Municipalities and the Opioid Crisis

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Municipalities and the Opioid Crisis

- A Brief History
- The Litigation—State and Federal
- Whether to File, and Where
- Attacking the Problem

Brief History: Runaway Success

- 1980: Purdue brings MS Contin to market
- 1980: Porter and Jick study (less than 1% addiction)
- 1996: Purdue brings OxyContin to market
- 1996: American Pain Society adds “Pain” to 4 vital signs (pulse, temperature, blood pressure, respiration rate)
- 2001/2002: Oxy sales reach $3 Billion (1996-$44 Million)
- 2003: more than half of Oxy prescribers are primary care doctors (not end-of-life or acute pain specialists)

Brief History: Marketing Strategies

- Advertising in medical journals: aura of legitimacy
- Key Opinion Leaders: national experts
- Conference sessions: continuing medical education
- Local influencers: paid to attend
- Off-label promotions: beyond FDA-approved statements
- “Pseudo-addiction”: withdrawal requires greater doses

Brief History: 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: Mallinkrodt cited--$35 million in fines
- 2017: McKesson again cited--$150 million in fines (only reported 16 orders out of 1.6 million)

Brief History: Sobering Facts

- US opioid prescriptions in 2012: 282 million
- Doses to Kermit, WV (pop. 292) during 2 years: 9 million
- FL overdose deaths in 2015: 7,293
- US overdose deaths in 2016: 64,000
- Americans addicted to opioids in 2017: 2.1 million
- 70% of heroin addicts begin with opioids
- Palm Beach cost to respond to overdose: $1,500
- National Economic burden: Over $500 Billion/year (CEA)

Opioid Litigation: Who are the Plaintiffs?

- Municipalities: States, Counties, Cities, Townships, Fire Districts
- Third Party Payors: Unions, Healthcare plans, Risk Pools
- Healthcare Providers: Hospitals, EMS
- Tribes: Cherokee, Choctaw, Arapaho
- Individuals

Opioid Litigation: Who are the Defendants?

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

Opioid Litigation: What are the Claims?

- Nuisance: injury to community, rehabilitation costs, EMS, crime, child protective care, worker's comp
- Negligence: allowed diversion of opioids
- Consumer fraud/deceptive practices: deceived consumers/prescribers, promoted off-label use
- False claims: obtained reimbursement for ineffective/improper products
- Conspiracy/RICO: collusion among manufacturers, distributors, experts, others

Opioid Litigation: What are the Defenses?

- No proximate cause: too many intervening factors
- Statute of limitations: time has expired to bring claims
- Preemption: FDA approved opioids, still controls them
- Safe harbor: State laws exempt liability for drugs
- Learned intermediary: doctors made own decisions
- Statewide concern: municipalities have no authority
- Contingency fees: ethical breach by municipal lawyers

Opioid Litigation: State Courts

- Nationally, hundreds of municipal filings in state courts
- FL - Pam Bondi files in Pasco County 5/15/2018; same day as AGs from TX, TN, NV, NC and ND file in-state
- TX - 16 municipal cases moved into Texas MDL
- AR - Omnibus complaint: AG/75 counties/210+ cities
- OK - AG case on track for trial by 5/2019
- NY - “mini-MDL” - all cases go to Supreme Court, Suffolk County (denied manufacturers’ MTDs 6/18/2018)

Opioid Litigation: State Courts-Jurisdictional War

- Removal if “complete diversity”(28 U.S.C. § 1332)
- Defendants are citizens where incorporated and where home office located (CA, PA, DE, NY, TX, etc.)
- Plaintiffs add in-state defendants (doctors, clinics)
  - Fraudulent joinder: added party has nothing to do with case, or no possibility of recovery
  - Fraudulent misjoinder: added party is connected to case, but not needed to resolve this action
  - Inconsistent results (e.g. WV, Fourth Circuit)

Opioid Litigation: State Courts-Jurisdictional War

- Even if no "complete diversity," AG's *parens patriae* suit avoids federal removal (*AU Optronics,* SCOTUS 2014); *however--*
- Removal if "Federal Question"- "arising under the . . . laws . . . of the United States" (28 U.S.C. §1331)
  - OK AG battling FQ removal – referenced CSA
  - AGs in NM, DE and WV have all defeated FQ removal
- "Federal Person"- suit is essentially action against federal entity (ie VA purchased and distributed opioids)

