Criminal Liability Under the Responsible Corporate Officer Doctrine
By Lise T. Spacapan

Targeting Drug and Device Executives to Modify Corporate Conduct

Today’s pharmaceutical and device companies function in a world of complex and changing statutes and regulations. Robust and independent compliance programs are essential. Even with the best programs in place, however, rogues within the company can expose the entire operation to enormous potential liability. After attacking industry with a vengeance in recent years, the government has collected billions of dollars annually in settlements of False Claims Act and other matters in which activities such as the off-label marketing of drugs and devices were alleged.

Despite aggressive enforcement actions, regulators recently expressed the belief that the billions in payments arising from FDCA violations are viewed by the industry as a “cost of doing business” and that corporate conduct is not changing in the face of these fines. Therefore, the FDA rekindled the long dormant “Responsible Corporate Officer (RCO) Doctrine,” also known as the “Park Doctrine” after the United States Supreme Court opinion in United States v. Park, 421 U.S. 658 (1957). Under the doctrine, executives may be found criminally liable for company violations of the Federal Food, Drug, and Cosmetic Act (FDCA) even without evidence that they knew or should have known about the violations. If an executive’s position within the company puts him or her in a position of responsibility, with the authority to prevent the conduct, then he or she can be held liable for FDCA violations committed by others.

Defendants raise forceful due process concerns based on the fact that liability arises without culpability, but cases typically settle before these constitutional challenges are resolved. Thus, the governments’ large stick—that of holding individuals responsible criminally without proof of scienter—remains intact.

This article presents a brief overview of the nature of FDCA “crimes” and traces the genesis of the RCO Doctrine. It then sets forth the government’s recent statements of intention to use the doctrine and government’s guidance regarding its use. The article also addresses several specific circumstances in which the government wielded the doctrine in the context of FDCA violations. Finally, it agrees with commentators who have argued that there is little if any deterrence in holding officers responsible for conduct when they were not even negligent, much less knowledgeable, about that illegal conduct. Rather, if a company has robust policies in place to prevent culpable conduct, but it occurs in any event, only individuals with knowledge of the wrongdoing should be held liable.

Nature of FDCA Crimes and the Genesis of the Responsible Corporate Officer Doctrine
There are many illegal activities for which the government (FDA and DOJ) will pursue charges against the drug and device industry. Most commonly, charges are brought under the False Claims Act, often when an inside employee “whistleblower” brings conduct to the attention of the government. These types of actions are intended, at least facially, to punish and prevent actions that are unsafe for the public—such as selling drugs for a harmful or ineffective purpose. After being challenged by Congress recently for weak enforcement, the FDA announced that it would renew its use of the RCO Doctrine to pursue claims against individual corporate officers, even when there is no evidence the officers were culpable.

One commentator vividly illustrates through a hypothetical how charges brought under the RCO Doctrine can play out against corporate officers, even when they have no prior knowledge of wrongdoing. Suppose a company’s portfolio includes a product with substantial off-label use. The CEO implements a robust compliance program, through which he receives reports on regular auditing and investigative efforts. He supports strong disciplinary actions against employees who violate policy. Nevertheless, if behavior—such as a sales representative’s dissemination of information about off-label uses of the product—is reported by a whistleblower to the government rather than through the company compliance program, the CEO may first learn of it after a False Claims Act case is brought by the government. Despite the fact that the company had appropriate compliance programs in place, and the CEO had no prior knowledge of violations, “under the strict and vicarious liability standard [of the RCO Doctrine], the hypothetical CEO could be jailed, subject to substantial fines, and excluded from participating in federal health care programs.” J. Bragg, “Onus of Responsibility,” 65 Food & Drug L.J. 2010. The following are tools that the government uses in such prosecutions. Thus, understanding this doctrine and planning for potential challenges to it may be important for today’s pharmaceutical and device executives.

Off-Label Promotion and Government Prosecution to Prevent It Through the New Drug Application pro-

Lise T. Spacapan is a partner in Jenner & Block LLP’s Chicago office. She is co-chair of the firm’s Products Liability/Mass Tort Defense Practice and a member of the Complex Commercial Litigation, Class Action, and Environmental Litigation Practices. Ms. Spacapan is a national director on the board of DRI, and a past chair of DRI’s Toxic Torts and Environmental Law Committee.
FDCA, the misdemeanor provision, creates the crime of “misbranding.” Section 333 (a)(1) of the FDCA, the misdemeanor provision, creates a true strict liability crime because the misbranding need not be intentional, reckless, or even negligent. If a drug is misbranded or adulterated and is distributed into interstate commerce, a crime has been committed. Further, any person with a previous misdemeanor conviction, who on a second occasion acts with intent to defraud or mislead, is guilty of a felony.

