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The Current State of the Opioid Crisis

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Disclosures

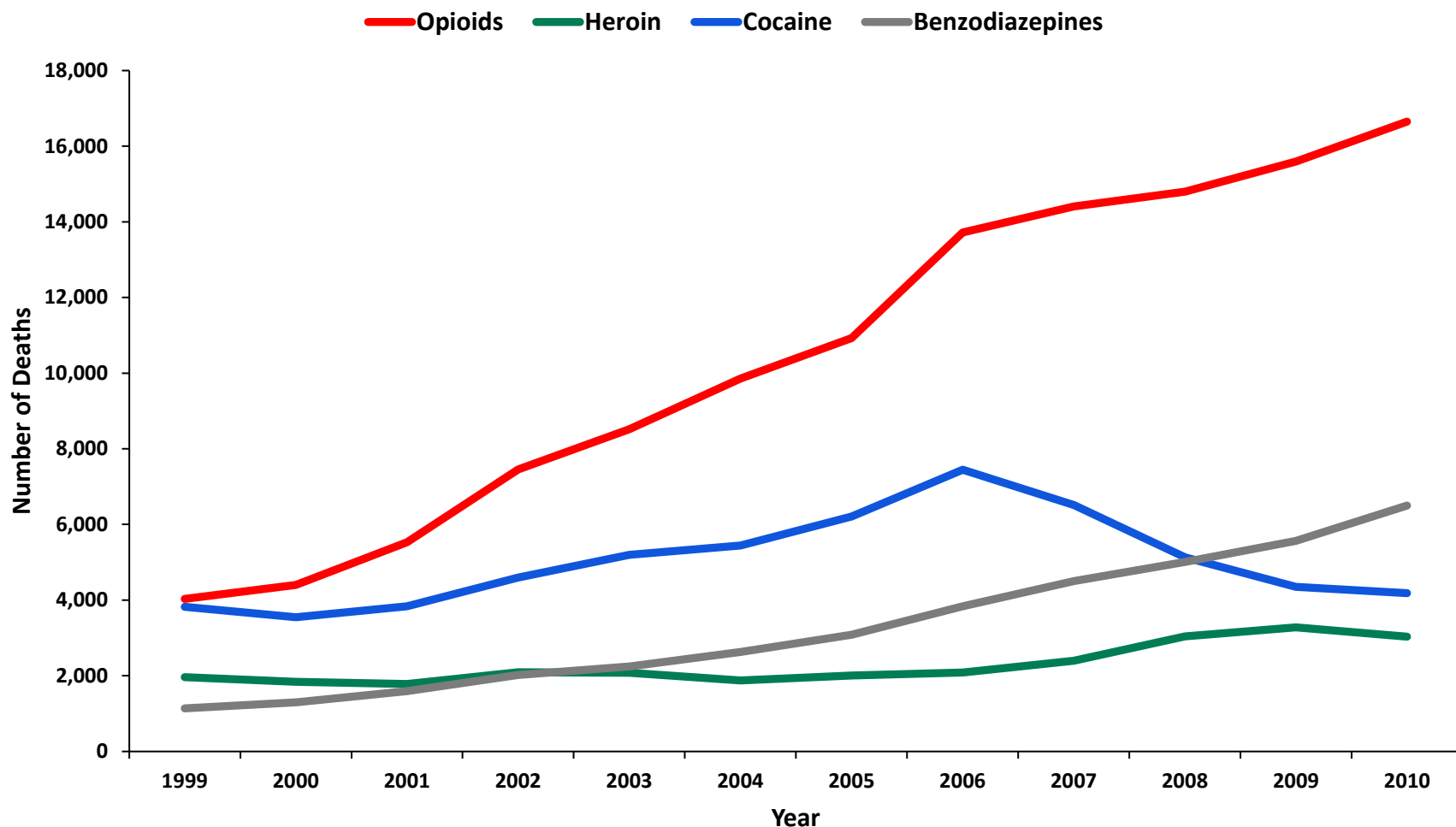
- **Dr. Kolodny has no financial relationships with pharmaceutical companies or other life sciences corporations.**
- **Dr. Kolodny serves as an expert witness against the opioid industry on behalf of government entities.**

*The content of this activity may include discussion of off label or investigative drug uses.
The faculty is aware that is their responsibility to disclose this information.*

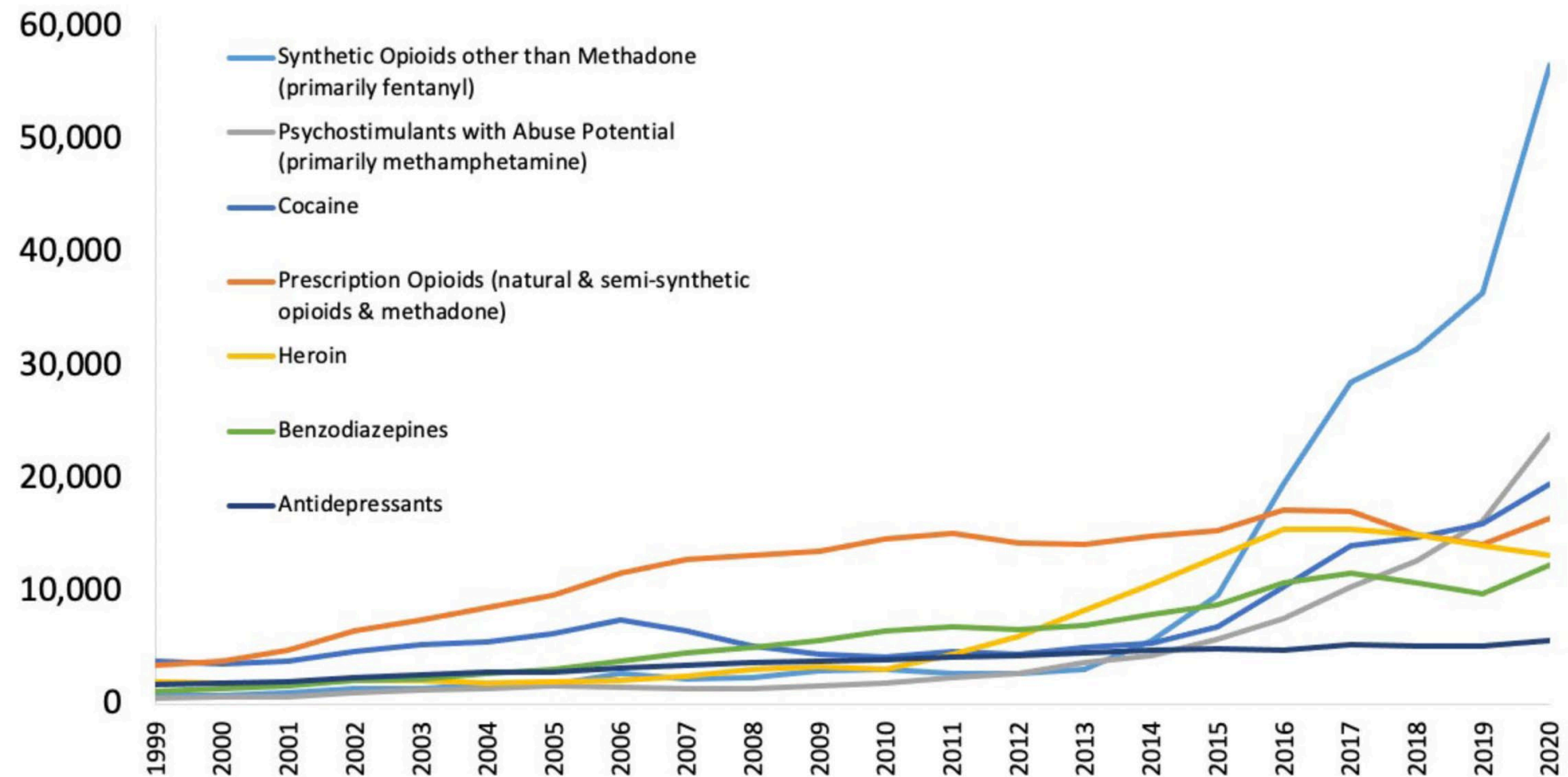
Objectives

- At the conclusion of this roundtable participants will be able to:
- Provide an overview of the national opioid crisis
- Describe the epidemiology of opioid use in the United States
- Review the contributors to the current opioid crisis
- Outline interventions to bring the crisis under control

Drug Overdose Deaths by Major Drug Type, United States, 1999–2010

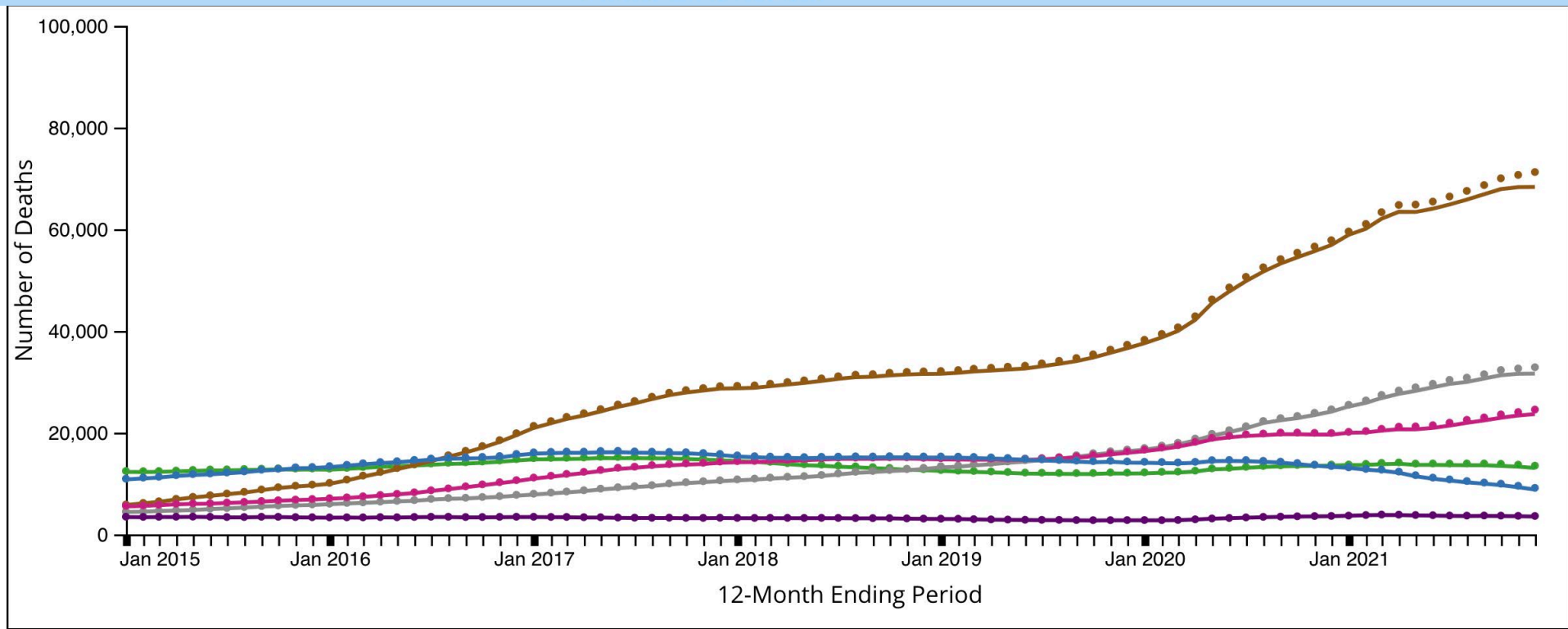


National Drug-Involved Overdose Deaths by Specific Category—Number Among All Ages, 1999-2020



*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database. released 12/2021.

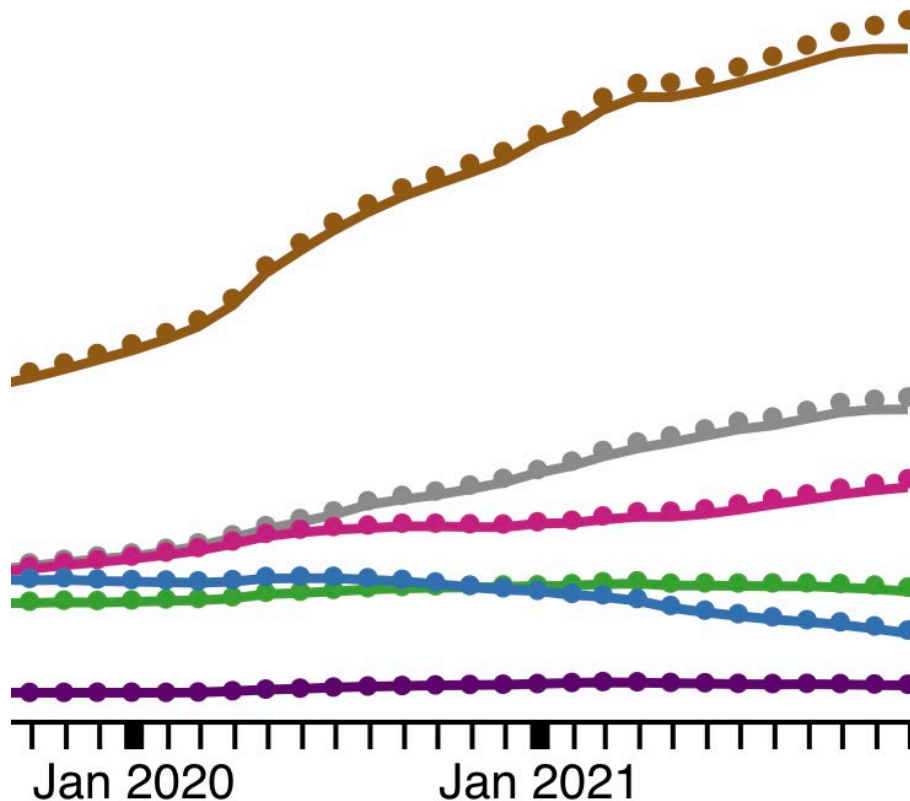
12 Month-Ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Legend for Drug or Drug Class

