, directly or indirectly, controls any person liable under any provision of this title or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, *unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.*
(Emphasis added).
59. SEC Litig. Rel. No. 21162 (July 31, 2009) (emphasis supplied).
60. Complaint in Nature's Sunshine Products case, at 8, ¶ 45.
61. See *id.* at 8-9, ¶ 48.
62. Petrin, *Circumscribing the "Prosecutor's Ticket to Tag the Elite": A Critique of the Responsible Corporate Officer Doctrine*, at 14.

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