Importantly, the off-label prescription of drugs and devices by physicians—as opposed to off-label marketing by companies—is not only considered legal, but it is often recognized by the government as essential to good medical care. The FDCA expressly recognizes the legality of off-label prescription: “nothing in the Food and Drug and Cosmetic Act shall be construed to limit or interfere with the authority of a health-care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease...” 21 U.S.C. §396.

According to the United States Supreme Court in Buckman “Off-label use is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine. Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care...” Buckman v. Plaintiffs Legal Comm, 531 US 341 (2001). Indeed, off-label drug prescriptions are very common, and account for perhaps 22 percent of all prescriptions. A. Kesselheim, Off-label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech, 37 A. J.L. & Med. 225, 233–34 (2001). Medicare and private insurers pay for some off-label uses of drugs, and such can be state of the art. A. Burroughs, et al., Off-Label Promotion: Government Theories of Prosecution and Facts That Drive Them, 65 Food & Drug L.J. 555, 563 (setting forth an untested but clear argument regarding why drugs should be exempt from the “adequate directions for use” provision of the misbranding statute).

Despite the recognized importance of off-label prescription, off-label marketing or promotion of drugs or devices by manufacturers is considered illegal. Nevertheless, there is conflict in cases and ambiguity in legislation regarding whether it is illegal to make truthful statements to physicians about off-label uses of drugs or devices. In the Washington Legal Foundation (WLF) cases, there was a successful challenge to the constitutionality of FDA restrictions on speech regarding off-label uses of the FDA-approved products. 13 F. Supp. 2d 51, 66, 74 (D.D.C. 1998); see also Kesselheim. The district court in WLF II struck down the government restrictions as unconstitutional. On appeal, the government abandoned its prior position, and told the court that its guidance documents recognized that it could not criminalize truthful speech, thus mooting the important issue. Current FDA policy allows pharmaceutical companies to respond to unsolicited requests for information from health care providers and penalizes only proactive “promotion” of off-label uses. (See FDA, Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, 76 Fed. Reg. 82303). In December 2012, the Second Circuit reviewed the case of a drug representative and found that he made truthful statements about off-label uses and, thus, the court held under the First Amendment that “government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” United States v. Caronia, Docket No. 09-5006-cr (2d Cir., Dec. 3, 2012)

Despite the controversy, as currently applied by the government, when a drug or device company promotes in a way inconsistent with the label, the FDCA supports a charge that the company either: 1) introduced a new drug into commerce, 21 U.S.C. §331 (d) (prohibiting the introduction into interstate commerce of a “new drug”); or 2) misbranded a drug, 21 U.S.C. §331 (a) (prohibiting the introduction into interstate commerce of any drug that is misbranded); id. §352 (a) (defining any drug as misbranded if its labeling is false or misleading) or §352 (f)(1) (lacks adequate directions for use).

The DOJ first brought a criminal prosecution against a drug company, Genentech, for promotion of a human growth hormone for an unapproved use. Finding “patterns” of off-label promotion that amounted to a misbranding scheme, the DOJ concluded that if a manufacturer markets for an off-label purpose, then it “causes” a prescriber to file a false claim for reimbursement with federal health care programs. After later challenges to FDA authority to regulate speech in the WLF matters, the DOJ aggressively pursued FD&C ACT violations arising from the promotion of off-label uses. V. Girard, Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong RX, 12 J. Health Care L. & Pol’y 119, 126 (2009).

Prosecutions have grown exponentially since 2000. There are currently over 100 ongoing civil and criminal investigations brought by the DOJ and units of HHS, as well as investigations run by state attorneys general. Attorney General Eric Holder stated that “in 2009... recoveries exceeded a stunning $2.2 billion dollars.” J. Osborne, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 Yale...
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Responsible Corporate Officer Doctrine
Specifically, the doctrine provides that an executive at a company that makes or distributes a misbranded or adulterated drug can be convicted of violating the FDCA, even if he or she had no personal knowledge, if the prohibited act took place in the company and the executive’s position gave him or her responsibility and authority to either prevent the violation or to correct it.

