The Municipal Opioid Litigation

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IMLA Annual Conference
Houston, Texas – October 20, 2018

***(Presentation produced by Erich Eiselt)**

The Municipal Opioid Litigation

- A Brief History-How We Got Here
- The Litigation-State Courts/Federal MDL
- Decisions-Whether to File, and Where
- Solutions-Attacking the Problem

Brief History: Sobering Facts

- Post-Civil War: 200,000+ addicts in US
- 1914: Harrison Act-drastically limited medical narcotics

- US opioid prescriptions in 2012: 282 million doses
- Doses to Kermit, WV (pop. 292) 2012-2013: 9 million
- TX economic cost in 2015: $1.96 Billion (2nd most in US)
- TX overdose deaths in 2016: 1,375 (70% opioids/heroin)
- US overdose deaths in 2017: 72,000 (vs. 64,000 in 2016)
- Americans addicted to opioids in 2017: 2.1 million
- Annual Burden on US: $500 Billion (CEA)

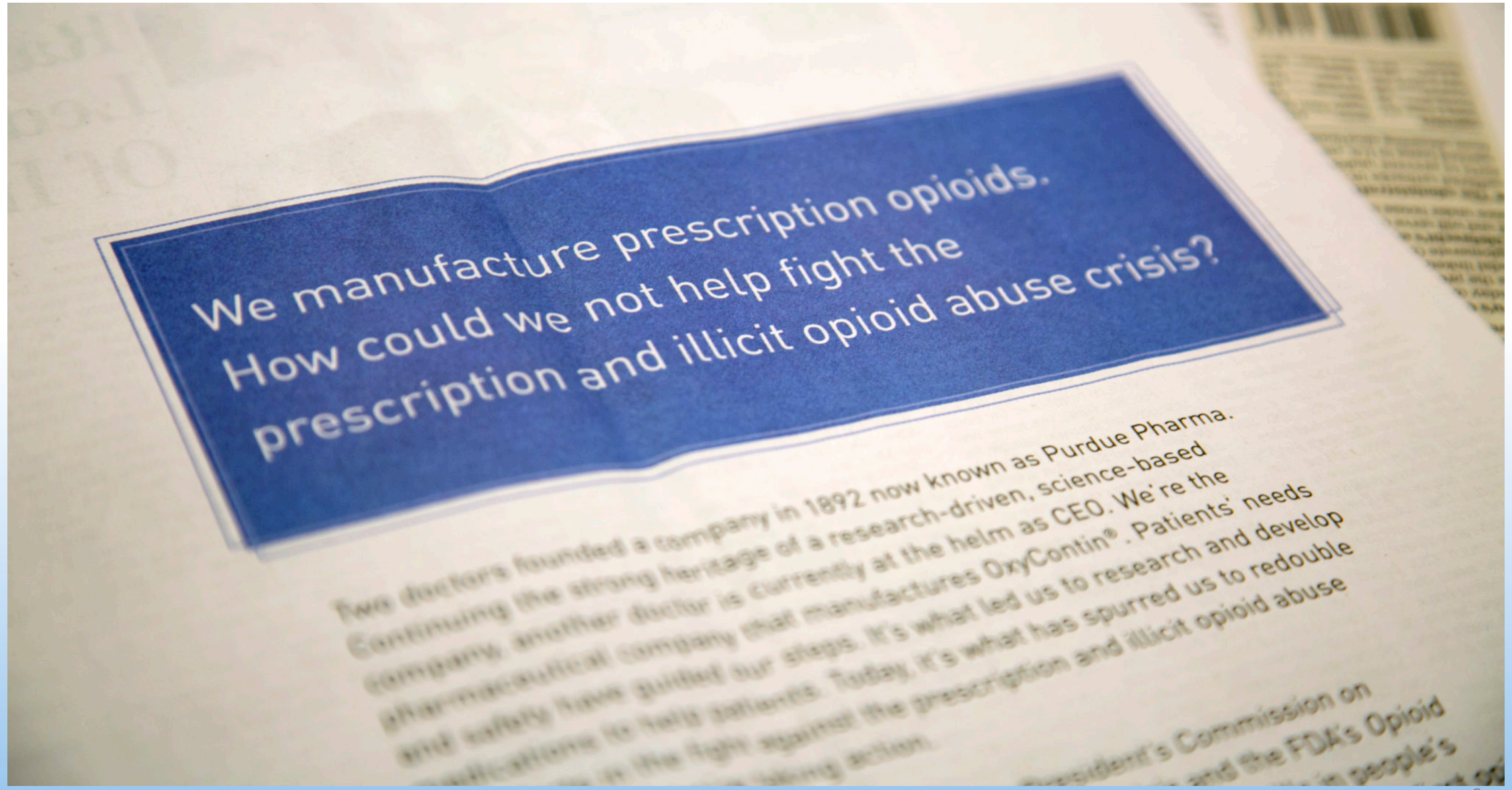
Brief History: Purdue's Runaway Success

- 1952: Sackler brothers acquire Purdue Frederick Co.
- 1980: Purdue brings MS Contin to market
- 1980: Porter and Jick study (less than 1% addiction)
- 1996: MS Contin patent expires, OxyContin introduced
- 1996: American Pain Society adds "Pain" to 4 vital signs
- 2001/2002: Oxy sales reach $3 Billion (1996-$44 Million)
- 2003: more than half of Oxy prescribers are primary care doctors
- 2003: Purdue patents "crush resistant" OxyContin

Brief History: Opioid Sales/Marketing Strategies

- Medical journals: advertising gave opioids legitimacy
- Key Opinion Leaders: national experts endorsed opioids
- Continuing Medical Education: professional imprimatur
- Local influencers: paid to attend small collegial events
- Salespeople: promoted off-label benefits (beyond FDA)
- Researchers: coined “Pseudo-addiction”- withdrawal symptoms required even greater doses

Brief History: Continuing PR Campaign



Brief History: Opioid Industry Repeated Violations

- 2007: Purdue pleads guilty to understating OxyContin's potential for addiction--$634 million in penalties
- 2008: McKesson and Cardinal cited by DEA for under-reporting "suspicious orders"--$48.5 million in fines
- 2016: Cardinal again cited--$44 million in fines
- 2017: Mallinckrodt cited--$35 million in fines
- 2017: McKesson again cited--$150 million in fines (only reported 16 "suspicious orders" out of 1.6 million)
- 2018: Insys pays $150 million (bribery/kickback crimes)

Opioid Litigation: Who are the Plaintiffs?

