

Litigation Against Opioid Manufacturers: Lessons from the Tobacco Wars

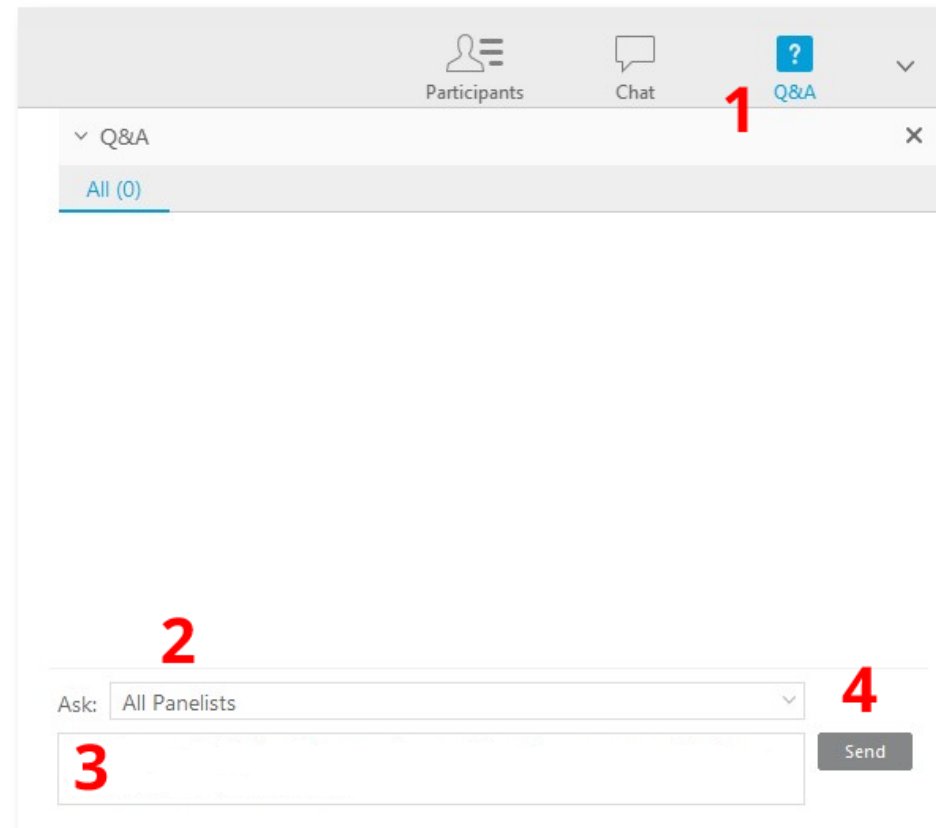
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- Research interests/areas of expertise:
 - Legal and Policy efforts to address opioid epidemic
 - Substance use disorders
 - Health care reform issues

Presenter



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 - Health equity
 - Alcohol and drug abuse prevention
 - Affordable Care Act and Medicaid

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 - Tobacco Control
 - Drug Policy
 - Chronic Disease Prevention
 - Health Equity
 - Preemption