Cocaine (T40.5)	Synthetic opioids, excl. methadone (T40.4)
Heroin (T40.1)	
Methadone (T40.3)	
Natural & semi-synthetic opioids (T40.2)	
Psychostimulants with abuse potential (T43.6)	

12 Month-Ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



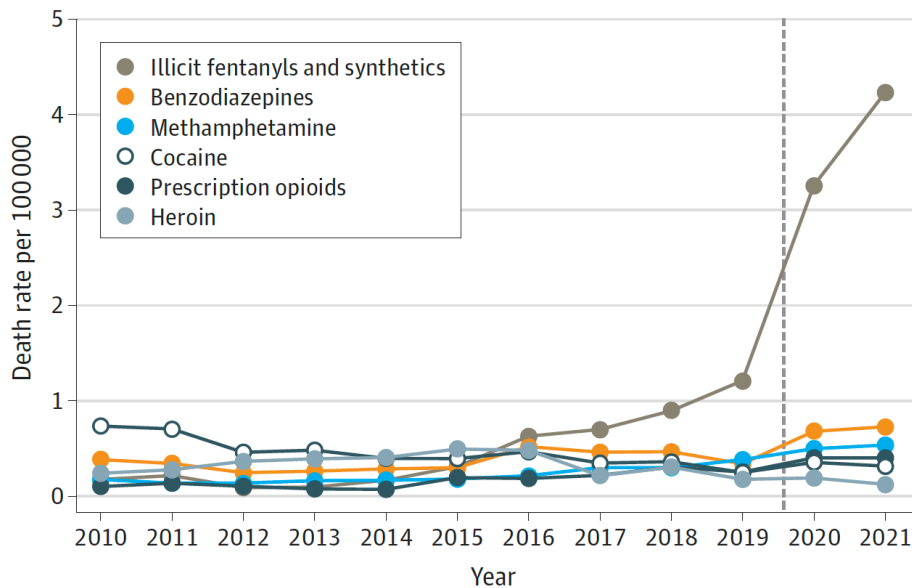
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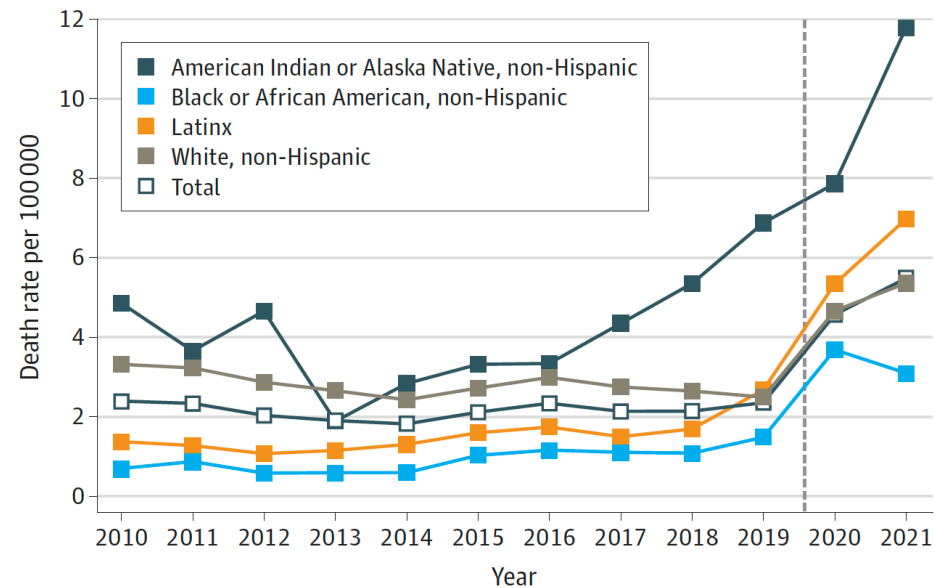
Synthetic opioids, excl. methadone (T40.4)

Figure. Adolescent Overdose Deaths, 2010-2021

A Overdose mortality among adolescents by substance type



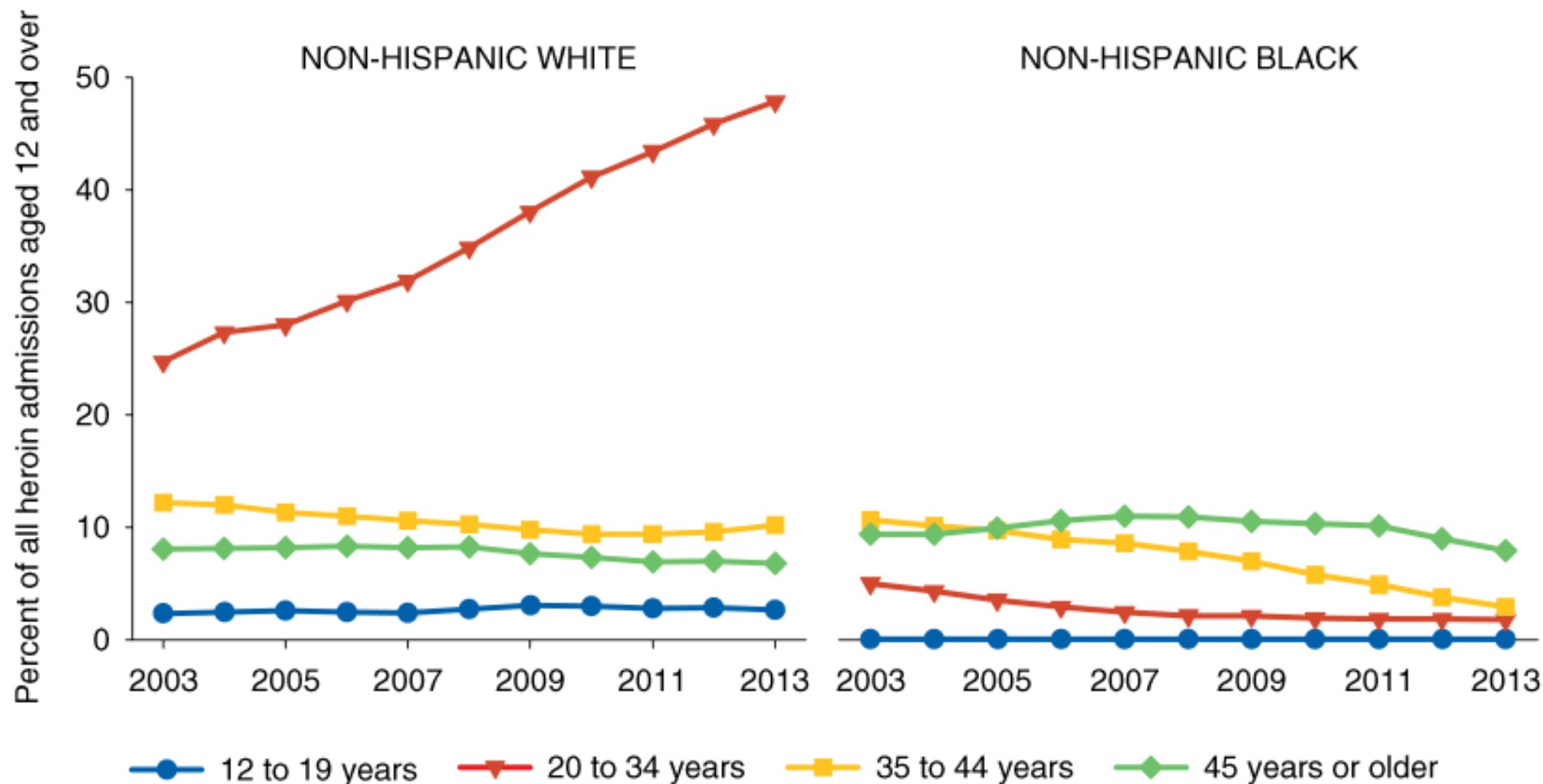
B Overdose mortality among adolescents by race and ethnicity



Drug overdose rates per 100 000 adolescents are shown by (A) substance involved and (B) race and ethnicity. The year 2021 refers to January to June 2021, and rates have been annualized. The vertical dashed lines delineate the pre-pandemic and pandemic periods of observed data.

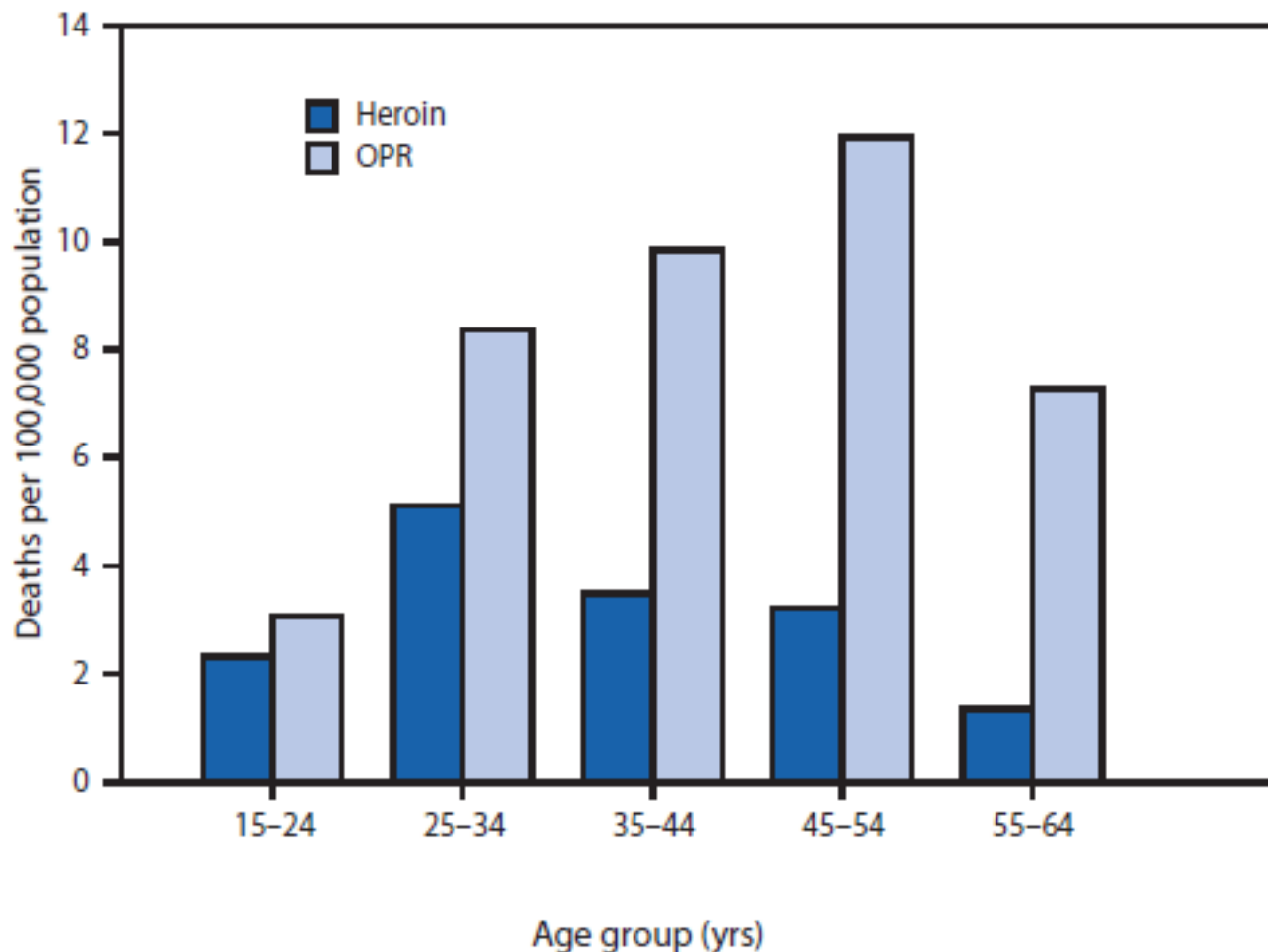
Friedman J, Godvin M, Shover CL, Gone JP, Hansen H, Schriger DL. Trends in Drug Overdose Deaths Among US Adolescents, January 2010 to June 2021. JAMA. 2022 Apr 12;327(14):1398-1400.

Heroin treatment admissions : 2003-2013



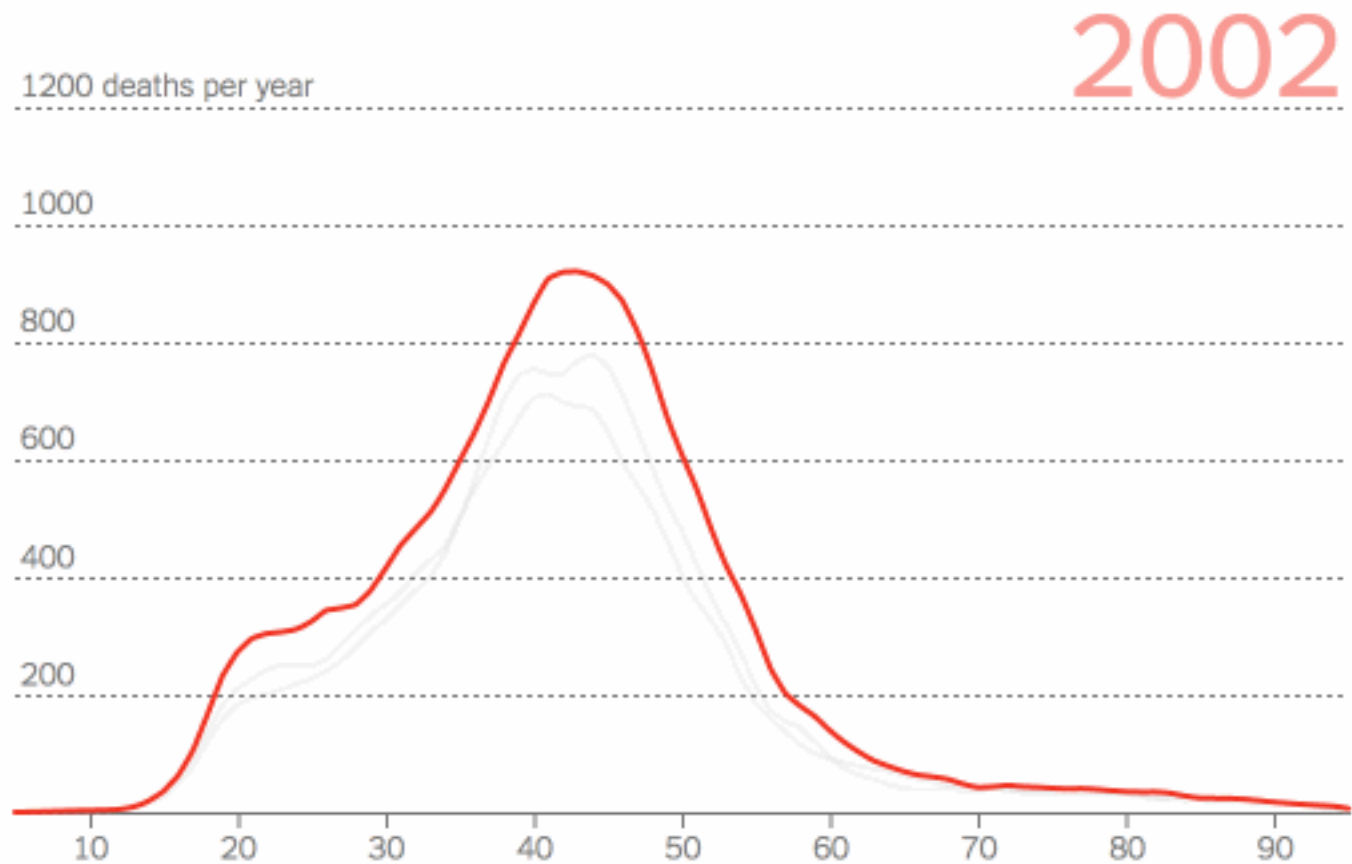
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 01.23.15.

