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

Enforcement and Litigation Strategies

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On October 22, 2019, Skadden hosted our Ninth Annual Pharmaceutical and Medical Device Enforcement and Litigation Seminar in New York, which focused on U.S. enforcement issues companies face throughout the industry. The key takeaways from this panel are summarized below.

DOJ and OIG Enforcement Update

Panelists: John Bentivoglio and Jennifer Bragg, Skadden Health Care and Life Sciences

The panelists provided an overview of recent U.S. Department of Justice (DOJ) enforcement actions, explaining that opioids are arguably the largest area of focus. The DOJ also has focused on regulating drug prices in a number of ways, including by bringing enforcement actions against companies providing co-pay support to patients through independent charitable foundations. Further, panelists recounted that the DOJ has used enforcement actions with allegedly egregious conduct to try new enforcement tools, including RICO charges, undercover agents and tape recordings.

Regarding 2019 settlements, panelists explained that the DOJ's primary enforcement tool, including in civil-only resolutions, was the Anti-Kickback Statute (AKS). Panelists noted that the DOJ has retreated from prosecuting purely off-label claims. Rather, it has used a "refined" off-label cause of action to investigate the provision of false or misleading information and violations of Risk Evaluation and Mitigation Strategy (REMS) requirements. Most 2019 settlements were small, civil-only and related to financial relationships with physicians.

Panelists highlighted recent co-pay enforcement actions in which the DOJ continued to allege that companies inappropriately provided co-pay support to patients through independent charitable foundations. Review of settlements and press releases revealed that the government frequently mentions high drug costs, viewing these support services as elaborate schemes to support drug prices. Panelists stated that many of the activities featured in the co-pay settlements are not problematic in and of themselves, but can be problematic once combined. While the settlements and resulting corporate integrity agreements provide companies some guidance for structuring relationships with charitable foundations, panelists observed that companies remain without guideposts for all aspects of the relationships, including how to set an appropriate donation budget without commercial involvement.

As stated in the Office of the Inspector General's (OIG) 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, product support services alone do not implicate the AKS if they are structured properly. Panelists stated that the 2003 guidance was reaffirmed in recent DOJ filings moving to dismiss *qui tam* actions which asserted that nurse-educator services were inappropriate. Panelists explained that the DOJ's filings were a positive development for manufacturers, reinforcing the legitimacy of certain support services, such as toll-free hotlines. Panelists emphasized, however, companies must consider not only what services they are providing to patients, but what services they are, in effect, rendering to physicians' offices.

Addressing prospective areas of risks, panelists explained that future DOJ enforcement actions are likely to grow from today's environment. Speaker bureaus and payments to physicians remain the single largest area of risk for pharmaceutical companies. In particular, companies should keep in mind that data is increasingly becoming available to the government and relators, and that the DOJ is proactively analyzing data on payments and prescriptions. In addition, panelists noted, companies should expect to see increased enforcement activity related to product quality issues.

Advertising, Promotions and Trade Complaints

Panelists: Karen Corallo, Skadden Health Care and Life Sciences; Anthony Dreyer, Skadden Intellectual Property Litigation; and Michelle Kloecker, Director and Pharmaceutical Counsel, Novartis Pharmaceuticals Corporation, Global Oncology

The panelists first discussed ways in which companies can bring forth actions against competitors for purportedly false or misleading advertisements. Specifically, they highlighted litigation of false advertising claims through both federal courts under the Lanham Act and proceedings with the National Advertising Division (NAD).

The panelists explained that in light of the Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co*., 134 S. Ct. 2228 (2014), compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) does not immunize the content of labels from false advertising challenges under the Lanham Act. Rather, a false advertising claim may be brought if a claim is literally false, literally false by necessary implication (*i.e*., the context of communication conveys only one message and that message implies a false message) or misleading. A claim is misleading if it conveys an implied message and deceives a portion of the recipients. Typically, if over 20% of surveyors are confused by a claim, the claim is actionable as "misleading."

