

# Understanding the opioid epidemic

A look at its origins, key players and potential responses

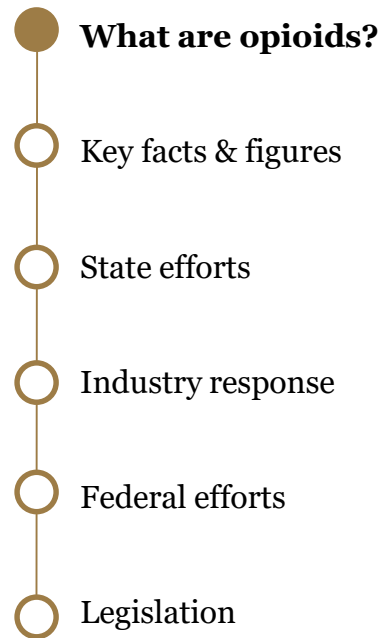
**May 17, 2018**

**Featuring**

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Alistair Taylor and Erin Durkin*

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# Roadmap



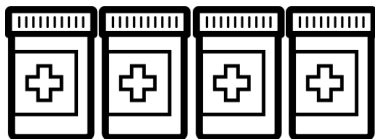
# What are opioids?

**Opioids are compounds that contain opiates, which are derived from opium, and are commonly used for pain relief**

## Chemical effects of opioids

Opioids bind to opioid receptors on cells in the brain and throughout the body. These cells control a variety of functions including digestion and pain

When ingested, opioid drugs attach to these same receptors, they dull pain and can also cause individuals to feel a euphoric “high”



**There are four main types:**

- Naturally occurring endogenous opioids
- Opium alkaloids
- Semi-synthetic opioids
- Fully synthetic opioids

**Potential for misuse & abuse**

- While opioids are effective painkillers, they also have significant potential for dependence, misuse and abuse

# There is a wide variety of different types of opioids

Painkillers that produce a euphoric effect have become commonly misused and abused

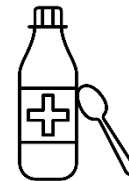
**Morphine:** the first opiate, derived from the poppy plant



**Heroin:** originally marketed as a solution to morphine addiction, it is now one of the most commonly abused illegal drugs



**Codeine:** often used to treat coughs and diarrhea, codeine is more powerful than non-opioid painkillers and is widely subject to abuse



**Buprenorphine:** can produce a euphoric effect, it is generally used to treat long-term chronic pain



**Hydrocodone:** one of the most frequently prescribed and abused opioids

**Oxycodone:** at 1.5x the strength of morphine, it is the opioid in Oxycontin, Percocet and Percodan

**Fentanyl:** at 50-100x the strength of morphine, fentanyl is one of the most potent street drugs

**Carfentanyl:** 10,000x stronger than morphine, it is an elephant sedative that is beginning to be mixed into heroin

# Some street opioids are up to 10,000 times stronger than morphine

**Fentanyl and carfentanil are cheap and used to cut other substances such as heroin and cocaine**

Strength of street opiate painkillers compared to morphine



Sources: Dan Keating & Samuel Granados, "See how deadly street opioids like 'elephant tranquilizer' have become," The Washington Post, October 25, 2017.

# Lasting effects of opioid use and abuse

## Opioid abuse can lead to brain damage or overdose

**Opioids can cause adverse reactions in several organ systems, and long-term opioid therapy can result in:**

- Constipation
- Sleep-disordered breathing
- Increased fractures
- Hypothalamic-pituitary-adrenal (HPA) dysregulation
- Overdose

Because of the potential side effects, scientists have recommended opioid prescriptions be restricted



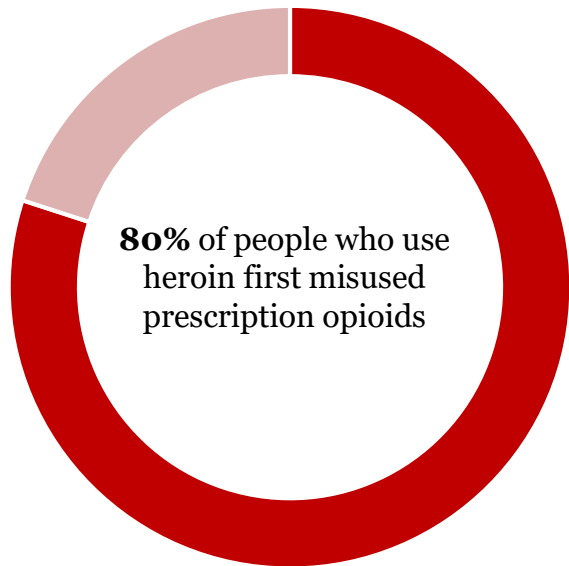
**Long-term heroin use has been shown to significantly impact the brain**

Repeated heroin use can change the physical structure and chemistry of the brain

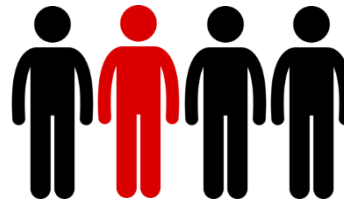
Long-term heroin use has resulted in deterioration of white and grey matter in the brain

# Relationship between legal and illegal opioids

## Most people who use heroin initially used prescription opioids



Today, **21-29%** of patients prescribed opioids for chronic pain misuse them



**4-6%** of people who misuse prescription opioids transition to **heroin**

Of the patients who misuse prescribed opioids, **8-12%** develop an opioid use disorder



Sources: "Opioid Crisis," NIDA, June 2017; "Public Opinion on the Use and Abuse of Prescription Opioids," KFF, November 2015, Schallhorn "Trump declares opioid epidemic national emergency – here's what that means," Fox News, August 11, 2017.

# A brief history of the opioid epidemic

## Timeline of laws & major developments relating to opioids

- 3400 BCE** ● The earliest reference to the growth and use of opium, from ancient Mesopotamia
- 1806** ● Morphine was isolated from opium by a German chemist
- 1860s** ● Widespread use of morphine to treat pain and injuries during the Civil War resulted in a sharp rise in addiction – the “Soldier’s Disease”
- 1898** ● Heroin was synthesized as a morphine derivative and marketed as a “non-addictive” substitute for morphine
- 1909** ● The Opium Exclusion Act barred opium imports into the US
- 1916** ● Oxycodone was synthesized by German scientists looking to develop a painkiller that would reduce the addictive qualities of morphine and heroin
- 1924** ● The Heroin Act made the importation, manufacture, sale and possession of heroin illegal
- 1978** ● Hydrocodone was introduced in the US
- 1996** ● The American Pain Society’s “Pain, the Fifth Vital Sign” campaign proved influential in raising awareness of pain assessment and management; new standards for pain management were later introduced by the JCAHO
- Mid-1990s** ● New prescription opioids were introduced, including extended-release versions of morphine, fentanyl, oxycodone and hydromorphone
- 1999** ● Around 4m people in the US were using prescription drugs for non-medical purposes
- 2002** ● 6.2m Americans were abusing prescription drugs
- 2009** ● ER visits linked to abuse of narcotic pain relievers reached 730,000 in the US



# Roadmap

- 
- What are opioids?
  - **Key facts & figures**
  - State efforts
  - Industry response
  - Federal efforts
  - Legislation
-

# Prescribing rates peaked in 2012 and have fallen in most states since then

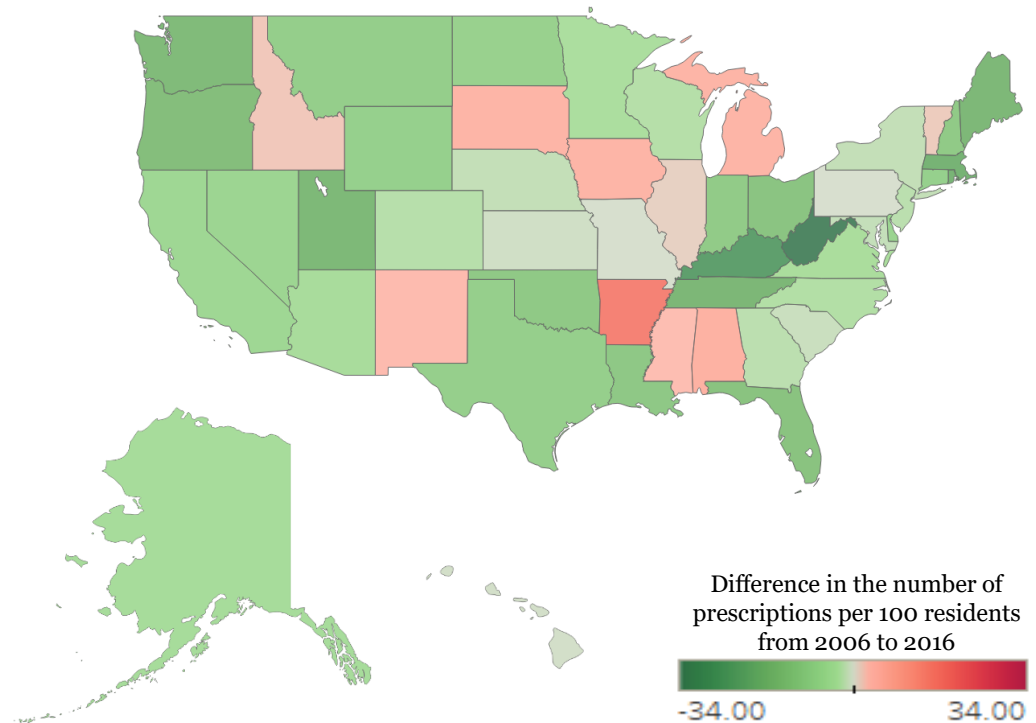
Despite the decline in prescribing rates, overdose rates have risen

## Prescribing rates

- The number of opioid prescriptions rose steadily from 2006 to 2012
- The total number of prescriptions peaked in 2012 at more than 255m
- The rate declined after 2012
- Prescribing rates reached their lowest level in more than 10 years in 2016, at 214m total prescriptions



## Change in prescriptions per 100 residents 2006 to 2016

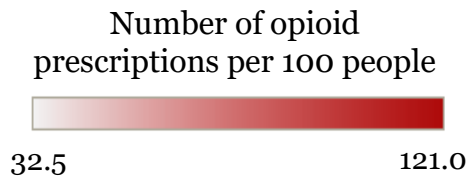


Sources: "U.S. Prescribing Rate Maps," CDC, 2016.

