



INSYS Therapeutics Reaches Settlement in Connection with Marketing of Opioid Painkiller

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On August 8, 2018, INSYS Therapeutics, Inc. announced that it had reached an agreement in principle with the U.S. Department of Justice (DOJ) to settle DOJ's investigation of INSYS's marketing of the drug Subsys. Subsys is a sublingual spray form of the opioid painkiller fentanyl and was approved by the Food and Drug Administration for the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, but have become tolerant to, around-the-clock opioid therapy.¹

In April, DOJ had intervened in five lawsuits against INSYS that were filed following allegations by former employees of the company that INSYS had paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. According to DOJ's complaint, these alleged kickbacks included improper payments to physicians for speeches, jobs for prescribers' relatives and friends, and improper payments for meals and entertainment. DOJ also alleged 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 federal health program beneficiaries.²

According to a press release provided by INSYS, the agreement in principle calls for the company to pay \$150 million over five years, with the potential for contingency-based payments associated with certain events that INSYS estimates could require additional payments ranging as high as \$75 million. This agreement in principle is subject to the negotiation of final settlement documents with the government.³

In October of 2017, INSYS founder, majority owner, and former board member, John Kapoor, was arrested along with six former INSYS executives and managers in connection with an investigation by the U.S. Attorney's Office in the District of Massachusetts.⁴ Dr. Kapoor has pleaded not guilty to charges that include racketeering, conspiracy to commit mail fraud, conspiracy to commit wire fraud and conspiracy to violate the Anti-Kickback Statute.⁵

As the opioid crisis continues to grow, opioid manufacturers are facing increased and stricter

¹ INSYS Therapeutics, Inc. (Aug. 8, 2018). *INSYS Therapeutics Reaches Agreement in Principle to Settle Department of Justice Investigation*. <http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-newsArticle&ID=2362758> (Last accessed Aug. 13, 2018).

² Department of Justice. (May 15, 2018). *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*. <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying> (Last accessed Aug. 13, 2018).

³ INSYS Therapeutics, Inc. (Aug. 8, 2018). *INSYS Therapeutics Reaches Agreement in Principle to Settle Department of Justice Investigation*. <http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-newsArticle&ID=2362758> (Last accessed Aug. 13, 2018).

⁴ Lord, Sara (Sept. 12, 2017) *The Growing Number of Civil, Criminal, and Legislative Investigations of Insys Therapeutics, Inc. by Federal, State, and Congressional Entities Raises the Stakes for the Pharmaceutical Industry in General and for Opioid Manufacturers in Particular*. <https://www.agg.com/The-Growing-Number-of-Civil-Criminal-and-Legislative-Investigations-of-Insys-Therapeutics-Inc-by-Federal-State-and-Congressional-Entities-Raise-the-Stakes-for-the-Pharmaceutical-Industry-in-General-and-for-Opioid-Manufacturers-in-Particular-09-12-2017/> (Last accessed Aug. 13, 2018).

⁵ Wiles, Russ (Oct. 30, 2017). *Arrested billionaire resigns from Chandler's Insys Therapeutics board*. <https://www.azcentral.com/story/money/business/2017/10/26/insys-founder-and-arizona-billionaire-john-kapoor-arrested-opioid-marketing-case/803139001/> (Last accessed Aug. 13, 2018); Mohan, Nishant (Aug. 8, 2018). *Insys to Pay \$150 Million to Settle Justice Department Investigation*. <https://www.wsj.com/articles/insys-to-pay-150-million-to-settle-justice-department-investigation-1533733598> (Last accessed Aug. 13, 2018).

scrutiny of their sales and marketing practices, particularly of their payments to physicians. As Arnall Golden Gregory previously reported in our series on state and federal investigations of opioid manufacturers, in October 2017, a bipartisan coalition of forty-one state attorneys general issued subpoenas to five large opioid manufacturers, Purdue Pharma LP, Endo International plc, Janssen Pharmaceuticals, Teva Pharmaceutical Industries Ltd, and Allergan, Inc.⁶ Numerous States' Attorneys General have since filed suit against Purdue Pharma, alleging that the company misled prescribers and consumers about the addiction and health risks of its opioid medications, which include OxyContin.⁷ As of July 2018, over 800 lawsuits have been filed by state, city, county and tribal governments against opioid manufacturers and distributors, which have borne the brunt of addressing the crisis, and this number is expected to grow.⁸

