



Understanding & Responding to an Epidemic of Addiction

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Physicians for Responsible Opioid Prescribing



Disclosure

- I have no relationship with pharmaceutical companies or other commercial entities.
- I have served as an expert witness in state litigation against opioid manufacturers.

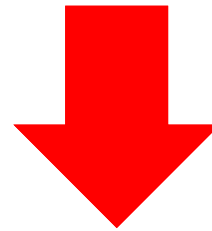
Opium



Opium

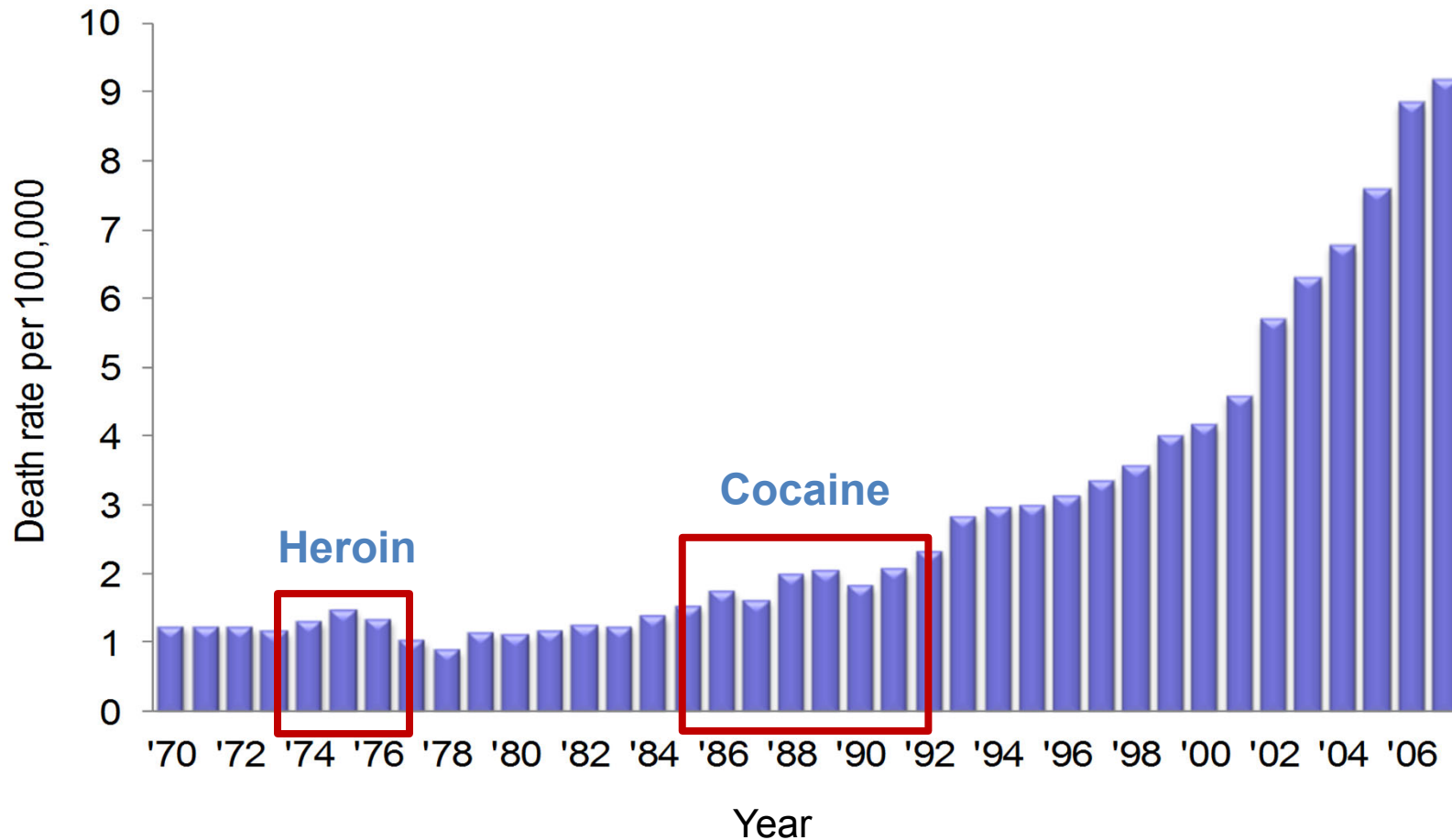


Codeine
Morphine
Thebaine

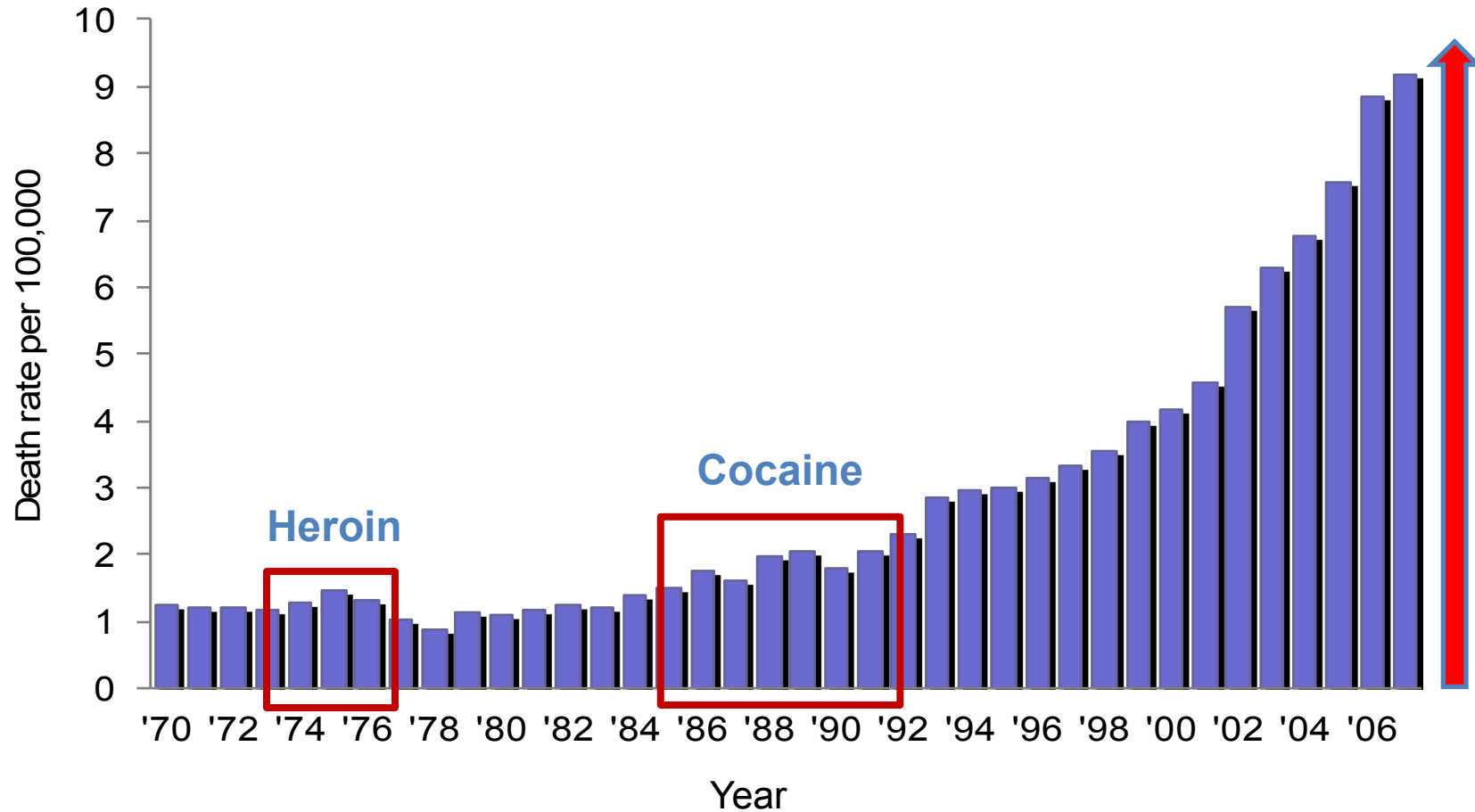


Heroin
Oxycodone
Hydrocodone
Hydromorphone
Oxymorphone

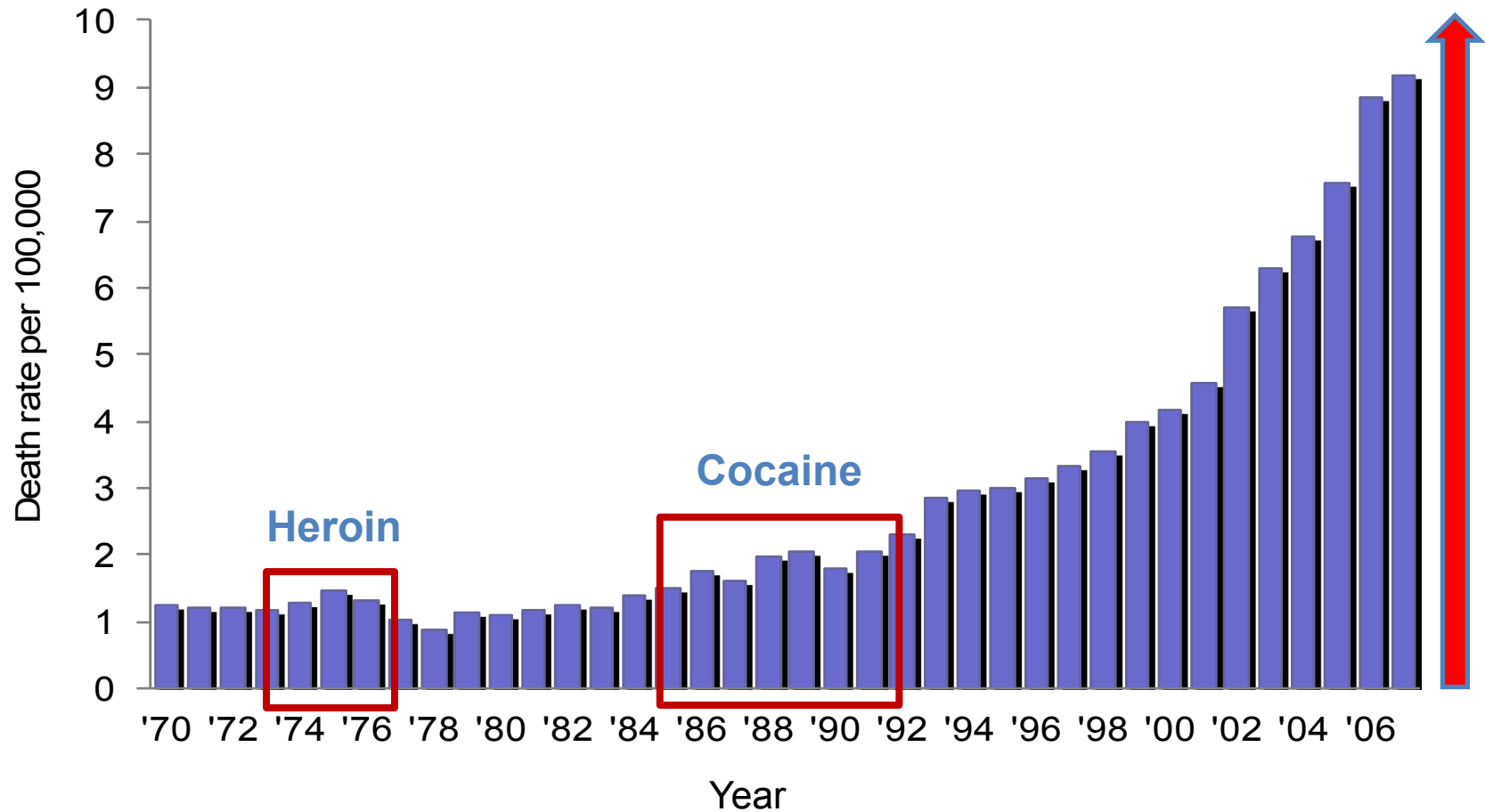
Unintentional Drug Overdose Deaths United States, 1970–2007



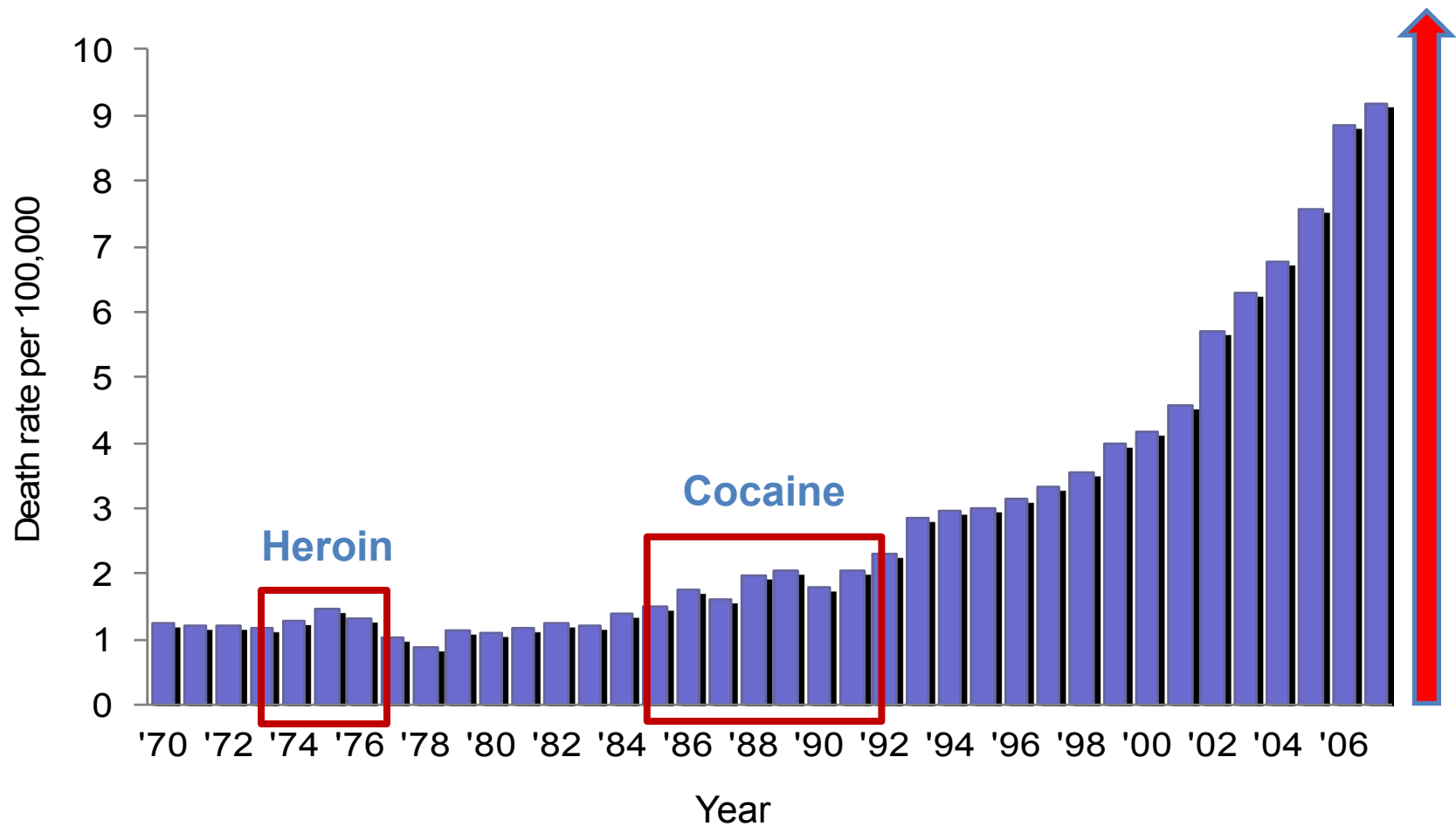
Unintentional Drug Overdose Deaths United States



