Key Takeaways

Skadden

Skadden's Fifth Annual Pharmaceutical and Medical Device Seminar

Enforcement and Litigation Strategies

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On November 17, 2015, a group of Skadden attorneys and corporate counsel joined representatives from more than 20 life sciences companies to discuss U.S. enforcement issues companies throughout the industry face. The key takeaways from the panels are summarized below.

DOJ Enforcement Update

Panelists examined major settlements from the last three years and identified key trends.

They discussed how financial relationships with physicians and other health care professionals (HCPs) remain the most significant enforcement risk area for pharmaceutical and medical device companies.

- Over the last decade, the threshold for bringing a case premised on an Anti-Kickback Statute violation has lowered, and financial relationships that may not have attracted scrutiny in years past are becoming the basis for today's enforcement actions. For example, though the number of cases in which companies allegedly offered HCP trips to resort destinations has declined, the government has now begun to focus on the substance of a company's speaker programs and on whether there is appropriate value to the company for the compensation that is being paid to health care providers.
- Panelists recommended that legal and compliance teams work with their colleagues to ensure that all financial relationships with 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.

They also examined how executives at small pharmaceutical and medical device companies are at greater risk for individual prosecution than their counterparts at larger companies, in part because they are more likely to have engaged in substantive decision-making and communications regarding day-to-day operations and tactical approach.

Additionally, they discussed how Current Good Manufacturing Practice violations have not been a significant factor in recent False Claims Act actions, and we expect that trend to continue except in cases demonstrating significant patient harm resulted from such violations.

They also looked at how it is no longer a foregone conclusion that when a life sciences company enters into a settlement agreement the company will also be expected to enter into a Corporate Integrity Agreement (CIA). In 2014, there were 13 settlement agreements and eight of those did not result in new CIAs. To date, there have been 12 settlement agreements in 2015 and six of those resulted in no new CIA. Furthermore, although settling a case while under a current CIA can result in exclusion, that outcome is not inevitable. By the end of October 2015, four companies under pre-existing CIAs entered new settlement agreements and none of those entities were excluded.

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 USC § 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 by filling out prior authorization forms, an employee (and consequently his employer) violated HIPAA by obtaining individually identifiable health information and using such information for financial gain. One Warner Chilcott charging document professed that a pharmaceutical sales representative violated HIPAA by merely viewing a patient's medical file.

The panel also discussed the recent Genzyme settlement and deferred prosecution agreement (DPA). Unlike previous DPAs, Genzyme's agreement with the Department of Justice and the U.S. Attorney's Office for the Middle District of Florida includes new provisions that resemble a "mini CIA" and signal that the DOJ is beginning to try its hand at compliance monitoring.

Panelists also examined recent trends in whistleblower civil litigation. For example, relators and their counsel are demonstrating increased willingness to pursue cases even after the government has declined to intervene or has allowed the case to become unsealed. This uptick in plaintiff-led civil suits is fueled by the substantial settlements over the past decade and supported by an increasing number of former prosecutors joining the relators' bar.

A few recent cases hint that the issue of statistical sampling of claims in FCA cases could become a major source of stress for government contractors, health care providers and other companies seeking government funding. While some courts reject the use of statistical sampling to establish any element of a case, others limit its application to determination of damages. But in one 2014 Eastern District of Tennessee case, the court allowed the use of statistical sampling to establish liability, knowledge and materiality.

Prosecution of Individuals: New DOJ Memo and Recent Developments

On September 9, 2015, the DOJ issued a memorandum titled "Individual Accountability for Corporate Wrongdoing" (often referred to as the Yates memo).[1] The memorandum outlines six "required" steps to "strengthen" government efforts to hold individuals accountable for corporate wrongdoing. Panelists discussed the steps most likely to have a new effect on life sciences 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 policy presumes the occurrence of the alleged wrongdoing and may preclude cooperation credit for investigations that do not reveal evidence of culpable conduct.

It also adds complexity from the start of even seemingly minor investigations because in order to gain any cooperation credit, companies must maintain flexibility to make any government-requested disclosures. Companies will need to consider retaining outside company counsel and individual employee counsel earlier, and ensure careful Upjohn warnings throughout to maintain their sole discretion to disclose information learned. Companies also may decide to involve their boards in investigations much sooner, especially if there is a possibility that executives or other senior management were involved in or were aware of the alleged misconduct.

Although the DOJ insists that a company can earn credit by disclosing just the underlying facts without waiving privilege, panelists agreed that this might prove difficult to implement because disentangling privileged communications from nonprivileged underlying facts can be challenging. Panelists questioned the true value of "cooperation credit" when many companies investigated in recent decades did not appear to realize meaningful benefits in exchange for their cooperation.

