

Insys Litigation Documents: Relying on “Whales” and Repurposing REMS

Key finding: The Insys business model relied upon a small number of prescribers who accounted for a large proportion of all products sold. In some cases, one physician wrote the vast majority of Subsys prescriptions for a given region or state. These prescribers, which internal documents refer to as “whales,” were selected and targeted through the use of data that the company bought from data aggregators, as well as data that was required to be collected to fulfill Food and Drug Administration (FDA) regulatory requirements as part of the FDA’s Risk Evaluation and Mitigation Strategy (REMS) program.

Why this is important: REMS is a drug safety program to help ensure the benefits of a medication outweigh its risks. Instead of using REMS for its original purpose, Insys used the data as a sales and marketing tool to maximize profits at the cost of patient safety, monitoring prescriber behavior to boost sales and incentivize sales staff.

Relevant Documents

Document Title: Fwd: 3rd quarter plan uncapped commission [sic] plan

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=snmn0267>

Date: 2012-07

Description: Michael Babich, CEO and president, emails the sales team to detail the Q3 incentive compensation plan, which includes the continuation of uncapped commissions and a new market share component. Babich states, “it bears repeating, target the whales, get them on board and you will succeed.”

Document Title: Re: I have to say, Mike is right to point his frustration out

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=hfnb0264>

Date: 2013-05

Description: This email from Alec Burlakoff, vice president of sales, includes a table of sales data for Drs. Judson Somerville and Kenneth Sun. Sunrise Lee, regional sales director, responds with numbers for Subsys net sales vs. ROO (rapid-onset opioids) net sales for several doctors and questions which doctors they should cater to.

Document Title: RE: IMPORTANT - Hartford, CT Daily REMS Report / Authorized Rx Count – 5.23.13

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=pmyd0262>

Date: 2013-06

Description: In response to a daily REMS report for sales representative Abe Rosenberg, regional sales manager Jeff Pearlman shares concerns about the prescribing pattern of Heather Alfonso, an Advanced Practice Registered Nurse (APRN). Rosenberg replies that he spoke to Alfonso about her script count and hesitancy to write higher unit scripts, and that she “has assured me she will continue to increase script units on a ‘individual patient’ basis and need. A practice mandated by the REMS board.” Rosenberg states that Alfonso is “constantly trying to identify new Subsys candidates” and is a great speaker for Subsys.

Document Title: Re: IMPORTANT - San Antonio, TX Daily REMS Report / Authorized Rx Count - 9.11.13

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=fh1h0276>

Date: 2013-09

Description: In response to a daily REMS report for sales representative Ty Rustin, regional sales manager Anna Marie Bolet asks Rustin for specifics on “potential whales” so they can work together to develop them. Bolet further pushes for information regarding “your ‘whales’ aka ‘New Business Prospects,’” and Rustin provides names of three new targets for Q4.

Document Title: RE: Sacramento Docs I want to see Activated

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=rtwp0275>

Date: 2013-09

Description: Bolet sends a data report sorted for REMS enrolled doctors in the territories of two sales representatives and highlights “I counted 18 docs HIGH for ROO’s [rapid on-set opioids] that have NEVER prescribed Subsys before.” She provides monetary incentives to the reps to get new activations from the list. Beth McKey, regional sales director, follows up and asks “could they potentially be a new “whale” target?”

Document Title: Re: I am now asking you where you stand.

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=qgjb0263>

Date: 2014-03

Description: An email exchange amongst the Miami sales staff discussing sales payouts. Sales representative Brittany Williams states that titration is the fastest way to get to the top 20 and she is “pushing that hard right now with Dr. Lubin specifically.” She also states “these last couple of weeks I will not leave Dr. Lubin and Victoria’s office...LITERALLY.” Karen Hill, district sales manager, praises Williams for “living with your whale.”

Document Title: REGIONAL ALIGNMENT COMBINED SLIDES A FINAL FINAL.PDF; TITLE SLIDE

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=szyc0233>

Date: 2016-04

Description: This presentation for regional sales meetings focuses on strategies to grow Subsys and address challenges. It includes a “New Patient Contest” in the Subsys incentive compensation plan for Q2 2016, with payout numbers per patient based on three groups of writers and involving data reported by REMS.

Document Title: SUBSYS Board of Directors Meeting

OIDA ID: <https://www.idl.ucsf.edu/opioids/docs/#id=hxld0262>

Date: 2016-06

Description: This new hire training presentation on business intelligence and sales operations includes two types of sales data sources used by Insys: TIRF (transmucosal immediate release fentanyl) REMS Access Reporting (hosted by Relay Health at McKesson) and third-party pharma data providers. The TIRF REMS Access Reporting provides the strength and unit level information for every transaction and is assessed as “the best data source for physician writing activity, Rx outcome intervention, and IC [incentive compensation] payout.”

Suggested Search Terms

- “REMS report”
- “whale”
- “Authorized Rx Count”