

Responsible Corporate Officer Doctrine: Federal government takes an aggressive approach aimed at corporate executives

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On April 13, 2011, Forest Laboratories, Inc. announced that its President and CEO, Howard Solomon, will challenge a potential action by the Department of Health and Human Services, Office of the Inspector General (HHS-OIG), to exclude him from participation in federal healthcare programs. The allegations against Solomon arise out of a 2010 civil and criminal settlement between Forest Laboratories and the Department of Justice. The action by HHS-OIG is the latest in a series of recent developments that threaten to substantially increase the personal risk that corporate executives face for their companies' non-compliance with federal law.

The Government Accountability Office (GAO) issued a report last year criticizing the Food and Drug Administration (FDA) for inadequate oversight of its Office of Criminal Investigations. The FDA responded in April of 2010 by stating that it would increase criminal misdemeanor prosecutions of drug company officers under the "Responsible Corporate Officer" doctrine. This doctrine is based on a line of U.S. Supreme Court cases that held that because the Federal Food, Drug & Cosmetic Act (FFDCA) is a "public welfare" statute, drug company officers could be strictly liable for their companies' criminal violations of the FFDCA, even if they were not personally engaged in wrongdoing. The FDA also announced that it would strengthen its debarment and disqualification procedures for companies and individuals.

The "Responsible Corporate Officer" doctrine was incorporated into the Clean Water Act and Clean Air Act criminal provisions in the 1980's. Increased use of that doctrine could expose executives in a myriad of industries to criminal prosecution for misconduct within their companies.

In October of 2010, HHS-OIG issued guidance on how it would exercise its discretionary authority to debar individual corporate officers when their company violates health care laws. Additionally, the FDA's head of litigation stated that the FDA would seek debarment of individual corporate officers for off label promotions and similar violations of the Food and Drug laws. HHS-OIG has debarred one corporate officer in the past. Last year, former KV Pharmaceutical chairman Marc Hermelin was excluded and later pled guilty to presiding over the

production and distribution of oversized morphine sulfate tablets. If debarred, Solomon will be the second corporate officer subject to the more aggressive enforcement standards being taken by the federal government.

The implications of these actions may not be limited to those involved in the healthcare or environmental fields, but potentially could impact all federal government contractors in every industry. Recent amendments to the Federal Acquisition Regulation, which governs most procurements of goods and services by federal agencies, make any “[k]nowing failure by a principal, until 3 years after final payment on any Government contract . . . to timely disclose . . . credible evidence of—(i) Violation of Federal Criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 . . . ; (ii) Violation of the civil False Claims Act . . . (iii) Significant overpayment(s) on the contract . . .” a cause for suspension. 48 CFR 9.407-2 (the so-called “mandatory disclosure rule.”) Since suspension/debarment reaches to individuals in a company, and since the acts of individuals may be imputed to the company, the new and far-reaching mandatory disclosure requirements impose significant compliance responsibilities on corporate executives in default of which executives face severe individual sanctions.

The Dodd-Frank Wall Street Reform and Protection Act requires the United States Sentencing Commission to review and consider increasing the sentencing guidelines for Securities Fraud, Bank Fraud and Mortgage Fraud. The Patient Protection and Affordable Care Act requires the Sentencing Commission to do the same for Federal health care offenses. The clear message coming from Congress and regulators is that companies and individual executives in regulated industries will face increased scrutiny, stiffer penalties and a higher risk of debarment or disqualification for non-compliance.

McGlinchey Stafford is prepared to assist you and your company in responding to these issues. The firm’s White Collar Defense & Corporate Investigations practice works with clients at all levels in defense of federal and state law enforcement. The team is headed by David Dugas and Gerard Wimberly. David served for almost a decade as the United States Attorney for the Middle District of Louisiana, working closely with government officials and enforcement agencies on a myriad of white collar cases and criminal investigations involving environmental issues, claims of tax and accounting fraud, government contracting, health care, banking and other areas. Gerard is head of the firm’s Government Contracts practice area and for years has handled civil and criminal matters for businesses and individuals involved in public procurements of goods and services.

Additionally, McGlinchey Stafford environmental attorneys routinely counsel on regulatory requirements and health and safety issues for our business clients in petroleum, chemical, manufacturing, real estate and other industries. The team represents and advises clients on matters involving regulatory compliance, government relations, litigation and business transactions and operations.

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David R. Dugas

Rick A. Curry