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Recent Cases Demonstrate DOJ Strategy of Deferred Prosecution Agreements Alongside False Claims Act Suits

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Two recent cases suggest that the Department of Justice (DOJ) may be more open to deferred prosecution agreements (DPAs) as a vehicle to resolve False Claims Act (FCA) suits. Just recently on January 4, the U.S. Attorney's Office for the Southern District of Illinois announced that a Pennsylvania medical device company simultaneously agreed to settle an FCA case against it, while entering into a DPA that included monetary penalties and an admission of guilt. The government deployed a similar strategy in July 2022 when a specialty pharmacy agreed to settle an FCA case brought in the District of Massachusetts in exchange for, among other things, a DPA. These two recent cases suggest a willingness on behalf of the government to consider DPAs in return for a corporate admission of liability to charges filed via criminal information as a means of resolving allegations of fraud typically addressed through civil False Claims Act cases.

The most recent case involved Jet Medical, Inc. (Jet), the manufacturer and distributor of Allevio, a device intended to treat migraine headaches. Jet was charged in a one-count information with introduction of misbranded devices into interstate commerce under the Food, Drug, and Cosmetic Act. The information alleged that Jet never sought the proper clearances to market Allevio, and instead, listed it as exempt from FDA approval under a regulation designed for “[e]ar, nose, and throat drug administration device[s].”

Concurrently with the filing of the information, the U.S. Attorney's Office for the Southern District of Illinois announced that Jet had entered into a DPA that included an acceptance of responsibility and a \$200,000 monetary penalty, while also requiring Jet to abide by a set of provisions in its compliance and ethics policy. The press release indicated that Jet also agreed to pay another \$545,000 to settle an FCA complaint against it and two related companies (although at the time of this writing the FCA complaint appears to be still under seal).

In July 2022, a similar resolution was reached by Solera Specialty Pharmacy LLC (Solera). Solera was charged in a criminal information for one count of health care fraud for conduct relating to the submission of falsified prior authorization forms for an opioid overdose drug. Solera simultaneously entered into a deferred prosecution agreement that included an acceptance of responsibility and required Solera to “implement and maintain a standard operating procedure concerning its prior authorization practices.”

As with Jet Medical, Solera also agreed to settle an FCA complaint (which also remains sealed at the time of this writing) for a higher dollar amount — the press release indicates Solera agreed to pay \$1.31 million.

These two cases may evidence a new approach to corporate criminal enforcement by DOJ. As [previously reported](#)

In October 2021, the DOJ announced the creation of the Corporate Crime Advisory Group, which was given “a broad mandate” to review criminal enforcement priorities, ensure prosecutors are adequately resourced, and examine “the factors bearing on the determination of whether a corporate case should be resolved through a deferred prosecution agreement” In September 2022, Deputy Attorney General Lisa Monaco announced further revisions to the department’s criminal enforcement policies in response to advisory group recommendations, writing that prosecutors should examine whether conduct demonstrates “weaknesses in a corporation’s compliance culture or practices.”

DOJ also made voluntary self-disclosure a key factor in weighing how it investigates and resolves misconduct by companies — a policy that will likely have implications for companies under investigation for potential FCA violations. In a February 2023 memorandum, DOJ announced that under its new mandatory guidance, “prosecutors should consider whether the criminal conduct at issue came to light as a result of the company’s timely, voluntary self-disclosure and credit such disclosure appropriately.”

Disclosures that qualify for the VSD benefits outlined in the policy are eligible for “resolutions under more favorable terms . . . than if the government had learned of the misconduct through other means.” To be covered by the policy, a company’s disclosure also must (1) not be made under a preexisting obligation to disclose; (2) be timely made; and (3) “include all relevant facts concerning the misconduct that are known to the company at the time of the disclosure.” Prosecutors “will not seek a guilty plea” in cases where the company meets these criteria, fully cooperates, and “timely and appropriately remediated the criminal conduct.”

However, and of particular import to companies facing FCA investigations, self-disclosure under the policy must be made “prior to an imminent threat of disclosure or government investigation; prior to the misconduct being publicly disclosed or otherwise known to the government; and within a reasonably prompt time after the company becoming aware of the misconduct, with the burden on the company to demonstrate timeliness.” Because of the nature of FCA investigations, which are often spurred by *qui tam* relators before the company learns of the alleged misconduct on its own, companies may be unable to take advantage of the relative safe harbor provided by DOJ’s new VSD policy. In fact, the policy specifically excludes “situations where disclosure of a company’s misconduct to the USAO was made by whistleblowers, including those who have informed the Department of fraud and other misconduct in *qui tam* actions.”

As seen in the Jet Medical and Solera settlements and policies noted above, DOJ is currently taking a broad approach to corporate liability, incentivizing companies to come forward before misconduct is known and demonstrating a willingness to bring criminal charges to achieve a global resolution when the target companies do not voluntarily disclose the misconduct. FCA cases provide U.S. attorney’s offices with an easy source of potential corporate criminal defendants who, by nature of the False Claims Act, are unlikely to qualify for the protections of the VSD policy. Companies facing FCA civil suits should be aware of the potential that they may become criminal targets and should explore with experienced counsel the ways to help deal with such risks.

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