



PROP

Physicians for Responsible
Opioid Prescribing



The Current State of the Opioid Crisis

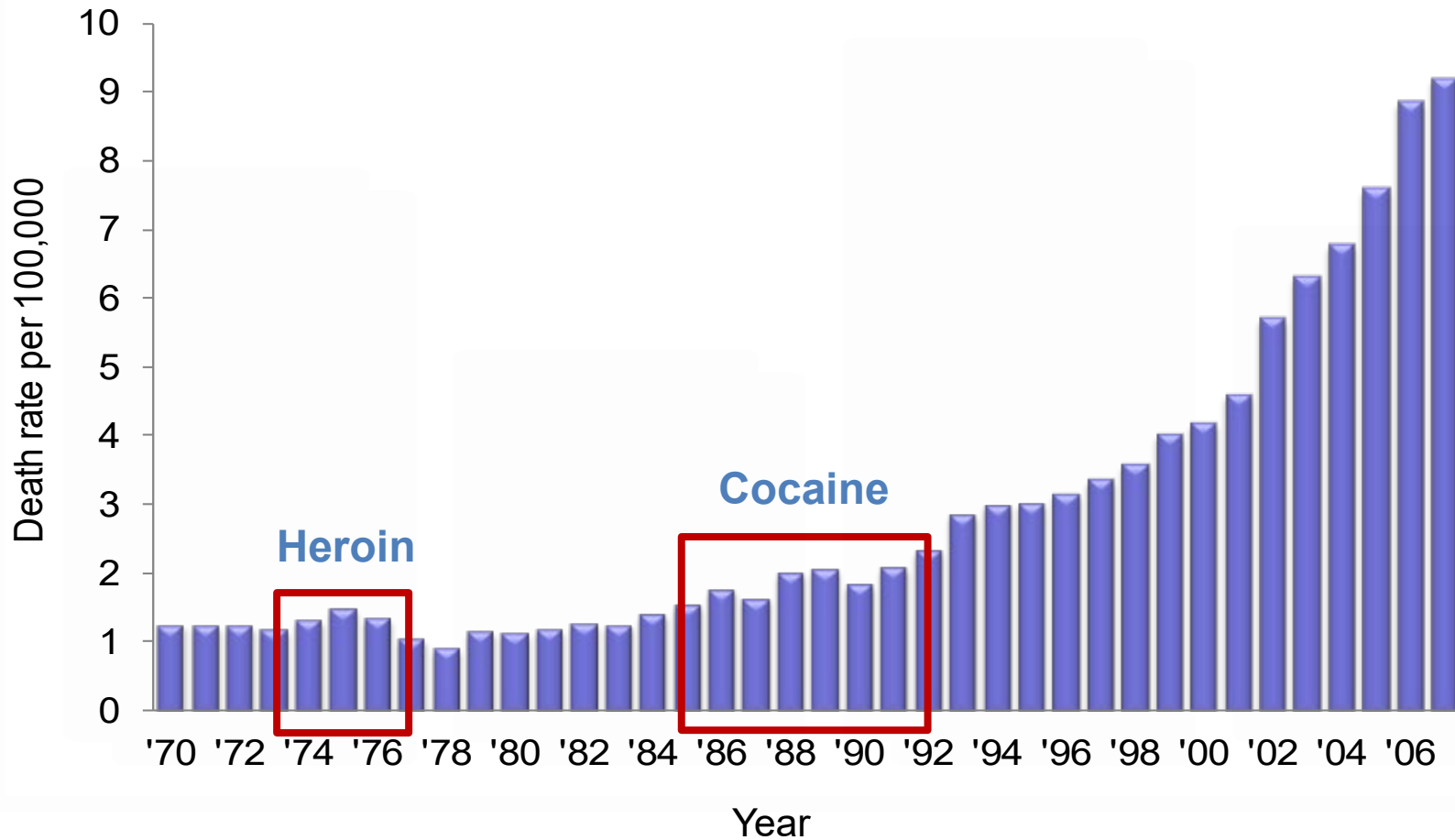
Andrew Kolodny, MD

Medical Director, Opioid Policy Research Collaborative
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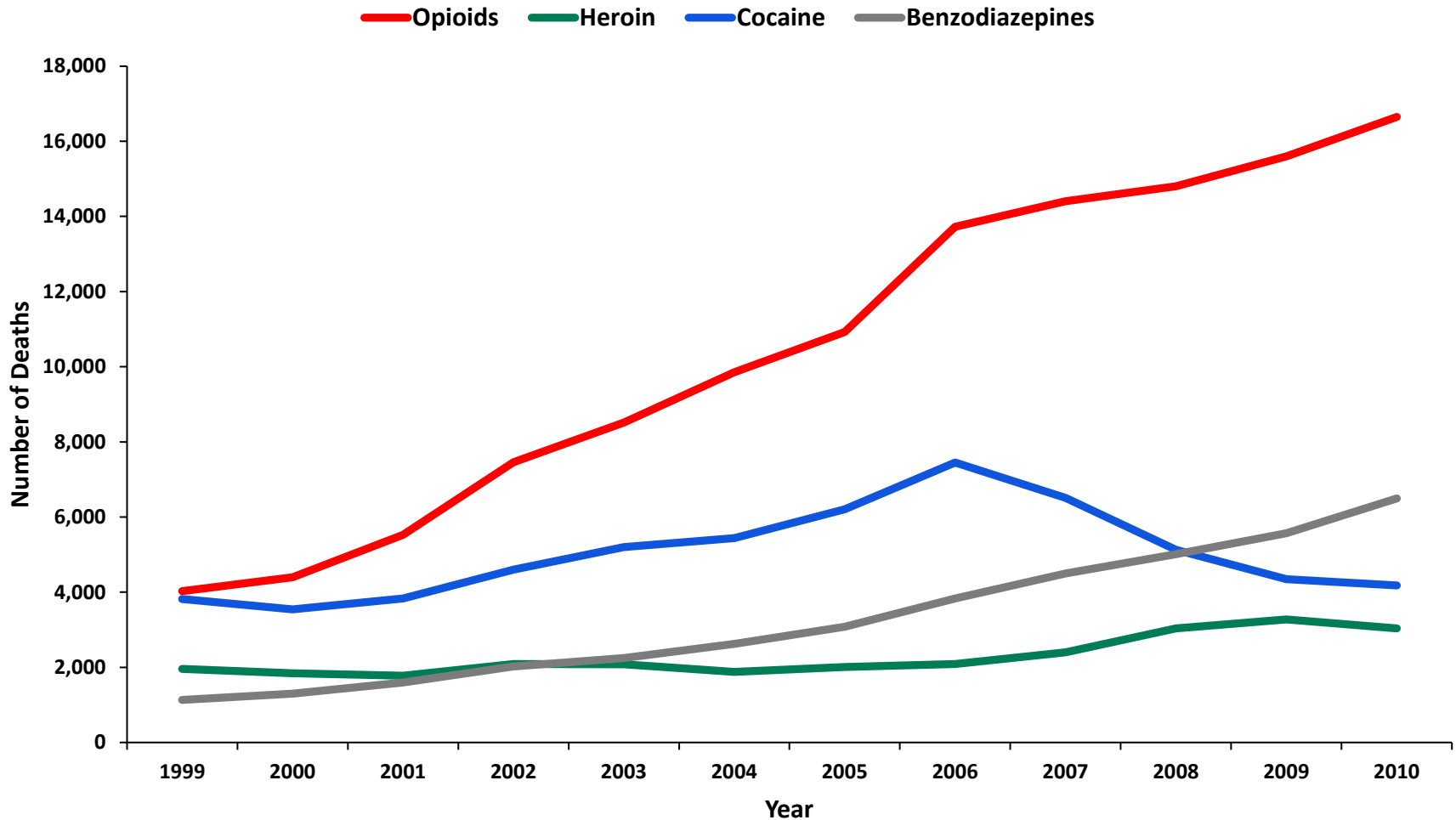
Vice President, Federal Affairs

Physicians for Responsible Opioid Prescribing

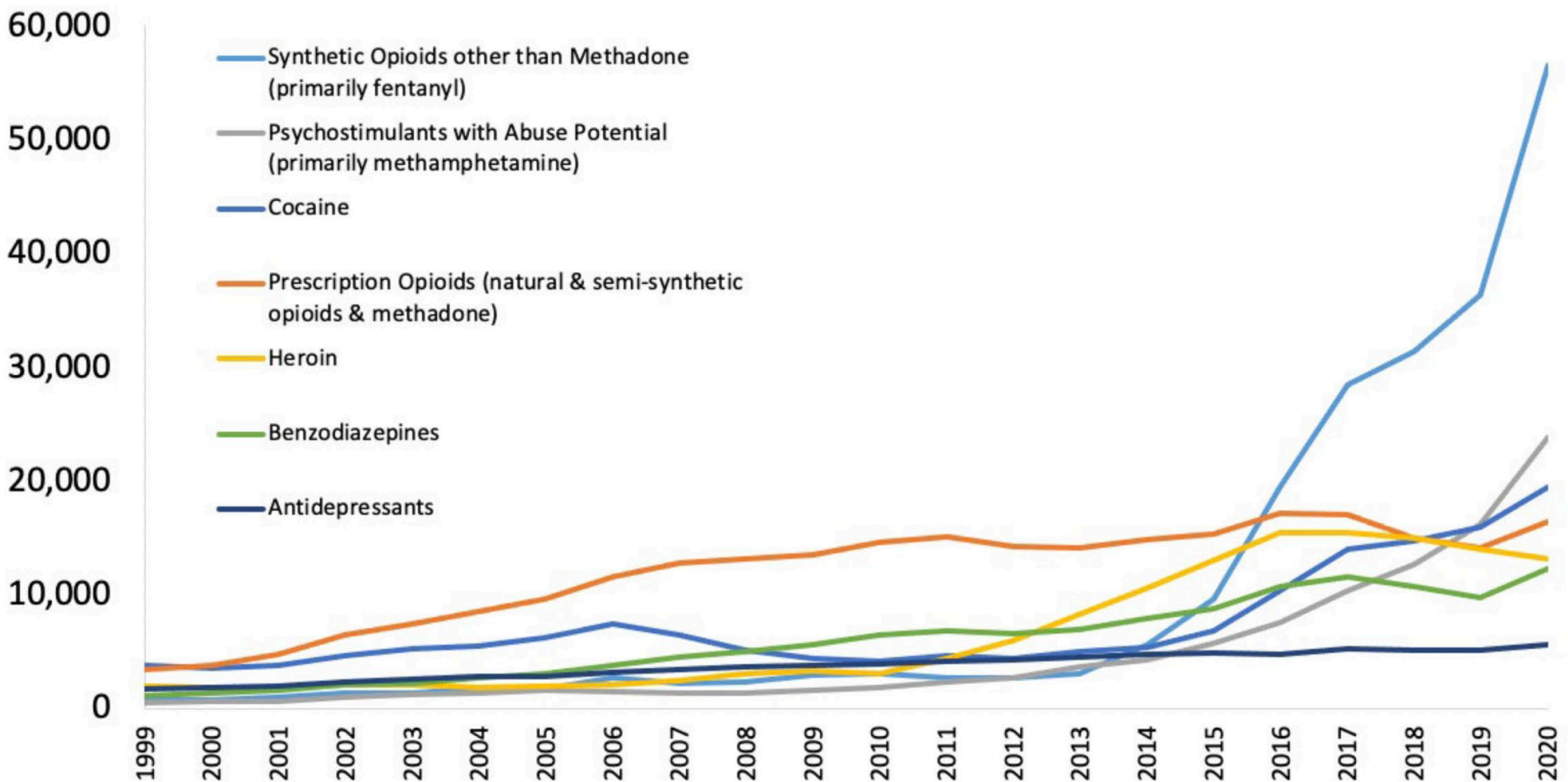
Unintentional Drug Overdose Deaths United States, 1970–2007



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

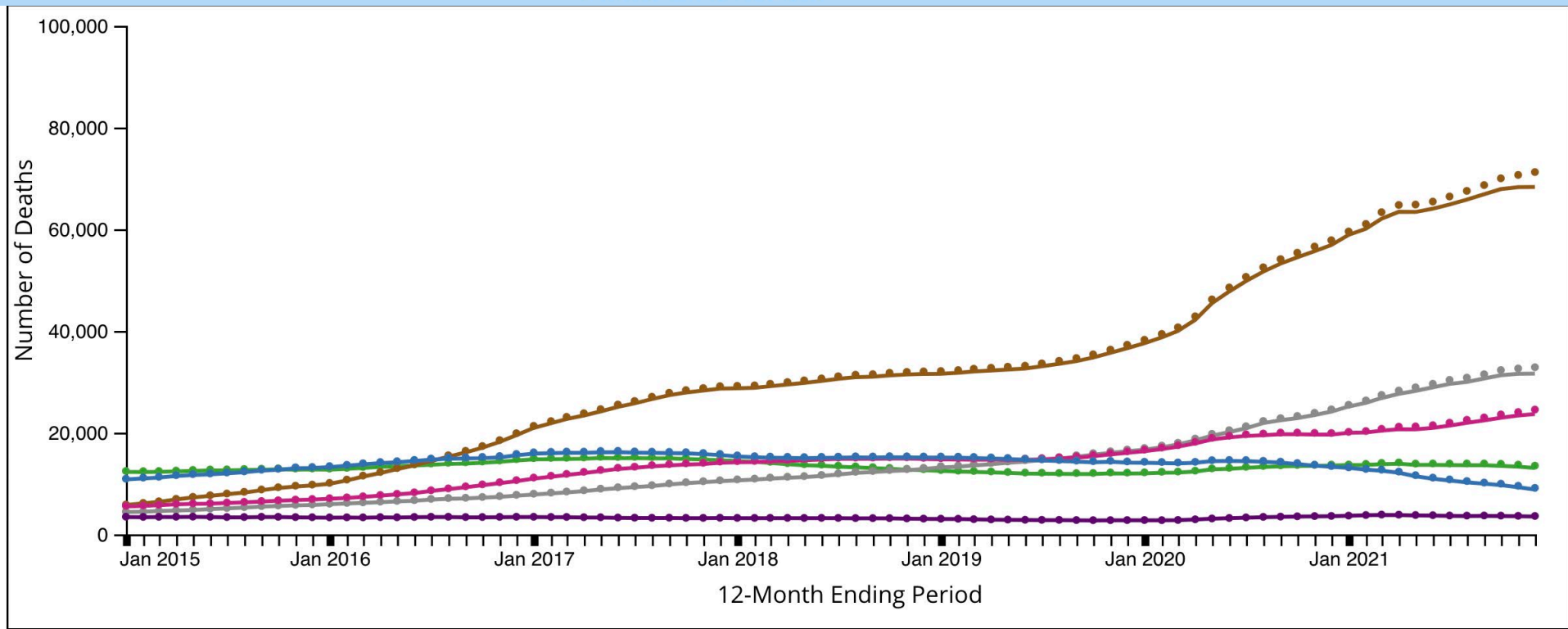


National Drug-Involved Overdose Deaths by Specific Category—Number Among All Ages, 1999-2020