- States
- Counties, Cities, Townships, Parishes, Fire Districts
- Third Party Payors: Unions, Insurers, Risk Pools
- Healthcare Providers: Hospitals, EMS
- Native Americans: Tribes
- Class actions: Insureds whose premiums increased
- Neonatal Abstinence Syndrome (NAS) Babies
- Individuals

Opioid Litigation: Who are the Defendants?

- Manufacturers: Purdue, J&J/Janssen, Cephalon/Teva, Allergan/Actavis, Insys, Endo, Mallinckrodt
- Distributors: AmerisourceBergen, Cardinal, McKesson
- Pharmacies: CVS, Walgreens, Costco
- PBMs: Express Scripts, Caremark, Optum
- Key Opinion Leaders: Webster, Portenoy, Fine, Fishman
- Non-Profits: AAPM, JCAHO
- Sackler family: individuals and estates

Opioid Litigation: What are the Claims?

- Nuisance: injured community, drove up costs
- Unjust enrichment: profited from crisis
- Negligence: allowed diversion of opioids
- Common law fraud/deceptive practices: deceived consumers and prescribers, promoted off-label use
- False claims: reimbursed for improper products
- Conspiracy/RICO: defendants acted in concert
- Willfulness: intentional acts

Opioid Litigation: What are the Damages?

- Overdose response: Police/EMS calls, naloxone
- Treatment: hospitalization, buprenorphine/suboxone
- Rehabilitation: counseling, support services
- Unneeded payments: for ineffective, improper drugs
- Crime: arrest, court proceedings, incarceration
- Children: protective services, foster parenting
- Worker's compensation: municipal employees' claims
- Death: coroners, morgues

Opioid Litigation: What are the Defenses?

- No public nuisance: not linked to physical property
- No proximate cause: too many intervening factors
- Statute of limitations: time to bring claims has expired
- Preemption: FDA has authority over opioids
- Safe harbor: states limit liability re-FDA approved drugs
- Learned Intermediary: doctors made own decisions
- Statewide Concern: municipalities have no authority
- Municipal Cost Recovery: no claim for routine expenses
- Derivative Injury: municipalities not actually harmed

Opioid Litigation: State Court Actions

- States
  - AGs - AL, DE, FL, MA, TX, TN, NV, NC, NY, OK (30+)
  - *State ex rel Hunter* (OK)-trial by 5/2019
- Municipalities - 800+ counties, cities, townships, etc.
  - MD - *Mayor/City Council of Baltimore* moving rapidly
- State MDLs - common factual bases
  - TX MDL - Texas Supreme Court - 16 municipalities
  - NY MDL - Suffolk County Supreme Court - 27 counties
  - CT MDL - Hartford Superior Court - 20+ towns
- Hybrid - AR - AG Brubaker + 75 counties + 210 cities

Opioid Litigation: State Court Actions-AG Battles

AG considerations:

- can avoid federal removal on *parens patriae* grounds-even if complete diversity exists
- lesser pleading thresholds in consumer fraud actions
- easier access to MDL proceedings and ARCOS data than individual municipalities
  - But potential conflicts with municipal plaintiffs:
    - request localities to refrain (WY, NB, TN)
    - may energize “statewide concern” dismissal efforts

Opioid Litigation: State Court Actions-AG Battles

TN AG Slattery to 14 municipalities-3/15/2018:

"[T]the lawsuits you have filed are of concern . . . . First, [they] are brought, in part, on behalf of the State . . . . [They] impede my ability to prosecute all of the opioid litigation implicating the State's interests. . . . Second, the Office of the Attorney General is in the best position both to represent the interests of the State and to obtain the best possible monetary recovery . . . . Last, you retained outside counsel . . . without the authorization required under state law . . ."

Opioid Litigation: State Court Actions-AG Battles

NB law firm letter to municipalities:

1. Last week, we sued 25 pharmaceutical manufacturers and distributors for Knox County, and The Ponca Tribe of Nebraska. Both governments have increased costs due to demands by users of drugs, including opioids and others, for public safety, health, emergency, court, and jail services. Housing is also an issue for the Ponca Tribe. The State pushed much of this program cost to the Counties over the past 30 years and funded little of it.

2. Nebraska's Attorney General has not filed suit. A group of AG's is "negotiating" with representatives of the Defendants for a solution out of court, without a single trial, and with no guarantee any recovery for any County or City. The State's costs, including attorney's fees for private legal services to the AG group, have not been disclosed.

3. Attorney General Peterson is an honorable public official. His office joined a group; it is not *leading*, for Nebraska. If this passive approach produces any money, the Legislature controls what is recovered. What will it do in view of a $900 million budget deficit? Well –Nebraska received tobacco money. How much did your community get?