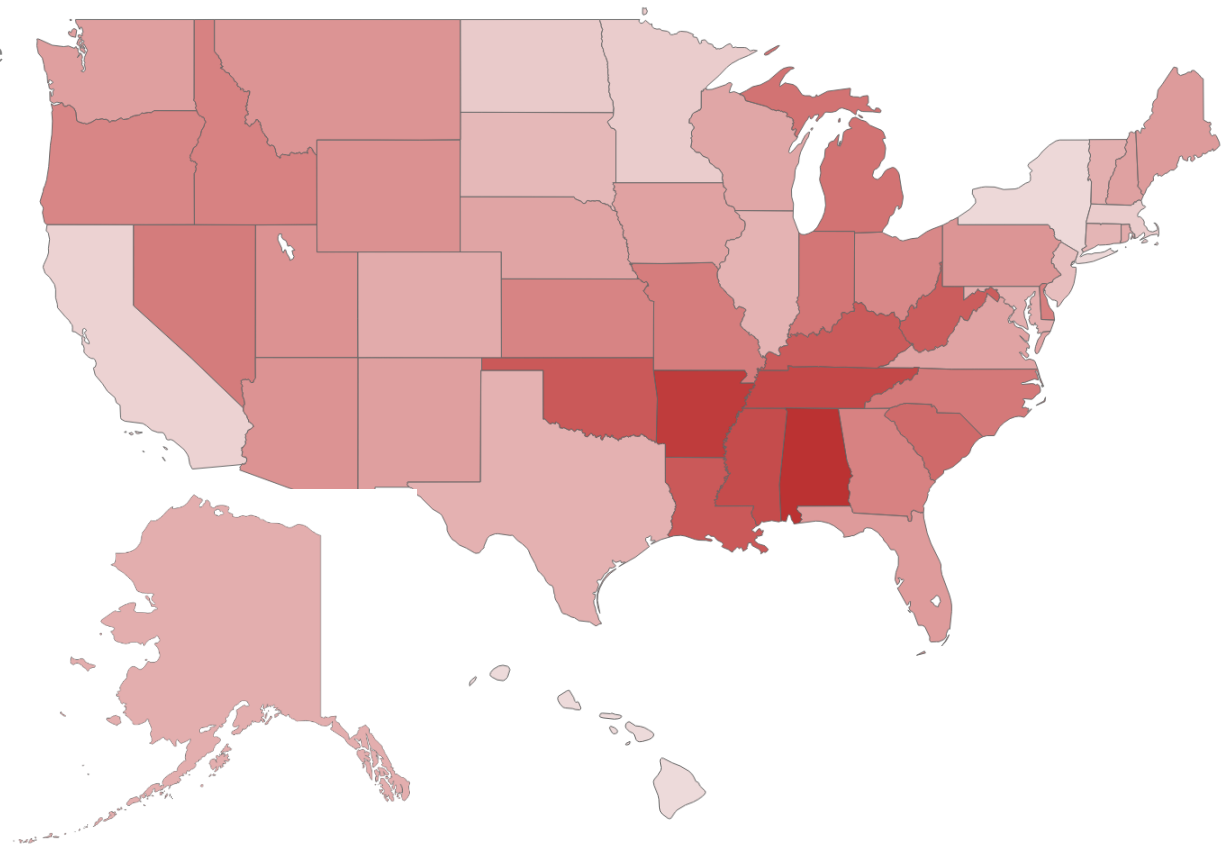
# Opioid painkiller prescriptions per 100 people are highest in southern states

Alabama has the highest prescription rate, at 121 prescriptions per 100 people

Number of opioid prescriptions per 100 people 2016



Not pictured: Washington, DC:  
32.5 opioid prescriptions per 100 people



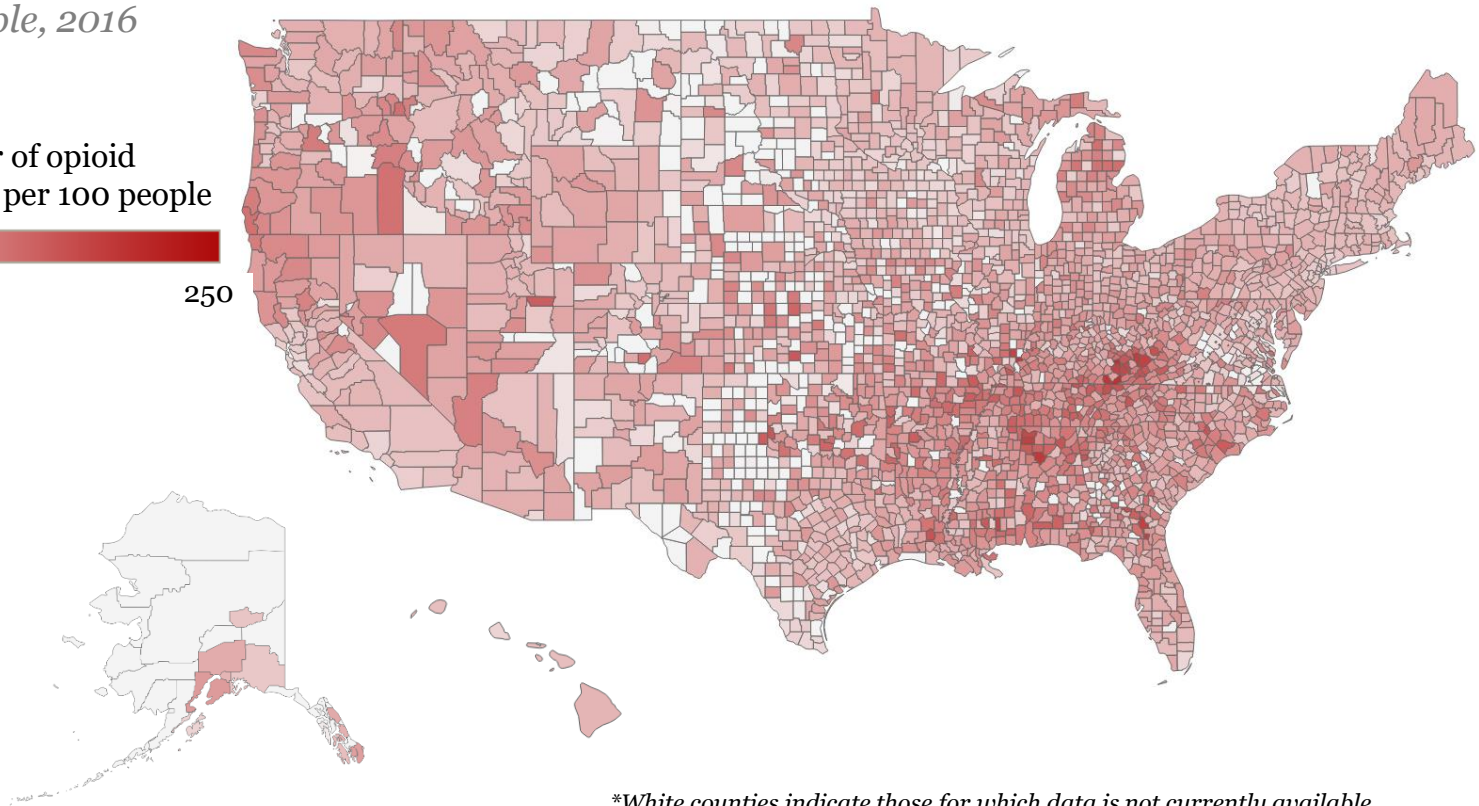
Sources: "Opioid Painkiller Prescribing infographic," CDC 2017.

# 728 US counties have opioid prescription rates of over 100 per 100 people

**Norton, VA has the highest opioid prescription rate, at 470.3 per 100 people**

**Opioid prescribing rate**  
*Per 100 people, 2016*

Number of opioid prescriptions per 100 people

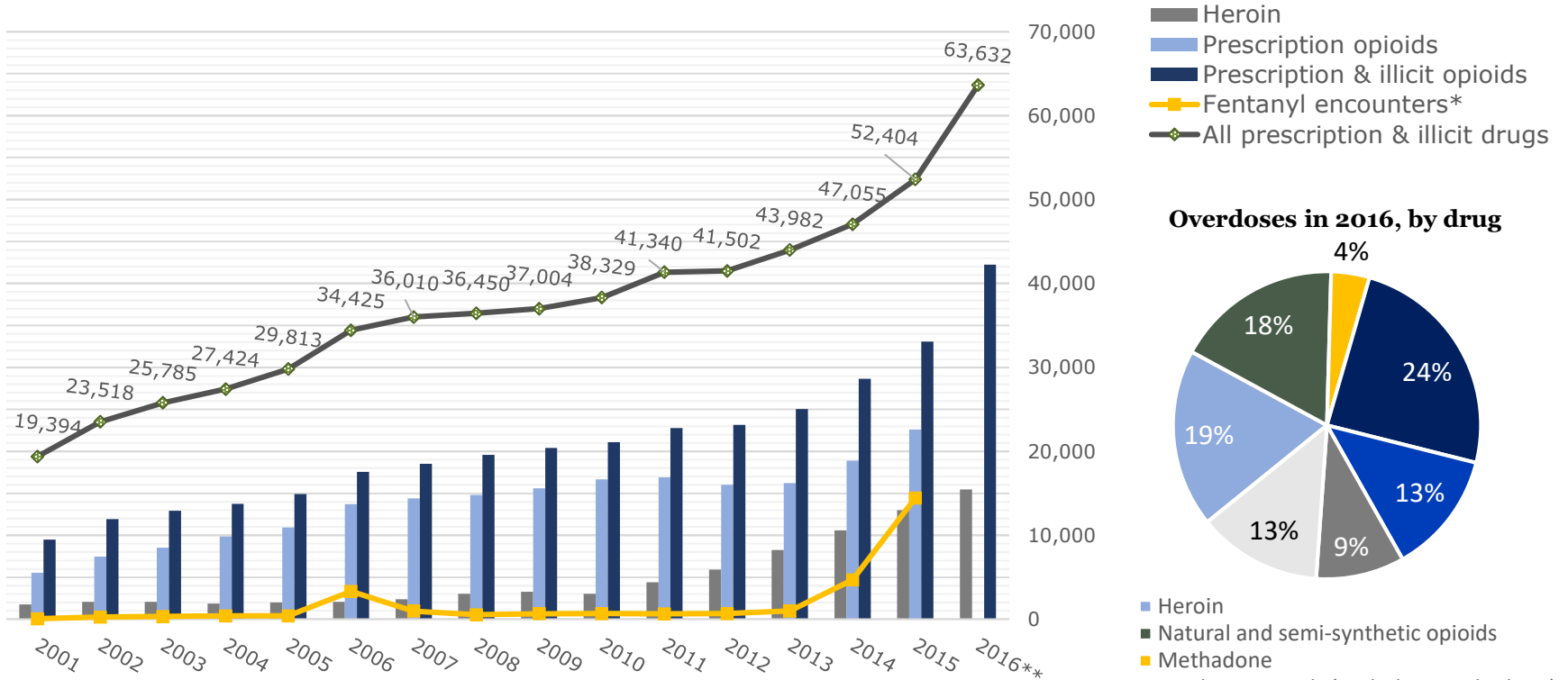


*\*White counties indicate those for which data is not currently available*

Sources: "U.S. Prescribing Rate Maps," CDC, 2016.

# Deaths due to fentanyl overdoses have increased by 540% in the past three years, exceeding those due to heroin

## A breakdown of drug overdose deaths, by year



\* According to the CDC, there is strong evidence of an association between reported fentanyl encounters and fentanyl-involved overdose deaths

\*\* Drug overdose data due to prescription drugs and fentanyl encounters is not currently available for 2016.