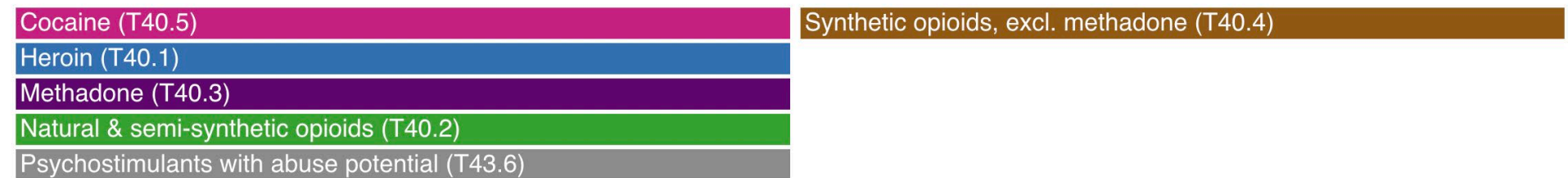


*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease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

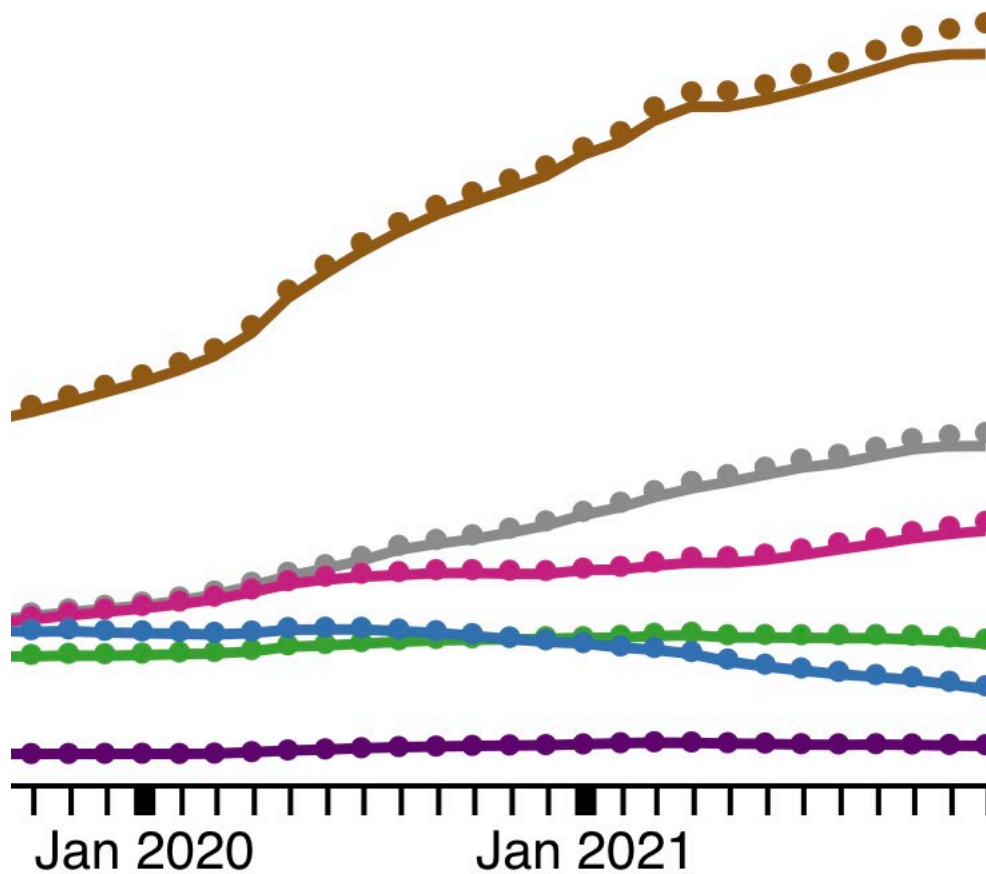
12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Legend for Drug or Drug Class



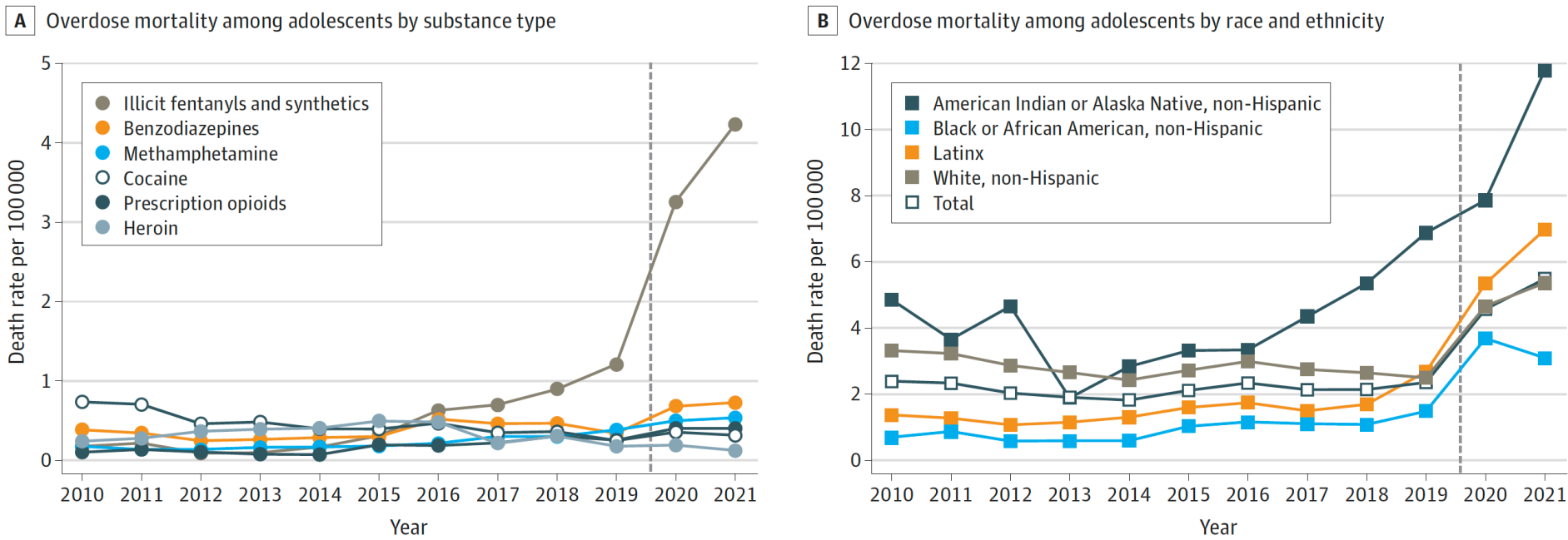
12 Month-Ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



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)	

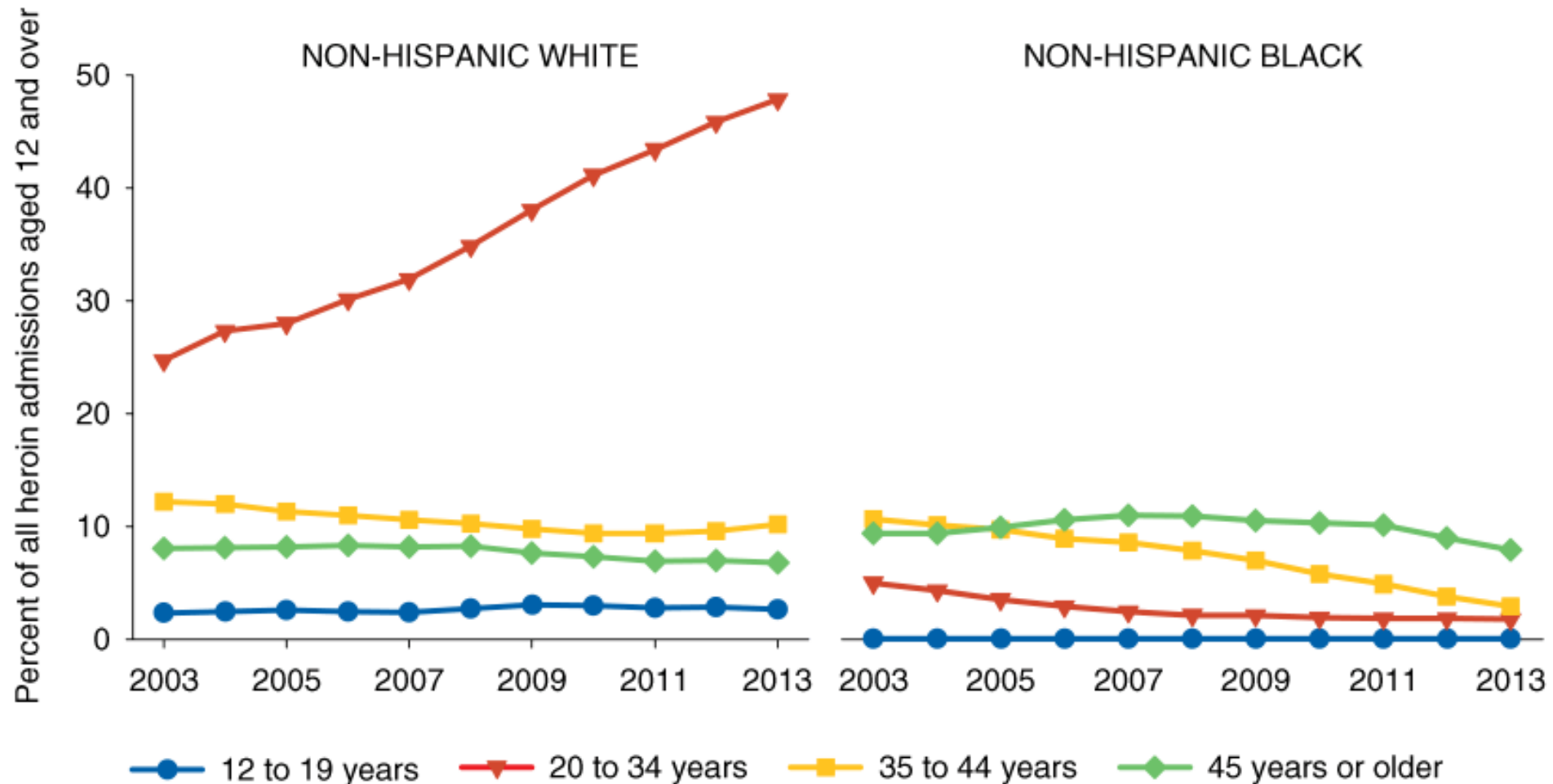
Figure. Adolescent Overdose Deaths, 2010-2021



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.