Opioid Litigation: State Courts-Avoiding Removal

Jurisdictional strategies:

- Federal court has original jurisdiction if complete diversity; case removable from state (28 U.S.C. § 1332)
- Diversity incomplete in states where defendants are incorporated/have home office (CA, PA, DE, NY, etc.)
- Defeat diversity w/ in-state defendants (doctors, clinics)
  - Fraudulent joinder: no basis at all for added party
  - Fraudulent misjoinder: added party is only peripheral
  - Varied results (*Mayor/City Council of Baltimore*, WV Districts, Circuits' adoption of joinder/misjoinder)

Opioid Litigation: State Courts-Avoiding Removal

Jurisdictional strategies:

- AG *parens patriae* suit: AG cases can remain in-state despite complete diversity (*AU Optronics,* US 2014)
- But AG and/or incomplete diversity cases risk removal:
  - Federal Question – claim "arising under the . . . laws . . . of the United States" (28 U.S.C. §1331)
    - Example - claim arises under FDCA or CSA
  - Federal Officer - claim vs. "any officer" of the US or "under color of such office" (28 U.S.C. § 1442)
    - Example - PPV contract-Tribes or *Center Point* case

Opioid Litigation: State Courts-Early Progress

Motions to Dismiss denied in multiple states:

- AK - *State v. Purdue Pharma, L.P.*, No. 3AN-17-09966CI (Ak. Super. Ct. July 12, 2018)
- MO - *Hawley v. Purdue Pharma, L.P.*, No. 1722-CC10626 (Mo. Cir. Ct. Apr. 25, 2018) (trial soon)
- NH - *State v. Purdue Pharma, L.P.*, No. 217-2017-CV-00402 (N.H. Super. Ct. Sept. 18, 2018)
- NY - *In re Opioid Litigation*, No. 400000/2017 (N.Y. Supr. Ct. Jun. 18, 2018/July 17, 2018)
- OH - *State ex rel. Purdue Pharma, L.P.*, No. 17 CI 261 (Ohio Ct. C.P., Ross Cty. Aug. 22, 2018)

Opioid Litigation: State Courts-Early Progress

Motions to Dismiss denied in multiple states:

- OK - *State ex rel. Hunter v. Purdue Pharma, L.P.*, No. CJ-2017-816 (Okla. Dist. Ct. Dec. 6, 2017) (trial by 5/2019)
- TN - *Staubus v. Purdue Pharma, L.P.*, No. C-41916, 2018 WL 3349093 (Tenn. Cir. Ct. May 8, 2018)
- WA - *State v. Purdue Pharma, L.P.*, No. 17-2-25505-0 SEA (Wash. Super. Ct. May 14, 2018)
- WV - *State ex rel. Morrisey v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Apr. 17, 2015/Feb. 19, 2016)

Opioid Litigation: State Courts-Early Progress

6/18/2018: NY MDL (Judge Garguilo) denies MTDs:

- Fraud: "defendants' argument that the plaintiffs must allege and prove [that] a particular misstatement led a specific physician to write a particular opioid prescription for a patient is rejected."
- Preemption: "the FDA's approval of opioids . . . does not mean that . . . the plaintiffs herein may not seek to protect their residents from the unlawful activities of defendants concerning those drugs . . ."

Opioid Litigation: State Courts-Early Progress

6/18/2018: NY MDL (Judge Garguilo) orders, cont'd:

- Public nuisance: claims can proceed--public health can be a right "common to the general public"
- Municipal cost recovery: defendants cite no case where governments are prevented from suing "to remedy public harm caused by intentional, persistent course of deceptive conduct"- "to do so would distort the doctrine beyond recognition."

Opioid Litigation: State Courts-Early Progress

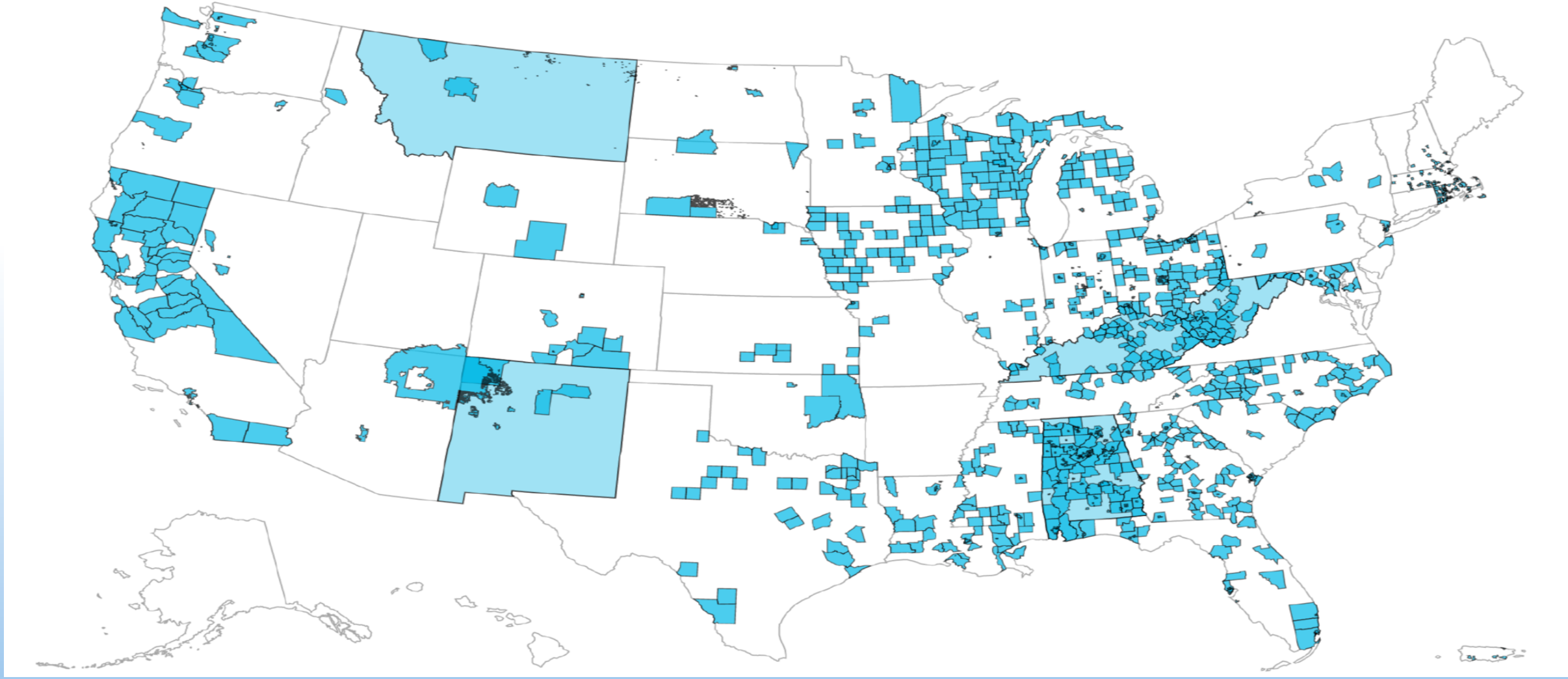
8/21/2018: *State of Ohio ex. rel Mike Dewine v. Purdue Pharma*, (Common Pleas, Ross County, OH)