Death rates from overdoses of heroin or prescription opioid pain relievers (OPRs), by age group



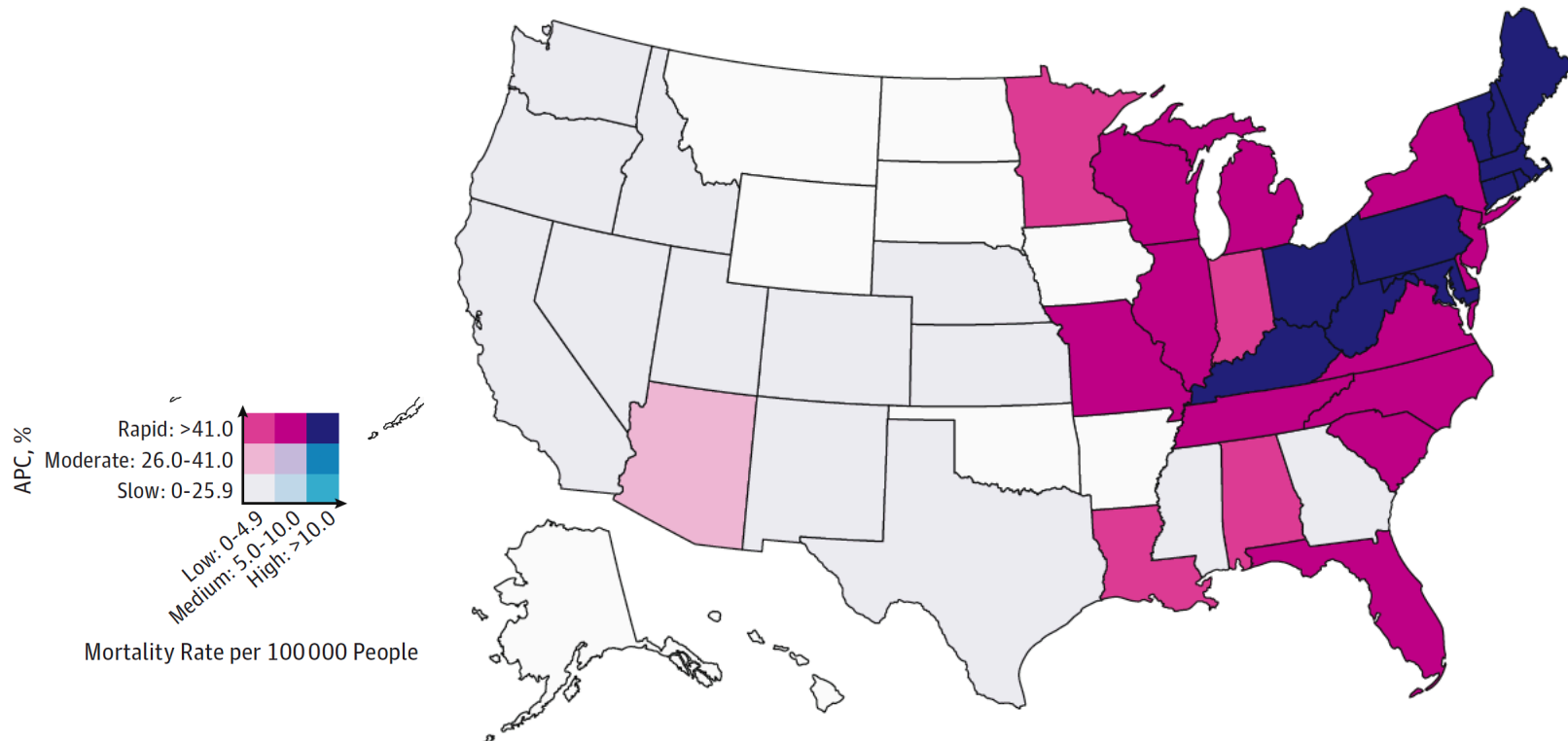
SOURCE: CDC. *Increases in Heroin Overdose Deaths — 28 States, 2010 to 2012*
MMWR. 2014, 63:849-854

Distribution of drug deaths by age



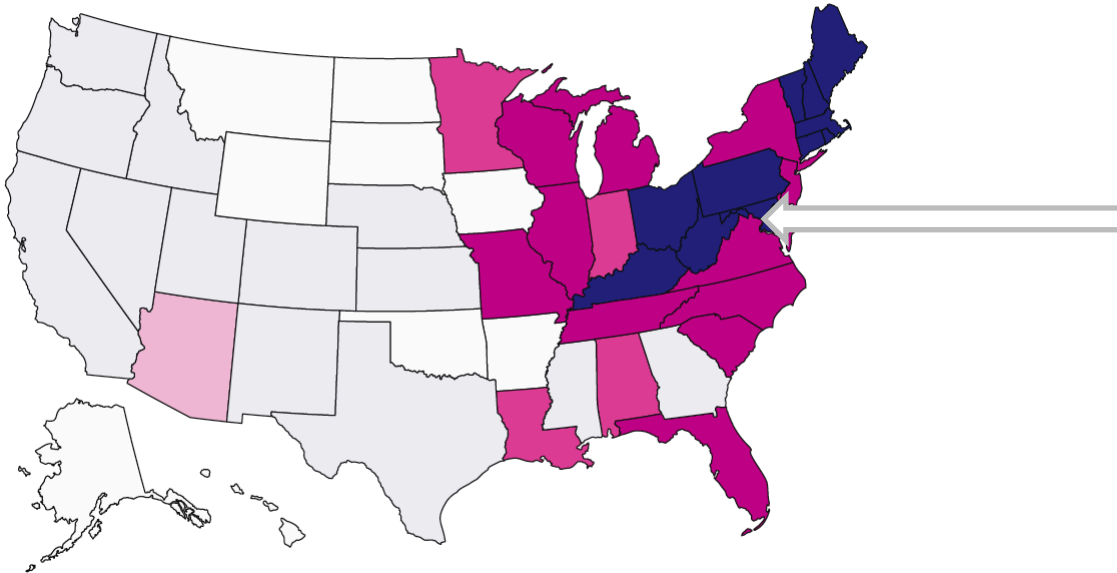
Growth and Level of the Synthetic Opioid OD Deaths, 2016

D Synthetic opioids



Source: JAMA Network Open. 2019;2(2):e190040. doi:10.1001/jamanetworkopen.2019.0040

D Synthetic opioids

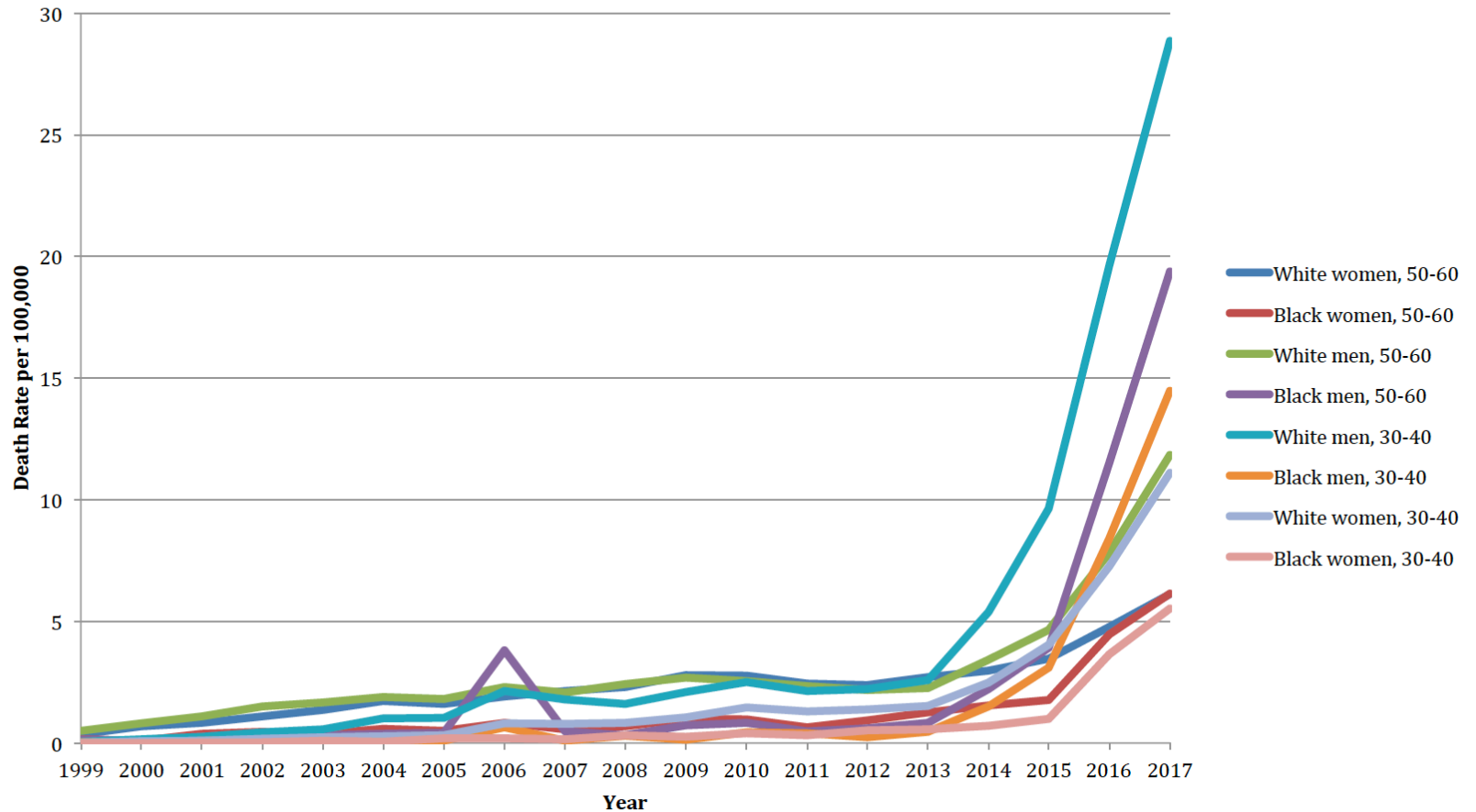


Source: JAMA Network Open. 2019;2(2):e190040. doi:10.1001/jamanetworkopen.2019.0040

Three Opioid-Addicted Cohorts

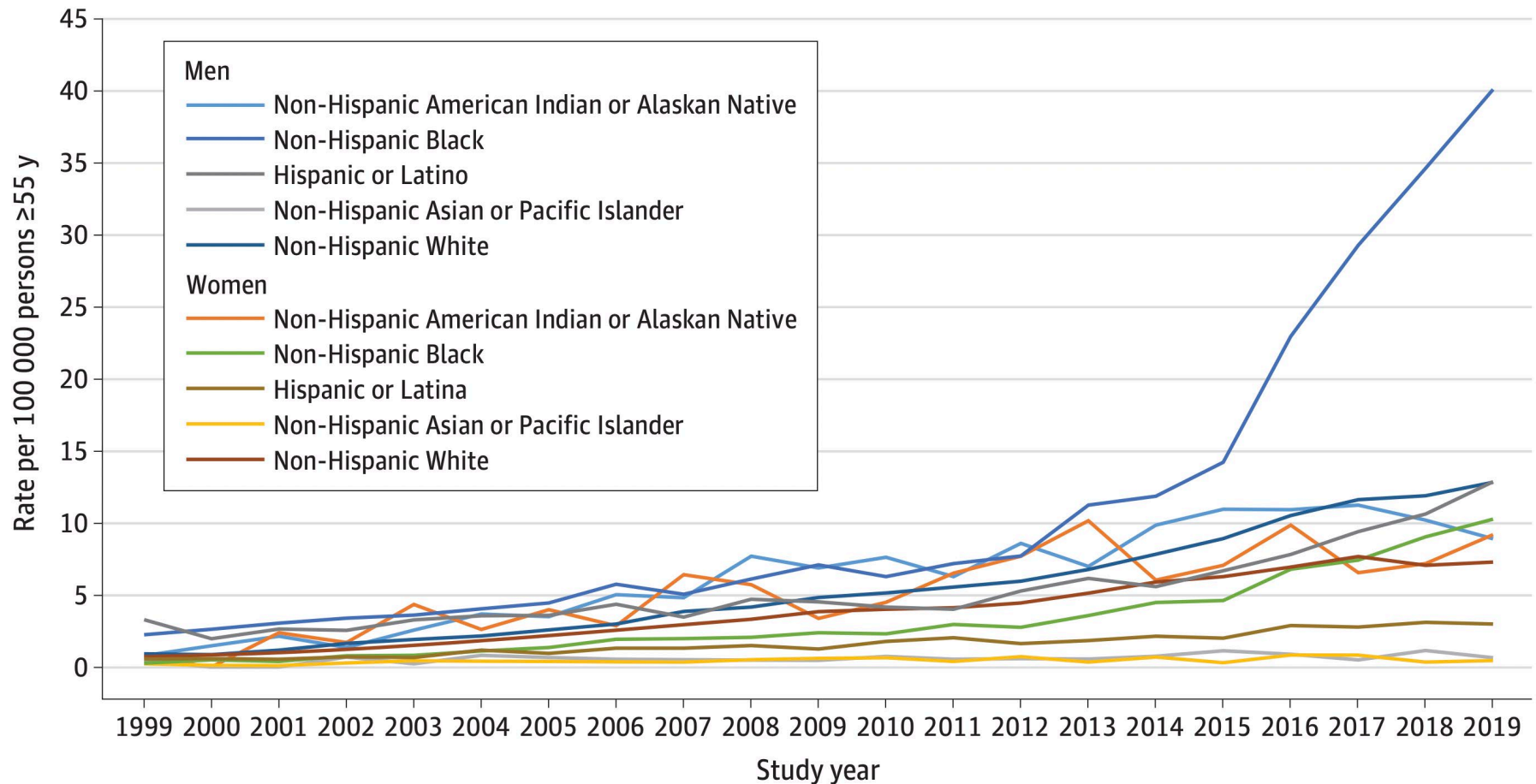
1. 20-40 y/o, disproportionately white, significant heroin use, opioid addiction began with Rx use (addicted after 1995)
2. 40 y/o & up, disproportionately white, mostly Rx opioids, opioid addiction began with Rx use (addicted after 1995)
3. 50 y/o & up, disproportionately non-white, mostly heroin users, opioid addiction began in teen years with heroin use (addicted before 1995)

