The Metropolitan
Corporate Counsel®

www.metrocorpcounsel.com

Volume 19, No. 4 April 2011

Hot Issues Alerts

Trends In White Collar Defense Practice: Stepped-Up Government Enforcement Efforts In The Pharma And Medical Device Industries

The Editor interviews ***Melissa Bayer Tearney,*** *a Partner in the Government Enforcement & Compliance Group at Choate, Hall & Stewart LLP in Boston, Massachusetts.*

Editor: There is a lot happening right now in the area of government enforcement and white collar criminal defense. Tell us about your practice and the type of trends you are seeing?

Tearney: My practice is currently focused primarily on the medical device and pharmaceutical industries. I represent both corporate executives and companies against allegations that they have violated federal statutes, such as the False Claims Act, the Anti-Kickback Statute and the Federal Food, Drug, and Cosmetic Act (FDCA). The Department of Justice (DOJ) and the U.S. Food and Drug Administration (FDA) are increasingly active right now in their enforcement efforts, particularly against senior executives who they believe are responsible for a company's misconduct.

I am seeing similarly aggressive enforcement initiatives by the Securities Exchange Commission (SEC) in light of the meltdown in the financial markets and by the DOJ across other business sectors.

Editor: Can you talk about the Park Doctrine and how the government is using this to investigate and prosecute corporate executives in the pharmaceutical industry even when they have done nothing intentionally wrong?

Tearney: The Park Doctrine refers to a line of cases which permits the government to hold "responsible corporate officers" strictly liable for a misdemeanor criminal offense under the FDCA. Under Park, it is not relevant whether the executive acted intentionally or even knew of the misconduct. An executive may be convicted solely based on his or her position in the company. While there are some limited defenses available, such as where it would have been "impossible" for an executive to terminate the conduct, these standards typically are too difficult for any individual to meet.

Melissa Bayer Tearney

A hypothetical example may be instructive. Under Park, a CEO, CFO, General Counsel, or VP of Marketing could be held criminally liable as a "responsible corporate officer" if sales representatives at his or her company promoted the company's product for a use not approved by the FDA. The government may charge the corporate executive with a misdemeanor, whether or not he/she was even aware of the marketing scheme developed and executed by the sales team. Some notable recent real examples include pleas by senior executives of Purdue Pharma and Synthes Corporation to misdemeanor charges that they "misbranded" products under the FDCA.

The Park Doctrine vastly expands criminal liability beyond traditional "intent" crimes and provides many challenges to an executive faced with charges based solely on the fact that he/she is a "responsible corporate officer."

Editor: What's behind the DOJ's increased white collar enforcement efforts? Why now?

Tearney: Over the last several years, the government has negotiated "big dollar" settlements with several pharma and medical device companies, sometimes requiring companies to pay billions of dollars. There has been a public outcry, particularly in Congress, questioning the DOJ for failing to hold individuals accountable for the misconduct. In Congress's view, the big health care companies have grown accustomed to paying large settlements, which have become nothing more than the "cost of doing business" or another tax obligation. As a result, Congress is publicly pressuring the DOJ to take more aggressive actions against individual executives, thus adding another disincentive for individuals to engage in illegal conduct.

Editor: What is at stake for executives being charged with these "unintentional crimes?"

Tearney: The stakes are extremely high. There are very serious collateral consequences arising out of executives being convicted of misdemeanor offenses under the Park Doctrine.

In addition to the imposition of large fines, federal law permits the government to exclude convicted individuals from participating in the federal health care system, including Medicaid and Medicare. For most individuals, exclusion means that they can no longer work in the health care industry, often losing their livelihood. The

Please email the interviewee at mtearney@choate.com with questions about this interview.

Office of Inspector General for the Department of Health and Human Services (OIG), which is charged with exclusion decisions and proceedings, has publicly committed to increasing its enforcement actions against individuals. To reinforce its public statements, OIG recently issued new guidelines regarding exclusion. For the first time, OIG has explicitly permitted the exclusion of officers and managers whether or not they knew, or should have known, of the illegal conduct.

Likewise, the FDA recently issued new guidelines for prosecuting responsible corporate officers under Park. The FDA guidelines make it clear that the agency supports the prosecution of individuals in certain instances, even though there may be no evidence that the individuals knew about the conduct for which they are charged.