- Under Ohio pleading standards, not necessary to identify physicians who relied upon the misrepresentations; their identification is solely within the knowledge of Defendants; complaint adequately states Plaintiff specifically relied upon the misrepresentations in issuing reimbursement payments under Medicaid.
- "[T]his Court finds that Plaintiff has sufficiently pled the

Opioid Litigation: The Federal MDL

- 2014-Chicago first major filer (removed to N.D. Ill.)
- By 2017-Dozens of cases, MDL formed: *In re National Prescription Opiate Litigation* (17-md-2804, N.D. Oh.)
- Judge Dan Polster-actively engaged, seeks resolution
  - Structure: 3 co-leads, 16-member PEC, liaison group
  - Early push for settlement talks, including state AGs
  - As of 10/18/2018, 59 CTOs: 1150+ federal cases transferred into MDL
    - MDL stays local cases, except remand actions

Opioid Litigation: The MDL-Where Cases Originate



Opioid Litigation: MDL Case Management-Evidence

- DEA ARCOS Data (2006-'14) and *City of Chicago* documents provided to all MDL parties
- Coordination: "this Court intends to coordinate with State courts . . . to the fullest extent possible" including "coordination of written discovery and deposition protocols and cross-noticing of depositions"
- As of 10/1/2018-12 million documents (60 million pages) from Defendants, 100,000 documents from third parties
- 10/9/2018 – Judge Polster orders comprehensive joint MDL/state database and cross-noticing of depositions

Opioid Litigation: MDL Case Management-Timing

- "Track One" - Selected Ohio claims (*Summit, Cuyahoga, Akron, Cleveland*): trial begins 9/2019 (was 3/1/2019)
- Ohio and Illinois (*Summit, Chicago*): complaints filed 4/25/2018, motions to dismiss by 5/25/2018
- West Virginia, Michigan and Florida (*Cabell, Monroe, Broward*): Comp. 4/25/2018, MTD 6/8/2018
- Alabama: Comp. 5/9/2018, MTD 6/18/2018
- Tribes: Comp. 7/9/2018, MTD 8/6/2018
- Hospitals/West Boca: Comp. 5/3/2018, MTD 6/29/2018
- Third Party Payors: Comp. 6/18/2018, MTD 7/23/2018

Opioid Litigation: The MDL-Motions to Dismiss-Statewide Concern (*Broward County* Bellwether)

"Just as these principles preclude local ordinances that seek to regulate matters of statewide concern, the same limitations apply equally to *litigation* brought by political subdivisions. . . . The Florida AG "cited [the statewide concern] in initiating her own lawsuit against manufacturers and distributors of opioids. Through that suit, the AG seeks to vindicate the interests of Florida and its citizens."

Opioid Litigation: MDL Motions to Dismiss- Municipal Cost Recovery (*Broward Co.* Bellwether)

"[T]he municipal cost recovery rule forbids Broward County from recovering the damages that it seeks. Plaintiff's claimed damages are textbook examples of the costs that a government entity may not recover through litigation: the costs of police, fire, and emergency services; expenses incurred providing residents with medical care; and the burden on the judicial system."

Opioid Litigation: MDL Motions to Dismiss- Fraud (*Broward County* Bellwether)

"[T]he County fails . . . to identify any County prescriber who was exposed to the . . . alleged deceptive marketing; . . . to identify when or by whom any alleged misrepresentation or omission was made to any County prescriber; and to identify any County prescriber who wrote an allegedly harmful or medically unnecessary opioid prescription as a result of the alleged deceptive marketing."

Opioid Litigation: MDL Motions to Dismiss- Statutory Immunity (*Monroe Co. MI* Bellwether)

"MCL § 600.2946(5) provides broad immunity . . . sellers of prescription drugs are immune from all tort liability, so long as "the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller." "[A] manufacturer or seller of a drug . . . approved by the FDA has an absolute defense to a products liability

Opioid Litigation: Early Progress-MTDs

10/5/2018-MDL Magistrate Ruiz recommends denial in 12 of 13 MTDs in Track One cases:

- RICO-lost taxes are "property;" no Municipal Cost Recovery Rule; "but for" causation; no preemption; "enterprise" and "racketeering activity;" S/L tolled
- Negligence-duty/breach/proximate causation
- Fraud-intent, justifiable reliance, proximate cause
- Unjust enrichment-plaintiffs bore externalities
- One MTD granted-OPLA bars common law public nuisance-(but not statutory public nuisance claim)

Opioid Litigation: Early Progress-Discovery

10/6/2018-MDL Special Master Cohen issues ruling that plaintiffs must identify and document 500 specific unauthorized/improper prescriptions and 300 persons addicted due to defendants' wrongful acts

10/16/18-Judge Polster upholds ruling, but allows plaintiffs option of relying solely on "aggregate proof"

Opioid Litigation: Whether to File?

