Skadden

A Skadden Seminar for Pharmaceutical, Biotechnology and Medical Device Companies

A Dialogue on Regulation, Litigation and Shareholder Activism

Costa Mesa

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Seminar Takeaways

On June 6, 2013, Skadden hosted a seminar for representatives of pharmaceutical, biotechnology and medical device companies in Southern California. The seminar focused on the current and emerging challenges facing these industries and included interactive panel presentations from Skadden partners as well as a dialogue between in-house counsel and Skadden partner and Los Angeles office leader Brian J. McCarthy.

DOJ Enforcement Update

John Bentivoglio / Washington, D.C.
Jennifer Bragg / Washington, D.C.

In recent years the U.S. Department of Justice (DOJ) has recovered billions of dollars in settlements against health care companies under the False Claims Act (FCA). Panelists reviewed the biggest settlements from 2012 and 2013 and highlighted enforcement issues.

- Of the 15 largest settlements in 2012, five included a criminal component: one felony plea, three misdemeanor pleas and one deferred prosecution agreement.
- The most common allegations against pharmaceutical and biotechnology companies remain off-label promotion and improper payments to physicians. While inducement allegations typically are resolved on a civil basis (since a criminal plea would trigger mandatory exclusion), prosecutors remain very focused on such allegations.
- The largest settlements in 2012 (for $1.5 billion and $3 billion, respectively) involved both off-label promotion and patient safety allegations.
- In recent years, the DOJ's decision to pursue criminal charges in pharmaceutical and medical device sales and marketing cases can be attributed to: (1) allegations of harm to patients; (2) direct management involvement in, or knowledge of, improper conduct; and (3) promotion of products for indications after the FDA considered and rejected marketing applications for such uses. Companies should pay particular attention to these issues when assessing their compliance risks.
- In recent cases, the DOJ has focused on false statements made in FDA filings as the basis for criminal and civil actions. In one significant matter (the criminal settlement with Ranbaxy), DOJ cited nonprivileged internal audit reports as evidence that management knew of (and failed to timely address) manufacturing problems, thereby justifying criminal charges. Companies should pay careful attention to audit and assessment findings and have systems and controls to ensure problems are resolved promptly.

- Other trends in DOJ settlements are provisions focused on "drivers" of behavior that have created compliance problems. For example, several recent plea agreements and corporate integrity agreements include clawback provisions for executive compensation and prohibitions on territory-based incentive compensation for sales personnel.

When Negotiations Fail: Litigating False Claims Act Cases

Jack DiCanio / Palo Alto / Los Angeles
Matt Sloan / Los Angeles

FCA filings have steadily increased since the passage of the 1986 amendments to the act, which substantially expanded the role and recoveries available to private *qui tam* plaintiffs (relators) and provided for treble damages. The U.S. government has recovered more than $24 billion during that time, including $13.3 billion between 2009 and 2012. Since the 1990s, health care and pharmaceutical-related cases have been a major focus of FCA filings. In 2012, 60 percent of all FCA recoveries were in the health care field.

Given the increasingly novel and attenuated theories advanced by the government and relators, the increased pace of filings and the growing size of the settlements, the panelists advocated a new and more aggressive approach to FCA cases that involves holding the government and relators to their burden and filing aggressive, early motions to challenge the plaintiffs' case.

- The FCA allows private "whistleblowers" — such as relators — to file actions against federal contractors for defrauding the U.S. government.
- In *qui tam* cases, the initial complaint remains sealed — on average, for up to 13 months — while the DOJ investigates the case and decides whether or not to intervene. During this time, defendant companies often are in the dark regarding the specific details of the claims against them, putting them at a severe disadvantage to the government and relators.
- Before the seal is lifted, companies can take proactive steps to improve the strength of their position. Counsel should try to assess information from the subpoena and early negotiations, such as the nature of the charges and whether the investigation is civil, criminal or both. Defendants also may consider moving to partially unseal the complaint early on so that they can negotiate — or start planning their litigation strategy — from a position of strength. Exercising this sort of diligence in the early stages of an FCA investigation can provide significant advantages later in the litigation.
- After the complaint is unsealed, defendants should consider filing aggressive and early motions to improve their litigating position. Recently, health care defendants have been successful in moving for the return of privileged documents that relators improperly took from the defendant company, disqualifying relator's counsel for failing to return — and improperly using — such privileged documents, and obtaining discovery sanctions for the government's spoliation of important evidence.
- Defendants have also recently succeeded on motions to dismiss *qui tam* complaints under the "public disclosure" bar (which prohibits relators from bringing FCA cases on behalf of the government based on prior public disclosures) and for failing to allege fraud with sufficient particularity, pursuant to Fed. R. Civ. P. 9(b).
- Companies should conduct a careful cost/benefit analysis prior to pursuing litigation. While many FCA defendants opt to settle rather than pursue litigation, with proper preparation and by pressing the government to meet its proof, companies are able to improve their negotiating position in settlement, or when such negotiations fail, are able to prevail at trial.