Opioid Litigation: The Federal MDL

- 2014-Chicago first large city to file (removed to N.D. Ill.)
- 2017-Dozens of cases, MDL formed: *In re National Prescription Opiate Litigation* (17-md-2804, N.D. Oh.)
- Judge Dan Aaron Polster – activist, seeking resolution
  - Structure: 3 co-leads, 16-member PEC, liaison group
  - Early push for settlement talks, including state AGs
  - At 6/26/2018, 40 CTOs: 857 federal cases to MDL*
    - MDL stays local cases, except remand actions

Opioid Litigation: MDL Case Management-Evidence

- DEA "ARCOS" Data (2006 - 2014) provided to all parties
- *City of Chicago* documents/ESI from all defendants provided to all parties
- Depositions: strict calendar, limits-number and time
- 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."

Opioid Litigation: MDL Case Management-Timing

- "Track One" - 3 Ohio cases (*Summit, Cuyahoga, Cleveland*): trial begins 3/1/2019
- Ohio and Illinois (*Summit, Chicago*): complaints by 4/25/2018, motions to dismiss by 5/25/2018
- West Virginia, Michigan and Florida (*Cabell, Monroe, Broward*): complaints 4/25/2018, MTD 6/8/2018
- Alabama: complaint 5/9/2018, MTD 6/18/2018
- Tribes: complaint 7/9/2018, MTD 8/6/2018
- Hospitals/Third-Party Payors: select by 5/11/2018

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

"Municipal corporations are established for purposes of local government, and, in the absence of specific delegation of power, cannot engage in any undertakings not directed immediately to the accomplishment of those purposes." *City of Miami Beach v. Fleetwood Hotel, Inc.,* 261 So.2d 801 (Fla. 1972).

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

"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 County*)

"Even if Plaintiff's claims were otherwise viable, the 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- Municipal Cost Recovery (*Broward County*)

"In Florida, as elsewhere, the government may not seek 'reimbursement for expenditures made in its performance of governmental functions' absent 'express legislative authorization.'" (*Penelas v. Arms Tech., Inc.*, 1999 WL 1204353, at *4 (Fla. Cir. Ct. Dec. 13, 1999), aff'd, 778 So.2d 1042 (Fla. Dist. Ct. App. 2001).

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

"[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 County, MI*)

"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 claim."

Opioid Litigation: MDL - Early Indications?

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

- **Fraud: "defendants' argument that the plaintiffs must allege and prove 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: MDL - Early Indications?

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."

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"—back to 2008)
- Are there resources/processes to marshal the data?
- Effect on operations? (litigation hold, etc.)
- Will the municipality actually receive funds for use in attacking the problem (Tobacco MDL-funds not sent to localities, low percentage used to curb smoking)

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**
  - **State-specific fraud and false claims laws**
  - **Not lost among 1000+ plaintiffs-differing size/damages**
  - **More direct contact with defense counsel**

Where to File

- **In-state disadvantages:**
  - **Unless consolidated with other state actions (as in AR, TX, NY, CT), results in dozens of duplicative and competing suits**
  - **MDL will still exert influence**
  - **Smallest jurisdictions cannot afford own actions**
  - **Local counsel may not have experience or resources**
  - **If AG action, will recovery get to municipalities?**

Where to File

- **Federal/MDL advantages:**
  - **Judge Polster's activist approach—first trials set for March 2019, rigorous push for settlement**
  - **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**
  - **Subsequent filers can mimic/join action**

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**
  - **Might forego benefits of state-specific fraud and false claims protections**
  - **Will recovery be divided equitably among all municipalities?**
  - **Juries from large Districts, must be unanimous**

Attacking the Problem: Federal

- White House - “public health crisis” 10/2017; set up Commission. 3/2018 - death penalty for dealers
- DEA - Move fentanyl and analogues to Schedule I
- FDA - Remove opioid ads 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 - $1 Billion divided among:
  - $300 million-medications for opioid addiction
  - $300 million-first responder training/naloxone
  - $200 million-long-term recovery programs
  - $100 million-pregnant/postpartum women
  - $100 million-criminal justice and education

