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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.

Joint Promotional Programs With Physicians Raise Compliance Risks

A recent civil False Claims Act (FCA) settlement between the DOJ and a medical device maker highlights the risks of in-kind inducements to physicians; in this case, in the form of various types of advertising assistance and educational programs.[1] Specifically, the settlement resolved allegations that Merit Medical Systems Inc. (MMSI) improperly paid physicians, medical practices and hospitals to use MMSI products in medical procedures performed on federal health care program beneficiaries. Under the auspices of an internal program known as the Local Advertising Program, MMSI allegedly provided remuneration to health care providers in the form of millions of dollars in free advertising assistance, practice development, practice support and unrestricted "educational" grants. Despite public statements that its financial assistance was designed to "increase th[e] awareness" of medical treatments, MMSI allegedly provided assistance only to select health care providers to reward past sales, induce future sales, and steer business to MMSI and away from MMSI's competitors.

Notably, the initial allegations in the case were brought to the DOJ's attention via a *qui tam* lawsuit filed by the company's chief compliance officer (CCO). The DOJ alleged that during the course of the alleged misconduct, the company ignored numerous warnings from the CCO that its conduct may violate the Anti-Kickback Statute (AKS), although the civil settlement does not specify the nature of such warnings or what actions the company took in response to the concerns.

[1] DOJ Office of Public Affairs, "Medical Device Maker Merit Medical To Pay $18 Million To Settle Allegations of Improper Payments to Physicians," October 14, 2020. Notably, the civil settlement agreement did not contain any admission of liability by the company.

Joint Promotional Programs With Physicians Raise Compliance Risks

Compliance Implications

The MMSI case reinforces the straightforward notion that any financial relationship with a physician in a position to purchase, prescribe or recommend a company's product poses AKS risk, and also highlights specific practices that may raise compliance red flags.

First, the case is an important reminder that in-kind transfers of value — which may take a range of forms, such as furnishing practice development tools or advertising assistance, or aiding staff with office tasks — pose the same AKS risks as direct payments do insofar as each constitutes remuneration, or something of value. Second, providing anything of value only to select providers with a sales goal in mind may be viewed by prosecutors as powerful evidence of an attempt to reward past or induce future sales. While such activities may also benefit a manufacturer, case law provides that the AKS may be violated if one purpose of a transfer of value is to reward or induce sales.

Given this reality, companies that pursue programs that benefit both a manufacturer and a health care provider (HCP), such as joint marketing programs, should develop and employ clear safeguards to address the risk that program activities may be perceived as solely intended to benefit the HCP. Such programs also create promotional risks where health care professionals are provided information about a company's products. The AdvaMed Code of Ethics on Interactions With Health Care Professionals (AdvaMed Code) sets forth examples of potential controls, and provides that companies may partner with physicians and other health care professionals to conduct joint education and marketing programs designed to highlight both the company's medical technology and the professional's ability to diagnose or treat medical conditions. At the same time, the AdvaMed Code provides that any such joint arrangement should include fraud and abuse controls, including (among other requirements):

- establishing a bona fide need for the company to engage in the activity for its own benefit;
- ensuring information provided by the company's products is consistent with its labeling;
- arranging for both parties to make equitable contributions towards the activity and costs; and
- documenting the arrangement in a written agreement that specifies the purpose of the arrangement and the roles, responsibilities and contributions of each party, including payment of costs.[2]

Notably, compliance with the AdvaMed Code does not provide a legal safe harbor, as activities that employ these controls but that are intended to induce or reward sales will still violate the AKS. Companies may wish to develop other controls suited to their business models. However, employing these or similar controls can substantially reduce risks that joint marketing activities may present under both the AKS and the Food, Drug, and Cosmetic Act and establish a company's good faith effort to structure arrangements in compliance with the law.

[2] AdvaMed Code of Ethics, Section V: Jointly Conducted Education and Marketing Programs (July 2020).