

Insys Litigation Documents: Disregarding the Dangers of Subsys

Key finding: Insys disregarded the dangers of Subsys, an extraordinarily potent and addictive fentanyl product. Insys promoted Subsys for uses and indications much broader than those approved by the FDA, despite the fact that other uses and indications were not safe or effective. Insys also misrepresented safe and effective dosage amounts by encouraging providers to prescribe high strengths of Subsys. Insys pushed these high-strength prescriptions because the company made far more money; in 2013, the price of the highest strength of Subsys was at least five times higher than the lowest strength.

Why this is important: The sales and marketing tactics used by Insys, in direct contravention of its FDA-approved label, jeopardized the health and safety of patients. Subsys—an example of the most powerful type of opioid—was pushed to a broader patient population, often when medically unnecessary, thereby putting patients at increased risk of overdose. Insys disregarded the fact that higher strengths could be fatal to patients who had not taken the medicine at lower doses.

Relevant Documents

Document Title: Differentiated Message

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=yfqv0270>

Date: 2012-08

Description: A sales training document on messaging to doctors that emphasizes the importance of titrating to an “effective dose.” The document states “the majority of your patients will require a dose north of 600 mcg” and includes a bar chart of “distribution of Subsys patients by effective dose,” with the highest percentage of patients at 800 mcg and 1200 mcg.

Document Title: Fwd: impt

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=mjch0258>

Date: 2012-08

Description: Michael Babich, president and CEO, emails regional sales managers that “our number 1 goal right now is effective dose and having rep promoting 60 units of the low strengths is not going to cut it.” Babich states that “reps having doctors write scripts for 60 units at 100 mcg will be monitored.”

Document Title: URGENT – Please note you have reversed scripts from yesterday

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=ykfg0268>

Date: 2012-09

Description: Alec Burlakoff, vice president of sales, instructs the southeast sales team to respond to every message indicating a prescription written for less than 400 mcg, including “you must follow up with the physician within 24 hours and provide specific details to the conversation.” He emphasizes “THIS IS VERY SERIOUS,” and states, “I do not know how I can

stress enough just how detrimental prescriptions for 200 mcg and 100 mcg are to the company, patient, and overall state of business.” Burlakoff threatens that “anyone whom ignores these instructions is subject to immediate negative consequences...”

Document Title: 100 mcgs – and reporting explanations within 24 hours

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=kswl0269>

Date: 2012-09

Description: This email thread starts with Burlakoff and Matt Napoletano, vice president of marketing, detailing the “effective dose” message to the sales team, including how prescriptions of 60 units of 100 mcg do not lead to repeat customers. Sales representative Susan Beisler expresses concerns to Frank Serra, northeast regional sales manager, on calling doctors because they wrote scripts for 100 mcg. Beisler states, “I’m very uncomfortable jumping all over him [Dr. Wroblewski] for writing 100 mcgs as it’s not often.”

Document Title: ACTIQ SWITCH PROGRAM_10-19-12.DOCX

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=kkfy0270>

Date: 2012-10

Description: A sales document titled “Actiq Switch Program Primer” detailing the switch program to convert patients on generic Actiq (fentanyl citrate) to Subsys. The program is specifically focused on identifying and converting Actiq 1200 and 1600 mcg patients to the equivalent Subsys dosage and offers free products (for any dosage strength) and prior authorization assistance.

Document Title: PA INITIATION FORMS AND RECORDS SENT.PDF

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=mylb0273>

Date: 2013-02

Description: A preauthorization/medication exception request fax form with a letter of medical necessity signed by Dr. Roy Blackburn. The patient is a “chronic pain patient” diagnosed with “breakthrough pain, intractable cephalgia” and the indication for the trial of Subsys at 600 mcg is for “migraine rescue (significantly interfering with function).”

Document Title: duplicate opt in rcvd

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=rlqp0273>

Date: 2013-02

Description: Liz Gurrieri, prior authorization specialist, emails Jaimi Hooker, sales representative, about receiving a duplicate opt-in for a patient of Dr. Blackburn. The request is for 240 units per month of 600 mcg for migraines. Gurrieri predicts they will not be able to get it approved and asks, “why is the doctor not prescribing 1200 mcg in a lesser amount?”

Document Title: Re : Make it happen for yourself

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=hjbc0271>

Date: 2013-09

Description: Karen Hill, district sales manager, provides the Miami sales team with strategies to get doctors to titrate current patients to higher strength and dosage, including getting medical assistants to stick vouchers in patient charts. Hill states, “These patients are LOW HANGING FRUIT! They’ve already been approved! This is the fastest way to make \$\$\$\$\$\$!”

Document Title: Advancements in the Treatment of Breakthrough Pain in Cancer Patients (BTCP)

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=kyxj0271>

Date: 2013-09

Description: In this slide deck for Insys speakers, breakthrough pain in cancer patients (BTCP) is defined as “a transitory exacerbation, or flare, or mild to severe pain in patients with otherwise stable persistent pain.” Instructions include how to titrate to find an effective dose and information on the Effective Dose Patient Savings Program, which involved free units of Subsys for patients and prior authorization assistance.

Document Title: Fwd: SSP 5k base salary increase

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=lxcn0264>

Date: 2016-06

Description: Daniel Brennan, chief operating officer, emails concerns about overall sales representative compensation to a group including founder John Kapoor. Brennan states, “I believe we are still creating an environment of non-compliance,” in regards to the company’s compensation scheme of a low base salary and very high incentive pay. He notes that such a model encourages off label marketing and quid pro quo behavior. Brennan also writes, “with a potent pain product like we have, it is dangerous to have so little previous pharma experience/training” in regards to the incoming recruiting class.

Suggested Search Terms

- “effective dose”
- “daily rep report for low strength”
- “low-hanging fruit”
- “super voucher” or “SV”