Opioid Overdose Death Rate per 100,000 (1999-2017) From Fentanyl + No Heroin + Any Other Opioid



SOURCE: CDC WONDER

Figure 2. Rates of Opioid Overdose Deaths per 100 000 Persons 55 Years and Older by Sex and by Race and Ethnicity, 1999 to 2019



Mason M, Soliman R, Kim HS, Post LA. Disparities by Sex and Race and Ethnicity in Death Rates Due to Opioid Overdose Among Adults 55 Years or Older, 1999 to 2019. JAMA Netw Open. 2022;5(1):e2142982. doi:10.1001/jamanetworkopen.2021.42982

Non-Hispanic Whites

Non-Hispanic Blacks

Figure 2. Heroin Treatment Admission Rates by Age Category Among Non-Hispanic White Individuals, US, 2000-2017

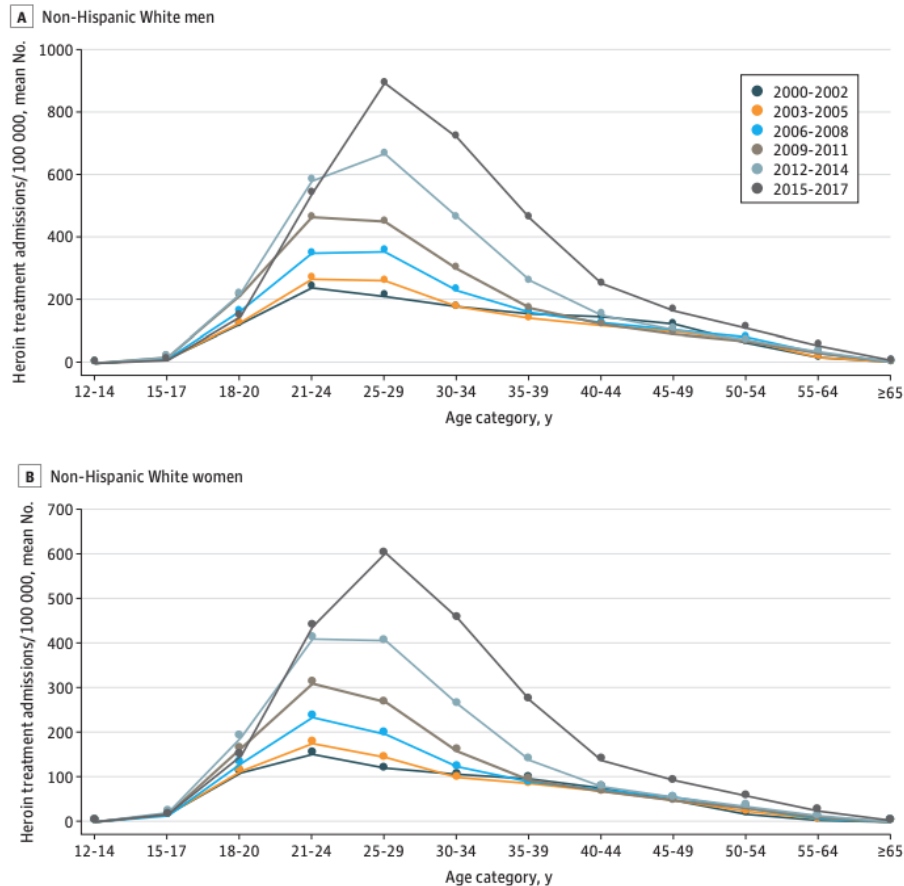
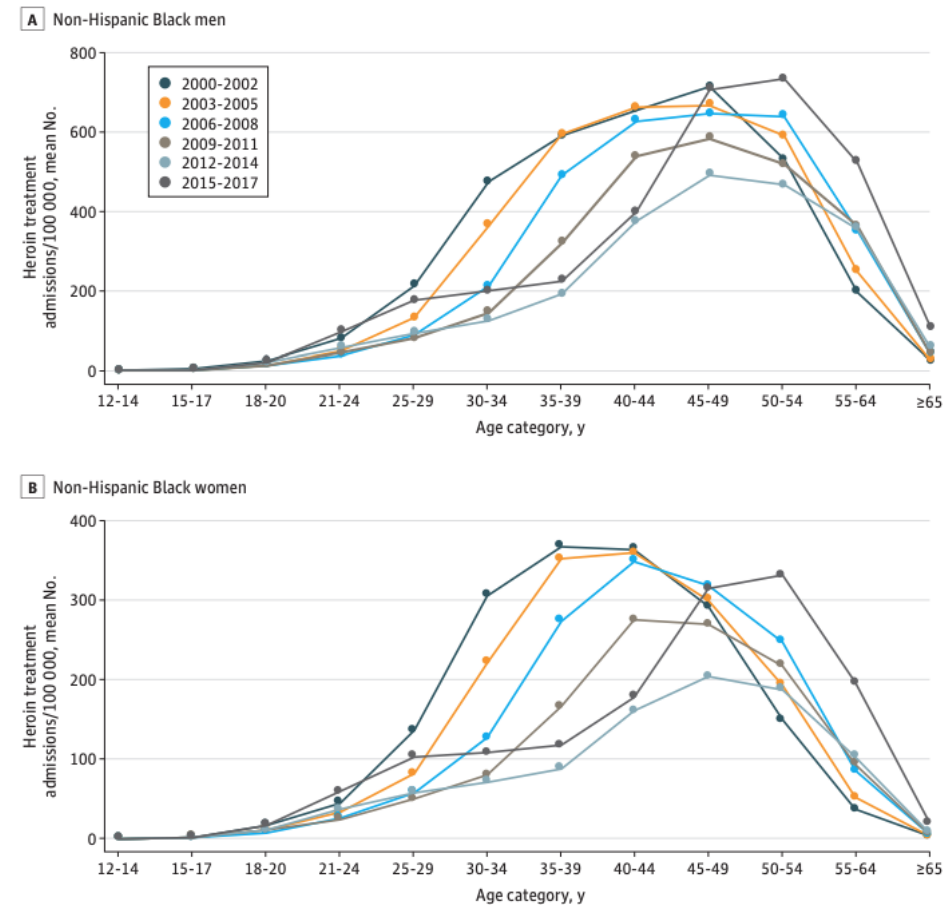


Figure 1. Heroin Treatment Admission Rates by Age Category Among Non-Hispanic Black Individuals, US, 2000-2017



Source: Warren EC, Kolodny A. Trends in Heroin Treatment Admissions in the United States by Race, Sex, and Age. JAMA Netw Open. 2021 Feb 1;4(2):e2036640. doi: 10.1001/jamanetworkopen.2020.36640.

In one year, drug overdoses killed more Americans than the entire Vietnam War did

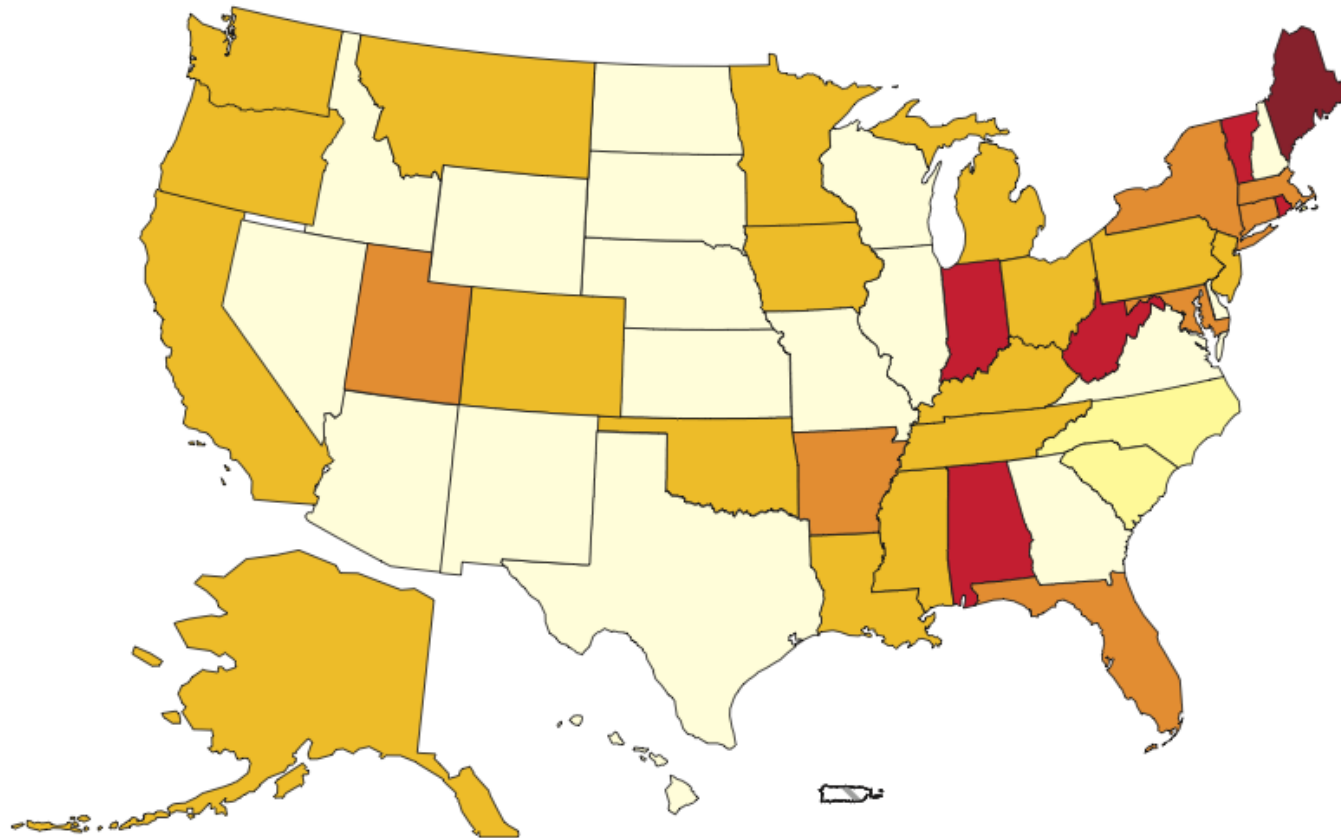
Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome

Children of the Opioid Epidemic Are Flooding Foster Homes. America Is Turning a Blind Eye.