Currently, Congress is considering amendments to the Federal Sentencing Guidelines which could be interpreted as requiring any individual convicted of a misdemeanor offense under the FDCA to be sentenced under harsher fraud guidelines. The amendments could make it more likely that individuals convicted under Park serve jail time.

Editor: In health care fraud cases white collar lawyers are increasingly handling both a criminal investigation and civil litigation at the same time. Why is this happening more frequently now, and how do you juggle these competing demands?

Tearney: Under the federal False Claims Act, the court seals cases filed by whistleblowers to provide the government with an opportunity to investigate the allegations outside of public scrutiny. Traditionally, the cases remained sealed until the government and the company settle any criminal and civil matters. The court then simultaneously dismisses the whistleblower case when the settlement is announced without the case ever being litigated.

Increasingly, the judiciary has lost patience with the slow pace of the government's investigations, which often take several years. Judges now are unsealing complaints more quickly, even while the government still is conducting its investigations and bringing witnesses before grand juries. The white collar defense bar now is in the position of defending the whistleblower's civil case and the government's criminal investigation at the same time.

The parallel proceedings raise complex legal and strategic issues. One issue is whether or not the government will decide to intervene in the whistleblower litigation and what that means for the defense of the case. Another important issue is how to conduct aggressive motion practice while potentially negotiating a resolution with the government.

There are also many issues around the scope and conduct of discovery. Clearly, there are Fifth Amendment implications when civil discovery is ongoing before the resolution of criminal liability for the company or individuals. As a result, corporate executives, who may be targets of a criminal investigation, can find themselves in a particularly difficult and uncomfortable legal position.

Editor: You have a lot of experience representing clients in their dealings with Federal Monitors. Please tell us about that.

Tearney: The government often has used Deferred Prosecution Agreements (DPAs) to settle criminal investigations. Under a DPA, the government defers its decision to prosecute a company, typically from 18 months to two years. If the company demonstrates ongoing compliance with the government's terms, then the government will not prosecute the company. In this context, the government has appointed monitors to oversee a company's business during the probationary period and to report regularly to the DOJ about the company's progress with compliance and/or its deficiencies. The company pays the monitor's fees, which often amount to several million dollars over the DPA period.

In my experience, it is more difficult for a company to conduct its business with any normalcy when a monitor is in place. The monitor has significant access to every aspect of the company's business and often plays a prominent role in the company's decision-making processes at all levels. The monitor audits the company for compliance "in real time" and the process requires a company to commit tremendous resources during the DPA period to satisfy the monitor's investigatory requests. In recent years, there has been significant controversy over the fees the monitors have charged companies for their services as well as allegations of favoritism by U.S. Attorney's Offices in the position to award monitorships. As a result, the DOJ has imposed restrictions over the appointment of monitors.

Editor: How can corporate executives enhance their focus on compliance efforts in order to prevent investigations from occurring?

Tearney: It is no longer sufficient for a company to simply have all the right policies in place. That is the easy part. The government looks behind a compliance program to assess its effectiveness. Companies must be in a position to demonstrate to the government that they are truly implementing their policies.

Many health care companies now operate under Corporate Integrity Agreements (CIAs). The CIAs outline what the government expects from companies in terms of compliance. The CIAs cover several areas of a company's business, including interactions with health care providers, research and development, clinical trial programs, training, and monitoring and auditing.

The bottom line is that companies cannot ignore clearly stated government mandates and argue "we did not know."

Editor: What should corporate executives do when the government raises concerns with their conduct? What steps should they take to defend themselves?

Tearney: Individuals must take any government interest in their conduct very seriously. First, they should immediately retain their own counsel. Company counsel is loyal to the company and the company alone. Conflicts of interest may arise between the company and individuals, and individuals must protect themselves by hiring counsel who is loyal to them alone and will look after their interests. What is good for the company may not be good for the executives, and often is not. For example, a company may want a senior executive to speak with the government during the course of an investigation. However, such a step could put the executive at serious risk of criminal liability.

Executives also should be aware that their employer may be required to pay for their legal costs. The by-laws of major companies often provide for indemnification relating to issues arising out of executives' employment.

Individuals must understand their rights so they can vigorously defend themselves.