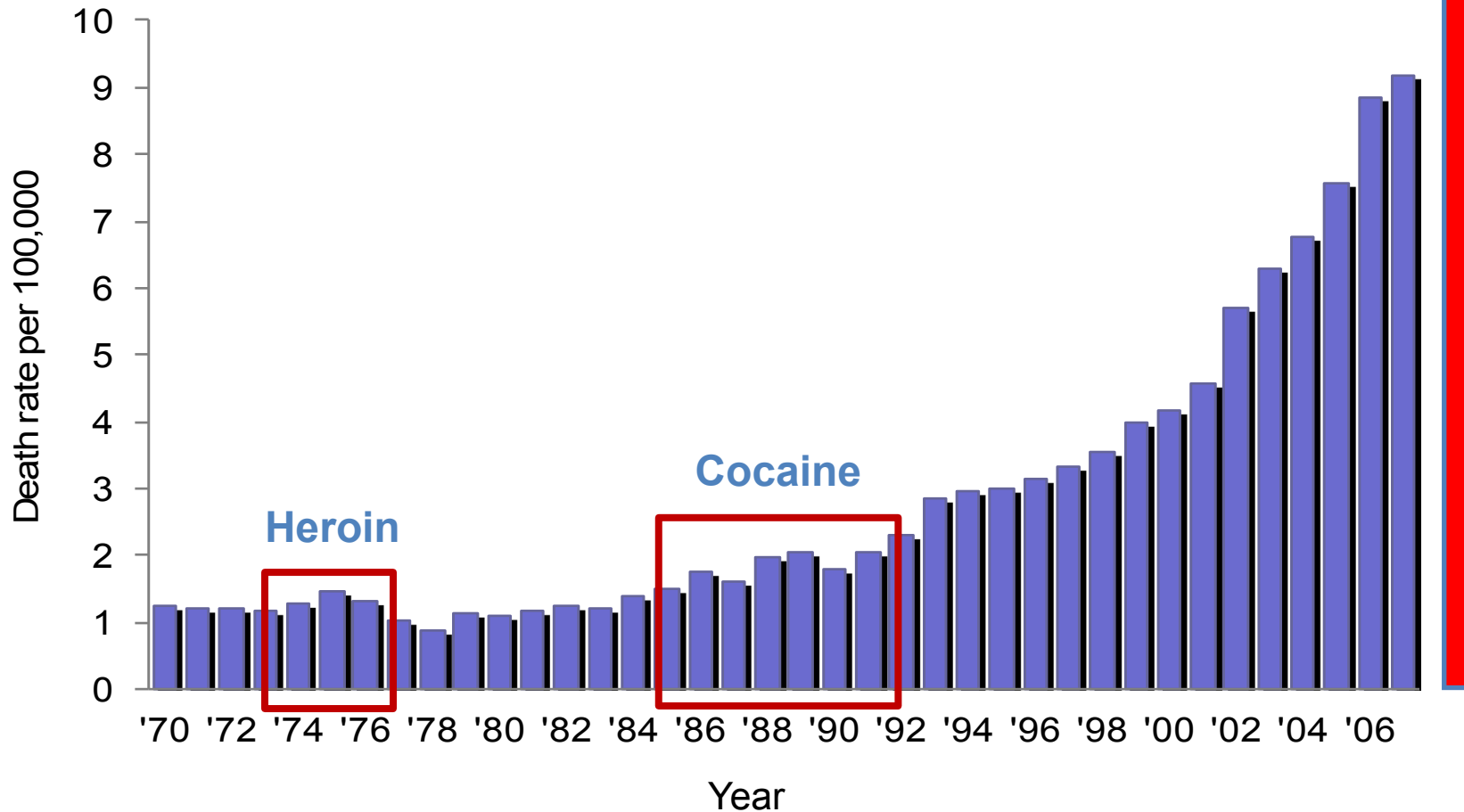
Unintentional Drug Overdose Deaths United States



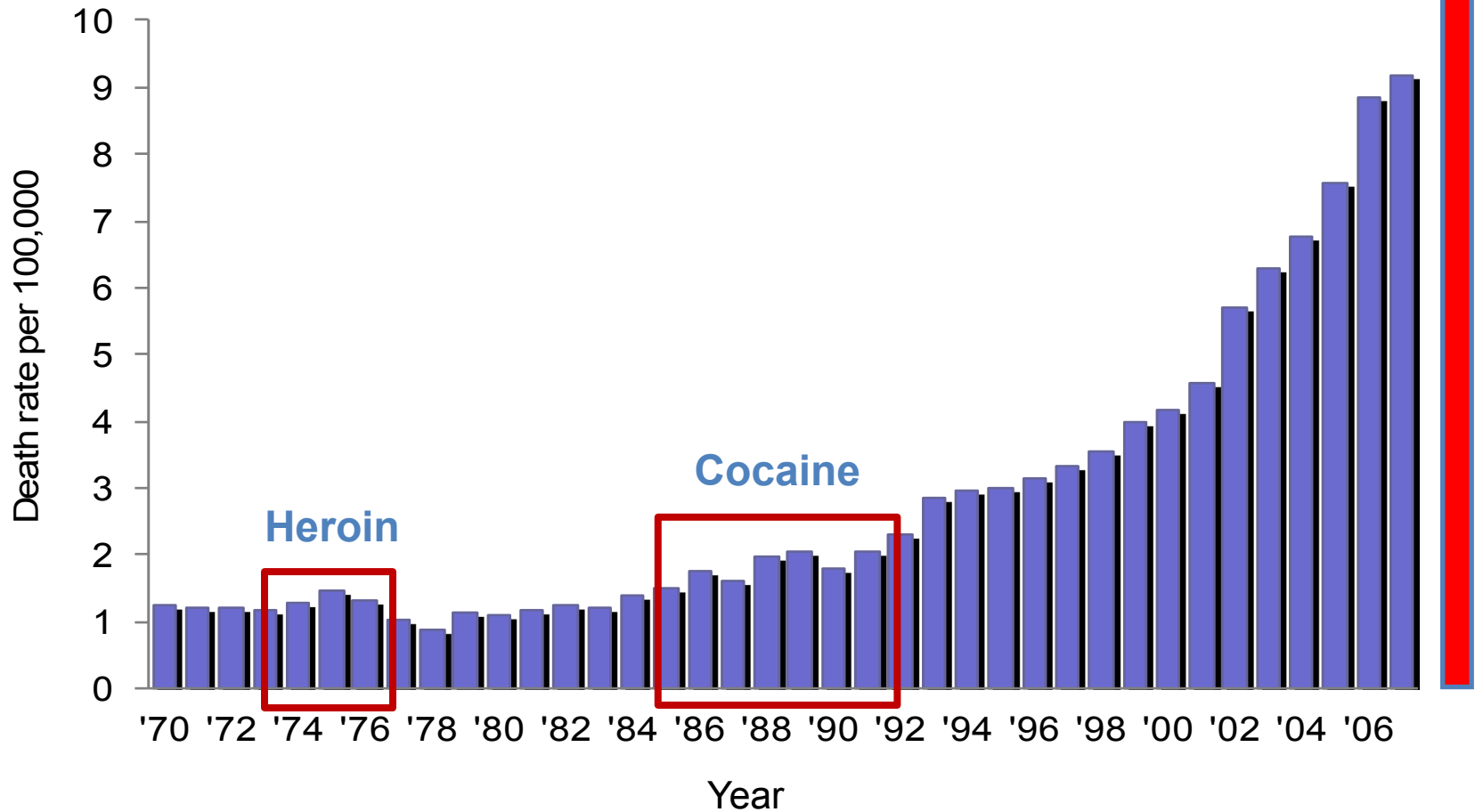
Unintentional Drug Overdose Deaths United States



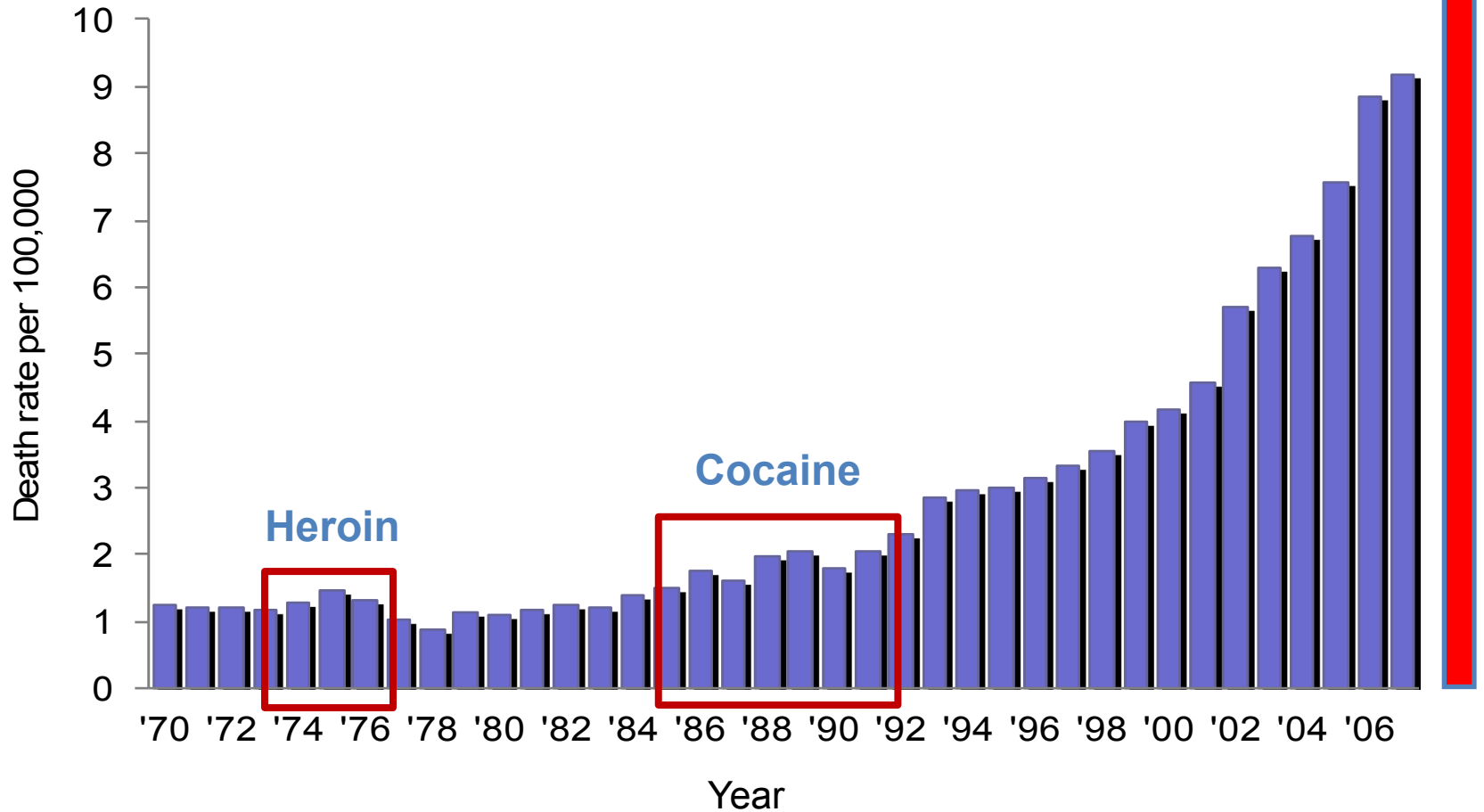
Unintentional Drug Overdose Deaths United States



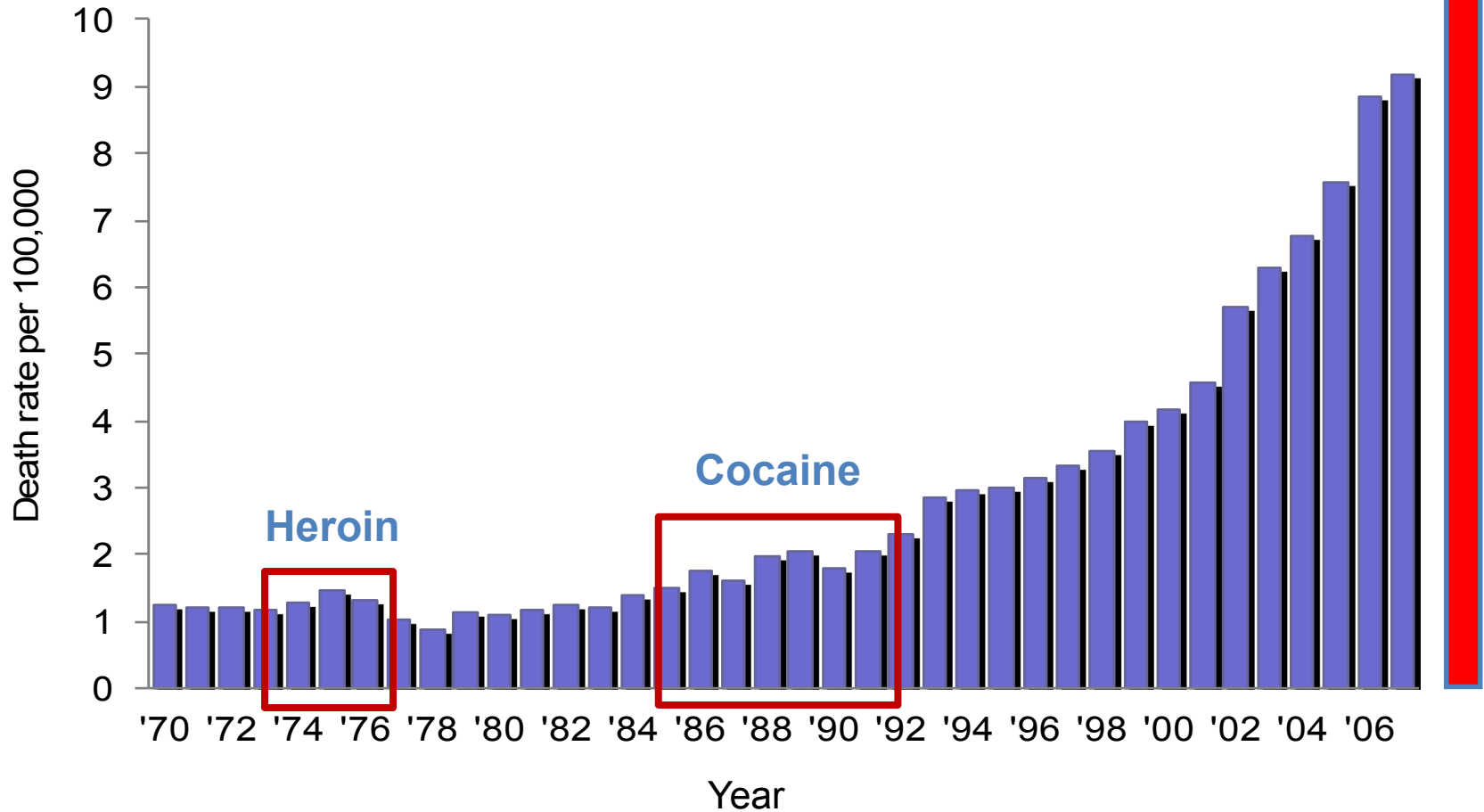
Unintentional Drug Overdose Deaths United States