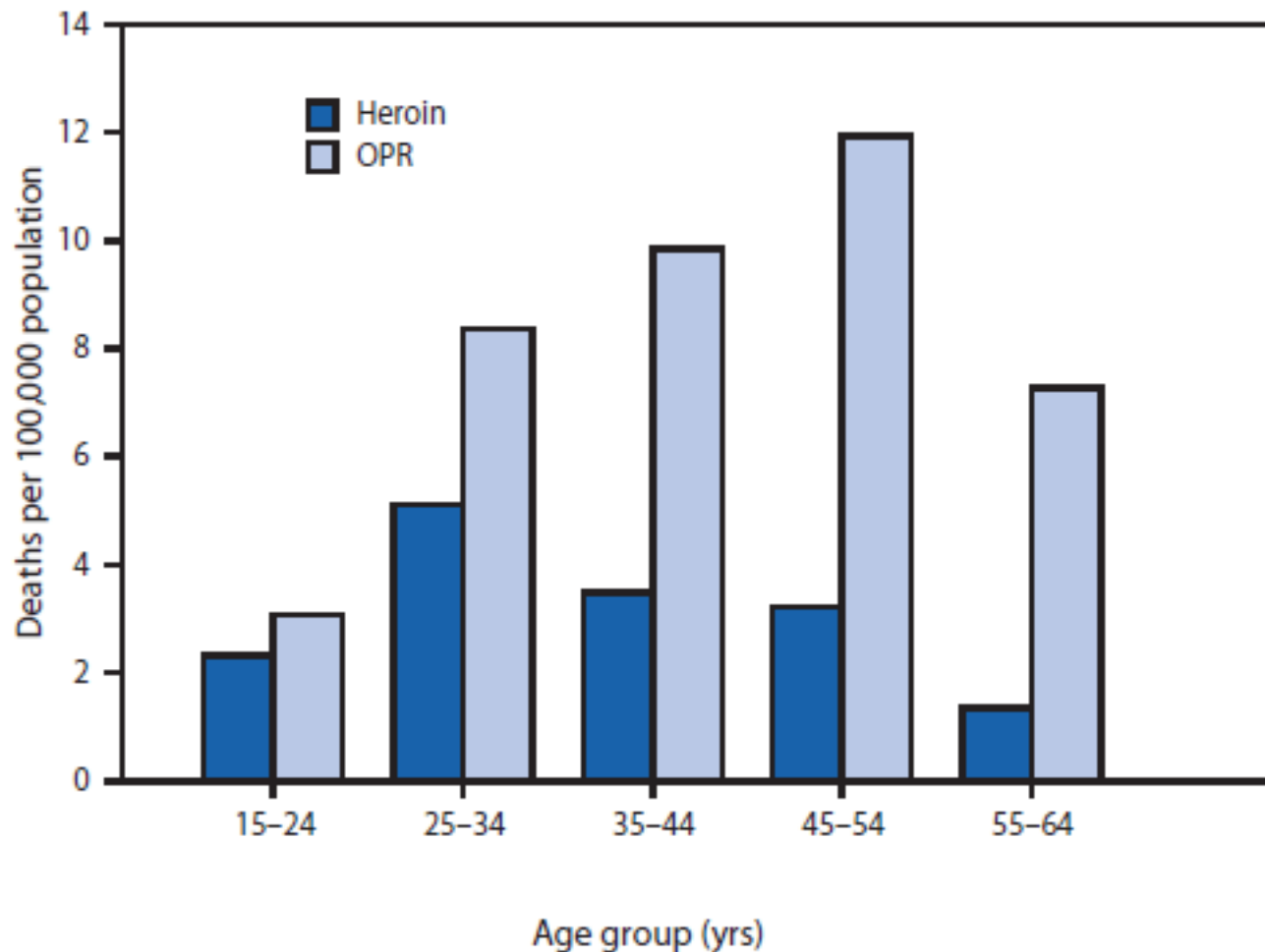
Friedman J, Godvin M, Shover CL, Gone JP, Hansen H, Schriger DL. Trends in Drug Overdose Deaths Among US Adolescents, January 2010 to June 2021. JAMA. 2022 Apr 12;327(14):1398-1400.

Heroin treatment admissions : 2003-2013



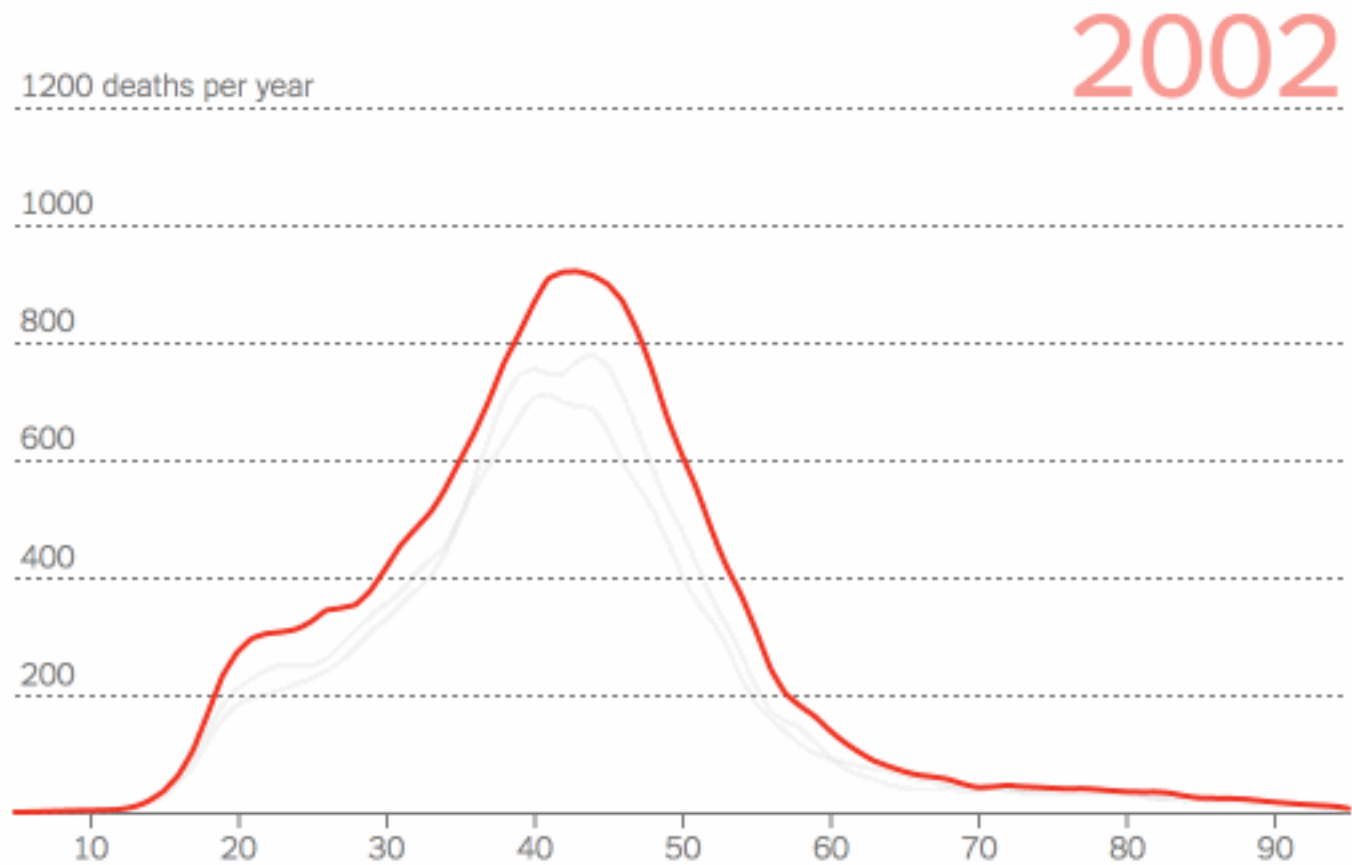
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 01.23.15.

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

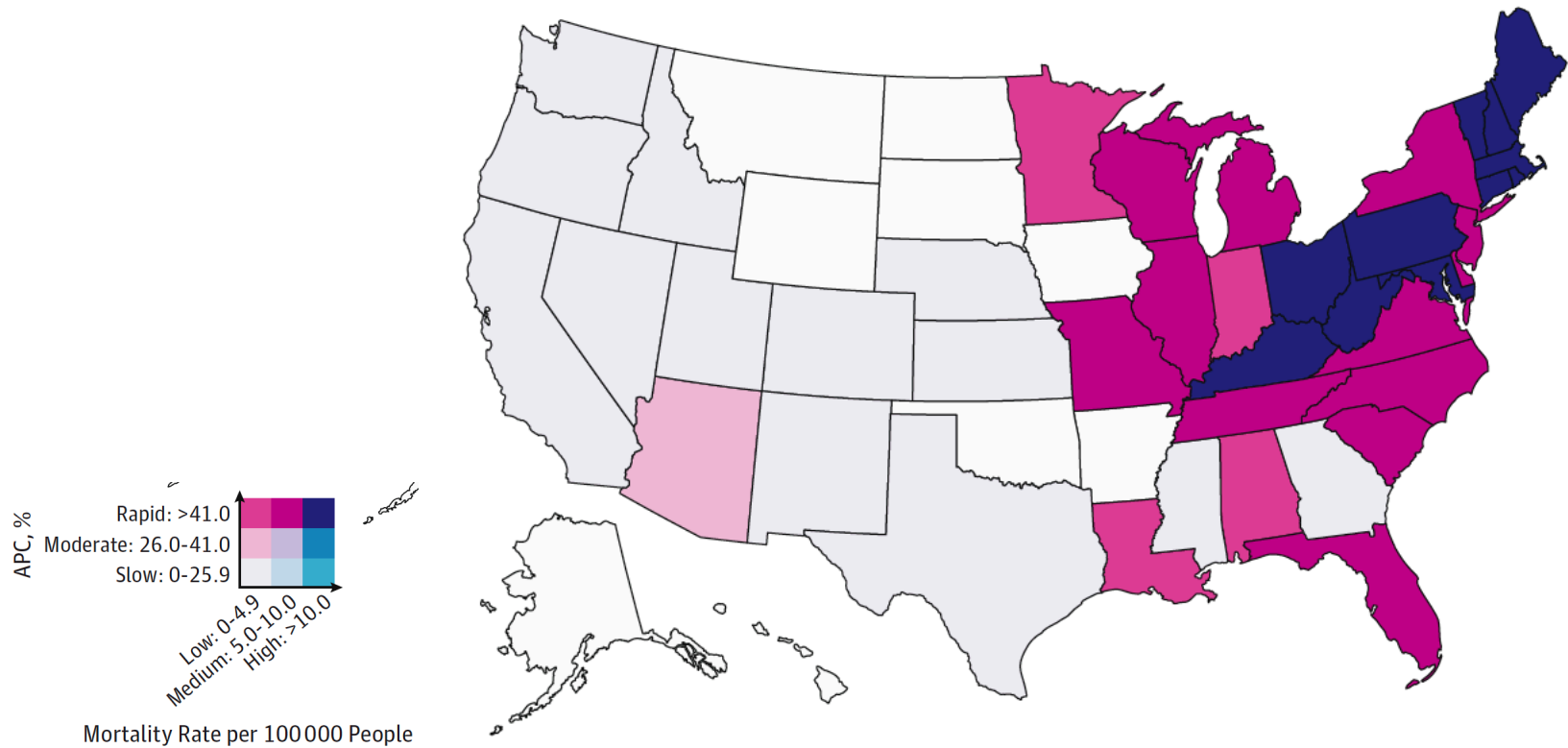
Distribution of drug deaths by age



Source: J. Katz. NYT Short Answers to Hard Questions About the Opioid Crisis August 10, 2017

