

Insys Announces Settlement-in-Principle with DOJ Over Alleged Subsys Kickback Scheme

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Last month, Insys Therapeutics, Inc. announced that it reached a settlement-in-principle with the U.S. Department of Justice (DOJ) to settle claims that it knowingly offered and paid kickbacks to induce physicians and nurse practitioners to prescribe the drug Subsys and that it knowingly caused Medicare and other federal health care programs to pay for non-covered uses of the drug. The drugmaker agreed to pay at least \$150 million and up to \$75 million more based on “contingent events.” According to a status report filed by DOJ, the tentative agreement is subject to further approval and resolution of related issues. The settlement does not resolve state civil fraud and consumer protection claims against the company.

The consolidated lawsuits subject to the settlement allege that Insys violated the False Claims Act and Anti-Kickback Statute in connection with its marketing of Subsys, a sub-lingual spray form of the powerful opioid fentanyl. The Food and Drug Administration has approved Subsys for, and only for, the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy. The government’s complaint alleges that Insys provided kickbacks in the form of arrangements disguised as otherwise permissible activities. Specifically, it alleges that Insys instituted a sham speaker program, paying thousands of dollars in fees to practitioners for speeches “attended only by the prescriber’s own office staff, by close friends who attended multiple presentations, or by people who were not medical professionals and had no legitimate reason for attending.” Many of these speeches were held at restaurants and did not include any substantive presentation. Insys also allegedly provided jobs for prescribers’ friends and relatives, visits to strip clubs, and lavish meals and entertainment.

According to the government, Insys improperly targeted Subsys to patients who did not have cancer. Among other allegations, it notes that most of the physicians that Insys paid through its speaker program were not oncologists. The government also alleges that Insys lied to payors, including Medicare, to induce payment for such off-label prescriptions, and that its deceptive statements were material to the government’s reimbursement decisions.

The relator in the consolidated cases filed claims on behalf of 28 states and the District of Columbia. On the same day that the Insys settlement was announced, six of those states plus Colorado filed an intervenor complaint alleging violations of their respective state false claims acts, other state statutes and common law. Those claims are separate and apart from the ones resolved by the settlement-in-

principle.

The allegations against Insys have also given rise to a number of criminal actions against former officers and employees. The same day that the settlement was announced, a former district sales manager, Jeffrey Pearlman, pled guilty in a Connecticut federal court to conspiracy to defraud the United States in connection with the alleged scheme. See Plea Agreement, *United States v. Pearlman*, 17-CR-27-MPS (D. Conn. Aug. 8, 2018), ECF No. 147. Currently, there are four additional pending criminal actions against a total of 14 other defendants related to the case. Those cases are *United States v. Freedman et al.*, 18-CR-217-KMW (S.D.N.Y. filed Mar. 14, 2018); *United States v. Patel*, 17-CR-114-VPC (D. Nev. filed Dec. 6, 2017); *United States v. Clough*, 17- CR-37 JL (D.N.H. filed Mar. 22, 2017); and *United States v. Babich et al.*, 16- CR -10343-ADB (D. Mass. filed Dec. 6, 2016). These criminal cases show a continuing commitment to the principles set forth in the DOJ's 2015 [Yates Memorandum](#), which called for increased accountability for individuals responsible for corporate wrongdoing.

The five consolidated lawsuits subject to the settlement-in-principle are *United States, et al., ex rel. Guzman v. Insys Therapeutics, Inc., et al.*, 13-cv-5861; *United States ex rel. Andersson v. Insys Therapeutics, Inc.*, 14-cv-9179; *United States ex rel. John Doe and ABC, LLC v. Insys Therapeutics, Inc., et al.*, 14-cv-3488; *United States ex rel. Erickson and Lueken v. Insys Therapeutics, Inc.*, 16-cv-2956; and *United States ex rel. Jane Doe, et al. v. Insys Therapeutics, et al.*, 16-cv-7937.

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National Law Review, Volumess VIII, Number 256

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