- Has the municipality been damaged?
- Is there an insurer or third party payor?
- Are there sufficient records? (MDL requires "Government Plaintiff Fact Sheet"- data back to 2008)
- Are there resources/processes to marshal the data?
- How will it affect operations? (litigation hold, etc.)

Opioid Litigation: Whether to File?

Litigation burden-One county's experience: discovery

- Information required back to January 1, 2008:
  - Categories of damages-budgets/actual expenditures
  - Grants/other funding specifically related to opioids
  - Employees in specified positions
  - Health care providers/pharmacies targeted by law enforcement
  - Overdose rates
  - Programs related to opioids (with dates)

Opioid Litigation: Whether to File?

Litigation burden-One county's experience: discovery

Data marshalling and production presents various issues:

-numerous departments

-differing systems and databases

Opioid Litigation: Whether to File?

Litigation burden-One county's experience: discovery

12 Departments / more than 30 Employees-

- Health/Human Services
- Police
- Fire and Rescue Services
- Correction and Rehabilitation
- Emergency Management and Homeland Security
- Circuit Court
- State's Attorney
- Sheriff
- Management and Budget
- Finance/Workers' Compensation
- Human Resources
- Public Schools

Opioid Litigation: Whether to File?

Litigation burden-one county's experience: discovery

Advice:

- Start early
- Brainstorming meeting with key players, if feasible
    - Determine what information you have/don't have
    - Get department heads in the same room
- Need to turn anecdotal evidence into hard data
- Begin tracking opioid-related information now
- Look ahead-resources for discovery beyond Fact Sheet
- Expert review (depending on forum)

Opioid Litigation: Where to File?

- In-state advantages:
  - Familiarity with local courts and judges
  - Sympathetic jurors, drawn from small area
  - Jury unanimity not required in all states
  - Potentially easier pleading standards
  - Not lost among 1100+ plaintiffs
  - More direct contact with defense counsel

Opioid Litigation: Where to File?

- In-state disadvantages:
  - Unless consolidated with other state actions (AR, TX, NY, CT, PA), creates duplicative/competing suits
  - Immediately subject to full-blown merits discovery
  - MDL will still exert influence
  - Not defendants' primary focus
  - Smallest jurisdictions may not afford own actions
  - Local counsel may not have experience or resources
  - If AG action, will recovery get to municipalities?

Opioid Litigation: Where to File?

- Federal/MDL advantages:
  - Judge Polster's push-trial by 9/2019, settlement talks
  - Reduces duplicative discovery and pleadings
  - Participation by US as Friend of Court
  - Federal RICO-treble damages
  - Defendants' focus, ahead of/in lieu of state actions
  - Most experienced/qualified plaintiffs' counsel-can divide tasks, coordinate as a team
  - Subsequent filers can mimic/join action

Opioid Litigation: Where to File?

- **Federal/MDL disadvantages:**
  - **Generalizes/merges disparate claims and damages**
  - **Handful of firms control process and govern outcome**
  - **Smaller jurisdictions have little voice or influence**
  - **Will recovery be divided equitably among all municipalities?**
  - **Juries from large Districts, must be unanimous**

Attacking the Problem: Federal

- White House - 10/2017 declared “public health crisis” set up Commission; 3/2018 - death penalty for dealers; 8/2018: calls on DOJ to sue pharma co’s, set production limits, pressure China re: fentanyl
- DEA - 2/2018 - Move fentanyl and analogues to Schedule I
- FDA - Remove ads for online sale of opioids w/out prescriptions from social media
- Congress - CARA 2.0-Comprehensive Addiction/ Recovery Act

Attacking the Problem: Federal

CARA 2.0-Comprehensive Addiction/Recovery Act

- **3-day limit on initial opioid prescriptions**
- **PAs/nurses can prescribe buprenorphine**
- **Doctors/pharmacists must use PDMPs**
- **Increased penalties re: Suspicious Order Reports**
- **National standard for addiction recovery housing**

Supported by Sens. Portman (R-OH), Whitehouse (D-RI), Capito (R-WV), Klobuchar (D-MN), Sullivan (R-AK), Hassan (D-NH), Cassidy (R-LA), Cantwell (D-WA).

Attacking the Problem: Federal

CARA 2.0 - $1 Billion in Funding:

- $300 million-medication-assisted treatment (MAT)
- $300 million-first responder training/naloxone
- $200 million-long-term recovery programs
- $100 million-pregnant/postpartum women
- $100 million-criminal justice and education

HR 6 “SUPPORT” Act– passed Senate 9/18/2018:

- Increased buprenorphine prescribing
- Increased Medicare funding for in-patient services

Attacking the Problem: Federal

How to Spend $100 Billion Solving the Opioid Crisis:

- Treatment - 47% (MAT, prisoner services)
- Demand - 27% (Counseling, community resources)
- Harm Reduction - 15% (Naloxone, syringe exchange)
- Supply - 11% (Interdiction)

Josh Katz, "How a Police Chief, a Governor, and a Sociologist Would Spend $100 Billion to Solve the Opioid Crisis" NEW YORK TIMES, Feb. 14, 2018.