Litigation Against Opioid Manufacturers

Corey Davis, JD, MSPH, EMT-B

March 15, 2018

Brief Background

~44,000 Americans died from opioid overdose in 12 months ending July 2017

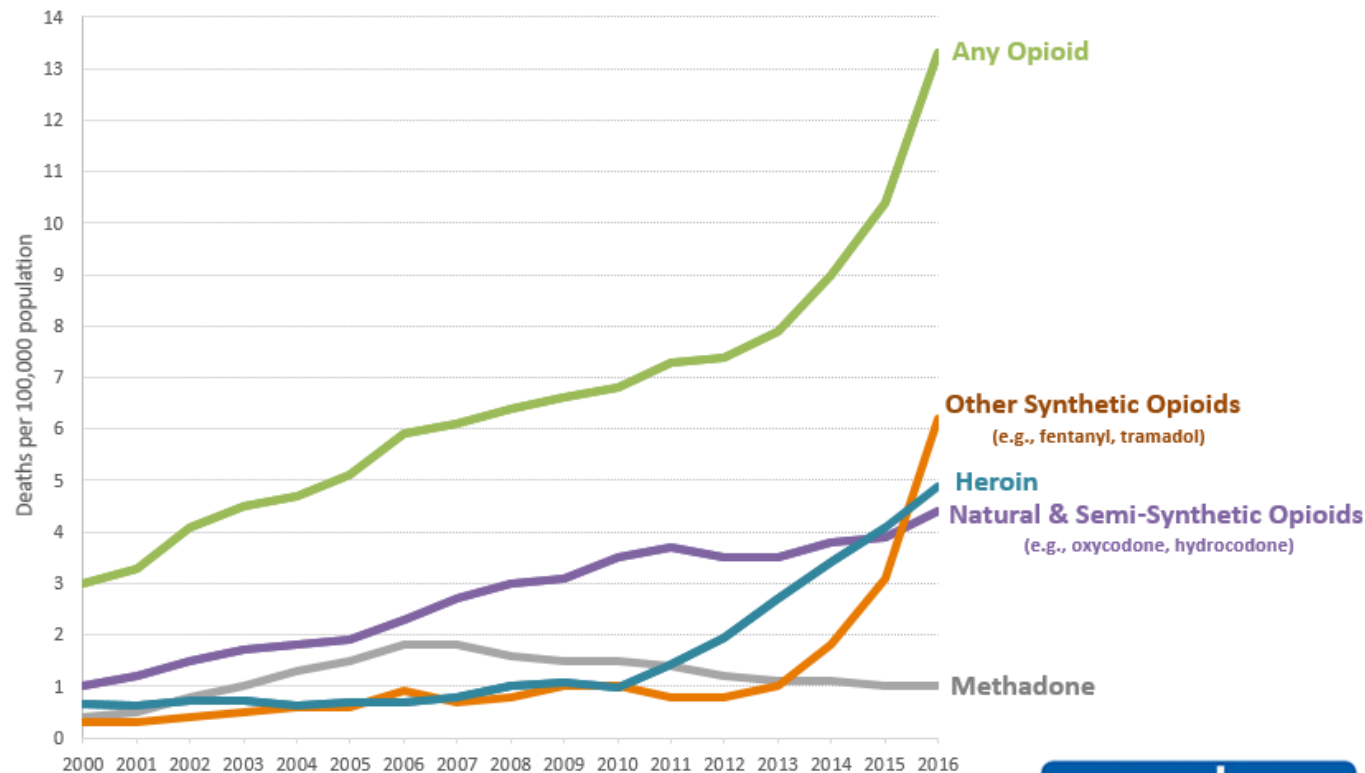
- » **Leading cause of death for Americans under age 50**
- » **More than from car crashes and guns**
- » **More than died of HIV/AIDS at the height of the epidemic**
- » **Still increasing**

Opioid pain relievers (OPRs) accounted for about 40% of all opioid-related overdose deaths in 2016...

...but deaths from heroin and synthetic opioids are increasing dramatically (as are deaths from other drugs)

The epidemic is rapidly shifting...

