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Enforcement in Life Sciences Series

Key Cases in 2020 Reflect Emerging DOJ Focus for Pharmaceutical and Medical Device Makers

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About the Enforcement in Life Sciences Series

Recent settlements between the U.S. Department of Justice (DOJ) and a range of FDA-regulated drug and medical device manufacturers provide a snapshot of the DOJ's enforcement focus. These settlements involve new DOJ theories of liability or new ways of evaluating long-standing industry practices and may be harbingers of future DOJ enforcement activity. In this six-part series of client alerts, we take an in-depth look at the facts and legal theories in each case or set of cases, discuss what makes each novel and consider the compliance implications for each. You can find all the client alerts in the series here.

DOJ Puts Teeth in Sunshine Act Reporting Requirements

A recent settlement involving a medical device manufacturer involved a novel theory of liability: underreporting of information under the Sunshine Act.[1] The October 2020 civil settlement resolved allegations under the False Claims Act (FCA) that the company agreed to pay for social events at a restaurant owned by a neurosurgeon as an inducement for the doctor to use the company's implantable infusion pumps. The DOJ alleged that the neurosurgeon selected and invited the attendees for the events, who included his social acquaintances, business partners, favored colleagues, and potential and existing referral sources.

While these types of allegations are common fodder for Anti-Kickback Statute cases typical under the FCA, the settlement also resolved the company's liability under the Centers for Medicare & Medicaid Services (CMS) Open Payments Program. In particular, the DOJ alleged that for 74 events between August 2013 and July 2019, the company made payments to the restaurant at the direction of the physician, and the DOJ asserted that these payments constituted transfers of value to the physician and were reportable as such to the CMS. Although the settlement agreement does not explain the damages calculation, $1.1 million of the overall settlement amount was allocated to resolve the alleged Sunshine Act violations. This amount approximates slightly less than

[1] DOJ Office of Public Affairs, "Medtronic To Pay Over $9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon," October 29, 2020. Notably, the civil settlement agreement did not contain any admission of liability by the company.

the maximum civil monetary penalties (CMPs) available for one annual submission,[2] while the settlement resolves liability for unreported payments across seven years.

Although this settlement raises the question of whether it represents a singular matter involving unique facts, it is more likely a harbinger of increased enforcement of underreporting under the Open Payments Program. In connection with the resolution, CMS' chief legal officer stated that CMS "looks forward to continued partnership with the Department of Justice to resolve allegations of manufacturers skirting their Open Payments obligations." In addition, the government's growing use of data analytics to identify trends and outliers, combined with multiple years of Sunshine Act data, bolsters the view that the DOJ and the CMS will be looking out for similar underreporting cases in the future.

Compliance Implications

Companies confronting fact patterns like the one above face a dilemma. Characterizing money paid to a third party (such as a restaurant, although the logic would also apply to other entities such as a consulting company) as a transfer of value to a physician under the Sunshine Act could implicate the AKS insofar as the third-party payment could be viewed as remuneration to the physician. Failure to report the payments, however, creates its own liability under the Sunshine Act.

Companies might discover these types of payments in the course of defending a DOJ investigation, during an internal investigation or as part of a review of Sunshine Act data. Once discovered, the better course may be to correct any prior underreporting to CMS while evaluating whether, even if payments are considered transfers of value to a physician, such payments were offered as inducements, which is a fact- and context-dependent inquiry.

In the case described above, while the compliance department that was responsible for Sunshine Act reporting initially was not made aware of the relationship between the physician and the restaurant, enforcement authorities nevertheless viewed the payments as a transfer of value on behalf of the physician. Given this, companies may wish to consider using this case to train their commercial personnel on the perils of arrangements with businesses owned by health care professionals, and reinforce the need for full disclosure where a business to which payments will be made is affiliated with a physician in a position to purchase, prescribe or recommend the company's products.

[2] Under implementing regulations, pharmaceutical and medical device manufacturers may be liable for CMPs of up to $150,000 per annual submission for failing to report required information. In addition, CMPs between $10,000 and $100,000 may be imposed for knowingly failing to submit required information, up to $1,000,000 per annual submission. These CMPs are adjusted for inflation.