THE VALUE OF LITIGATION IN MITIGATING THE OPIOID CRISIS

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TODAY’S DISCUSSION

- Public health litigation functions
- Opioid crisis & litigation landscape
- Value of opioid litigation

PUBLIC HEALTH LITIGATION: OVERVIEW

- Tort: civil wrong for which a court will provide a remedy.
- Mass tort litigation: increasingly common in the public health sphere (firearms, asbestos, lead paint, tobacco, obesity)

Individualistic view – tort suit as a private transaction

VS.

Collectivist view – tort law as a means for maintaining, protecting the population health & well-being
PUBLIC HEALTH LITIGATION STRATEGIES

- Obtain compensation (average Plaintiff)
- Change defendant’s future behavior
- Deter negligence
- Enforce legal obligations to act
- Destroy defendant
- Bankrupt company
- Remove jurisdiction over program from government unit

PUBLIC HEALTH LITIGATION to Address

Regulatory Failures

Market Failures

Tort Litigation Objectives

- Compensation
- Deterrence
- Accountability
- Equity Jurisdiction

LITIGATION AS POLICYMAKING

- When, if ever, should public health policy be made through the judicial rather than the legislative or executive branches?
- Should courts focus narrowly on correcting past wrongs, or broadly on shaping policy?
- “Dynamic view: Courts can produce social change
- Constrained view: Courts cannot produce social change

Strengths of Litigation

- Counter-majoritarian function
- Judiciary less subject to industry capture
- Courts relatively insulated from political pressure
- Authoritative & specific vindication of rights
- Publicity

Drawbacks of Litigation

- Lengthy, expensive
- Reactive, not generally proactive
- Not all injuries are redressable
- Range of remedies is limited
- Hard to enforce decrees
- The legal issue is not always the problem

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DUAL PUBLIC HEALTH OPIOID CHALLENGES

Opioid Misuse and Overdose

- Address opioid over-prescribing
- Address opioid misuse, reduce overdoses
- Effectively treat opioid use disorder

Under Treatment of Pain

- Ensure patients adequately treated for acute pain
- Ensure patients adequately treated for chronic pain
AGE-ADJUSTED OPIOID OVERDOSE DEATH RATES, 1999-2017


OPIOID SALES, DEATHS, AND TREATMENT ADMISSIONS BY MAJOR DRUG TYPE, UNITED STATES, 1999-2010


SOURCES OF PAINKILLERS

OPIOID CONSUMPTION IN U.S.

- 4x consumption in U.S. compared to Europe in 2015
- Still 66.5 prescriptions per 100 people in U.S. in 2017
- 4.5% of world’s population, consumed 73% of world’s Oxycontin & ~99% of world’s hydrocodone in 2016
- ~$24B worldwide industry profits for opioid prescription painkillers

OPIOID PRESCRIBING (MME) PER PERSON BY U.S. COUNTY, 2015

OPIOID LITIGATION EVOLUTION

<table>
<thead>
<tr>
<th>Type of Suit</th>
<th>1st iteration (early 2000s)</th>
<th>2nd iteration (2000s)</th>
<th>3rd iteration (2000s to present)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public perception of opioids</td>
<td>Individual personal injury</td>
<td>Class action (resurging now)</td>
<td>Government suits</td>
</tr>
<tr>
<td>Claims</td>
<td>Prescribed liberally for pain</td>
<td>Prescribed liberally; growing concerns</td>
<td>Not appropriate for some chronic pain; over-prescribed</td>
</tr>
<tr>
<td>Usual winner</td>
<td>Design defect, negligent distribution, failure to warn, fraud</td>
<td>Similar to individual suits</td>
<td>Fraud, unjust enrichment, public nuisance, negligence, FDCA, CSA, RICO violations</td>
</tr>
<tr>
<td></td>
<td>Opioid co. (Defenses: product misuse, wrongful conduct, lack of causation)</td>
<td>Opioid co. (failure of commonality req’t for class certification)</td>
<td>Many settlements TBD…</td>
</tr>
</tbody>
</table>
PROMINENT OPIOID LAWSUIT SETTLEMENTS