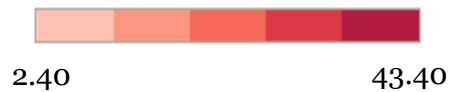
Sources: "Drug overdose data," CDC, 2018; Josh Katz, "The First Count of Fentanyl Deaths in 2016: up 540% in Three Years," The New York Times, September 2, 2017

# West Virginia has the highest rate of deaths due to opioid overdoses

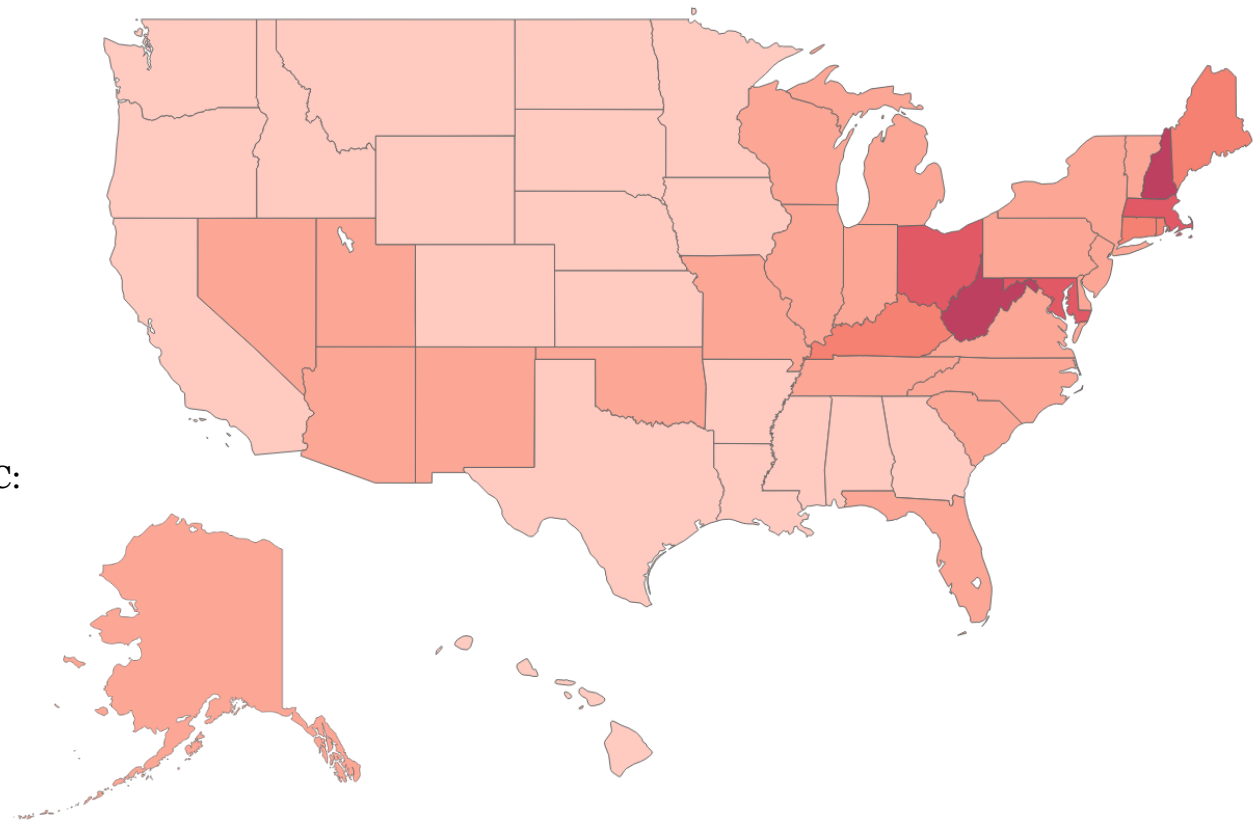
The nationwide opioid overdose death rate in 2016 was about 13 in 100,000

## Deaths due to opioid overdoses 2016

Age-adjusted opioid overdose  
death rate, per 100,000



Not pictured: Washington, DC:  
30 deaths per 100,000

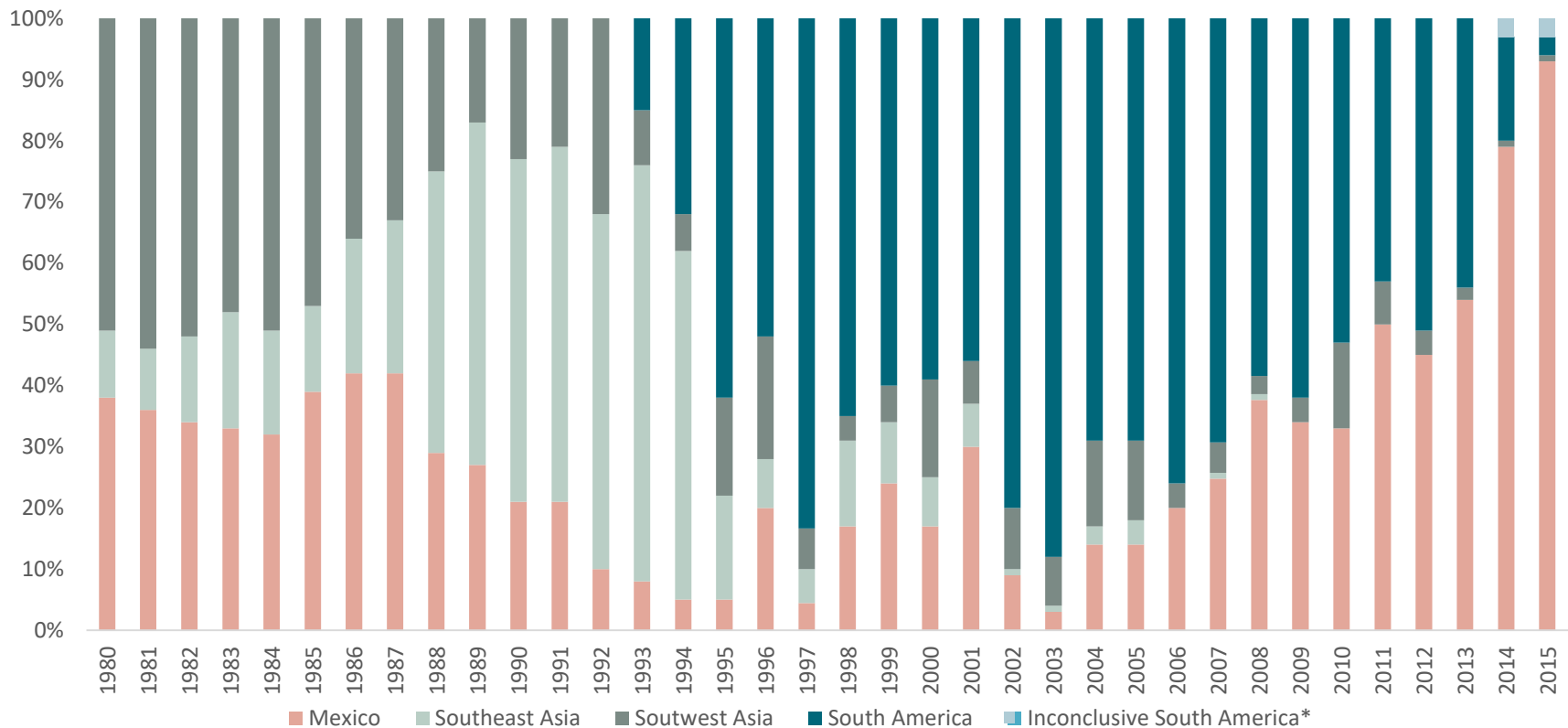


Sources: "Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted)," Kaiser Family Foundation.

# The amount of heroin entering the US from Mexico increased dramatically between 2003 and 2015

## Heroin source distribution

By percentage of total net weight of heroin seized and analyzed, 1980 – 2015



\* Heroin in this category may be from Mexico or South America, but is produced or refined using South American processing methods

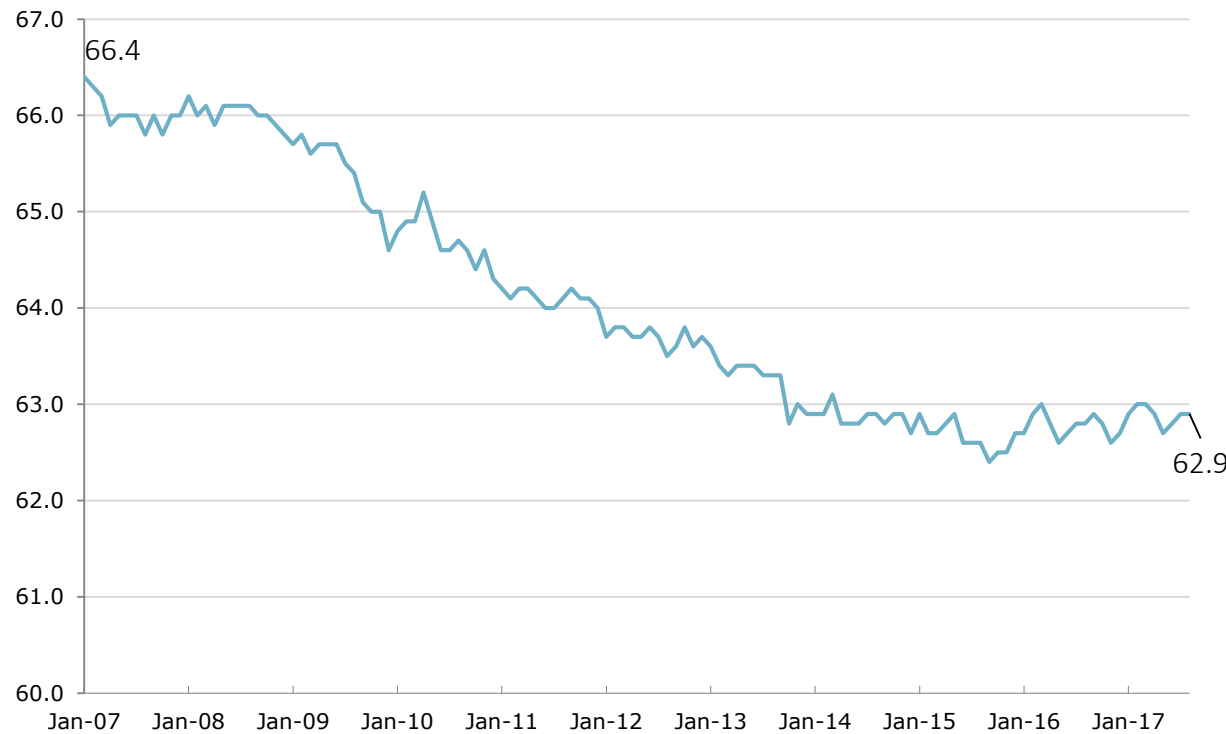
Sources: "The 2015 Heroin Signature Program Report," DEA, August 2017.