The panelists provided an overview of the pleading requirements to support a violation of the Lanham Act. They emphasized that the claim must be made in connection with commercial advertisements, and the burden generally falls on the challenger to show that a statement is false. While claims made to investors are generally not actionable, the SEC is likely to scrutinize such statements. On the issue of damages, the panelists explained that circuit courts are split as to whether a plaintiff must prove willfulness to obtain disgorgement. This split is likely to be resolved, as the Supreme Court has granted *certiorari* this term in *Romag Fasteners v. Fossil*, Dkt. No. 18-1233.

Panelists noted that the case law is unclear as to whether consumer survey evidence is necessary to meet the *Iqbal/Twombly* pleadings standard. Although many courts have held that survey evidence is not needed at the district court stage and anecdotal evidence can assist a plaintiff in surviving a motion to dismiss, the U.S. Court of Appeals for the Tenth Circuit held that consumer survey evidence may be necessary by affirming the dismissal of plaintiff's claim on the grounds that the complaint failed to cite any survey or other evidence that consumers were deceived by the allegedly misleading advertisement. See *Drake Vincent v. Utah Plastic Surgery Society*, No. 13-4146 (10th Cir. Aug. 31, 2015).

Next, panelists discussed advertising challenges through the NAD, which is administered by the Better Business Bureau (BBB) as a self-regulating sector of advertising. To initiate these proceedings, a challenger files a letter with the NAD raising reasonable questions as to whether the advertisement contains false or misleading claims. While the advertiser's mere reasonable basis for making the claim may support its efficacy, the panelists noted that the leading question in a NAD proceeding is whether the challenged advertiser has prior substantiation for the claims it is making. The NAD relies on the U.S. Food and Drug Administration (FDA) or other relevant agencies to determine whether the claims at issue are substantiated. Unlike in actions under the Lanham Act, a NAD dispute places the burden on the challenged party.

The panelists expressed the importance for companies facing a NAD complaint to understand what facts to substantiate and what tools to use. Companies also need to involve the right people in the claims review and clearance process and bear in mind that results may be discoverable in future litigation. While participation in and compliance with NAD proceedings is voluntary, the failure of a challenged advertiser to participate or comply can lead to a referral to, or investigation by, the Federal Trade Commission (FTC).

Finally, the panelists discussed how various factors impact whether a company should challenge false advertising in the federal courts or through the NAD. These factors include time and cost, burdens of proof and risks, confidentiality, relief and enforcement. Companies must weigh the costs and risks of litigation and understand the business appetite for the time and resources that go into bringing a false advertisement challenge. Companies launching a challenge must also make sure their operations and recordkeeping is in order, as competitors will explore ways to fight back.

FDA Enforcement Update

Panelists: Jennifer Bragg and Maya Florence, Skadden Health Care and Life Sciences; and Ami Simunovich, Senior Vice President and Chief Regulatory Officer, Becton, Dickinson and Company

Panelists provided an overview of recent FDA enforcement trends. Overall, the FDA has continued to take a strong enforcement interest in the food and tobacco space, with additional focus on dietary supplements. The FDA generally takes a proactive approach to resolving compliance concerns, providing companies early feedback to prevent later enforcement action. This approach has resulted in fewer consent decrees and long-term monitoring requirements. Further, the Office of Prescription Drug Promotion (OPDP) has issued letters cautiously, and the Center for Devices and Radiological Health (CDRH) has taken little action in the promotional space.

More specifically, the FDA has increased resources at the border and is now checking imported products for 510(k) status. The FDA also has increased its use of import alerts, halting products from entering the country and affecting manufacturers' ability to receive necessary materials from overseas suppliers. The use of import alerts has, in turn, reduced the number of seizures. Panelists also highlighted several recent FDA warning letters, and observed that the FDA continues to focus on new products and on products with higher-risk profiles.

