

The background features a dark blue gradient with a starry space pattern. Overlaid on this are several technical diagrams, including circular gauges with numerical scales (e.g., 140, 150, 160, 170, 180, 200, 210, 220, 240, 250, 260) and various circular arrows, some solid and some dashed, indicating motion or flow. The text is centered in a clean, white, sans-serif font.

# THE OPIOID EPIDEMIC IN RURAL KENTUCKY: RISK ENVIRONMENTS & BUPRENORPHINE DISPENSING

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NOVEMBER 2 2019

# OVERVIEW

- Background:
  - The implementation chasm for buprenorphine
- CARE2HOPE methods and results
- Conclusions: Recommendations to support dispensing

# IMPLEMENTATION CHASM FOR BUPRENORPHINE

- Buprenorphine is a partial opioid agonist
- Effective treatment for opioid use disorder (OUD)
- Reduces vulnerability to HIV, HCV, overdoses, and other drug-related harms
- Available in office settings without long period of abstinence

# IMPLEMENTATION CHASM FOR BUPRENORPHINE

- Significant implementation chasm for evidence-based OUD treatment in the US
  - 20% of people living with a substance use disorder (SUD) received specialty treatment in the past year
- Chasm worse in rural areas
  - 30% of rural residents live in a county without a buprenorphine provider, compared with only 2.2% of urban residents. (Andrilla, Moore, Patterson, & Larson, 2019)

# IMPLEMENTATION CHASM FOR BUPRENORPHINE

- Several federal initiatives to close this chasm
  - 2016: Comprehensive Addiction and Recovery Act (CARA)
    - Expanded categories of health professionals permitted to prescribe buprenorphine
    - → between 2012 to 2017, per capita waived providers doubled in rural counties.(Pew Charitable Trust, 2019)
  - 2018: SUPPORT for Patients and Communities Act
    - Made these expansions permanent

# IMPLEMENTATION CHASM FOR BUPRENORPHINE

- These initiatives assume that pharmacists will dispense buprenorphine
  - Emerging evidence from Appalachia suggest that this assumption may not be correct in these rural areas
    - Thornton et al, 2017: 46% of West Virginian pharmacists did not stock buprenorphine, and 25% did not stock buprenorphine/naloxone
    - Ventrucelli et al 2019: Tennessee-based physicians express frustration with pharmacists who refuse to dispense their buprenorphine prescriptions

# IMPLEMENTATION CHASM FOR BUPRENORPHINE

## Research Question:

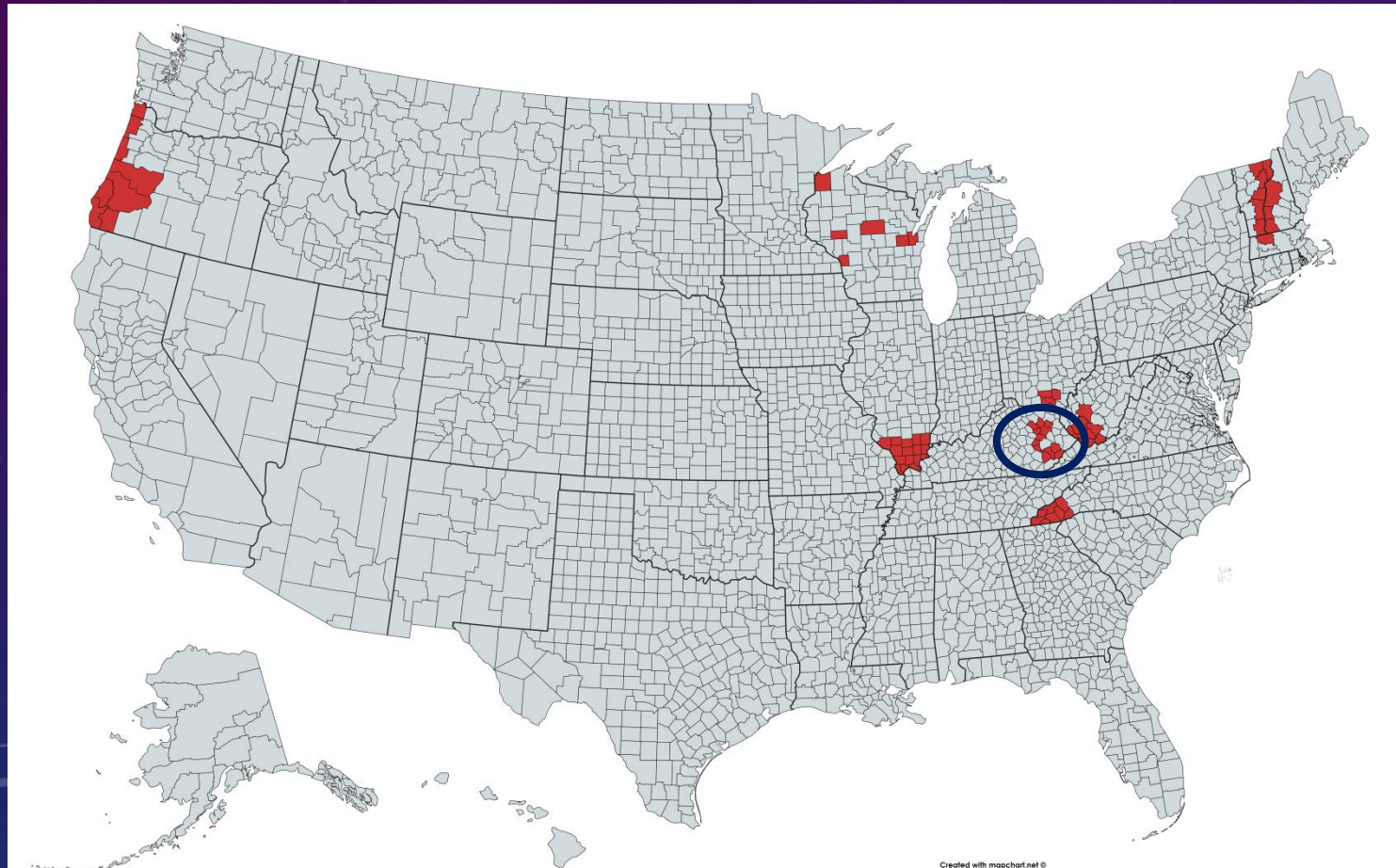
- What are the buprenorphine dispensing attitudes and practices of pharmacists in Appalachian Kentucky, and how are these attitudes and practices shaped by their risk environments?