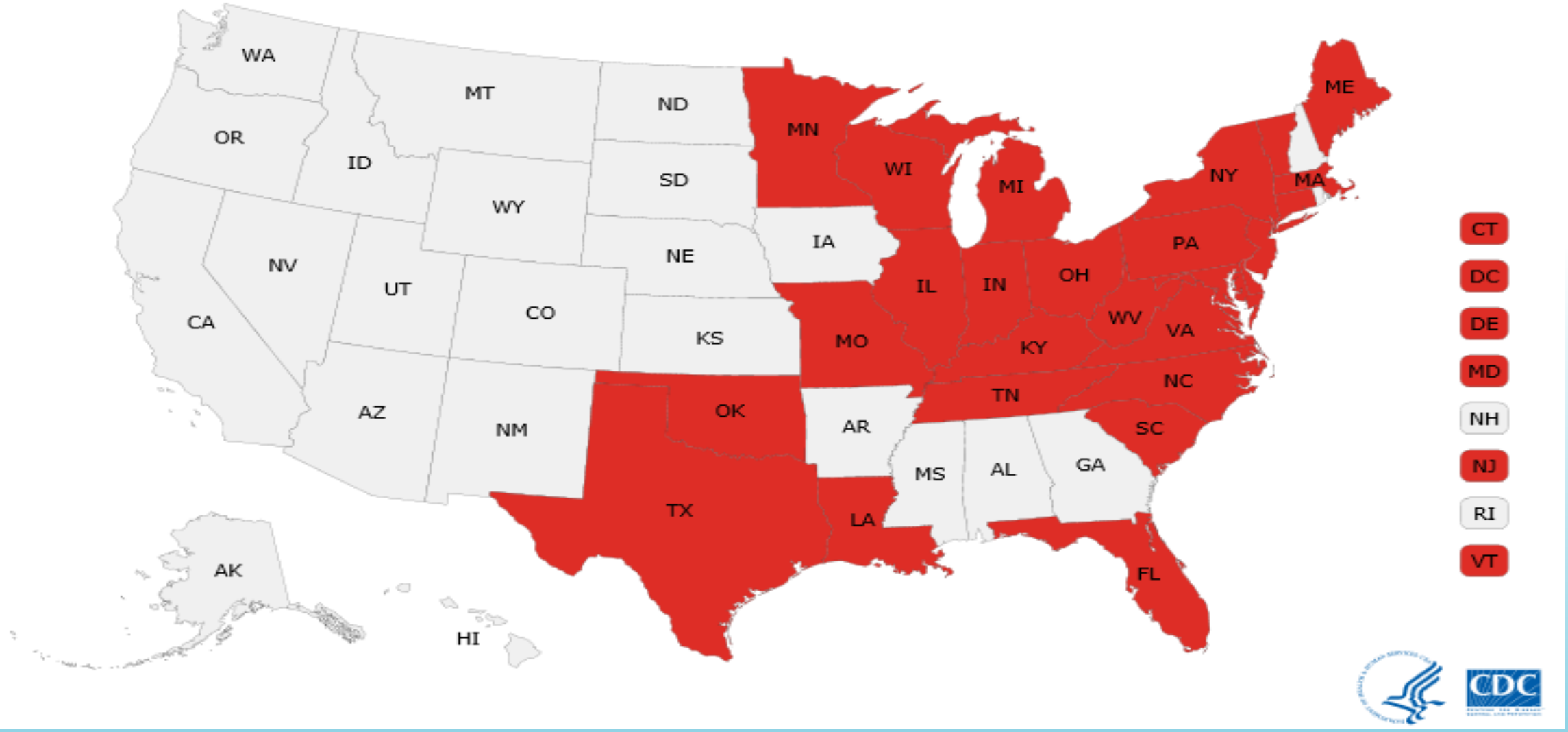
Attacking the Problem: Federal

- How to Spend $100 Billion on the Opioid Crisis
  - Treatment - 47%
  - Demand - 27%
  - Harm Reduction - 15%
  - Supply - 11%

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

States with significant opioid death increase 2015-2016:



Attacking the Problem: States

- State Solutions
  - 6 states including FL declared public health crisis
  - AL-State of Alabama Opioid Action Plan 12/2017 http://www.mh.alabama.gov/Downloads/CO/AlabamaOpioidOverdose_AddictionCouncilReport.pdf
  - NJ-Gov. Christie initiatives
  - NY-“Healing New York” program
  - DE-Opioid Guidelines for Healthcare Providers http://www.helpisherede.com/Content/Documents/Prescription_Opioid_Fact_Sheet_for_Providers.pdf

Attacking the Problem: States

- State Solutions
  - 49 states now require PDMPs (except MO)
  - 28 states now impose caps on opioid prescriptions
  - NE - HB 931: 7 day maximum for 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