Attacking the Problem: States

- 28+ states now impose caps on opioid prescriptions
- NE - HB 931: 7 day maximum for age 18 and under
- TN - 5 day maximum new patients, 40 MMEs /day
- MI – SB 274: 7 day maximum beginning 7/1/2018
- http://www.affirmhealth.com/blog/opioid-prescribing-guidelines-a-state-by-state-overview
- 30 states + DC now have needle exchange programs
- 49 states + DC now have PDMPs

Attacking the Problem: States - Florida



Attacking the Problem: States - Florida

Counties with highest controlled substance prescribing

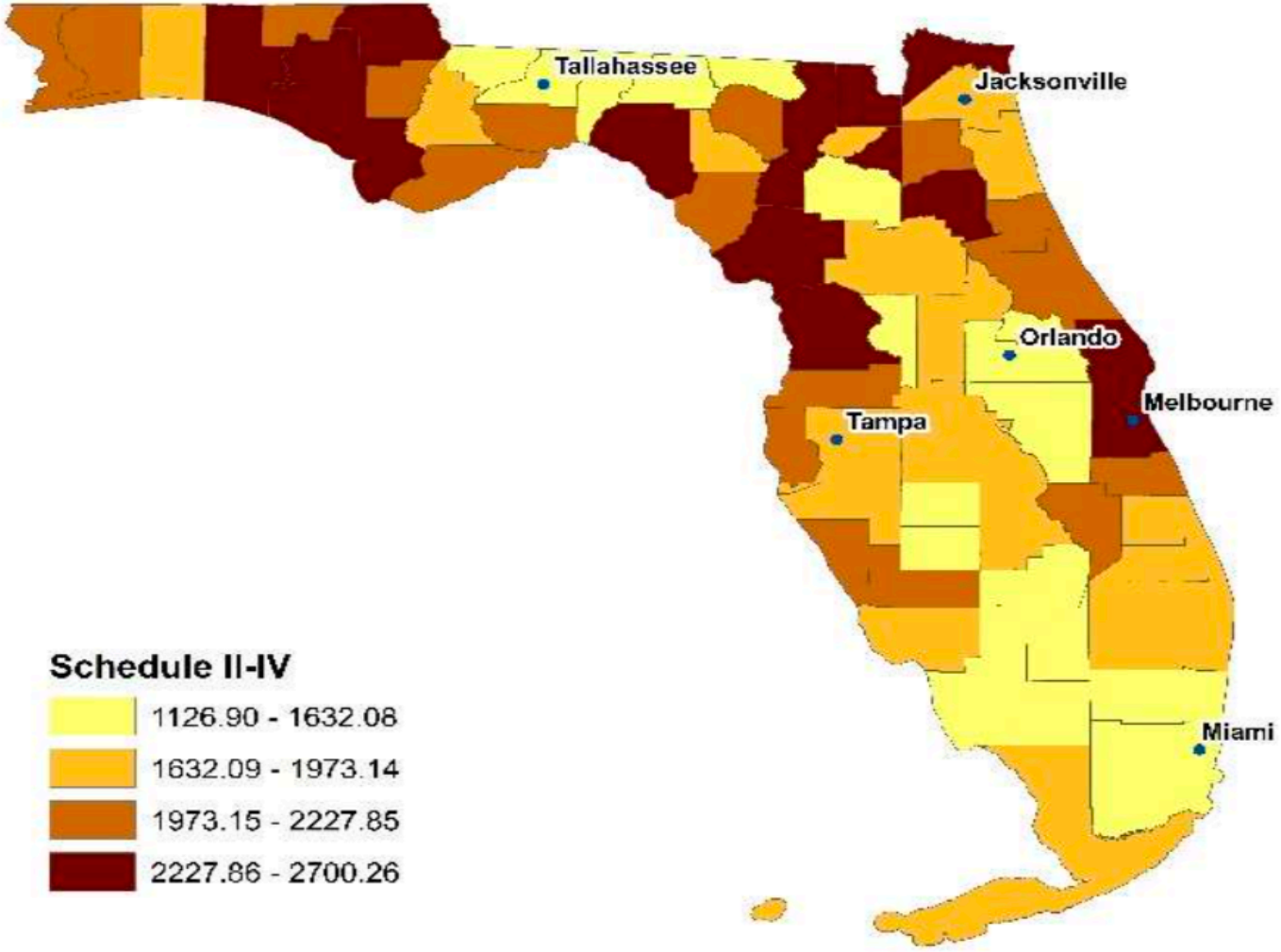


Figure 4(a) Schedule II-IV controlled substance prescribing is highest in the Panhandle, rural areas of north Florida and the Melbourne area.