# CARE2HOPE OVERVIEW

The background is a dark blue gradient with a subtle pattern of small white dots. On the right side, there are several technical diagrams: a large circular gauge with a scale from 80 to 210, a smaller circular gauge with a scale from 100 to 140, and a circular diagram with concentric dashed lines and arrows. In the bottom left corner, there is a partial circular diagram with a dashed arrow pointing left.



# RURAL OPIOID INITIATIVE (ROI)



- 8 rural sites
- Funded by NIDA, the CDC, SAMHSA, and the Appalachian Regional Commission

# CARE2HOPE

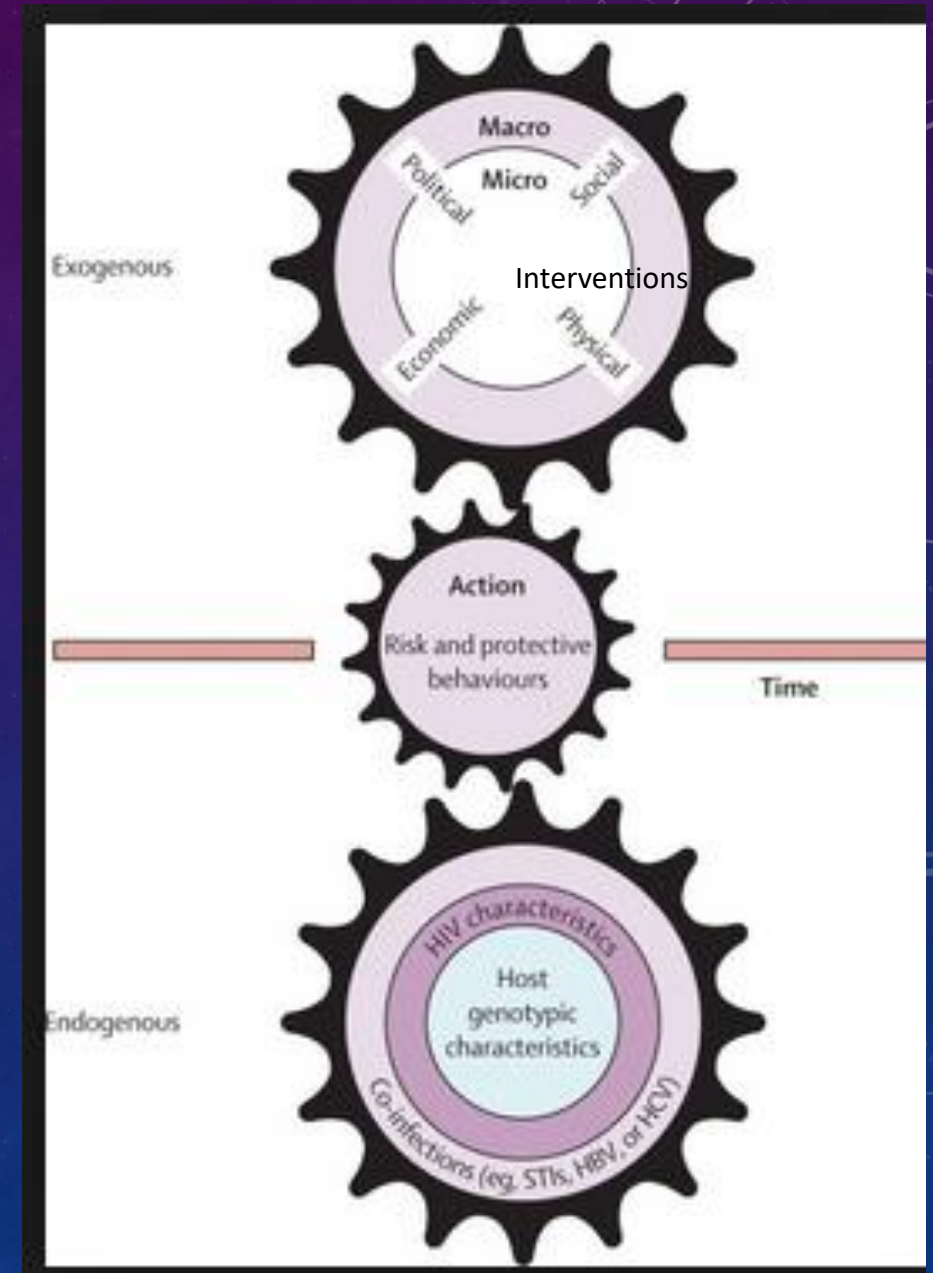
- CARE2HOPE was designed, in part, to:
  - Partner with community coalitions to assess (1) the local opioid epidemic in each county, and (2) the resources and needs of each county's risk environment.
  - Based on these assessments, implement evidence-based public health interventions in each county to address the local opioid epidemic. A stepped-wedge community randomized trial design with continuous quality improvement will be used.