- WV v. Cardinal Health (2017): $38.4M from 3 distributors
- IL v. Insys (2017): $4.5M, no deceptive marketing
- OK v. Purdue (2019): $270M, no promoting opioids
- *U.S. v. Purdue (2007): $600M (Co.); $34M (3 executives)
- *U.S. v. McKesson (2017): $150M, suspension of controlled subst. sales
- U.S. v. Mallinckrodt (2017): $35M, DEA allowed to analyze order data

MULTI DISTRICT LITIGATION (MDL), N.D. OH

- Late 2017: Opioid MDL, N.D. OH
- Mar. 2018: Bellwether Ohio case begins
- June 2018: DOJ joint settlement talks
- Nov. 2018: Market share data by county

- Feb. 2018: First settlement hearing
- Aug. 2018: DEA ARCOS data disclosed
- Oct. 2018: Disputes re: bellwether evidentiary motions
- Jan. 2019: 2nd bellwether track for WV

LOCAL GOVERNMENTS PARTY TO OPIOID MDL, JULY 2018

OTHER STATE AND TRIBAL CASES
- 100's other state and tribal cases
- Resisting consolidation with MDL:
  - concern local needs get overlooked
  - concern multiple defendants in MDL will complicate single defendant cases
  - seek tactical advantage of arguing before a local judge
- Early trial date (Oklahoma) scheduled for May 2019

DEFENSES ASSERTED IN RECENT OPIOID LAWSUITS
- Preemption of state claims & misleading marketing claims under federal law
- Intervening causes (physicians, pharmacies, illegal trafficking)
- CSA & state analogues don’t create a cause of action
- Distributors unaware of activities of other distributors
- Can’t demonstrate diversion of pills

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## OPIOID LITIGATION TO COMPENSATE FOR OTHER FAILURES

### MARKET FAILURES
- Some opioid manufacturers deliberately oversold drugs, despite known risks & REMS
- Some distributors supplied opioids in quantities beyond what was plausibly medically necessary
- Some pharmacies dispensed opioids in alarmingly high dosages

### REGULATORY FAILURES
- Congress: $102M campaign contributions, stripped DEA of powers
- FDA: passive post-marketing surveillance; approved Opana then Zohydro; engaged in pay-for-play; big proportion of budget paid by pharma; innovation policy flaws
- DEA/DOJ: ↓ enforcements vs. wholesalers (131 in 2011; 40 in 2014; 64 in 2016)
- Governments: slow to regulate thru ~2015

## OPIOID LITIGATION TO ACHIEVE TORT LITIGATION GOALS

### Compensation
- $100-600M U.S. societal costs/year
- Settlements with Purdue alone: $20B+

### Deterrence
- Opportunity to deter future bad behavior
- More responsible marketing, distribution

### Accountability
- Hold manufacturers, distributors, sellers responsible
- Evidence of deliberate wrongdoing, sales > PH

### Equitable Relief
- Stop marketing opioids; report suspicious sales
- Pay for counter-advertising & addiction treatment

## HELPFUL DEVELOPMENTS

- Evidence
  - Change in public attitudes, compelling evidence of deceit (esp. Purdue)
- Suits by state attorneys general / counties / MDL
  - Co.’s can’t litigate individual plaintiffs’ firms into ground
  - Co.’s can’t exclude epi studies as irrelevant
  - Individual choice & specific causation less relevant
  - Can seek equitable remedies
  - Overwhelming pressure to settle
OPIOID LITIGATION AS A PUBLIC HEALTH TOOL

Successes:
- Some financial hit for smaller companies
- Negative publicity
- Spillover effects; public education, investigations
- Injunctions that can change behavior

Limitations:
- Settlement money small relative to profits
- Some not used towards opioid harms
- Litigation not a panacea

SETTLEMENT PRIORITIES: COMPENSATE FOR ACUTE HARMs

- Treatment (MAT, naloxone): substantially ramp-up
- Child care services: resources, supports
- Recovery services: employment services, housing
- Criminal justice: MAT, recovery, transitions
- Pain clinic regulation: patients into treatment
- Evaluation of system-level policies