[1] Memorandum from Sally Quillian Yates on Individual Accountability for Corporate Wrong Doing (Department of Justice Sept. 9, 2015), *available at* http://www.justice.gov/dag/file/769036/download.

The second step requires both criminal and civil corporate investigations to focus on individuals from the inception of the investigation. Panelists debated whether this was a real policy shift or just a political gesture codifying long-standing practices. They noted that the Warner Chilcott, HDL and Acclarent prosecutions of individuals all predate the Yates memo. Whatever the official policy, in recent years the government's focus on corporate liability likely is because such cases promise higher financial recoveries and the government's exclusion power provides greater settlement leverage against corporations. The government also might have avoided criminal cases against individuals because they are more difficult to prove. If pushed to hold more individuals accountable, the government may elect to pursue misdemeanor prosecutions under the Federal Food, Drug, and Cosmetic Act and other strict liability statutes that demand only a "preponderance of the evidence."

The third through fifth steps in the Yates memo require cooperation across criminal and civil investigations, prohibit corporate resolutions that provide individuals with protection from criminal or civil liability, and direct federal prosecutors to resolve corporate cases only after establishing a clear plan to resolve related individual cases. The fifth step also requires that any declinations as to individuals should be memorialized and approved. Panelists agreed that these steps could prolong many investigations and obstruct efforts to achieve a "global peace."

While the first step incentivizes higher-level executives to produce evidence implicating lower-level employees, steps three through five create a counter pressure to encourage lower-level employees to incriminate the company and its executives. In many cases, these lower-level employees might possess the evidence the government needs to establish the most difficult elements of its case (*e.g.*, intent).

The last step described 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 some might applaud an effort to empower assistant United States attorneys to pursue cases against guilty individuals that might otherwise escape accountability, panelists questioned whether this policy will encourage wasteful investment of government resources to pursue cases without hope of commensurate financial recovery.

State Attorney General Enforcement Actions and Defense Strategies

Investigations initiated by state attorneys general (AGs) are similar to federal investigations in many ways, but there are some notable differences that may influence a company's litigation strategy.

Panelists agreed that state AGs are often more likely than their federal counterparts to be influenced by and beholden to politics and the media. Panelists expressed the opinion that many state AGs have political aspirations and may use their investigation of a company as a platform to highlight their political ideologies.

State consumer protection and Medicaid fraud statutes are generally broader and more prosecution-friendly than similar federal statutes. These provisions, therefore, are rarely challenged, leaving little case law to help defendants develop a litigation strategy in a potentially unfriendly forum.

Panelists provided practical tips for document and data production:

- Regardless of who is conducting the investigation, it is important to build rapport with your investigator. The investigator may be able to tell you whether he has heard a detailed account of the facts from other prosecutors or whistleblowers.
- State AGs are likely to make sweeping and overly broad document and data requests. Panelists suggested that companies make an early effort to narrow the scope of the requests and productions by time, geography, relevant personnel and tailored search terms.
- If the state investigation is trailing a federal investigation, consider whether to offer to produce relevant information that already has been provided to the federal government or other state investigators. State AGs may have limited resources to review your productions and therefore may be flexible with their requests and open to negotiation.
- Not all states offer privacy and data protection for materials produced in the course of an investigation. Before providing materials to the AG, panelists encouraged counsel to review state statutes and append state-specific protective language to each production.

When multiple state and federal investigations arise, companies should explore opportunities to reduce the risk that other states will join:

- Although unlikely to halt all interested investigators, proactive outreach to states that have not yet initiated a formal investigation may help them decide not to pursue action or to limit the scope of their investigations. When presenting your case to a state AG, be thoughtful about ways to explain what went wrong; present evidence of the company's efforts to comply during the same time period; explain changes in policy, controls, culture or personnel in the period following the relevant timeframe; and demonstrate the company's effort to redress or mitigate harm.
- Develop strategies for dealing with states. In some cases it may be best to engage in individual, rather than collective, commu-

nications regarding an approach to the investigation. Such a strategy is advisable when states seem to disagree regarding the necessary scope, depth, timeline and anticipated outcome of the investigation.

- Some states prefer to settle, so it may be possible to engage in early, straightforward discussion of settlement terms.

Panelists also emphasized that companies should be cautious and thoughtful about negotiating settlement terms and injunctive relief. Injunctions, in particular, can cause long-term competitive harm; accordingly, it is important to negotiate a firm sunset provision on settlement terms to ensure that prohibitions on product development, promotion, marketing or distribution are not indefinitely deferred.

The terms in early settlement agreements may influence what terms are proposed in later negotiations with other states. Additionally, many companies are not in a position to have different business practices in each of the 50 states. Panelists suggested that before entering an agreement with one state, consider whether the company would be willing to accept the terms of the proposed agreement if they applied nationwide.