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Panel Discussion Among Government Lawyers Provides Key Insights into the Future of FCA Enforcement

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During a recent panel discussion hosted virtually by the American Bar Association, attorneys from the Department of Justice (DOJ) and certain U.S. Attorneys' Offices known for health care fraud enforcement provided valuable insight into key areas of health care fraud enforcement, including opioid-related enforcement, kickbacks to providers involving speaker programs, and allegations involving electronic medical records (EMR) vendors. The panel also addressed the role of private equity funds as owners and operators of companies under investigation and provided observations and recommendations about effective compliance programs and their role in resolving health care fraud matters.

Panelists included, among others: (1) Ed Crooke, Assistant Director, Commercial Litigation Branch, U.S. Department of Justice; (2) Owen Foster, Assistant United States Attorney, U.S. Attorney's Office ("USAO"), District of Vermont; (3) Charlene Keller Fullmer, Deputy Chief Affirmative Litigation, Eastern District of Pennsylvania USAO; (4) Abe George, Acting Chief, Affirmative Civil Enforcement, District of Massachusetts USAO; and (5) Gregg Shapiro, former long-time Chief of Affirmative Civil Enforcement in the District of Massachusetts USAO recently turned relators' counsel.

Opioid Enforcement

The discussion started with highlights from the $2 billion Indivior settlement, which resolved criminal and civil allegations against the company, its former parent company, Reckitt Benckiser Group, and its former CEO arising from Indivior's marketing of its opioid addiction treatment drug, Suboxone. Mr. Crooke commented on this settlement, noting that it was a good example of a few areas that are continuing priorities for DOJ: opioid enforcement and individual liability. Mintz predicted in our annual health care enforcement report published earlier this year that DOJ would continue to focus on opioid-related enforcement and to use the responsible corporate officer doctrine to hold individual executives accountable.

Mr. Crooke emphasized that this case also involved a potential growing area for future enforcement:

misrepresentations made to health plans by drug companies for purposes of securing formulary placement. More specifically, Indivior was accused of making misrepresentations to the Massachusetts Medicaid plan, MassHealth, in the context of marketing and promotional efforts aimed at getting Indivior products on MassHealth's formulary. In particular, Indivior was accused of falsely representing to MassHealth that Indivior's Suboxone Film was less susceptible to accidental pediatric exposure than other buprenorphine drugs.

In discussions related to this case, other panelists predicted that, as health care providers continue to consolidate and health plans have increasing influence and control over access to such providers, pharmaceutical companies and others will dedicate increasing energy and resources to marketing to those health plans in an effort to receive favorable placement on their formularies. Such marketing activities are an area that the government is and will be monitoring for enforcement purposes.

Anti-Kickback Statute Enforcement

The Anti-Kickback Statute (AKS) dominated much of the remainder of the discussion, with a number of panelists providing their candid views on the purpose and intent of speaker programs and similar arrangements. The panel focused on the following types of arrangements as posing risk under the AKS and remaining a focus of government enforcement efforts in 2021:

Speaker Programs

Ms. Fullmer observed that the government has been seeing an increase in questionable practices related to speaker programs, prompting a fresh wave of enforcement actions in 2020 and a Special Fraud Alert from the Office of Inspector General for the Department of Health and Human Services (OIG). The panelists noted various areas of risk associated with speaker programs. In particular, the panelists cautioned against speaker program events that "wine and dine" attendees rather than educate them.

The panelists referred to the Novartis and Medtronic settlements, both of which involved speaker programs. Novartis allegedly hosted "tens of thousands" of social events at expensive restaurants that were disguised as speaker programs but offered little to no educational content. Similarly, Medtronic allegedly paid a South Dakota neurosurgeon to host hundreds of events at a restaurant he owned. The Novartis CIA requires that future speaker program events featuring non-Novartis employee speakers be held in virtual settings only, with caps on remuneration to speakers.

Comments made during the discussion of speaker programs included the following:

- Speaker programs held virtually or in a classroom setting that do not involve alcohol pose less AKS risk. CIAs increasingly implement these requirements. Mr. George did not believe that live events inherently violate the AKS, but, as Mr. Foster recommended, attention should be paid to the investment of resources devoted to education versus marketing.

- This subject prompted an interesting conversation among panelists regarding whether and when a safe harbor provision protects these arrangements. Notably, at one point during the discussion, a number of the panelists agreed that if one purpose of the arrangement was to induce referrals, then, generally speaking, the arrangement violates the AKS *even if it meets the elements of a safe harbor*. Mr. Crooke later walked back this position slightly, explaining that if a speaker arrangement truly met every element of the applicable AKS safe harbor, then such an arrangement would not violate the AKS, but opined that, when you drill down to the

facts, speaker programs rarely do.

