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Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations

Company Admits Illegal Conduct Regarding Promotion of Subsys, a Powerful Opioid Painkiller

Opioid manufacturer Insys Therapeutics agreed to a global resolution to settle the government's separate criminal and civil investigations, the Department of Justice announced today. As part of the criminal resolution, Insys will enter into a deferred prosecution agreement with the government, Insys's operating subsidiary will plead guilty to five counts of mail fraud, and the company will pay a \$2 million fine and \$28 million in forfeiture. As part of the civil resolution, Insys agreed to pay \$195 million to settle allegations that it violated the False Claims Act. Both the criminal and civil investigations stemmed from Insys's payment of kickbacks and other unlawful marketing practices in connection with the marketing of Subsys. Insys's drug Subsys is a sublingual fentanyl spray, 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.

Today, the U.S. Attorney's Office for the District of Massachusetts filed an Information charging Insys and its operating subsidiary with five counts of mail fraud. According to the charging document, from August 2012 to June 2015, Insys began using "speaker programs" purportedly to increase brand awareness of Subsys through peer-to-peer educational lunches and dinners. However, the programs were actually used as a vehicle to pay bribes and kickbacks to targeted practitioners in exchange for increased Subsys prescriptions to patients and for increased dosage of those prescriptions. One practitioner targeted by Insys was a physician's assistant who practiced with a pain clinic in Somersworth, New Hampshire. During the first year that Subsys was on the market, the physician's assistant did not write any Subsys prescriptions for his patients. In May 2013, the physician's assistant joined Insys's sham speaker program knowing that it was a way to receive kickbacks for writing Subsys prescriptions. After joining the sham speaker program, the physician's assistant wrote approximately 672 Subsys prescriptions for his patients – many of which were medically unnecessary – and in turn, received \$44,000 in kickbacks from Insys.

As part of the criminal resolution, Insys agreed to a detailed statement of facts outlining its criminal conduct with respect to the illegal marketing of Subsys. Insys will enter into a five-year deferred prosecution agreement with the government, while Insys's operating subsidiary will plead guilty to five counts of mail fraud pursuant to the plea agreement that will be filed in the District of Massachusetts. According to the terms of the criminal resolution, Insys will pay a criminal fine of \$2 million and forfeiture of \$28 million. The Court has not yet scheduled the plea hearing. Last month, five former Insys executives were convicted after trial of racketeering conspiracy in connection with the marketing of Subsys. In total, eight company executives have now been convicted in Boston for crimes relating to the illegal marketing of Subsys.

In April 2018, the United States intervened in five *qui tam* lawsuits accusing Insys of violating the civil False Claims Act. In its Complaint, the United States alleged that Insys, headquartered in Arizona, paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. In addition to payments for sham speaker program speeches, the kickbacks also allegedly took the form of jobs for the prescribers' relatives and friends, and lavish meals and entertainment. The United States also alleged that Insys improperly encouraged physicians to prescribe Subsys for patients who did not have cancer, and lied to insurers about patients' diagnoses in order to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries.

"The Department of Justice is committed to taking steps to address the opioid epidemic," said Principal Deputy Associate Attorney General Claire Murray. "Illegal conduct by pharmaceutical manufacturers, especially in the midst of the opioid crisis, will not be tolerated. We will continue to investigate and vigorously prosecute these types of allegations and hold opioid manufacturers accountable under the law."

"The opioid epidemic has devastated communities and ravaged families across this country," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "The Department of Justice is committed to using the legal tools at our disposal to combat the illegal marketing and distribution of opioids, including fentanyl. Today's settlement sends a strong message to pharmaceutical manufacturers that the kinds of illegal conduct that we have alleged in this case will not be tolerated. I want to assure the families and communities ravaged by this epidemic that the Department of Justice will hold opioid manufacturers accountable for their actions."

"This criminal resolution today with Insys, coupled with the convictions of the eight executives, shows this Office's resolve to hold both corporations and individuals accountable for their crimes," said United States Attorney for the District of Massachusetts Andrew E. Lelling. "For years, Insys engaged in prolonged, illegal conduct that prioritized its profits over the health of the thousands of patients who relied on it. Today, the company is being held responsible for that and for its role in fueling the opioid epidemic. This global resolution is the culmination of years of work by prosecutors and agents, and these successful prosecutions and civil enforcement efforts should be a model for confronting corporate criminal activity."

"Today's settlement underscores our determination to hold opioid manufacturers accountable for pushing these highly addictive narcotics on the public via kickbacks to doctors and nurses, and other illegal means," said United States Attorney for the Central District of California Nick Hanna. "Our goal is to bring about an end to the tragic epidemic of opioid addiction and to go after those who profit from that epidemic."

"Paying bribes and providing other incentives to prescribe opioids with little regard to patient welfare surely signals a company is 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. "Today's settlement reaffirms our commitment to ensuring that companies pay a very heavy price for attacking vital government health programs."

Insys entered into an unprecedented 5-year Corporate Integrity Agreement (CIA) and Conditional Exclusion Release with OIG. Because of the extensive cooperation provided by Insys in the prosecution of culpable individuals and its agreement to enhanced CIA requirements, OIG elected not to pursue exclusion of Insys at this time. The CIA includes several novel provisions, including enhanced material breach provisions, designed to protect Federal health care programs and beneficiaries. In addition, Insys admitted to a Statement of Facts and acknowledged that the facts provide a basis for permissive exclusion. OIG did not release its permissive exclusion authority, as it generally does for CIA parties in False Claims Act settlements. Instead, OIG will provide such a release only after Insys satisfies its obligations under the CIA.

"The announced settlement is a vivid example of the Department of Defense's dogged efforts to protect the integrity of the U.S. military's health care system and its beneficiaries" said Bryan D. Denny, Special Agent

in Charge of the Defense Criminal Investigative Service, Western Field Office. “DCIS remains committed to working with its law enforcement partners and the U.S. Attorney’s Office to combat health care fraud, especially when pharmaceutical companies use taxpayers’ dollars to induce physicians with bribes and kickbacks to prescribe their drugs for unauthorized off-label usage that may very well endanger the recipient’s health and safety.”

“I applaud the Department of Justice and the U.S. Attorney for their continued efforts to hold pharmaceutical companies accountable to the American taxpayer,” said Vice Adm. Raquel Bono, director of the Defense Health Agency. “The efforts of the Department of Justice safeguard the health care benefit for our 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 all those who participated in fraudulent practices.”

The allegations resolved by the settlement stem from five lawsuits that were filed under the *qui tam*, or whistleblower, provisions of the False Claims Act, which permit private citizens to bring suit on behalf of the United States for false claims and share in any recovery. The lawsuits 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 whistleblowers’ share of the settlement announced today has not yet been determined.

These matters were handled by the Department of Justice’s Civil Division, the United States Attorney’s Office for the District of Massachusetts, the United States Attorney’s Office for the Central District of California, and the Department of Health and Human Services, Office of Inspector General. Investigations were conducted by the FBI, Boston Field Division; the Food and Drug Administration, Office of Regulatory Affairs; the Drug Enforcement Administration, New England Field Division; Department of Defense, Defense Criminal Investigative Service; U.S. Department of Labor, Employee Benefits Security Administration, Boston Regional Office; U.S. Postal Inspection Service’s Boston Division; United States Postal Service, Office of Inspector General, Northeast Area Field Office; Department of Veterans Affairs, Office of Inspector General, Criminal Investigations Division; Office of Personnel Management, Office of Inspector General; and the Defense Health Agency.

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