Attacking the Problem: States

- Florida Solutions
  - 2009-PDMP law: prescribers must report in 7 days- but do not have to consult PDMP before prescribing
  - 2010-FL was home to 98 of top 100 prescribers (DEA)
  - 2018-HB 21 - E-FORCSE: beginning 7/1/2018, dispensers must report by close of next business day; prescribers must consult PDMP for age 16 and older
  - Must designate “acute pain” or “nonacute pain” - 3-day limit for acute (7 days via “special exception”)

Attacking the Problem: States

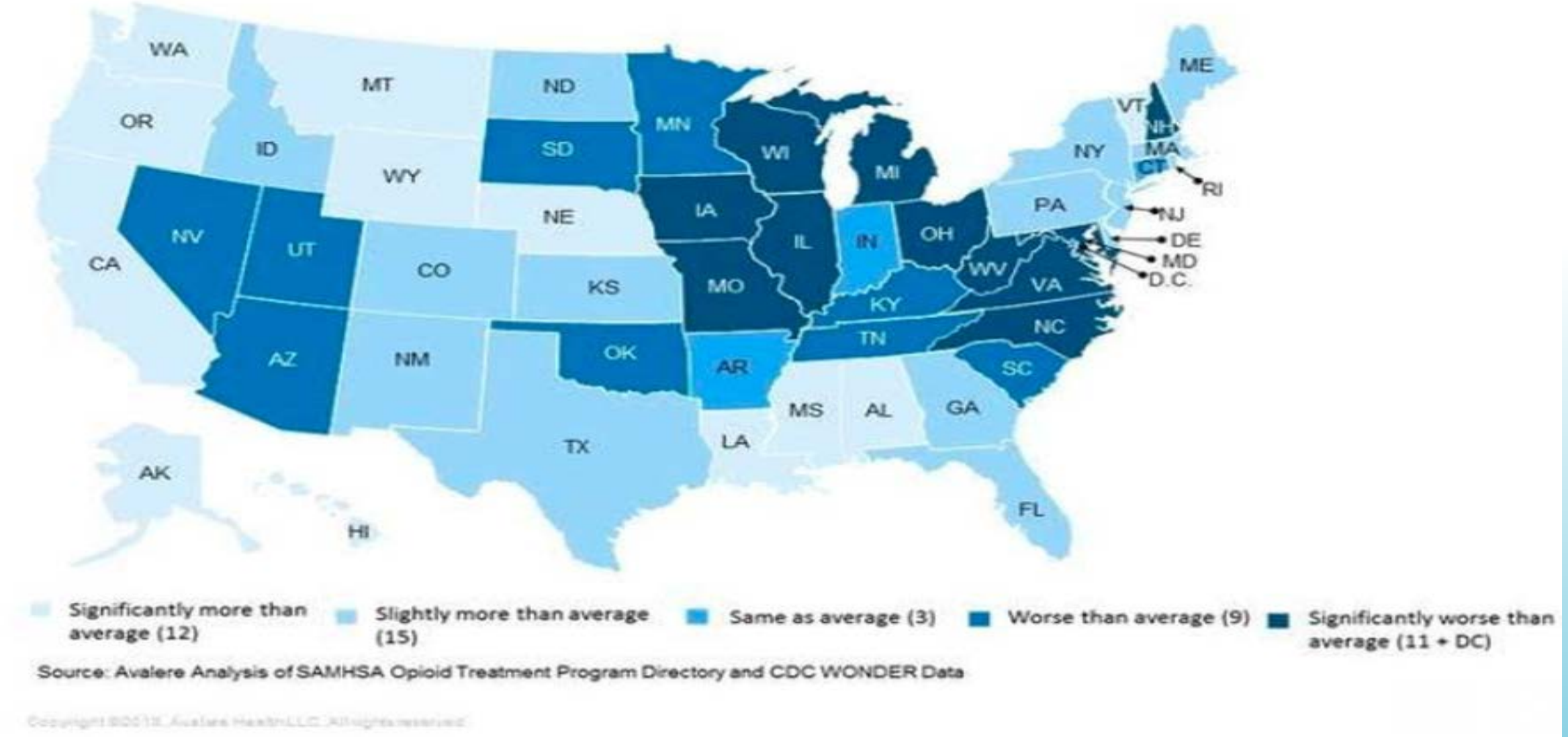
- Florida Solutions, cont'd
  - For traumatic injury, must also prescribe opioid "agonist" (methadone, buprenorphine)--binds to receptor and produces serotonin, but less addictive
  - No limit on prescriptions for chronic pain
  - Effective 1/1/2019, pain clinics (dispense opioids to more than 50% of clients in any month) must register or file for exemption (previously, no need to file)
  - https://flmedical.org/Florida/Florida_Public/Docs/FMA-Opioid-HB21.pdf

