Key Takeaways

Skadden

Fourth Annual Seminar for
Pharmaceutical, Biotechnology and Medical Device Companies

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On October 5, 2016, Skadden hosted its Fourth Annual Seminar for Pharmaceutical, Biotechnology and Medical Device Companies. The seminar focused on the current and developing challenges facing such companies and included panels comprising of Skadden partners and industry professionals.

Recent Enforcement Actions

Panelists examined major settlements with the Office of the Inspector General in the Department of Health and Human Services (OIG), Department of Justice (DOJ), and Food and Drug Administration (FDA) from the last 18 months and identified key trends.

Decrease in High-Dollar Settlements. Panelists first noted that billion-dollar settlements have become less common and there are several possible reasons for this trend. For one, settlement amounts tend to correlate to the products that are being investigated, and there are fewer investigations today across multiple products with significant sales. Another potential explanation is that judicial decisions have limited enforcement and regulatory restrictions on truthful, nonmisleading off-label statements by FDA-regulated manufacturers. Just as importantly, the panelists noted that the decrease in high-dollar settlements likely reflects the robust compliance programs that many companies have implemented over the past decade.

Scrutiny of Speaker Programs. While larger settlements have become more the exception than the rule, scrutiny and enforcement have not abated. Kickback allegations have supplanted off-label marketing investigations as the dominant issue in enforcement actions. Speaker programs, in particular, are drawing significant attention. Moreover, investigations into speaker programs are probing wider and deeper, and traditional defenses — such as the company performed a fair market value analysis — may no longer be sufficient on their own.

Panelists recommended that legal and compliance teams work with their colleagues to ensure that all financial relationships with health care providers (HCPs) are justified through a robust assessment process. For example, it is a best practice to examine whether a particular product actually needs an expansive speaker program in light of factors such as how long the product has been on the market and whether there are any new indications, warnings or contraindications that can support significant speaker program activity.

Impact of Investigations on Smaller Companies. Panelists also discussed how smaller and emerging life sciences companies — and executives and managers at such companies — have equal or greater risk compared with large companies. The panel noted that whistleblowers — who trigger most federal health care investigations — can and do work at both large and small companies. However, investigations can be more impactful, disruptive and damaging to a smaller company. In addition, executives at small companies are more likely to have engaged in substantive decision-making and communications regarding day-to-day operations and tactical approach, and thus are more likely to be scrutinized by law enforcement and regulatory agencies.

Absence of Corporate Integrity Agreements. Panelists also identified the recent trend that many settlement agreements do not include a corporate integrity agreement (CIA). Since 2013, 21 of 36 settlements have not included a CIA. One of the reasons for this development is that the government does not have the resources to negotiate or implement CIAs in every case. While there are benefits to a company in not entering a CIA, it should be noted that most companies get a release from the OIG in exchange for entering into a CIA. Thus, companies that do not enter into a CIA may face increased future scrutiny from the OIG.

Evolving Prosecutorial Approach. The panelists examined how recent indictments and guilty pleas of a Warner Chilcott subsidiary — as well as several Warner Chilcott executives, employees and speakers — provide insight into the evolving federal prosecutorial approach. Importantly, prosecutors are seeking and securing guilty pleas for health care fraud violations under 18 U.S.C. § 1347. This provision enables prosecution of false or misleading statements made to both public and private insurers.

The government also has pursued the theory that an employee (and consequently his employer) violated HIPAA by obtaining individually identifiable health information, and using that information to fill out prior authorization forms for financial gain. One Warner Chilcott charging document alleged that a pharmaceutical sales representative violated HIPAA by merely viewing a patient's medical file.

Prosecution of Individuals: Yates Memo

In September 2015, the U.S. Deputy Attorney General Sally Yates issued an internal memorandum titled "Individual Accountability for Corporate Wrongdoing" (often referred to as "the Yates memo"). The memo outlines six "required" steps to "strengthen" government efforts to hold individuals accountable for corporate misconduct. Panelists discussed the steps and how they are likely to impact companies.

The first and most widely discussed step from the Yates memo instructs that to be eligible for any cooperation credit, a corporation must investigate and disclose all relevant facts and identify all individuals involved in the corporate misconduct. Panelists noted that this is an all-or-nothing proposition: No longer is there an option to give up some information or information about select individuals or areas of the company. This creates an expectation that companies investigate relevant areas to show the government that the company has conducted a reasonable inquiry into any potential misconduct.

The focus on complete cooperation should prompt companies to consider, at the outset of an internal investigation or review, whether to conduct the inquiry under privilege and/or require that individual employees find separate counsel. It also should encourage company counsel (whether in-house or outside) to provide appropriate *Upjohn* warnings to avoid potential conflicts or disqualification issues down the road. Companies also may decide to involve their boards in investigations early in the process, especially if there is a possibility that executives or other senior management may be scrutinized in the course of an investigation or inquiry. Although the DOJ insists a company can earn credit by disclosing just the underlying facts without waiving privilege, panelists agreed that this can be challenging to implement because disentangling privileged communications from nonprivileged underlying facts can be difficult.