# CARE2HOPE

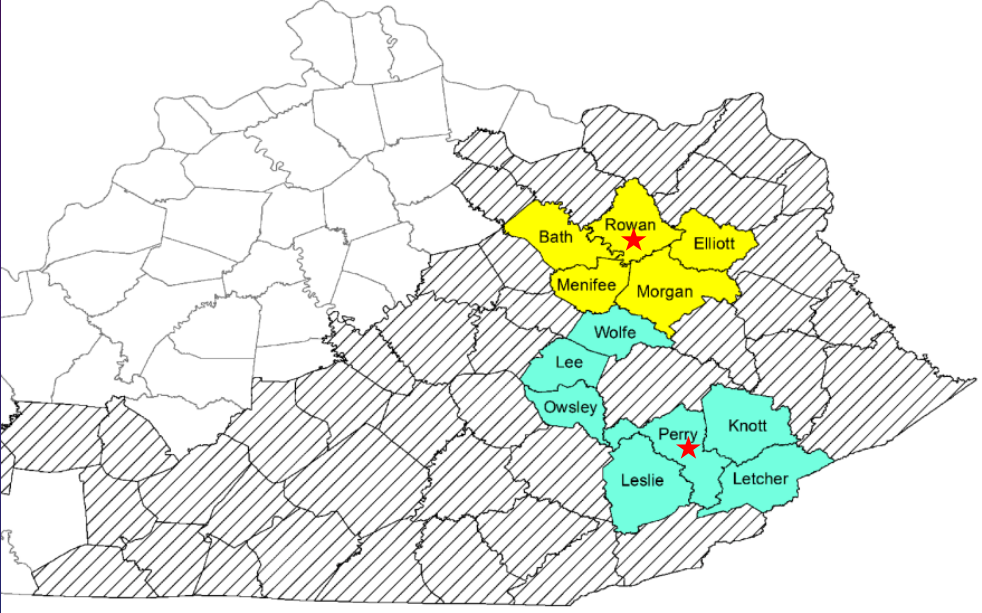
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# RISK ENVIRONMENT MODEL

- Multilevel conceptual model
- Domains
  - Political
  - Social
  - Economic
  - Physical
  - Healthcare/criminal justice interventions
- Levels
  - Macro
  - Micro
- Intersections across domains & levels to shape vulnerability & resilience to HIV

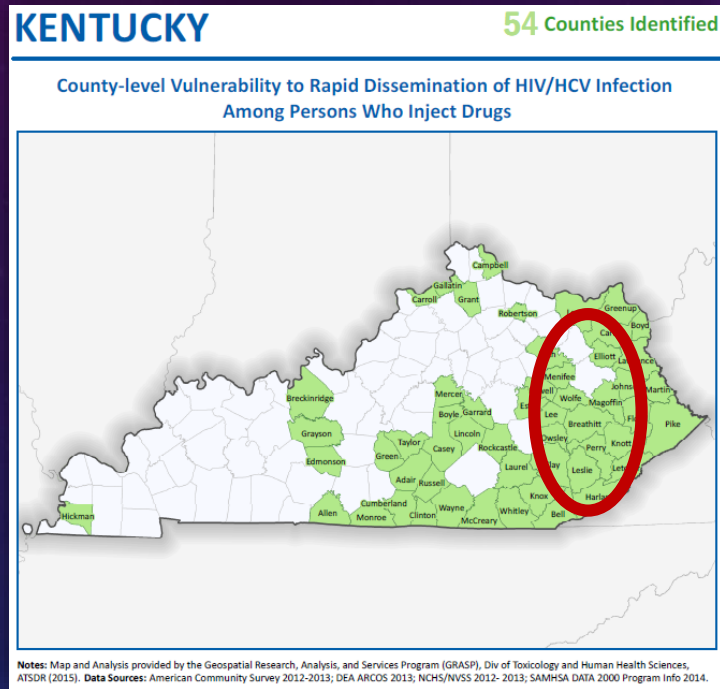


# CARE2HOPE



- ★ CARE2HOPE Field Offices
- Gateway Health District
- Kentucky River Health District
- Appalachia

# CARE2HOPE



- CDC Vulnerability assessment rankings for CARE2HOPE counties
  - **Wolfe** ranked 1st
  - **Perry** ranked 4<sup>th</sup>
  - **Leslie** ranked 8<sup>th</sup>
  - **Owsley** ranked 12<sup>th</sup>
  - **Knott** ranked 17<sup>th</sup>
  - **Lee** ranked 30<sup>th</sup>
  - **Menifee** ranked 31<sup>st</sup>
  - **Letcher** ranked 50<sup>th</sup>
  - **Elliott** ranked 56<sup>th</sup>
  - **Bath** ranked 125<sup>th</sup>

# CARE2HOPE SETTING

*Table 1. Description of the 12-county Gateway and Kentucky River (GKR) Health Districts*

County Characteristics	Kentucky River District Counties						Gateway District Counties					
	Perry	Leslie	Knott	Letcher	Owsley	Lee	Wolfe	Menifee	Morgan	Elliott	Bath	Rowan
Pop/sq mi <sup>32</sup>	84.5	28.2	46.5	72.6	24.1	37.8	33.1	31	36.5	33.5	41.6	83.4
Poverty rate <sup>32</sup>	27.5	33	33.7	30.1	45.1	35	36.2	27.1	30.4	32.4	22.7	23.4
HIV/HCV Vulnerability Rank <sup>1</sup>	4 <sup>th</sup>	8 <sup>th</sup>	17 <sup>th</sup>	50 <sup>th</sup>	12 <sup>th</sup>	30 <sup>th</sup>	1 <sup>st</sup>	31 <sup>st</sup>	--	56 <sup>th</sup>	125 <sup>th</sup>	--
Coal-producing, 2014 <sup>11,12</sup>	√*	√*	√*	√*	√ (2012)	√	√	--	√ (2009)	√	--	--





# WOLFE COUNTY, KY



# METHODS



# METHODS

- Case study approach
  - Explore dispensing practices and attitudes in multilevel context of the local risk environment
  - Mixed methods
    - Conducted and analyzed qualitative interviews with pharmacists → identified salient features of the risk environment
      - Perceived “DEA cap”
      - Pharmaceutical company marketing of opioid analgesics and physician overprescribing
      - Intense war on drugs
    - Gathered and analyzed existing data to describe these features

# METHODS

- Qualitative interviews with pharmacists
  - Conducted between Feb 2018-Jan2019
  - Purposively sampling pharmacists
    - County representation
    - Independent + chain
  - 1-1 semi-structured interviews conducted by trained C2H staff
  - Private location, \$10 incentive
  - Covered perceptions of the local opioid epidemic, and harm reduction practices, attitudes, and barriers.
  - Transcripts analyzed using thematic methods

