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Current Trends: Investigations, Suits and Settlements (Opioid Edition)

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Overview

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- What is really going on in the "opioid litigation" world?
- DOJ opioid-enforcement toolbox: TRO/Injunctions against dispensers and prescribers
- What's next? DOJ/IG recommendations to DEA

Disclaimer: This presentation is offered for discussion purposes only and shall not constitute legal advice.

National Prescription Opioid Litigation

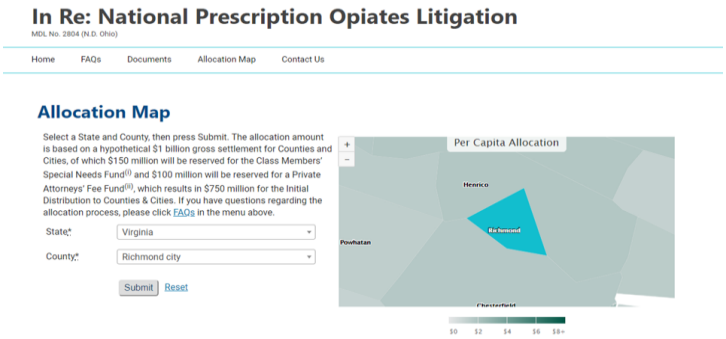
- Categories of plaintiffs:
  - Government plaintiffs
    - States
    - Cities, Counties, Towns
  - Indian Tribes
  - NAS Babies https://tnbabydoe.com/
  - *Hospitals
- Federal and State Cases
  - Multidistrict litigation – the MDL
  - State cases

Opioid Negotiation Class

https://www.opioidsnegotiationclass.info/

https://allocationmap.iclaimsonline.com/

Richmond example:



Opioid Negotiation Class – allocation example

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Richmond example continued:

County-level Allocation for Richmond city*

Total Allocation Value: $574,678 **Per Capita Value** $2.73**

* This Initial Distribution will be shared between the county and all incorporated municipalities within the county.

** "Per Capita Value" refers to the amount the county would receive per resident based on a hypothetical $1 billion gross settlement for Counties and Cities. The per capita value was calculated by dividing the allocation to the county by the county's population

The county and the cities within the county will have the opportunity to reach agreement on how the county-level allocation will be shared amongst them. If the county and cities are unable to reach agreement, the funds will be distributed as shown in the table below, according to the default intra-county allocation formula explained in FAQ 12. Under the default intra-county allocation formula, when a city's share is less than $500, that amount will instead be distributed to the county in which the city lies to allow practical application of the abatement remedy. Affected cities could seek recovery through intra-county allocation, see FAQ 12, or from the Class Members' Special Needs Fund, see FAQ 20. In the rare circumstance that a city with a share of less than $500 lies in a county that does not have a county government, the amount would instead go to the Class Members' Special Needs Fund, and Class members could seek recovery from that Fund.

Richmond city	$0
Richmond	$574,678

Opioid Negotiation Class – allocation math

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- The allocation model uses three factors, based on reliable, detailed, and objective national data, to determine the share of a settlement fund that each county will receive.

  (1) the amount of opioids shipped to the county adjusted as described below;
  (2) the number of opioid deaths that occurred in that county; and
  (3) the number of people who suffer opioid use disorder in that county.

- The amount of opioids shipped to a county is adjusted based on opioid use disorder prevalence or the rate of opioid-involved deaths in the county, whichever is worse relative to national averages. The model makes this adjustment because the oversupply of opioids had more deleterious effects in some counties than in others. Thus, the allocation model is designed not to favor either small or large counties based solely on population. Ultimately, the model allocates settlement funds in proportion to where the opioid crisis has caused actual harm.

Hospitals as plaintiffs

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- Groups of hospitals in West Virginia, Tennessee, Arizona and other jurisdictions have filed suit against opioid manufacturers, distributors, and other defendants in the supply-chain
- Accusing pharma companies of “peddling their pills in single-minded pursuit of profit, leaving local hospitals to revive the bodies, treat the babies born with symptoms of withdrawal, and pay for the care for those with lives too devastated to pay for it on their own.”
- [Pharma] companies extracted “billions of dollars of revenue from the addicted American public while hospitals sustain tens of millions of dollars in losses caused as a result of the reasonably foreseeable consequences of the prescription opioid addiction epidemic.”
- “In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme.”