# Labor participation rate has declined over the past 10 years

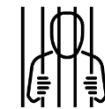
New research suggests opioid epidemic has contributed to the decline in labor participation

## Percentage of labor participation

Ages 16 and over, Jan 2007-Aug 2017



## Major costs



**\$5.1 billion** to the criminal justice system



**\$25 billion** to the health care system



**\$25.6 billion** to the workplace, in the form of lost earnings and employment

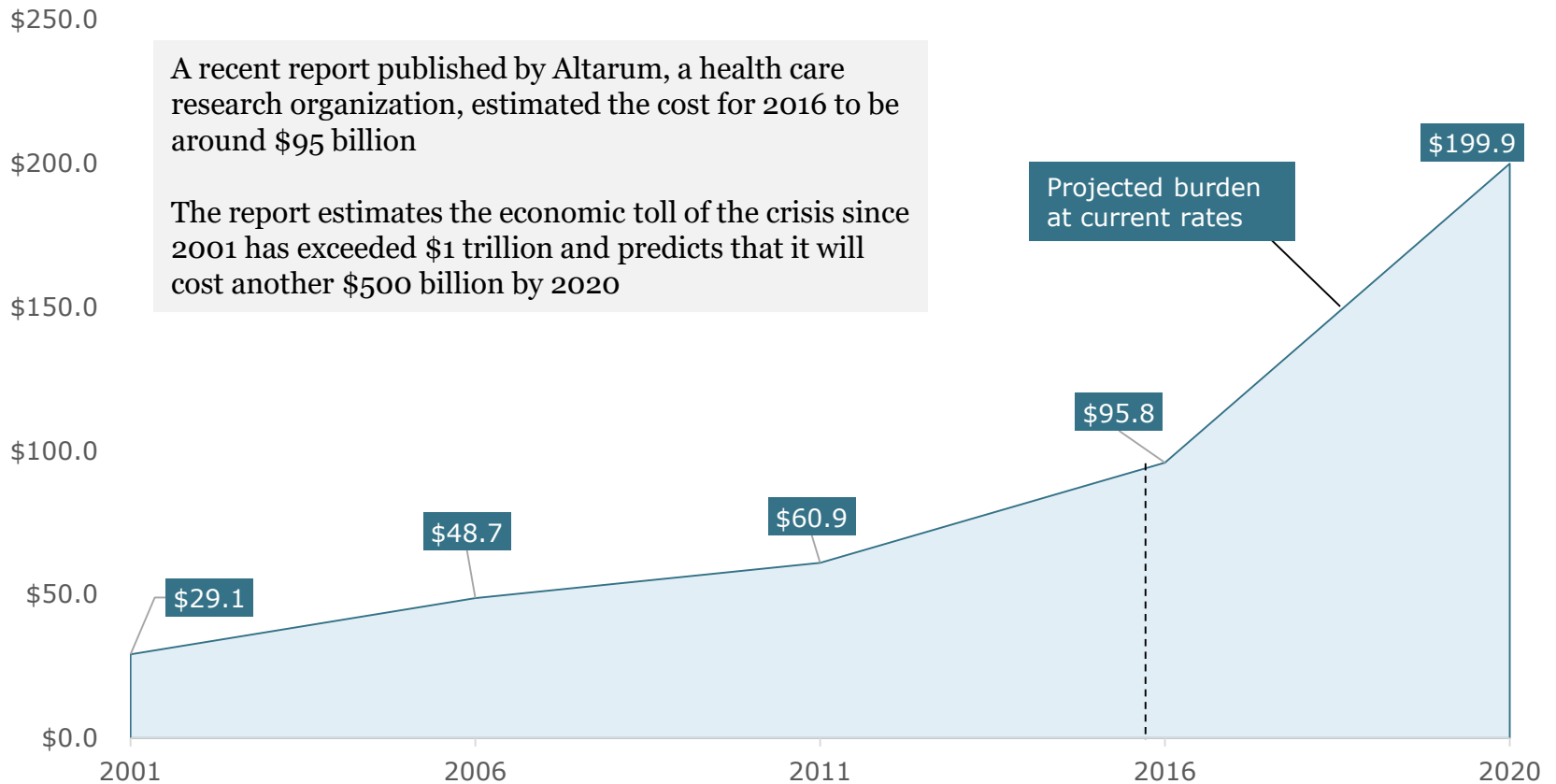
Sources: Bureau of Labor Statistics, "Labor Force Statistics from the Current Population Survey," U.S. Department of Labor, September 11, 2017.



# Economic cost of the opioid crisis

## Altarum analysis

*In billions of USD*

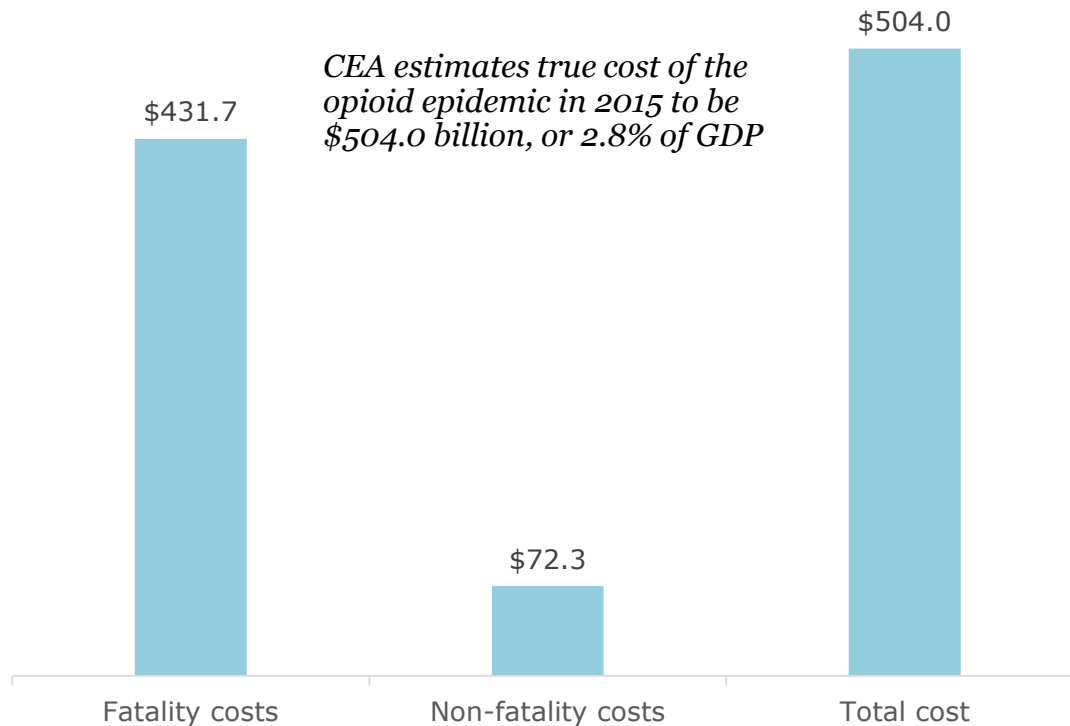


Sources: German Lopez, "White House: one year of the opioid epidemic cost the US economy more than \$500 billion," Vox, November 20, 2017; The Council of Economic Advisers, "The Underestimated Cost of the Opioid Crisis," November 2017.

# Economic cost of the opioid crisis

## Council of Economic Advisors analysis

*In billions of USD*

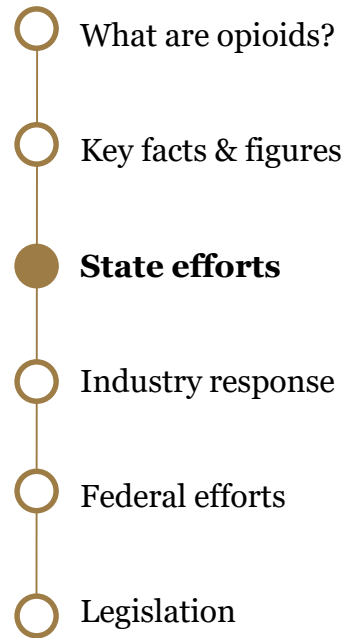


### Understanding the report

- There is no consensus on the exact value of a life, so the CEA used a range of values, as well as a set of values that were adjusted to be age-dependent, with **25-34 and 35-44 year-old age groups having the greatest value**
- The CEA report includes both the cost of non-fatal opioid misuse and the economic cost of prescription and illicit opioids
  - No previous report discussed the cost of illicit opioids

Sources: German Lopez, "White House: one year of the opioid epidemic cost the US economy more than \$500 billion," Vox, November 20, 2017; The Council of Economic Advisers, "The Underestimated Cost of the Opioid Crisis," November 2017.

# Roadmap

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  - Key facts & figures
  - **State efforts**
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  - Federal efforts
  - Legislation
-

# Overview of state initiatives to battle the opioid crisis



## Implementing effective public education/awareness campaigns

- Many states have state-sponsored public campaigns to raise awareness



## Introducing Prescription Drug Monitoring Programs (PDMPs)

- The overprescribing or inappropriate prescribing of opioid medications profoundly increases the risk of opioid misuse and addiction and overdose deaths



## Creating and adopting new prescribing guidelines

- Kentucky, North Carolina, Oregon and Wisconsin have adopted the CDC's guidelines to limit opioid abuse



## Increasing access to Naloxone

- Naloxone is a prescription medication that reverses the effects of overdose from illicit and prescription opioids, and is relatively easy to administer



## Implementing syringe exchange programs (SEPs)

- These community-based programs are designed to provide individuals with access to clean needles, reduce unsafe needle sharing and help decrease the risk of disease transmission



## Improving insurance coverage for addiction care

- A critical means of increasing access to the full spectrum of quality addiction care is the provision of comprehensive insurance coverage

# Governors from across the country have banded together to fight the opioid crisis



In 2016, governors from 43 states signed a compact to fight opioid addiction, promising to take steps to reduce inappropriate opioid prescribing

The states that have been the most drastically affected by the opioid crisis are:

- West Virginia
- Ohio
- New Hampshire



– Gov. Jim Justice  
(R-WV)



– Gov. John Kasich  
(R-OH)

## West Virginia

WV is home to a **disproportionately high number of physically strenuous jobs that can cause pain**, such as coal mining

- Combined with WV's high rates of poverty and unemployment, this has led to many residents self-medicating in unsafe ways