**Table 1. Risk environment data sources**

<b>Risk Environment Feature</b>	<b>Data source(s)</b>
DEA cap	(1) Kentucky and federal statutes, regulations, and case law governing pharmacist dispensing of buprenorphine; (2) Media and grey literature on enforcement
Opioid analgesic marketing and resulting overprescribing	(1) Kentucky Attorney General lawsuits against pharmaceutical companies (2) Center for Medicaid and Medicare (CMS) data on opioid-analgesic marketing expenditures by pharmaceutical companies (2013-2015) (3) KY PDMP data on opioid analgesic dispensing (2017)
War on drugs	(1) Vera Institute of Justice Incarceration trends database (1980-2015) (2) Gateway2Health survey data (2018-present)

# METHODS

- Analyses
  - Thematic analysis methods for textual data
  - Descriptive statistics for quantitative data
  - Case memos

## RESULTS

I. Setting

II. DEA cap

III. Opioid analgesic “OA” marketing & OA prescribing

IV. War on drugs

# RESULTS

- Achieved saturation with a sample of 14 pharmacists
  - Operated 15 pharmacies in nine of the 12 counties
  - 2/3rds were men; all identified as non-Hispanic White
  - Deep roots in the community
- Only able to interview one pharmacist at a retail pharmacy chain
- Pharmacists constituted >70% of all retail (i.e., non-hospital based) pharmacies in the 12-county area.



# RESULTS: SETTING

- Celebrated multiple community strengths
  - “Tight-knit” communities where residents are “loyal” and “trustworthy” people
  - Residents are “kind” and “took care” of one another
- Operate “hometown pharmacies”

“These people, I know their kids’ names. I know that they got a dog last week. I know what the dog’s name is, that they are going out of town to visit their grandkids.”

# RESULTS: SETTING

- Acutely aware of the local opioid crisis.
  - Pharmacists reported that they still dispensed a high volume of OA prescriptions:  
“it’s incredible, like, the amount of opioids that we [dispense] here, anything from...Oxycodone [to] methadone.”
- Perceived a high prevalence of OUD
  - On average, estimated that 40% of local adults either used opioids to get high or injected drugs
  - Five reported having family members who struggled with some kind of substance use disorder.

## RESULTS: SETTING

- Described multiple social and health harms from the opioid epidemic

Drugs have “hindered what we could become by ...not allowing our community to reach its full potential...who knows what [we] could be if there was not a drug problem?”

# RESULTS

- Buprenorphine dispensing
  - 6 pharmacists dispensed >100 prescriptions/month
  - 5 dispensed 20-50 prescriptions each month

But

- 4 refused to dispense at all, or even stock buprenorphine
- 12 of the 15 pharmacies limited the number of prescriptions they filled

DEA cap

War on  
drugs



OA marketing

DEA cap

War on  
drugs



OA marketing

## RESULTS: DEA CAP

- 10 of the 14 pharmacists discussed a perceived “DEA cap” on dispensing
  - DEA directly monitors the percent of controlled substances that are opioids that each pharmacy dispenses

Opioids  
controlled substances

## RESULTS: DEA CAP

- 10 of the 14 pharmacists discussed a perceive “DEA cap” on dispensing
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Opioid analgesics + buprenorphine

controlled substances

- Buprenorphine included in the percentage calculation
- Five of the 10 pharmacists who discussed the cap reported that they curtailed dispensing to avoid exceeding it.



# RESULTS: DEA CAP

## *Are there 'caps' on buprenorphine dispensing?*

- DEA regulations and the SUPPORT Act require that **wholesalers** create surveillance systems for opioids
  - Require wholesalers to design and implement a system to detect and report **suspicious orders** of buprenorphine and other controlled substances
  - Impose a duty to promptly notify DEA officials of any “suspicious orders”

# RESULTS: DEA CAP

## *Are there caps on buprenorphine dispensing?*

- In response to DEA sanctions and their threat, wholesalers have devised internal systems to detect ‘suspicious orders’.
  - McKesson Corporation:

“Our CSMP (controlled substance monitoring program) uses sophisticated algorithms designed to monitor for suspicious orders, block the shipment of controlled substances to pharmacies when certain thresholds are reached and ultimately report those suspicious orders to the DEA.”

## RESULTS: DEA CAP

- The “DEA cap” was highly salient to the ten pharmacists who discussed it:

“The DEA has a magic number. No one knows what that number is...So everybody says, ‘we’re going to assume that the number is 20%... No one knows, but you want [the percentage of buprenorphine prescriptions you dispense] to be low.”

## RESULTS: DEA CAP

- Five pharmacies set internal caps on dispensing to avoid exceeding this cap of unknown magnitude
- Demand outstripped these caps:
  - [Each new prescription] takes the medicine away from people that have been coming here for a year and a half...

## RESULTS: DEA CAP

- Pharmacists developed rationing systems
  - Limited dispensing to local residents or to long-term customers.

“[Each new prescription] takes the medicine away from people that have been coming here for a year and a half... [I want to support] my people that live...where I work and where I prosper.”

## RESULTS: DEA CAP

- Rationing itself created problems
  - Damaged relationships with local prescribers
  - Endangered pharmacy staff when patients became angry
  - Undermined drug-use cessation efforts

“You can have all the funding in the world to have all these programs to [prescribe] all of these medicines. If your pharmacies can’t physically get it [from the wholesalers], it ain’t doing no good.”

## RESULTS: DEA CAP

- Five pharmacists did not ration
  - Confident that would not exceed the cap
  - Did not want to hinder recovery efforts

“We do not [limit buprenorphine dispensing]...And I don't think we should because...if I limit to 20 individuals a day...then I just don't think that that's fair to the 21<sup>st</sup> person. Because the 21<sup>st</sup> person could be the person that's actually about to get clean.”

# RESULTS: DEA CAP

Why is the “DEA cap” a rural Appalachian issue?