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016

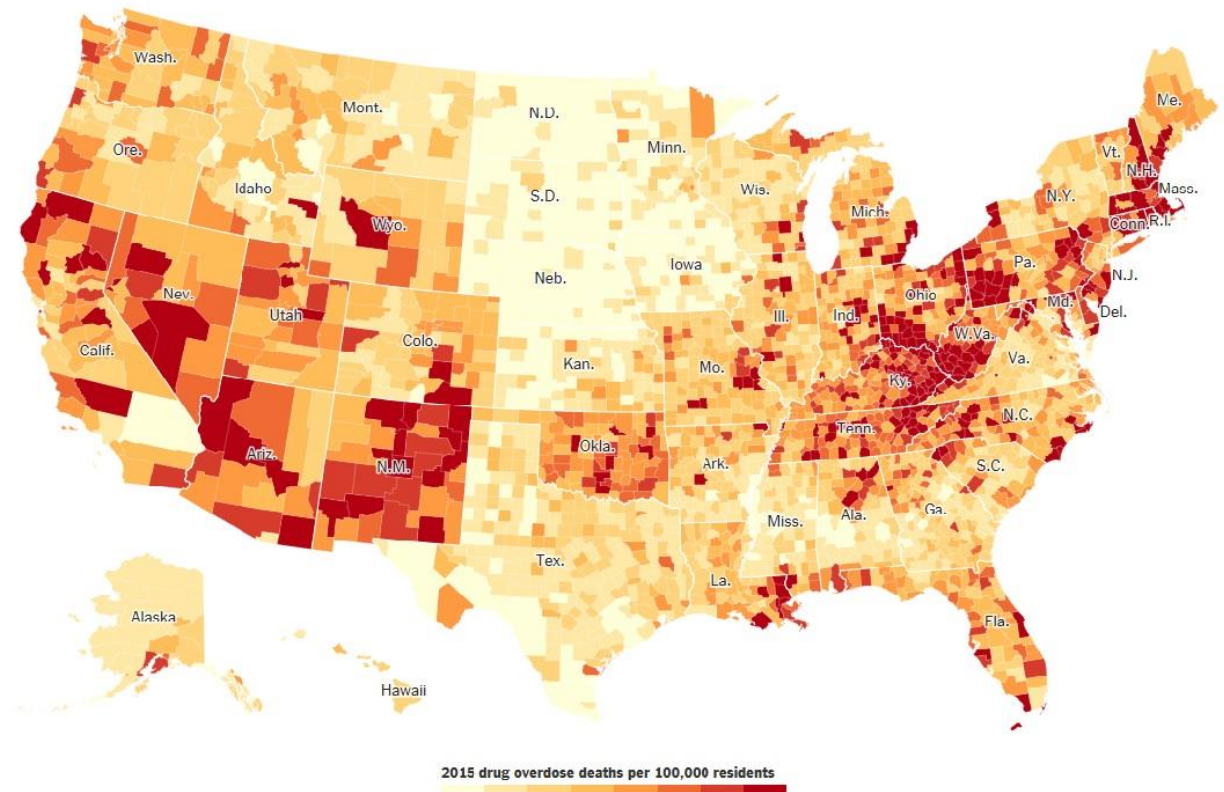


SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2017.
<https://wonder.cdc.gov/>.

...and it's unevenly distributed

Overdose burden falls most heavily on states with large rural and working-class communities

New England, Appalachia, rural Southwest hit particularly hard



..as is pain

- » Women, on average, experience more pain than men
- » Lower-income Americans more likely to be injured, and less likely to be insured
 - » Which translates into less and worse care
- » Hispanic, Latino, and African Americans are more likely to work blue-collar jobs and less likely to be prescribed opioid analgesics than Whites
- » Pain is a serious, important and prevalent problem in the US and worldwide

