Key Takeaways

Skadden

A Dialogue With Corporate Counsel: Skadden's Seventh Annual Pharmaceutical and Medical Device Seminar

Enforcement and Litigation Strategies

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On November 14, 2017, Skadden hosted its Seventh Annual Pharmaceutical and Medical Device Seminar in New York City, which focused on U.S. enforcement issues faced by companies throughout the industry. The key takeaways from the panels are summarized below.

DOJ and OIG Enforcement Update

Panelists examined major enforcement actions from 2017 and identified key trends.

Aggressive Enforcement With a Decrease in High-Dollar Settlements. Panelists noted that the Department of Justice (DOJ) continues its aggressive pursuit of criminal enforcement actions and civil False Claims Act (FCA) cases against companies. While promotional activities and anti-kickback practices remain the most common areas of scrutiny, the DOJ has expanded its focus on patient assistance programs, reimbursement support and related privacy issues.

In 2017 to date, the DOJ has reached settlements with eight pharmaceutical and medical device manufacturers, totaling approximately $1.2 billion. This is three fewer settlements than in 2016, and $400 million short of 2016 recoveries. Panelists observed that this trend may be due to the existence of fewer "blockbuster" drugs, as settlement values often are correlated with sales of the relevant products. The lack of Senate-confirmed U.S. attorneys in key districts also may have contributed to the modest number of settlements in the first 10 months of 2017.

- Panelists noted the increased prevalence of alleged Health Insurance Portability and Accountability Act of 1996 (HIPAA) violations in recent settlements. They suggested that companies handling protected patient health information could look to the compliance provisions in Aegerion Pharmaceuticals, Inc.'s (Aegerion) recent deferred prosecution agreement for guidance when reviewing their privacy controls.

New Focus on Liability for Patient Assistance Programs. Panelists discussed the ongoing investigation based out of the District of Massachusetts examining manufacturers' donations to patient assistance programs (PAP) sponsored by third-party charitable organizations. Approximately 20 manufacturers have publicly disclosed inquiries relating to this investigation.

- Panelists highlighted the PAP allegations in the recent Aegerion settlement documents, which suggest that manufacturer donations may run afoul of the Anti-Kickback Statute (AKS) if the receiving charity begins to function as a "conduit" for the manufacturer.

They observed that, while the controls in Aegerion's corporate integrity agreement (CIA) are stringent and provide useful guidance for manufacturers looking to continue charitable donations in the context of the ongoing investigation, the CIA controls do not address all of the risk areas associated with such donations.

- Additionally, panelists observed that the DOJ's focus on PAPs appears to stem from the government's larger concern with drug pricing. Panelists noted that manufacturers may wish to consider ways to minimize the risks associated with drug pricing, such as transparent documentation of drug pricing review processes.

Continued Focus on Speaker Programs and Promotional Activities. Panelists commented that speaker programs and promotional practices remain the most common risk areas.

- The DOJ continues to scrutinize the legitimacy of speaker programs and is likely to review, for example, the number and type of health care providers (HCP) on program sign-in sheets and the frequency with which those HCPs previously attended similar programs. The panelists noted that a former pharmaceutical company district manager and sales representative recently were charged under a novel application of the aggravated identity theft statute (18 U.S.C. §1028A) based upon allegations that they signed speaker program sign-in sheets on behalf of HCPs who did not actually attend programs.
- Panels noted decreased enforcement against off-label promotion now that case law has firmly established that the First Amendment applies to manufacturers' promotional speech. However, panelists cautioned that allegedly false and misleading statements are not protected under the First Amendment, and there may be an uptick of enforcement against false and misleading statements in 2018.

Decreasing Use of Corporate Integrity Agreements (CIA). In the past, a settlement with the DOJ almost always guaranteed that the Office of the Inspector General in the Department of Health and Human Services would enter into a new CIA with the HCP, but panelists explained that CIA agreements no longer are a foregone conclusion, particularly for civil-only settlements. In 2017, only two of the eight civil settlement agreements involved a new CIA.

After the Prescription: Recent Developments and Considerations in Patient Assistance

Panelists highlighted four primary areas of risk in patient assistance and reimbursement support programs: the AKS, the FCA and criminal health care fraud statute, HIPAA and privacy considerations, and off-label promotion. Panelists described off-label promotion as the lowest overall area of risk in the current environment, but noted that two recent settlements involving patient assistance have been in the context of alleged off-label promotion.

Panelists discussed the recent criminal charges against former Insys Therapeutics, Inc. employees, as well as the settlements involving Warner Chilcott U.S. Sales LLC and Aegerion. In each case, company employees allegedly assisted with the reimbursement process, including by completing prior authorization (PA) forms and letters of medical necessity (LMNs) in a manner that resulted in false or fraudulent claims for reimbursement being submitted to public and private health care payors. Panelists emphasized that filling out LMNs and PAs gives rise to risk under the AKS, FCA and HIPAA, particularly if companies provide assistance beyond completing basic demographic information.

Panelists then focused on the increase in enforcement activity concerning patient assistance programs. They explained that while these programs provide important patient benefits and can be operated consistent with relevant laws and regulatory guidance, the government is skeptical of programs that they believe interfere with a patient's incentive to make cost-effective treatment decisions or involve the manufacturer in the completion of patient or clinical documentation that is submitted to payors. The ongoing District of Massachusetts PAP investigation demonstrates this concern, as do other ongoing investigations involving copay coupons, relationships with pharmacy benefit managers and nurse educators.

