



RESPONSIBILITY for Subordinates HAS ITS COST

By Joel R. Levin and Charles W. Mulaney

When a corporation engages in misconduct, government prosecutors typically try to pin the blame on the most senior executives who authorized or condoned the wrongdoing. But, in a series of recent cases, the government has taken this a step further by reviving the once obscure “responsible corporate officer doctrine” (RCOD). RCOD provides that executives can be held criminally liable for certain offenses if they have the authority to correct or prevent the corporation’s unlawful conduct and fail to do so, even if they were unaware of the misconduct.

For this reason, an RCOD conviction can be based

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solely on the executive's position in the corporation and the duties and responsibilities that come with that title. The doctrine has recently been used to target executives for corporate violations of the Food, Drug and Cosmetic Act (FDCA), and could potentially expand to other areas. All executives should be aware of this doctrine to avoid becoming the next target of its unusual theory of criminal liability.

Origins of RCOD

RCOD has its origin in a 1943 Supreme Court case (*United States v. Dotterweich*), in which the president of a pharmaceutical company was charged with the corporation's mislabeling and shipment of adulterated drugs under FDCA.

The Court held that a corporate officer can be criminally liable even without "the conventional requirement for criminal conduct — awareness of some wrongdo-

ing," if the officer was in a position to prevent the misconduct and failed to do so.

The Supreme Court clarified the doctrine in a 1975 case (*United States v. Park*) when it upheld the conviction of the president of a 36,000-employee retail food chain based on an infestation in a handful of warehouses, despite the fact that the president had delegated responsibility for this issue to a vice president.

In upholding Park's conviction, the Court held that in order to be convicted under RCOD, the officer must merely be in a "responsible relation" to the corporation's misconduct — that is, he or she must have the responsibility and authority to prevent or correct the violation and fail to do so.

The Court acknowledged, however, that a corporate officer cannot be held liable for conduct which he did not have the power to prevent, or could not prevent despite the exercise of "extraordinary care" (the so-called

"impossibility defense"). But this is a very narrow defense that the executive has the burden of proving.

Health Care Industry Enforcement

RCOD was used sparingly by prosecutors after the *Park* decision, but the federal government has embraced it in a number of recent cases against pharmaceutical executives. In 2010, the Food and Drug Administration began urging federal prosecutors to charge executives criminally under RCOD to deter off-label promotion of drugs. The FDA issued guidelines as to when an RCOD prosecution is appropriate, and emphasized such factors as whether the violation:

- ▶ Involves actual or potential harm to the public;
- ▶ Is obvious;
- ▶ Reflects a pattern of illegal behavior and/or failure to heed prior warnings; and
- ▶ Is widespread or serious.

The government has also been using its civil enforcement powers to punish executives under RCOD. In October 2010, the Department of Health and Human Services announced that it would use its authority to exclude executives from federal health programs, such as Medicare and Medicaid, based on the health care-related offenses of the company.

In doing so, HHS made clear that executives could be excluded based solely on the corporation's conviction. HHS advised that it would look to a number of factors in determining whether to exclude an executive, including the circumstances of the misconduct and the seriousness of the offense, the individual's role in the sanctioned entity, the individual's actions in response to the misconduct and information about the entity such as its compliance history, size and structure.

When it appears that the executive knew or should have known about the misconduct, HHS will operate with a presumption in favor of exclusion that can be overcome only if "significant

factors weigh against exclusion.”

The Department of Justice and HHS have been swift to implement their new policy. In 2009, four executives of medical device manufacturer Synthes Inc. pled guilty to misdemeanor charges of selling mislabeled or adulterated products under RCOD, and prosecutors are now seeking jail time.

In March of this year, Marc Hermelin, former chief executive of KV Pharmaceutical Co., pled guilty to a misdemeanor FDA violation as a responsible corporate officer and was sentenced to 30 days in jail, a \$1 million fine and a \$900,000 forfeiture. After Hermelin’s guilty plea, HHS initiated exclusionary proceedings against him, forcing him to resign from the company and sell off his stock.