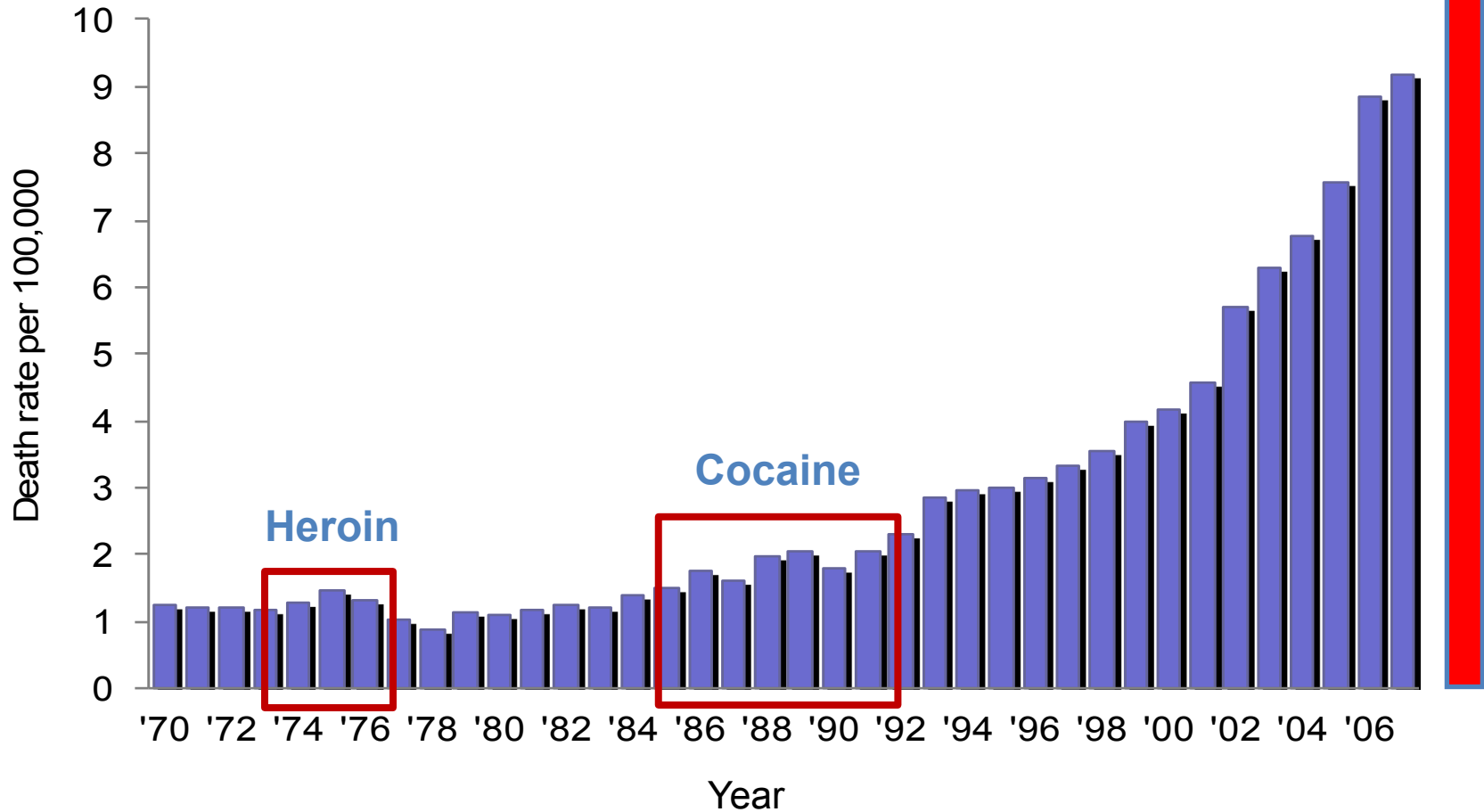
Unintentional Drug Overdose Deaths United States



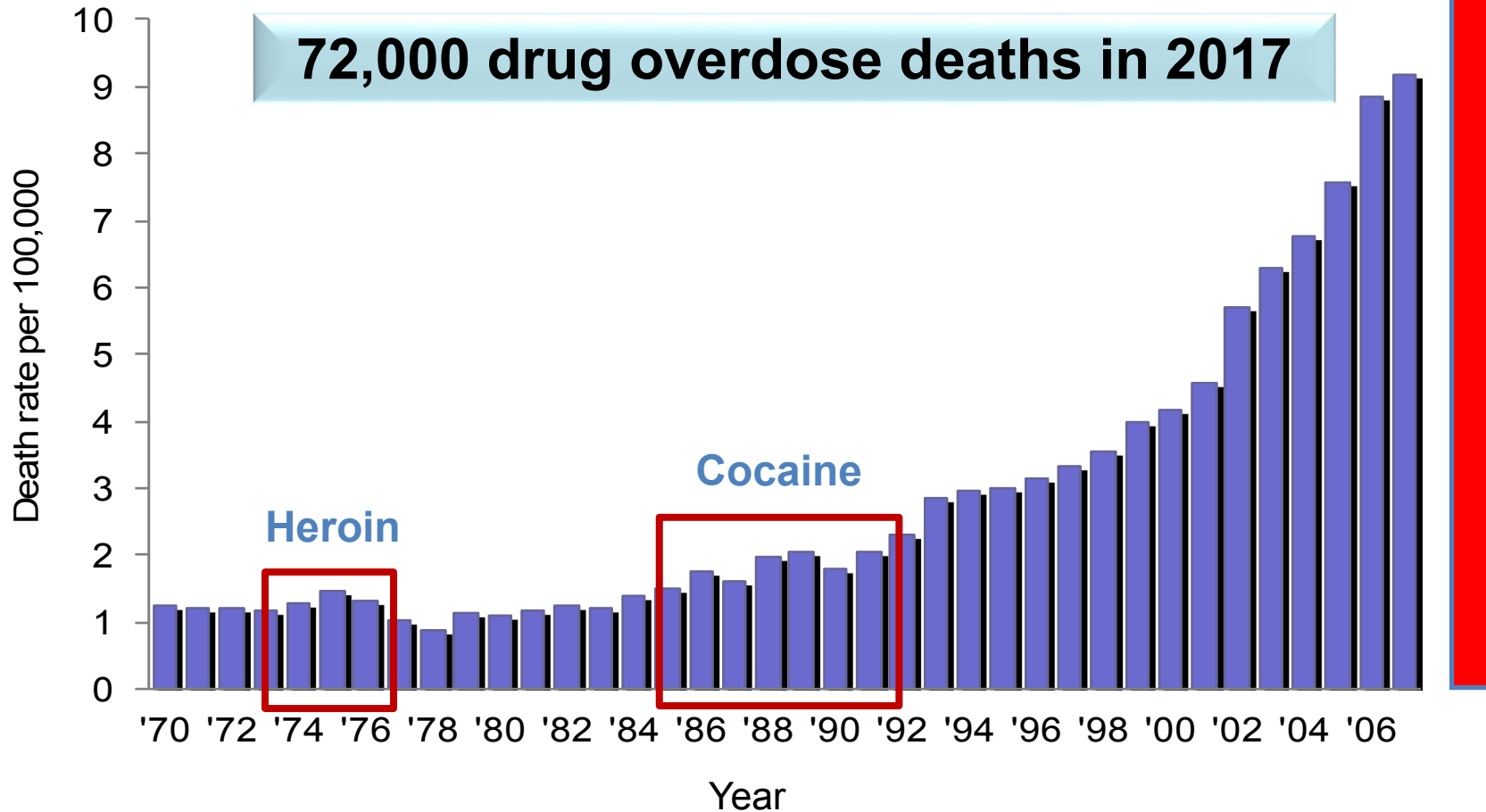
Unintentional Drug Overdose Deaths United States



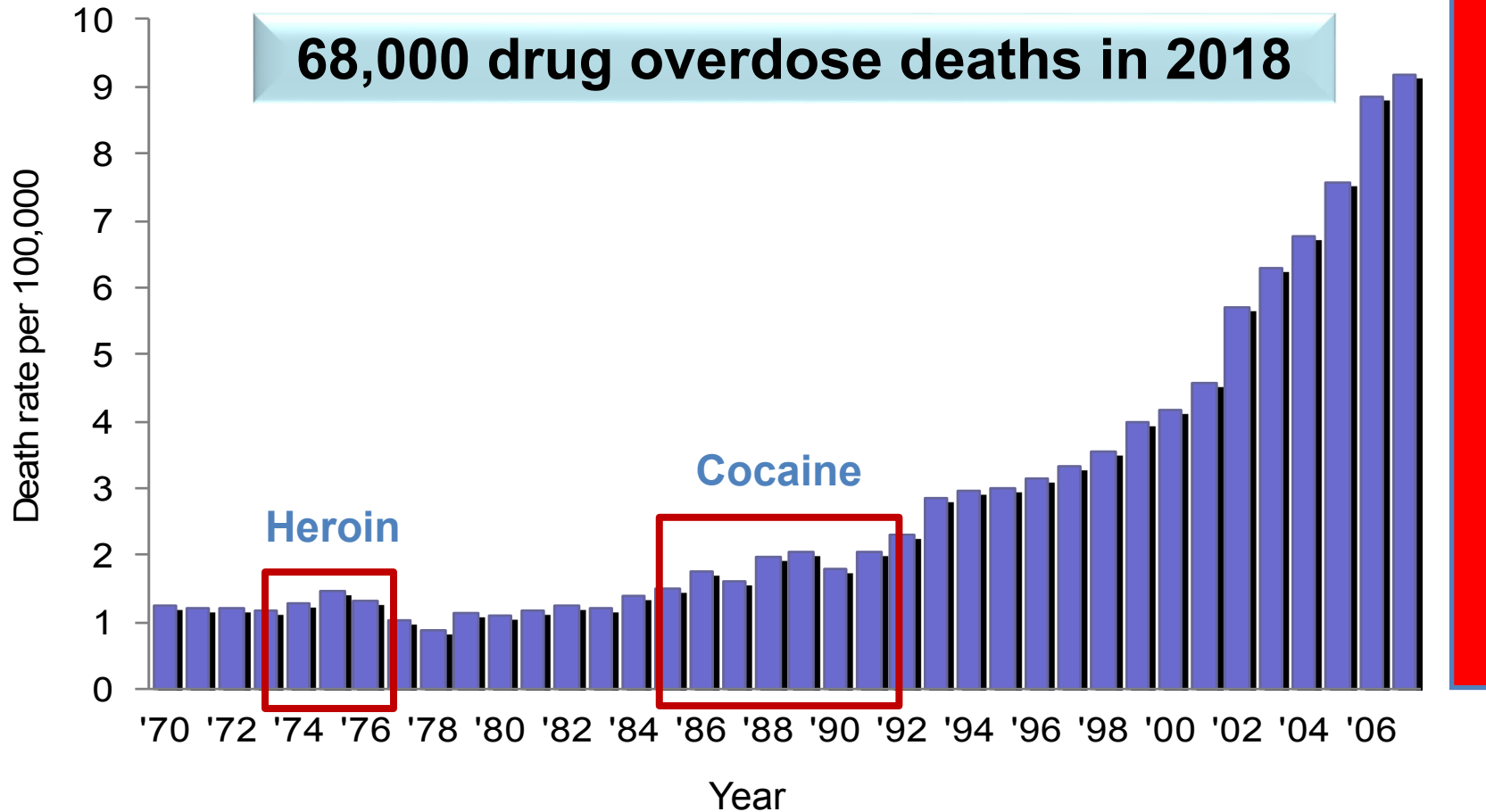
Unintentional Drug Overdose Deaths United States



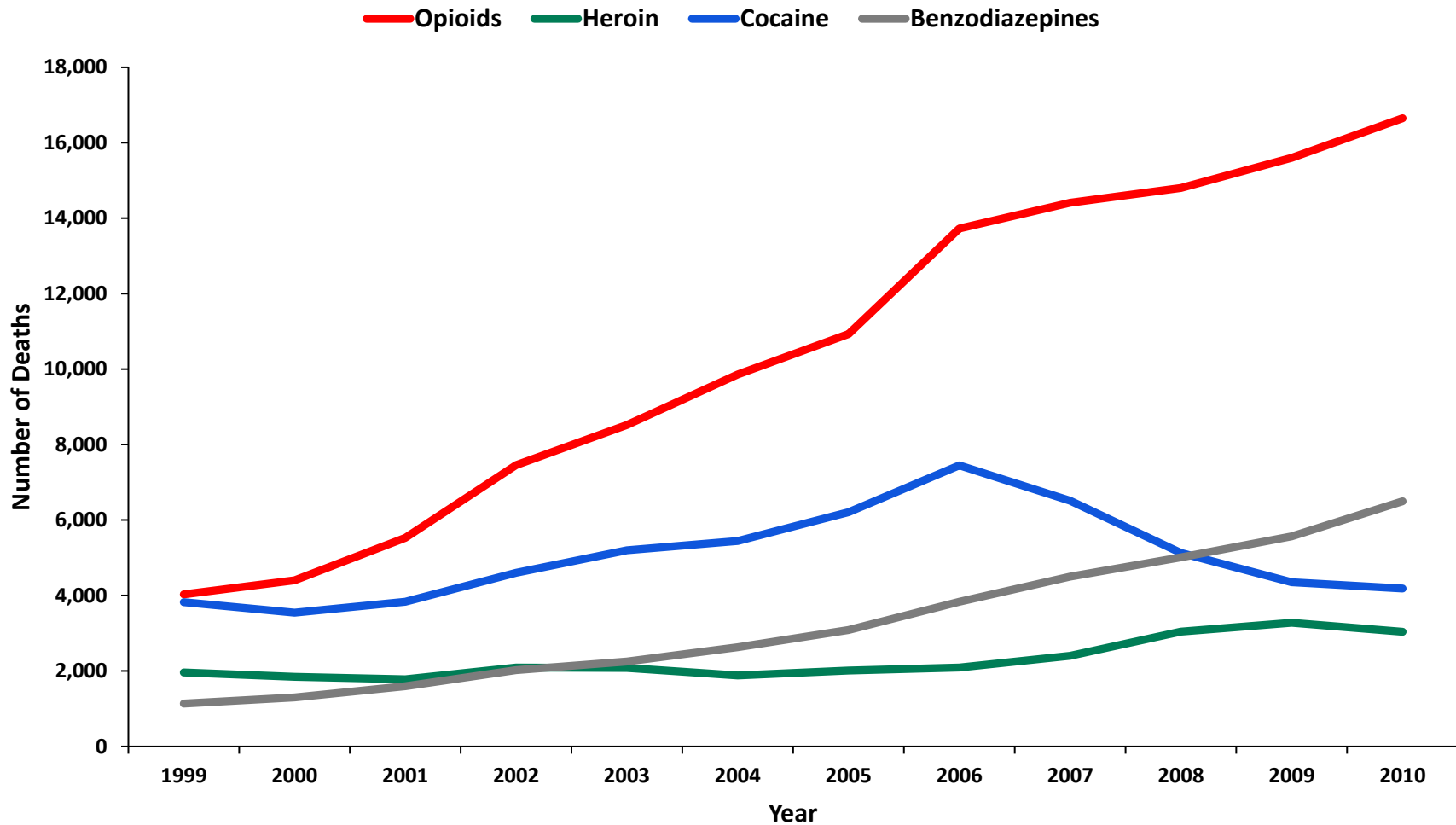
Unintentional Drug Overdose Deaths United States



Unintentional Drug Overdose Deaths United States

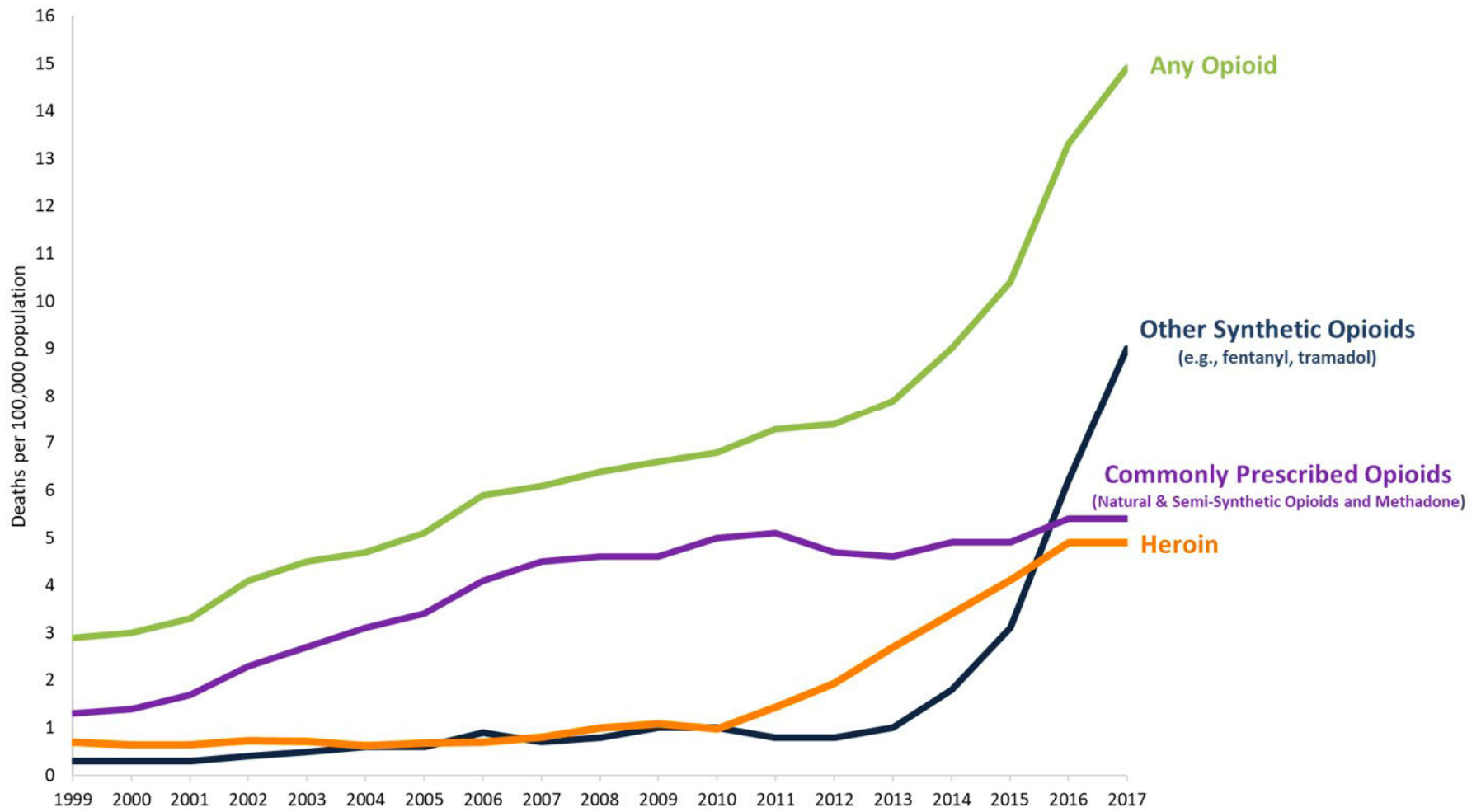


Drug Overdose Deaths by Major Drug Type, United States, 1999–2010



CDC, National Center for Health Statistics, National Vital Statistics System, CDC Wonder. Updated with 2010 mortality data.