## Ohio

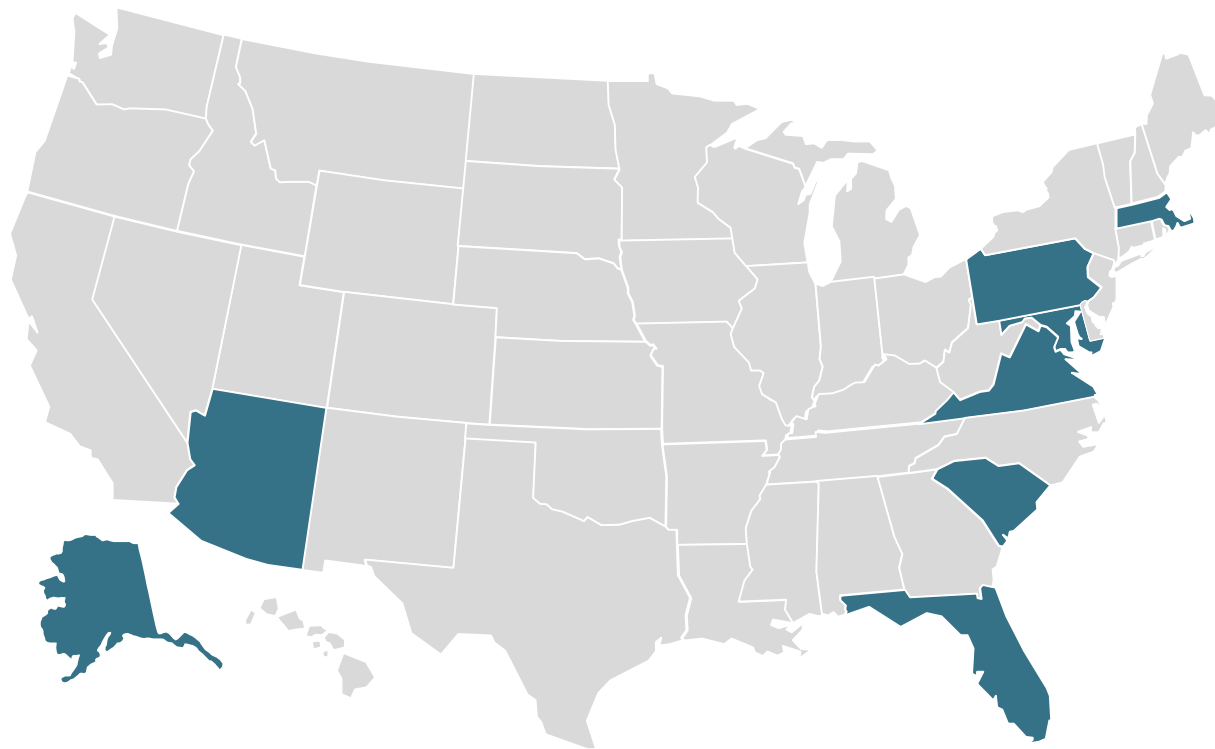
Ohio Governor John Kasich (R) has been one of the most active governors in the fight against the opioid crisis

- Kasich enacted a rule **limiting the number of opioids** doctors can prescribe at once
- Proposed allocating up to **\$20 million** from a state technological innovation fund to research methods to control overdoses and addiction

# Eight states so far have declared public health emergencies in response to the opioid crisis

**This declaration allows them to implement new guidelines for prescribing, tap into funding reserves and expand access to naloxone**

- States that have not declared public health emergencies
- States that have declared public health emergencies



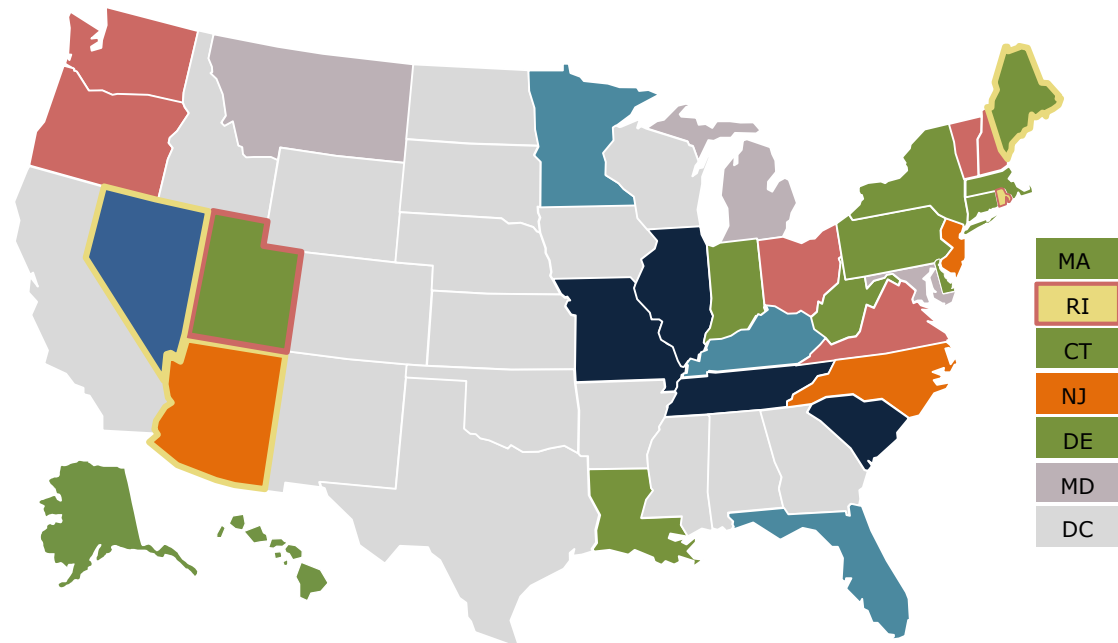
Sources: Mershon & Joseph, "How U.S. states have used emergency declarations to fight the opioid epidemic," Stat news, August 9, 2017; Vestal, "In States, Some Resistance to New Opioid Limits," The Pew Charitable Trusts, June 28, 2016

# Nearly two-thirds of states have enacted opioid-related restrictions or are considering them

## States with a limit, guidance or other requirement related to opioid prescriptions

AS OF APRIL 5, 2018

- >30-day limit
- 14-day limit
- 7-day limit
- 5-day limit
- 3- to 4-day limit
- Morphine milligram equivalent (MME) dosage limit
- Direction given to another entity to set limits or guidelines
- Legislation introduced or considered
- No limits



### Notes:

- *Arizona allows prescriptions up to 14 days following surgical procedures*
- *North Carolina allows up to seven days for post-operative relief*
- *Maryland requires the “lowest effective dose”*
- *Minnesota’s limit is for acute dental or ophthalmic pain*
- *This map does not reflect limits for minors or program-specific limits such as those for patients on Medicare or Medicaid*

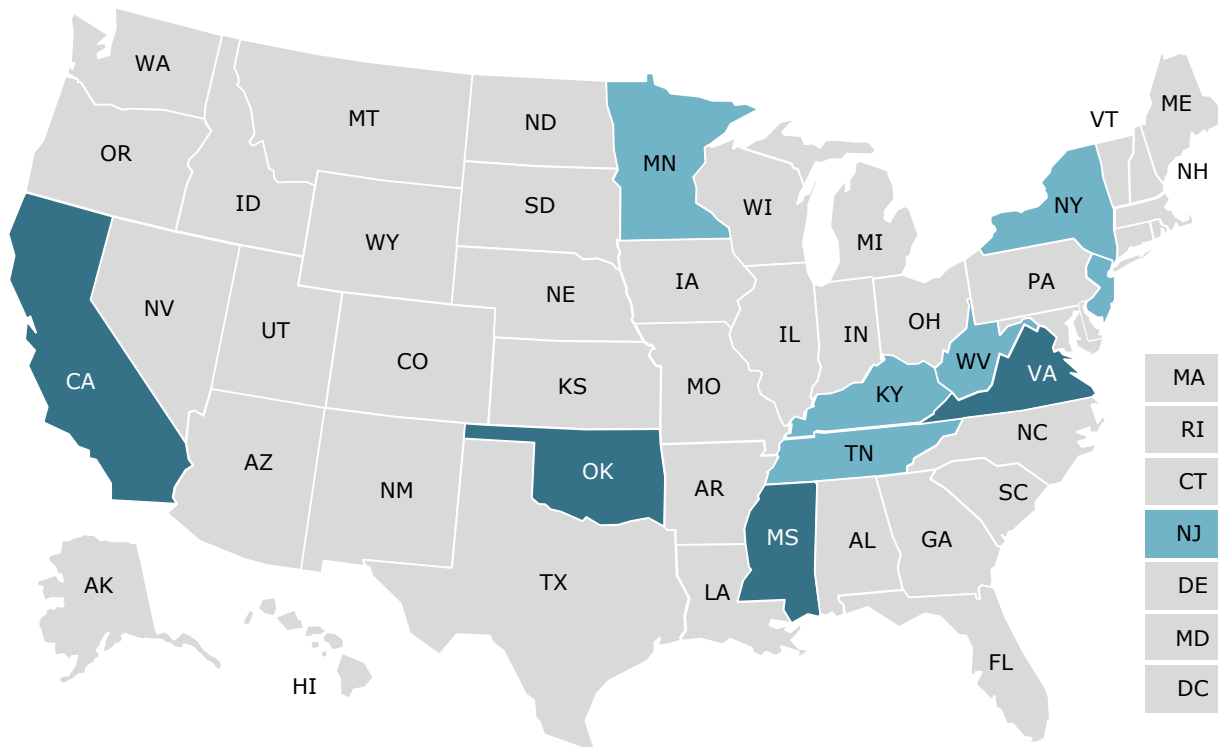
Sources: “Prescribing Policies: States Confront Opioid Overdose Epidemic,” National Conference of State Legislatures, April 5, 2018; “Infographic: State-by-state breakdown of opioid regulations,” AthenaInsight, April 2017; “With drug overdoses soaring, states limit the length of painkiller prescriptions,” The Washington Post, August 9, 2017.

# Six states are considering 12 measures that would tax the production, distribution and sale of opioids

## States contemplating opioid tax proposals

BLOOMBERG

■ Bills have been proposed ■ Legislation anticipated



- MA
- RI
- CT
- NJ
- DE
- MD
- DC

State	Legislation
Kentucky	H.B. 337
Minnesota	H.F. 1140; S.F. 730
New Jersey	S. 1349
New York	Opioid tax passed in state budget
Tennessee	H.B. 2617; S.B. 2445; H.B. 2618; S.B. 2444
West Virginia	H.B. 4543 S.B. 620

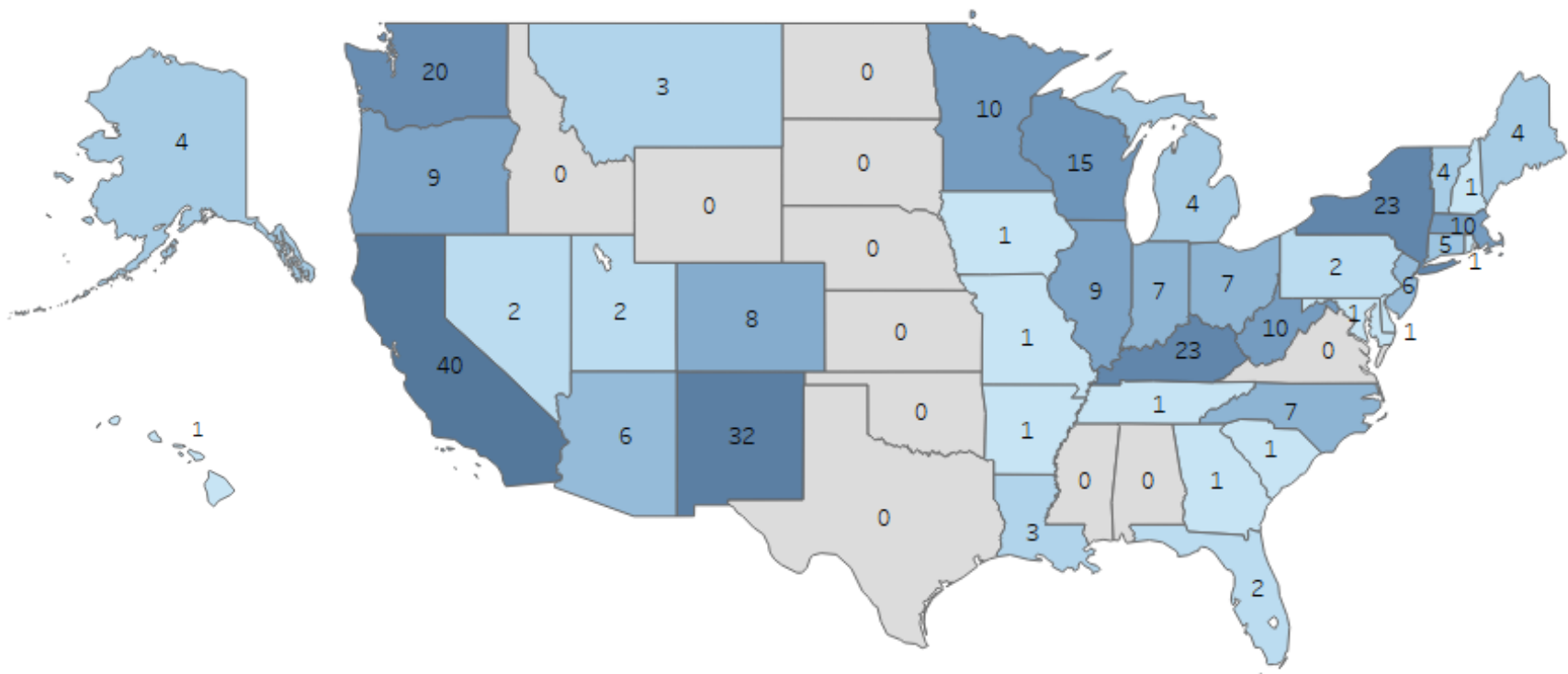
*This list is not exhaustive*

Sources: Ryan Prete, "States increasingly eyeing sales, excise taxes on opioids," Bloomberg, February 28, 2018.