Hospitals as plaintiffs: two-pronged attack

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MDL 2804 – West Boca Medical Center

- Selected as the hospital “bellwether” case
- No rulings on motions
- Not set for trial

State court actions

- West Virginia
- Tennessee
- Arizona
- Over 400 hospitals on board and other state actions planned

Defendants

- Known manufacturer and distributor defendants
- “National Retail Pharmacies” – CVS, Kroger, Rite-Aid, Walgreens, Walmart

Hospitals as plaintiffs: hospitals targeted

- From the beginning, hospitals were directly targeted by the Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Defendants Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) identified an objective of developing a "successful distribution program" to "hospitals."
- Initial plans called for marketing to "[a]ll 1,200 cancer centers," "[a]ll 1,200 major teaching institutions," and "[a]ll 2,500 community hospitals with >= 100 beds."
- All Defendants Have, and Breached, Duties to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

DOJ enforcement: opioid-related task force work

- Department of Justice Prescription Interdiction & Litigation (PIL) Task Force - to fight the prescription opioid crisis. The PIL Task Force will aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors.
- As part of PIL – Consumer Protection Branch is pursuing both criminal and civil actions against wrongdoing entities and individuals up and down the prescription opioid supply chain.
- The Branch is aided in its work by its expertise in enforcing the Controlled Substances Act and the Food, Drug, and Cosmetic Act, as well as its experience with complicated and multi-district litigation.
- Local flavor: Appalachian Regional Prescription Opioid Strike Force – 10 jurisdictions, including the Western District of Virginia

DOJ enforcement toolbox: TRO and Injunction

- "Justice Department Files First of its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids" (February 2019)
  - The Justice Department announced an action today to stop two pharmacies, their owner, and three pharmacists from dispensing controlled substance medications, including powerful opioids that have been linked to abuse and diversion.
- "Justice Department Takes First-of-its-Kind-Legal Action to Reduce Opioid Over-Prescription" (August 2018)
  - The Justice Department filed a complaint to bar two Ohio doctors from prescribing medications after an investigation revealed they recklessly and unnecessarily distributed painkillers and other drugs.

DOJ enforcement toolbox: TN Pharmacy

- The complaint alleges that the pharmacies and pharmacists filled numerous prescriptions for controlled substances outside the usual course of professional practice and in violation of the pharmacists' corresponding responsibility to ensure that prescriptions were written for a legitimate medical purpose.
- Defendants routinely dispensed controlled substances while ignoring numerous "red flags" or warning signs of diversion and abuse, such as unusually high dosages of oxycodone and other opioids, prescriptions for opioids and other controlled substances in dangerous combinations, and patients travelling extremely long distances to get and fill prescriptions.
- Filed ex parte and under seal
- "Pharmacists frequently are the last line of defense before a controlled substance that was prescribed without any legitimate medical purpose is sold to a patient. The Defendant pharmacies, pharmacists, and the pharmacies' owner here failed to muster that defense."

DOJ enforcement toolbox: TN Pharmacy

- "By filling those thousands of illegitimate prescriptions, Defendants crossed the legal line between pharmacy practice and violating the Controlled Substances Act ("CSA"). The United States files this motion to stop Defendants from distributing or dispensing any more controlled substances."
- "Although the prescribing physician has a responsibility to prescribe and dispense controlled substances properly, 'a corresponding responsibility rests with the pharmacist who fills the prescription.'"
- Injunctive relief under 21 U.S.C. § 843(f)(1) to remedy Defendants' violations of 21 U.S.C. § 842(a)(1) for dispensing controlled substances without a valid prescription
- Injunctive relief under 21 U.S.C. § 882(a) to remedy Defendants' violations of 21 U.S.C. § 841(a)(1) for distributing and dispensing controlled substances outside the usual course of professional practice

DOJ enforcement toolbox: Ohio prescribers

- "These doctors were simply drug dealers in white lab coats," said U.S. Attorney Justin Herdman.