SETTLEMENT PRIORITIES: INJUNCTIVE RELIEF

- Internal monitoring/reporting of shipments, Rx’s
- Rx opioid marketing/detailing bans
- Public awareness campaigns
- Training providers on pain prescribing, addiction treatment from graduate education up
- Spurring innovation: alternative pain & addiction treatments
UNRESOLVED COMPLEXITIES/CHALLENGES

• Magnitude of settlement?
• How to reach all injured parties
• How to allocate relative responsibility among defendants
• Overseeing/structuring remedy administration
• Contingency basis creates perverse incentives

POTENTIAL PUBLIC HEALTH VALUE OF OPIOID LITIGATION

• ↓ “public bads” of malfeasant opioid marketing, distribution
• Changes to industry behavior (product mix, design, info)
• Signaling function to regulators
• Sorely needed $$$$
• Heightened public awareness
  • Prescription opioid risks
  • Industry practices

QUESTIONS?

Thank you!

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Percent Change in MME Per Capita from 2015 to 2017

TORT LIABILITY LAW

- Negligence claims:
  - Based on a standard of reasonable care

- Products liability:
  - Design defect:
    - Most products: defective if there is a reasonable alternative safer design
  - Manufacturing defect
  - Failure to warn (labeling and advertising)
  - Negligent distribution

Elements:
1. Defendant had a duty to Plaintiff
2. Defendant breached it
3. Defendant's breach proximately caused injury

TORT LIABILITY LAW

Misrepresentation – intentional tort typically found under consumer protection law (e.g., food claims as “natural”, “fresh”, “sugar free”)

Nuisance – unlawful interference with enjoyment of a person’s or community’s legally protected interests.
  - Private nuisance (e.g., noxious odors from chemical plant)
  - Public nuisance (e.g., lead-paint manufacturers; Oxycontin manufacturers)

Unjust enrichment – Defendant was unjustly enriched at the plaintiff’s expense.

CLASS ACTION LAWSUITS

Requirements:
1. Numerosity (at least 40-100 individuals)
2. Commonality
3. Typicality
4. Representativeness

Advantages:
- Efficiency
- Consistency (single standard for defendant’s conduct)
- Equitable allocation of money available for damages
- Bigger fees for attorneys
TOBACCO LITIGATION EVOLUTION

<table>
<thead>
<tr>
<th>Era</th>
<th>1st wave</th>
<th>2nd wave</th>
<th>3rd wave</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultural view of smoking</td>
<td>Popular, glamorous, accepted</td>
<td>Unhealthy, frowned upon</td>
<td>Despised by most; industry reviled</td>
</tr>
<tr>
<td>Claims</td>
<td>Negligence, misrepresentation</td>
<td>Failure to warn, strict liability</td>
<td>Fraud and deceit, unjust enrichment</td>
</tr>
<tr>
<td>Usual winner</td>
<td>Tobacco co. (assumption of risk)</td>
<td>Tobacco co.</td>
<td>Plaintiff</td>
</tr>
</tbody>
</table>

WHAT MADE THE DIFFERENCE IN TOBACCO LITIGATION?

- Tobacco papers
  - Change in public attitudes, compelling evidence of deceit
- Use of class action suits. Companies no longer able to:
  - Litigate individual plaintiffs' firms into the ground
  - Discredit indiv. plaintiffs/specific causation
  - Exclude epi studies as irrelevant
- Suits by state attorneys general
  - Individual choice & specific causation irrelevant
  - Could seek equitable remedies

TOBACCO MASTER SETTLEMENT AGREEMENT (MSA)

- Agreement b/w 3 big tobacco co's agree with 26 state AGs, 6 territories
- Components:
  - Co's pay for smoking-related medical costs, in perpetuity
  - Injunctions: advertising restrictions; shut trade association; fund anti-smoking campaigns
  - Co's receive liability-immunity
- 20 years later, $120 billion paid out, but many critiques
TOBACCO LITIGATION AS A PUBLIC HEALTH TOOL

Successes:
- Large financial hit, likely necessitating price increase (MSA: $205B+)
- Generous fund for anti-tobacco programs
- Exposed dirty laundry; win in the court of public opinion

Failures:
- Scuffling over use of settlement money
- Haven't stemmed the tide of new smokers: kids, overseas customers
  - Tobacco stocks still strong
  - Most measures that reduce smoking = legislative, regulatory functions