Skadden

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

Enforcement and Litigation Strategies

Four Times Square
New York, NY 10036
212.735.3000

On October 30, 2018, Skadden hosted its Eighth Annual Pharmaceutical and Medical Device Enforcement and Litigation 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.

The Skadden panelists included **John Bentivoglio**, **Jennifer Bragg**, **Maya Florence**, **Michael Loucks**, **Gregory Luce**, **Avia Dunn** and **Alexandra Gorman**, health care and life sciences; **Warren Feldman**, government enforcement and white collar crime; and **Andrew Lawrence**, securities enforcement.

The guest panelists included **Andrew Gaillard**, assistant general counsel, Pfizer; **Sandra Cohen Kalter**, vice president and chief regulatory counsel, Medtronic; **Brett Kraemer**, chief compliance officer, KCA; **David Layfer**, senior counsel, AbbVie; **Jennifer Trevett**, associate general counsel, UCB; **Julie Wagner**, assistant general counsel, PhRMA; and **Carlton Wessel**, senior vice president, associate general counsel and chief litigation counsel, Pfizer.

DOJ and OIG Enforcement Update

Panelists noted that life sciences enforcement by the U.S. Department of Justice (DOJ) and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), while still active, has scaled back recently in terms of fewer cases and smaller settlement amounts. They attributed this in part to fewer off-label promotion cases, driven both by successful First Amendment challenges to FDA restrictions on the dissemination of truthful, non-misleading information about company products and enhanced compliance efforts by industry participants. Participants also highlighted recent policy statements indicating that the DOJ will avoid criminal enforcement actions based solely on technical regulatory violations or that are premised on violation of sub-regulatory agency guidance.

Next, panelists discussed major trends in DOJ enforcement. First, they discussed enforcement actions focusing on patient assistance and reimbursement support services. This trend reflects a shift in the business model of pharmaceutical and medical device companies toward more complex, higher-value specialty products, which necessarily require manufacturers to have greater contact with, and provide more support to, patients in order to ensure access and effective use. These relationships have garnered

enforcement attention particularly when the government believes an arrangement has the effect of inflating prices.

Second, panelists discussed increased anti-kickback scrutiny of manufacturers' relationships with health care providers (HCPs). Prosecutors have continued to pursue a more granular focus on specific aspects of those relationships, such as the content, cost and attendees of HCP speaker programs. Panelists noted that these cases highlight the need for manufacturers to have robust controls in place to ensure such programs provide value and are conducted in a compliant manner and for legitimate purposes.

Third, panelists discussed the shift away from promotional activity cases and toward enforcement actions focusing on conduct that could result in patient harm. Panelists highlighted the importance of ensuring that manufacturers' legal and compliance departments have adequate visibility into U.S. Food and Drug Administration (FDA) inspections and other regulatory and quality issues, so they can address potential patient harm issues before they rise to the level of attracting enforcement scrutiny.

FDA Activities, Including Digital Health Initiatives

Panelists noted that the past year has been slower than usual on the FDA enforcement front, with fewer warning and untitled letters and consent decrees than prior years. However, panelists observed that FDA has been very active in a number of interesting policy areas. In particular, panelists discussed FDA's efforts in conjunction with HHS to contain drug pricing by focusing on increasing generic competition and reducing "gaming" by branded manufacturers. Panelists noted that although FDA's ability to impact drug pricing is limited by its jurisdiction, recent efforts by the Department of Health and Human Services may have a more direct impact.

Panelists then discussed two new developments in the area of transparency: FDA's draft guidance relating to civil money penalties for failing to comply with regulatory obligations relating to posting trial information on clinicaltrials.gov, and the expansion of the Sunshine Act to require reporting of payments to midlevel providers, such as nurse practitioners and physician assistants, effective in January 2022.

Next, panelists discussed innovative efforts by FDA's Center for Devices and Radiological Health in the area of digital health, which have included revising guidances relating to software as a medical device to clarify where FDA will exercise enforcement discretion in connection with lower-risk software products, and rolling out a novel precertification program for software developers. Panelists observed that these efforts reflect FDA's attempt to best utilize its resources to address the significant volume of software products being developed, and discussed a recent Congressional letter that questioned the authorization for and potential impacts of the precertification program. Panelists noted that FDA's efforts to provide cybersecurity guidance are appreciated by industry.

