Key Takeaways

Skadden

Enforcement and Litigation Strategies: Skadden's Eighth Annual Pharmaceutical, Biotechnology and Medical Device Seminar

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On March 15, 2018, Skadden hosted its Eighth Annual Pharmaceutical, Biotechnology and Medical Device Seminar in Palo Alto, California, 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 recent enforcement actions 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, the DOJ reached settlements with nine pharmaceutical and medical device manufacturers, totaling approximately $1.45 billion. This is two fewer settlements than in 2016, and $235 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, and improved compliance programs throughout the industry.

- 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 U.S. Attorney's Office for 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, and one company – United Therapeutics (UT) – entered into a settlement with the DOJ in late December 2017 that included a five-year corporate integrity agreement (CIA).

- In its civil FCA settlement, UT agreed to pay $210 million to resolve allegations that its relationship with an independent charitable foundation operated as a conduit for co-pay assistance to patients using UT's products. The DOJ also alleged that UT violated the Anti-Kickback Statute (AKS) and FCA through its policy of not permitting needy Medicare patients to participate in its free drug program — which was open to other financially needy patients — and instead referring them to the charitable foundation so claims could be submitted to Medicare.
- Next the panelists discussed the extensive controls in the UT CIA surrounding relationships with independent charitable foundations. These controls include the separation of commercial organization involvement in intermediate care facility (ICF) activities; strict requirements regarding the review and approval of donations to ICFs; and policies, procedures and training governing all aspects of UT's interactions with ICFs.
- 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 on 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 false and misleading statements are not protected under the First Amendment, and that the DOJ has continued to bring off-label enforcement cases involving allegedly false and misleading promotional activity.

Decreasing Use of CIAs. 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 settling entity, but panelists explained that CIAs no longer are a foregone conclusion, particularly for civil-only settlements. In 2017, only three of the nine civil settlements with the DOJ were followed by 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. They described off-label promotion as the lowest overall area of risk in the current environment, but noted that the DOJ has continued to pursue off-label promotion in cases involving false and misleading statements and patient harm.

They also discussed the pending 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 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. Speakers also discussed ongoing government activity involving reimbursement support and patient assistance activities, including the District of Massachusetts PAP investigation and FCA inquiries relating to the use of nurse educators.

Panelists then addressed commonly asked questions relating to reimbursement support and patient assistance, including the role of field- and hub-based reimbursement personnel versus sales personnel, company support for the PA and LMN processes, and considerations regarding whether to provide support proactively as well as reactively. Speakers emphasized that reimbursement support and patient assistance activities are likely to be the focus of continued government scrutiny and may present heightened risk because there is limited government guidance in this area.

Escobar and Beyond: Developments in Life Sciences Litigation

Panelists discussed the impact of the 2016 U.S. Supreme Court opinion in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (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 if a two part test was satisfied. 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 differing interpretations of *Escobar*'s pronouncement on materiality and application of the two-part test, but agreed that a renewed emphasis on materiality is creating 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. They highlighted the importance of determining the government's knowledge about the alleged misrepresentation and discovering how the government may have treated similar circumstances in the past.

The panelists discussed recent cases in interpreting *Escobar* and highlighted a pending circuit split over whether the *Escobar* two-part test was mandatory. They addressed the importance of following the petition for writ of *certiorari* to the Supreme Court in *United States ex rel. Campie v. Gilead Sciences, Inc.* Case No. 17-936, seeking the high court's opinion as to whether the two-part *Escobar* test is mandatory.

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 new use of enforcement tools. They reviewed the DOJ's use of risk evaluation and mitigation strategy (REMS) liability to bring enforcement actions involving promotional activity that was purportedly inconsistent with the company's REMS obligations. The panel also discussed the settlement involving AmerisourceBergen Specialty Group's failure to register its repacking facility as a manufacturing facility. Panelists highlighted recent FDA focus on companies adverse event reporting compliance practices and noted that the FDA seems to inspect companies relatively quickly following an acquisition to evaluate whether the new entity is complying with current good manufacturing practices and quality system regulation obligations.

Panelists also discussed the recent Philips North America Consent Decree. In addition to serving as a reminder of the tremendous expense and business disruption that significant manufacturing problems can mean for a company, the facts in the Philips North America Consent Decree also reflect that the FDA can and sometimes will pursue civil enforcement actions without first issuing a warning letter.

In reviewing recent individual prosecutions, the panelists discussed recent pronouncements by senior FDA and DOJ officials indicating that they are examining the appropriate use of the *Park* Doctrine. The discussion also juxtaposed the success the DOJ has had in pursuing prosecutions in the food industry compared to the lesser success it has had in bringing individual prosecutions in the drug and medical device sectors. Panelists analyzed the status of recent First Amendment case law developments and related FDA pronouncements.

Handling Whistleblowers and Internal Compliance Complaints: Legal, Ethical and Practical Considerations

The final panel discussed the challenges of handling whistleblower complaints and other internal reports of potential misconduct. They noted that the proper handling of such matters is a separate risk area for companies and for the lawyers and compliance professionals involved in the intake, review and disposition of such complaints.

Numerous laws provide differing routes for whistleblowers to bring their concerns to the government, including the False Claims Act, Sarbanes-Oxley and Dodd-Frank laws, and provisions in the internal revenue code. While each of these statutes has specific procedural requirements for filing such complaints, all three provide strong financial incentives that allow whistleblowers to obtain a portion of any subsequent recovery by the government. All three also prohibit companies from retaliating against whistleblowers and impose penalties for engaging in such conduct.

The panelists discussed practical strategies for reducing whistleblower risks, including:

- designing and implementing a robust compliance program to (1) reduce the likelihood that someone will file a whistleblower complaint and (2) ensure appropriate handling of a complaint should one be received. Among other things, companies should have a formal written policy regarding the intake, investigation and resolution of whistleblower and other internal complaints of potential misconduct, with clear lines of responsibility and reporting;
- drafting and enforcing written policies that prohibit retaliation for good faith reporting of potential misconduct. Such policies should be widely distributed and promoted within the company;
- ensuring confidentiality provisions for departing employees comply with legal requirement;
- understanding and complying with affirmative obligations if/when misconduct is reported; and
- recognizing and addressing challenges presented by a current employee whistleblower and ensuring compliance with applicable anti-retaliation statutes.