Growth and Level of the Synthetic Opioid OD Deaths, 2016

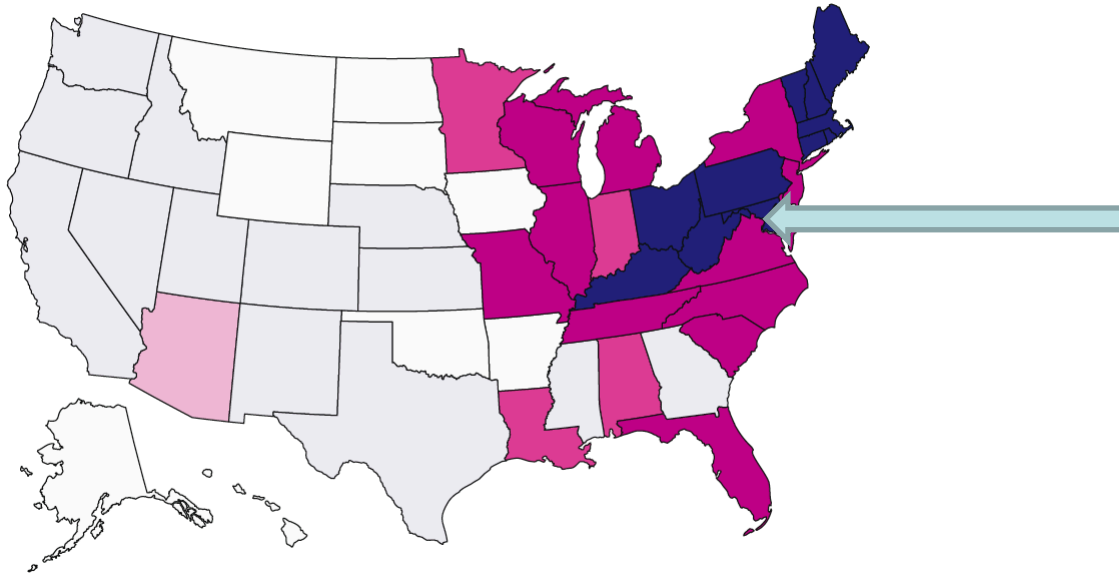
D Synthetic opioids



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

Growth and Level of the Synthetic Opioid OD Deaths, 2016

D Synthetic opioids

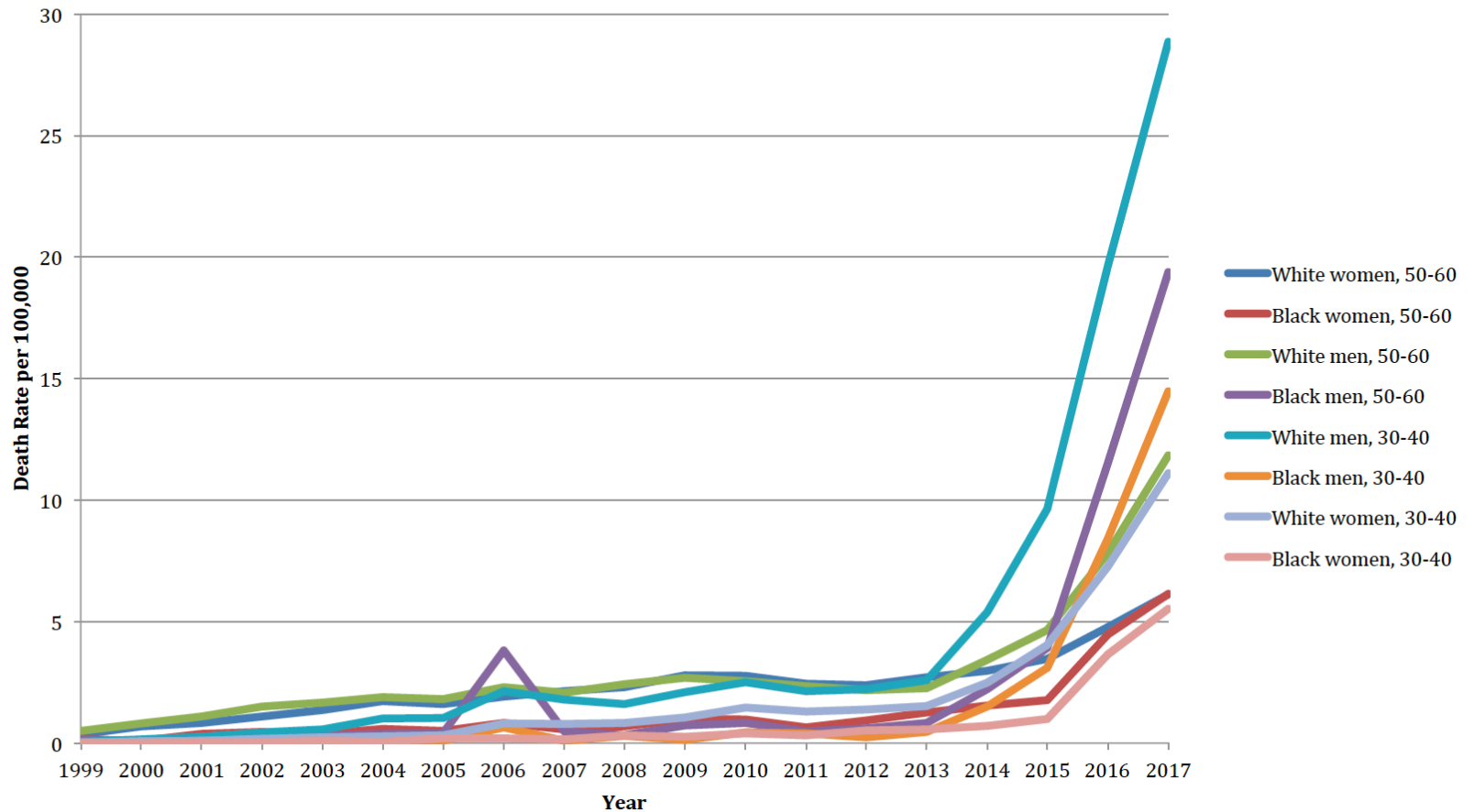


The District of Columbia had the fastest rate of increase in mortality from opioids in the country, more than tripling every year since 2013

Three Opioid-Addicted Cohorts

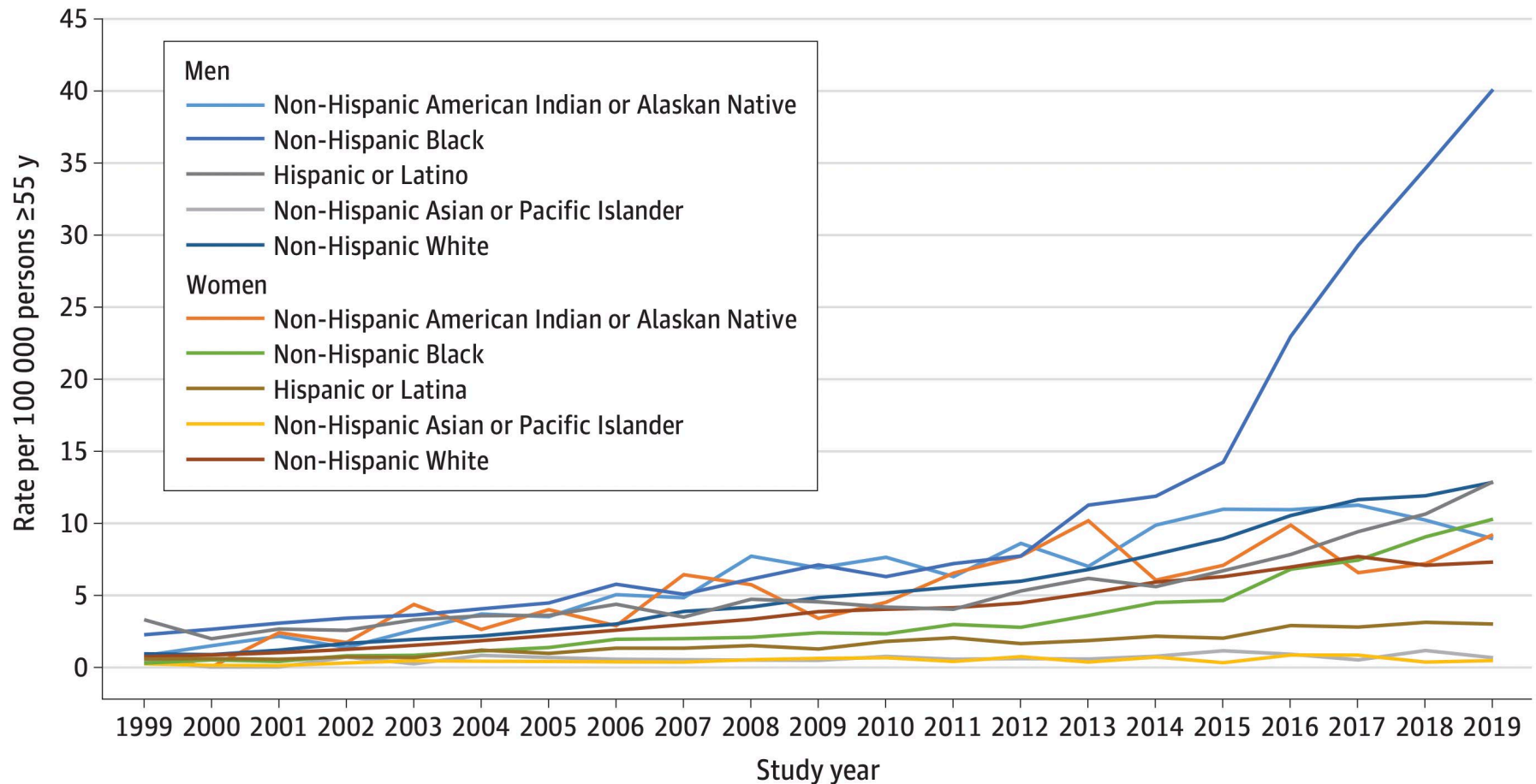
1. 20-40 y/o, disproportionately white, significant heroin use, opioid addiction began with Rx use (addicted after 1995)
2. 40 y/o & up, disproportionately white, mostly Rx opioids, opioid addiction began with Rx use (addicted after 1995)
3. 50 y/o & up, disproportionately non-white, mostly heroin users,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



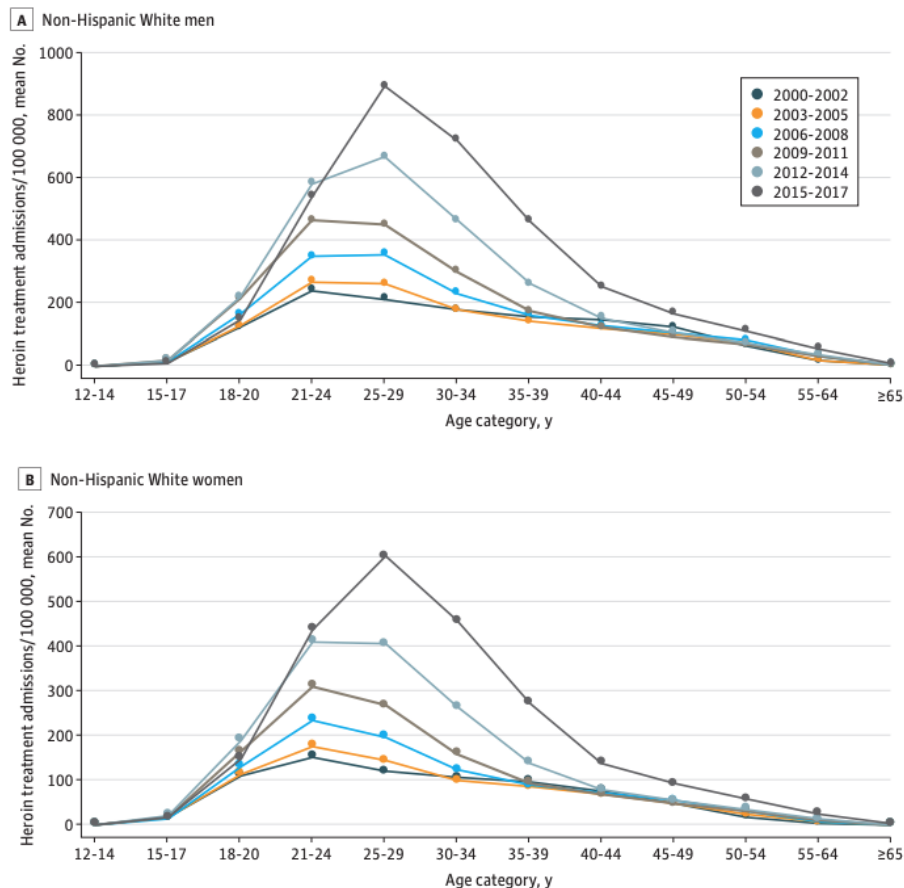
SOURCE: CDC WONDER

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



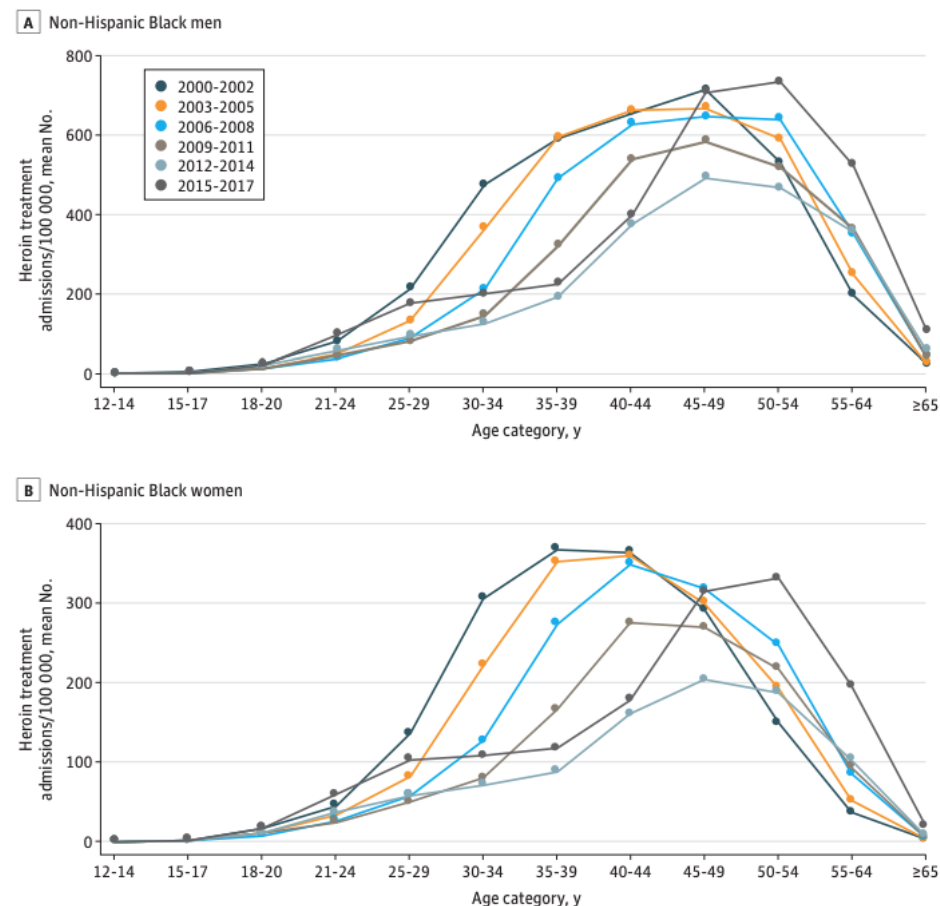
Non-Hispanic Whites

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



Non-Hispanic Blacks

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

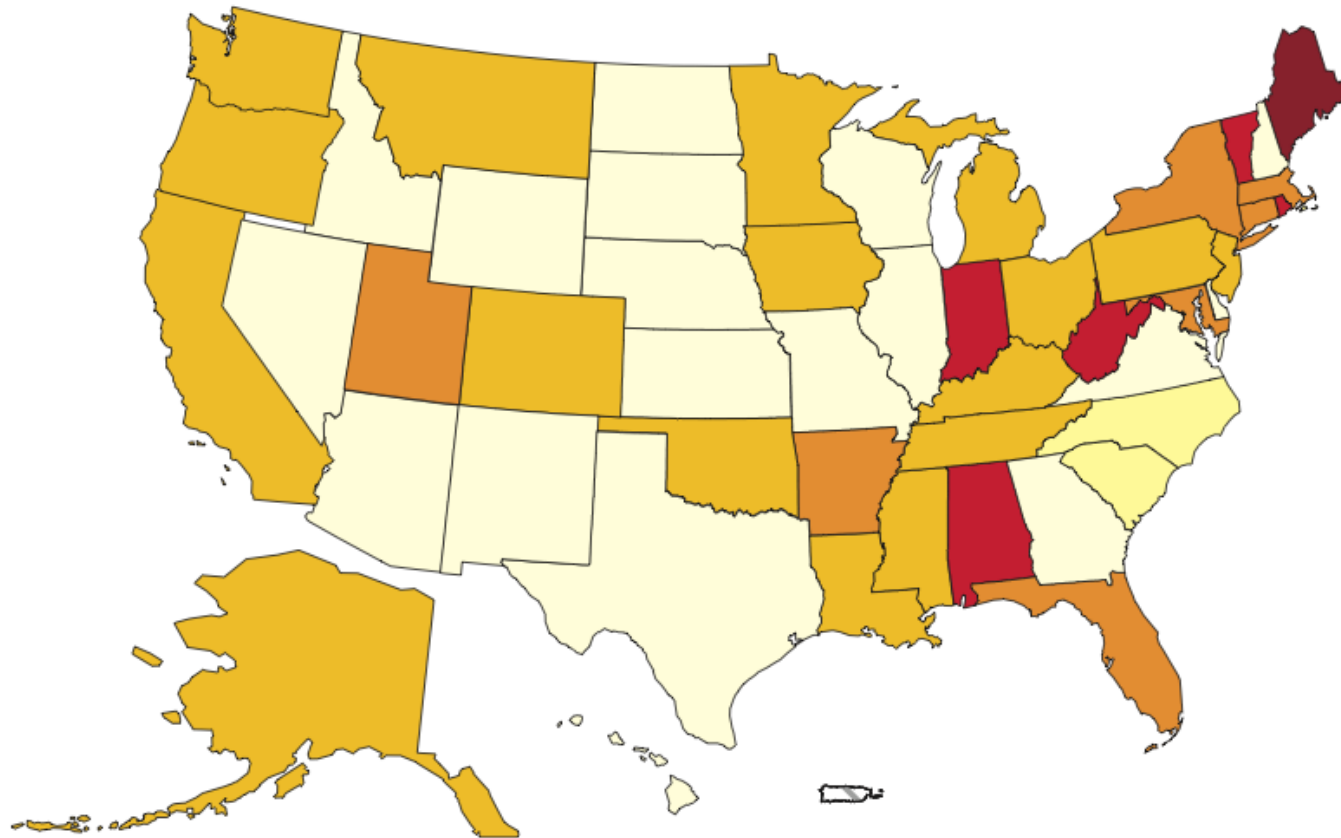
Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome

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

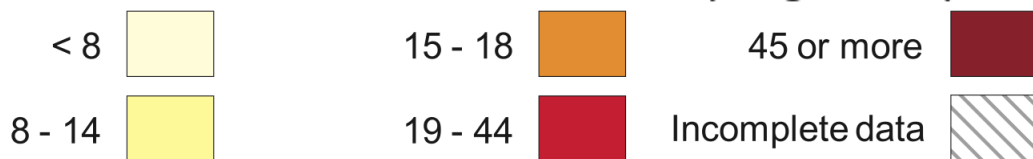
For the first time, drug overdose deaths have surpassed 100,000 in a 12-month period

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)

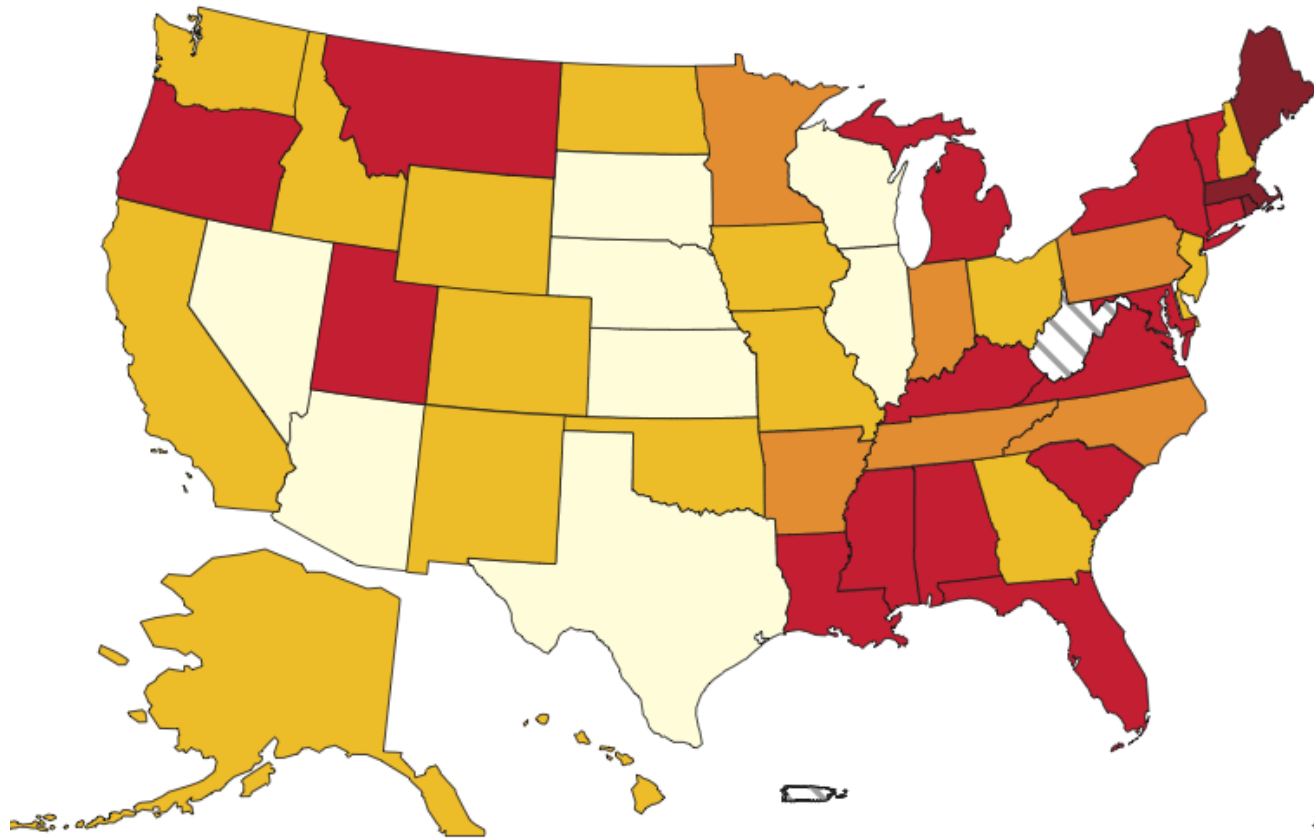


1999
(range 1 - 50)



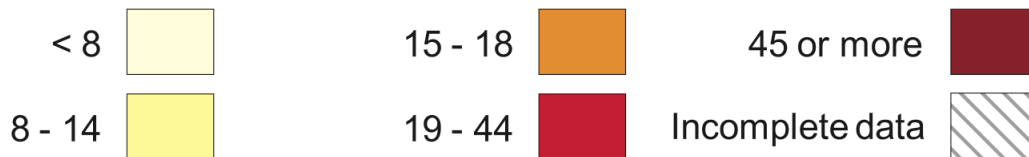
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



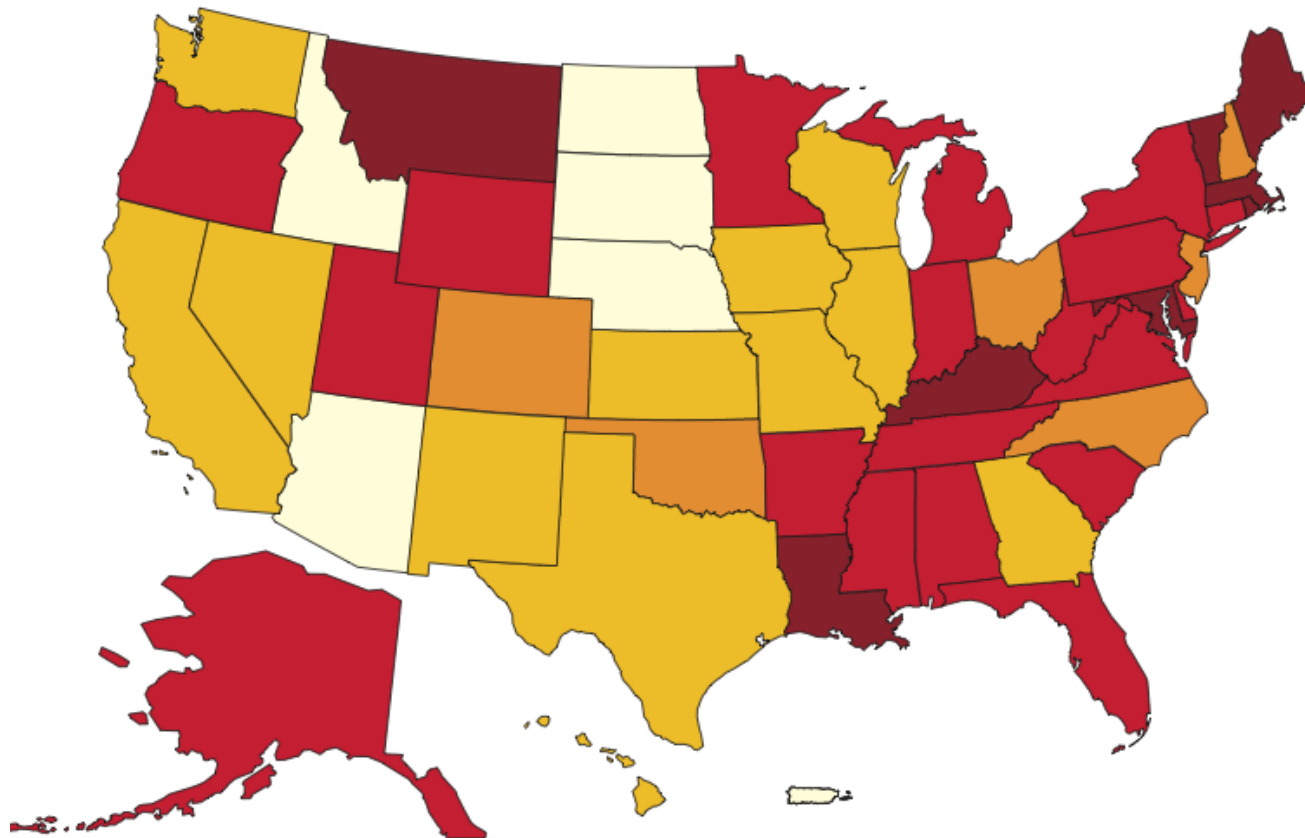
2001

(range 1 – 71)



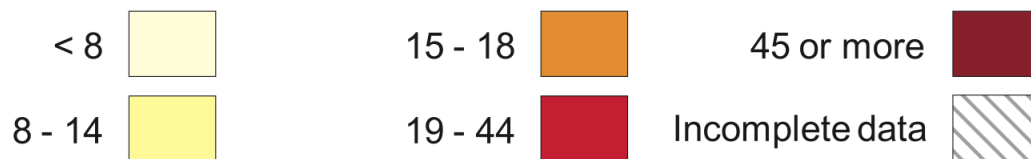
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



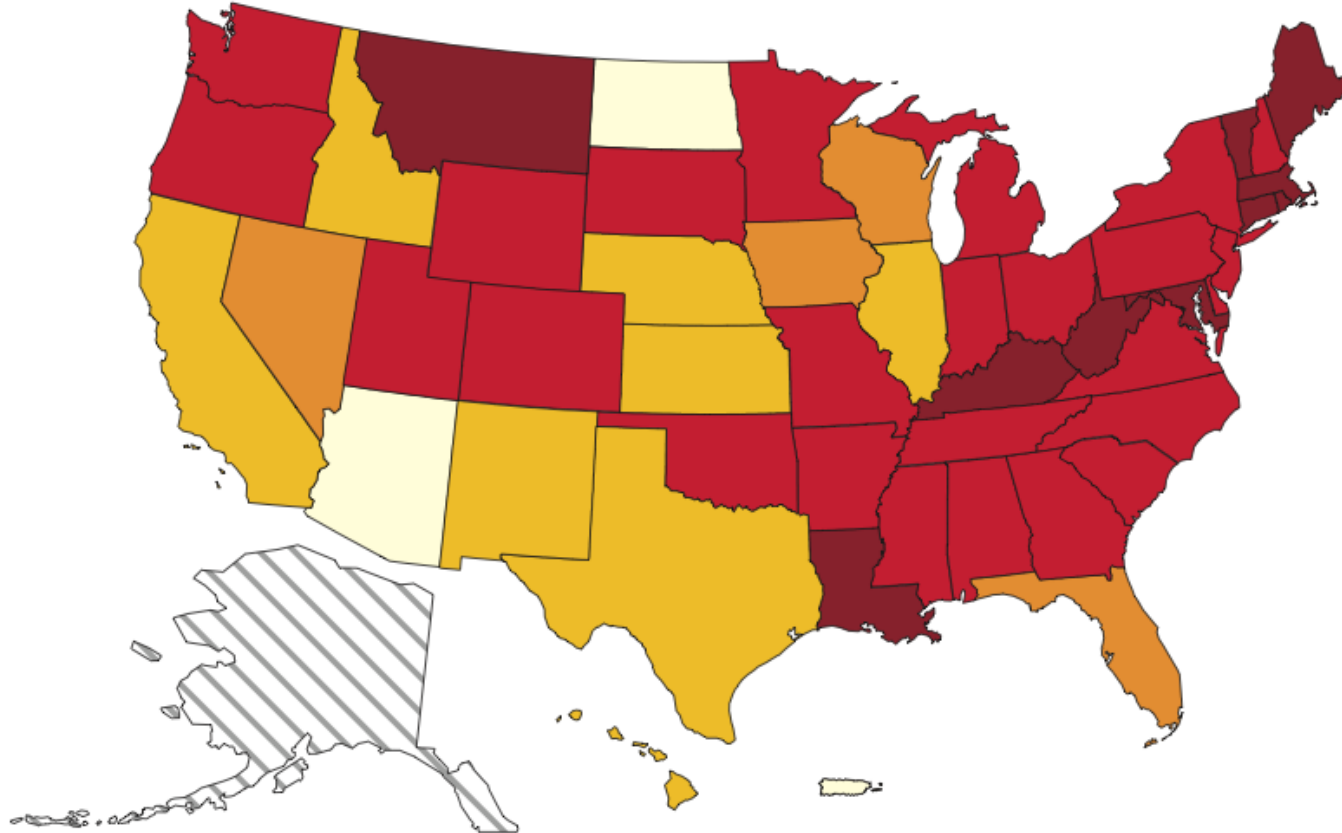
2003

(range 2 – 139)