The role of Opioid Analgesics

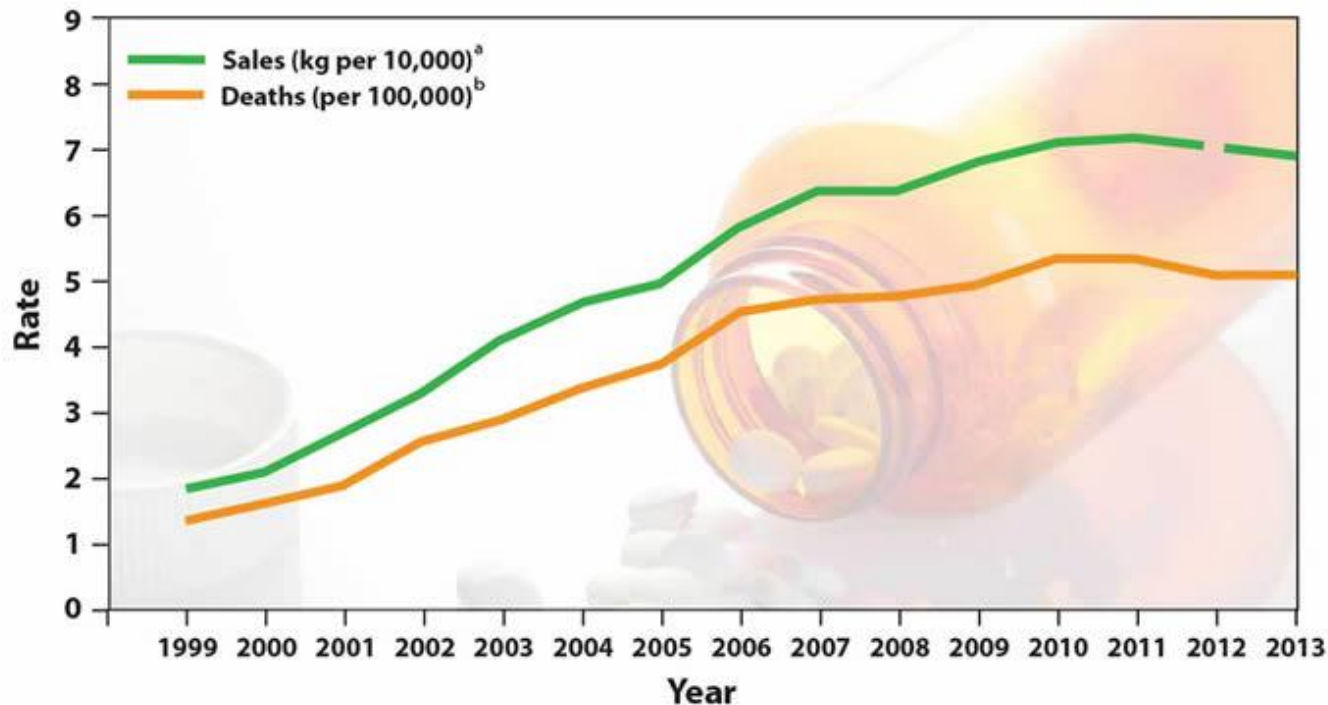
- » Opioids can be beneficial for some post-surgical pain, cancer pain, HIV pain, palliative care
- » Limited, no, or negative evidence OPR therapy superior to other treatment for chronic back pain, osteoarthritis, rheumatoid arthritis, chronic non-cancer pain, headache, fibromyalgia
- » No evidence of correlation between dramatic increase in opioid Rx and population-level pain measures

Rx, OD, and pain all increased

- » Doesn't mean OPRs should never be prescribed; does mean that population-level risks of current Rx levels outweigh benefits

The role of Opioid Analgesics

Prescription Painkiller Sales and Deaths



Sources:

^aAutomation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2012 data not available.

^bCenters for Disease Control and Prevention. National Vital Statistics System mortality data. (2015) Available from URL: <http://www.cdc.gov/nchs/deaths.htm>.

The role of law

- » **Some federal legislative action (and solid efforts from some federal agencies)**
 - But response is not commensurate with the crisis
 - » “They figure if there is bipartisan support now, there will be bipartisan support later, and they can pick up after the dust has settled in some other legislative areas.” – DC lobbyist
- » **States and localities are filling the void**
 - » Numerous legislative and policy initiatives
 - » ..and many, many lawsuits

Litigation Against the Tobacco Industry

Lainie Rutkow, JD, PhD, MPH
Associate Professor, Health Policy and Management

March 15, 2018

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Early Lawsuits Against the Tobacco Industry

- 1950s: individual smokers sue tobacco companies
 - Argue that companies **negligently** failed to disclose harmful nature of tobacco products
 - Argue for **strict liability** due to marketing dangerous product
- 1954-1994: over 800 cases filed
 - None were successful



Second Wave of Litigation

- 1980s: Plaintiffs' attorneys and public health advocates develop new legal theories
 - Tobacco companies pay no financial judgments
- *Cipollone v. Liggett* (1992):
 - Rose Cipollone, lifetime smoker
 - Federally mandated health warnings on cigarette packages preempt most litigation based on failure to warn
 - Federal law does NOT prohibit lawsuits based on tobacco companies' efforts to mislead the public
 - Internal documents become publicly available



Third Wave of Litigation

- *Cipollone* + internal documents → litigation focused on tobacco industry misconduct
- Mid-1990s: several individual and class action lawsuits with verdicts/settlements that favor plaintiffs
- State attorneys general:
 - May 1994, Mississippi AG files first state lawsuit
 - Details tobacco industry's effort to mislead the public
 - Argues that tobacco companies should be responsible for Medicaid and other health costs incurred by state due to tobacco-related disease

Third Wave of Litigation

- Action taken by state attorneys general
 - 1994-95: similar lawsuits filed by AGs from Minnesota, West Virginia, Florida, and Massachusetts
 - 1998: 43 states filed similar lawsuits against tobacco companies
- Increasing AG-initiated lawsuits + on-going release of damaging internal documents → settlement discussions