Attacking the Problem: States - Florida

Compare: Counties with highest PDMP utilization rates

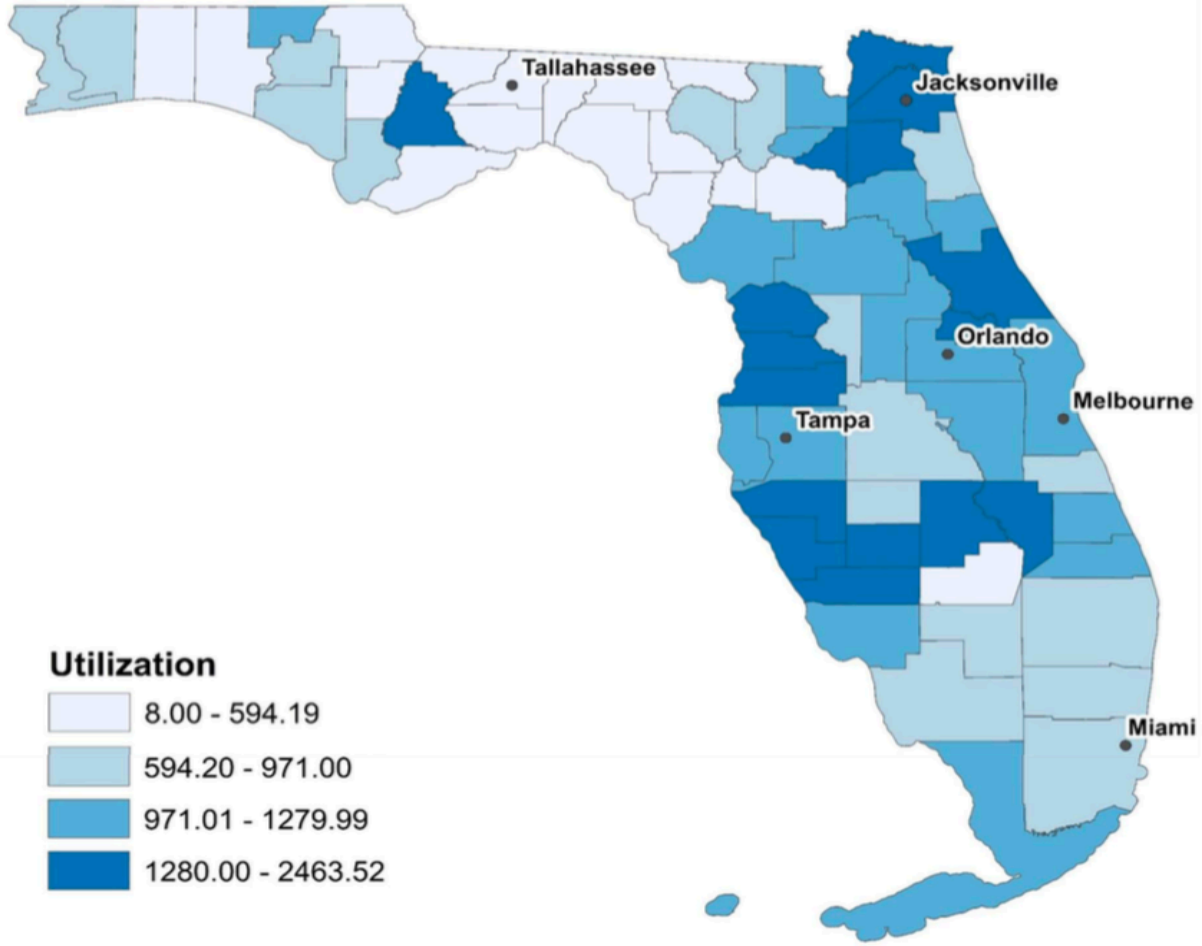


Figure 4(e) The highest PDMP utilization rates are concentrated in urban areas and near large health systems.

Attacking the Problem: States - Georgia

2017: Ga Assembly makes naloxone available OTC
7/1/2017-must report to PDMP w/in 24 hours (vs. 7 days)

§ 16-13-63. Liability; review of PDMP data when filling certain prescriptions; cause of action for civil damages:

As of July 1, 2018- "any person initially prescribing a schedule II opioid . . . shall seek and review a patient's PDMP information" - Except 3 days or less, up to 26 pills;

Attacking the Problem: States - Georgia

But-"Prescribers who violate the requirement to check the PDMP will be held administratively liable to their licensing board"

(C) A prescriber who violates this paragraph shall be held administratively accountable to the state regulatory board governing such prescriber but shall not be held civilly liable for damages to any person in any civil or administrative action or criminally responsible for injury, death, or loss to person or property on the basis that such prescriber did or did not seek or obtain information from such data base. ..

Attacking the Problem: States - Texas

2017-HB 2561-TX Prescription Monitoring Program (PMP):

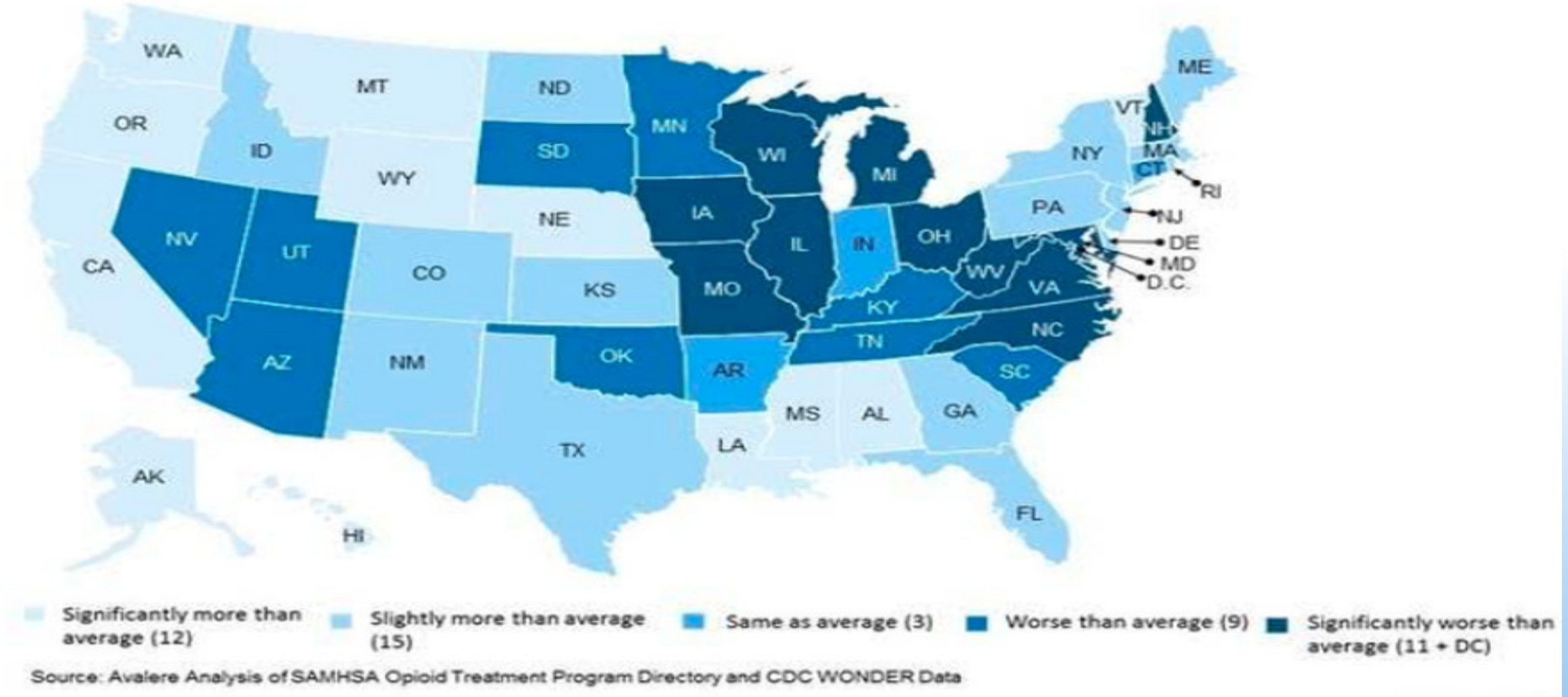
- **Reporting: 9/1/2017-pharmacies must report filled prescriptions of controlled substances to PMP no later than the next business day (previously, seven days).**
- **Checking: 9/1/2019 pharmacists and prescribers (not veterinarians) must check PMP history before dispensing or prescribing opioids/benzodiazepines/barbiturates. "Currently, [they] *are encouraged to check the PMP* to help eliminate . . . overprescribing of controlled substances . . ." .**

