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MONDAY, DECEMBER 9, 2013

Chicago Daily Law Bulletin®

Volume 159, No. 240

Real peril exists in application of responsible corporate officer doctrine

In recent years, prosecutors have relied ever more heavily on the Responsible Corporate Officer (RCO) doctrine to charge company executives with criminal felonies even where these executives have no actual knowledge of the alleged corporate wrongdoing.

The RCO, which is basically criminal strict liability for executives, has been enacted in a limited number of federal statutes and regulations, most prominently in the area of food, drugs and medical devices, as well as the environment. Companies and their executives should be aware of the RCO doctrine.

The government's stated goal in the use of the RCO is to "change the corporate culture" of companies. This thinking is based on the premise that penalties imposed on companies do not sufficiently impact a corporation's culture. In an interview with the Philadelphia Inquirer in late 2010, the FDA litigation chief stated that the FDA was going to be targeting company executives for off-label marketing.

"They need to take this seriously and find out what is going on in the marketing and sales divisions of their companies," he said of pharmaceutical executives. "In my view, one thing that will get executives' attention is a few cases in which we have convicted two-legged defendants." (Christopher K. Hepp, "Big Pharma Executives Facing Legal Threat," The Philadelphia Inquirer, Oct. 31, 2010.)

This statement is consistent with comments previously made by Food and Drug Administration Commissioner Margret Hamburg regarding the use of misdemeanor prosecutions in a letter to Sen. Charles Grassley, R-Iowa, addressing issues raised by a Government Accountability Office (GAO) report titled "Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations."

This report focused on the FDA's Office of Criminal Investigations (OCI). With regard to a recommendation to "increase the appropriate use of misdemeanor prosecutions ... to hold responsible corporate officers accountable," Hamburg stated that the FDA would revise its policies and procedures to address the issue. (March 4, 2010, Letter from Com. Hamburg to Sen. Grassley, available at grassley.senate.gov.)

Even before the GAO report and congressional inquiry, there was already a shift underway at the FDA and the Department of Justice to use strict liability prosecutions, including felony charges, as an enforcement tool.

For example, in 2009 the government brought felony charges against the medical device company Synthes Inc. and four of its executives for testing spinal repair products on patients without FDA approval. Four corporate officers pleaded guilty to a misdemeanor in 2011 in the U.S. District Court for the Eastern District of Pennsylvania and received sentences ranging from six to nine months and fines of $100,000 each.

As part of their pleas, the executives accepted responsibility for the company's crime of running unauthorized clinical trials and for engaging in off-label marketing. This was the first time that executives had gone to prison for such a charge. *U.S. v. Synthes, Norian, et al.*, No. 09-cr-403 (E.D. Pa. 2009).

Rather than plead guilty, some executives have chosen to fight charges brought under the RCO doctrine, with varying degrees of success. In *U.S. v. Schulte and Pham*, No. 10-cr-455 (D. Colo. 2010), a case involving the alleged importation and marketing of unapproved medical devices, the government charged two former executives with felony violations of the Food, Drug and Cosmetic Act stemming from an investigation that began in September 2008.

The company, Spectranetics Corp., paid $5 million to settle the matter in December 2009. However, it wasn't until March 2012 that two of the executives were acquitted after a five-week jury trial. The CEO was not as successful and was convicted of making false statements during the FDA's investigation.

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The defendants in *U.S. v. Stryker Biotech* were even more successful than those in *Schulte*. *U.S. v. Stryker Biotech LLC*, No. 09-cr-10330 (D. Mass. 2009). There, the government charged Stryker Biotech's executives with mail and wire fraud, conspiracy to defraud the FDA and misbranding in connection with a bone surgery device.

However, on the first day of trial in February 2012, the government's case fell apart. It appeared that the allegedly concealed reports of adverse events related to the unapproved use of the product were extremely low; the evidence showed that there were 63 reported adverse events out of 10,000 unapproved uses. Therefore, the defense argued that nothing material had been concealed from the medical community and there was no harm.

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The DOJ dropped its charges against the individuals and accepted a misdemeanor guilty plea against the company. Although there is no guarantee that the defendants' successes in *Schulte* and *Stryker* can be repeated, what is guaranteed is that the cost of defending these cases over three years was high.

Moreover, the body of law supporting defenses to the RCO doctrine is not well-defined. Obviously, the strongest defense is showing that the regulations in question were outside of the executive's area of responsibility.

Affirmative defenses based on arguments that it was impossible for the defendant to prevent the regulatory violations, the executive took extraordinary care to prevent the violations or the violation was caused by a subordinate's failure to follow orders have not been consistently successful and often depend on the specific facts of each case.

Compare *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980) (defendants were entitled to present evidence to establish an affirmative defense that they exercised extraordinary care) with *United States v. Starr*, 535 F.2d 512 (9th Cir. 1976) (rejected a defense that the executive could not prevent rodent infestation because a subordinate didn't follow his orders).

Based on these cases, the recent increase in felony charges seem to indicate an overly aggressive application of the RCO doctrine when determining what, if any, charges should be filed.

Similarly, it appears that the courts' acceptance of particular defenses to the RCO doctrine is based on essentially ad hoc judicial assessments of how blameworthy an officer is for having been neglectful.

At both stages, there is a real peril, not to mention a lack of predictability, in the application of the RCO doctrine.