Settlement


- 1996: five states settle with Liggett Corporation
- 1997-98: four states settle with other tobacco companies
- 1998: remaining states and DC (“settling states”) enter **Master Settlement Agreement (MSA)** with four largest tobacco companies
 - Largest civil settlement in U.S. history
 - Settling states receive \$206 billion over 25 years
 - Additional payments in perpetuity based on annual volume of cigarette sales



Additional Features of MSA

- Funds for national foundation and advertising campaign to reduce tobacco-related disease and youth tobacco use
- Public release of additional internal documents
- Restrictions on tobacco companies' advertising and marketing practices
- Disband industry research entities and front groups
- Tobacco companies released from current and future medical care cost reimbursement claims
- MSA does not affect lawsuits brought by individuals or entities other than the settling states





Thank you!

Questions?

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Litigation Against Prescription Opioid Manufacturers



DEREK CARR, JD

All views expressed are solely my own and do not necessarily represent those of any individual or organization with whom I am affiliated.

Opioid Litigation Timeline

2007

Purdue Pharma:

- Settles class-action lawsuit filed by 26 states and the District of Columbia.
- Pleads guilty to federal criminal charges for illegally marketing OxyContin.

2015

- Insys settles with Illinois over off-label marketing and improper payments to prescribers.
- Purdue settles lawsuits brought by New York and Kentucky over alleged improper marketing of OxyContin.
- Mississippi Attorney General sues Purdue, Cephalon, Teva, Janssen, Johnson & Johnson, Endo, and Allergan.

2018

At least 19 states and hundreds of local jurisdictions—including Chicago, New York City, and Philadelphia—have filed suit.

West Virginia sues Purdue Pharma over OxyContin marketing

2001

Cephalon pleads guilty to illegally marketing 3 drugs, including Actiq, which contains the powerful opioid fentanyl

2008

- Additional states—including Missouri, New Mexico, Ohio, and Oklahoma—file suit against prescription OPR manufacturers.
- 41 state attorneys general announce bipartisan investigation.

2017

- More lawsuits?
- Settlement agreement?

What's Next?

Purdue Pharma Pleads Guilty to Federal Criminal Charges (2007)



- **Admitted to telling certain health care providers that:**
 - “OxyContin did not cause a ‘buzz’ or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to ‘weed out’ addicts and drug seekers.”¹
 - “[P]atients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug”¹
- **\$635 million in criminal fines**

First Wave of Opioid Litigation



- Focused on individual OPR manufacturers and company executives
- Settled for relatively small sums
 - Purdue
 - ✦ West Virginia: \$10 million
 - ✦ 26 States & D.C. Class-Action: \$19.5 million
 - Insys
 - ✦ Illinois: \$4.45 million
 - ✦ Massachusetts: \$500,000
- By 2015, annual OPR sales reached nearly \$10 billion

Second Wave of Opioid Litigation



- **Collective accountability**
- **Coordinated investigations**
- **Seeking more significant financial concessions**

Legal Claims Against Opioid Manufacturers



- **Medicaid Fraud**
- **Unfair and Deceptive Trade Practices**
- **Negligent Misrepresentation**
- **Public Nuisance**
- **Unjust Enrichment**
- **Racketeering**

Alleged Misconduct by Opioid Manufacturers



- Paid front groups to make activities appear independent.
- Avoided regulatory restrictions through unbranded marketing.
- Promoted scientifically suspect research, medical education, and treatment guidelines.
- Promoted increased OPR use while misrepresenting its risks and benefits.
- Targeted certain practitioners to foster new high-volume OPR prescribers.

Federal Regulatory Landscape

Key Differences and Implications



Cigarettes*

- **Limited Regulation**
 - Required health warnings on cigarette packaging
 - Prohibited advertising cigarettes on radio and television
 - Prohibited smoking on domestic flights and interstate buses

Opioid Pain Relievers

- **Expansive Regulation**
 - Food, Drug, and Cosmetic Act (FDCA)
 - Controlled Substances Act (CSA)
- **Primary Jurisdiction**

* At time of the lawsuits leading to the tobacco Master Settlement Agreement

Current Status of Opioid Litigation



- 300+ lawsuits consolidated into multidistrict litigation (MDL) in the federal district court for the Northern District of Ohio.
- United States Department of Justice intends to file a statement of interest.
- Ongoing settlement discussions.