As these cases grow in number, healthcare providers, as well as manufacturers and distributors, can expect to come under increased scrutiny as well. In several recent cases, physicians, including Key Opinion Leaders (KOLs) in pain management, have been individually named in lawsuits based on their associations with opioid manufacturers.⁹ Lawsuits focusing on physicians' and prescribers' roles have alleged that the drug companies cultivated and promoted only KOLs who would help expand the opioid therapy market, and that physicians have acted as "vehicles" who disseminated and validated "false, misleading, imbalanced, and unsupported messages" through unregulated unbranded marketing.¹⁰

In addition to their relationships with opioid manufacturers, physicians and prescribers have been under increased scrutiny for their opioid prescribing practices, as well. Recent cases have included civil actions by patients and their families alleging malpractice and negligence;¹¹ criminal actions by states alleging crimes ranging from fraud and illegal administration of a narcotic to murder;¹² and federal actions alleging illegal distributions of controlled substances, and related offenses.¹³ Depending on the specific facts surrounding a physician's alleged improper prescribing of opioids, even where there is no basis for criminal charges, physicians may face exclusion and debarment from federal health care programs, and sanctions by state licensing boards.

While charges and cases involving INSYS have loomed large on the opioid-abuse front, the recently announced settlement of the DOJ case not only leaves open various other cases that may involve allegations against the company, but also leaves DOJ free to pursue cases against other manufacturers and prescribers. Manufacturers and distributors can expect continued scrutiny of their physician relationships, their marketing materials, and their sales force's practices and performance. Physicians and prescribers can also expect significant federal, state and local oversight of their opioid prescriptions, with potential administrative, licensing, civil and criminal consequences for overprescribing opioid pain medications.

6 Lord, Sara (Oct. 4, 2017) *Here, There, and Everywhere: Opioid Manufacturers and Distributors Under a Brighter Spotlight*. <https://www.agg.com/Here-There-and-Everywhere-Opioid-Manufacturers-and-Distributors-Under-a-Brighter-Spotlight-10-04-2017/> (Last accessed Aug. 13, 2018).

7 See, e.g., Massachusetts's Office of Attorney General (June 12/2018). *AG Healey Sues Purdue Pharma, Its Board Members and Executives for Illegally Marketing Opioids and Profiting From Opioid Epidemic*. <https://www.mass.gov/news/ag-healey-sues-purdue-pharma-its-board-members-and-executives-for-illegally-marketing-opioids> (Last accessed Aug. 13, 2018); Tennessee Office of Attorney General (May 15, 2018). *Investigations of Other Opioid Manufacturers and Distributors Continue*.

8 Hopkins, Jared S., and Harris, Andrew M. (July 23, 2018). *One Man's \$50 Billion Vendetta Against Opioids*. <https://www.bloomberg.com/news/features/2018-07-23/lawyer-paul-farrell-s-50-billion-vendetta-against-opioids> (Last accessed Aug. 13, 2018).

9 See Complaint ¶ 91, *County of Erie v. Purdue Pharma, L.P., et al.* (Sup Ct, Erie County 2017). Available from <http://www2.erie.gov/exec/sites/www2.erie.gov/exec/files/uploads/erie%20v.%20purdue%20complaint%20filing%20version%202.1.pdf> (Last accessed Aug. 13, 2018).

10 See Complaint ¶¶ 91-98, *County of Erie v. Purdue Pharma, L.P., et al.* (Sup Ct, Erie County 2017). Available from <http://www2.erie.gov/exec/sites/www2.erie.gov/exec/files/uploads/erie%20v.%20purdue%20complaint%20filing%20version%202.1.pdf> (Last accessed Aug. 13, 2018).

11 See, e.g., Messenger, Tony (June 28, 2016). *Messenger: St. Louis jury sends \$17.6 million message in opioid abuse verdict*. https://www.stltoday.com/news/local/columns/tony-messenger/messenger-st-louis-jury-sends-million-message-in-opioid-abuse/article_b7628f83-0e94-5bc7-a2a8-38a12ab6d7d6.html (Last accessed Aug. 13, 2018).

12 See, e.g., Indictment. *State vs. Ruben*, (Sup. Ct., Pima County 2018) available from the Arizona Daily Star at https://tucson.com/indictment/pdf_0dd53124-19c4-55cd-9990-ee2131f92fcb.html (Last accessed Aug. 13, 2018); Oklahoma Attorney General (June. 23, 2017). *Attorney General Hunter Charges Doctor with Five Counts of Second Degree Murder*. <http://www.oag.ok.gov/attorney-general-hunter-charges-doctor-with-five-counts-of-second-degree-murder> (Last accessed Aug. 13, 2018).

13 See Drug Enforcement Agency. (Oct. 12, 2017). *Cases Against Doctors*. https://www.deadiversion.usdoj.gov/crim_admin_actions/doctors_criminal_cases.pdf (Last accessed Aug. 13, 2018).

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