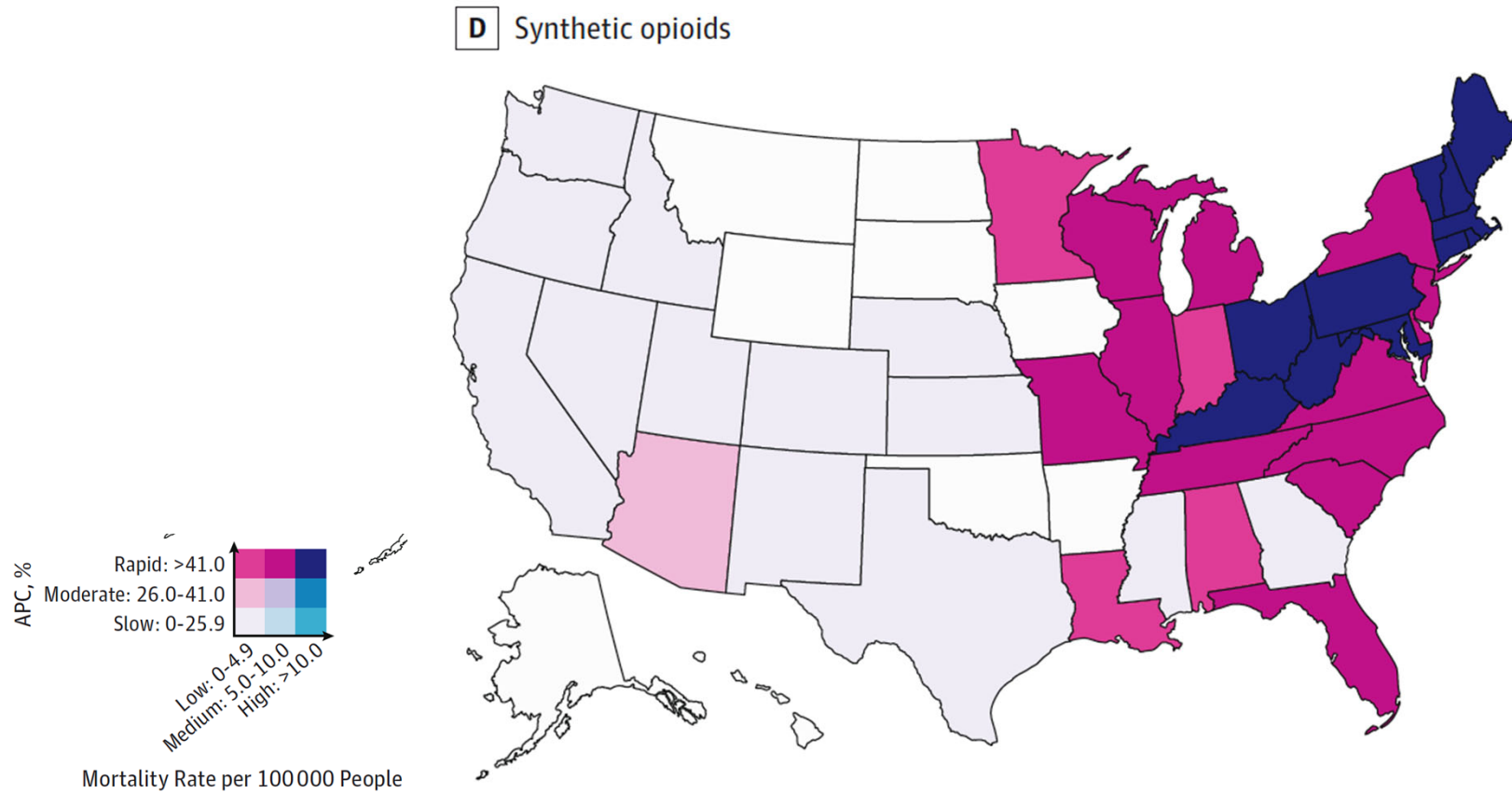
Overdose Death Rates Involving Opioids, by Type, United States, 2000-2017



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2018.
<https://wonder.cdc.gov/>.

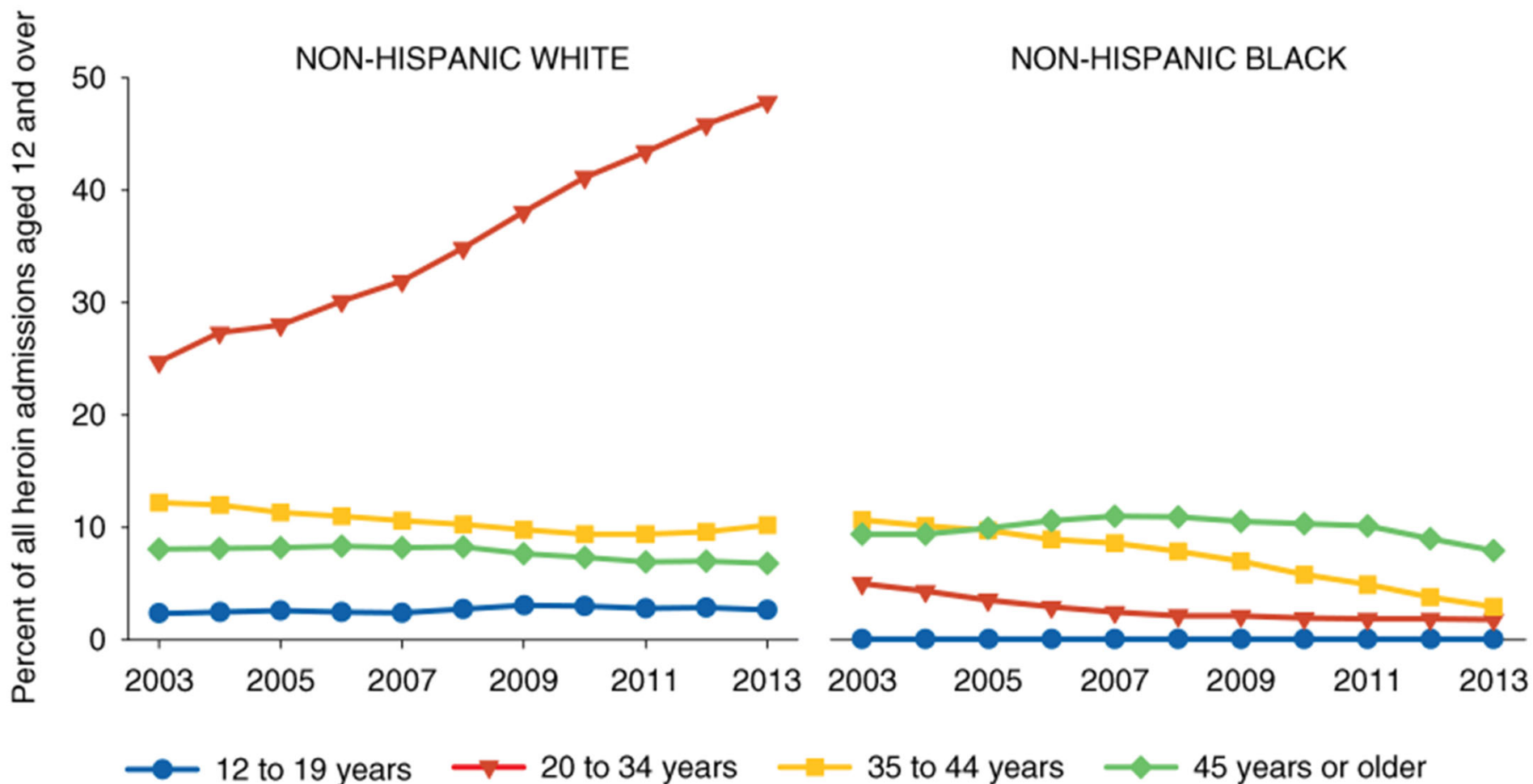


Growth and Level of the Synthetic Opioid OD Deaths, 2016



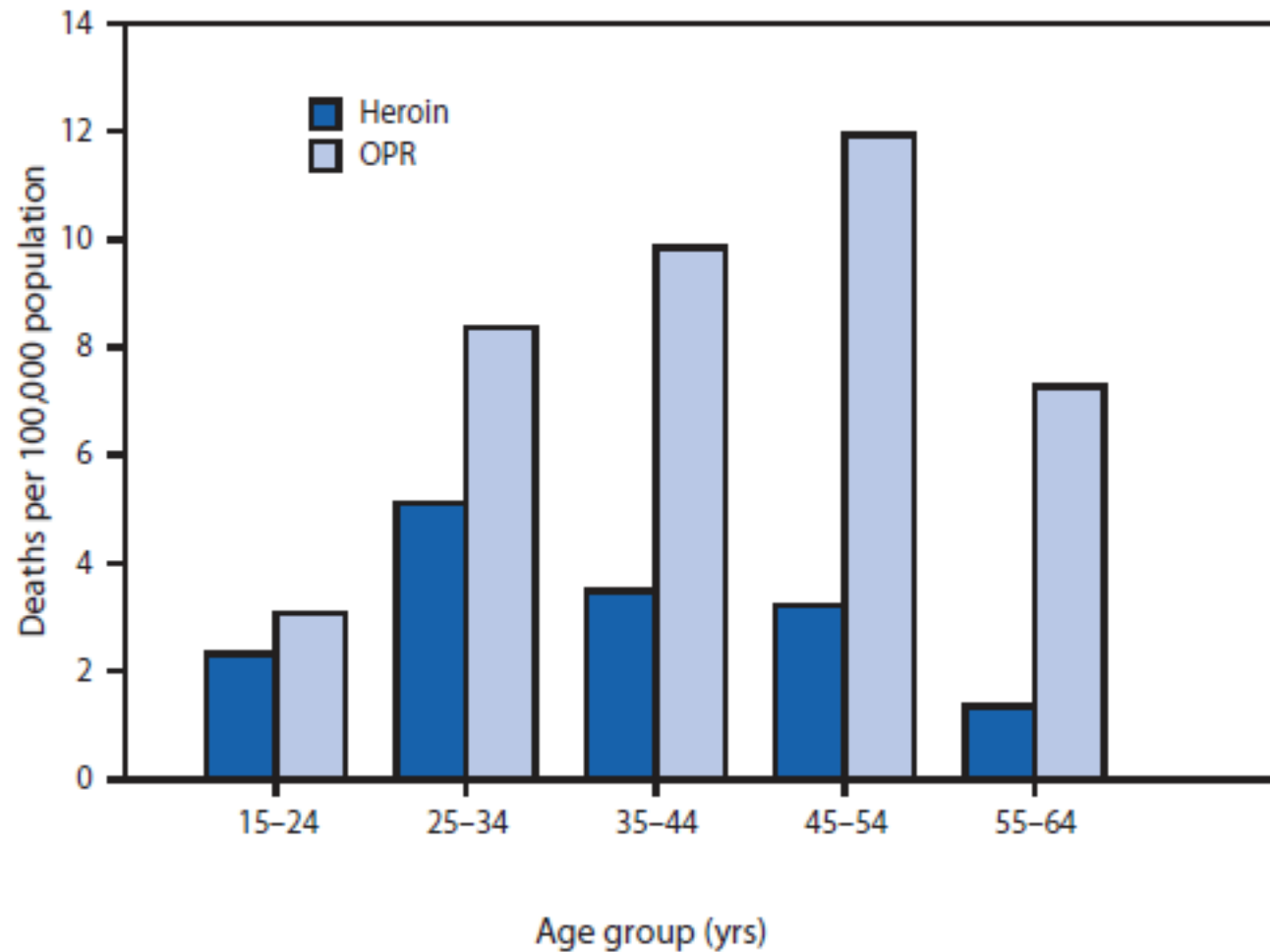
Source: JAMA Network Open. 2019;2(2):e190040. doi:10.1001/jamanetworkopen.2019.0040

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

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)

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

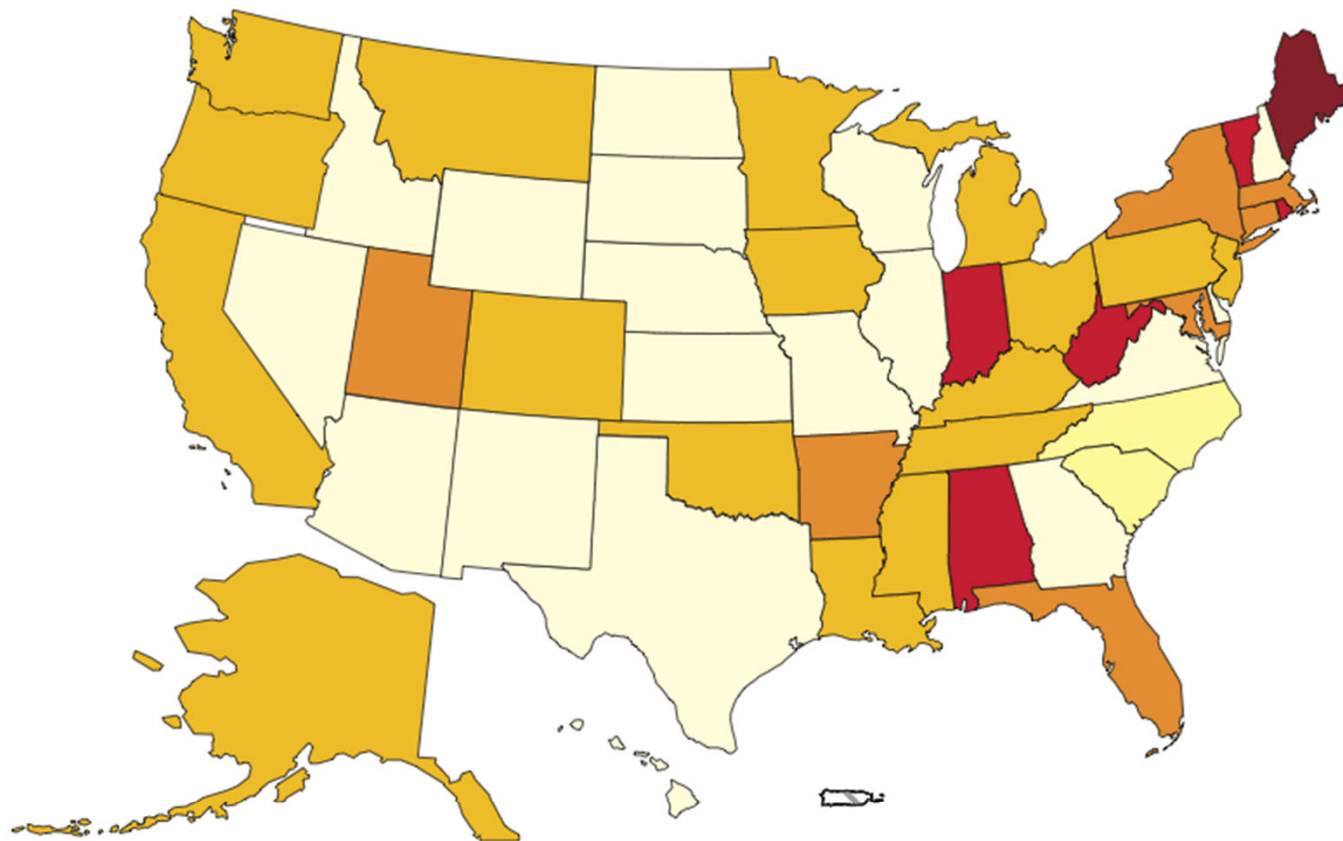
Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome

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

The First Count of Fentanyl
Deaths in 2016: Up
540% in Three Years

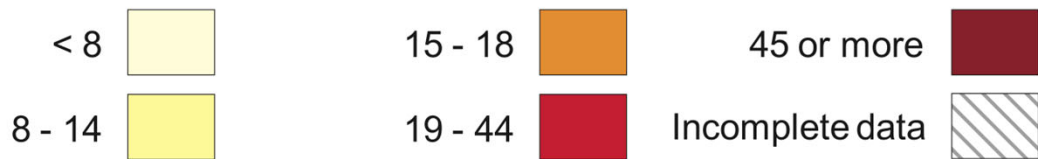
How the opioid crisis decimated the American workforce

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



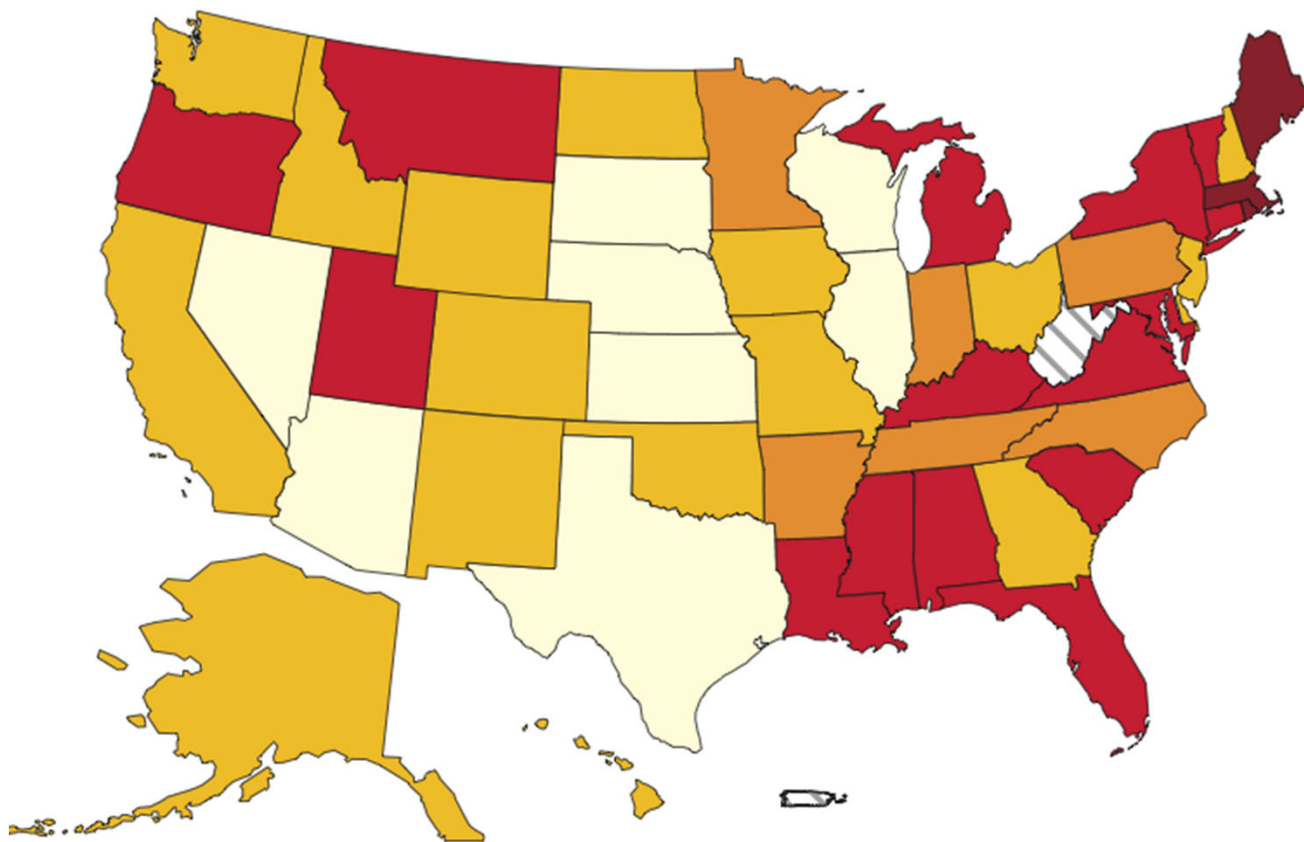
1999

(range 1 - 50)



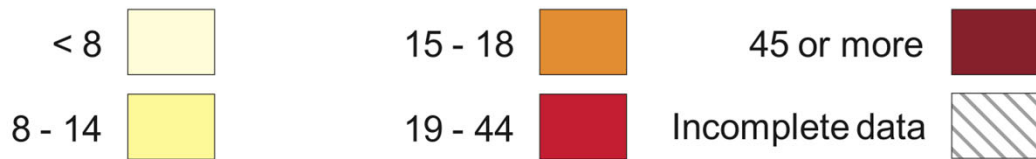
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



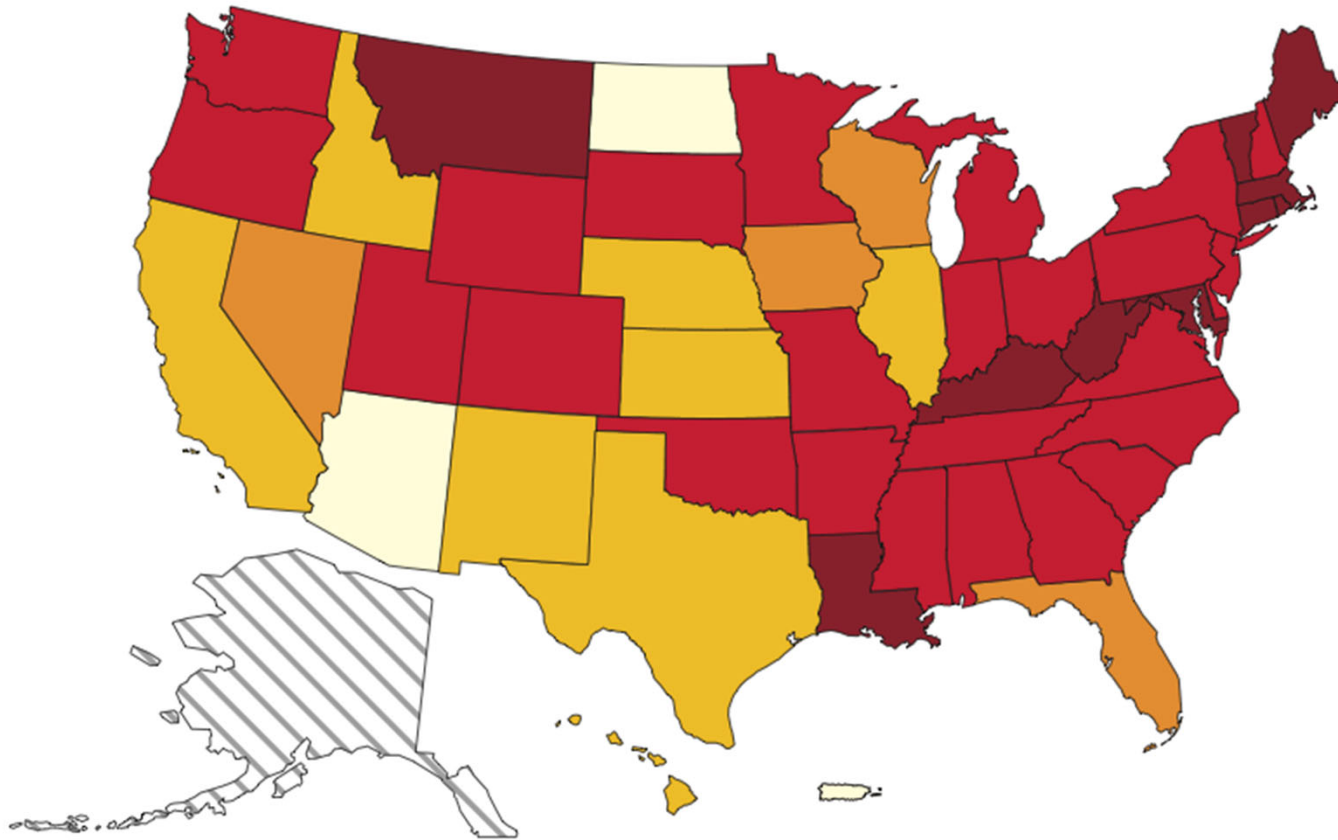
2001

(range 1 – 71)



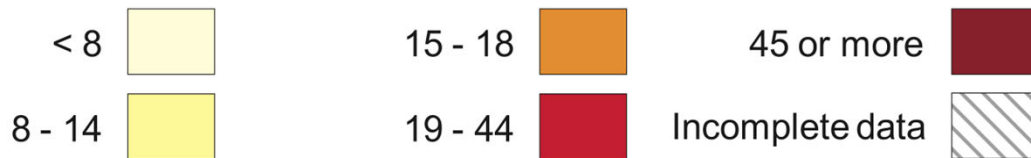
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



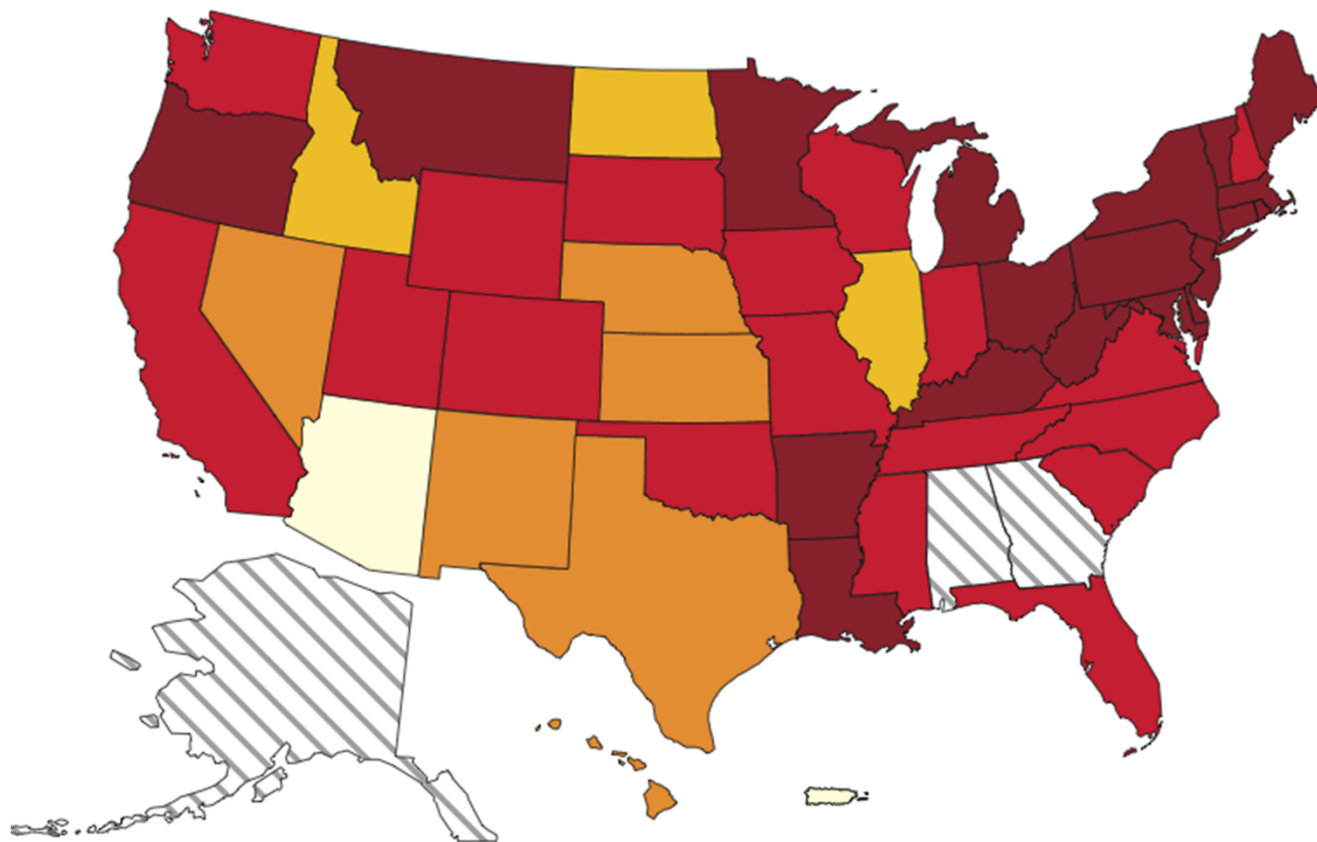
2005

(range 0 – 214)



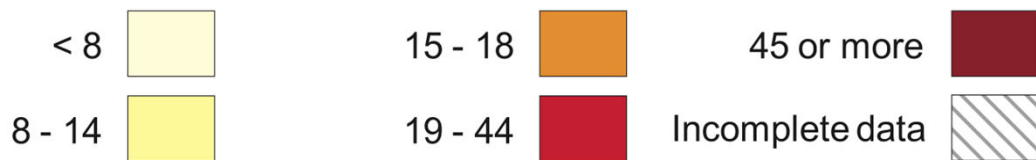
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



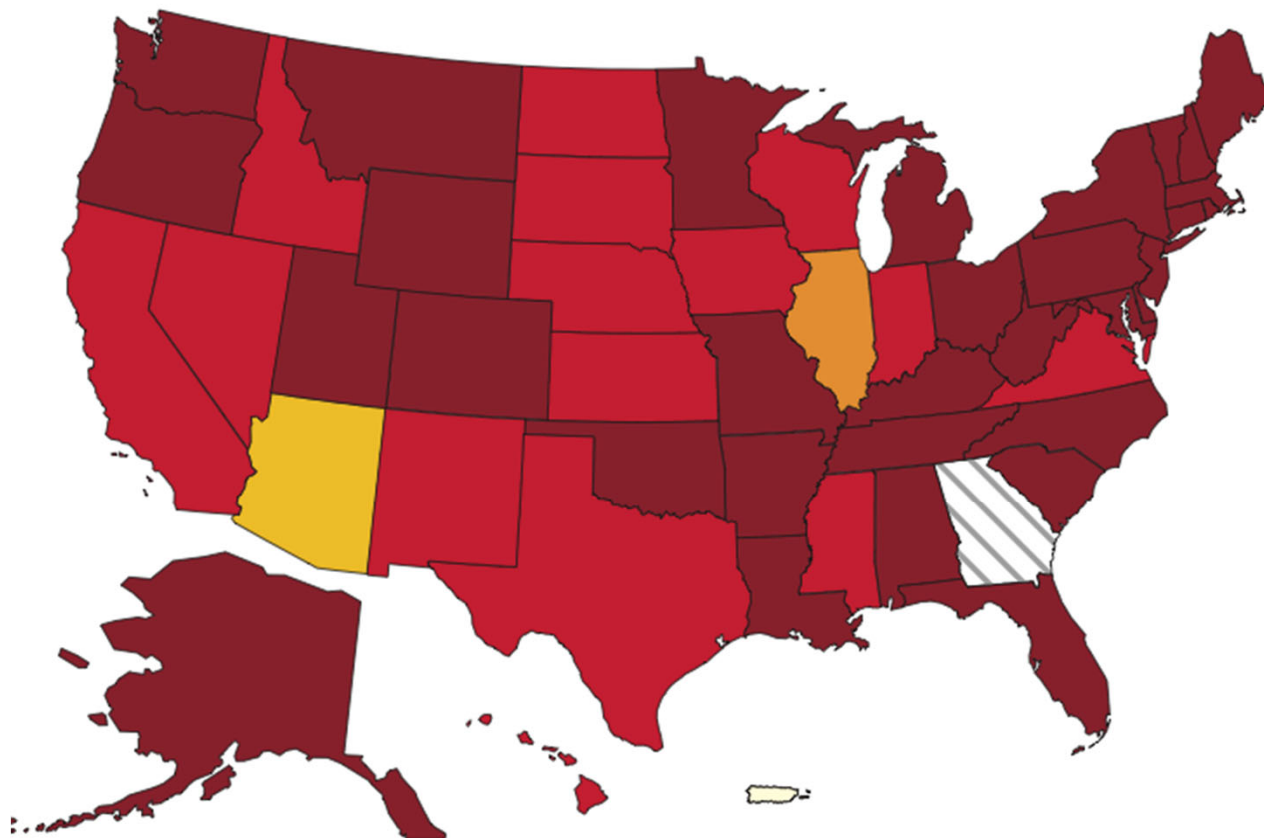
2007

(range 1 – 340)