Finally, panelists discussed FDA's recent guidances on Communications With Payors and Communications Consistent With an FDA-Approved Label. Panelists observed that these guidances are part of a notable effort by FDA in recent years to provide guidance to manufacturers regarding the agency's approach to considering various types of communications.

Foreign Corrupt Practices Act Update

Panelists reviewed trends and recent enforcement activities involving the Foreign Corrupt Practices Act (FCPA), as well as related shifts in DOJ policies. They agreed that both the DOJ and the Securities and Exchange Commission (SEC) remain committed to enforcing the FCPA and expect continued aggressive enforcement with respect to life sciences companies.

Panelists observed that FCPA corporate resolutions in 2018 have outpaced 2017 resolutions but have lagged behind the high 2016 numbers at the end of the Obama administration. These trends apply both to FCPA corporate resolutions generally and to FCPA resolutions involving life sciences companies specifically. A continued trend in the life sciences industry has been the occurrence of second FCPA actions against companies that settled initial FCPA matters years earlier. In 2017 and 2018, three of the four companies to settle second FCPA actions were in the life sciences industry. In addition, panelists noted the continued heightened exposure of life sciences companies to potential FCPA misconduct in certain high risk jurisdictions, such as Brazil, China, India, Mexico and Russia.

Panelists also discussed recent DOJ policy pronouncements, including the creation and expansion of the FCPA Corporate Enforcement Policy, the anti-piling-on policy, and the release of a new policy memo on corporate monitors.

- Regarding the Corporate Enforcement Policy, panelists focused on the steps a company must take in order to be eligible for a range of mitigation credit, including a presumption of declination. The panel also touched on the expansion of that policy to cover FCPA misconduct discovered in the M&A context, as well as its expansion as "nonbinding guidance" for all Criminal Division corporate criminal cases, not just those involving FCPA violations.
- Panelists highlighted the continued increase in enforcement of anti-bribery laws by foreign countries and the effect of DOJ's anti-piling-on policy aimed at avoiding duplicative penalties for the same misconduct. Several recent DOJ FCPA resolu-

tions have reduced disgorgement and penalties owed to DOJ in light of settlements reached by companies with other U.S. regulators, foreign regulators and, in one instance, a company's shareholders in a class litigation settlement.

- The announcement of the anti-piling-on policy was followed shortly thereafter by the release of a new memo by Assistant Attorney General Brian Benczkowski, which adjusted the factors DOJ will consider in determining whether a corporate monitor is appropriate in a settlement, including the individualized cost and burden borne by a company as a result of the imposition of a monitor.

Finally, panelists discussed Benczkowski's announcement that the Criminal Division will not hire a new compliance consultant to assess targeted companies' compliance programs, a position that has been unfilled since the departure of Hui Chen in June 2017. Rather, the Division will seek to hire more attorneys with compliance experience and will further develop training for its attorneys on compliance programs.

False Claims Act Developments, Including *Escobar*

Panelists discussed recent developments in the two years since the 2016 Supreme Court case *Universal Health Services v. United States ex rel. Escobar*, 579 U.S. – (2016). *Escobar* held that the implied false certification theory can be a basis for liability under the FCA when a defendant submitting a claim makes specific representations about the goods or services being provided but fails to disclose noncompliance with material requirements that make the defendant's representations misleading. In particular, panelists highlighted recent appellate decisions demonstrating the impact of *Escobar*'s "rigorous" and "demanding" materiality requirement on summary judgment and post-trial verdicts. For example, in *United States ex rel. Ruckh v. Salus Rehabilitation*, *LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018), app. pending, the court reversed a $350 million jury verdict for the relator based on *Escobar*. In *Ruckh*, the relator alleged a pattern of false billing to Medicare and the Florida Medicaid program perpetrated by two defendant skilled nursing facilities and their management company, which the relator claimed was additionally liable for similar alleged acts at over 50 other facilities across the state of Florida. The court held that, despite multiple weeks of trial testimony, "[t]he record [wa]s effectively barren of evidence on how the governments might have addressed the disputed practices and ... the dearth of evidence left the jurors to guess." Discussing *Escobar* at length, the court stated that it was insufficient for the relator to show that the requirements at issue were "'important' or 'essential' or 'prescribed' or the like to an extent that in some hypothetical or generic circumstance a government might refuse to pay one or two or several invoices or even the invoices from a facility or two or a physician or two." The court therefore reversed a jury verdict totaling nearly $350 million for the relator.

