Insys Litigation Documents at a Glance

Founded in 1990 and incorporated in 2002, Insys Therapeutics found success in a niche of the opioid market selling transmucosal immediate-release fentanyl (TIRF) medications, which are intended for "breakthrough" pain in cancer patients already taking other opioid painkillers. Subsys, the company's patented spray-delivery TIRF, was launched in 2012; prescriptions for Subsys amounted to about $330 million dollars in net revenue for Insys in 2015.

The U.S. Department of Health and Human Services Office of Inspector General investigated Insys in 2013 for its sales and marketing practices, after a former Insys employee filed a whistleblower suit. Arrests of physicians writing high numbers of Subsys prescriptions prompted further investigation of Insys. States, counties, cities, and individuals sued Insys, with many suits being consolidated into a multidistrict case. Federal investigations culminated in a 2019 federal criminal trial against top Insys executives, in which the company's founder and four other executives were found guilty of racketeering conspiracy.

In June 2019, Insys settled criminal and civil charges with the Department of Justice by agreeing to pay $225 million. The company filed for bankruptcy, sold the Subsys license to another pharmaceutical company, and stopped selling drugs in 2019.

Key Legal Documents

- Background of bankruptcy case
- Case docket
- Transcripts of the 2019 federal racketeering trial
- August 2022 agreement outlining the terms of Insys's document release
- Search terms used to produce documents in the multidistrict litigation between Jan. 1, 1998, and Dec. 31, 2017

Selected Cases and How They Evolved

Oregon Department of Justice, in the matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution (July 2015)
Oregon sent Insys a Notice of Unlawful Trade Practices and Proposed Resolution in July 2015, and Insys signed an Assurance of Voluntary Compliance in August 2015. Oregon was the first government entity to settle with Insys for their alleged misconduct. The settlement resolved allegations including that Subsys was marketed in Oregon for off-label uses such as non-cancer neck and back pain; the use of improper financial incentives to some doctors to increase Subsys prescriptions; targeting doctors who were not qualified to prescribe the powerful drug; and deceptively promoting Subsys for treatment of mild pain.

State of New Jersey v. Insys Therapeutics, Inc., and John N. Kapoor (October/November 2017)
In October 2017, the State of New Jersey filed suit against Insys Therapeutics, Inc., charging that despite Subsys only having received FDA approval for the "narrow" purpose of treating "breakthrough cancer pain" in opioid-tolerant patients, Insys unlawfully directed its sales force to push Subsys for prescription to a broader patient population—patients suffering any type of chronic pain—and at higher doses. In November 2017, the State of New Jersey filed an amended complaint against Insys adding John N. Kapoor, billionaire founder of the company, as a defendant, accusing both the company and Kapoor of endangering the public through a greed-driven, unlawful marketing campaign designed to exponentially increase sales of Subsys by making fraudulent claims and unlawfully incentivizing health care providers to prescribe Subsys to an inappropriately broad array of pain patients. In January 2021, the State of New Jersey announced an anticipated $5 million dollar settlement with Kapoor; most of the recovery will be dedicated to fund opioid abatement purposes.

State of New York v. Insys Therapeutics, Inc. (February 2018)
New York's suit describes how "Insys marketed Subsys with no regard to the health and safety of patients." Allegations include sales tactics such as promoting off-label use, minimizing the risks of fentanyl addiction, and marketing to doctors who the company knew had previously been arrested and charged for illegal prescribing practices; rewarding high prescribers with paid speaking engagements; and Insys staff calling insurers and representing themselves as working in a doctor's office in order to get prior authorizations for prescriptions.

State of Minnesota v. Insys Therapeutics, Inc. (May 2018)
Minnesota's complaint echoes New York's in focusing on Insys's practices of promoting off-label use and paying doctors for speaker programs. This suit describes in detail how sales representatives were instructed to "live with" and focus on individual doctors to market to, and to press the doctors to increase the number of patients taking Subsys and to increase doses prescribed. Salespersons' low baseline salaries with promises of bonuses "incentiviz[ed] sales above education on the risks and proper use of Subsys."

State of Maryland v. Insys Therapeutics, Inc. (September 2018)
Maryland's complaint centers on the "thousands of violations of the Maryland Consumer Protection Act." The suit describes Insys's strategies to drive prescriptions for inappropriate patients and mislead insurance companies.

USA v. Alfonso (June 2015)
Heather Alfonso was sentenced to three years of probation for accepting $83,000 dollars in kickbacks through Insys's Speaker Bureau program. An advanced practice registered nurse (APRN), Alfonso was the highest prescriber of Subsys in Connecticut, and her conduct resulted in a loss to Medicare of more than $2.5 million dollars. In addition to probation, she was ordered to pay full restitution, jointly and severally with other defendants convicted in the kickback scheme.

United States v. Babich et al. (January 2019)
A federal jury convicted the founder and four Insys executives—John Kapoor, Michael Gurry, Sunrise Lee, Joseph Rowan, and Richard Simon—of racketeering conspiracy in May 2019, per the Racketeer Influenced and Corrupt Organizations Act (RICO). These Insys leaders were found guilty of conspiring to bribe practitioners in various states to prescribe Subsys and to mislead insurance providers to approve payment for the drug. Prior to the start of the trial, two other executives, Alex Burlakoff and Michael Babich, pleaded guilty.