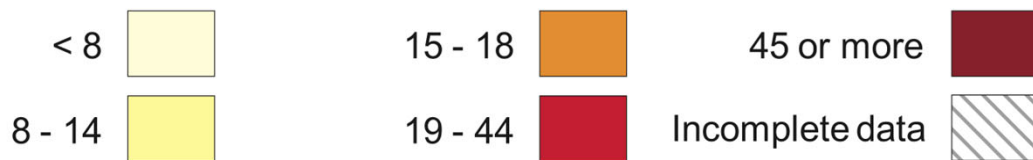
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



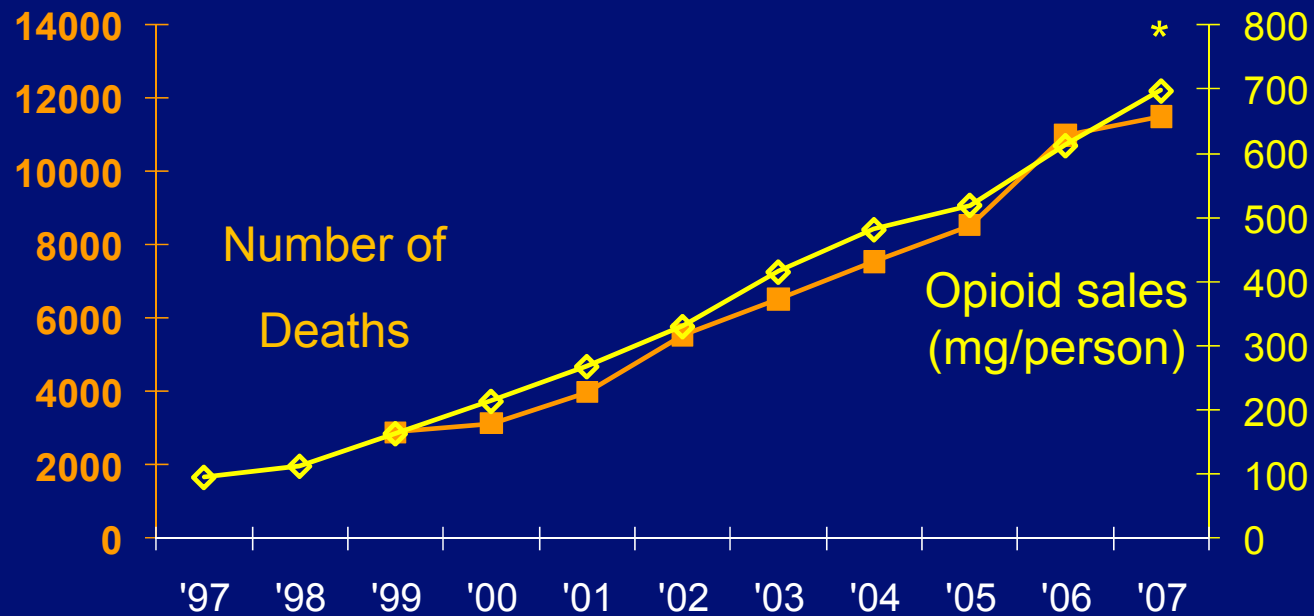
2009

(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.

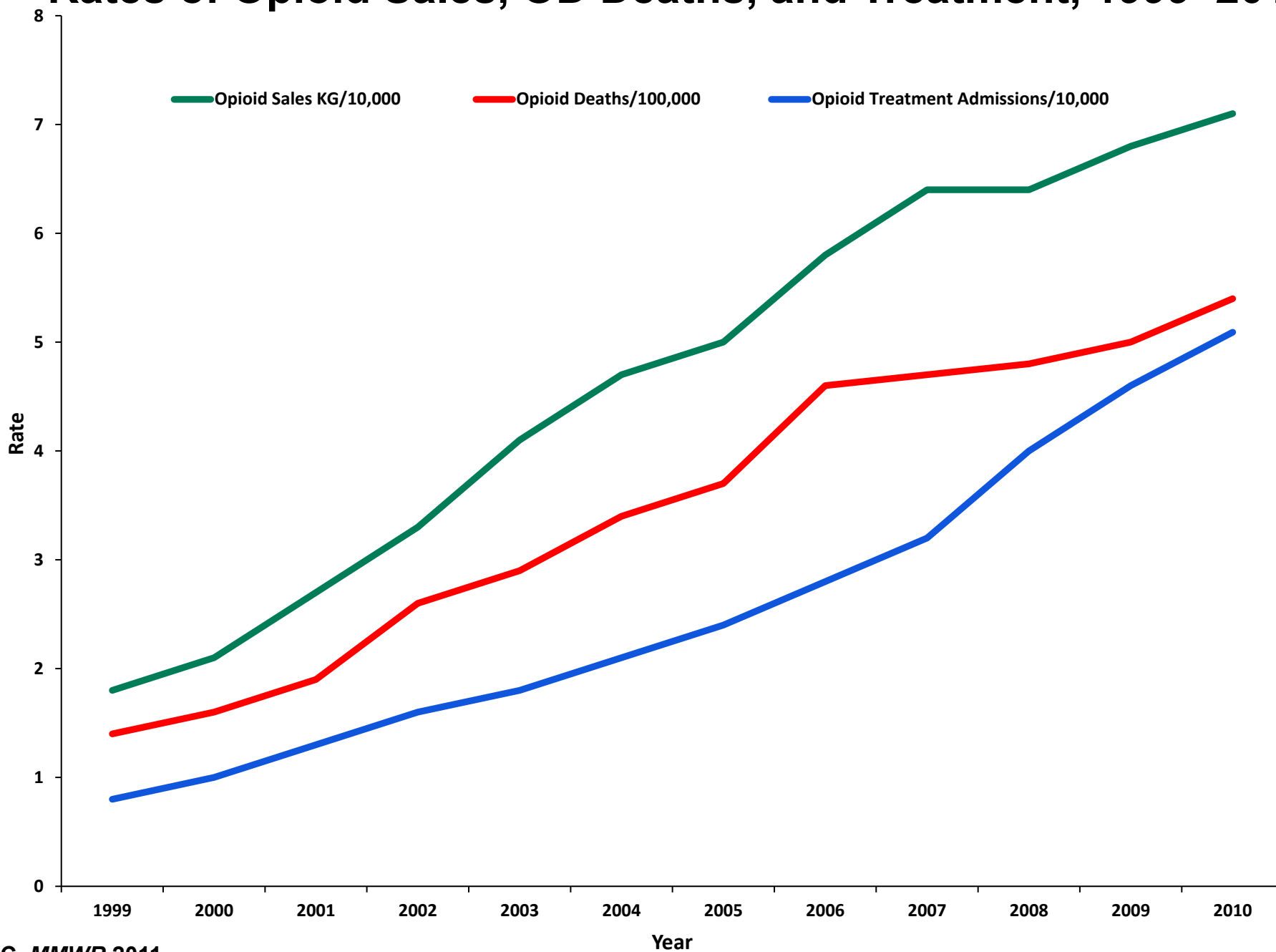
Unintentional overdose deaths involving opioid analgesics parallel per capita sales of opioid analgesics in morphine equivalents by year, U.S., 1997-2007



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

Over the past decade, drug companies and opioid-friendly groups spent more than

\$880 million

on lobbying and political contributions.
That's more than:

8 times

the gun lobby's spending

200 times

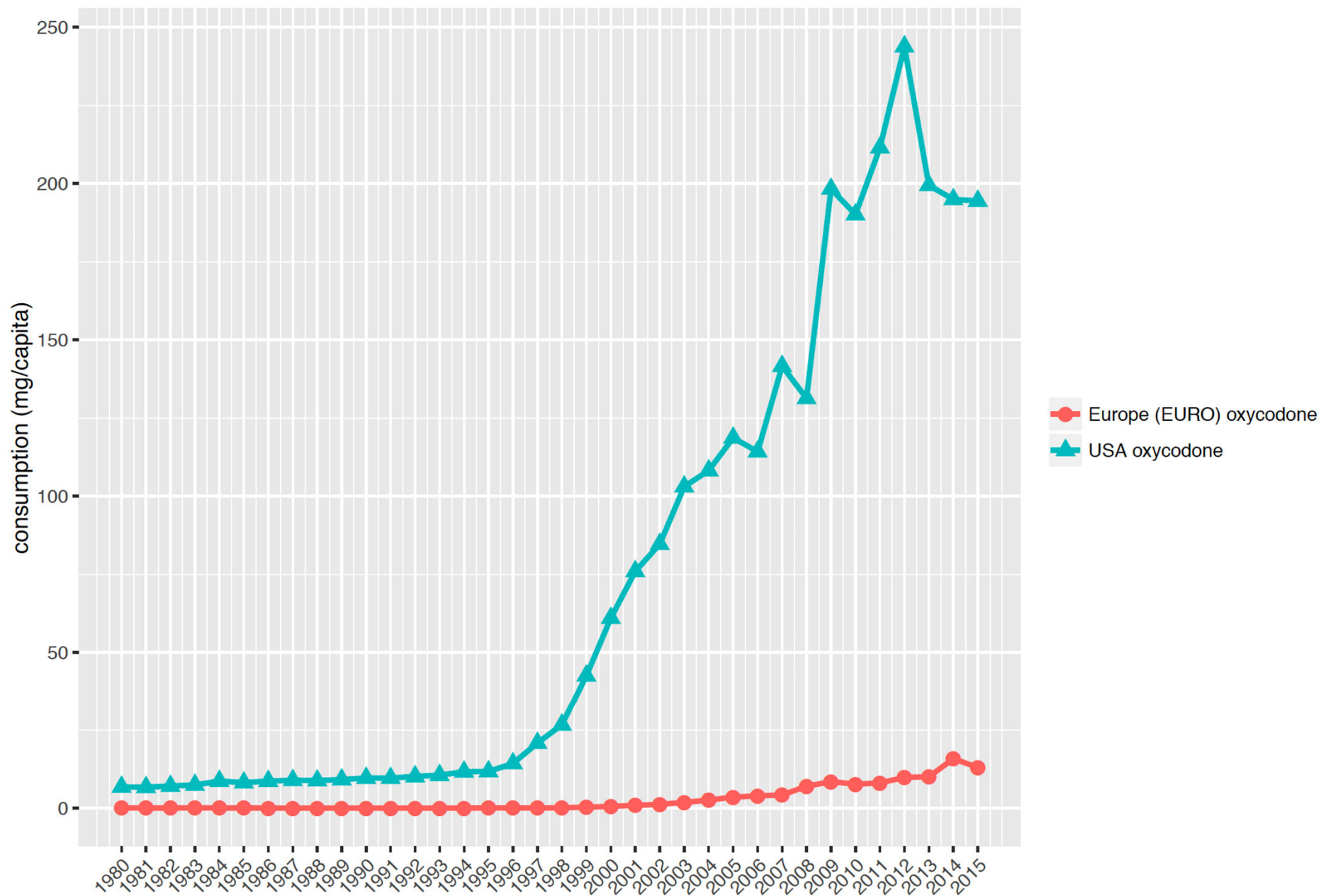
the spending of groups advocating stricter opioid prescription rules

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:

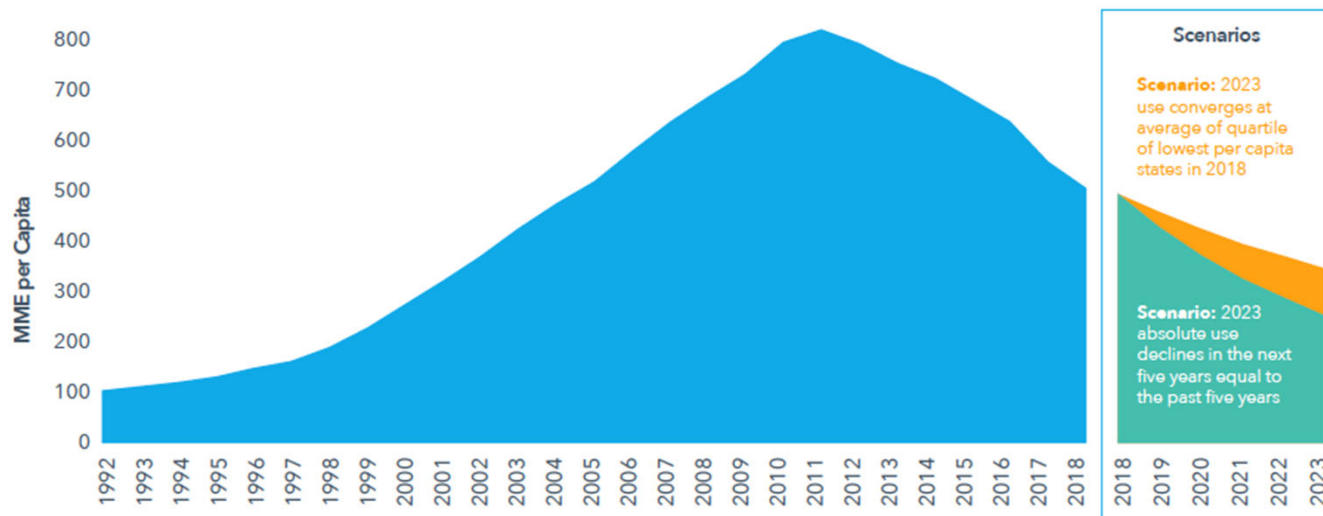
to State	to Federal	for State/Federal candidates	
\$109 mil.	\$716 mil.	45% Dems	54% Reps

USA oxycodone consumption (mg/capita) 1980–2015



Sources: International Narcotics Control Board; World Health Organization population data

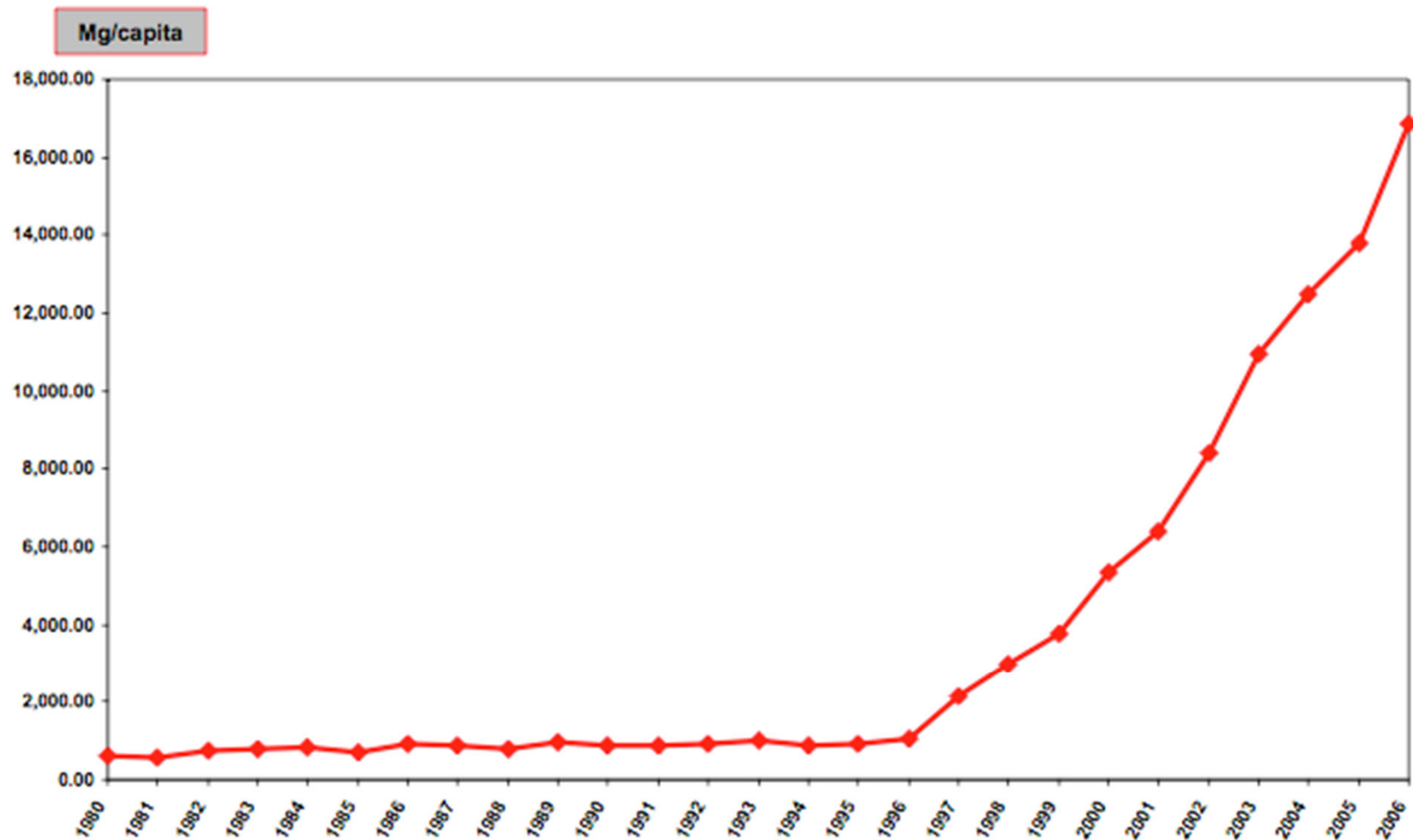
Exhibit 28: Scenarios for Prescription Opioid Volumes in the United States per Capita in Morphine Milligram Equivalents (MME)