The RCO Doctrine is a Supreme Court-based theory. After a period of dormancy, the doctrine is being increasingly used by the government to hold corporate officers responsible for public welfare-based crimes, without any evidence that the officers knew about or participated in the underlying conduct. As one commentator noted 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.

Origin: U.S. v. Dotterweich
In United States v. Dotterweich, the Supreme Court first held that corporate executives can be held criminally liable for other employees’ FDCA violations based on their responsibility and authority over the employee. 320 U.S. 277 (1943). It is not necessary to show the executive had any knowledge or was negligent. The Dotterweich case involved a manager who bought drugs wholesale and repackaged them under a new label. An ingredient of less potency was used by an employee who repackaged the drugs. Dotterweich had no knowledge of the conduct. The government charged that Dotterweich shipped misbranded and adulterated drugs in violation of §331(a). The Court noted that the FDCA “dispenses with the conventional requirement for criminal conduct—awareness of the wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.” Id. at 281.

The Court upheld the misdemeanor conviction under the FDCA, finding that criminal liability extends to all those having “a responsible share in furtherance of the transaction which the statute outlaws.” No guidance was offered by the Court as to how to identify a person with a “responsible share.” But the Court expressed confidence that the doctrine would be given fair application based on the “conscience and circumspection in prosecuting officers.” 320 U.S. at 285, quoting Nash v. United States, 229 U.S. 373.

Extension: U.S. v. Park
The RCO Doctrine was rarely used until the Supreme Court reaffirmed the holding of Dotterweich 30 years later in United States vs. Park, 421 U.S. 658 (1975).
Liability as a responsible corporate officer does not turn upon a corporate officer's approval of wrongdoing, but rather on whether the officer had, by reason of his or her position in the corporation, responsibility and authority to either prevent, or promptly correct, the violation at issue, and the officer failed to do so.


*Park* involved the prosecution of the CEO of a national food chain that had 900 stores and 35,000 employees. Over a three-year period, FDA inspectors cited the company for rodent contamination in two warehouses. The company and CEO, John Park, were charged with misdemeanor counts under §301(k) for causing the adulteration of food. During the trial, the government introduced corporate bylaws defining the role of the CEO and presented testimony from a VP regarding Park’s responsibility for the broad operation of the company. Park admitted that he was responsible for the entire operation of the company, and therefore for providing sanitary storage conditions. The jury was instructed that Park’s title alone was not sufficient to prove guilt, but that the question is whether the defendant, “by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.”

The Supreme Court affirmed his conviction by the jury, upholding a $250 fine. The Court found that the FDCA “imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.” Thus, the government establishes a prima facie case under the FDCA when it introduces evidence “sufficient to warrant a finding by the trier of fact that the defendant had, by reason of his position in the corporation, responsibility and authority” either to prevent or promptly correct the violation. *Id.*

It has been noted that the line between a conviction based on corporate position alone and one based on a responsible relationship is a fine one, “no wider than a corporate bylaw.” *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass. 1980). Surely, many executives within a company, including perhaps general counsel, have broad authority and responsibility that may reach across all corporate operations.

**Park Doctrine Defenses**

Defenses to the doctrine are not well developed and have rarely been successful.

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**Park Doctrine Rekindled**

Over the last 50 years, there have been a small number of reported decisions in which the government charged a corporate executive with a misdemeanor FDCA violation based solely on the executive’s “responsible relation” to the violation. See Gurney, supra, at F 17 in 39, citing 13 cases including *Park*. Until recently, longstanding FDA enforcement policy stated that any FDA recommendation for criminal prosecution “should ordinarily contain proposed criminal charges that show a continuous or repeated course of violative conduct…this is because the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown.” FDA Regulatory Procedures Manual §6-5-1 (Mar. 2007).