Additionally, panelists provided an overview of recent developments within the FDA. For example, the FDA recently realigned its Office of Regulatory Affairs, replacing a geographic structure with a commodity-based structure. Panelists reported that the industry overall believes that the transition is a positive development that will facilitate information sharing. However, panelists cautioned, companies should be aware that responsibilities have shifted, and the transition has resulted in a learning curve for new offices. Additionally, the Medical Device Single Audit Program now provides a harmonized approach to allow one joint audit to cover multiple regulatory agencies' standards, which similarly holds the promise of increased efficiency and decreased business interruptions, but the new process has still presented some challenges in its early implementation phase.

Patient and Physician Support Programs

Panelists: John Bentivoglio and Alexandra Gorman, Skadden Health Care and Life Sciences

Panelists addressed the evolving business model of pharmaceutical companies, which increasingly has grown to encompass specialty products that treat a small number of patients. This model has led to complexity in various industry relationships, allowing increased touchpoints with patients, physicians, independent charitable foundations, pharmacies and payors. In each relationship, manufacturers need to clearly understand the flows of money, assessments of value, information or promotional materials, and products involved.

Panelists explained that manufacturers are increasingly providing product support services to both physicians and patients. Although the OIG has stated that providing product support services with no substantial independent value may not implicate the AKS, little guidance has arisen since the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers. Most recently, the DOJ affirmed that it supported the 2003 guidance by moving to dismiss several *qui tam* actions filed against manufacturers alleging that the provision of nurse educators to support both physician offices and patients resulted in a violation of the False Claims Act (FCA).

In providing reimbursement services, manufacturers not only have increased interactions with physician offices, they also receive additional flows of information about patients. When providing services, panelists explained, manufacturers need to know what actions are being taken, who is taking those actions and the relevant risks. Panelists highlighted that increased patient information flow can raise Health Insurance Portability and Accountability Act (HIPAA) concerns and noted that the DOJ has investigated and settled cases involving sales representatives reviewing patient files and inappropriately accessing patient information. Additionally, instances have been discovered of employees lying to insurance companies about patient profiles or their identities or employers in an attempt to secure reimbursement approval. Companies can reduce these risks by, among other things, making the reimbursement support function separate from sales and ensuring incentive compensation is appropriately structured to eliminate any incentive to lie or cherry pick information in discussions with insurance companies. Finally, panelists explained that manufacturers should publicize and provide reimbursement support to all offices, not merely to high prescribers.

Next, panelists explained that although enforcement of typical off-label promotion has decreased in recent years, the DOJ may begin to allege that manufacturers have caused medically unnecessary prescriptions to be submitted to federal health care programs. Specialty products are often expensive, and if a small number of physicians aggressively prescribe the specialty product, the DOJ may consider why those physicians are outliers and inquire into manufacturer activities (including speaker fees and other forms of remuneration) that may have led to such prescriptions. Manufacturers should keep in mind that they often have data, including from a company-sponsored hub, that will reveal the types of prescriptions written.

The panelists predicted that the government is likely to take an increasing interest in manufacturers' relationships with specialty pharmacies. Often specialty pharmacies can serve as a company-sponsored hub to provide patient and physician support services. Companies should understand not only the services set forth in those contracts but also conduct back-end monitoring to see what actions the specialty pharmacies are taking.

Finally, panelists noted that a fair amount of guidance is available relating to free drug programs. The OIG and the DOJ are concerned about the use of free drug programs as starter programs that, the agencies believe, are meant to hook patients on high-cost drugs. Panelists stated that free drug programs are not the same as sample programs, and companies should keep in mind that the Prescription Drug Monitoring Act does not address anti-kickback risks.

State of the Industry: A Wall Street Perspective

Panelists: Danielle Antalffy, Andrew Berens, Ami Fadia, Jim Kelly and Richard Newitter, Managing Directors, SVB Leerink

Over the past decade, panelists reported, health care has been the third best-performing sector overall, generally outperforming the market. Drug pricing, innovation — particularly in the biotechnology space — and increased access to health care have contributed to this standing, while product recalls and DOJ investigations have impacted premiums over the years.

