



# Insys Litigation Documents – Diversion & Pharmacy Distribution

## Summary and Sample Documents Explained:

Insys targeted specialty pharmacies, such as <u>Linden Care</u>, to dispense and ship prescriptions of Subsys nationwide. Linden Care filled prescriptions for widespread off-label and illegitimate uses, despite the high potential for abuse and the Food and Drug Administration's (FDA) narrow approval of the drug for breakthrough cancer pain for opioid tolerant patients. Linden Care was also used to assist with the prior authorization process.

Insys bypassed drug wholesalers and provided product directly to at least one specific pharmacy, the <u>C&R Pharmacy</u>. Owned by Drs. <u>Xiulu Ruan</u> and <u>John Patrick Couch</u> – both Alabama pain specialists and top prescribers for Insys – used these direct shipments to bypass a highly regulated distribution system that includes monitoring to ensure compliance with federal laws.

# Sample Documents:

**Document Title:** FW: Top Subsys dispensing ind. pharmacies **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=qfjv0270

Date: 2012-10

**Description**: <u>Alec Burlakoff</u>, vice president of sales, instructs regionals sales managers to review with their teams a list of pharmacies that assist with <u>prior authorizations</u>. Burlakoff states that "it is absolutely necessary that the representatives whom have failed to produce 1 Subsys rx per day ( begin to work with a 'Linden Care' or similar pharmacy in nature ) ASAP."

**Document Title:** Linden Care Detailed Steps and Suggested Talking Points for Program **OIDA ID:** <u>https://idl.ucsf.edu/opioids/docs/#id=qlwp0270</u>

Date: 2012-11

**Description**: <u>Mike Gurry</u>, vice president for managed markets, emails the sales team the steps to utilize Linden Care Specialty Pharmacy with prescribing offices in their territories, as well as talking points. He notes the circumstances when Linden Care would process a <u>Super Voucher</u> if a prior authorization has been denied. Gurry emphasizes "Linden Care is a tool to assist in the filling and processing of prescriptions. They will not do the PA from start to finish, they will assist!"

Document Title: Re: Protocol OIDA ID: <u>https://idl.ucsf.edu/opioids/docs/#id=ztyb0271</u> Date: 2013-09

**Description**: An internal email regarding issues with a patient not being approved for Subsys. <u>Karen Hill</u>, Southeast regional sales manager, states "this particular patient should be provided with free product indefinitely" per the Insys <u>Guaranteed Access Program</u>. Gurry responds that having all new eligible patients start on free product "is essential to the model," and Hill states "Lindencare normally does this automatically."

#### Document Title: RE: Abstral heads up

OIDA ID: <u>https://idl.ucsf.edu/opioids/docs/#id=sxkw0272</u> Date: 2013-12

**Description:** An email chain started by <u>Natalie Perhacs</u>, sales representative, who reports that C&R Pharmacy has an "unlimited supply" of competitor product <u>Abstral</u> (fentayl sublingual tablets) since they are being allowed to order directly from the manufacturer, <u>Galena</u>. <u>Dion</u> <u>Reimer</u>, director of trader and distribution, replies "if C&R moves to a process where the monitoring is absent, I would propose certain parties would be at risk."

#### Document Title: Fwd: 4 PM Abstral Call

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=ktfd0271

Date: 2013-12

**Description:** An email from Burlakoff with bullet points for a call about Abstral, including "direct distribution to Pain management specialty pharmacy i.e. Dr Ruan and Dr. Couch." Burlakoff suggests that Abstral may be out of compliance. <u>Matt Napoletano</u>, vice president of marketing, replies "I would recommend moving forward these type of initiatives be reviewed by compliance, CIS, and or Legal to assess the level of risk."

### Document Title: Fwd: GALENA -Fw: subsys stocking issue

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=trbc0276

### **Date**: 2013-12

**Description**: Reimer emails <u>Arjun Ajbani</u>, operations manager of <u>Benzer Pharmacy</u>, about Subsys 1200 mcg being out of stock and rushing an order from <u>McKesson</u>. Ajbani asks if Insys has a distribution center that Benzer can order Subsys directly from. A potential pharmacy speaker program and \$3000 sponsorship of Benzer's Christmas party is also discussed.

### **Document Title:** Re: Dr Raun [sic] meeting

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=ghcb0277

Date: 2014-01

**Description**: Reimer reports on a meeting with Dr. Ruan, who want to "expand his operation on the pharmacy side and asked about the Linden Care model." Ruan wants to order directly from Insys to address limits on CIIs (Schedule II controlled substances) in place by current wholesaler <u>AmerisourceBergen</u>. Gurry suggest a group call with Dr. Ruan to explain the "specialty pharmacy model in place by them."

### Document Title: Playbook\_05 - Trade and Distribution.pdf

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=xhvd0233

Date: Unknown

**Description**: This training document describes the trade and distribution of Subsys, including product flow and supply chain management, special requirement for CII Products, and inventory management. It mentions independent pharmacies such as Linden Care and C&R.

### **Document Title:** RE: Lindencare

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=mjcj0264

Date: 2016-01

**Description**: This internal email chain discusses the issue of Linden Care refusing to fill any Medicare prescriptions without an active diagnosis of cancer due to "the outstanding Humana situation." Suggestions include diverting prescriptions to a different pharmacy, including <u>Avella</u> Retail and <u>Dunn Meadow Pharmacy</u>.

Document Title: RE: Dunn Meadow

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=xqnx0264 Date: 2016-02

**Description**: Bryan Bloom, co-founder and vice president of sales at Dunn Meadow Pharmacy, emails <u>Dan Brennan</u>, executive vice president and chief operating officer, to see how Dunn Meadow can get involved in the Subsys Super Voucher program. Bloom states they "are getting a lot of new referrals and want make sure that we have all resources available to help the patients while the authorizations are being worked on."

**Document Title:** launch packet for SYNDROS and SUBSYS direct ship update **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=zlfp0267

Date: 2016-07

**Description**: Reimer addresses how to handle the current inventories held at wholesale distributor <u>Rochester Drug Cooperative</u> (RDC), which serviced both Linden Care and Dunn Meadow. Reimer suggests "having them sell out current inventory and reduce order volumes to match demands without LC and DM."

Document Title: RE: Go Live Day for Vouchers

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=gkmy0264

Date: 2016-08

**Description**: <u>Bill White</u>, vice president of managed markets & patient access, emails <u>Glenn</u> <u>Bortnick</u> and <u>Scott Kantor</u> of Linden Care that "today is go live date for the direct shipments and voucher program."

**Document Title:** Insys Trial Transcript – Day 28 – in United States v Kapoor et al. **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=zqqf0232

Date: 2019-03

**Description:** In this trial transcript, Burlakoff describes a meeting in his early days as vice present with Reimer, who advised to never offer a pharmacy customer direct shipment due to high risk and optics. Burlakoff also details meetings with Dr. Couch and Dr. Ruan regarding direct shipments to their pharmacy, the role of wholesalers on Schedule II limits, and competition from Galena.