# Syringe exchange programs provide free sterile syringes and collect used syringes to reduce disease transmission

## Number of syringe exchange programs in each state

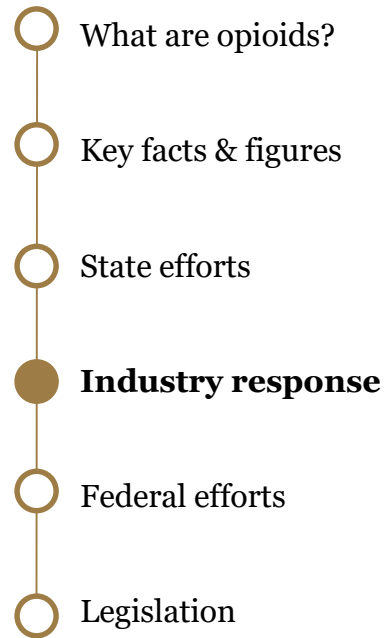


*The directory of syringe exchange programs is aggregated by self-reporting to the North American Syringe Exchange Network and is therefore unlikely to be an exhaustive list of all programs. The map above also does not include programs that do not distribute syringes*

Sources: "Sterile Syringe Exchange Programs," Kaiser Family Foundation, 2017.





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# Roadmap



# Medical associations and pharmaceutical companies approach the opioid crisis from different sides

Pharma lobbyists support pharmaceutical companies expanding research into non-addictive pain management methods, while medical lobbyists support furthering awareness and education for caregivers

Organization	Position
	<p>Stephen J. Ubl, president of Pharmaceutical Research and Manufacturers of America, has publicly expressed support for Gov. Christie's (R-NJ) decision to include pharmaceutical companies in the effort to fight the opioid crisis</p> <ul style="list-style-type: none"> <li>• This effort includes pharmaceutical companies researching non-addictive treatments as well as anti-overdose drugs</li> </ul>
	<p>The American Medical Association has applauded the Trump Administration's decision to create a commission to fight the opioid crisis</p> <ul style="list-style-type: none"> <li>• The AMA's Task Force to Reduce Opioid Abuse has thus far issued recommendations and worked with caregivers to raise awareness and enhance education and training</li> </ul>
 <p>American Hospital Association</p>	<p>The American Hospital Association has worked with the CDC to create patient education resources about prescription opioids</p> <ul style="list-style-type: none"> <li>• The AHA has also encouraged caregivers to review their procedures to ensure that opioids are handled and prescribed carefully and properly</li> </ul>
	<p>Physicians for Responsible Opioid Prescribing has worked with CMS to remove the financial incentive for prescribing pain medication</p> <ul style="list-style-type: none"> <li>• PROP is also working to urge the FDA to enforce regulations for more cautious prescribing, based on recommendations from the CDC</li> </ul>

Sources: Michael Catalini, "Christie: Drugmakers to Work on Nonaddictive Pain Medication," Associated Press, September 18, 2017; American Medical Association;

# Health insurance industry response to the opioid crisis

## Several major insurance companies have taken steps to fight the opioid epidemic

### *Anthem, a BCBS associated company*

- In October 2016, Anthem announced a plan to reduce filled opioid prescriptions by 30% by 2019, but it reached this goal early, in August 2017
- This process included limiting coverage for newly prescribed short-acting opioids to seven days with the exception of individuals receiving palliative care or those who have cancer

### UnitedHealthcare

- UnitedHealthcare has expanded their Retrospective Narcotic High Utilization program to better identify members who are at risk of developing an opioid use disorder in order to implement better prescribing practices
- In 2016, UnitedHealthcare saw a 49% drop in the number of opioid prescriptions written

### Centene

- Centene, Harvard Pilgrim, AmeriHealth Caritas and other providers have been pursuing non-pharmacologic pain management methods
- In conjunction with this new research avenue, they have also begun offering coverage for therapies like acupuncture, when deemed medically necessary

### Cigna

- Cigna aims to reduce opioid use among its customers by 25% by 2019, and has announced that beginning this year, it will no longer cover most OxyContin prescriptions, guiding patients instead towards a covered abuse-deterrent equivalent

# Health insurance industry response to the opioid crisis

## 16 insurance companies have agreed to adopt Shatterproof's "National Principles of Care"

*Shatterproof is a nonprofit aiming to end the stigma associated with addiction and help those suffering from it*

1. Universal screenings for substance use disorders

2. A personal plan for every patient

3. Fast access to treatment

4. Disease management, rather than 28 days of inpatient treatment

5. Coordinated care for every illness

6. Behavioral health care from legitimate providers

7. Medication-assisted treatment

8. Support for recovery outside of the doctor's office



### Insurance companies that have signed on:

- Aetna
- AmeriHealth
- Caritas Family of Companies
- Anthem, Inc.
- Beacon Health Options
- BCBS of Massachusetts
- CareOregon
- CareSource
- Centene Corporation
- Cigna
- Commonwealth Care Alliance
- Envolve Health
- Horizon BCBS of New Jersey
- Magellan Health
- UnitedHealth Group
- UPMC Insurance Division
- WellCare

# Pharmaceutical industry & the opioid crisis

The following are major drug companies that have faced lawsuits in recent years over their marketing and sale of opioids



## Key products: Norco & Kadian

- Allergan has been served with a subpoena by a coalition of 41 states' attorneys general who are seeking information about how Allergan markets and sells its opioids

## Key product: Duragesic

- In 2006, a Texas court ruled that Johnson & Johnson was to pay over \$770,000 to a woman who died after a Duragesic, a patch containing fentanyl, leaked
- J&J has more recently been accused of fraudulently marketing opioids and misleading the public about the risk of taking opioid painkillers for extended periods of time, but the company has vehemently denied these accusations, saying that allegations in similar lawsuits have been "legally and factually unfounded"



## Key product: Embeda

- In 2016, Pfizer agreed to a written code of conduct for marketing opioids after it faced accusations regarding alleged misleading marketing practices
- As part of the agreement reached with the city of Chicago, Pfizer will disclose in its promotional materials that narcotic painkillers carry serious risk of addiction even when used properly and that there is currently no good research on opioids' effectiveness beyond 12 weeks

# Purdue Pharma announces that it will stop promoting opioids to physicians

The announcement comes less than one week after Alabama joined over a dozen other states and filed a lawsuit against the company



- As part of the move, Purdue Pharma announced that they cut their sales force in half, to 200 representatives

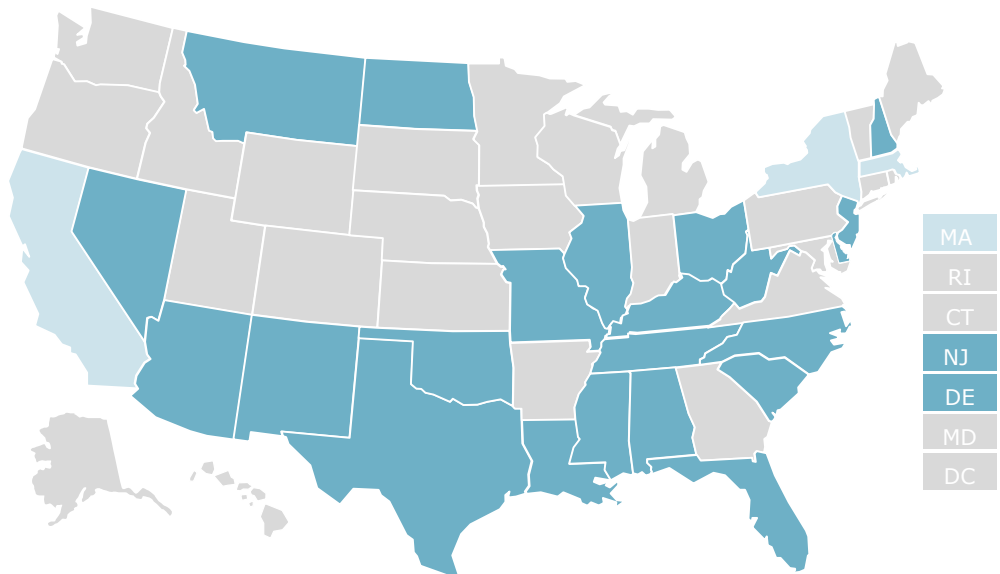


- The move is likely a response to widespread criticism of how pharmaceutical companies have been marketing addictive painkillers



- Many blame opioid manufacturers for misrepresenting their products' addictive properties, with more than 42,000 people dying from opioid overdoses in 2016

## 22 states so far have filed lawsuits against Purdue Pharma



Sources: National Journal Research; Sara Randazzo, "Montana Is Latest State to Sue Purdue Pharma Over Opioid Crisis," The Wall Street Journal, December 4, 2017; "OxyContin maker stops promoting opioids, cuts sales staff," Reuters, February 10, 2018.

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# Department of Justice files intent to join multi-district lawsuit filed against drug companies

Attorney General Jeff Sessions announced that the DOJ will be participating in settlement discussions as a “friend of the court”

“ We will use criminal penalties. We will use civil penalties. We will use whatever laws and tools we have to hold people accountable if they break our laws... We will seek to hold accountable those whose illegality has cost us billions of taxpayer dollars.”

— Attorney General Jeff Sessions, at a news conference attended by several state attorneys general

## Recent DOJ actions

July 2017

*DOJ seizes AlphaBay*

- Home to 220,000 drug listings

August 2017

*AG creates Opioid Fraud & Abuse Detection Unit*

- To help find evidence of overprescribing and opioid-related health care fraud

January 2018

*DOJ announces new resource J-CODE*

- To target online drug traffickers

February 2018

*AG Sessions establishes PIL & classifies all fentanyl analogues as Schedule I drugs*

May 2018

*DOJ joins whistleblower litigation against Insys Therapeutics Inc.*

Sources: “Department of Justice Files Motion in Multi-District Opioid Case,” US Department of Justice, April 2, 2018; Nate Raymond & Jonathan Stempel, “U.S. joins whistleblower case against Insys over kickbacks,” Reuters, May 14, 2018.