Current FDA leadership has recently and publicly announced the interest and intention to revive the doctrine as part of an aggressive enforcement strategy. First, Margaret Hamburg, Commissioner of Food and Drugs, announced that OCI intends to “increase the appropriate use of misdemeanor prosecutions…to hold responsible corporate officers accountable.” March 4, 2011, Letter from M. Hamburg to Sen. Chas. Grassley. Several months later, in September 2011, Mary Riordan, Senior Counsel at the Administrative & Civil Remedies Branch of the Department of Health and Human Services Office of Inspector General, spoke at a FDLI conference and stated that the government will continue to bring fraud cases against both the drug and device manufacturers, as well as individuals at the companies. She said that the government is requiring increased accountability from individuals such as members of the companies’ boards of directors and key managers in

F.2d 508 (9th Cir. 1976). Similarly, in *U.S. v. Starr*, a food company executive argued it was impossible for him to stop rodent infestation because a field was plowed nearby the facility and he instructed a janitor to fix the infestation problem and he failed to do so. The court rejected these defenses—finding it was objectively possible to anticipate and follow-up to prevent the infestation, 535 F. 2d 512 (9th Cir. 1976).
areas such as sales and accounting. As she noted, “The responsible corporate officer doctrine is a broad theme in both the law enforcement community and in the exclusion context.” BloombergBNA, Health Law Resource Center, Health Care Fraud Report, 10/05/2011. She said the government is seeking to change corporate behavior by holding executives accountable for the illegal actions of their companies. See Office of Inspector General Update; FDLI’s Advertising and Promotion Conference, September 26, 2011.

In the same vein, Lewis Morris, Chief Counsel to the Inspector General of HHS, stated “If writing a check for $200 million isn’t enough to have a company change its ways, then maybe we have got to have the individuals who are responsible for this held accountable. The behavior of a company starts at the top.” R. Alonso-Zaldivar, Feds Now Target Execs, Not Just Companies, In Health Fraud, Associated Press, May 31, 2011.

FDA Regulatory Procedures Manual
In addition to these and other statements by government prosecutors, the FDA Procedures Manual was amended in response to Sen. Grassley’s congressional inquiry in March 2011. Manual 6-5-3: Special Procedures and Considerations for Park Doctrine Prosecutions. The manual states that “the Park doctrine... provides that a responsible corporate official can be held liable for a first time misdemeanor (and possibly subsequent felony) under the [FDCA] 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.”

Once a person is convicted of a misdemeanor, any subsequent violation of the FDCA is a felony, even without proof that the defendant acted with intent to defraud or mislead. A misdemeanor can lead to debarment or exclusion from government health care programs. The government considers several factors when determining whether to recommend a Park prosecution: a) the individual’s position in the company and relationship to the violation, b) whether the official had the authority to correct or prevent the violation, and c) knowledge of and actual participation in the violation.

Also, the manual provides that additional considerations are important to the determination of whether to prosecute including:
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.

Commentators have said these developments “suggest a crucial shift in the government’s strategic use of its enforcement arsenal, and serve as a cautionary tale of how the FDA and the DOJ are using strict liability prosecutions to essentially ‘felonize’ strict liability responsibility and to enhance the scope of other statutory penalties (debarment and exclusion).” Cohen and Peregrine, “The Return of the RCOD,” National Law Journal (March 14, 2011).

Related Exclusion Power of OIG
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The government’s vast power to exclude companies and individuals from participating in any federal government-sponsored health care program is a powerful tool, see 42 U.S.C. §1320a-7; 42 C.F.R. Part 1001. “Individuals who are officers or managers of the sanctioned entity can be excluded simply based on their status as a current officer or managing employee of the sanctioned entity,” BloombergBNA, Health Law Resource Center, Health Care Fraud Report 10/05/2011. Recently the government has expanded FDCA strict liability misdemeanor prosecutions by pursuing “exclusion” against corporate officers, thus depriving them of their abilities to earn a living, as well as alleging during the sentencing phase that admissions made as part of prior pleas prove “fraudulent” activity supporting RCO misdemeanors.

Mandatory exclusion for a minimum of five years occurs when a person or entity is convicted of a felony related to FDCA violation. More critically, however, there are over 20 bases for exclusion, many of which are permissive and can be based merely on status of the individual. In October 2010, OIG published guidance on permissive exclusion. Permissive exclusions including a misdemeanor conviction related to health care fraud carry a minimum exclusionary penalty of three years.

First arising in 1998, the government has expanded authority to exclude drug manufacturers from receiving federal health reimbursement monies if they are found to have engaged in significant financial or other impropriety. See Health Care Programs: Fraud and Abuse: Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg, 46,676 (Sept. 2, 1998). Before this law, only institutions that provided services directly to patients could be excluded or debarred from federal financing program eligibility.