A opioid master settlement seems inevitable...

- Purdue proposed a global settlement
- Judge overseeing MDL ordered parties to prepare for settlement discussions
- Settlement would benefit all parties involved

But will it reduce opioid-related harm?

The Tobacco MSA—20 Years Later



The Good

- Truth Initiative
- Tobacco industry documents
- Cigarette price increases
- Some investment in tobacco control & public health

The Bad

- Increased tobacco marketing expenditures
- Questionable effect on reducing smoking rates

The Ugly

- Perverse incentives
- Diverted funding
- Protected an industry dedicated to selling a deadly product

DÉJÀ VU ALL OVER AGAIN

Previous Opioid Settlements Repeated Many of the Same Mistakes...

- West Virginia spent millions to build a new police gym and remodel their police academy
- Continued industry misconduct (e.g. Purdue, Insys)

What's Next?

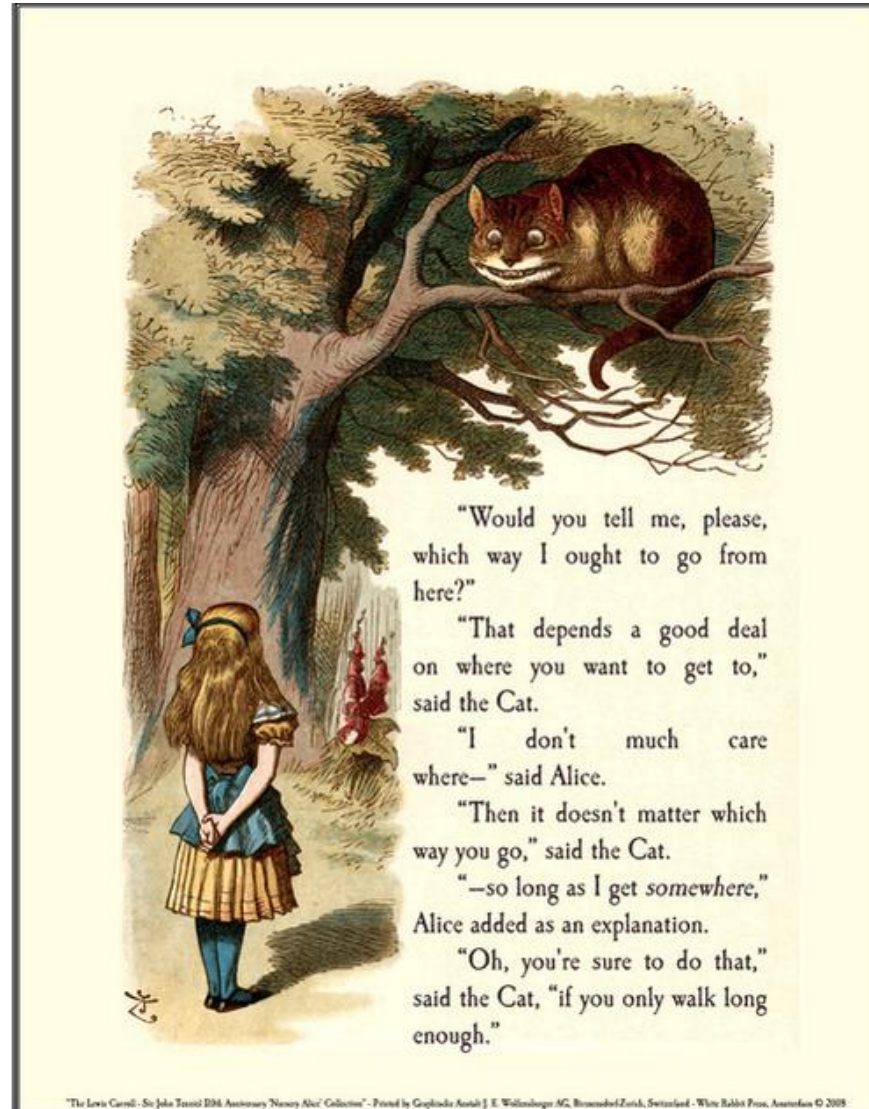


“[M]y objective is to do something meaningful to abate this crisis and to do it in 2018. ... [W]hat I'm interested in doing is not just moving money around...we need a whole lot -- some new systems in place, and we need some treatment.” - Judge Aaron Polster