- The panelists also discussed several novel theories recently advanced by relators and the government, including the "fraud on the FDA" theory of liability, where plaintiffs have argued that defendant pharmaceutical companies made false statements by failing to report post-market "adverse events" to the FDA. The relators in these cases have argued that because FDA approval was a precondition for payment, and the FDA allegedly would have withdrawn approval if the adverse events were reported, the company's claims for payment were false. Three federal district court judges in Boston recently have rejected this theory, holding that FCA liability cannot be predicated on assumptions about how the FDA would have responded had it been made aware of certain post-market adverse effects.

Securities Litigation Developments

Eric Waxman / Los Angeles
Peter Morrison / Los Angeles

While securities class action filings have slowed in 2012 as compared to prior years, the consumer noncyclical industry continues to be the most targeted sector, and health care, biotech and pharmaceutical companies made up 67 percent of all 2012 consumer noncyclical filings, according to a report by Cornerstone Research. Panelists discussed some of the reasons why pharmaceutical, biotech and medical device companies are common targets of securities class action filings and highlighted some ways in which companies can avoid or mitigate risk.

- Recent securities class action litigations against industry companies have focused on: (1) allegedly false representations of product efficacy or safety; (2) allegedly false statements concerning clinical trials; (3) forward-looking statements regarding market share or commercial viability; (4) forward-looking statements regarding regulatory matters; (5) off-label marketing; (6) acquisitions; and (7) joint ventures and collaborations.

- Companies can put measures in place to protect against many of the most common securities class action allegations. For example, companies that have issued "meaningful cautionary statements" in compliance with the Private Securities Litigation Reform Act's "safe harbor rule" prior to making forward-looking statements have been successful in defeating class action suits based on such forward-looking statements that later turn out to be false.

- While both big and small industry companies face the threat of securities class action filings, many recent cases have produced encouraging results for those that have taken proactive steps to keep the market adequately informed.

Under the Microscope: Activist Shareholders' Focus on the Health Care Industry

Brian McCarthy / Los Angeles
Rod Guerra / Los Angeles

Shareholder activism has increased significantly in recent years, including activist campaigns targeting companies in the health care industry. Approximately 20 companies in the pharmaceutical, biotechnology and medical device industry have been targets of activist shareholders in 2012 and 2013 alone. While almost every public company is a potential target of shareholder activism in this environment, panelists explained that with advanced planning companies may be able to make themselves less attractive targets and will be in a better position to defend against a campaign.

- Activists generally attempt to identify companies they believe are undervalued and then take a position in the company with the aim of advocating for changes they believe can unlock the business' value. Activists frequently pressure target boards to pursue one or more extraordinary actions, such as the sale of the target, divestiture of assets in a sale or spin-off, or distributions of cash through increased dividends or stock repurchases.
- Recent developments have enabled activists to enjoy a higher success rate and in many cases the ability to negotiate settlements without the need to consummate lengthy proxy contests. These developments include greater financial resources, greater support from traditional long-term investors and greater vulnerability of companies as a consequence of governance trends resulting in the elimination of stockholder rights plans and classified boards.
- Companies can minimize the risk of surprise by putting in place certain procedures such as instituting a stock watch program, monitoring ownership reporting on SEC forms and adding an advanced notice bylaw, each of which allow the company to recognize accumulators who may be potential activist shareholders as early as possible.
- Companies also should take steps to make themselves less of a target to potential activists by reviewing and revising governance policies that may make the company vulnerable, maintaining regular relations with shareholders and conducting a periodic review of their business plans, their performance relative to peer groups and the effectiveness of their communication program.
- Finally, companies should develop a plan of action to respond to any activist demand well before one is actually made. Such plans would include, among others, developing a communication strategy, drafting standby press releases, preparing talking points to respond to activists, advising management and directors of their options and duties under the circumstances and assembling both an internal and external team to deal with potential activist demands.

Panel Discussion: Major Legal Challenges Affecting Pharmaceutical, Biotechnology and Medical Device Companies

Moderator:
Brian McCarthy / Los Angeles

Panelists:
Elona Kogan / Vice President, Legal Affairs, Avanir Pharmaceuticals
Bill Bowen / Senior Vice President and General Counsel, Sequenom, Inc.

Skadden partner and Los Angeles office leader Brian McCarthy moderated a lively discussion between in-house counsel of two of California's leading health care industry companies that focused on the challenges their businesses face.

- For molecular diagnostics companies, anxiety loomed over the then-unsettled status of gene-related IP, as well as the FDA's "uneven" stance on regulating clinical laboratory testing.
- Counsel discussed the difficulties of advising their boards and management on enterprise risk management issues when the industry operates in areas in which there is little black-letter law and is subject to changing interpretations by regulatory agencies. One panelist noted that enterprise risk management is within the purview of that

company's governance committee of the board of directors, eliciting nods of agreement from the audience.

- With respect to managing litigation and e-discovery, panelists noted a need for a thorough understanding of IT policies and a strong partnership with the IT department. They reviewed the limitations of and challenges with moving to more progressive technology platforms and the need to regularly review and augment document retention policies. A clear understanding of the impact of using other means of electronic communications, such as texting, is still elusive, and there was unanimous agreement for the need to exercise extreme care when using all platforms.
- Also of concern to panel counsel were patient privacy issues and the government's focus on HIPAA enforcement. Use of a dedicated internal privacy specialist and internal billing services was cited as aligning with HIPAA compliance mandates. Best practices suggested include regular communication and coordination among the legal, compliance and IT groups.