Attacking the Problem: States

Opioid prescriptions declined more than 10% in 2017

Work to be Done:

Ratio of buprenorphine providers to overdose deaths



Work to be Done:

Work to be Done:

Counties with highest PDMP utilization rates

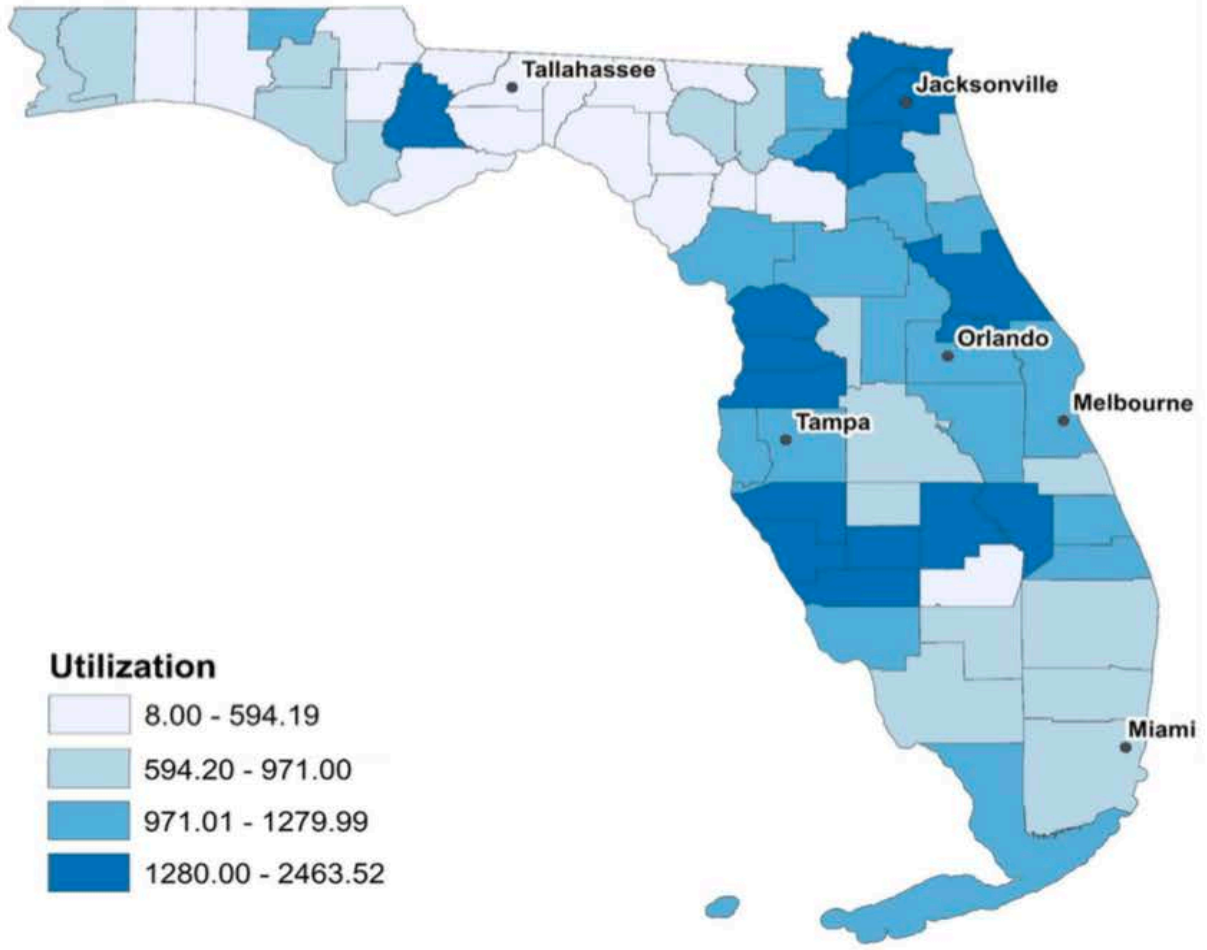


Figure 4(e) The highest PDMP utilization rates are concentrated in urban areas and near large health systems.