OIG guidance now provides that there is a presumption in favor of exclusion if an owner knew or should have known of the conduct that led to the sanction. Similarly, there is a presumption in favor of exclusion if an officer or managing employee know or should have known of the conduct that led to the sanction. Although presumptions may be overcome, that is little comfort to the executive who faces the end of his or her career if exclusion is imposed.

The OIG will consider four categories of information: “1) Circumstances/Seriousness of the Offense; 2) Individual’s Role in the Sanctioned Entity; 3) Individual’s Actions in Response to Misconduct; 4) Information about the Entity.” M. Rior- dan, Office of Inspector General Update,
FDLI’s Advertising and Promotion Conference, September 26, 2011.

According to OIG, pending cases fall into these categories: a) off-label and kick-back conduct by drug and device companies; b) unapproved/less-than-effective drug issues; and c) Medicaid drug rebate issues.

Examples of Recent Park Doctrine and Exclusion Matters

One of the most notable of cases in which the government wielded its permissive exclusion authority arose in the context of allegations that Purdue Frederick violated the FDCA by marketing Oxycontin as less addictive and less subject to abuse that other drugs of its class. In that case, the CEO, Chief Medical Officer, and GC were not charged with having intent to defraud or mislead. Specifically, the executives pled guilty based on their positions and the RCO Doctrine, and denied personal knowledge.

The district court accepted their pleas and sentenced them to probation and ordered them to disgorge millions of dollars of income. Eight months later, the HHS OIG notified the individuals that it would exercise its permissive exclusion authority to prevent the individuals from participation in all federal health care programs for 20 years, later reduced to 12 years, under 42 U.S.C. § 1320a-7(b)(1),(3). The case was appealed, and spawned outrage from industry, given the fact that the individuals were not even charged, nor was the company informed before the pleas of the government’s intention to seek exclusion of the executives. See Stimson, “Responsible Corporate Officer,” Washington Legal Foundation Legal Backgrounder, April 9, 2010. Industry amici argued on appeal that “because strict liability offenses violate due process when they result in more than relatively small penalties or cause grave damage to reputation, the Court should interpret the exclusion statute narrowly to not include strict liability RCO convictions.” Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal, Friedman et al. v. Sebilius, No 11-5028 (brief filed June 29, 2011).

There have been several other recent cases brought against executives under the RCO Doctrine. It is understandable that these executives, who are not charged with having had personal knowledge of the events giving rise to the charges, typically plead guilty and ask for the imposition of a lesser sanction than the government seeks.

For example, three former executives at Synthes, Inc., pled guilty to a single misdemeanor of introducing adulterated and misbranded medical devices into interstate commerce. The facts involved off-label promotion of bone cement Norian to treat vertebral compression of the spine. The company’s bone cement was used on the operating table without first obtaining an Investigational New Drug exemption, and three patients died during surgery. The defendants sought to pay a fine rather than serve jail time, but they were sentenced to up to nine months in prison, three months of probation, and $100,000 fines. United States v. Noria Corp., E.D. Pa., No, 09-cr-403-LDD. After the prison sentences were announced in November 2011, the special agent in charge for HHS OIG said, “Holding executives accountable for corporate wrongdoing continues to be a priority for our office…. The conviction of these…executives exemplifies the successful efforts by FDA’s Office of Criminal Investigations and its law enforcement partners to hold these individuals accountable and not allow them to escape liability by hiding behind a corporate shield.” BloombergBNA, Health Law Resource Center, Health Care Fraud Report 11/30/2011.

In 2010, Forest Labs pled guilty to marketing an anti-depressant drug for children before the drug won approval for that use and paid $313 million in criminal and civil fines. Thereafter, and without prior notice of additional sanctions, HHS OIG informed the elderly CEO Howard Soloman that he would be excluded even though he was not even accused of wrongdoing personally. Thereafter, the government reversed itself and notified Soloman that it had decided not to pursue his exclusion—but no clear basis for the decision was given.

Although rare, some defendants have fought such charges without entering a guilty plea. In 2009, the government charged executives of Stryker Biotech with mail and wire fraud, conspiracy to defraud the FDA and misbranding in connection with a bone surgery device, United States v. Stryker Biotech LLC, D. Mass., No, 09-cr-10330-GAO. The company had received approval to market a putty product for very limited purposes, when bone autografts were infeasible. But allegedly, after the company received information from doctors that the putty did not work well, the company began marketing another product for this purpose, even though the FDA had only approved the product as a bone void filler. According to the indictment, the company received reports of multiple adverse reactions such as inflammation and unwanted bone growth, necessitating additional surgeries.