Panelists also discussed an increase in relators continuing to pursue their FCA actions after the government has declined to intervene, and the role of the government in those matters where it does not intervene. Panelists highlighted recent appellate decisions, including *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 848 F.3d 330 (4th Cir. 2016), which held that after the government declined to intervene in the action, "under the plain language of § 3730(b)(1), the Attorney General possesses an absolute veto power over voluntary settlements in FCA *qui tam* actions," even when the government does not intervene. Relatedly, panelists noted the rise of "litigation funding" employed by relators to fund their *qui tam* suits during the typically protracted period before unsealing and ensuing litigation. In addition, panelists discussed the recent DOJ memorandum from Michael Granston that listed factors the DOJ should consider in determining whether to intervene in an FCA action to dismiss the action.

Panelists also discussed steps that pharmaceutical and medical device companies are undertaking as a result of *Escobar*'s materiality requirement. In addition to the value of those compliance measures, the results of those measures may be able to assist in future litigation to prove whether the government would have paid a specific claim in light of the alleged noncompliance. Finally, panelists advised attendees that these interpretations will continue to be crucial in gauging the risks involved in FCA litigation.

PhRMA Update: View From Washington

PhRMA Assistant General Counsel Julie Wagner first discussed the U.S. administration's recent proposal to mandate disclosures of list prices in direct-to-consumer (DTC) advertising of certain drug products. In response to the proposal, PhRMA revised its voluntary Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines. PhRMA believes that requiring publication of a drug's list price alone, without additional context regarding what a patient might expect to actually pay at the pharmacy counter, could be confusing and misleading to patients and could deter consumers from seeking treatment because of perceived cost barriers. The administration's feedback in response to this proposal was that it was a positive step but not sufficient, and it followed up with proposed rulemaking on this topic.

Next, Ms. Wagner discussed the administration's proposed changes to the AKS discount safe harbor, which it has cited as a factor in raising drug prices. The Office of Inspector General's proposed rule is currently pending before the U.S. Office of Management and Budget. It is not clear if the proposed change would only affect rebates or if it also would restrict other types of payments, such as administrative service fees between pharmacy benefit managers and manufacturers.

Finally, Ms. Wagner discussed regulatory initiatives relating to coordinated care models and value-based contracting. HHS has issued two requests for information (RFIs) seeking public input about ways to modify the Stark Law and AKS safe harbors to improve care coordination, both of which were in connection with HHS' "Regulatory Sprint to Coordinated Care" initiative. In addition, FDA has issued guidance regarding drug and device manufacturer communications with payors, which serves to facilitate the industry's shift toward value-based payment arrangements.

Patient Assistance Programs: Legal and Practical Considerations

Panelists addressed the evolving model of patient assistance activities, which have grown to encompass increasingly complex relationships among patients, HCPs, manufacturers and other industry participants, and payors. Panelists observed that the increasing complexity can make risks harder to evaluate and that many newly emerging activities and programs are not neatly addressed by OIG guidance.

A key driver behind the evolution in this area has been the growth in specialty therapies, which may require a broader spectrum of patient assistance and reimbursement support. Manufacturers therefore are more likely to interact with patients, HCPs, payors and others to provide product education, support treatment compliance and facilitate insurance coverage. Panelists explained that these expanding relationships have resulted in more and new participants in this area, such as patient educators and specialty pharmacy staff. Manufacturers accordingly must be vigilant that their compliance efforts adequately train and supervise new personnel and oversee other novel aspects of these interactions.