- Rural areas are often home to fewer pharmacies per capita than urban areas (Bissonnette, Goeres, & Lee, 2016; Klepser, Xu, Ullrich, & Mueller, 2011)
  - Appalachia has exceptionally high rates of OUD
- Each existing pharmacy in this setting may thus receive large per capita volumes of buprenorphine prescriptions and approach the cap
- particularly as federal efforts to increase prescribing escalate.



DEA cap

War on drugs



OA marketing

DEA cap

War on drugs



OA marketing

- KY AG lawsuits
- CMS data on pharma company payments to prescribers for OA prescriptions
- PDMP data on OA prescribing patterns

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Misleading messages about OA risks and purpose saturated KY physicians professional environments
  - Addiction risk “modest” and “manageable”
  - Could screen to identify patients at risk of OUD
  - No withdrawal risk if dosed <60 mgs
  - Less euphoria than other OAs

“Quick[ly] reminded him that Oxy gives flat blood levels, so less buzz than Lortab.”

“[The physician] loves the idea of getting effective pain relief, but not euphoria to get rid of druggies”

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Aggressive sales tactics in KY
  - Teva salespeople visited Kentucky physicians 3013 times between 2012-2017 to sell Fentura<sup>®</sup>.
  - Purdue salespeople visited each physician in their “territory” every 3-4 weeks to sell OxyContin<sup>®</sup>.
  - InSys salespeople contacted each physician who prescribed a low dose of Subsys<sup>®</sup>, request an explanation, and admonish them for improperly treating pain.

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Aggressive sales tactics
  - Salespeople had strong incentives to sell large volumes of OA
    - Low base salaries + high sales bonuses
    - Job security linked to sales
      - Could not make quota if didn't sell off-label

“Fridays, we literally do half in sales as the other 4 days. Every rep that does not produce a script two consecutive Fridays will be placed on a [performance improvement plan]...Below is the list [of salespeople] that failed to produce this past Friday, if you are on the list you must produce 1 single script this Friday to avoid a [performance improvement plan.]”

- 2013 email, sent by the InSys Vice President of Sales to sales managers

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Physician compensation
  - Speakers Bureaus
  - Paid clinical staff
  - Staffed clinics for free

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- High per capita payments to physicians documented in the CMS data for the 12-county C2H area
- Between 2013-2015: \$421,468 flowed from pharmaceutical companies to local physicians
  - \$2712.35 per 1000 residents
  - US national average: \$1.57 per 1000 residents, 0.06% of the value for the 12-county region.

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Very high rates of OA dispensing in these counties
  - 136.9 OA prescriptions per 100 residents in these 12 counties in 2017
  - Nationally, 58.7 prescriptions per 100 residents in 2017



# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Disbelieved claims that buprenorphine was a legitimate treatment for OUD

“It is supposed to be the drug to help them [recover]. They want Suboxone<sup>®</sup> worse than they do the hydrocodone...It’s not what it’s designed to be.”

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

## Low Trust: OA prescribing

- Distrust physicians
  - Poor stewards of OAs
  - Motivated by greed

## Low Trust: Buprenorphine prescribing

- Distrust physicians
  - Poor stewards of buprenorphine
  - Motivated by greed

“It's almost like more of a greed thing... Especially if the same doctor decides that you're addicted to the hydrocodone or whatever, and decides to put you on Suboxone<sup>®</sup>, and when they've written [the OA prescription] for the last 10 years.”

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- Potent implications for buprenorphine dispensing
  - 3 low-trust pharmacists refused to stock buprenorphine at all
  - 2 refused to accept new buprenorphine patients

“Since we have seen the increase in the amounts [of buprenorphine] that’s being prescribed...we do try to limit [dispensing] to those [patients] that we initially started filling for. We try not to pick up any new ones because it is such an abused [drug].”

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- High-trust group (N=8)
  - Continued to express trust in prescribers
    - Did not blame them for the OUD epidemic
      - “I don’t think the majority of [the doctors] knew...[that they were] contributing, that it was going to get as bad as it did. I believe that.”
  - Believe buprenorphine is a legitimate treatment for OUD

Buprenorphine is “...a tool to help you get off [opioids...or you can] take it forever...This will make you a better wife, husband, employee, whatever. I’ve seen people turn their life around and function.”

# RESULTS: OPIOID ANALGESIC MARKETING & OVERPRESCRIBING

- High-trust pharmacists dispensed buprenorphine and accepted new patients
- Four limited dispensing to align with the “DEA cap”
  - Limit to patients who lived in the community or to known prescribers
  - Ambivalent about these limits
- Four did not limit dispensing at all