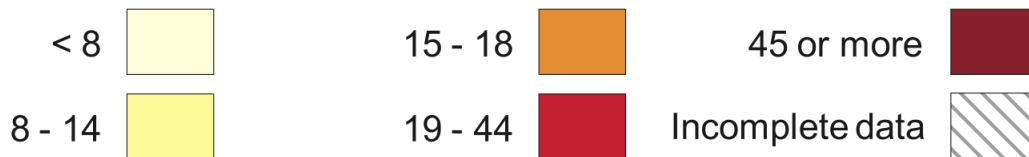
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



2005

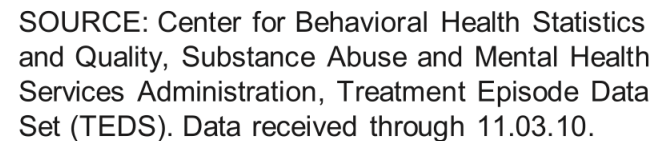
(range 0 – 214)



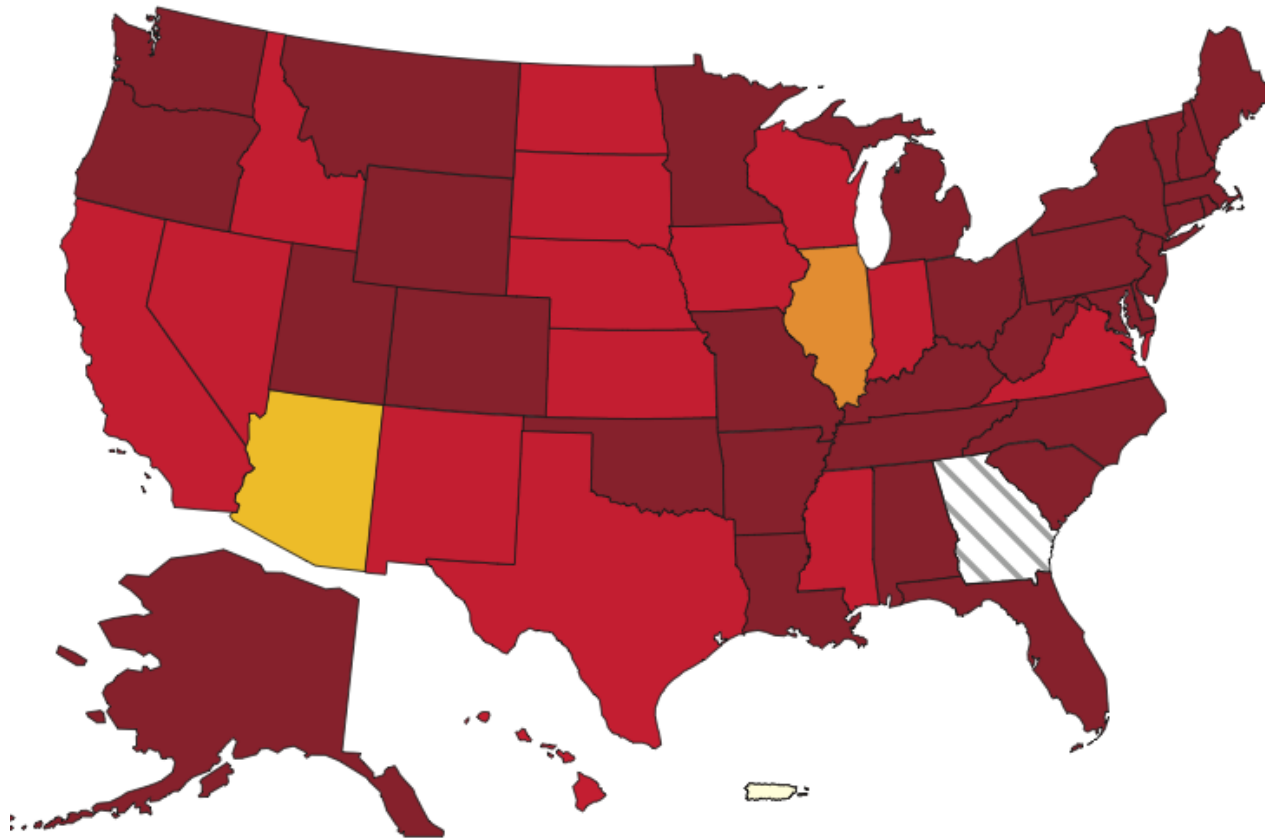
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

The map displays the distribution of the elderly population across the United States. States with the highest percentages (dark red) include New York, Pennsylvania, New Jersey, Maryland, Delaware, Virginia, North Carolina, South Carolina, Florida, and several states in the Northeast and Midwest. States with moderate percentages (orange and red) include California, Texas, and many others. States with lower percentages (yellow and light orange) include Nevada, Arizona, and parts of the West and Midwest. Alaska, Georgia, and West Virginia are marked with diagonal hatching.

(range 1 – 340)

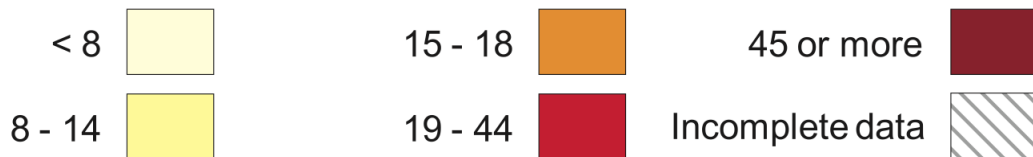


Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



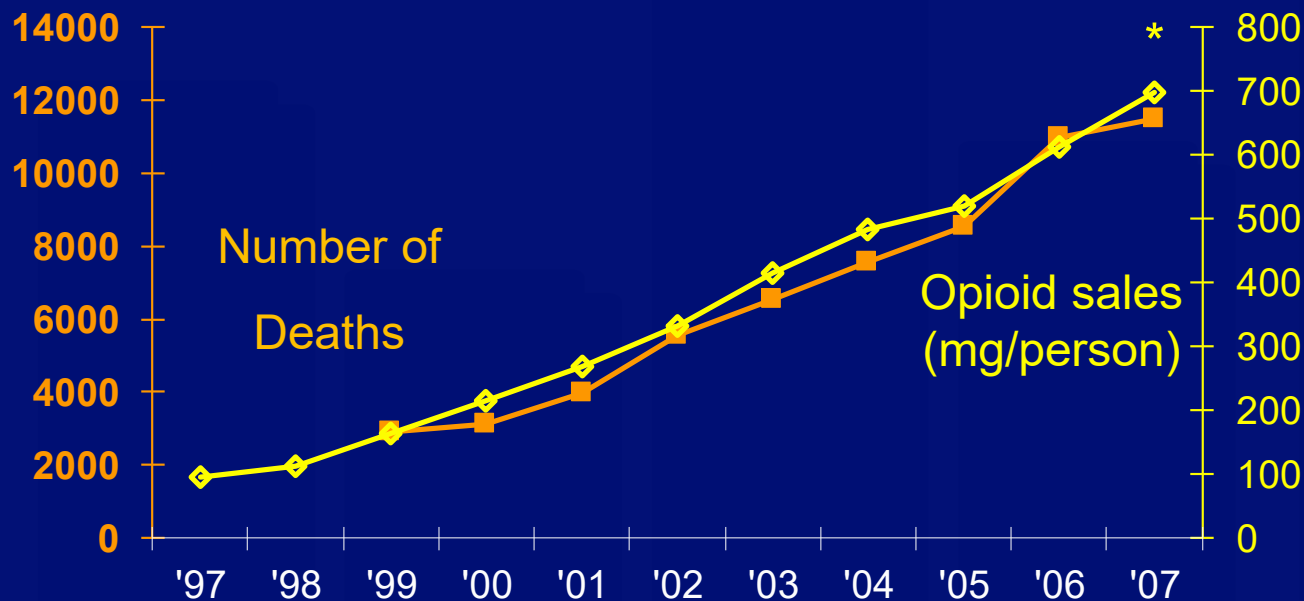
2009

(range 1 – 379)



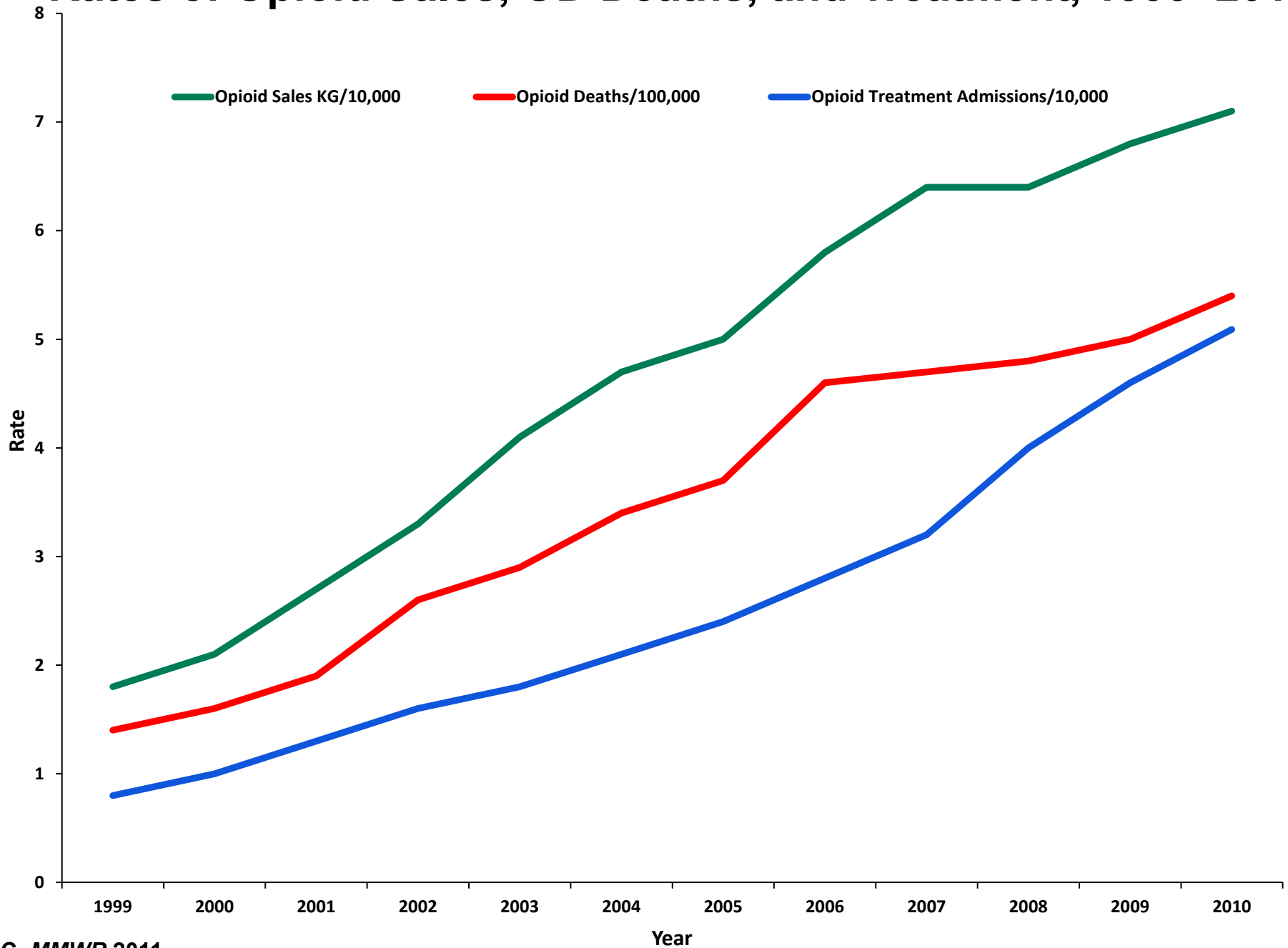
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



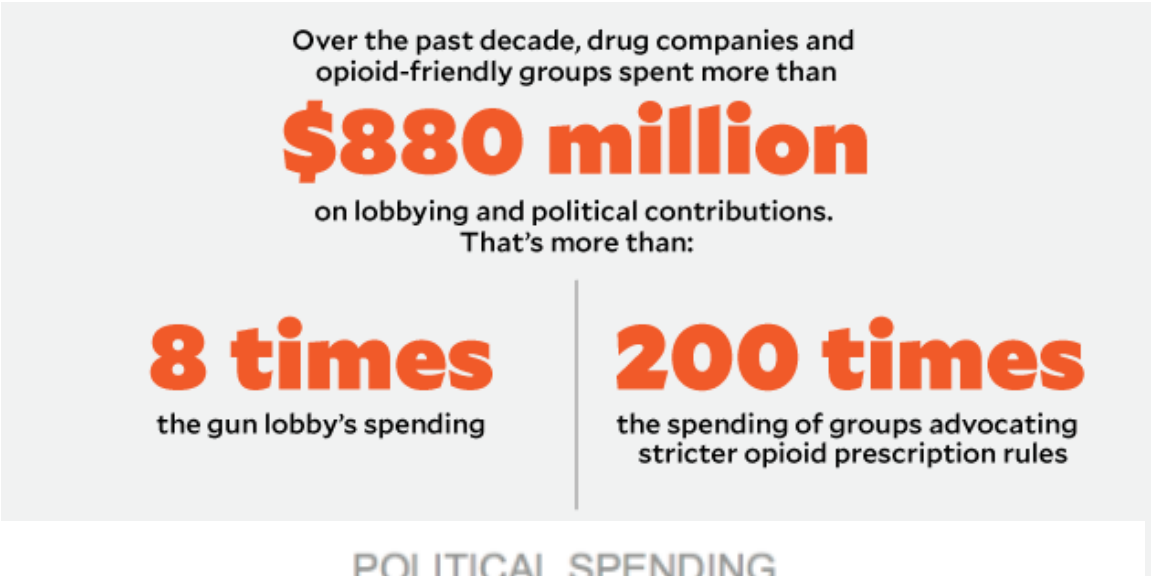
Source: National Vital Statistics System, multiple cause of death dataset, and DEA ARCOS
* 2007 opioid sales figure is preliminary.

