



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

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On September 6, 2017, the U.S. Senate Homeland Security and Government Affairs Committee (HSGAC) released a Minority Staff Report: *Fueling An Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.¹ The report, which is part of a wide-ranging congressional investigation of opioid sales and marketing efforts by major opioid manufacturers, focuses on Insys's alleged efforts to increase sales of Subsys®, its fentanyl drug, which is approved by the Food and Drug Administration (FDA) for the management of breakthrough pain in adult cancer patients,² by fraudulently abusing the prior authorization process. Other civil and criminal investigations of Insys' sales and marketing of Subsys by a range of federal, state, and local authorities have included allegations that Insys also engaged in various schemes to bribe practitioners to prescribe Subsys for non-FDA-approved uses. For pharmaceutical companies, as well as prescribers, the expanding governmental focus on opioids in general, and the multi-faceted, multi-party investigations of Insys in particular, constitute a clear warning to review their sales practices, strengthen their internal oversight, and upgrade their compliance policies regularly.

The opioid crisis is pushing enforcement efforts in new directions, and an industry that has become familiar with federal anti-kickback and (primarily civil) false claims actions is facing an increasing government emphasis on individual, as well as corporate, criminal prosecutions; expanding coverage of other federal statutes, particularly criminal narcotics statutes, to industry behaviors; and a growing number of state actions, including cases under a range of state consumer protection laws. The shift toward broader and stricter enforcement of the industry by *all* levels of government is particularly evident in the ever-expanding range and types of actions that have been brought against Insys in the last year and a half.

Federal Actions Related to Subsys

The most significant of these cases is the indictment last December, in a case brought by the U.S. Attorney's Office for the District of Massachusetts, of six former high-ranking Insys employees on various criminal charges related to the sales and promotion of Subsys. The indictment charged the defendants, who included the CEO/President, Vice President of Sales, National Director of Sales, two Regional Sales Directors, and the Vice President of Managed Markets, with conspiring to bribe practitioners, many of whom operated pain clinics, to prescribe Subsys for non-approved uses, and to defraud health insurers reluctant to pay for non-approved uses by establishing a "reimbursement unit" dedicated to fraudulently obtaining prior authorization directly from insurers and pharmacy benefit managers.³ Some of the defendants, who are variously charged with conspiracy to commit racketeering, conspiracy to commit wire and mail fraud and conspiracy to violate the Anti-Kickback Statute (AKS), could face up to twenty years in prison, as well as significant fines and penalties. On June 19, 2017, the company's former Manager of Reimbursement Services, who was not one of the six named defendants in the indictment, pleaded guilty to conspiracy to commit wire fraud in connection with Insys' alleged scheme to deceive insurers and pharmacy benefit managers to obtain payment authorizations for Subsys.⁴

1 <https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html>

2 Most recent approved labeling for Subsys, available on Drugs@FDA at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202788s016lbl.pdf

3 <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>

4 U.S. v. Gurrieri, No. 17-cr-10083 (D. Mass June 19, 2017); <https://www.cnn.com/2017/06/19/reuters-america-ex-insys-employee-pleads-guilty-in-us-opioid-drug-probe.html>

While the Massachusetts case is particularly noteworthy for its use of serious criminal charges against top ranking officials in a company, other U.S. Attorney's Offices have also brought far-reaching criminal cases against various Insys employees and high-volume prescribers in the past year. In each of these cases, the charges have centered on allegations of the payment of kickbacks, in the form of speaking fees and entertainment, to induce prescribers to prescribe higher volumes of the drug, and the provision of false information to obtain prior authorization approvals for non-approved uses of the drug. In certain instances, including the use of RICO charges in the Massachusetts case, these offices have extended the charges beyond the traditional health fraud statutes to include charges of wire and mail fraud, as well as charges of illegal distribution of narcotics and controlled substances.

On July 11, 2017, the U.S. Attorney's Office for the District of Connecticut announced that a former Insys sales representative had pleaded guilty to a count of engaging in a kickback scheme to defraud federal healthcare programs.⁵ The former employee admitted that she had induced certain medical practitioners to prescribe Subsys by paying them to participate in hundreds of sham "Speaker Programs" that were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and where there was no educational component to the event. This recent plea follows an earlier plea in June 2015 by a pain clinic nurse in Connecticut, who pleaded guilty to accepting \$83,000 in kickbacks in the form of payments for "speaking engagements" that were part of these alleged sham "Speaker Programs."⁶

