



Minnesota Attorney General Opioid Update

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AGO Litigation

- AGO initially filed two lawsuits against opioid manufacturers
 - State v. Insys (May 30, 2018)
 - Maker of fentanyl spray that paid kickbacks to prescribers
 - Filed for bankruptcy in June 2019; plan confirmed Jan. 2020
 - Summary of allegations

State v. Insys (evidence)

Your team is in a **launch** phase, there should never be a decline for a week's numbers out of this region. Please **make sure each of your reps has at least one doctor they can count on for a daily prescription.**

If you can not average 1.7 Rx's per day you can not do this job.

Patient-On-Therapy Cycle for SUBSYS



An average patient stays on ROO therapy for 9 - 12 months since inception of treatment. That's 3 - 4 quarters worth of monthly sales to you, **an annuity that keeps paying**

For each SINGLE patient on SYBSYS, you will make:

Quarter 1 *	Quarter 2 *	Quarter 3 *	Quarter 4 *
\$974	\$974	\$974	\$974

NOTE: * Assuming 1 TRx per patient per month at 400MCG; 75 units per TRx; as well as IC plan based on 10% net sales.

For internal planning purposes only

Hi [REDACTED]

We are heading into [REDACTED]'s 2nd ISP and now **it's time for him to step it up with accountability.** *What can he possibly be talking about if he's not applying what he's learned into clinical practice?* It's a simple question that, quite frankly, I'd like to learn the answer to.

He simply MUST identify the 'right' patients for this product and stop playing around and throwing you the train wreck 'crazies'. This is not a game, it's your CAREER.

After today's ISP, you will sit in his office and OPT IN FIVE PATIENTS... All will go to [REDACTED] and his staff will comply. Once his staff understands that you work for the doctor, that all these ISP's are to educate the market and shake them out of their PARANOIA, his staff will funnel more and more patients your way.

Never have I seen a rep with the kind of relationship you have with [REDACTED] not be able to pull this off. He is just as accountable to you as you are to him. What in the world is he afraid of?

I don't want to loose sleep over this anymore. Today is Wednesday. In order to get your Rx's to show up on Friday (shoot, I'll do a happy dance if they show up on SATURDAY), [REDACTED] **MUST prescribe for FIVE patients TODAY.**

AGO Litigation

- AGO initially filed two lawsuits against opioid manufacturers
 - State v. Purdue Pharma (July 2, 2018)
 - OxyContin manufacturer that misled public about opioid risks
 - Amended suit in May 2019 to add the Sacklers as defendants
 - Purdue filed for bankruptcy in Sept. 2019
 - Summary of allegations

State v. Purdue (evidence)

The other opioids can relieve severe pain. Their doses can be gradually increased over time. There is no ceiling dose as there is with the NSAIDs. As pain worsens, these medications continue to be useful unless side effects occur. It is a myth that opioids, like morphine should only be used at the final stages of a seriously painful disease. When pain is severe, opioids should be considered.

Pseudoaddiction

- The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction
- Caused by undertreatment of pain
- Behaviors cease when adequate pain relief is provided
- Not a diagnosis *per se*, but rather a description of a clinical interaction

Weissman DE, Haddock JD. Opioid pseudoaddiction—an iatrogenic syndrome. *Pain*. 1989;39:363-366.

That same year, in an email exchange discussing whether people dependent on opioids “**want to be addicts,**” Richard wrote: “**I’ll tell you something that will totally revise your belief that addicts don’t want to be addicted. It is factually untrue. They get themselves addicted over and over again.**” Richard emphasized: “**[Opioid addicts] are criminals, and they engage in it with full, criminal intent. Why should they be entitled to our sympathies?**” He further wrote: “**This vilification is shit.**” (¶243, p. 73)

AGO Settlements

- Settlements with opioid companies
 - Insys
 - McKinsey & Company
 - Purdue Pharma
 - Distributors (AmerisourceBergen, McKesson, Cardinal)
 - Johnson & Johnson
 - Mallinckrodt

Opioid Fund

- Typically, unless paid out as restitution to harmed victims, funds recovered by the AGO must go into state general fund

16A.151 PROCEEDS OF LITIGATION OR SETTLEMENT.

Subdivision 1. **State funds; general fund.** (a) This subdivision applies, notwithstanding any law to the contrary, except as provided in subdivision 2.

(b) A state official may not commence, pursue, or settle litigation, or settle a matter that could have resulted in litigation, in a manner that would result in money being distributed to a person or entity other than the state.

(c) Money recovered by a state official in litigation or in settlement of a matter that could have resulted in litigation is state money and must be deposited in the general fund.

Opioid Fund

- HF 400 created an exception that allowed AGO opioid recoveries to be deposited within special opioid fund
 - Updated this year to broaden scope to all opioid-related recoveries

Subd. 2. Exceptions.