Work to be Done:

Counties with highest controlled substance prescribing

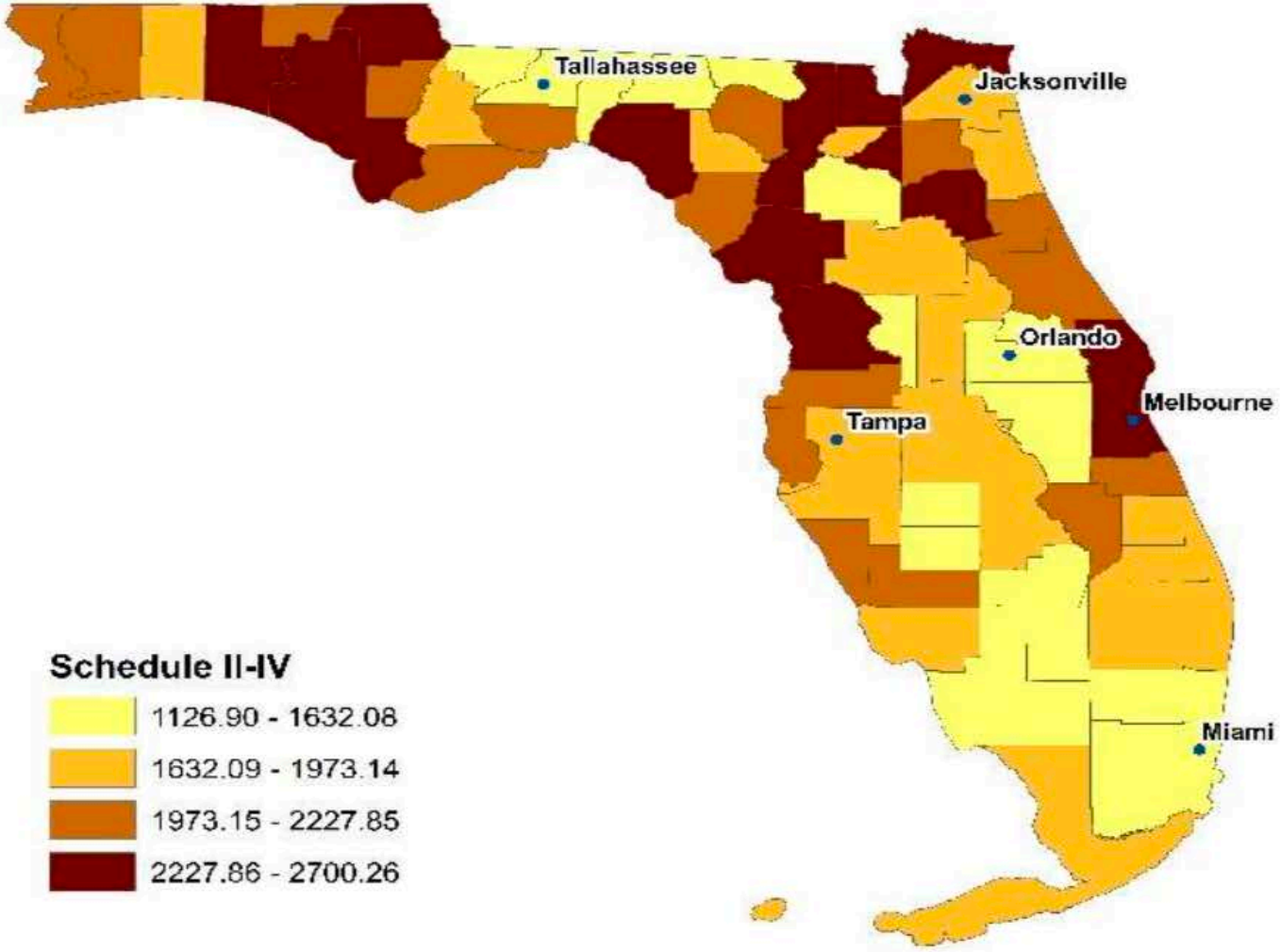


Figure 4(a) Schedule II-IV controlled substance prescribing is highest in the Panhandle, rural areas of north Florida and the Melbourne area.

Work to be Done:

How Much Will Kill You? Photo Courtesy Bruce Taylor, New Hampshire State Police Forensics Laboratory

Work to be Done:

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

Thank you-

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