Also on July 11, 2017, in a case brought by the U.S. Attorney's Office for the District of Alabama, another former Insys employee pleaded guilty to charges of conspiring to pay illegal kickbacks to doctors in exchange for their prescribing Subsys. On July 12, 2017, the former Regional Manager for the southeastern United States admitted that she had conspired with others within Insys to pay illegal kickbacks in the form of speaking fees, and that the speaking programs were merely a pretext through which Insys could line the pockets of certain doctors.⁷ This plea, too, followed an earlier federal case in Alabama that involved Insys – in February 2017, following a two month trial, two doctors were convicted of over-prescribing addictive pain killers, including Subsys, to their patients; receiving illegal kickbacks from Insys; and engaging in insurance fraud.⁸ They have since been sentenced to twenty and twenty-one years in prison, respectively.⁹ A key witness in the trial of the two doctors was another Insys sales representative, who had previously also pleaded guilty on February 17, 2016 to conspiring to violate the AKS, and whose plea agreement included the statement that she was actually hired by Insys as a kickback in exchange for one of the doctors continuing to prescribe Subsys.¹⁰

On March 24, 2017, the United States Attorney's Office for the District of New Hampshire announced the indictment of a Physician Assistant on charges of receiving kickbacks in exchange for prescribing Subsys.¹¹ From 2013 to 2014, New Hampshire had the second highest number of patients receiving Subsys prescriptions in the country, 84% of which were written by this one PA.

On August 9, 2016, the U.S. Attorney's Office for the Southern District of New York filed an indictment charging a former Insys District Sales Manager and former sales representative with conspiring to violate the AKS, and violating the AKS, based on the same alleged scheme of paying sham speaking fees to induce physicians to prescribe Subsys.¹² On June 1, 2017, charges were added against one defendant claiming that he conspired to commit honest services wire fraud and aggravated identity theft.¹³

In November 2016, in the Eastern District of Michigan, a neurologist, described as the top dispenser of Subsys in the country, pleaded guilty to charges of unlawful distribution of controlled substances – an offense that carries a possible

5 <https://www.justice.gov/usao-ct/pr/drug-company-sales-rep-admits-role-kickback-scheme-related-fentanyl-spray-prescriptions> .

6 <https://www.nytimes.com/2015/06/26/business/nurse-pleads-guilty-to-taking-kickbacks-from-drug-maker.html>

7 <https://www.justice.gov/usao-sdal/pr/insys-regional-manager-pleads-guilty-kickback-conspiracy> <http://www.businessinsider.com/alabama-doctors-guilty-of-running-opioid-pill-mill-2017-2>

8 <http://www.businessinsider.com/alabama-doctors-guilty-of-running-opioid-pill-mill-2017-2>

9 <https://www.justice.gov/usao-sdal/pr/insys-regional-manager-pleads-guilty-kickback-conspiracy>

10 <http://fusion.net/story/272611/fentanyl-drug-hired-to-please-doctor/>

11 <https://www.justice.gov/usao-nh/pr/former-physician-assistant-charged-healthcare-kickback-scheme>

12 <http://www.agg.com/files/uploads/Footnote%2012.pdf>

13 <http://www.agg.com/files/uploads/Footnote%2013.pdf>

penalty of up to thirty years in prison – and health care fraud, based on accusations of defrauding Medicare of \$1.9 million and Blue Cross Blue Shield \$1.2 million.¹⁴ Sentencing in the case is currently set for October 30, 2017.

State Actions

As the federal government has raised the stakes in the opioid cases, state and local governments have joined the battle. In July, the Washington Post reported that, in the preceding year alone, more than 25 states, cities and counties had filed suit against opioid makers, distributors and drugstore chains.¹⁵ Since then, more states and localities have either filed or announced plans to file similar actions. In addition to expanding the laws under which they are charging or suing, however, states and counties have extended the terms of settlement agreements in new and novel ways to require specific actions beyond the typical requirements to comply with law and make reports, and to prohibit specific marketing activities.

On August 18, 2017, the Illinois Attorney General's Office announced that Insys had agreed to pay \$4.45 million to settle claims regarding its promotion of Subsys. The State had sued the company for “deceptively marketing and selling” the drug for treatments that were not approved by the FDA, including for breakthrough pain associated with chronic conditions, such as back and neck pain, and pushing doctors to prescribe higher and more expensive doses of the drug. The State's press release announcing the settlement stated that doctors “were rewarded for prescribing Subsys to non-cancer patients for off-label uses, including payments for sham speaking events and dinners at expensive restaurants.”¹⁶ While a \$4.45 million settlement may seem relatively inconsequential compared to the large numbers we've become accustomed to seeing in other pharmaceutical settlements, the focal point of the settlement is not its financial cost, but the specific conditions attached to it and the implications of those conditions for the industry. In addition to requiring Insys to comply with the Illinois Consumer Fraud Act, the Illinois and Federal Food, Drug, and Cosmetic Acts, and the Federal Anti-Kickback Statute, the agreement also requires Insys to:

- Create an Opioid Abuse Detection Program to identify prescribers who are abusing or aiding in the abuse of opioids;
- Restrict promoting Subsys only to oncologists and prescribers who have affirmatively stated they currently treat or are likely to treat patients with cancer pain;
- Prevent Insys employees from communicating with an Illinois patient's insurance company regarding prior authorization of an opioid;
- Limit the number of times a prescriber can host an Insys speaker program and the number of times a prescriber can attend an Insys speaker program; and
- Prohibit sales representatives from communicating about a particular patient with a prescriber, initiating direct communication with a patient, or having access to a patient's medical records.