(f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, ~~against one or more opioid manufacturers or opioid wholesale drug distributors~~ related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall notify the chairs and ranking minority members of the Finance Committee in the senate and the Ways and Means Committee in the house of representatives that an account has been created. Notwithstanding section 11A.20, all investment income and all investment losses attributable to the investment of this account shall be credited to the account. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section [151.065, subdivision 1](#), clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section [256.043](#), subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response fund under section [256.043](#) an amount that ensures that \$20,940,000 each fiscal year is available for distribution in accordance with section 256.043, ~~subdivisions 2 and subdivision 3~~.

McKinsey & Company Settlement

- Marketing consultant that worked for Purdue Pharma and other opioid makers
- \$573 million national settlement; \$7.98 million received by Minnesota
 - \$6.6 million already paid
 - Annual payments of \$341,668.30 over the next four years
- This money will be placed into the state's opiate epidemic response fund for use by OERAC

Purdue Pharma Bankruptcy

- Purdue filed bankruptcy in Sept. 2019
 - Before filing, offered states a deal of company assets + \$3 billion payment by the Sackler family
 - Minnesota and 24 other states refused and fought for more in bankruptcy
- In bankruptcy, states sought information from Purdue and the Sacklers and continued negotiations
 - State court litigation was put on hold

Purdue Pharma Bankruptcy

Resolution

- Minnesota announced a settlement on July 8, 2021
 - Still subject to voting and confirmation
- Main component is extremely robust document disclosure
 - Company will disclose tens of millions of documents, including hundreds of thousands of *privileged* documents
- Payments
 - Minnesota's share of national payments is about 1.3%
 - Sacklers are paying the states \$4.325 billion over 9/10 years
 - Minnesota's share is about \$56 million
 - Minnesota will receive share of Purdue's assets through 2025
- Injunctions
 - Sacklers will not manufacture or sell opioids
 - Purdue's post-bankruptcy operation will be subject to strict conditions and oversight

Purdue Pharma Bankruptcy

Default* Abatement Framework Concepts

- Statewide + regional spending model
- Block grants to large political subdivisions
- Funds must be used for abatement
 - Within approved uses
 - Monitoring requirements
- Gives flexibility for states to craft state-specific abatement plan alongside local governments
- Importance of input and representation from local governments

*States can agree to an alternative framework via agreement between state and its subdivisions.

Distributors + J&J Settlement

Distributors Publicly Announced Framework

- \$21 billion total available (assuming 100% national participation) over 18 years
- Timing
 - Annual payments distributed over 18 years
- Default* intrastate allocation structure splits payment into three “buckets”
 1. **15%:** State fund for remediation (AGO will put into opioid fund)
 2. **70%:** Common abatement fund (MN opioid fund)
 3. **15%:** Subdivision fund to be spent on opioid remediation unless otherwise directed
 - Subdivisions must “opt in” to settlement to receive direct benefits
- Structure of financial terms
 - Base/Bonus payments and moratorium/offsets
- Injunctive relief
 - Anti-diversion controls and monitoring
- Contingencies
 - Deal requires critical mass of support to go forward (TBD)
 - States have 30 days to join; local governments will have 120 days to join after that (likely cutoff date of **January 2, 2022**)

*Funds distributed within each state according to state law or agreement between state and its subdivisions

Distributors + J&J Settlement

Johnson & Johnson Publicly Announced Framework

- \$5 billion total available (assuming 100% national participation) over 9 years
 - Deductions for outstanding litigation risk and attorney fees and costs
- Timing
 - Annual payments distributed over 9 years, with \$3.7 billion paid in first 3 years
- Same default intrastate allocation structure
- Structure of financial terms
 - Base/Bonus payments similar to distributors
- Injunctive relief
 - Ban on manufacturing, selling, and promoting opioids
- Contingencies (same as distributor deal)
 - Like distributors, deal requires critical mass of support to go forward (TBD)
 - States have 30 days to join; local governments will have 120 days to join after that (likely cutoff date of **January 2, 2022**)

Mallinckrodt Bankruptcy

- Another large opioid manufacturer investigated by the AGO
- Filed for bankruptcy in Oct. 2020
- States entered bankruptcy with settlement requiring Mallinckrodt to fund a \$1.6 billion opioid trust
 - Still subject to court approval
- *MN AGO is leading the effort on Mallinckrodt's document disclosure
 - Company turned over documents to AGO on July 12; will be published by UCSF and Johns Hopkins opioid archive in the future

AGO Litigation and Investigations

- Other investigations and negotiations are ongoing, and may result in additional settlements that recover money for the opioid fund

Participation by Local Governments

- Counties are essential to these settlements
 - Full participation will maximize available funds
 - We want to work directly with local officials to ensure Minnesota gets the most money possible
- Counties benefit directly from the state's opioid fund
 - 50% of OERAC funds flow to counties for social services
 - Local governments can also apply for OERAC grants
- AGO wants to figure out a plan that works for all of Minnesota

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