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



Pro-painkiller lobby shapes policy amid drug epidemic

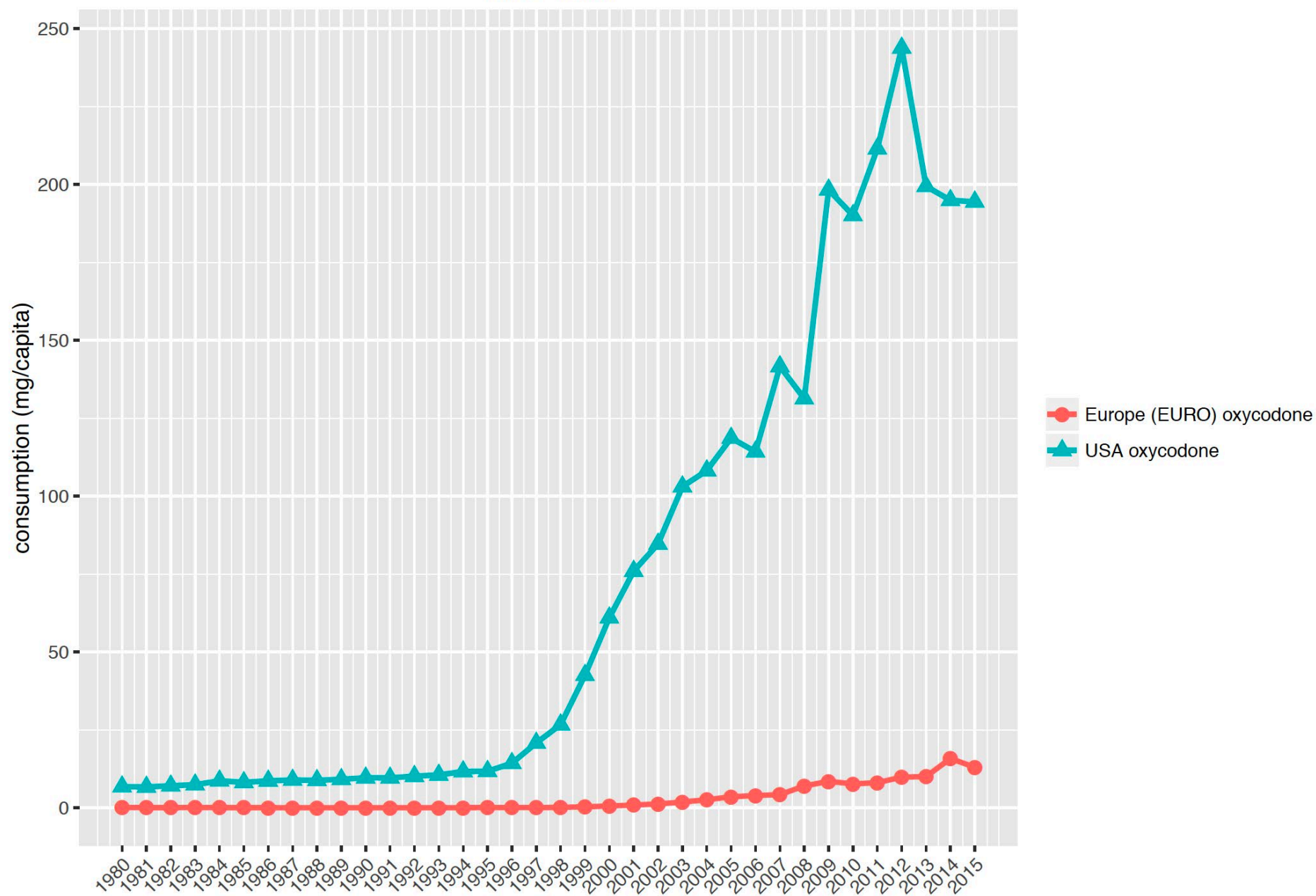
Matthew Perrone and Ben Wieder, Associated Press and Center for Public Integrity



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%	54%
		Dems	Reps

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

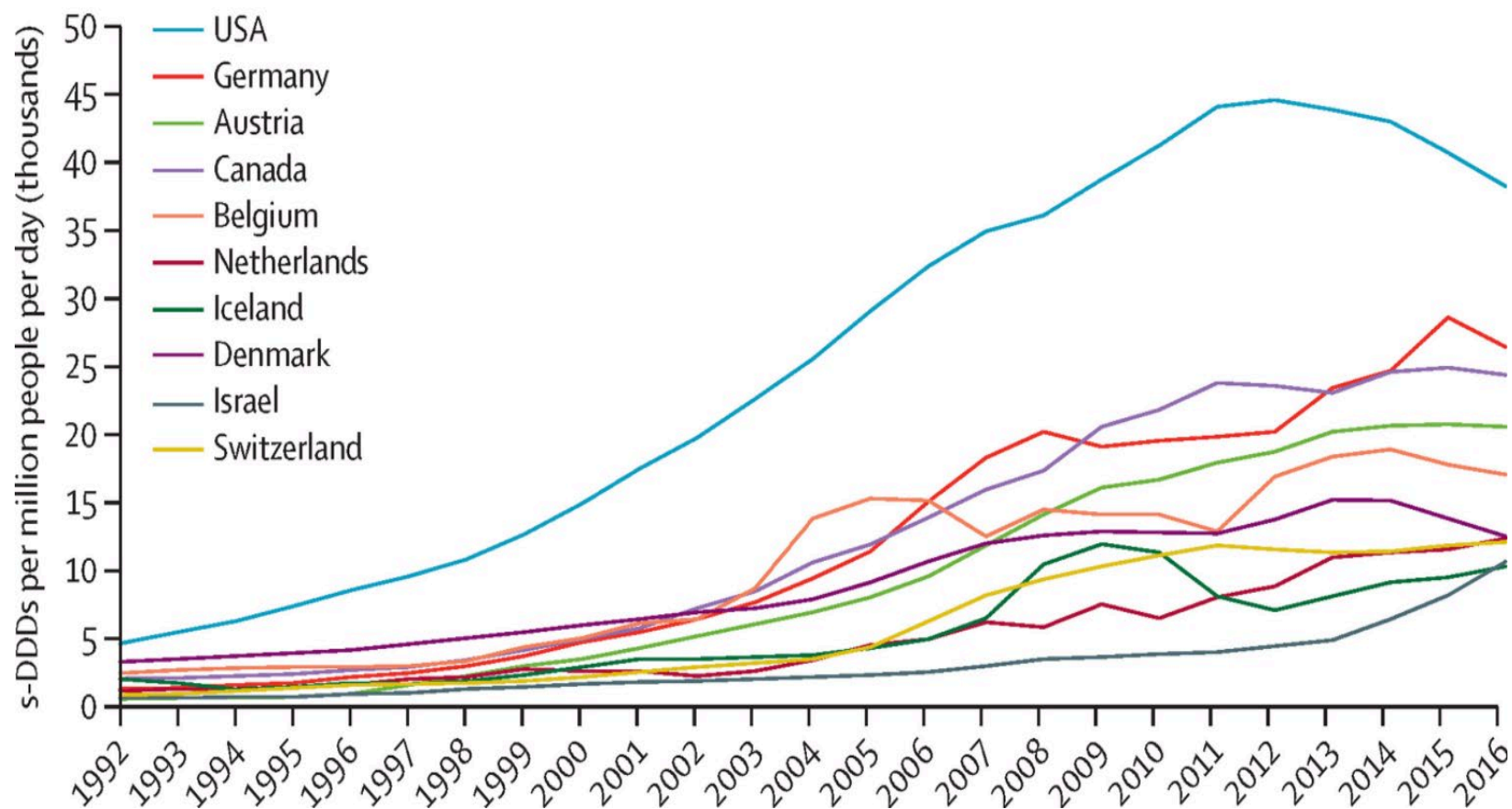


Johnson & Johnson And Drug Distributors Finalize \$26 Billion Settlement To End Opioid Crisis Lawsuits

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

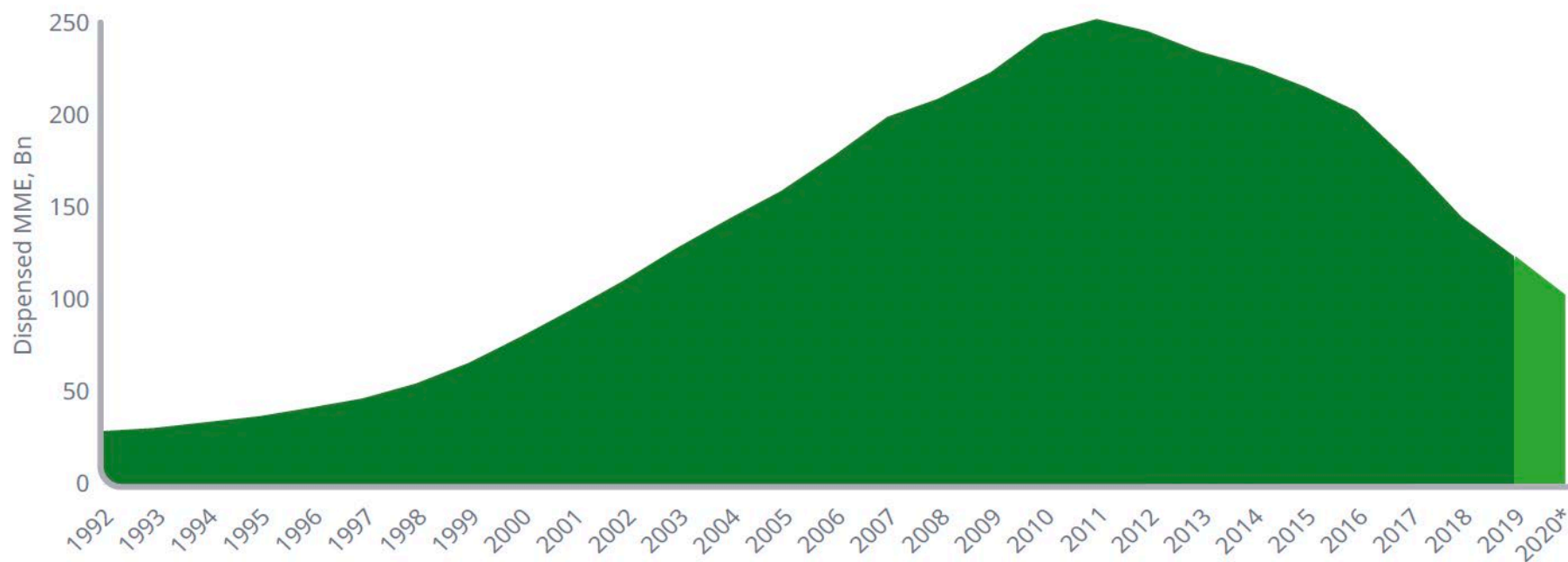
Walgreens to pay \$683m to settle claims it exacerbated opioid crisis in Florida

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

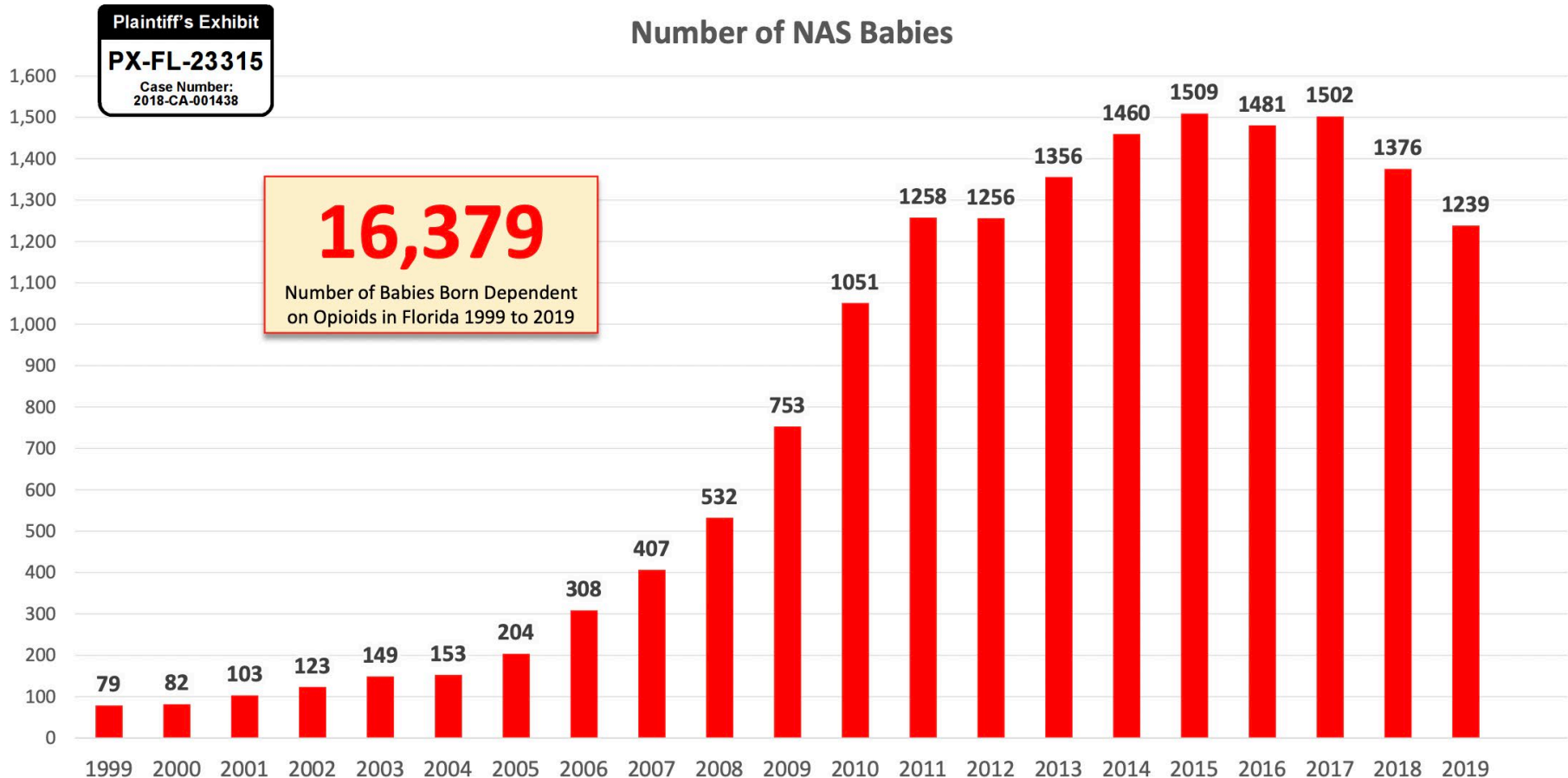
Exhibit 1: Prescription Opioid Use in Morphine Milligram Equivalents (MME) Bn, 1992–2020*