Litigation in context

- » **States are increasingly taking action to address the epidemic**
 - » Some responses driven by public health, some by criminal justice, some by \$, some by a desire to do *something*
 - » Some make sense, some don't, jury still out on many
- » **It's complicated, but it's important to get it right, or at least *try to get it right***

Where does litigation fit in?



What are the goals of litigation?

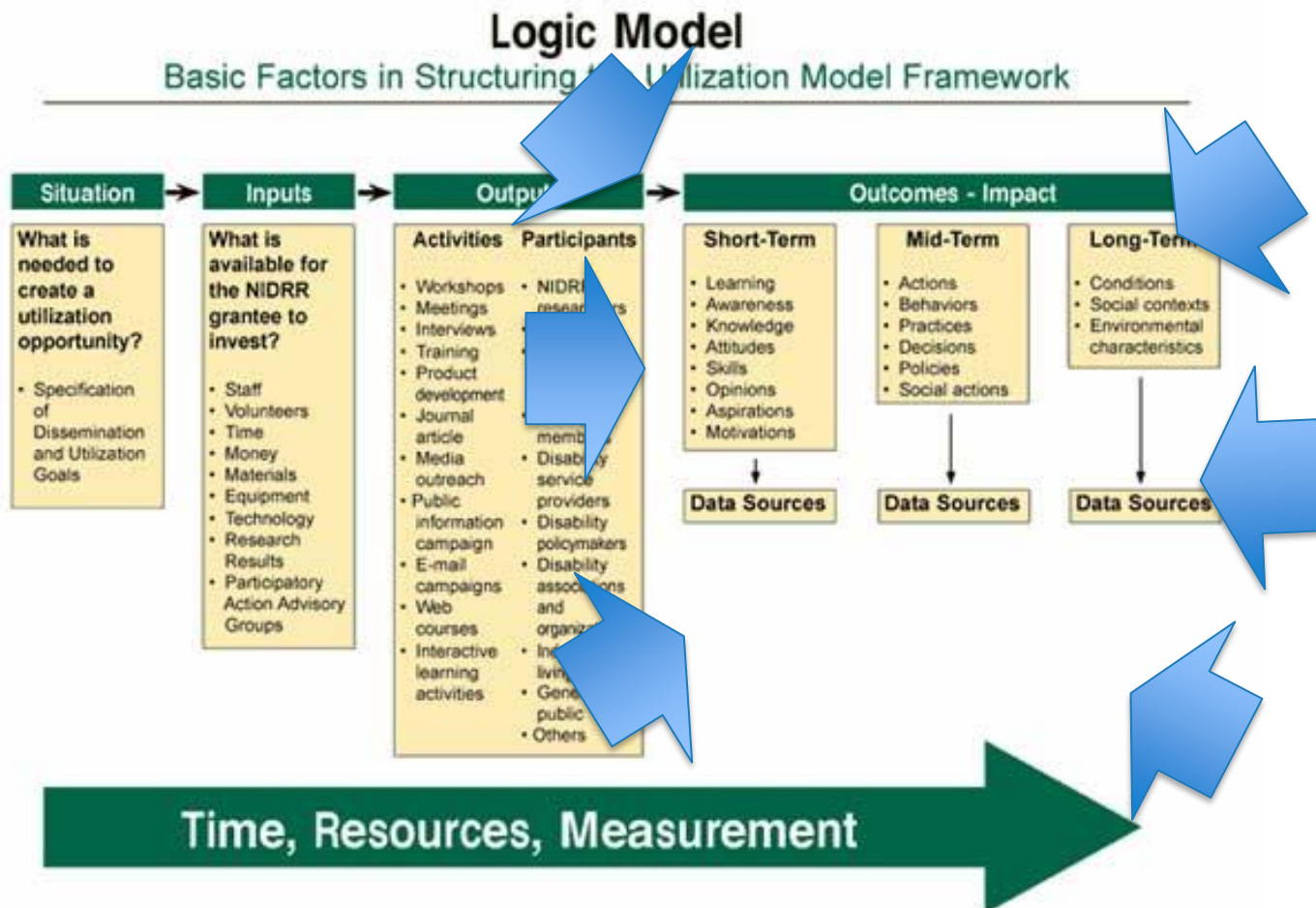
» **The main driver seems to be \$\$\$**