While it is common for pharmaceutical settlements to include provisions to bring sales and marketing practices into compliance, *these conditions appear to be specifically designed to set and enforce limits on sales of the drug, as well.* Illinois Attorney General Lisa Madigan left no doubt that her chief concern was opioid addiction when she charged that corporate behavior had “creat[ed] the opioid epidemic and resulting overdose deaths in our state,” and set aside the \$4.45 million in settlement funds to fight opioid abuse.

In requiring the funds to be used to fight opioid abuse, the Illinois settlement tracks two other state settlements that have required funds from Insys to be used for preventing and remediating problems related to opioid abuse in the state. In January 2017, Insys reached a settlement with the New Hampshire Attorney General's Office, in which the company agreed to pay \$2.9 million to settle allegations related to its marketing of Subsys, and another \$500,000 to the New Hampshire Charitable Foundation to be used for preventing and remediating problems related to the abuse of opioid

¹⁴ <http://www.detroitnews.com/story/news/local/oakland-county/2016/11/07/doc-coin-collection/93446828/>

¹⁵ https://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f_story.html?utm_term=.bb535607da64

¹⁶ http://www.illinoisattorneygeneral.gov/pressroom/2017_08/20170818.html

drugs in the state.¹⁷ In an earlier settlement with the State of Oregon, in August 2015, Insys agreed to pay \$1.1 million, with \$533,000 to be paid to the state and \$567,000 to be paid to an organization, selected by the Attorney General, to help prevent opioid abuse and misuse in the state.¹⁸ With the states on the front lines of the opioid crisis, Insys and other opioid manufacturers can expect future settlements to continue to focus on direct funding for the prevention and remediation of the problems created by the abuse and misuse of their products.

On August 31, 2017, the State of Arizona, which is home to Insys, filed a civil suit under the state's Consumer Fraud Act against the company, two former employees, and three top-prescribing physicians, whose prescriptions allegedly accounted for 64% of the total Subsyst sales in Arizona over a five-year period. The state's lawsuit seeks injunctive relief barring Insys from engaging in deceptive marketing practices, restitution for consumers, disgorgement of unlawful profits, and civil penalties of up to \$10,000 for each violation.¹⁹

AGG Observations

- To the extent the opioid cases may represent a shift from holding companies accountable for off-label sales and marketing practices per se to holding them accountable for the consequences of off-label promotions (i.e., the increase in opioid addiction and overdoses and fatalities), the conditions in the recent state settlements, in particular, are likely to be the harbingers of more attempts to regulate and limit the industry. This swelling wave of litigation – and the effort to hold third parties responsible – will continue to grow as the dimensions of the opioid crisis become more apparent.
- The state and federal, civil and criminal cases involving Insys, its employees, and/or prescribers in different areas of the country illustrate the state and federal governments' shared purpose of addressing the opioid problem, at least in part, through heightened enforcement of the pharmaceutical industry. As more states join with the federal government to exercise oversight of the promotional and distributional activities within and outside the industry, adding their own independent causes of action, companies and individuals should expect stricter oversight of – and standards for – promotional activities by multiple overseers.
- Whether this heightened scrutiny will be confined to activities related to opioid drugs remains to be seen. Opioid addiction is a clearly stated priority for the federal and many state governments. The illegality of the alleged behaviors that form the basis of most of these actions is not, however, dependent on the involved drug product's being an opioid (cases under the Controlled Substances Act being the exception).

¹⁷ <https://www.doj.nh.gov/media-center/press-releases/2017/20170118-insys.htm>; <https://www.justice.gov/usao-nh/pr/former-physician-assistant-charged-healthcare-kickback-scheme>

¹⁸ <https://www.doj.state.or.us/media-home/news-media-releases/ag-rosenblum-settles-with-pharmaceutical-company-insys-over-unlawful-promotion-of-the-powerful-opioid-subsyst/>

¹⁹ <http://www.reuters.com/article/us-insys-court/arizona-accuses-drugmaker-insys-of-fraudulent-opioid-marketing-idUSKCN1BB23U>; http://tucson.com/news/local/arizona-sues-chandler-opioid-company-over-safety-of-drug-deceptive/article_d6aa2273-cbc0-5790-877d-f9d08e4695d8.html; <http://www.az-central.com/story/money/business/health/2017/08/31/arizona-sues-insys-therapeutics-three-doctors-over-improper-marketing-and-prescribing-synthetic-opioid/619060001/>

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