Source: IQVIA "SMART - Launch Edition", Sep 2018; IQVIA Institute, Dec 2018

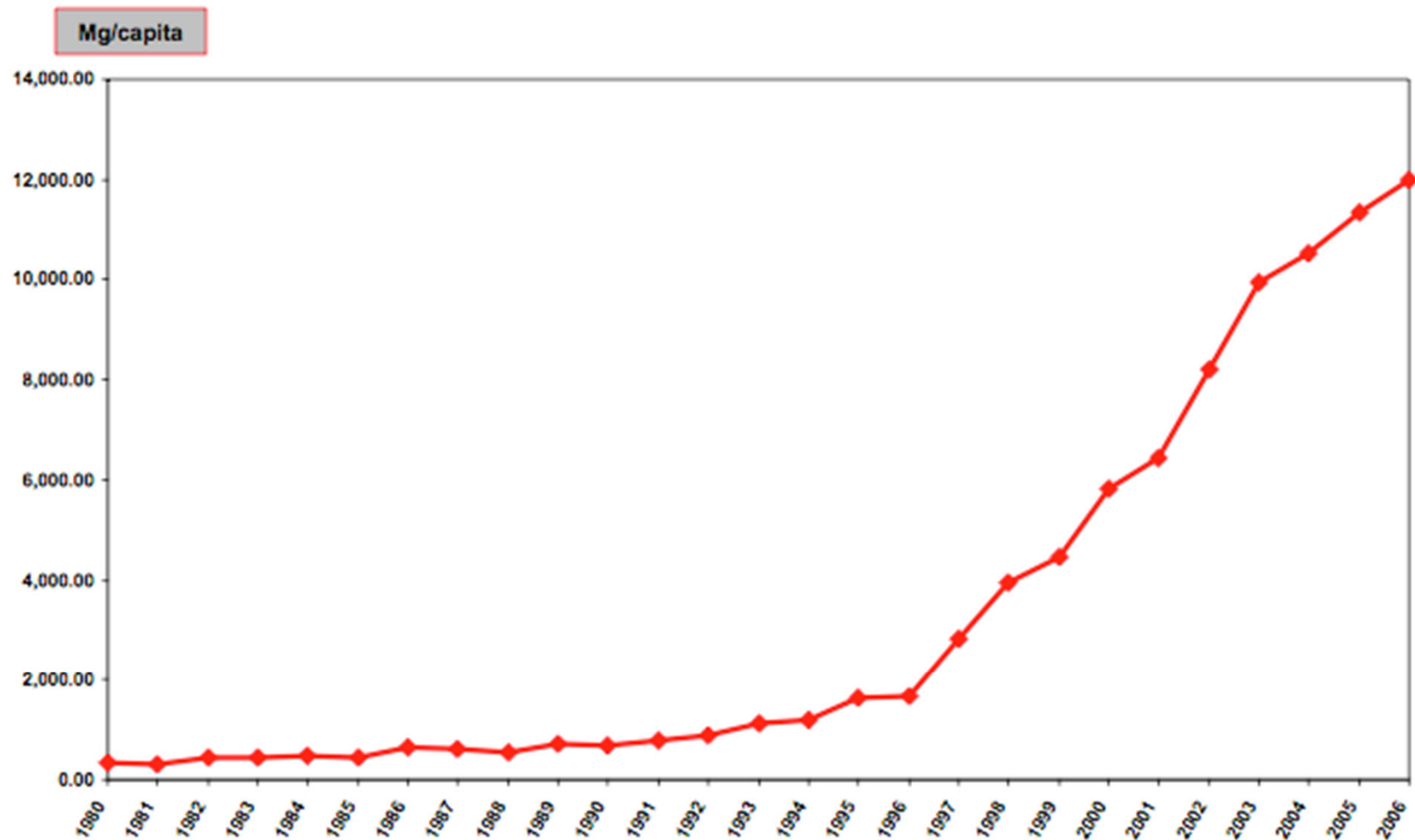
Notes: States with MME per capita below the average of the lowest quartile do not change in the convergence scenario.

New York Consumption of Oxycodone 1980 - 2006



Sources: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control

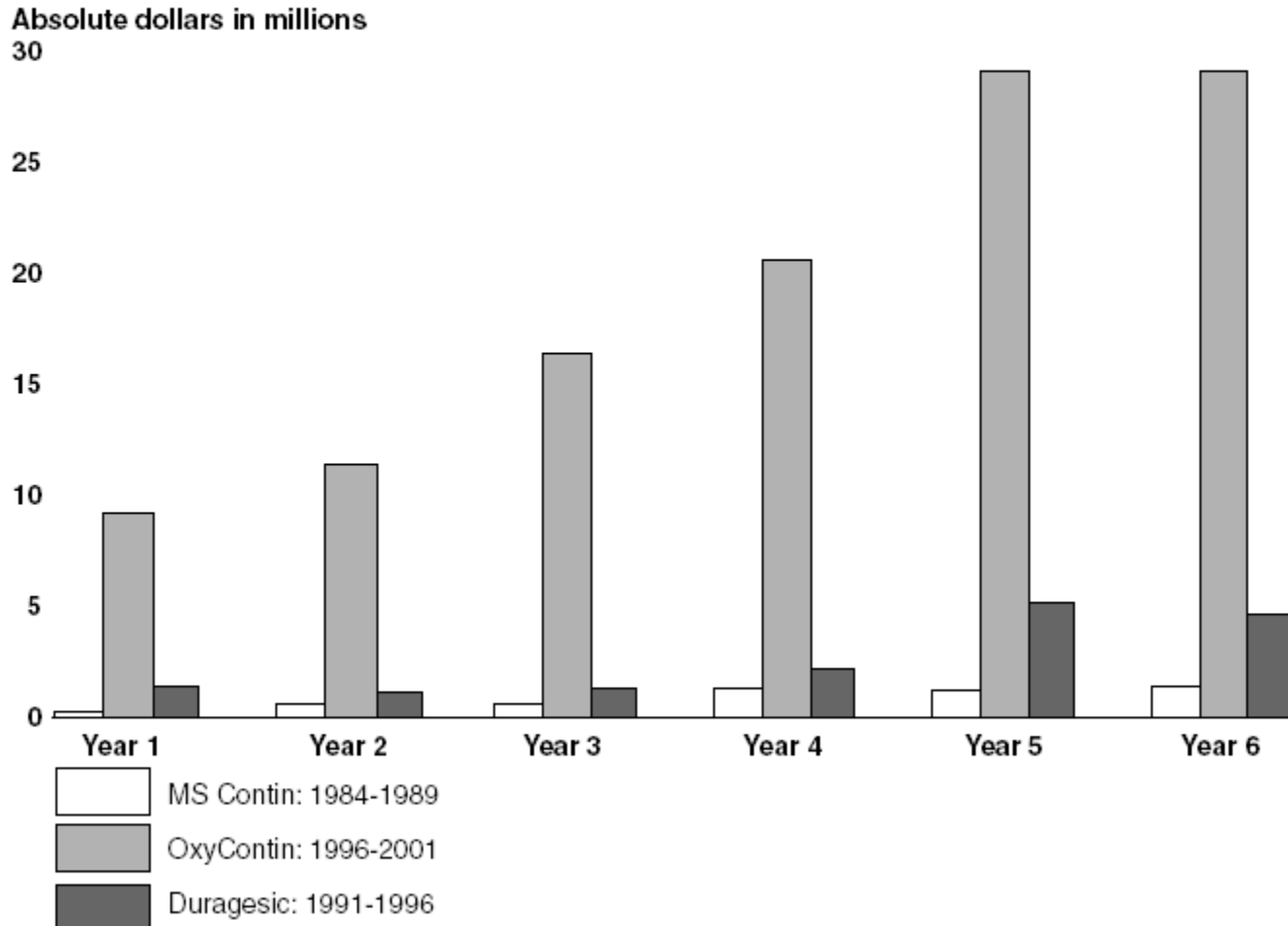
New York Consumption of Hydrocodone 1980 - 2006



Sources: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control

Dollars Spent Marketing OxyContin (1996-2001)

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales



Source: United States General Accounting Office: Dec. 2003, "OxyContin Abuse and Diversion and Efforts to Address the Problem."

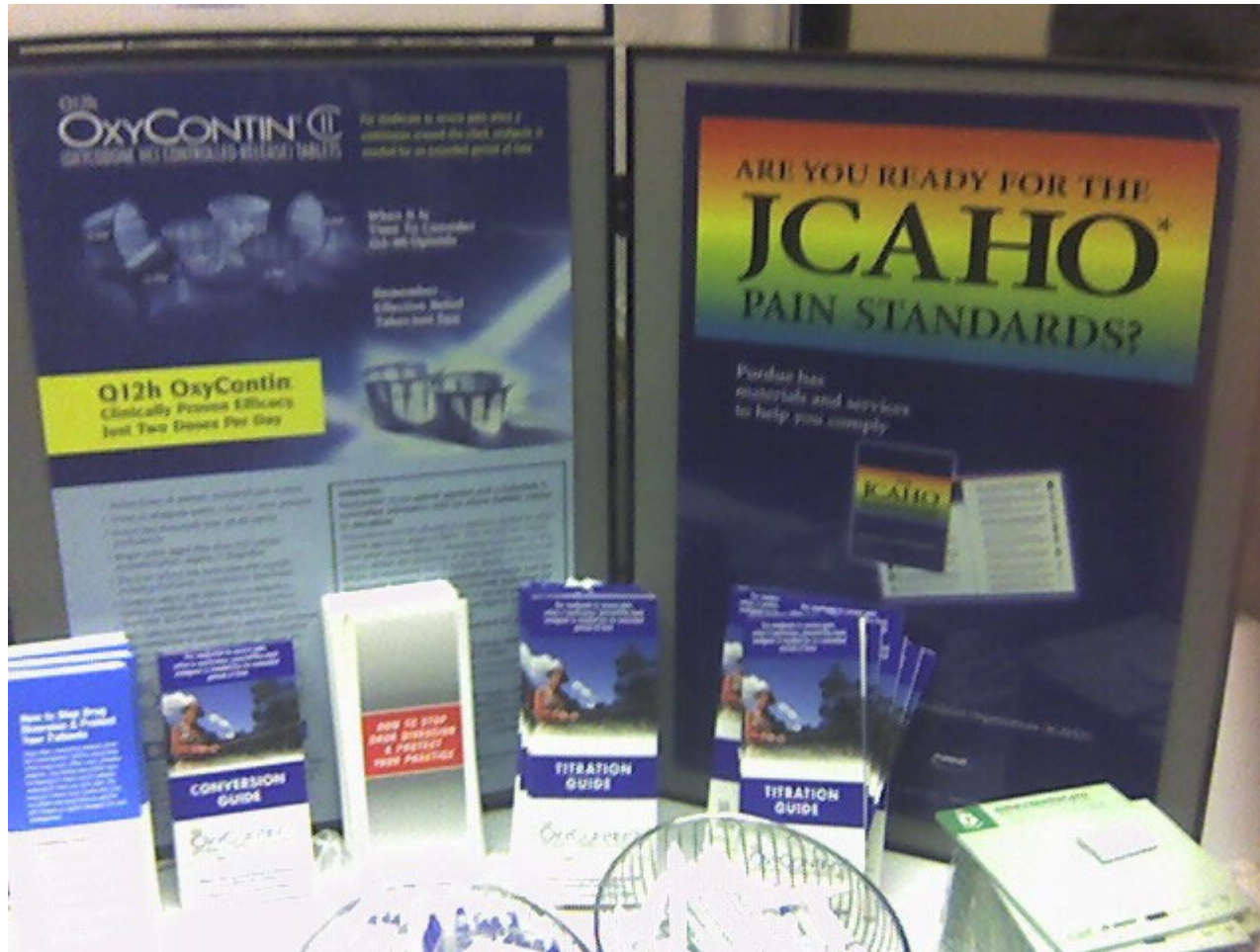
Industry-funded “educational” messages

- Physicians are needlessly allowing patients to suffer because of “opiophobia.”
- Opioid addiction is rare in pain patients.
- Opioids can be easily discontinued.
- Opioids are safe and effective for chronic pain.

Industry-funded organizations campaigned for greater use of opioids

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





Purdue booth at pain conference exhibit hall. New York, NY 2007

“The risk of addiction is much less than 1%”

Porter J, Jick H. *Addiction rare in patients treated with narcotics*. N Engl J Med. 1980 Jan 10;302(2):123

Cited 824 times (Google Scholar)

N Engl J Med. 1980 Jan 10;302(2):123.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop

Roger Chou, MD; Judith A. Turner, PhD; Emily B. Devine, PharmD, PhD, MBA; Ryan N. Hansen, PharmD, PhD; Sean D. Sullivan, PhD; Ian Blazina, MPH; Tracy Dana, MLS; Christina Bougatsos, MPH; and Richard A. Deyo, MD, MPH

Background: Increases in prescriptions of opioid medications for chronic pain have been accompanied by increases in opioid overdoses, abuse, and other harms and uncertainty about long-term effectiveness.

Purpose: To evaluate evidence on the effectiveness and harms of long-term (>3 months) opioid therapy for chronic pain in adults.

Data Sources: MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL (January 2008 through August 2014); relevant studies from a prior review; reference lists; and ClinicalTrials.gov.

Study Selection: Randomized trials and observational studies that involved adults with chronic pain who were prescribed long-term opioid therapy and that evaluated opioid therapy versus placebo, no opioid, or nonopioid therapy; different opioid dosing strategies; or risk mitigation strategies.

Data Extraction: Dual extraction and quality assessment.

Data Synthesis: No study of opioid therapy versus no opioid therapy evaluated long-term (>1 year) outcomes related to pain, function, quality of life, opioid abuse, or addiction. Good- and

fair-quality observational studies suggest that opioid therapy for chronic pain is associated with increased risk for overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction, although there are few studies for each of these outcomes; for some harms, higher doses are associated with increased risk. Evidence on the effectiveness and harms of different opioid dosing and risk mitigation strategies is limited.

Limitations: Non-English-language articles were excluded, meta-analysis could not be done, and publication bias could not be assessed. No placebo-controlled trials met inclusion criteria, evidence was lacking for many comparisons and outcomes, and observational studies were limited in their ability to address potential confounding.