Work to Be Done:

- More than 2 million Americans with opioid disorders
- Needed: Treatment centers, medical expertise, counseling/behavioral specialists
- Buprenorphine/Suboxone (Buprenorphine+Naloxone) extremely useful (with counseling/behavioral therapy)
  - faster-dissolving version just patented in 2018
  - But are municipalities now liable for failing to provide it, on ADA grounds?
    - *Kortlever v. Whatcom County,* no. 2:18-cv-00823 (W.D. Wa. June 6, 2018) – ACLU ADA class action

Work to be Done:

Ratio of buprenorphine providers to overdose deaths



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Some Progress:

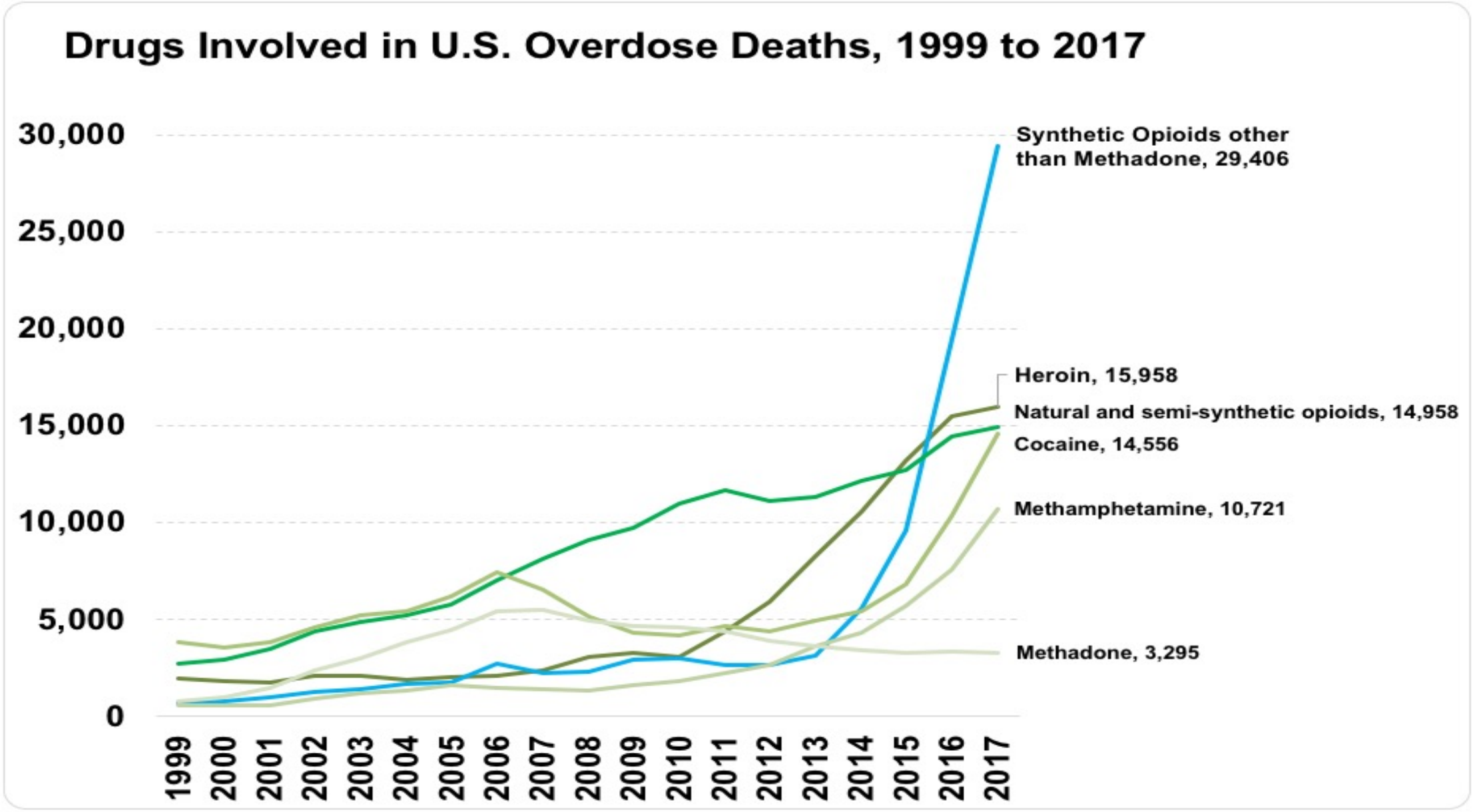
Opioid prescriptions declined more than 10% in



Work to be Done: Increasingly lethal alternatives



Work to be Done: 2017-Overdose deaths up 7%



Work to be Done:

Municipalities will play a major role in reversing the damage done to American society by the opioid epidemic.

Thank you-

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