In another prominent case, three top executives of the Purdue Frederick Co., Inc. pharmaceutical company pled guilty under RCOD for the corporation’s misbranding of OxyContin, and HHS subsequently excluded them from federal health programs. Because Medicare and Medicaid participation is essential to the pharmaceutical and health care industries, HHS effectively ended their careers in the industry.

Could RCOD Creep into the Financial Sector?

Although RCOD has been used principally in FDCA prosecutions, state and federal authorities have also applied it to other public welfare laws, including environmental regulations such as the Clean Water Act. Given the public outcry that no executives were prosecuted for fraud that contributed to the financial crisis, it is possible that the RCOD could also expand to the financial sector.

The U.S. Securities and Exchange Commission adopted a quasi-RCOD policy in a recent enforcement of the executive compensation “clawback” provision of the Sarbanes–Oxley Act of 2002. In that case, a federal court held that, the CEO and CSK Auto Corp. was required to pay back his bonus even if he was unaware of the misconduct that led to a financial restatement.

A similar policy may be implemented under the Dodd-Frank Wall Street Reform and Consumer Protection Act, given the breadth of its clawback provision. Commentators have also urged prosecutors and policymakers to incorporate RCOD into other enforcement areas, such as mortgage fraud, and some have observed that the Federal Deposit Insurance Corp.’s administrative enforcement division could potentially invoke it when regulating the banking industry.

Preventative Measures to Avoid RCOD Liability

Executives can mitigate the risk of RCOD enforcement by maintaining effective and well-documented compliance programs. Because the government’s guidelines on RCOD look to the officer’s efforts to prevent misconduct, a robust compliance program is essential. Elements of such a compliance program might include:

- ▶ Effective training of all personnel who have responsibilities in risk areas, particularly compliance with public welfare regulations;
- ▶ Confidential internal reporting mechanisms to ferret out misconduct, such as an anonymous whistleblower hotline;
- ▶ The use of periodic external audits in which the auditors have direct communication with management;
- ▶ Clarification of each officer or manager’s area of supervision and responsibility for ensuring compliance, as well as each employee’s reporting responsibilities up the chain of command;
- ▶ Prompt remedial measures whenever misconduct is suspected or detected; and
- ▶ Thorough documentation of all efforts to prevent misconduct.

The best way to avoid RCOD is to prevent any misconduct from happening in the first place. So executives must keep themselves apprised of compliance and remedial efforts more than ever. Though RCOD imposes criminal liability without regard to fault, an executive who tries in good faith to

ensure corporate compliance is less likely to be a target of RCOD.

One recent example demonstrates that an executive can ward off an RCOD enforcement action. In April 2011, HHS announced that it would exclude Howard Solomon, CEO of Forest Laboratories Inc., from participation in federal health programs. Solomon’s exclusion was to be based on the fact that Forest Labs entered a plea agreement on charges that it had illegally marketed the anti-depressant drugs Celexa and Lexapro as a treatment for minors and paid kickbacks to doctors to prescribe those drugs.

Solomon fought the notice of exclusion, presumably by presenting HHS with evidence that he was not culpable, and HHS dropped its exclusionary proceeding.

Although HHS’s reversal is encouraging to potential targets of HHS exclusions, it demonstrates that the executive will have the burden of showing that he or she is not an appropriate RCOD target. That is why documentation of all compliance efforts is essential for protection from an RCOD prosecution.

Because most corporations face a complex web of regulations, executives rarely have the time to monitor all areas of corporate compliance. Nevertheless, all upper-level management, including financial executives, need to be aware of the RCOD and its potential consequences.

Although executives in the health and pharmaceutical industries are most vulnerable under the current trend, the government could apply RCOD more broadly in the future, and executives should not be taken by surprise when that happens. 🌀

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