

Opioid Industry Documents Archive

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Insys Litigation Documents – Timeline of Events

2002

Insys Therapeutics formed with <u>John Kapoor</u> and George <u>Kottayil</u> in Illinois.
 Kapoor brought in employee <u>Mike Babich</u> from a previous investment venture.
 Insys wanted to develop a generic version of <u>Marinol</u> [dronabinol/synthetic tetrahydrocannabinol (THC)], since it is cheap to bring to market and would finance expensive development of branded products down the line. One of those products was <u>Subsys</u>, a sublingual fentanyl spray.

2007

Insys moves to Arizona and tries to go public. The initial public offering (IPO) fails. Generic Marinol not a viable revenue stream.

2009-2010

- Subsys still in trial phase. Second attempt at an IPO fails.
- Babich made CEO.

2011

- Kapoor decides Insys will bring the drug to market on its own.
- Matt Napoletano hired as vice president of marketing.

2012

- United States Food and Drug Administration (FDA) approves Subsys for the treatment of "breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain," and the drug is launched.
- Start of sales visits to prescribers
- Alec Burlakoff hired as regional sales manager and promoted to vice president of sales within three months.
- Insys Speaker Program (ISP) pilot launched under Mike Gurry's leadership.
- Sales representative <u>Ray Furchak</u> files first *qui tam* whistleblower lawsuit.
 Government declines to pursue the case and Furchak ultimately drops it.

2013

Insys Reimbursement Center (IRC) created to evade prior authorization policies.

- IPO success ticker symbol is INSY. Insys was the best performing IPO that year.
- Sales representative <u>Mia Guzman</u> files *qui tam* whistleblower lawsuit after being fired.
- Insys receives subpoena from the Department of Health & Human Services (HHS) Office of Inspector General (OIG) for marketing and sales documents of Subsys.
- Insys hires Skadden, Arps, Slate, Meagher & Flom law firm to start an internal investigation.
- Internal audits recommend shelving the speaker program, but Insys does not follow through.

2014

- Top prescriber Dr. <u>Gavin Awerbuch</u> is arrested, cooperates with the U.S.
 Attorney's Office and meets with Insys executives to record them.
- Insys agrees to direct-ship Subsys to C&R Pharmacy (owned by Drs. <u>John Patrick Couch</u> and <u>Xiulu Ruan</u>) to bypass the distributor and circumvent the supply throttle in place due to Suspicious Order Monitoring (SOM).
- Napoletano resigns.
- Revenue trending up and Subsys at record market share, nearly 40%.
- Insys received second federal subpoena, signaling criminal investigation.

2015

- Insys stock climbs to high of \$46/share and record sales with net revenue of \$330 million.
- Drs. Couch and Ruan arrested on federal conspiracy charges.
- Grand jury proceedings start.
- Nurse practitioner Heather Alfonso pleads guilty regarding Insys speaker program engagements as kickbacks.
- Burlakoff leaves Insys. Babich fired.

2016

- Natalie Perhacs, sales representative to Drs. Ruan and Couch, becomes first employee convicted of committing a crime.
- Burlakoff meets with federal authorities to attempt a deal, which was unsuccessful.
- Babich, Burlakoff, Gurry, Sunrise Lee, Joseph Rowan, and Richard Simon are arrested and charged with bribery and fraud.

2017-2018

- Kapoor arrested.
- United States Attorney's Office in Boston builds the case and brings Racketeer Influenced and Corrupt Organizations Act (RICO) charges.

 Several employees (Burlakoff, Babich, Elizabeth Gurrieri, Karen Hill, and Perhacs) found guilty. They agree to cooperate with the case, along with prescribers Awerbuch and Alfonso.

2019

- Trial of Insys executives begins in Boston in January.
- All defendants found guilty in May. Most sentenced in 2020.
- Insys agrees to pay \$225 million along with admission of guilt to resolve the United States Department of Justice investigations. Settlement stems from five whistleblower lawsuits, including Guzman's.
- Insys files for bankruptcy.
- Subsys sold to BTcP Pharma LLC.

Note: The arrests in this timeline are not a comprehensive list of physicians arrested for conduct related to Insys.

Sources

Hughes, E. (2022). The Hard Sell: Crime and Punishment at an Opioid Startup.

Raymond, N. (2019, September 19). <u>Drugmaker Insys wins bankruptcy court approval</u> to see off opioid. Reuters.

Romo, V. (2019, June 10). <u>Insys Files For Chapter 11, Days After Landmark Opioid</u> Settlement Of \$225 Million. NPR.

Senate Homeland Security and Governmental Affairs Committee. (2018 October). Minority Staff Report: <u>Fueling an Epidemic Report Four: Inside the Insys Strategy for Boosting Fentanyl Sales.</u>

United States Attorney's Office, District of Connecticut (2019, November 26). <u>APRN Who Received Kickbacks from Insys Therapeutics for Prescribing Fentanyl Spray is Sentenced.</u>

United States Attorney's Office, District of Massachusetts (2019, May 2). <u>Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy</u>.

United States Department of Justice. (2019, June 5). <u>Opioid Manufacturer Insys</u> <u>Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations</u>.