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

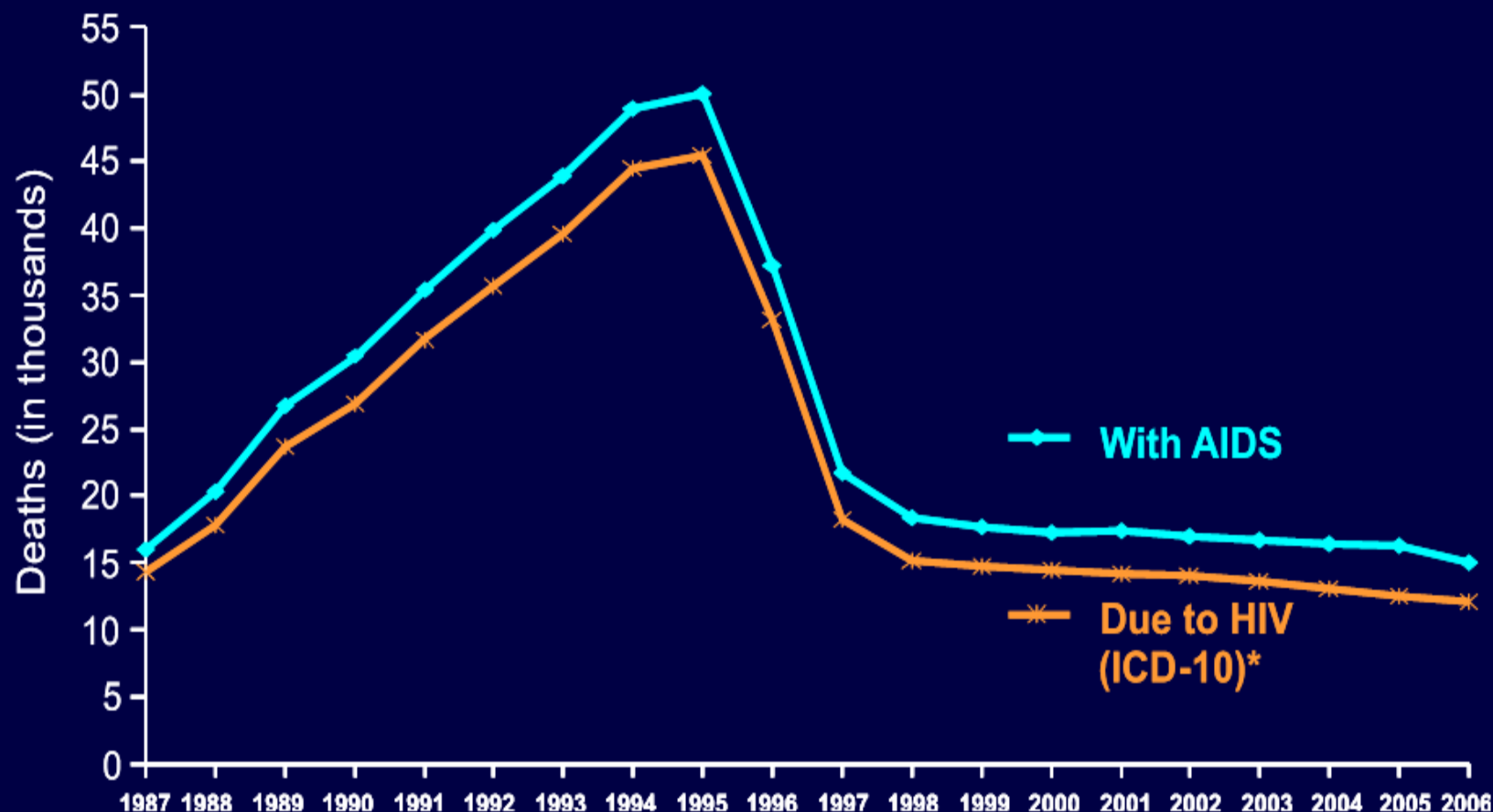


Source: Expert Report of Andrew Kolodny at 5, 17-18; DOH data.

Controlling the epidemic:

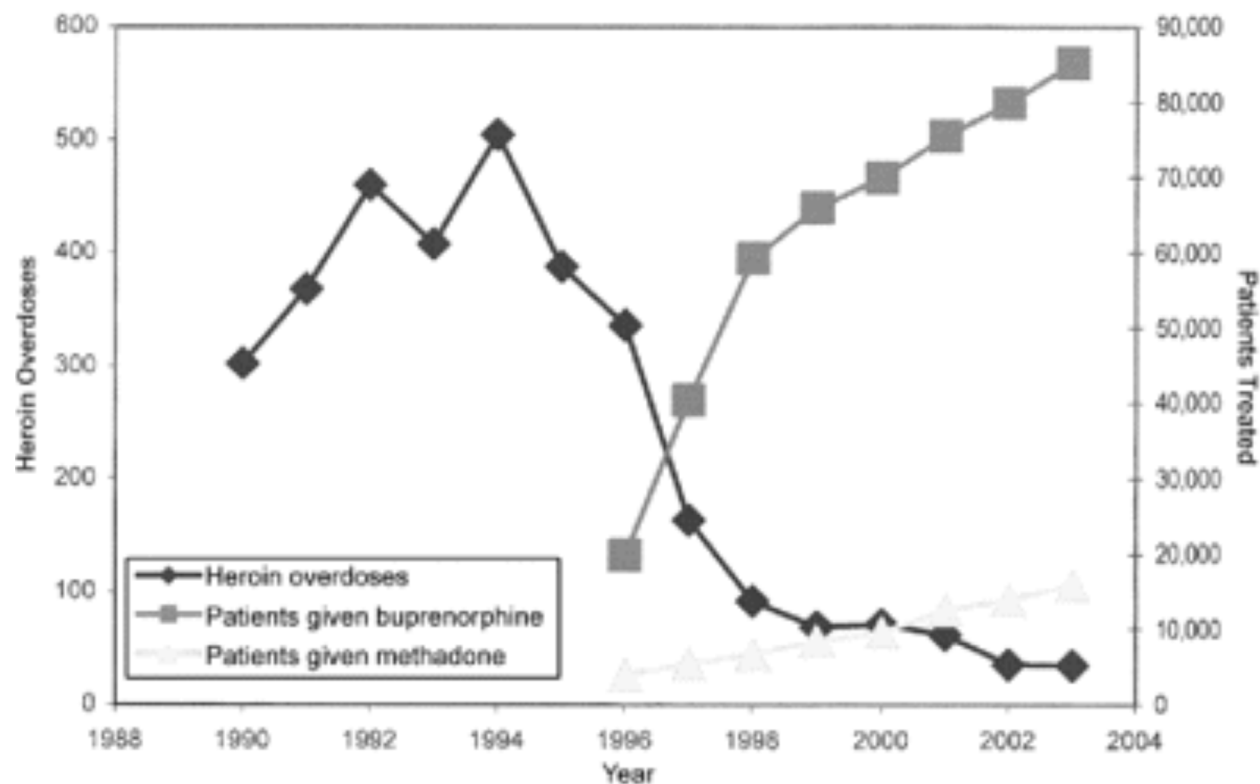
- **Prevent** new cases of opioid addiction
- **Treat** people who are already addicted
- **Harm Reduction**
- **Interdiction (Law Enforcement)**

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.



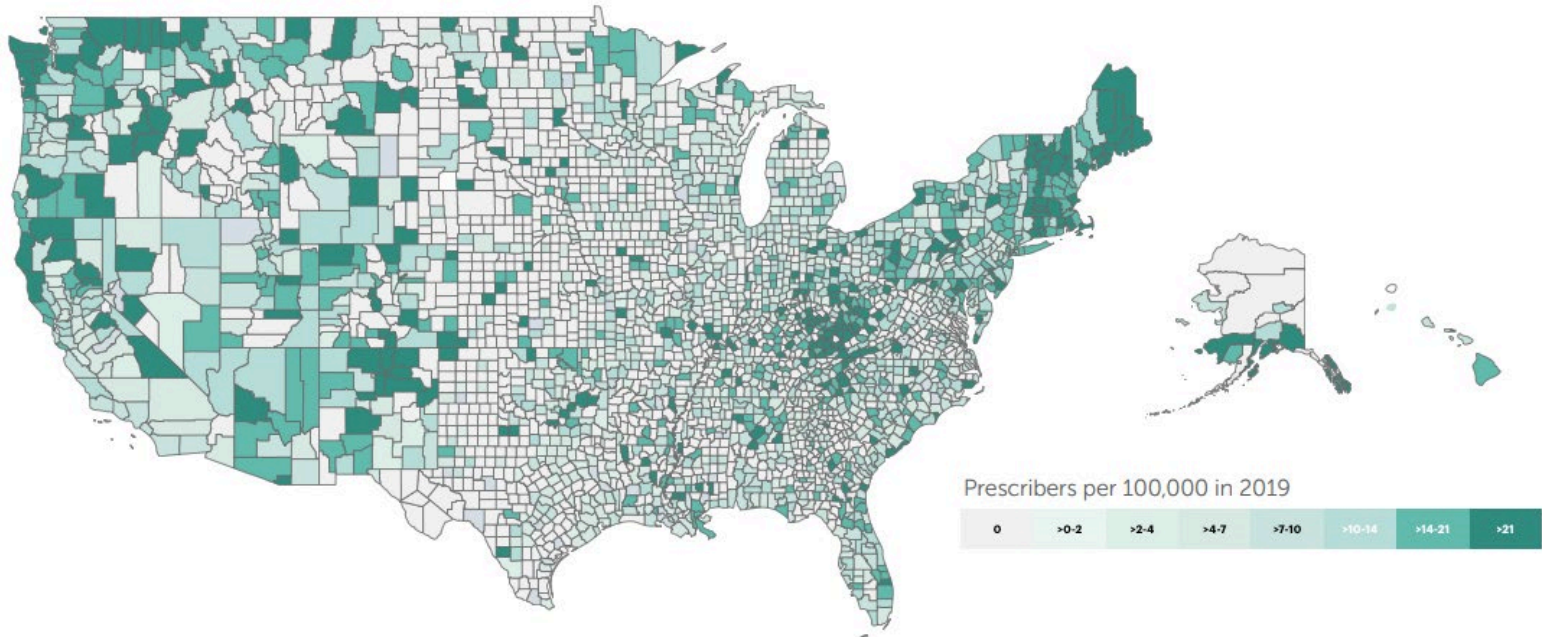
74,000 (5.7%)
are **waived** to prescribe buprenorphine.

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.



Impact of COVID-19 on the Opioid Crisis

- OD deaths increased at a faster rate
- Ability to provide direct services and psychosocial support impeded
- Litigation against opioid industry slowed

OUD Increases COVID Risks

- Increased susceptibility to infection
 - Opioid-induced immunosuppression
 - Psychosocial factors (homelessness, treatment settings)
- Increased risk for complications
 - Opioid-induced immunosuppression
 - Respiratory depression from opioids
 - Other medical problems

OUD Increases COVID Risks

- Addictive disorder increases risk for COVID, with opioid use disorder followed by tobacco use disorder, having highest risk.
- Addictive disorder increases risk for death from COVID, with greatest risk in Black patients with OUD.

Source: Wang, Q.Q., Kaelber, D.C., Xu, R. et al. COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States. Mol Psychiatry (2020).

Treatment System Changes

- Feds relax Methadone rules on take-home doses and allow home deliveries.
- Buprenorphine home inductions
- Expansion of tele-medicine treatment
- Naloxone home deliveries

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

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

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

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Published online: 22 April 2021

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?

Summary

- The U.S. is in the midst of a severe epidemic of opioid addiction and overdose deaths, which worsened during Covid.
- To bring the epidemic to an end:
 - We must prevent new cases of opioid addiction
 - We must improve access to treatment for people already addicted