DEA cap

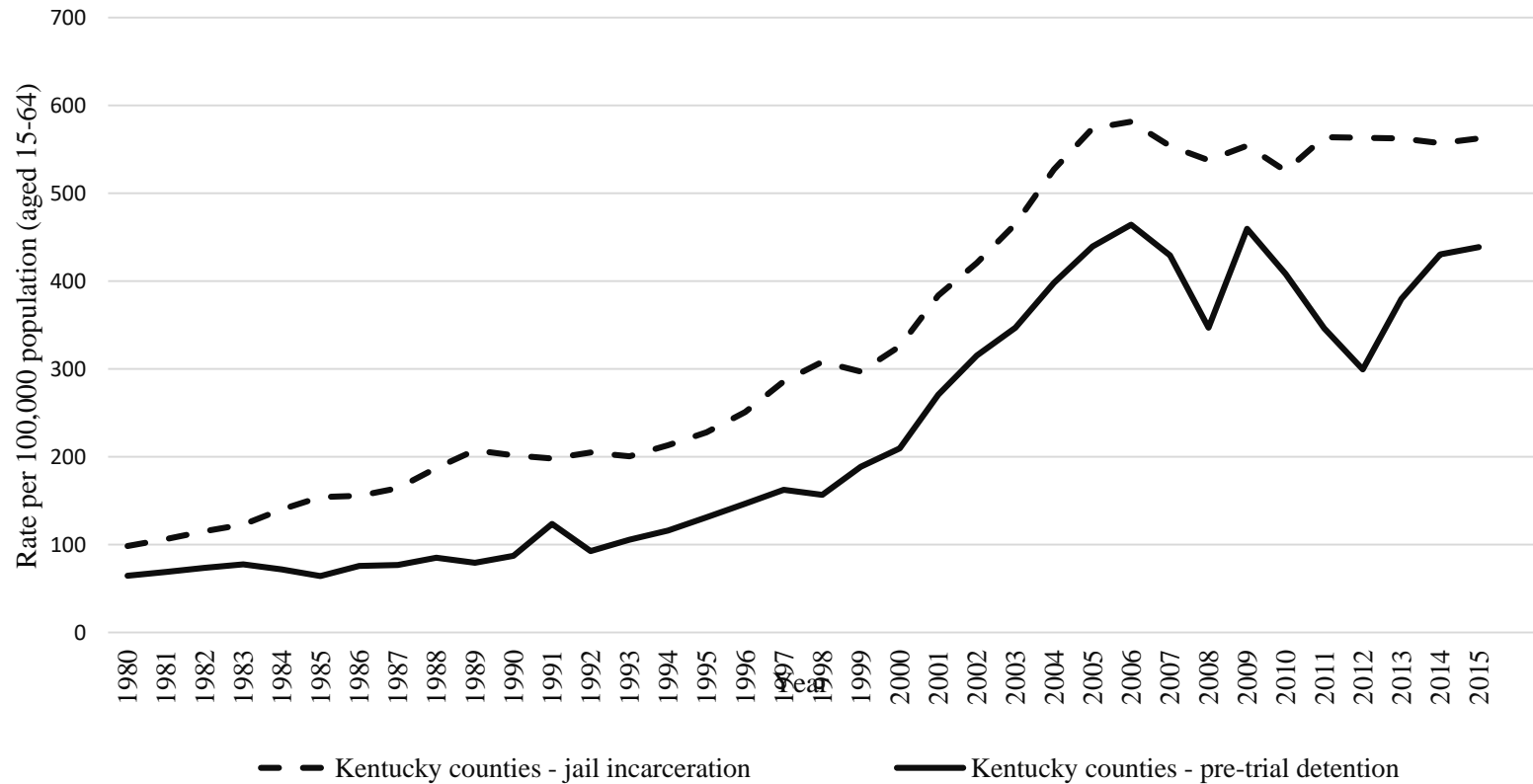
War on  
drugs



OA marketing

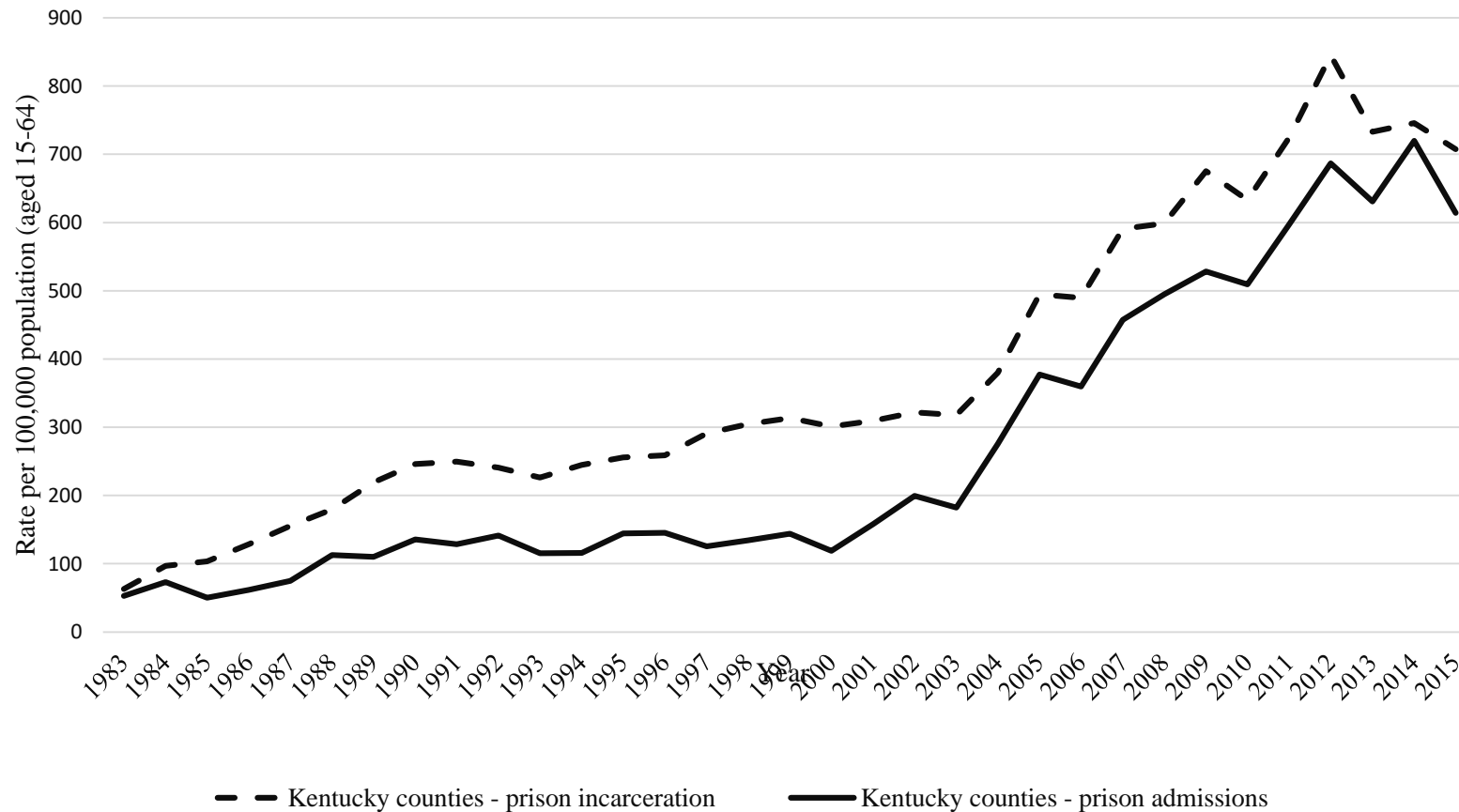
# RESULTS: WAR ON DRUGS

Figure 3: Jail pre-trial detention and incarceration trends for 12 Kentucky counties and the 12 most populous U.S. counties per 100,000 population (aged 15-64), 1980-2015