- On the subject of return on investment (ROI) analyses following a speaker program event, the panelists noted that they rarely see this type of evidence anymore and thus implied that companies no longer conduct such analyses due to government concerns. The panelists seemed more concerned with ROI analyses involving speakers as opposed to attendees.

Electronic Medical Record Vendors

Mr. Foster described the EMR industry as youthful and ripe for abuse. Unlike more mature health care industry sectors, EMR companies often lack compliance and risk mitigation infrastructure. He also described the varying kinds of arrangements that have been the subject of investigation and enforcement to date, including allegedly cheating the Electronic Health Records Incentive Program to obtain certification for an EMR company's product and paying kickbacks to providers to use the vendor's product and recommend it to prospective clients of the vendor. Going forward, Mr. Foster noted that the government will continue to target EMR vendors who manipulate their software to influence a provider's prescribing decision in exchange for kickbacks, as exemplified by the Practice Fusion settlement. Practice Fusion received kickbacks from pharmaceutical companies, including an opioid manufacturer, in exchange for implementing clinical decision support (CDS) alerts designed to influence providers into prescribing the pharmaceutical companies' and opioid manufacturers' drugs. Mr. Shapiro also commented that physicians and other providers who find out they have been manipulated into prescribing certain drugs or services based on an EMR's recommendation, or targeted advertising, will be "outraged" and will make great witnesses at trial. In addition to being great witnesses, providers who feel manipulated by an EMR vendor's machinations to influence prescribing decisions may be motivated to bring their own *qui tam* suits.

In response to a question from the virtual audience, Mr. Foster concluded his comments by explaining that EMR companies may compliantly advertise products or services via their EMR, but that the government will look closely at such practices where the advertisement is structured to influence the provider's medical decision by, for example, popping up at the time the provider should choose what to prescribe, or using a patient's protected health information to determine what product to advertise.

Holding Private Equity Funds Responsible for Portfolio Companies and the Importance of Robust Compliance Programs

The panelists also discussed the role of private equity funds that own and operate companies subject to investigation and enforcement, as well as the importance of robust compliance programs in helping mitigate enforcement risk and potentially achieving favorable outcomes.

Recognizing that private equity funds play a role in operating the health care companies in which they invest, the government attorneys noted that private equity funds that buy health care companies with known compliance issues that are not rectified, or that engage in abusive practices to increase profits may find themselves the target of enforcement activities. They recommend that private equity funds thoroughly vet the strength of a target company's compliance program and practices during the diligence process and to take action to address compliance issues before or right after closing.

All panelists agreed on the importance of an effective compliance program and an empowered chief compliance officer. Mr. Crooke is encouraged when the compliance officer is a member of the C-

suite. Ms. Fullmer recommended that compliance officers be aware of the bright-line, non-binding guidance set forth in other companies' CIAs.

The robustness of a company's compliance program may affect Mr. Foster's recommendation as to what the remedy should be for non-compliance. If a company has no compliance program, criminal penalties may be necessary as a deterrent. Red flags for the government include no culture of compliance, no compliance officer, no avenues for employees to safely report compliance concerns, or a static compliance program. Compliance should not be a "set it and forget it" measure.

Conclusion

The panel discussion reinforced DOJ's message regarding priorities in the new year, as previewed by Michael Granston's remarks made at the ABA Civil False Claims Act and *Qui Tam* Enforcement Institute presentation on December 2, 2020. Enforcement efforts dedicated to combatting the opioid epidemic are likely to reach others in the opioid supply chain, including individual prescribers. DOJ will closely monitor marketing efforts made by opioid and other manufacturers to secure advantageous formulary placement; as Mr. Crooke noted, such efforts may implicate Medicare Advantage, which we know from Mr. Granston's remarks is a priority for DOJ. Mr. Foster's comments on the youthful EMR industry and its lack of compliance infrastructure indicate that these vendors will continue attract the government's scrutiny. Speaker programs continue to pose risks, but perhaps the OIG's newly available guidance in this area and the various CIAs available to the industry will result in more compliant arrangements and fewer government investigations.

DOJ's reliance on outside help from whistleblowers and its own increasing data mining and analytics capabilities combined with a new administration that many anticipate will be more enforcement-friendly than the last should result in a very active period for False Claims Act investigations.

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