Panelists explained that they, as Wall Street analysts, try to understand the fundamentals behind a company so that investors can in turn know the impact of investing in company stock. Analysts often try to define a framework around an event so that investors can comprehend its potential impact and defined risks. For example, analysts will try to evaluate the contingent liabilities of a warning letter or of patent litigation and define the resulting worst-case scenario. Often, panelists shared, uncertainty is more problematic than bad news. It is difficult, for example, to predict FDA actions and their impact.

Large investment decisions are often made with imperfect information. Panelists agreed that a company maintains responsibility to frame what it knows and what it does not know, and investors want to know all the information that the company can share. Panelists encouraged companies to take a straightforward approach and provide accurate information, since giving vague, incomplete or delayed information can lead to consequences later.

The Next Frontiers: Data Privacy, HIPAA and Cybersecurity

Panelists: Maya Florence, Skadden Health Care and Life Sciences; Bill Ridgway, Skadden Litigation, Cybersecurity and Privacy; and David Bloch, Principal Legal Counsel, Medtronic

Panelists discussed the application of both health care-specific and generally applicable statutory schemes regulating data privacy and cybersecurity. With respect to HIPAA, panelists observed that historical HIPAA enforcement recoveries have been relatively modest compared to DOJ enforcement activity, and generally have involved health care providers rather than life sciences companies. Panelists speculated that this trend may change over time, as life sciences companies increasingly have access to additional patient data through activities such as reimbursement support and product support applications. Panelists also cautioned that life sciences companies may have access to more patient data than they appreciate, including data collected through clinical trials and adverse events. Panelists noted that HIPAA-related enforcement involving life sciences companies generally have involved sales representatives who mishandled or inappropriately accessed patient data to help increase drug sales, and panelists warned that these types of actions involve a high risk of reputational damage.

The FDA recently issued draft industry guidance, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, to highlight its view that cybersecurity issues now represent a known risk for medical devices and must be addressed through a manufacturer's quality systems. Panelists then addressed the increasingly complex cybersecurity landscape, focusing on the heightened threat posed by ransomware. Panelists emphasized the need for information technology personnel, regulatory personnel and in-house counsel to be in constant communication to assess the likelihood of a compromise to company data and the severity of any perceived issue. Finally, panelists discussed

the increase in cybersecurity whistleblowers, and recommended that companies examine their reporting channels for IT compliance concerns.

False Claims Act and Big Data

Panelists: Alexandra Gorman, Michael Loucks, Greg Luce, Skadden Health Care and Life Sciences; and Brad Rice, Vice President, Analysis Group

Panelists addressed the growing trend of using statistics and extrapolation from representative samples of claims to establish liability under the FCA. They reported that the use of statistics and extrapolation to establish damages in FCA cases is not a novel proposition. Courts have often accepted the discipline as an appropriate way to deal with large numbers of claims at issue after liability has been imposed. This approach is common when information may not exist otherwise, for instance, due to missing patient files or incomplete sets of claims, or when a claim-by-claim review would be too costly. Ultimately, courts are cognizant that a factfinder can decide what weight to give the extrapolated data.

Panelists also explained that less frequently, but more controversially, relators have proposed using sampling to establish FCA liability. However, the panelists noted that use of extrapolation for liability is in tension with the decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), where the Supreme Court held that a company's misrepresentations about compliance with governing laws must be material to the government's decision to pay in order to be actionable under the FCA. Moreover, the FCA requires a plaintiff to establish the defendant's scienter. Panelists noted that trying to meet the *Escobar* standards through extrapolation from limited sets of data may be inappropriate because it does not help decipher intent.

With respect to the validity of extrapolation methods, panelists explained that best practice requires a purely random and large sample size, which may require an oversampling for certain subgroups, or potentially the use of machine learning/AI methods currently at the forefront in this area. Although relators have at times included only a selection of small subsets of data, this is a statistically flawed approach. Regardless of extrapolation methods, panelists noted the importance for companies early in proceedings to examine and, when necessary, challenge the quality of extrapolation methods in FCA investigations. Panelists further noted that, as many *qui tam* cases were filed years ago, companies must maintain historic knowledge of their data systems over time in order to develop counterpoints to the relator's or government's data.

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