Pitfalls and Protections: Ethical Considerations in FCA Investigation and Litigation

Panelists focused on the ethical considerations in-house counsel face during internal investigations and FCA litigation. They emphasized that in every case, all counsel should consider the question: Who is the client? They cautioned that a failure to address this issue during interviews and other investigative activity can create challenges in future litigation.

The panelists discussed the decision in-house counsel face in determining whether to engage outside counsel for an investigation, noting that the decision will turn on the facts of each particular case. Panelists also addressed the considerations involved in dealing with potential whistleblowers during investigations. They emphasized the importance of documenting all employment actions related to suspected whistleblowers, but also suggested that appropriate precautions can be taken to protect the company when confidentiality is in question.

Panelists then turned to discussing the scope of the attorney work product protection. While many companies in the heavily regulated pharmaceutical and medical device space face a constant threat of investigation or litigation, some courts refuse to apply the attorney work product protection unless there is an immediate threat of litigation. They also commented on efforts by *qui tam* relators to use improperly obtained confidential or privileged materials in FCA litigation, including recent successes by the plaintiff's bar in asserting the crime-fraud exception to make use of privileged communications. Accordingly, in-house counsel should be careful to take all necessary steps to maintain privilege, but also anticipate that relator's counsel may challenge privilege claims during litigation.

Finally, panelists discussed counsel's ethical obligation to report findings of wrongdoing during investigations. In many instances, attorneys have an ethical obligation to report up the chain of command at the company even if they are not required or allowed to report to the government. Counsel should carefully consider their ethical obligations, and what they must report, during these situations. It is often helpful to call on outside counsel for ethical advice, and to document the basis for decisions that are made.

Escobar and Beyond: Developments in Life Sciences Litigation

Panelists discussed the impact of the 2016 Supreme Court opinion in *Universal Health Services v. United States ex rel. Escobar*, 579 U.S. — (2016). The panelists highlighted what changes have followed *Escobar* and what the case means for parties litigating FCA cases going forward. *Escobar* focused on the question of whether the implied false certification theory could serve as a basis for liability under the FCA and predictably found that it could. Equally important, *Escobar* affirmed that the FCA's materiality requirement is a "rigorous" and "demanding" standard requiring the government or relators to show that the defendant's non-compliance influenced or was capable of influencing the government's payment decision. Panelists acknowledged that lower courts have differed in their interpretation of *Escobar*'s pronouncement on materiality, but agreed that a renewed emphasis on materiality creates more opportunity for defendants to move for dismissal and summary judgment. They also noted that a meaningful materiality standard provides avenues for factual and expert discovery to examine whether the government would or would not have paid a specific claim in light of an alleged falsity.

FCPA: Where Are We Now? Where Are We Heading?

Panelists reviewed trends and recent investigative and enforcement activities involving the Foreign Corrupt Practices Act (FCPA). They agreed that both the DOJ and the Securities and Exchange Commission (SEC) appear committed to enforcing the FCPA, and they highlighted recent major settlements with life sciences companies.

Panelists observed an increase in significant multinational FCPA investigations and an uptick in settlements with foreign enforcement agencies alongside settlements with the DOJ and SEC. For life sciences companies, they identified recent FCPA investigative activities in China, Russia, Mexico, Brazil, Argentina and Colombia. Panelists also observed that the DOJ and SEC are pursuing novel theories of liability involving a company's charitable donations as well as a company's hiring of friends and family of government officials — both are deemed a thing of value within the scope of the FCPA and require additional diligence by companies to avoid such allegations. The panel also reported on the DOJ "pilot program" and its limited application to relatively small matters and the government's requirement of disgorgement even where no prosecution is warranted. They also discussed DOJ guidance on compliance programs issued earlier this year and the apparent trend toward requiring a monitor or a lesser form of post-resolution oversight.

In 2017, there has been a decrease in corporate penalties secured through FCPA settlements. Panelists explored the extent to which this trend might stem from the administration's stated concern with the harm such corporate penalties can cause to innocent shareholders. They also predicted that the DOJ will continue prioritizing the prosecution of individuals and noted that the SEC has indicated that it remains focused on holding individual wrongdoers accountable.

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Meanwhile at the FDA … Current Enforcement Theories and Individual Prosecutions

Panelists reviewed recent trends in Food and Drug Administration (FDA) enforcement actions, including the agency's use of enforcement tools in new ways. The discussion included a review of the criminal liability that arose in connection with AmerisourceBergen Specialty Group's failure to register its repacking facility and Baxter's alleged failure to investigate compliance concerns raised by a plant employee.

Panelists also cautioned that, while recent injunctions have focused primarily on food and dietary supplement manufacturers and compounding facilities, the recent Philips North America consent decree serves as a reminder that the FDA can and will pursue an injunction for unremediated violations without first issuing a warning letter.

In discussing recent individual prosecutions, the panelists juxtaposed the success the DOJ has had in pursuing misdemeanor Food, Drug, and Cosmetic Act prosecutions in the food and drug compounding sectors against the mixed success in the drug and medical device sectors.

Panelists concluded the discussion with a review of the FDA's January 2017 Draft Guidance documents, questioning whether they reflect precedent on which the agency intends to build or are more reflective of the position of the former administration.

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