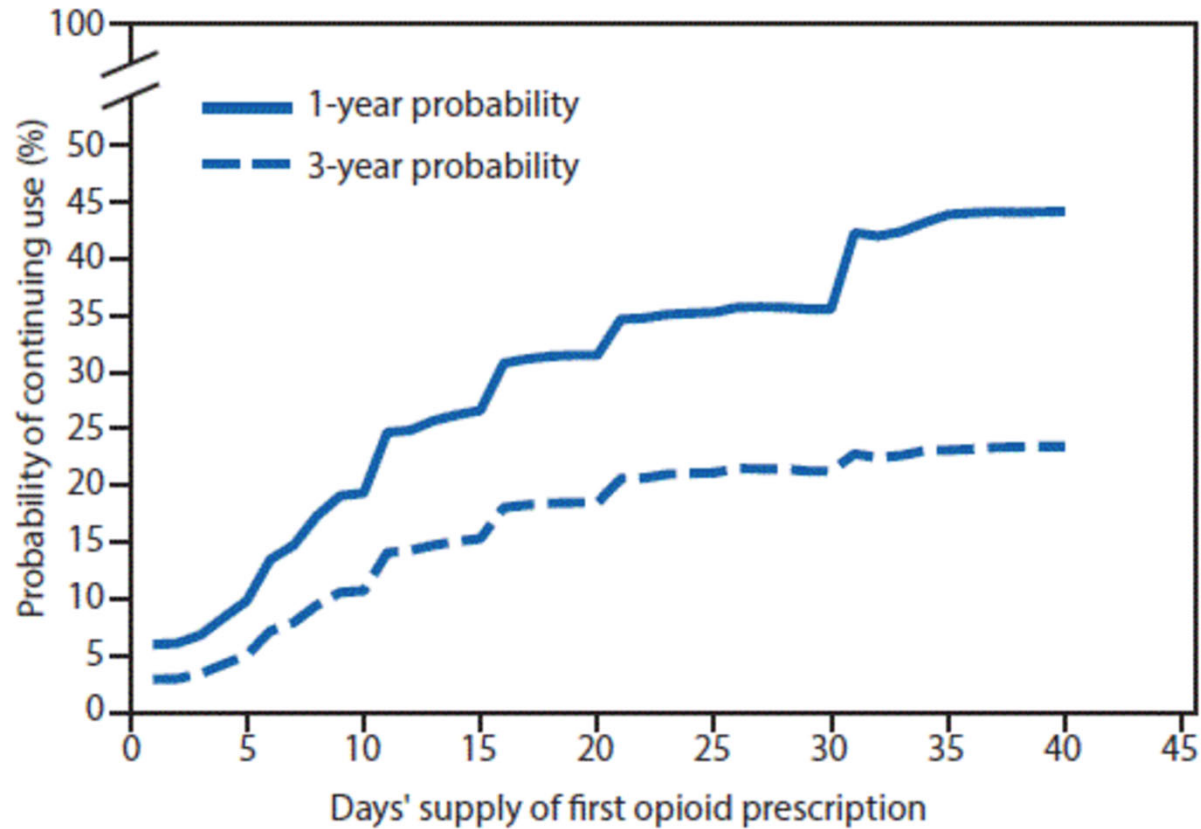
Conclusion: Evidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function. Evidence supports a dose-dependent risk for serious harms.

Primary Funding Source: Agency for Healthcare Research and Quality.

Ann Intern Med. 2015;162:276-286. doi:10.7326/M14-2559 www.annals.org
For author affiliations, see end of text.

This article was published online first at www.annals.org on 13 January 2015.

One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription — United States, 2006–2015



* Days' supply of the first prescription is expressed in days (1–40) in 1-day increments.

Source: Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. *MMWR Morb Mortal Wkly Rep* 2017;66:265–269.

Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department: A Randomized Clinical Trial

Andrew K. Chang, MD, MS; Polly E. Bijur, PhD; David Esses, MD; Douglas P. Barnaby, MD, MS; Jesse Baer, MD

Key Points

Question Do any of 4 oral combination analgesics (3 with different opioids and 1 opioid-free) provide more effective reduction of moderate to severe acute extremity pain in the emergency department (ED)?

Findings In this randomized clinical trial of 411 ED patients with acute extremity pain (mean score, 8.7 on the 11-point numerical rating scale), there was no significant difference in pain reduction at 2 hours. Mean pain scores decreased by 4.3 with ibuprofen and acetaminophen (paracetamol); 4.4 with oxycodone and acetaminophen; 3.5 with hydrocodone and acetaminophen; and 3.9 with codeine and acetaminophen.

Meaning For adult ED patients with acute extremity pain, there were no clinically important differences in pain reduction at 2 hours with ibuprofen and acetaminophen or 3 different opioid and acetaminophen combination analgesics.

Table 2. Numerical Rating Scale (NRS) Pain Scores and Decline in Pain Scores by Treatment Group

	NRS Pain Score, Mean (95% CI) ^a				P Value ^f
	Ibuprofen and Acetaminophen ^b	Oxycodone and Acetaminophen ^c	Hydrocodone and Acetaminophen ^d	Codeine and Acetaminophen ^e	
No. of patients ^g	101	104	103	103	
Primary end point: decline in score to 2 h	4.3 (3.6 to 4.9)	4.4 (3.7 to 5.0)	3.5 (2.9 to 4.2)	3.9 (3.2 to 4.5)	.053
Baseline score	8.9 (8.5 to 9.2)	8.7 (8.3 to 9.0)	8.6 (8.3 to 9.0)	8.6 (8.2 to 8.9)	.47
Score at 1 h	5.9 (5.3 to 6.6)	5.5 (4.9 to 6.2)	6.2 (5.6 to 6.9)	5.9 (5.2 to 6.5)	.25
Score at 2 h	4.6 (3.9 to 5.3)	4.3 (3.6 to 5.0)	5.1 (4.5 to 5.8)	4.7 (4.0 to 5.4)	.13
Decline in score to 1 h	2.9 (2.4 to 3.5)	3.1 (2.6 to 3.7)	2.4 (1.8 to 3.0)	2.7 (2.1 to 3.3)	.13

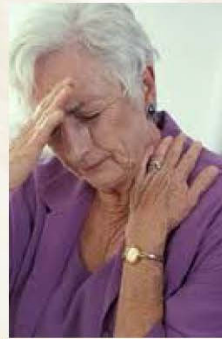
Controlling the epidemic:

A Three-pronged Approach

- **Prevent** new cases of opioid addiction.
- **Treat** people who are already addicted.
- **Reduce supply** from pill mills and the black-market.

How the opioid lobby frames the problem:

Who Will Be Affected by Rescheduling?



the AMERICAN ACADEMY *of* PAIN MEDICINE

2

Source: Slide presented by Dr. Lynn Webster at FDA meeting on hydrocodone upscheduling, Jan 25th, 2013.

This is a **false dichotomy**

Opioid harms are not limited to so-called “drug abusers”

41% met DSM V criteria for an opioid use disorder¹

Pain Patients



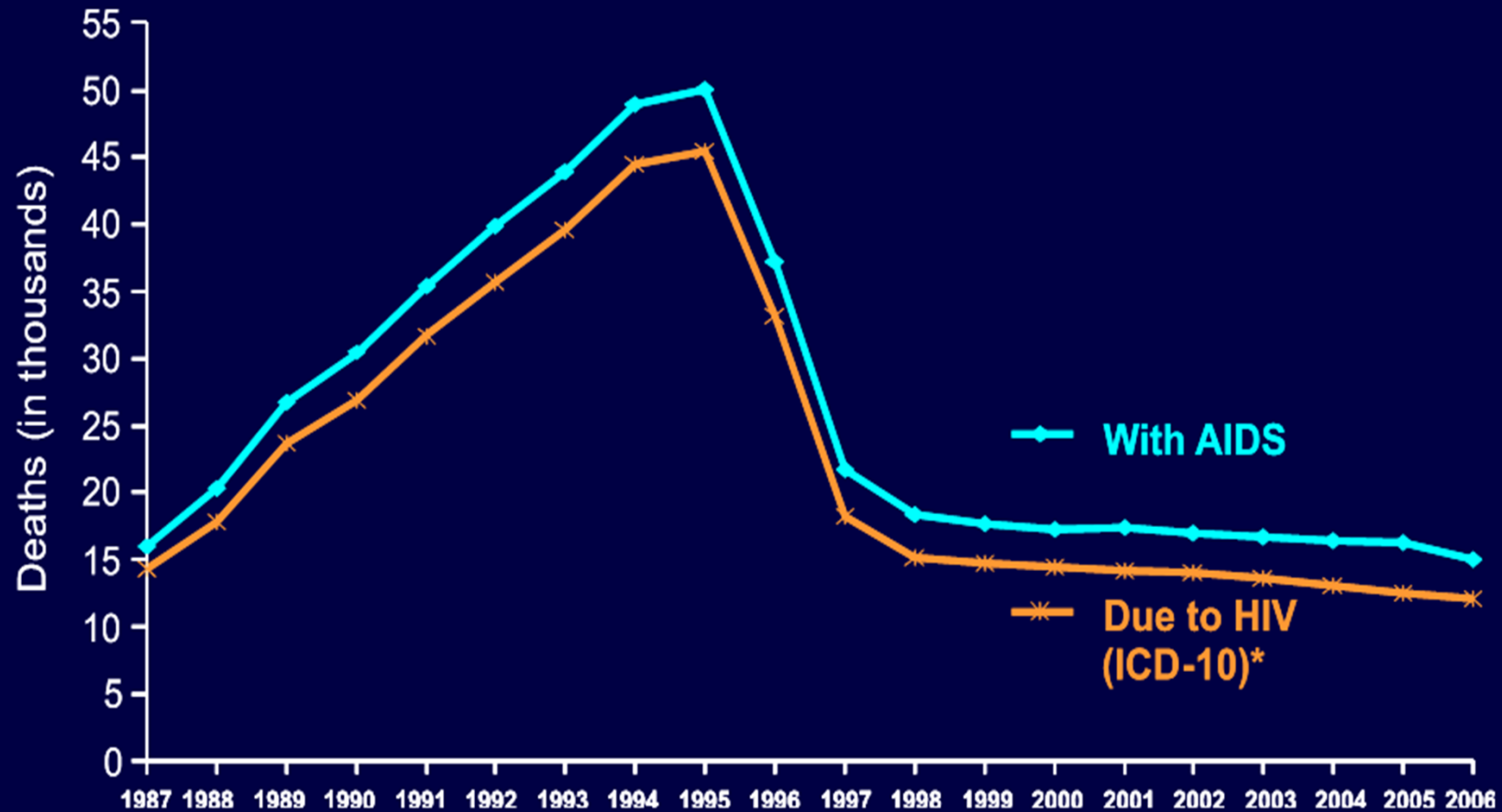
“Drug Abusers”

92% of opioid OD decedents were prescribed opioids for chronic pain.²

1. Boscarino JA, et al. Opioid-use disorder among patients on long-term opioid therapy: impact of final DSM-5 diagnostic criteria on prevalence and correlates. J Addict Dis. 2011;30:185-194.

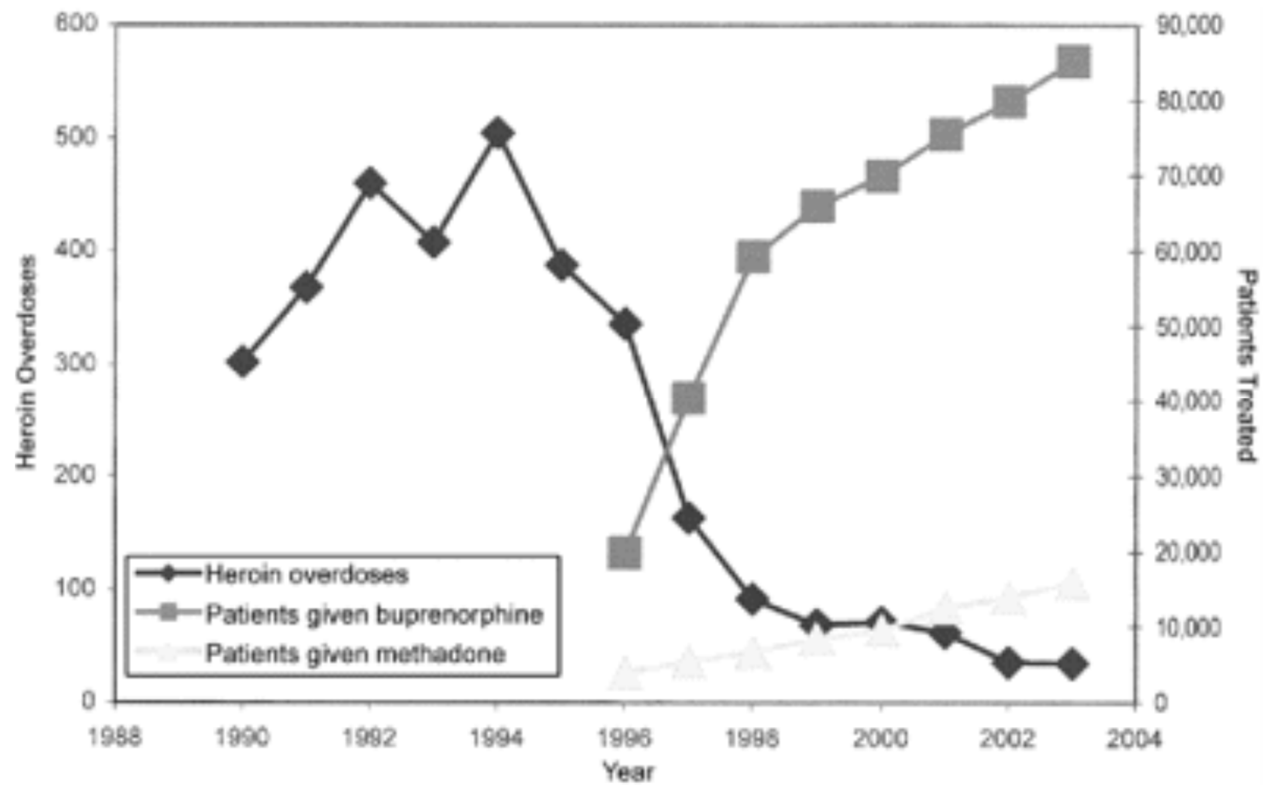
2. Johnson EM, Lanier WA, Merrill RM, et al. Unintentional Prescription Opioid-Related Overdose Deaths: Description of Decedents by Next of Kin or Best Contact, Utah, 2008-2009. J Gen Intern Med. 2012 Oct 16.

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

Based on data available for analysis on:

9/1/2019

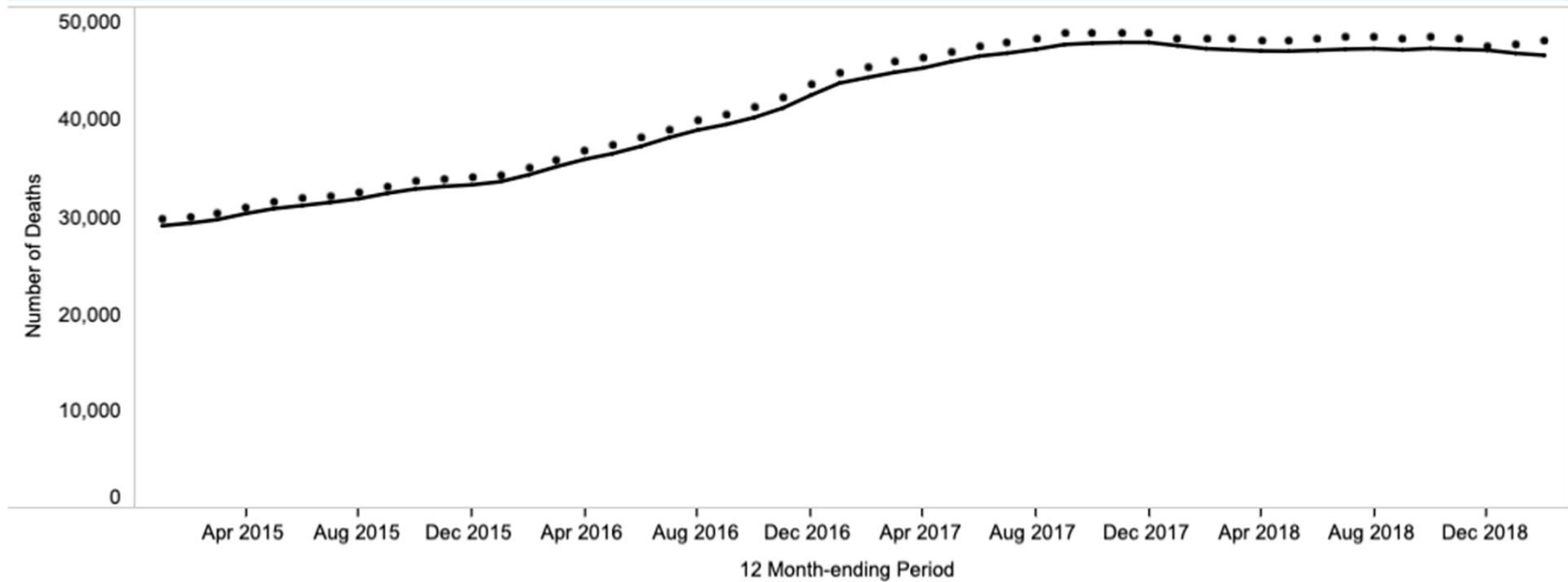
Select Jurisdiction

United States

Select specific drugs or drug classes

Opioids (T40.0-T40.4,T40.6)

Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Legend for Drug or Drug Class

Opioids (T40.0-T40.4,T40.6)

--- Reported Value

○ Predicted Value

Summary

- The U.S. is in the midst of a severe epidemic of opioid addiction
- To bring the epidemic to an end:
 - We must prevent new cases of opioid addiction
 - We must ensure access to treatment for people already addicted