The second element in the Yates memo requires both criminal and civil corporate investigations to focus on individuals from the inception of the investigation. Thus, it is becoming increasingly common for subpoenas to name individuals from the outset. Panelists debated whether this was a real policy shift or just a political gesture codifying long-standing practices. They noted that the Warner Chilcott and Acclarent prosecutions of individuals all predate the Yates memo.

The third through fifth steps require cooperation across criminal and civil investigations (Step 3), prohibit corporate resolutions that provide individuals with protection from criminal or civil liability absent extraordinary circumstances (Step 4) and direct prosecutors to resolve corporate cases only after establishing a clear plan to resolve related individual cases (Step 5). The fifth step also requires that any declinations as to individuals be memorialized and approved by senior DOJ officials.

Panelists noted that some U.S. Attorney offices will not provide individuals with cold comfort letters, let alone written releases of criminal or civil liability. They agreed that Step 4 could impact the dynamic of any potential settlement, particularly in small companies where certain individuals are critical to the company's operation. Panelists also observed that political considerations may present a challenge with prosecutors trying

to justify the settlement, in writing, to their superiors. Panelists anticipate that steps 3 to 5 may prolong many investigations and make it more difficult to achieve truly global resolutions of civil and criminal investigations.

The sixth and final step in the Yates memo instructs civil attorneys to evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay. While potentially laudable in the abstract, this step could encourage wasteful investment of government resources to pursue cases without hope of commensurate financial recovery.

Panelists pointed to a number of recent food safety cases in which the FDA has successfully pursued criminal charges against individuals as guideposts for what companies in the pharmaceutical and medical device fields may encounter because the underlying statutory regime — the Food, Drug and Cosmetic Act — is the same. Panelists emphasized the importance of a company being aware of the risk profiles of its products as well as of contraindicated uses. Companies should have proper controls in place to address such issues.

Securities and M&A Litigation Update

There were 189 securities fraud class action filings in 2015, an 11 percent increase over 2014. Once again, pharmaceutical, biotechnology and medical device companies were the most targeted. In the first half of 2016, that upward trend continued. The number of securities fraud lawsuits increased 37 percent over the first six months of 2015, and 27 percent were against pharma, biotech and medical device companies. The panelists discussed ways to attempt to reduce companies' securities litigation risk, including:

- The plaintiffs' bar continues to file securities fraud actions based on statements and opinions concerning FDA approval. The general rule when deciding whether/what to disclose from an FDA communication is that the statement, opinion or projection must fairly align with the information known and available to the company. In order to ensure that public statements meet that standard, companies should consider whether the FDA communicated a definitive opinion, as opposed to a preliminary view or a suggestion, whether data the company possesses contradicts any proposed statements, and whether any information the company is not planning to disclose renders a statement of optimism misleading.
- Another frequent target of securities fraud lawsuits arises from omissions regarding FDA communications. The general rule is that a company is under no obligation to disclose interim communications or feedback from the FDA. However, once a company communicates with the public about an issue, it must ensure that the communication accurately reflects the state of affairs on that issue. It is important to be aware, as the *OvaScience* case teaches, that a statement can become misleading if the company learns or receives additional information. Thus, it is critical that companies consistently re-evaluate and update their disclosures as necessary. One way to address this concern is to create a disclosure committee.
- Fraud claims also are frequently brought based on statements about clinical trials. Importantly, federal securities laws do not impose requirements regarding how a company must conduct its studies. Indeed, the case law makes clear that companies do not have to adhere to the highest research standards or conduct trials in accordance with best practices. However, any affirmative statement a company makes regarding trials must be accurate. Similarly, a company has no obligation to report interim data to the market, but if it does, that could impact what a company must disclose going forward.
- A trend has emerged in which plaintiffs are asserting claims against companies in the context of a joint venture or co-promotion agreement. A recent case in the U.S. Court of Appeals for the 2nd Circuit should serve as a warning. In that case, the plaintiffs brought claims against Company A based, in part, on statements made by employees of Company B under the theory that Company A should be liable for those statements because it had a co-promotion agreement with Company B. The 2nd Circuit applied the U.S. Supreme Court's *Janus* standard, which states that a company or individual can be held liable for a misrepresentation only if that person or entity had "ultimate authority" over the statement. Notwithstanding that seemingly demanding standard, the 2nd Circuit concluded that there was a dispute of material fact as to whether Company A had ultimate authority, even though the evidence of such authority was decidedly thin. Given the uncertainty engendered by this 2nd Circuit decision, companies should exercise care in how they draft co-promotion agreements, and in ensuring that partners, co-promoters and joint venturers abide by the terms of any such agreements.

The panel also discussed recent trends in merger litigation, noting that both the incidence of merger litigation and the prevalence of disclosure-only settlements to resolve such lawsuits have declined. This trend is likely the product of more companies utilizing forum selection bylaws to limit the jurisdictions where such claims can be brought, as well as several Delaware Court of Chancery opinions calling into question the propriety of disclosure-only settlements. The plaintiffs' bar has responded to this trend in a number of ways. As an example of one such response, rather than asserting claims for breach of fiduciary duty subject to forum-selection clauses, plaintiffs are bringing claims under Section 14 of the Securities Exchange Act.