# Surgeon General Jerome Adams issues public health advisory urging public to carry anti-overdose drug

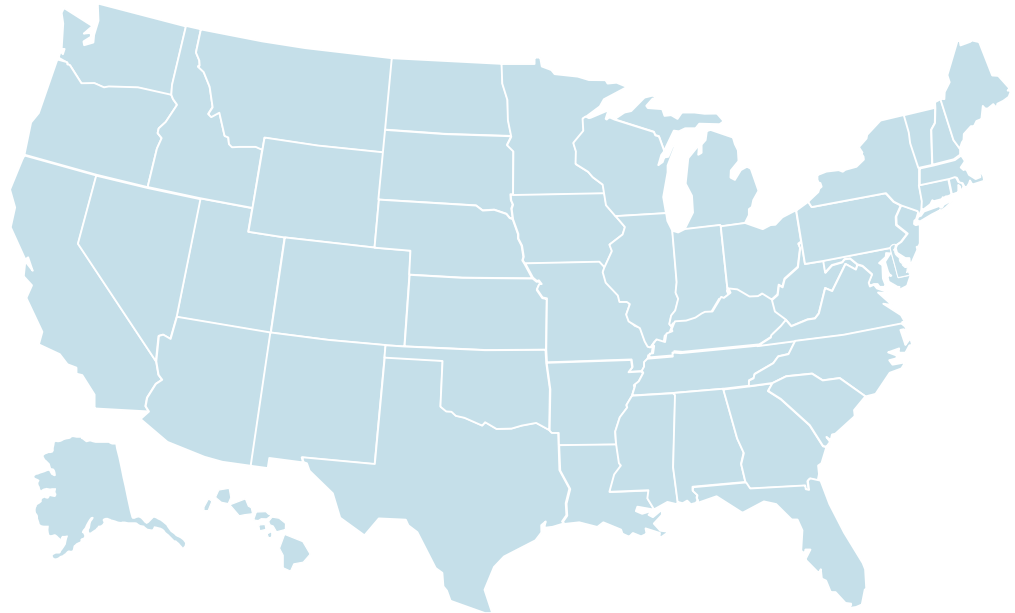
**This is the first public health advisory in over a decade. The last, issued in 2005, warned against drinking alcohol while pregnant**

“*Each day we lose 115 Americans to an opioid overdose – that’s one person every 12.5 minutes. It is time to make sure more people have access to this lifesaving medication, because 77 percent of opioid overdose deaths occur outside of a medical setting and more than half occur at home. To manage opioid addiction and prevent future overdoses, increased naloxone availability must occur in conjunction with expanded access to evidence-based treatment for opioid use disorder.*”



— United States  
Surgeon General  
Jerome Adams

## States with standing orders for Narcan



Sources: National Journal Research, 2018; Rachel Roubein, “Surgeon general urges public to carry opioid overdose reversal drug in rare advisory,” The Hill, April 5, 2018; “Surgeon General Releases Advisory on Naloxone, an Opioid Overdose-Reversing Drug,” HHS, April 5, 2018; NARCAN.com/availability, May 15, 2018.

# Despite the opioid epidemic's status as a national public health emergency, few steps have been taken to address it

The most recent announcement came in March, when the White House released President Trump's Initiative to Stop Opioids Abuse and Reduce Drug Supply and Demand

## The initiative aims to:

- Reduce drug demand
- Reduce over-prescription
- Cut off the supply of illicit drugs
- Help those struggling with addiction



## By:

- Launching a nationwide campaign to raise public awareness about the dangers of illicit prescription opioid use
- Supporting R&D of innovative technologies and therapies designed to prevent addiction and decrease the use of opioids in pain management
- Securing all points of entry into the country
- Require advance electronic data for 90% of all international mail
- Increase punishments
- Ensuring first responders have access to naloxone
- Expanding evidence-based treatment
- Change law prohibiting Medicaid from reimbursing residential treatment at certain facilities

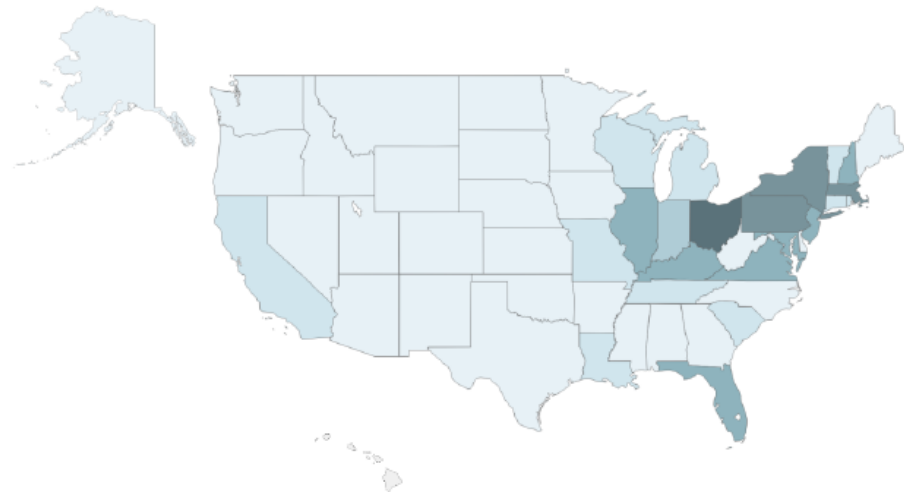
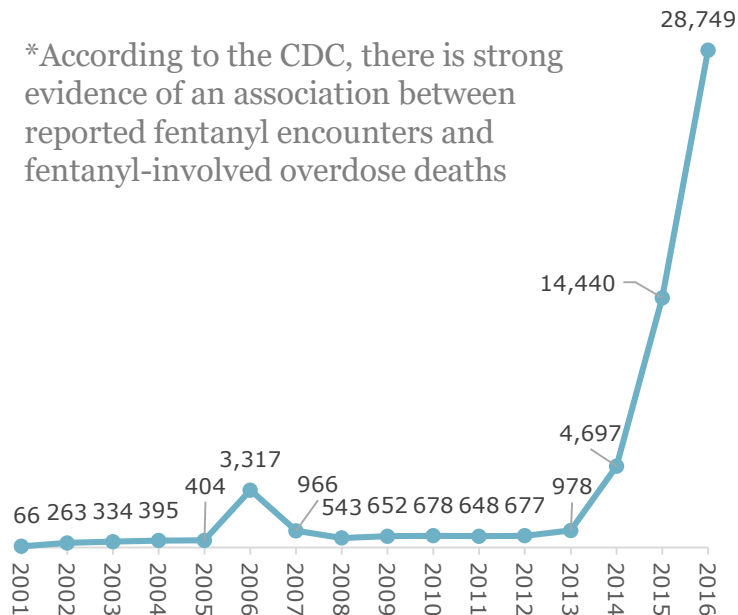
Sources: Sara Horwitz, Katie Zezima & Lenny Bernstein, "Justice Dept. to target opioid manufacturers, distributors in new push to curb deadly epidemic," February 27, 2018.

# Bipartisan Senate investigation finds that online drug traffickers in China shipped fentanyl to the US via USPS

Traffickers reportedly used the United States Postal Service (USPS) because they thought there was a lower risk of US Customs and Border Protection (CBP) seizing the package

Number of fentanyl encounters\*  
2001-2016

\*According to the CDC, there is strong evidence of an association between reported fentanyl encounters and fentanyl-involved overdose deaths



Number of fentanyl encounters  
By state, 2016



Sources: Rachel Roubein, "Congressional probe finds synthetic opioid easily shipped from China to US," The Hill, January 24, 2018; Ron Nixon, "Online Sales of Illegal Opioids from China Surge in U.S.," The New York Times, January 24, 2018; "2017 National Drug Threat Assessment," DEA, October 2017.

# Federal agency efforts to address the opioid crisis

## Recent actions taken by the FDA and SAMHSA

### FDA

### SAMHSA



Risk Evaluation and Mitigation Strategies (REMS)



Source of funding



Investigating current opioids



Resource for patients & providers



Promoting better prescribing and dispensing practices

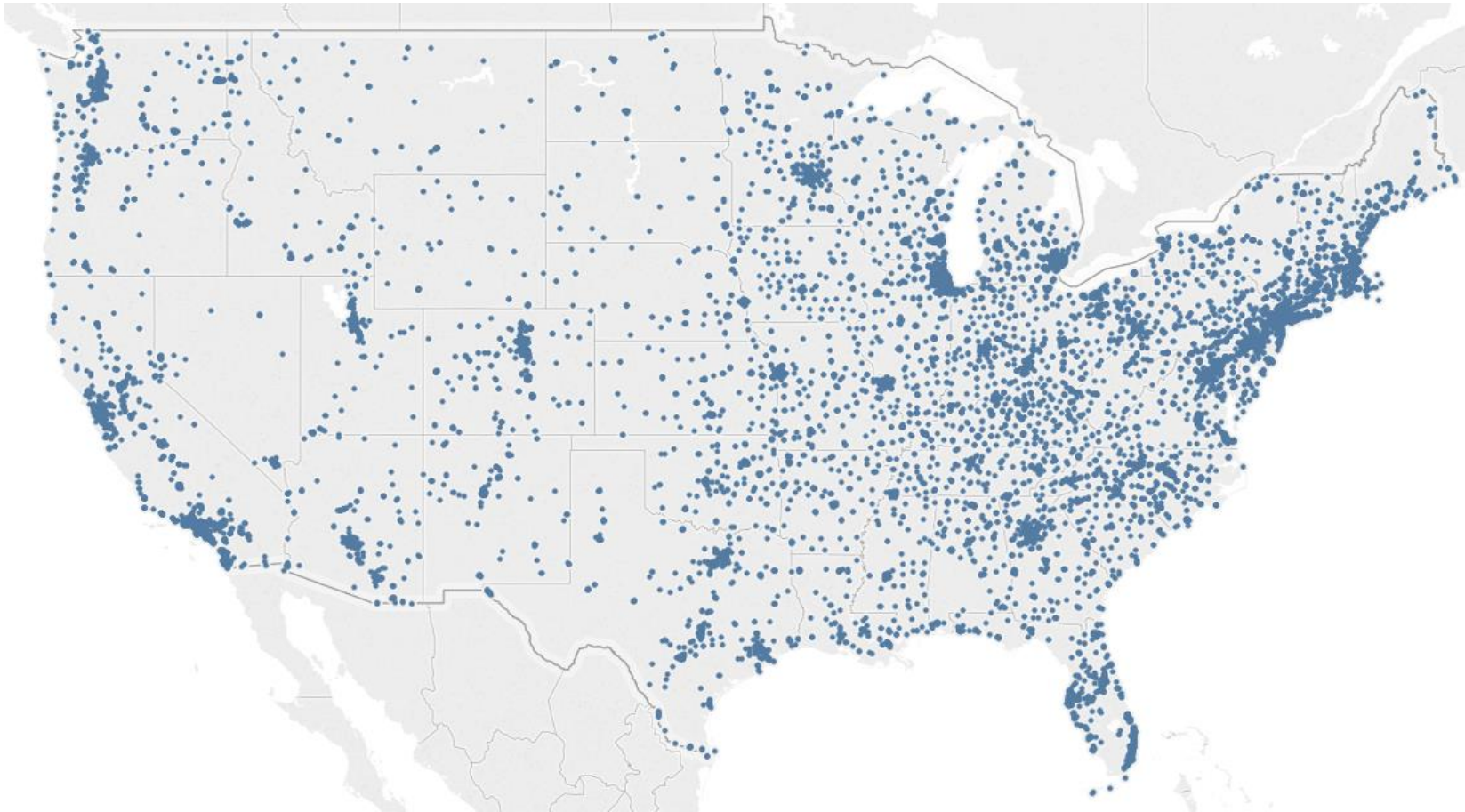


Enhancing operations at international mail facilities (IMFs)

Sources: Sheila Kaplan, "F.D.A. to Expand Medication-Assisted Therapy for Opioid Addicts," New York Times, February 25, 2018; Scott Gottlieb, "Combating the Opioid Crisis: Prevention and Public Health Solutions," FDA, March 21, 2018; Matthew Perrone, "FDA Chief Wants to Increase Package Inspection to Combat Opioid Crisis," Time, March 6, 2018.