# RESULTS: WAR ON DRUGS

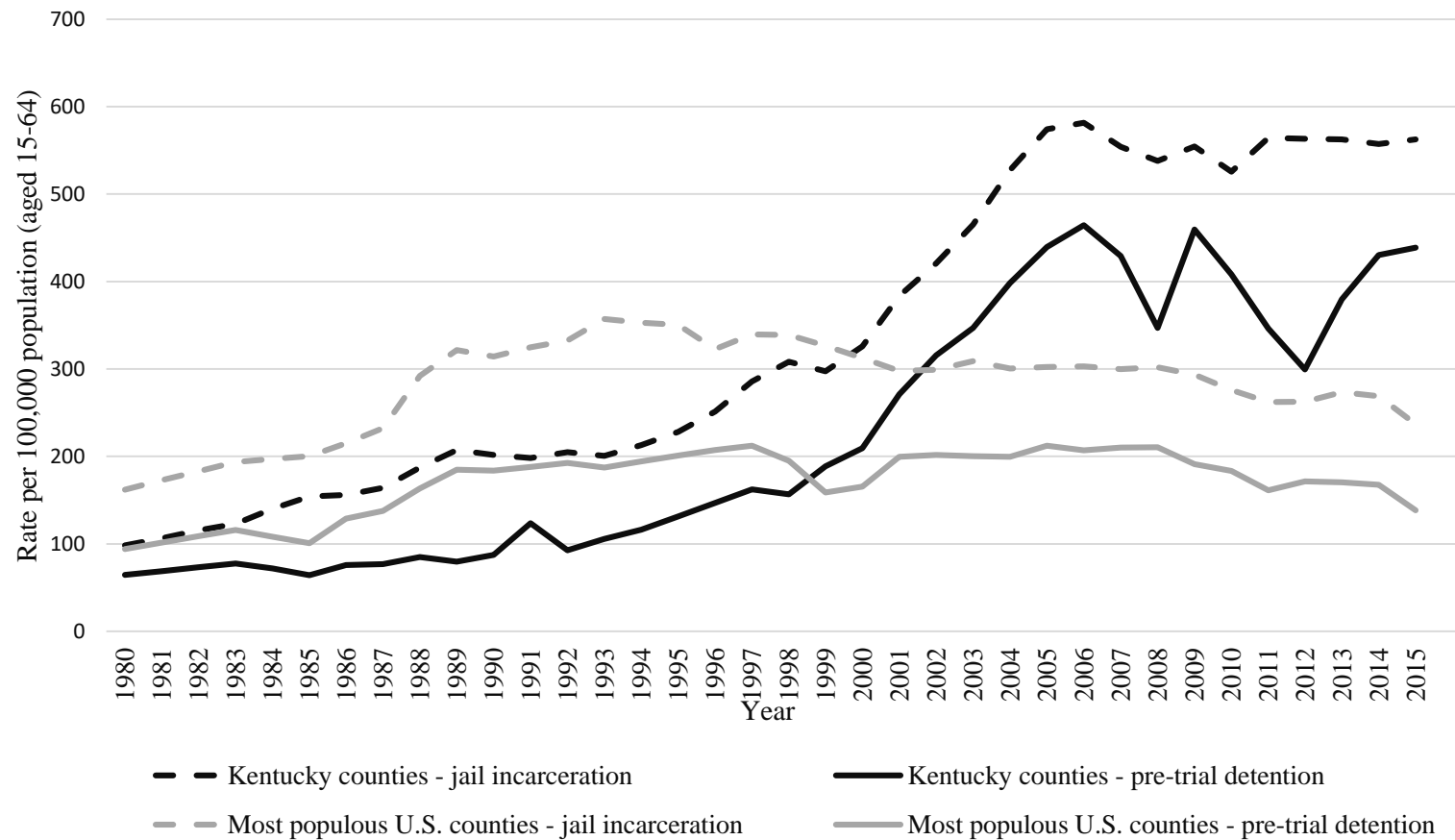
Figure 2: Prison admissions and incarceration trends for 12 Kentucky counties and the 12 most populous U.S. counties per 100,000 population (aged 15-64), 1983-2015