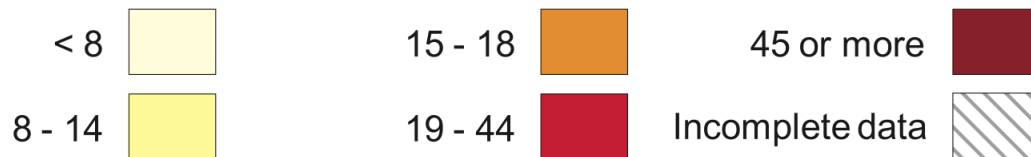
For the first time, drug overdose deaths have surpassed 100,000 in a 12-month period

How the opioid crisis decimated the American workforce

Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

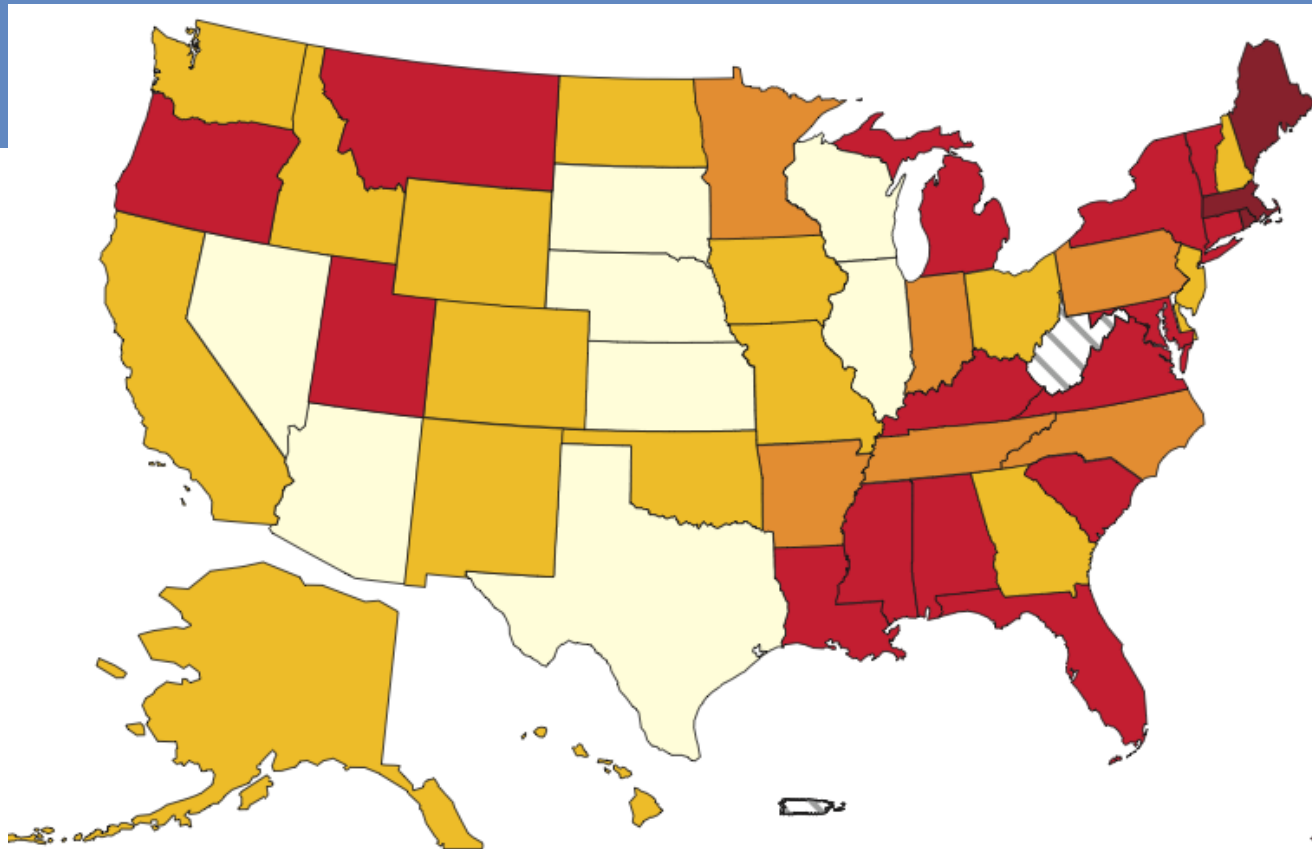


1999
(range 1 - 50)

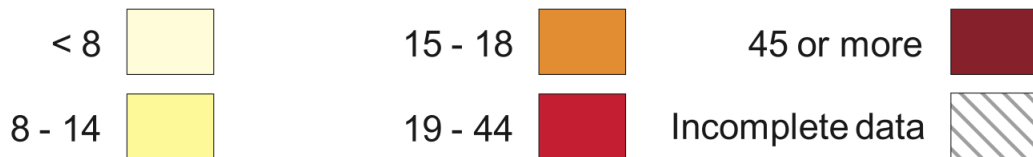


SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

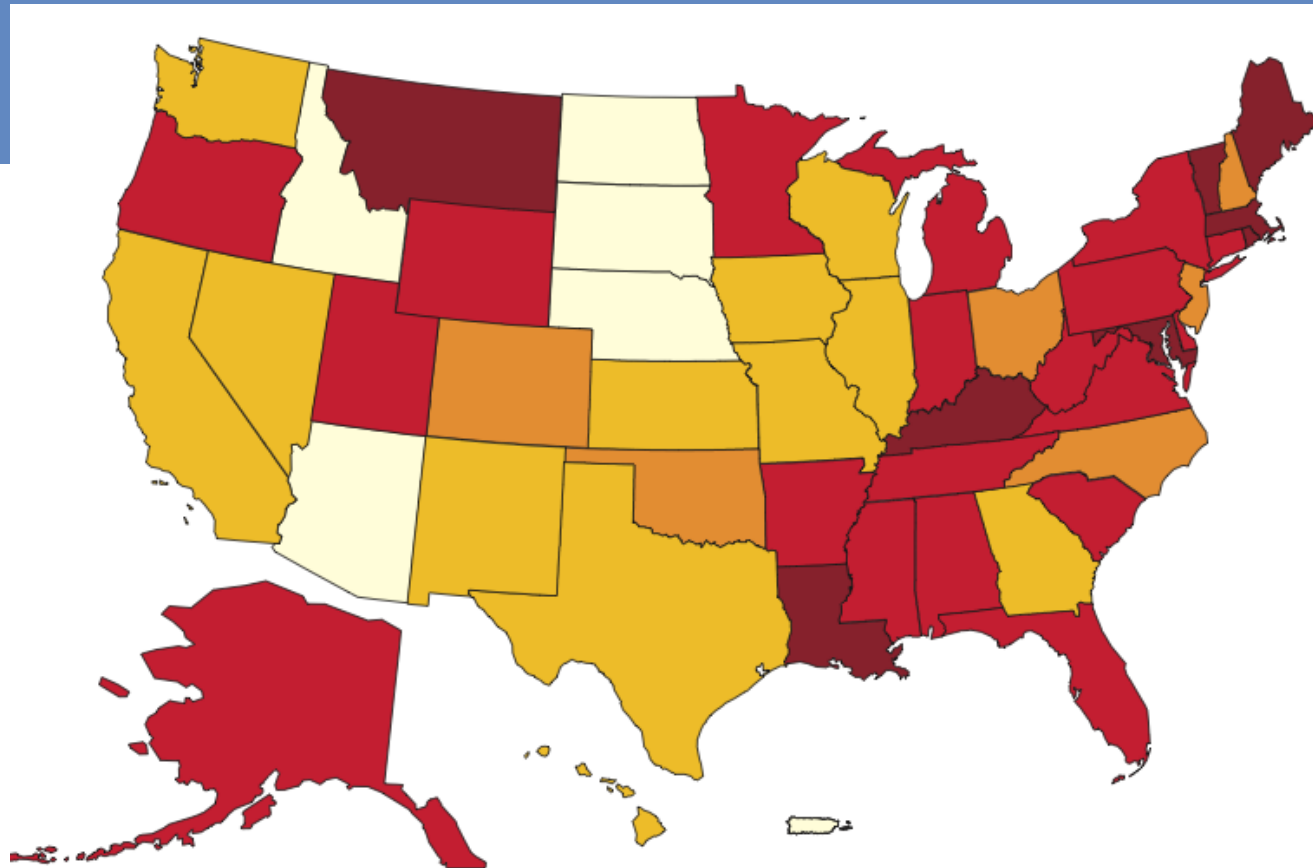


2001
(range 1 – 71)



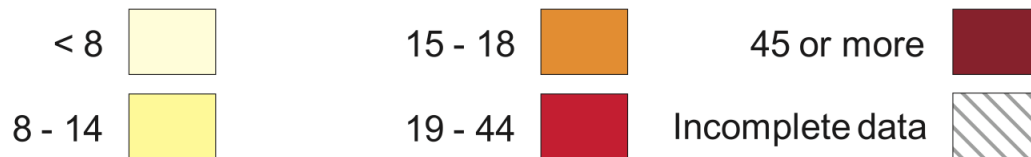
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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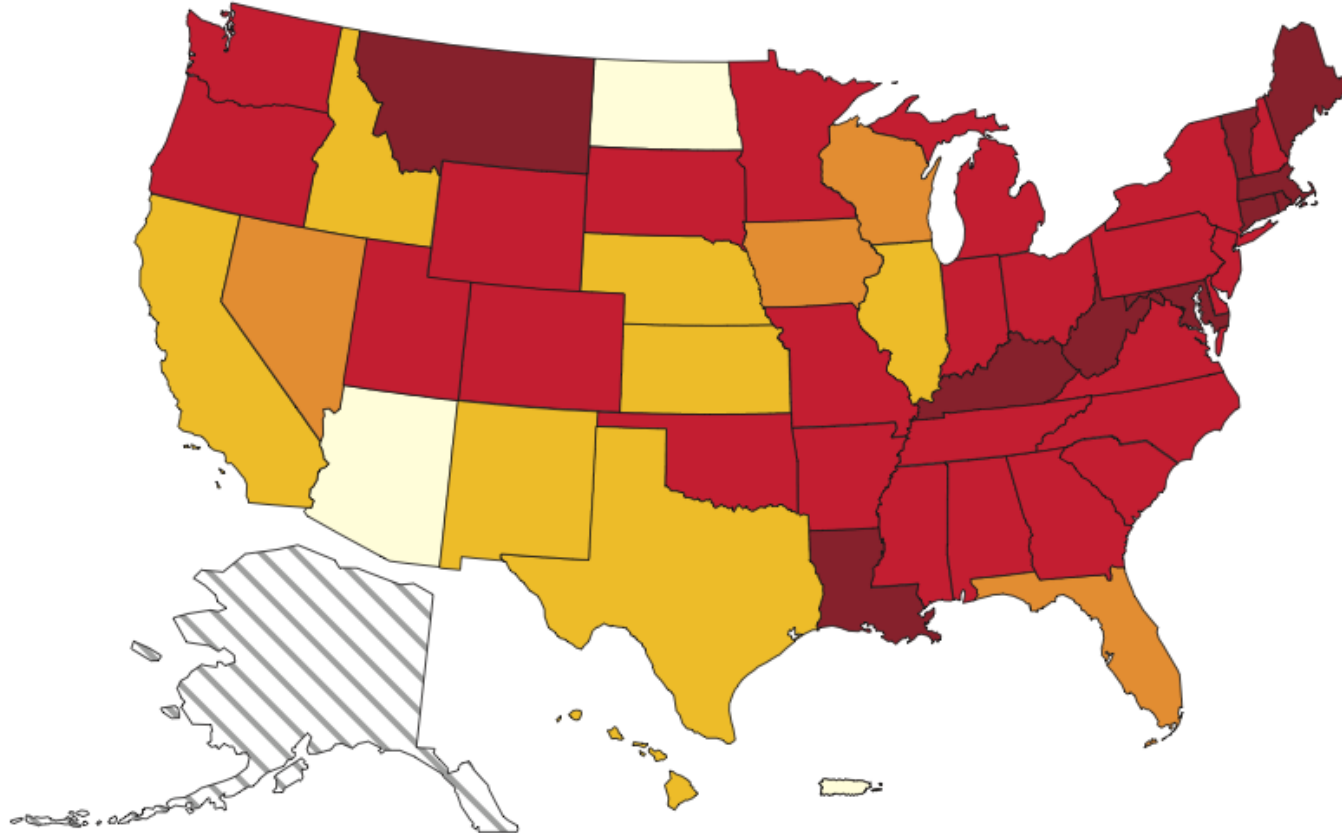
2003

(range 2 – 139)



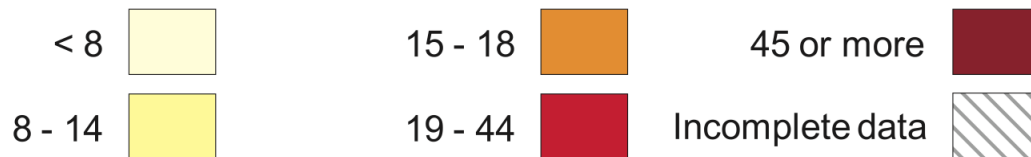
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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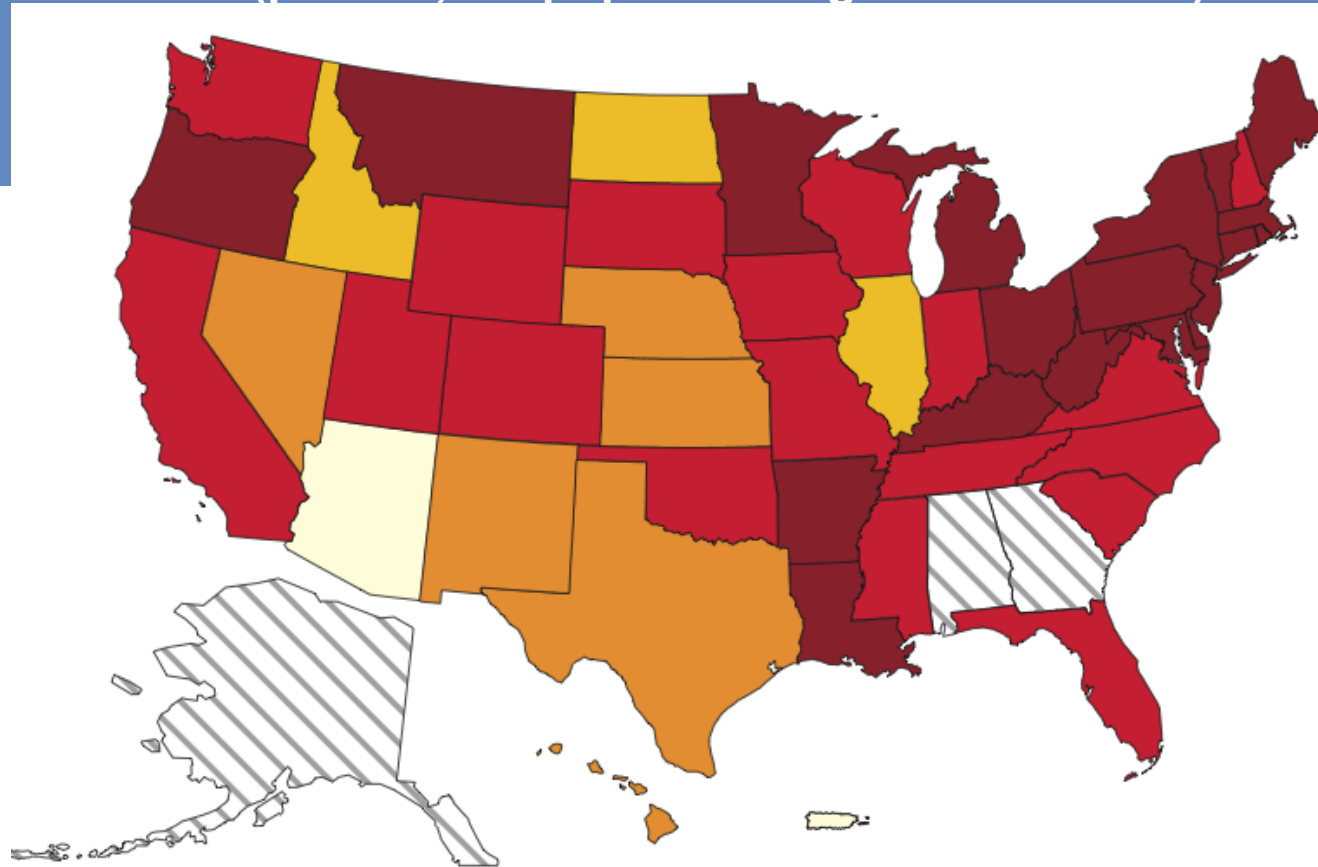
2005

