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United States Intervenes in False Claims Act Lawsuits Accusing Insys Therapeutics of Paying Kickbacks and Engaging in Other Unlawful Practices to Promote Subsys, A Powerful Opioid Painkiller

On April 13, 2018, the United States intervened in five lawsuits accusing Insys Therapeutics Inc., of violating the False Claims Act in connection with the marketing of Subsys, an opioid painkiller manufactured and sold by Insys, the Department of Justice announced today. Subsys is a sublingual spray form of fentanyl, a powerful, but highly addictive, opioid painkiller. In 2012, Subsys was approved by the Food and Drug Administration for the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy.

As stated in the complaint, which was unsealed today, the United States alleges that Insys, headquartered in Arizona, paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. Many of these kickbacks took the form of speaker program payments for speeches to physicians that were, in fact, shams; jobs for the prescribers' relatives and friends; and lavish meals and entertainment. The United States also alleges that Insys improperly encouraged physicians to prescribe Subsys for patients who did not have cancer, and that Insys employees lied to insurers about patients' diagnoses in order to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries.

"Improper financial relationships between physicians and drug companies can distort a physicians' best judgment for their patients, in addition to undermining patient health and trust. This is especially troubling when the drugs are opioids," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "Lying to federal health programs about patients' medical diagnoses is also completely unacceptable. The Justice Department will pursue these illegal actions and continue to hold drug companies and doctors accountable for their roles in contributing to this deadly epidemic."

"Insys allegedly bribed doctors who are more concerned with profits than patients," said Christian J. Schrank, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services.

"Encouraging the inappropriate use of this too-often deadly opioid is intolerable enough, but the abuse is compounded when taxpayers are forced to pick up the bill."

"I applaud the Civil Division and the U.S. Attorney for their untiring efforts to hold health care providers accountable to the American taxpayer," said Vice Adm. Raquel Bono, director of the Defense Health Agency. "The Department of Justice's efforts safeguard the health care benefit for American service members, veterans and their families. The Defense Health Agency continues to work closely with the Justice Department, and other state and federal agencies to investigate those who participate in fraudulent practices."

"Our intervention in these cases is just one part of the Justice Department's multi-pronged efforts to combat the opioid crisis," said United States Attorney Nicola T. Hanna. "The illegal marketing activities alleged in the government's case helped fuel the crisis by improperly introducing opioids into the market. We are committed to hold accountable corporations and individuals who use kickbacks, off-label promotions and other illegal activities to sell lethal and highly addictive narcotics. Our goal is bring about an end to the tragic epidemic that is harming untold numbers of people across the United States."

The *qui tam* provisions of the False Claims Act allow whistleblowers to file lawsuits on behalf of the United States when they believe that a party has submitted false claims for government funds, and to receive a share of any recovery. The United States has the right to intervene and take over responsibility for litigating these cases. Here, the United States has intervened in five separate lawsuits that have been consolidated together in the Central District of California. They 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.

The United States has separately pursued a number of criminal cases against Insys employees and Subsys prescribers. Some of these cases have resulted in criminal convictions or guilty pleas, while others are currently pending.

These cases are being handled by the Justice Department's Civil Division, the United States Attorney's Office for the Central District of California, the Office of Inspector General of the Department of Health and Human Services, and the Defense Health Agency. The claims asserted against Insys are allegations only, and there has been no determination of liability.

Attachment(s):

Download U.S. Complaint in Intervention

Topic(s):

False Claims Act

Component(s):

Civil Division

USAO - California, Central

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