Defendant Michael P. Tricaso, D.O. is a drug dealer. He sells opioid pills for cash in hotel parking lots. He writes illegal prescriptions for opioids. He writes illegal prescriptions for steroids. Dr. Tricaso does not practice medicine; he violates the Controlled Substances Act ("CSA"). Because of the ongoing threat that Dr. Tricaso's drug-dealing and illegal prescribing presents to the community, the United States moves for a temporary restraining order and preliminary injunction under 21 U.S.C. §§ 843(f) and 882(a), and Federal Rule of Civil Procedure 65(a)-(b) to immediately stop Dr. Tricaso's illegal activities.

DOJ enforcement toolbox: Ohio prescribers

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- A physician who prescribes controlled substances to patients "dispenses" them within the meaning of the CSA
- A physician may only dispense or distribute controlled substances to the extent authorized by the physician's registration and in conformity with the CSA. 21 U.S.C. § 822(b)
- The CSA limits a registered physician's dispensing authority to the course of his professional practice
- The court may grant injunctive relief under 21 U.S.C. § 882(a) to remedy Dr. Tricaso's violations of 21 U.S.C. § 841(a)(1) for unlawfully distributing or dispensing controlled substances
- The court may grant injunctive relief under 21 U.S.C. § § 843(f)(1) and 882(a) to remedy Dr. Tricaso's violations of 21 U.S.C. § 842(a)(1) for unlawful prescribing.

DOJ enforcement toolbox: Injunction standard

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1. The movant has established a strong likelihood of success on the merits
2. The movant would suffer irreparable injury if the motion were not granted
3. Substantial harm to others would result
4. The public interest would be served by issuance of the injunction

- Granted without prior notice to the defendants

Injunctions against fraud and payment suspension

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- No injunction will issue if there is an adequate remedy at law. See *Matthews v. Rodgers*, 284 U.S. 521, 525 (1932); *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U.S. 752 (1947*); Porto Rico Telephone Co. v. P.R. Communications Auth.*, 189 F.2d 39 (1st Cir.), cert. denied, 342 U.S. 830 (1951). Irreparable injury is an essential prerequisite to the issuance of a preliminary injunction. *County of Santa Barbara v. Hickel*, 426 F.2d 164 (9th Cir. 1970), cert. denied, 400 U.S. 499 (1971).

- Consider 18 U.S.C. § 1345 – *Injunctions against fraud*
- (a) (1) If a person is—(C) committing or about to commit a Federal health care offense; the Attorney General may commence a civil action in any Federal court to enjoin such violation.

- Payment suspension

What's next: the other Horowitz IG report

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- October 1, 2019 – DOJ/IG Michael E. Horowitz released a report: "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids"

- **DEA Increased Annual Opioid Production Quotas, Despite the Rise of Opioid Overdose Deaths.** The rate of opioid overdose deaths in the United States grew, on average, by 8% per year from 1999 through 2013 and by 71% per year from 2013 through 2017. Yet, from 2003 through 2013 DEA authorized manufacturers to produce substantially larger amounts of opioids. For example, DEA authorized a 400% increase in oxycodone production between 2002 and 2013, and it was not until 2017 that DEA significantly reduced oxycodone production quota, by 25%.

- Weaknesses Exist in DEA's Registration Process.
- DEA Did Not Fully Utilize its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances.
- DEA Does Not Collect the Data Necessary to Promptly Detect the Diversion of Opioids.

What's next: Horowitz IG report recommendations

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1.Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combating the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.

2. Require criminal background investigations of all new registrant applicants.

3. Implement electronic prescribing for all controlled substance prescriptions.

4. Require that all suspicious orders reports be sent to DEA headquarters.

5. Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants' history resulting in a prior registration being revoked by DEA.

6. Revise field division work plan requirements to allow the flexibility to target registrants for investigation.

What's next: Horowitz IG report recommendations

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7. Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues and respond to these threats in a timely manner.

To improve its efforts to combat the diversion of pharmaceutical opioids, as well as prosecute registrants that divert pharmaceutical opioids, we recommend that the Department:

8. Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs.

9. Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.

Conclusion

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- What is really going on in the “opioid litigation” world?
- DOJ opioid-enforcement toolbox: TRO/Injunctions against dispensers and prescribers
- What’s next? DOJ/IG recommendations to DEA

Questions/Discussion

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