Panelists discussed recent enforcement actions involving Independent Charitable Foundations (ICFs), which provide financial support and disease education to patients. Although the OIG has acknowledged the important role ICFs play in supporting patients and provided guidance regarding manufacturer donations to ICFs, it also has expressed concern about potential AKS issues involving manufacturer support for ICFs. Although the factual theories have varied, recent enforcement actions against manufacturers have involved cases where an ICF is viewed as a conduit for the manufacturer to provide co-pay assistance to patients using the manufacturer's products. Panelists also discussed DOJ theories of liability in recent ICF settlements involving free goods programs as well as the inappropriate use by manufacturers of information provided by ICFs to determine the amount and timing of manufacturer donations.

Next, panelists discussed enforcement actions relating to free drug programs and nurse educator programs. While OIG has stated that the AKS is not violated when a manufacturer provides product-specific support services that have no independent value, recent enforcement highlights the risk that these programs may be alleged to be an inducement to patients or prescribers. Panelists also noted that manufacturers should be mindful of state laws in this area, such as state anti-kickback laws containing all-payor provisions that apply to claims paid by commercial payors as well as federal healthcare programs.

Panelists then provided an overview of the Health Insurance Portability and Accountability Act (HIPAA) and other data privacy considerations in this area, including recent enforcement actions involving wrongful disclosure of personal information by manufacturer sales personnel. Panelists emphasized that manufacturers should carefully consider whether their activities result in use of or access to protected data and, if so, ensure that they have necessary rights to use and access that data. Manufacturers should also ensure that all personnel who may use or access protected data are trained on and understand the implications of HIPAA and other relevant laws.

Finally, panelists reflected on practical compliance implications for patient assistance programs and recommended that manufacturers take a holistic view when designing and administering these activities. This should include carefully weighing the objectives of each patient assistance program, which personnel are in contact with patients and HCPs and for what purposes, and how these programs and their staff are incentivized and evaluated.

Ethical Challenges With Whistleblowers, Internal Investigations and Proposed Transactions

Panelists began by discussing best practices for companies when dealing with whistleblowers, in light of the ongoing importance that FCA *qui tam* relators play in healthcare enforcement actions. In particular, if a company knows or suspects the identity of a whistleblower, care must be taken not to treat that person differently or adversely while they are employed with the company, and an exit interview should be conducted if they leave their position in order to document any concerns they raise.

Next, panelists turned to implications of the EU General Data Protection Regulation (GDPR), emphasizing the compliance difficulties this law presents to companies with U.S. operations.

For example, a U.S. subsidiary of a European company may be subject to GDPR requirements if its data is housed in a European data server. Companies may face particularly difficult decisions when facing GDPR issues in the context of U.S. discovery, government investigation or transactional diligence requirements. Panelists recommended that companies meaningfully involve specialized GDPR counsel at an early stage of any questions that might potentially involve GDPR questions.

Finally, panelists emphasized the critical importance of maintaining unimpeachably ethical behavior in all contexts, including when dealing with whistleblowers, conducting internal investigations, dealing with government regulators and negotiating transactions. They pointed to recent enforcement actions and the dispute arising from the failed Fresenius-Akorn merger as examples of the dangers that may arise when company personnel or outside counsel are perceived as insufficiently experienced, failing to exercise adequate diligence, or involved in concealing information from the government or contractual counterparties. Participants in an investigation or transaction should maintain a holistic view of the process and be prepared to defend their conduct should the need arise.

Contacts

John T. Bentivoglio
Partner / Washington, D.C
202.371.7560
john.bentivoglio@skadden.com

Jennifer L. Bragg
Partner / Washington, D.C
202.371.7980
jennifer.bragg@skadden.com

Maya P. Florence
Partner / Boston
617.573.4805
maya.florence@skadden.com

Michael K. Loucks
Partner / Boston
617.573.4840
michael.loucks@skadden.com

Gregory M. Luce
Partner / Washington, D.C
202.371.7310
greg.luce@skadden.com

Avia M. Dunn
Counsel / Washington, D.C
202.371.7174
avia.dunn@skadden.com

Alexandra M. Gorman
Counsel / Boston
617.573.4852
alexandra.gorman@skadden.com