(range 0 – 214)



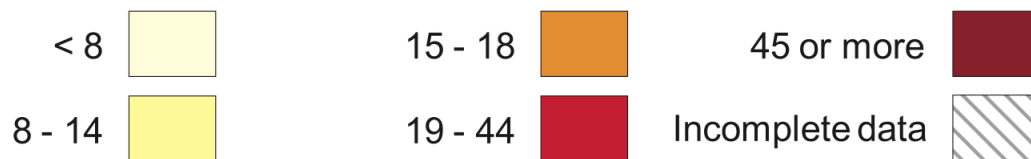
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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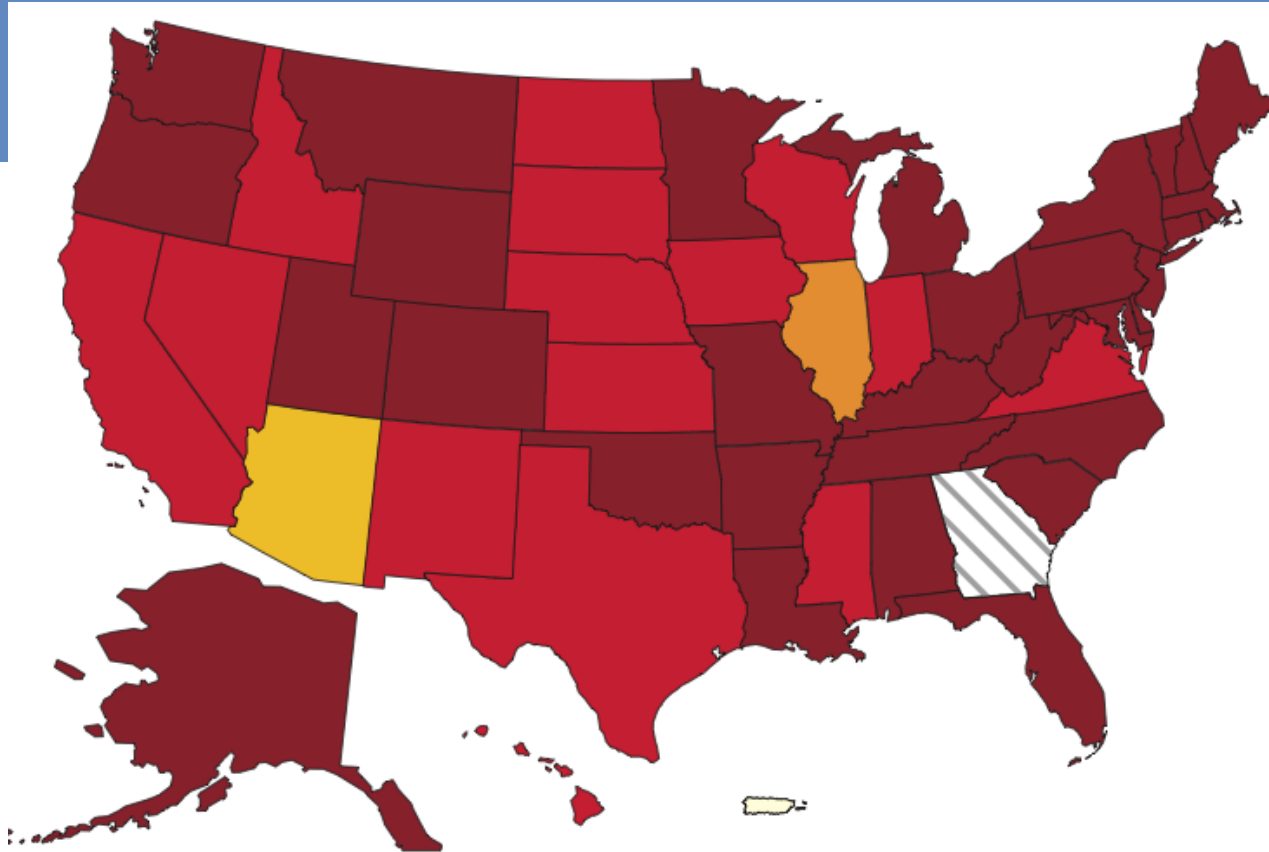
2007

(range 1 – 340)



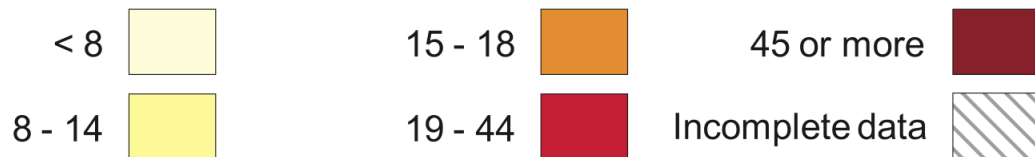
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



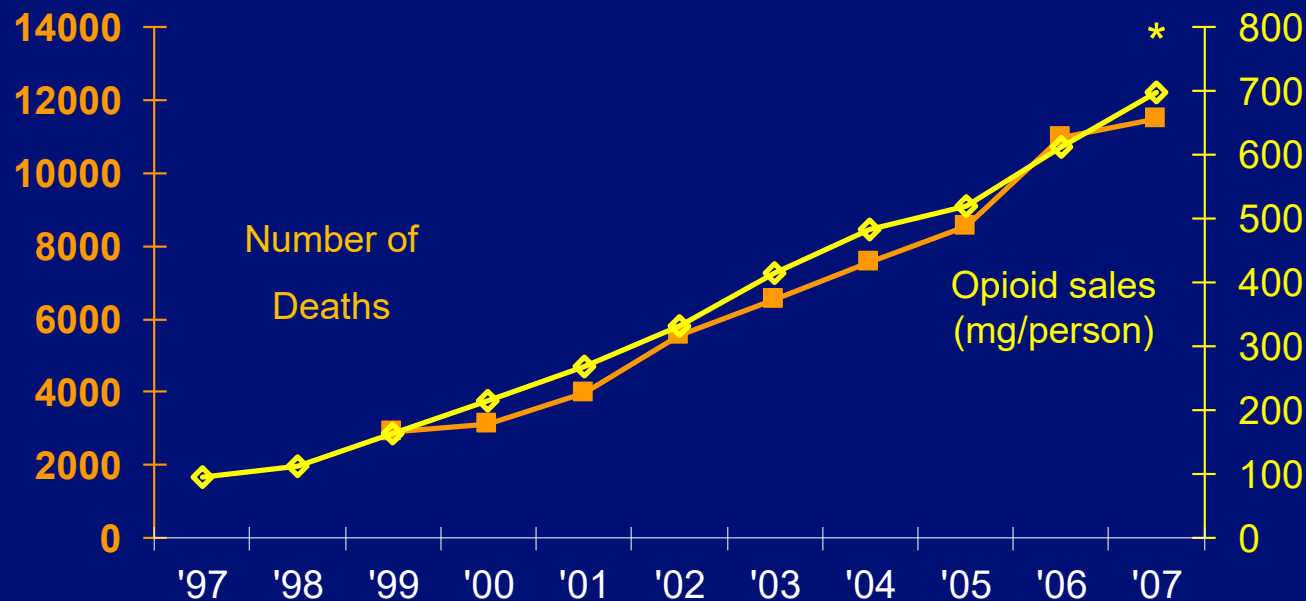
2009

(range 1 – 379)



SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

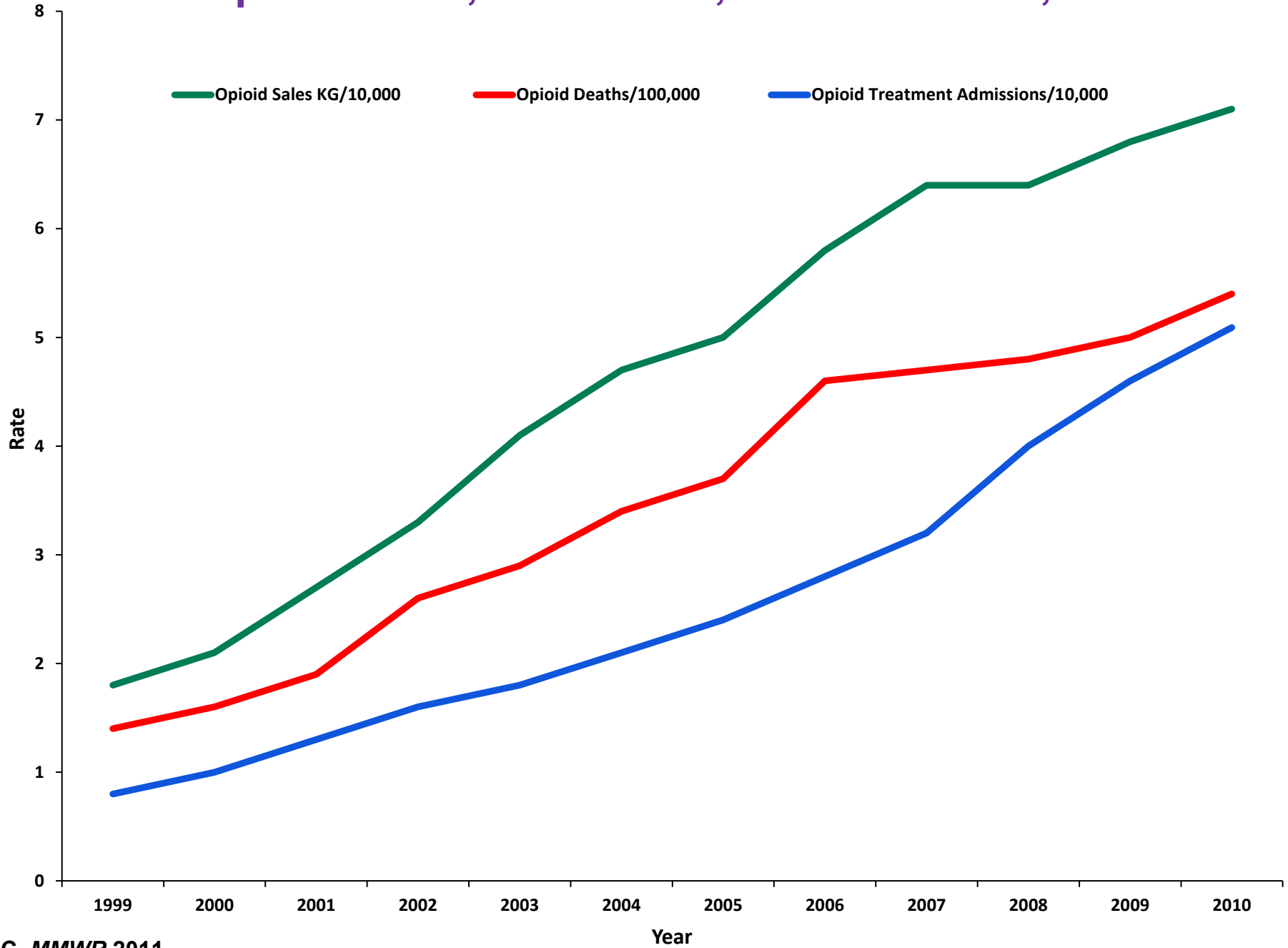
Unintentional overdose deaths involving opioid analgesics parallel per capita sales of opioid analgesics by year, U.S., 1997-2007



Source: National Vital Statistics System, multiple cause of death dataset, and DEA ARCOS

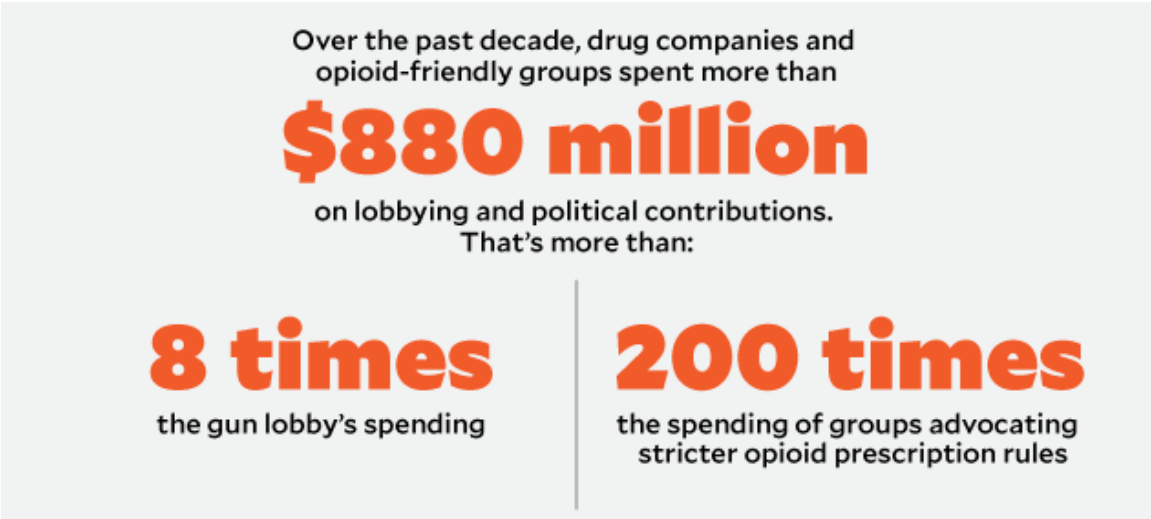
* 2007 opioid sales figure is preliminary.