It became apparent during discovery that the government brought the felony charges without even interviewing the surgeons who it claimed the company misled. When the defendants interviewed those surgeons, they established that the physicians had not been defrauded as the government claimed. Further, the evidence showed that out of 10,000 uses of the product for the unapproved purpose, there were only 63 reported adverse events. Bloomberg BNA Health Law Resource Center, Health Care Fraud Report 2/08/2012. Thus, according to the defendants, there was nothing material concealed from the medical community. In February 2012, on the first day of trial, the government dropped the case entirely against the former president and dropped the felony charges against the company.

In a fascinating matter, Allergan brought a complaint against the government...
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The case of Park v. Allergan provides a stark illustration of the distinct advantage of having an effective compliance program. The company officials could not “correct” conduct of which they had no knowledge, despite setting up robust policies for policing such conduct. Indeed, in the Park case, the company officials actually had prior notice of a violation. Thus, several commentators recommend adopting a gross negligence standard. See Glasner, “Are Misdemeanor Prosecutions Under Park Effective?”, FDLI Forum, July 26, 2011. They suggest the FDA Manual should eliminate the language that “knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution.” These commentators suggest that the government should pursue felony and misdemeanor prosecutions of the specific individuals with actual knowledge of the wrongdoing, rather than impose the strict liability crime under the RCO Doctrine.

As Gurney points out, criminal charges against the individual executive who had no knowledge of events makes much less sense today than it did in 1938. FDA should not indulge the fiction that executives—in pharmaceuticals or any other industry—can personally carry the burden of ensuring compliance. Modern day pharmaceutical executives supervise hundreds of thousands of employees and scores of corporate entities in dozens of countries. See B. Gurney, “The Crime of Doing Nothing,” ABA-CLE Health Care Fraud, May 16, 2007.

Because strict liability offenses violate due process when they result in more than relatively small penalties or cause grave damage to reputation, the Court should interpret the exclusion statute narrowly to not include strict liability RCO convictions. See Washington Legal Foundation Amicus Brief in Friedman v. Sebillius. Indeed, “[e]ven though strict liability crimes are morally objectionable and have generally been disfavored, courts have nevertheless permitted the imposition of strict liability for so-called “public welfare offenses,” but only where the penalties were “relatively small” and conviction did not cause “grave damage to an offender’s reputation.” Id., brief at 18, quoting Morissette, 342 U.S. at 256; see also Holdridge v. United States, 282 F.2d 302 (8th Cir. 1960) (Blackmun, J.).

Compliance is key to avoiding, or at least reducing, responsible corporate officer liability. Corporate officers and directors should focus on enhancements to the corporate compliance program aimed at making it “state of the art.” Cohen and Perigrine, “The Return of the RCOD,” National Law Journal (March 14, 2011). Such programs should prevent many violations, or if they occur, lead to the prompt reporting of violations to corporate officers. Of course, executives should know and understand the industry regulatory environment. They must understand the company’s compliance chain of command and take an active interest in the compliance program. Comprehensive compliance reports relating to both the plan and its effectiveness should be presented to the board and senior management at least annually. Executives should be personally engaged in some of the company’s public-safety activities, and should instill a culture of responsibility throughout the company. See New Jersey Law Journal, G. Herschman and A. Patel, “Health Care Executives Beware,” September 8, 2011.

Notably, the U.S. Sentencing Guidelines were revised in November 2010, adding a safe harbor to the culpability score provisions. This encourages companies to vest the individual with operational responsibility for compliance and ethics with “direct reporting obligations” to the board or an appropriate subgroup of the board, such as the audit committee. As a result, the compliance officer should develop processes in connection with his or her reports to the board, which aim to detect at an early stage any problems and permit correction. The senior executives should see these processes as a way to reinforce their duties to prevent and correct illegal marketing or distribution of products. These processes aim at the simultaneous goals of company compliance with the law and prompt reporting of any violations that may occur to protect officers and, hopefully, mitigate against government prosecution. J. Reiss, “Your Business in Court: 2009–2010,” 66 Food Drug L.J. 139; see 26 Crim Just 4, pg 10 (compliance).