

Q&A With Choate's Diana Lloyd

Law360, New York (April 01, 2013, 12:44 PM ET) -- Diana K. Lloyd co-chairs Choate Hall & Stewart LLP's government enforcement and compliance practice group in Boston. Her practice focuses on federal and state government enforcement and compliance matters, internal investigations, and related business and securities litigation. She also represents clients before the U.S. Securities and Exchange Commission and other governmental agencies. Before joining Choate, Lloyd was an assistant U.S. attorney in Boston.

Q: What is the most challenging case you have worked on and what made it challenging?

A: The cases I find most challenging are representing senior executives of public companies who find themselves embroiled in parallel criminal and civil proceedings that often last for many years. When the government or a whistleblower alleges wrongdoing, the process of ascertaining all the facts and persuading multiple government agencies of the defendant's point of view can be complex and challenging. While the same legal and fact-gathering challenges are also present in matters in which we represent the corporate entity, the personal toll these matters take on our individual clients cannot be overstated.

Sometimes, there is very little support for the government's view that a particular senior executive at a company has engaged in wrongdoing, yet our client's life is effectively put on hold, his or her reputation is at risk or already destroyed, and the client suffers tremendous emotional and/or financial strain. While we have achieved great results for these types of clients, often persuading the government to take no action against our clients at all, the length of time that it tends to take to resolve these matters is difficult for both lawyer and client.

Q: What aspects of your practice area are in need of reform and why?

A: In the health care fraud area, there has been a tension for years between free speech rights guaranteed under the First Amendment and the U.S. Food and Drug Administration's efforts to prevent pharmaceutical and medical device companies from "off-label marketing." The problem is that FDA's ability to review and approve new indications for products on the market often lags materially behind advances in research and clinical use for those products. The easiest way for busy physicians to learn new information about new uses for products on the market is to hear from pharmaceutical and medical device company representatives who are eager to share that information. If companies share this information prior to FDA approval for a new indication, though, they are at risk of governmental scrutiny and even prosecution for off-label marketing.

Recently, in *United States v. Caronia*, the Second Circuit overturned the conviction of a sales representative for conspiracy to introduce a misbranded drug into interstate commerce based on its finding that the sales representative could not be prosecuted for truthful speech about off-label use of a product. While the implications of this decision are unclear, the government's expansive view of the reach of the law governing "misbranding" should be re-evaluated. Hopefully the *Caronia* decision, and all the discussion the case has generated, will provide an impetus to the government to re-evaluate its approach.

Q: What is an important issue or case relevant to your practice area and why?

A: The Dodd-Frank's whistleblower provisions are an important issue that have dogged the corporate world in the past couple of years. Since the SEC implemented whistleblower regulations in July 2010, the agency has reported a steady stream of whistleblower tips. In its most recent annual report, the SEC reported receiving 3,001 tips during fiscal year 2012. However, while the SEC reported that there were 143 enforcement judgments and orders issued during fiscal year 2012 that potentially qualify for whistleblower awards, thus far only one payout has been made. The SEC has provided little guidance on the types of whistleblower tips it will deem significant enough to investigate. In addition, because there has been only one reward, it is difficult for practitioners to glean much from the SEC's enforcement activity.

For now, it remains important for companies to recognize the need continually to reinforce their own compliance programs to ensure that: the culture encourages employees to report suspected wrongdoing internally, systems exist to handle internal reporting, and mechanisms are in place to promptly investigate allegations of misconduct. While an employee or other individual with an ax to grind may still contact the SEC and report wrongdoing that was previously raised and investigated internally, companies will be in a much better position with the SEC if they can demonstrate that strong compliance programs have been established internally. This will assure regulators that suspected misconduct was investigated and, if necessary, remedied.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: Kathy Weinman of Collora LLP has impressed me for years. Kathy has navigated many clients through challenging government investigations with consummate skill. She has excellent judgment and a calm manner that puts clients at ease. In this practice area, it is important to be able to deal with prosecutors, agents, other defense attorneys and witnesses with a wide range of personalities, and Kathy excels in that area. I have also been impressed with Kathy's ability to balance a top-notch legal practice with extensive public and community service and still manage to raise a wonderful family.

Q: What is a mistake you made early in your career and what did you learn from it?

A: Early in my career, I tended to have a single-minded focus on keeping my head down and doing my work without any external focus. I did not engage in much outside activity like bar association work, serving on boards or general networking. As I've advanced in my career, I have gotten much more involved in outside activities that are related to the practice of law. This change has not only made my professional life much more rich and fulfilling, but has taught me how much can be learned by expanding one's horizons in ways I never contemplated in my early years as a lawyer. I regret that I did not get involved in more outside activities as a junior lawyer, and I often advise younger lawyers not to make the same mistake I did.

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