Rates of Opioid Sales, OD Deaths, and Treatment, 1999–2010



Pro-painkiller lobby shapes policy amid drug epidemic

Matthew Perrone and Ben Wieder, Associated Press and Center for Public Integrity



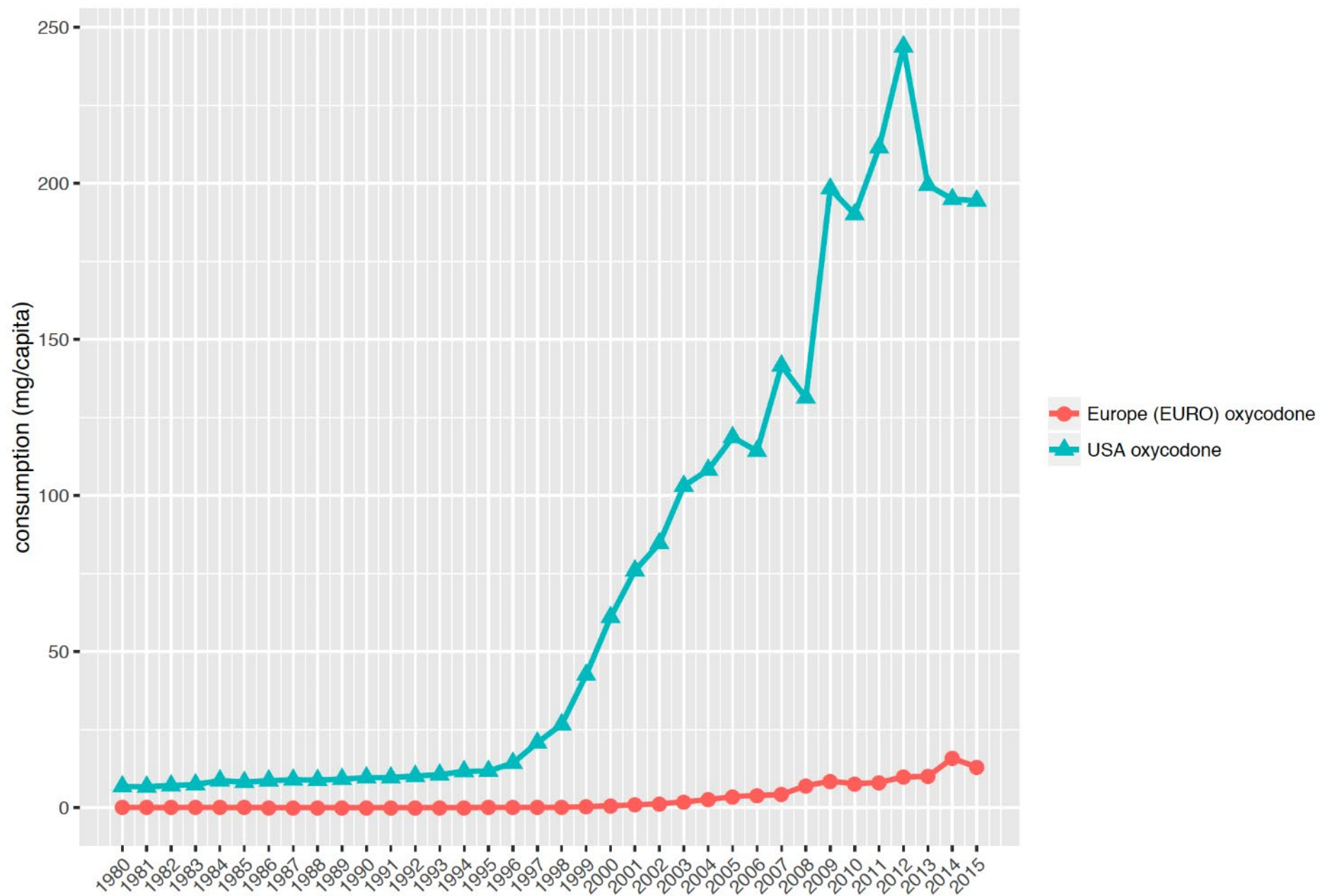
POLITICAL SPENDING

Opioid manufacturers and their allies have contributed roughly \$80 million to state and federal candidates and have spent about \$746 million on state and federal lobbying since 2006. How the spending breaks down:

to State	to Federal	for State/Federal candidates	
\$109 mil.	\$716 mil.	45% Dems	54% Reps

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USA oxycodone consumption (mg/capita) 1980–2015



Industry-funded organizations campaigned for greater use of opioids

- Pain Patient Groups
- Professional Societies
- The Joint Commission
- The Federation of State Medical Boards

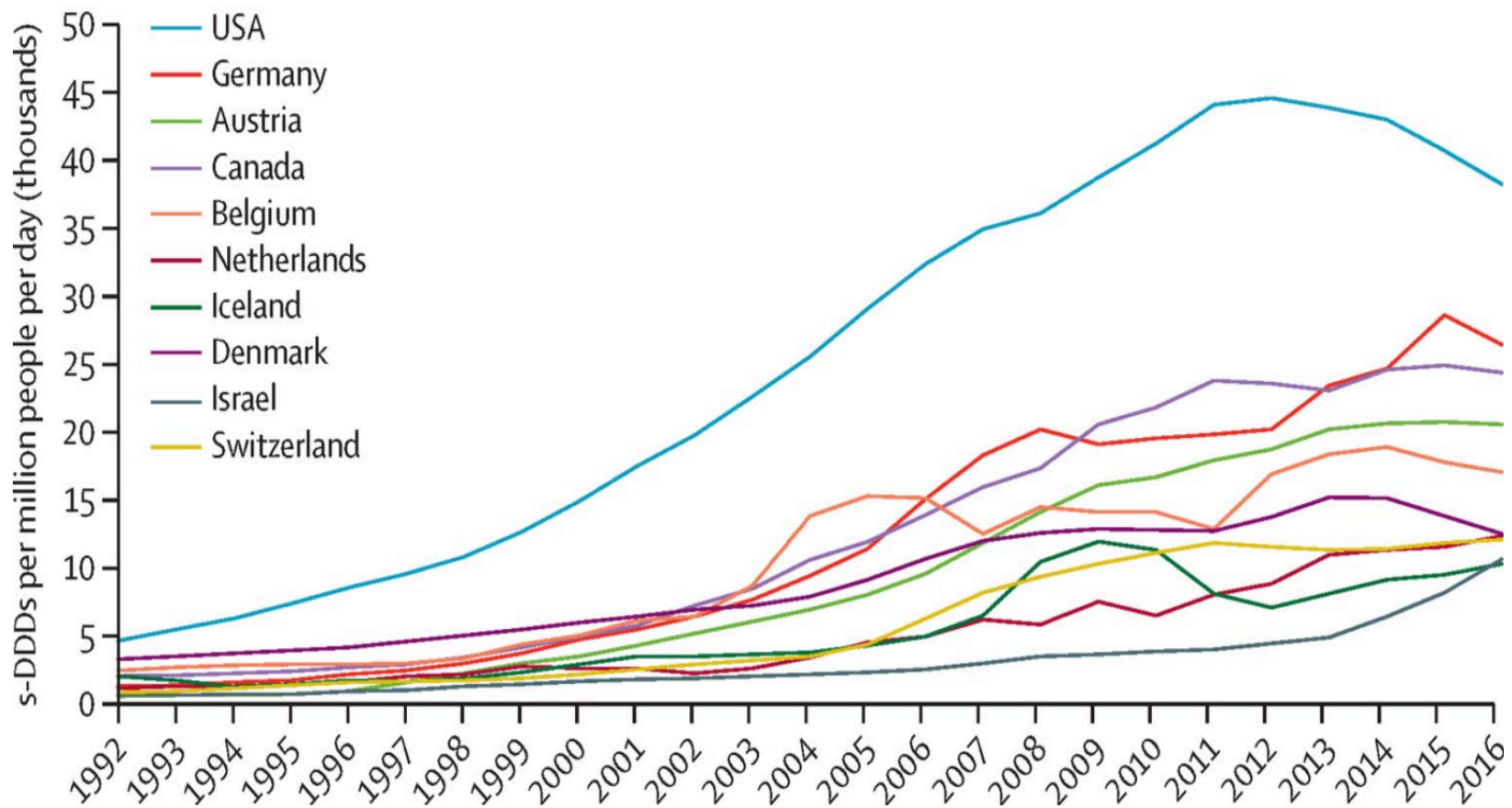


Johnson & Johnson And Drug Distributors Finalize \$26 Billion Settlement To End Opioid Crisis Lawsuits

Alabama settles opioid claims with J&J, McKesson, Endo for \$276 mln -attorney general

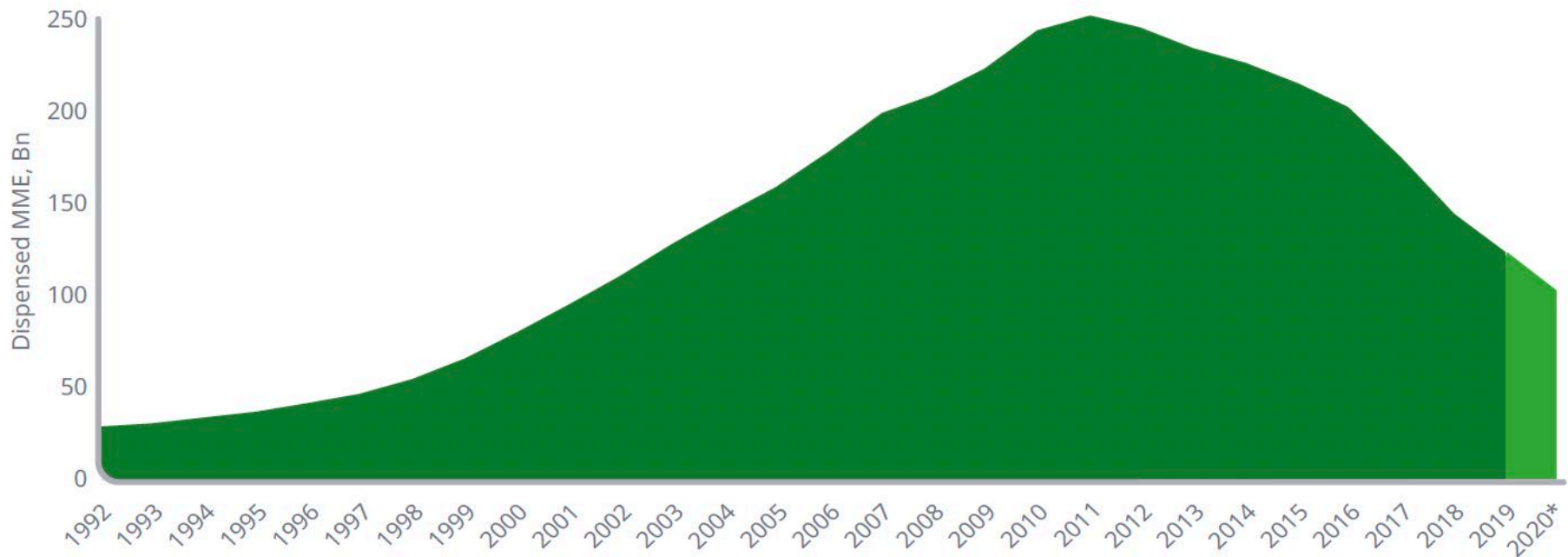
Walgreens to pay \$683m to settle claims it exacerbated opioid crisis in Florida

Teva Pharm expects U.S. opioid case settlements to cost \$2.6 bln



Prescription opioid use has declined to 60% of the peak volume in 2011 after another year of double-digit decline expected in 2020

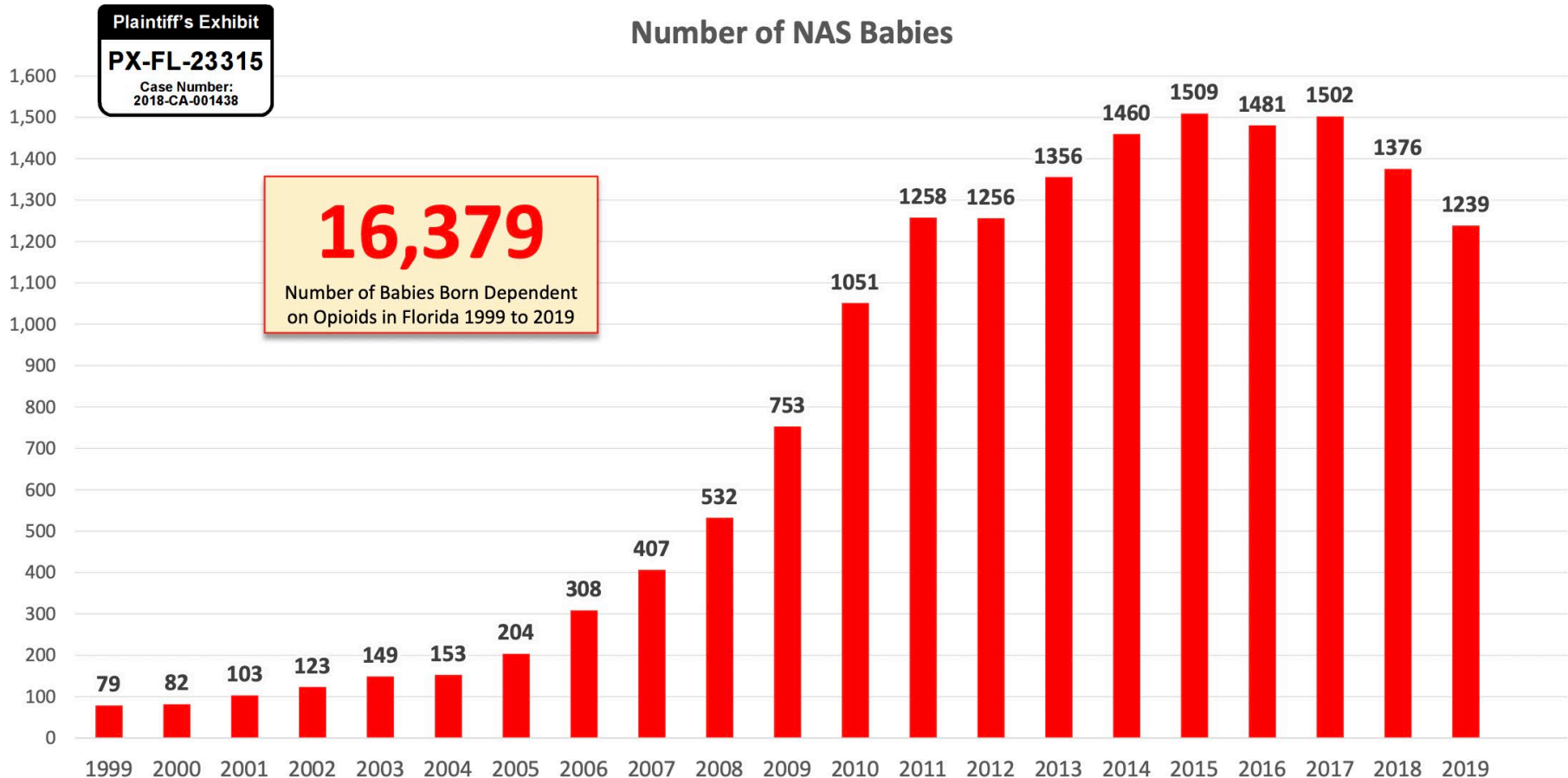
Exhibit 1: Prescription Opioid Use in Morphine Milligram Equivalents (MME) Bn, 1992-2020*