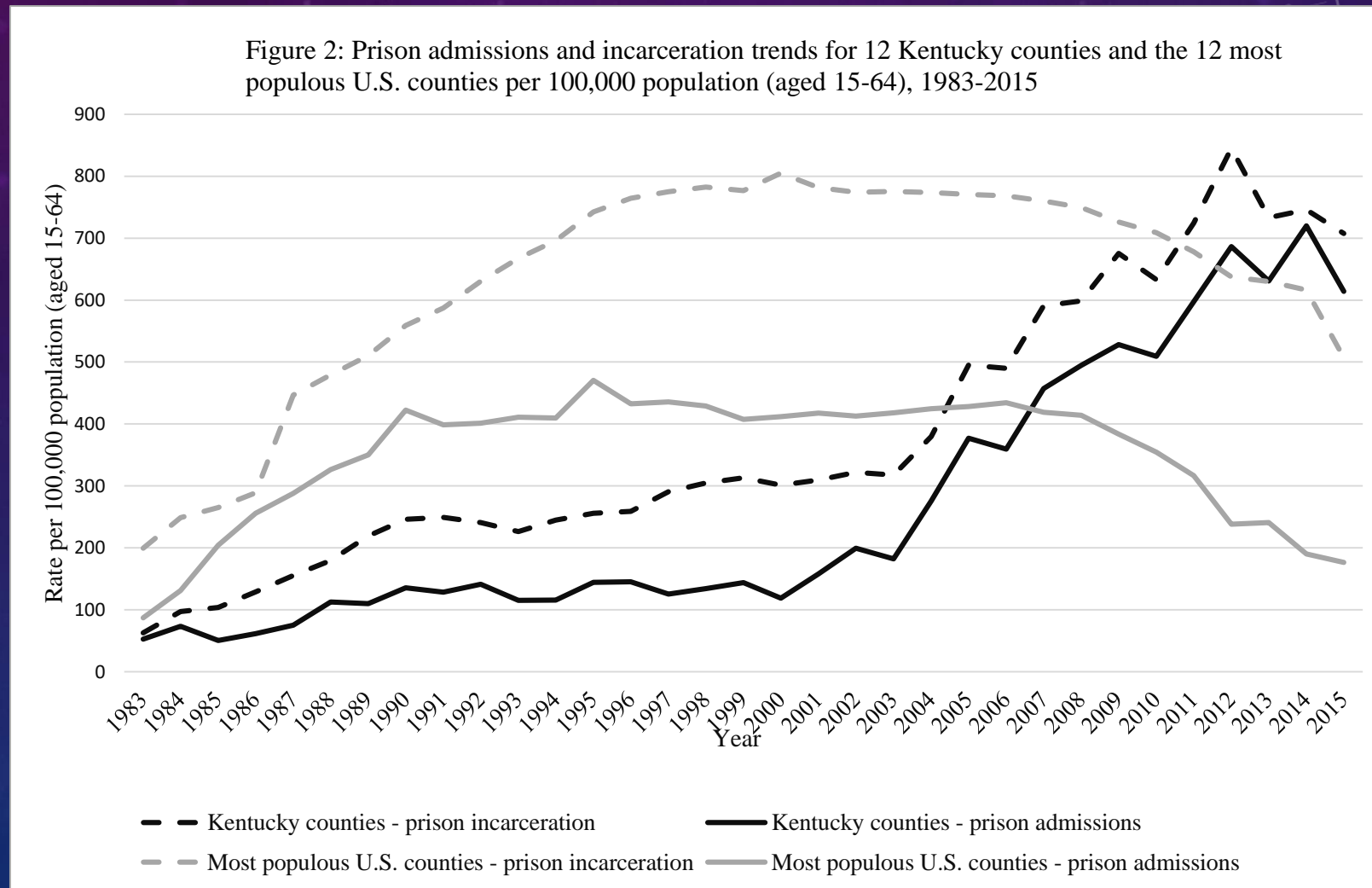


# RESULTS: WAR ON DRUGS

Figure 3: Jail pre-trial detention and incarceration trends for 12 Kentucky counties and the 12 most populous U.S. counties per 100,000 population (aged 15-64), 1980-2015



# RESULTS: WAR ON DRUGS



# RESULTS: WAR ON DRUGS

- Gateway2Health survey data (N=321)
  - 27.4% of the sample reported spending >1 day in jail or prison in the past 6 months
  - 2015 CDC surveillance data with people who inject and live in 20 large US metro areas: 36.5% spent >1 day in jail or prison in the past *year*

# RESULTS: WAR ON DRUGS

- Low-trust pharmacists view people who use drugs as “thieves” and criminals who endangered their tightknit communities
  - Explicitly reject the medical model of OUD

People play the victim a lot – say it’s a “disease.” “Not my fault.” “Evil drug has befallen me.”
  - Focus on diversion and profit from selling buprenorphine
  - Concerned how other customers would react if buprenorphine patients in their pharmacies

“Suboxone<sup>®</sup> draws a certain crowd that I don’t really want to deal with on a daily basis. And I don’t think my regular customers would appreciate coming in here and seeing [them].”

## RESULTS: WAR ON DRUGS

- High-trust pharmacists expressed positive views of buprenorphine patients

- “Commendable” and “brave” to embark on recovery process
- Actively tried to counter own biases

“I feel like there’s no bigger pain in the ass patient than a Suboxone<sup>®</sup> patient. With that said, every time I get fed up with them you’ll see someone that it worked for and it makes you just wonder like are these other people that I’m fed up with close to getting to that point...?”

## RESULTS: WAR ON DRUGS

- High-trust pharmacists embraced a medical model of OUD
  - “it’s a disease and you don’t get to choose.”
- Dispensing aligned with community strengths: a way to lend a helping hand to a neighbor in need

“Our goal here is to serve....If I can help any of the addicts out here, that’s going to serve the whole community.”

# RESULTS

- Negative case
  - High-trust pharmacist who did not stock buprenorphine
  - Reported that “no demand” for it
  - Context may have discouraged dispensing: County had ordinance prohibiting new buprenorphine clinics from opening

# DISCUSSION

## Preliminary recommendations

- Buprenorphine and other MOUD should be *excluded* from DEA and wholesaler monitoring protocols designed to reduce diversion of OAs.
- Professional organizations should convene local meetings of prescribing physicians and pharmacists to restore trust and build shared MOUD norms.



# DISCUSSION

- Preliminary recommendations, Cont'd
  - Multilevel interventions to reduce stigma toward people who use drugs and buprenorphine are needed
  - Expand advocacy efforts to end the war on drugs to include rural areas.
    - Expand research on how this war shapes harm reduction programs, practices, and health in rural areas

# ACKNOWLEDGEMENTS

- We would like to acknowledge
  - The people who took part in this study
  - The Rural Health Study Team
  - NIDA grant R21 DA042727
  - NIDA CARE2HOPE grants
  - The Emory Center for AIDS Research (*P30 AI050409*)

# RESULTS: WAR ON DRUGS

- Gateway2Health data on interpersonal stigma:
  - 2/3rds report somewhat/very true that people were uncomfortable around them because of their drug use
  - 2/3<sup>rd</sup> report that people avoid them because of their drug use
  - 45% of the sample report fearing that friends will reject them because of their drug use
  - 2/3rds report fearing that their family will reject them