Published on *The National Law Review* https://natlawreview.com

Government Continues to Closely Scrutinize Pharmaceutical Marketing Practices

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On September 4, 2019 the Department of Justice (DOJ) announced a $15.4 million settlement with pharmaceutical company Mallinckrodt ARD LLC (Mallinckrodt) to resolve alleged violations of the Anti-Kickback Statute (AKS) in two whistleblower suits filed under the False Claims Act (FCA). The settlement addresses allegations of AKS violations between 2009-2013 by sales representatives of a company later acquired by Mallinckrodt via the "wining and dining" of physicians to induce Medicare prescriptions of that company's drug. Interestingly, the settlements do not cover related allegations within those FCA suits that Mallinckrodt improperly used a patient assistance foundation to "pay illegal kickbacks in the form of copay subsidies" for the same drug.

As a reminder, the AKS in part prohibits paying or offering remuneration with the intent to induce or reward prescriptions of items or services – including prescription drugs – reimbursed under federal health care programs such as Medicare and Medicaid. And by law, claims submitted to federal health care programs for reimbursement that result from AKS violations constitute false or fraudulent claims under the FCA.

Here, DOJ intervened in two *qui tam* actions against Mallinckrodt alleging that sales representatives of Questcor Pharmaceuticals – a company later acquired by Mallinckrodt – provided remuneration to health care providers via "lavish meals and entertainment expenses" in order to induce drug prescriptions. DOJ took the position that claims submitted for such prescriptions were tainted by the AKS violations and thus caused the "submission of false claims to Medicare." According to DOJ, its "pursuit of these matters illustrates the government's emphasis on combating healthcare fraud," so providers and pharmaceutical companies would be well-advised to review their compliance policies and standards for health care provider interactions.

The Mallinckrodt settlement is emblematic of continued government scrutiny of pharmaceutical marketing, and comes shortly after the DOJ obtained its largest ever opioid-related settlement this summer. In July, 2019, DOJ entered into a $1.4 billion settlement with Reckitt Benckiser Group plc (RB Group) to resolve FCA allegations related to the marketing of Suboxone, an opioid used to reduce opioid addiction withdrawal symptoms. That settlement included forfeiture of $647 million in proceeds to resolve criminal liability as part of a non-prosecution agreement, and $700 million to resolve civil liability (with up to $200 million of that amount reserved for states that opt into the settlement). The settlement relates to allegations that a former subsidiary of RB Group misled

providers and payors by marketing Suboxone as “less-divertible and less-abusable and safer around children, families, and communities” than competing drugs, without a basis for such claims. The settlement – and a separate agreement with the Federal Trade Commission – also addresses allegations that RB Group’s subsidiary falsely represented that it had discontinued a tablet form of Suboxone for safety purposes, when that discontinuance was actually intended to “delay the entry of generic competition for Suboxone” according to the government. Finally, DOJ’s announcement of the settlement notes that DOJ is continuing a separate criminal prosecution of the former subsidiary, and that as part of the settlement RB Group agrees “to cooperate fully with all investigations and prosecutions by [DOJ] related, in any way, to Suboxone.”

In addition to the significant penalties and DOJ’s continued prosecution of the former subsidiary, this settlement is particularly notable because the government has extracted “the largest recovery by the United States in a case concerning an opioid drug” through an enforcement action focused on marketing of a drug intended to curb opioid addiction. This indicates the seriousness of the government’s concerns about violations of health care fraud and abuse laws, particularly in the pharmaceutical industry.

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National Law Review, Volume IX, Number 261