# Overview of alcohol and drug abuse treatment providers

## Facilities around the US



Sources: SAHMSA, 2016.

# Federal agency efforts to address the opioid crisis

## Recent actions taken by the VA and the CDC

### VA



Pain Management Best Practices Inter-Agency Task Force



Clinical practice guidelines



STOP PAIN initiative

### CDC



Guidelines for primary care physicians



Data collection

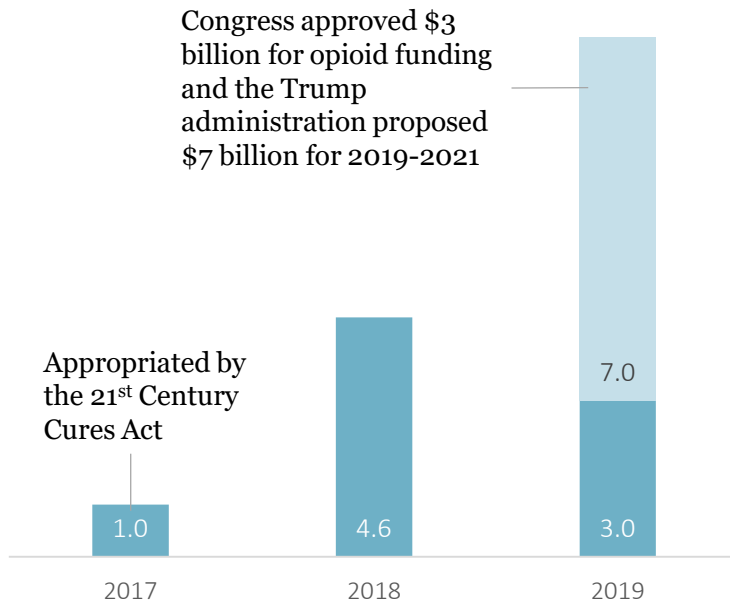


# Opioid funding overview

**Since CARA and the 21<sup>st</sup> Century Cures Act, the U.S. government has appropriated approximately \$15 billion to combat the opioid crisis**

*These two acts have been key drivers in addressing drug abuse issues and the opioid crisis*

## Aggregate funding for the opioid crisis *In billions of USD*

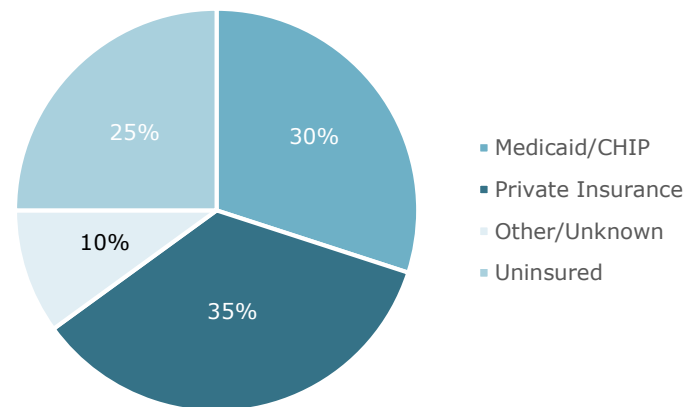


## Medicaid funding for substance abuse



Researchers found that Medicaid paid for about 25 percent — \$7.9 billion of \$31.3 billion in 2015— of projected public and private spending for addiction treatment

## Insurance distribution of people with an opioid addiction



Sources: National Journal Research, 2018; HHS Budget 2018, President’s Budget Request, 2019; NCBI, 2018.

# The omnibus provides almost \$4 billion for the opioid crisis

## Improving law enforcement efforts:



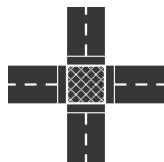
A **\$37M** increase to enhance opioid diversion investigations and prosecutions



**\$543M** for the Organized Crime and Drug Enforcement Task Forces



**\$447M** for Department of Justice grant programs that support drug courts, treatment, prescription drug monitoring, heroin enforcement task forces, overdose reversal drugs and at-risk youth programs



**\$280M** for the High-Intensity Drug Trafficking Areas program

## Supporting treatment & prevention:



**\$476M** for the CDC to support increased surveillance and prevention of opioid overdoses at the national, state and local levels



At least **\$500M** for NIH research on opioid addiction



**\$117.1M** for federal drug control programs under the Office of National Drug Control Policy

Sources: "FY 2018 Omnibus, Fighting the Opioid Epidemic," House Appropriations Committee, March 21, 2018.

# The omnibus provides almost \$4 billion for the opioid crisis

## Stopping the flow of illegal drugs:



**\$284M** for port and drug inspection technologies within Customs and Border Protection

- **\$71M** of this is specifically targeted at opioid detection



**\$94M** for the FDA to expand surveillance and analysis efforts by testing some of the millions of packages that come into the US through international mail facilities



**\$245M**, \$10.4M above the budget request, for the US Postal Service Office of the Inspector General to continue drug interdiction efforts and investigations

## Key demographics receiving additional funds:



**\$130M** for the **Rural Communities Opioid Response** program, aimed at targeting the unique issues associated with substance use disorder in rural America



**\$386M** in **Department of Veterans Affairs** medical care funding for opioid abuse treatment and prevention

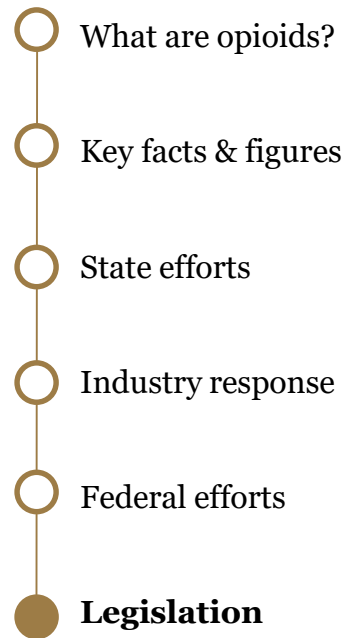


**\$1B** in new funding for grants to **states and Indian tribes** to address the opioid epidemic, **\$228M** for the Indian Health Service's Alcohol and Substance Abuse Program, and **\$7.5M** for the Bureau of Indian Affairs Law Enforcement Opioid initiative

Sources: "FY 2018 Omnibus, Fighting the Opioid Epidemic," House Appropriations Committee, March 21, 2018.

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# Roadmap





## Key legislation relating to the opioid crisis

### The Opioid Crisis Response Act of 2018 (S. 2680)

- Sen. Lamar Alexander (R-TN), 17 cosponsors (8 GOP, 9 Dem)
- Reallocates federal funds and increases flexibility for opioid related programs in the FDA, NIH, SAMHSA, CDC and other agencies
- Expands a CARA grant program to train first responders to safely respond to fentanyl cases



*Passed the Senate HELP Committee on April 24, 2018*

### The Comprehensive Opioid Recovery Centers Act of 2018 (H.R. 5327)

- Rep. Brett Guthrie (R-KY-2), 4 cosponsors (1 GOP, 3 Dem)
- Funds grants under the Public Health Service Act to create comprehensive opioid recovery centers and outreach programs



*H.R. 5327 passed through the House Energy & Commerce Committee, Health Subcommittee's markup on April 25, 2018*

### Jessie's Law (S. 581, H.R. 5009)

- Sens. Manchin (D-WV), 6 cosponsors (2 GOP, 3 Dem, 1 Ind.)
- Reps. Tim Walberg (R-MI), 15 cosponsors (8 GOP, 7 Dem)
- Requires HHS to develop standards for hospitals for physicians to readily access consenting patients' histories with opioid addiction



*House bill passed subcommittee and is waiting for a full Energy & Commerce Committee vote  
Though Jessie's law has not passed the House, language from the bill was included in the omnibus bill signed into law in March 2018*

### CARA 2.0 Act of 2018 (S. 2456, H.R. 5311)

- Sen. Rob Portman (R-OH), 10 cosponsors (3 GOP, 7 Dem)
- Rep. Marsha Blackburn (R-TN), 5 cosponsors (2 GOP, 3 Dem)
- Reauthorizes and expands many CARA programs and limits initial pain prescriptions to three days



# Senate HELP Committee passes S. 2680, the Opioid Crisis Response Act of 2018

**The act is the result of six bipartisan hearings on the opioid crisis with the FDA, NIH, CDC, SAMHSA, governors, experts and families**

*The legislation will impact several major agencies*

## SAMHSA

- Changes CARA grants to focus funds on state and tribes that have been hardest hit by the opioid crisis
- Establishes comprehensive opioid recovery centers
- Expands a CARA grant program to train first responders on how to respond to cases involving fentanyl
- Establishes a youth prevention and recovery initiative to be carried out by HHS and the Department of Education

## CDC

- Supports data collection on
  - Controlled substance overdoses
  - Infections associated with injection drug use
  - Neonatal abstinence syndrome
- Disseminates information to providers and the public including prescribing guidelines
- Establishes & enhances local evidence-based prevention activities

## FDA

- The FDA is directed to issue guidelines on
  - Opioid packaging
  - Safe disposal systems
  - Updates to the development and regulatory pathways for new non-addictive and non-opioid painkillers
- Equips the FDA and Customs & Border Protection with the latest technology and testing equipment to improve drug detection and coordination between the agencies

**Sponsored by Sen. Lamar Alexander (R-TN) and cosponsored by eight Republicans and nine Democrats, this bipartisan legislation will now proceed to the Senate floor**

- Only about 25% of bills are reported out of the Senate HELP Committee, and given that this bill has widespread bipartisan support, it has a relatively high chance of passing the Senate

Sources: "The Opioid Crisis Response Act of 2018," Senate HELP Committee, May 2018; "S. 2680 — 115<sup>th</sup> Congress: Opioid Crisis Response Act of 2018," GovTrack.us, May 9 2018.

**Questions?**