

Client Alert October 2010

The Department of Justice (DOJ), Office of Inspector General (OIG) and FDA recently stated they plan to more aggressively pursue misdemeanor prosecutions of CEOs, managers and other executives under the long established but sporadically used “Responsible Corporate Officer Doctrine” (“RCO Doctrine”) under the Food, Drug and Cosmetic Act to prosecute corporate officers for public welfare offenses. We feel this expanded view was not contemplated by the Congress that enacted these provisions. Coupled with that news, Deborah Wolf FDA’s Regulatory Counsel in charge of device advertising and promotion compliance, was recently quoted as saying her organization was expanding from one person to three and they would be pursuing physicians and clinics who are promoting off-label. These two developments make it imperative that clients revisit their compliance programs and conduct reviews of their promotional activities to ensure they are in compliance. This CLIENT ALERT briefly discusses the RCO doctrine and provides recommendations about what a company can do to protect itself in this era of ramped up enforcement.

Dear Clients and Friends of the Firm,

Recent government threats.

As reported by Jessica Bylander in “The Gray Sheet” September 29, 2010, the Department of Justice (“DOJ”), Office of Inspector General (“OIG”) and the FDA are setting their sites on prosecution of CEOs, executives and managers at device and drug companies for off-label promotion of drugs and devices. ***The government’s agenda:*** make CEOs, executives and managers of device and drug companies personally responsible for off-label promotion. Coupled with that news, Deborah Wolf, FDA’s Regulatory Counsel in charge device advertising and promotion compliance, was recently quoted as saying her organization was expanding from one person to three and they would be pursuing enhanced enforcement of off-label promotion, including enforcement against physicians and clinics promoting off-label use. ***The FDA’s agenda:*** also attack customer-affiliated promotion of off-label use. Penalties for off-label promotion include civil money penalties, disgorgement of profits and financial and corporate structural settlements, imprisonment and even exclusion from participating in federal health care programs. This is a disappointing and unprecedented extension of the “Responsible Corporate Officer Doctrine” (“RCO Doctrine”) discussed more fully below. It makes

criminal, activity by executives that may be completely unknown to them and essentially results in strict and vicarious criminal liability.

Last spring, newly appointed FDA Commissioner Margaret Hamburg, MD, announced FDA would increase its misdemeanor prosecutions of CEOs, executives and managers for off-label promotion. Ann Ravel, Deputy Assistant General, DOJ, said that the Justice Department is “intent on . . . prosecuting individuals when they market off-label” and that DOJ’s “emphasis is going to be much increased in this area.” Not to be outdone, on September 21, 2010, at a public meeting, Mary Riordan, Senior Counsel at OIG, said that device and drug companies need to increase “accountability for compliance both at the board level and at the level of individual managers,” and that a company compliance officer shouldn’t be the only employee to bear the brunt of compliance execution and failure.

How is the Responsible Corporate Officer Doctrine applied?

The government is now resurrecting and seriously extending the use of the RCO Doctrine also known as the “Park Doctrine” under the Federal Food, Drug and Cosmetic Act (the “Act”). The doctrine is named after a CEO who in 1975 was held criminally responsible for infractions under the Act (in this case a filthy and vermin infested food warehouse) even though he was not personally involved in and lacked knowledge of the wrongdoing. When prosecuting off-label promotion today, the government has announced it will employ the RCO or Park Doctrine. Under certain conditions, a defendant can be found guilty under the RCO Doctrine even if they didn’t have knowledge of or participate in the off-label promotion. The government accomplishes this by showing that by virtue of the defendant’s position, the CEO, executive or manager is responsible for compliance, i.e. for stopping and correcting wrongdoing. Mere delegation of duties does not absolve an executive or manager of this responsibility.

Legal scholars have passionately argued that the Park Doctrine is being used improperly today. In 1975, the defendant in the *Park* case was fined only \$250. The application of the law by today’s prosecutors is much different. Recently, in 2007, the government accepted a misdemeanor plea taken by three pharmaceutical company executives who paid a combined \$34.5 million and were excluded from participating in federal health care programs for 12 years each. Such harsh penalties were not contemplated by Congress for prosecution of a misdemeanor without deference to intent.

What is the government’s goal and what is our view?

The government’s goal is, in our view, to inappropriately stretch the law to scare executives by leveraging personal criminal allegations into large corporate settlements that put huge settlement dollars into government coffers and impose government organizational controls over the offending firm. This is unnecessary criminalization of white collar activity that is already adequately controlled with civil remedies. We understand cracking down on off-label promotion and holding organizations civilly

responsible for their actions. We even understand and agree that knowing violations of the law can merit criminal prosecution, but strict and vicarious criminal liability holding well-intentioned and extraordinarily busy executives responsible when they have no actual knowledge of the wrongdoing must be more closely examined as a policy issue. The government has gotten far too comfortable throwing around criminal allegations and prosecutions today in these settings.

Whether fair or not, prosecutors are not backing down from their current aggressive use of the Park Doctrine to prosecute device and drug CEOs, executives and managers for off-label promotion. Board members may even be at risk. Riordan stated that in recent corporate integrity agreements (“CIA”), board members are being required to sign off on compliance measures. In sum, government’s position is that ultimate responsibility for operational control and compliance with regulations lies squarely with these responsible individuals, whether or not responsibilities have been delegated.

What can companies do?

Prosecutors are sending a clear warning. Company executives and their board members must audit their promotional review processes, product messaging, marketing programs, grant programs, sales training, compliance program, etc. and track implementation. It is important to note that the government is not only looking at conventional promotion. It is focusing on more indirect forms of off-label “communication” that may not actually qualify as traditional promotion, but nonetheless communicates about off-label uses. These can include grants for continuing medical education (“CME”) and physician-initiated trials, use of consultancies, such as advisory boards, and the like. Any compliance review conducted by a company must be expansive and sophisticated enough to explore and capture these non-traditional avenues of communication that the government may consider.

Our firm has performed compliance “reviews” for many companies. We understand how marketers and sales professionals sell. We know where to look for problematic messaging, programs and behaviors and we help companies fix their problems under the protection of the Attorney-Client Privilege. We also help establish compliance programs and train organizations on how to comply with the law. Don’t hesitate to contact us if you require assistance.



CALL US FOR HELP WITH YOUR REGULATORY & COMPLIANCE NEEDS

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations, the Anti-kickback Statute and False Claims Act, Stark, HIPAA and related statutes that apply to FDA-regulated companies. Our clientele includes companies that market and manufacture pharmaceuticals, medical devices, biologics, nutritional supplements and foods. Our clients range in size from global Fortune 500 companies to small start-ups. We are one of the few law firms in the country dedicated to FDA regulatory law. Our mission and absolute focus is providing our clients appropriately aggressive, yet compliant guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources.

DuVal & Associates understands the corporate interaction between departments like regulatory affairs, sales, marketing, legal, quality, clinical, compliance, R&D, manufacturing, finance, etc. Because of our industry experience in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We actually work with FDA every day on pre-market submissions, clinical trials inspections, warning letters, administrative appeals, and the like. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results, while practical, timely advice can help companies succeed. For more information, visit our website at www.duvalfdalaw.com or call us today for a consult at (612) 338-7170.

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