- » That's not unreasonable; OUD costs tens to hundreds of billions every year
- » But the entire US opioid market is around \$10 billion a year
 - A lot, but much less than expenditures and much less than tobacco

» **The main driver does not seem to be harm reduction or public health**

- » A lot of opioid law and policy is this way
- » ..that's an incredible missed opportunity

What are the goals of litigation?



What should be the goals of litigation?

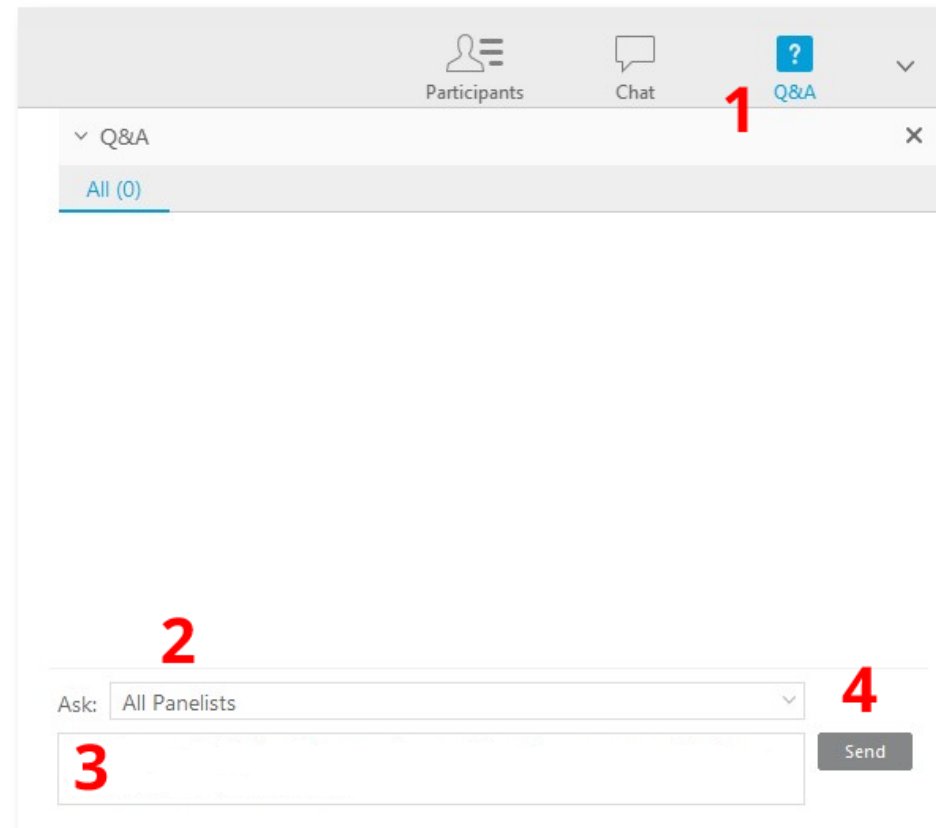
- » **Should the goal be \$? If so, what should be done with that \$?**
 - » MAT, naloxone, syringe access, supervised consumption..
- » **But remember..**
 - » Quality child care is OD prevention
 - » Safe streets are OD prevention
 - » Life skills training is OD prevention
 - » Quality education is OD prevention
 - » Job training is OD prevention
 - » Decarceration is OD prevention

Parting thoughts

- » **This is a public health crisis, and it demands a crisis-appropriate, evidence-based, equity-focused, well-funded public health response**
- » **Litigation is one tool in the box, but we should think of it more as a means than an end**
- » **Must ensure that any settlement is designed to direct \$ towards things that work, and away from things that don't**
- » **And should think hard about non-monetary conditions**
- » **In the meantime, many proven and promising practices that can be implemented today**

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