Source: IQVIA Xponent, Mar 2020; IQVIA National Prescription Audit; IQVIA Institute, Nov 2020

In states across the U.S., neonatal opioid withdrawal is declining

Number of **Babies Born Dependent on Opioids** in Florida Each Year

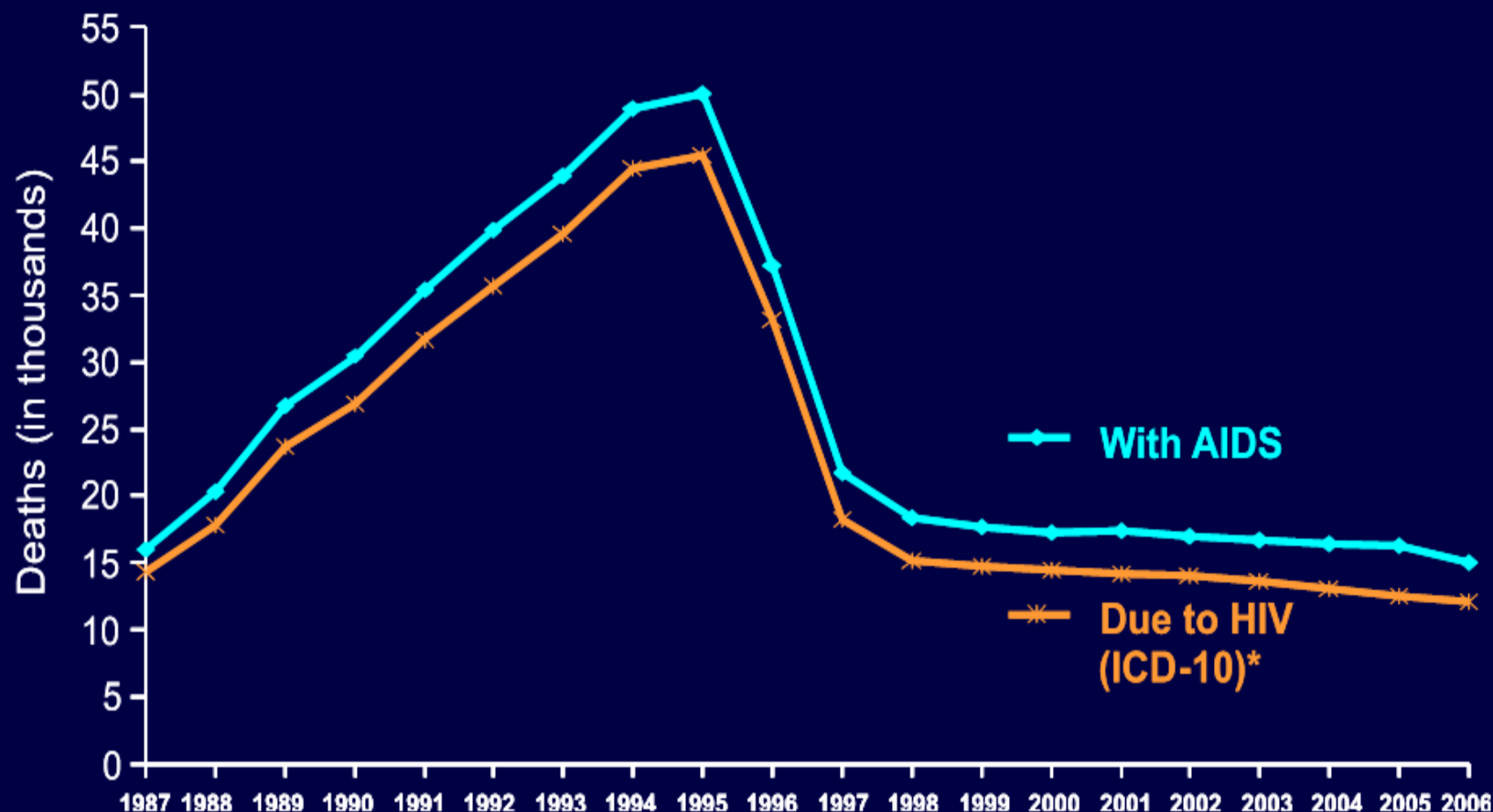


Source: Expert Report of Andrew Kolodny at 5, 17-18; DOH data.

Controlling the epidemic:

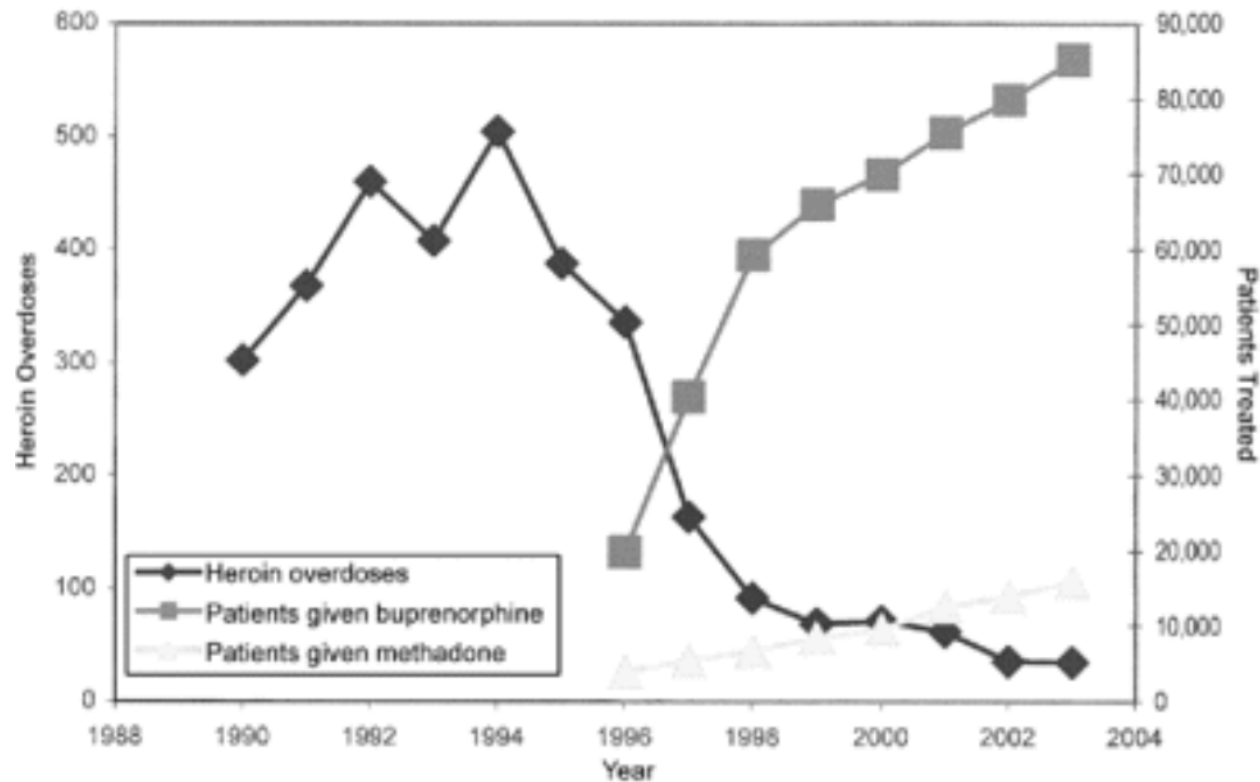
- **Prevent** new cases of opioid addiction
- **Treat** people who are already addicted
- **Harm Reduction**
- **Interdiction (Law Enforcement)**

Comparison of Mortality Data from AIDS Case Reports and Death Certificates in Which HIV Disease Was Selected as the Underlying Cause of Death, United States, 1987–2006



*For comparison with data for 1999 and later years, data in the bottom (red) line for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.





From: Buprenorphine Use: The International Experience
 Clin Infect Dis. 2006;43(Supplement_4):S197-S215. doi:10.1086/508184
 Clin Infect Dis | © 2006 by the Infectious Diseases Society of America

Buprenorphine Access Is Still Inadequate

The Supply of Buprenorphine Prescribers Across the U.S.¹³

100%
of these providers
can prescribe opioids.



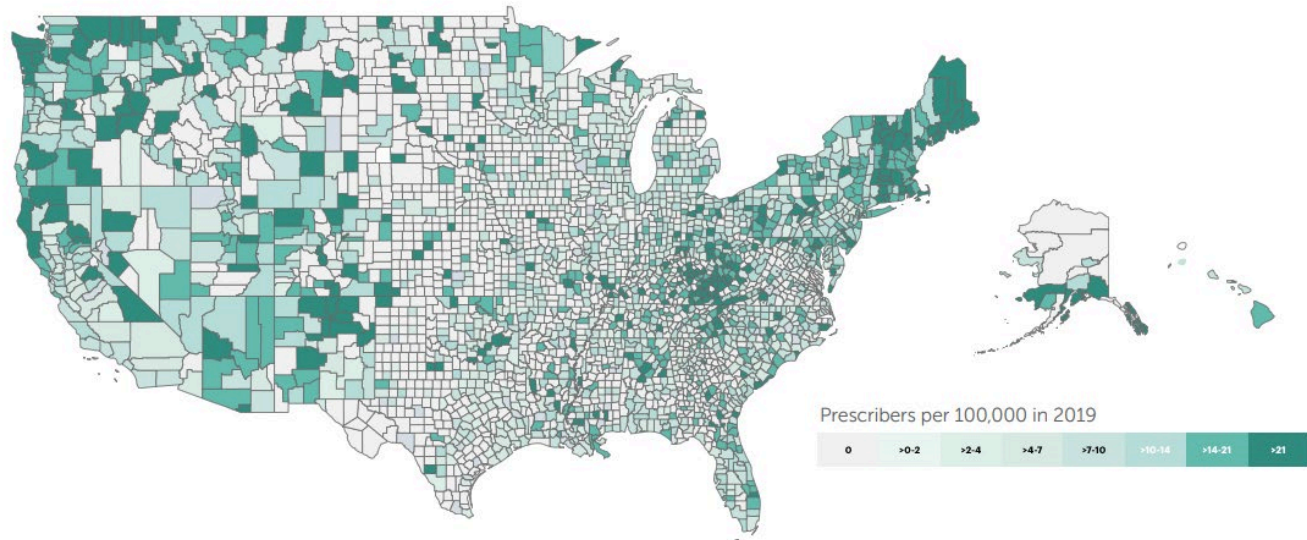
74,000 (5.7%)
are **waived** to prescribe buprenorphine.

Only 43,700 (3.4%)
of the total provider population **publicly disclose**
that they can prescribe buprenorphine.

Buprenorphine Access Is Still Inadequate

County-Level Waivered Prescriber Supply¹⁵

- The median buprenorphine capacity by county is 4 prescribers per 100,000 people.
- Thirty-nine percent (1,228) of counties do not have a waivered buprenorphine prescriber, creating an access challenge for any of these counties' 18 million residents.
 - Two-thirds (11.9 million) of these individuals live in rural areas.
 - One-third (6.1 million) of these individuals live in urban and suburban areas.



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April 2020

High-dimensional characterization of post-acute sequelae of COVID-19

<https://doi.org/10.1038/s41586-021-03553-9>

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Ziyad Al-Aly^{1,2,3,4,5}✉, Yan Xie^{1,2,6} & Benjamin Bowe^{1,2,6}

The acute clinical manifestations of COVID-19 are well characterized^{1,2}; however, its post-acute sequelae have not been comprehensively described. Here, we use the national healthcare databases of the US Department of Veterans Affairs to systematically and comprehensively identify 6-month incident sequelae including diagnoses, medication use, and laboratory abnormalities in 30-day survivors of COVID-19. We show that beyond the first 30 days of illness, people with COVID-19 exhibit higher risk of death and health resource utilization. Our high dimensional approach identifies incident sequelae in the respiratory system and several others including nervous system and neurocognitive disorders, mental health disorders, metabolic disorders, cardiovascular disorders, gastrointestinal disorders, malaise, fatigue, musculoskeletal pain, and anemia. We show increased incident use of several therapeutics including pain medications (opioids and non-opioids), antidepressants, anxiolytics, antihypertensives, and oral hypoglycemics and evidence of laboratory abnormalities in multiple organ systems. Analysis of an array of pre-specified outcomes reveals a risk gradient that increased across severity of the acute COVID-19 infection (non-hospitalized, hospitalized, admitted to intensive care). The findings show that beyond the acute illness, substantial burden of health loss – spanning pulmonary and several extrapulmonary organ systems – is experienced by COVID-19 survivors. The results provide a roadmap to inform health system planning and development of multidisciplinary care strategies to reduce chronic health loss among COVID-19 survivors.

Can We Learn From COVID-19?



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